PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form the collection instrument to be reviewed, the Supporting Statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 101022, 725 17th Street, NW, Washington, DC 20503.

1. Agency/Subagency originating request

Department of Labor , Occupational Safety and Health Administration, OSHA

2. OMB control number

a. **1218–0099** b. ☐ None ____ (new)

3. Type of information collection *(check one)*

a. ☐ New Collection
b. ☐ Revision of a currently approved collection
c. ☒ Extension of a currently approved collection
d. ☐ Reinstatement, without change, of a previously approved collection for which approval has expired
e. ☐ Reinstatement, with change, of a previously approved collection for which approval has expired
f. ☐ Existing collection in use without an OMB control number

For b-f, note item A2 of Supporting Statement instructions

4. Type of review requested (check one)

a. ☒ Regular submission
b. ☐ Emergency - Approval requested by: __/__/__
c. ☐ Delegated

5. Small entities

Will this information collection have a significant economic impact on a substantial number of small entities?

☐ Yes ☒ No

6. Requested expiration date

a. ☒ Three years from approval date?
b. ☐ Other Specify: __ / __ (month/ year)

7. Respiratory Protection Standard (29 CFR 1910.134)

8. Agency form number(s) (if applicable) None

9. Keywords: Occupational health standard, health hazard, toxic substances, carcinogens

10. Abstract: This standard requires employers to develop a written respiratory protection program, provide medical surveillance, fit test employees, obtain certificates of analysis on cylinders, change sorbent beds and filters, to inspect emergency-use respirators, mark emergency-use respirator storage compartments, and maintain accurate employee records for fit testing and medical surveillance.

11. Affected public *(Mark primary with "P" and all others that apply with "X")*

a. __ Individuals or households
b. **P** Business or other for-profit
c. **X** Not-for-profit institutions
d. __ Farms
e. **X** Federal Government
f. **X** State, Local or Tribal Government

12. Obligation to respond (Mark primary with "P" and all others that apply with "X")

a. __ Voluntary
b. __ Required to obtain or retain benefits
c. **P** Mandatory

13. Annual reporting and recordkeeping hour burden

a. Number of respondents	639,623
b. Total annual responses	22,547,185
1. Percentages of these responses collected electronically	%
c. Total annual hours requested	7,159,601
d. Current OMB inventory	6,551,314
e. Difference	608,287
f. Explanation of difference	
1. Program change	
2. Adjustments	608,287

14. Annual reporting and recordkeeping cost burden (in thousands of dollars)

a. Total annualized capital/startup costs	164,752
b. Total annual costs (O&M)	164,752
c.Total annualized cost requested	
d. Current OMB inventory	98,545
e. Difference	66,207
f. Explanation of difference	
1. Program change	
2. Adjustment	66,207

15. Purpose of information collection *(Mark primary with "P" and all others that apply with "X")*

a. __ Application for benefits
b. **X** Program evaluation
c. __ General purpose statistics
d. **X** Audit
e. **X** Program planning or management
f. __ Research
g. **P** Regulatory or compliance

16. Frequency of recordkeeping or reporting (check all that apply)

a. ☒ Recordkeeping b. ☒ Third party disclosure
c. ☐ Reporting
1. ☒ On occasion 2. ☐ Weekly 3. ☐ Monthly
4. ☐ Quarterly 5. ☐ Semi-annually 6. ☒ Annually
7. ☐ Biennially 8. ☐ Other (describe) _____

17. Statistical methods

Does this information collection employ statistical methods?

☐ Yes ☒ No

18. Agency contact (person who can best answer questions regarding the content of this submission)

Name: Jamaa N. Hill

Phone: (202) 693-2222

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9.

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8 (b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collections of information, that the certification covers:

(a) Is necessary for proper performance of the agency's functions and has practical utility;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It uses plain, coherent and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention periods for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8 (b)(3)

(h) Why the information is being collected;

(ii) Use of information;

(iii) Burden estimate;

(iv) Nature of response (voluntary, required for a benefit, or mandatory);

(v) Nature and extent of confidentiality; and

(vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of the Instructions);

(i) It uses effective and efficient statistical survey methodology; and,

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Agency Clearance Officer	Date
Todd R. Owen, OSHA Clearance Officer	
Signature of Senior Departmental Official or Designee	Date

SUPPORTING STATEMENT FOR THE INFORMATION COLLECTION REQUIREMENTS OF THE RESPIRATORY PROTECTION (29 CFR 1910.134)[1],[2] (OMB CONTROL NO. 1218-0099(2008))(December 2007)

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 employee 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 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, §1910.134, (the "Standard") assists employers in

[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.

protecting the health of employees exposed to airborne contaminants, physical hazards, and biological agents. The Standard contains requirements for program administration; a written respirator-protection program with worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; respirator use; respirator cleaning, maintenance, and repair; 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 (§1910.134(c))

§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 employees 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 employees.

B. Medical evaluation (§1910.134(e))

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

Using a respirator may place a physiological burden on employees 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 employee. Accordingly, this paragraph specifies the minimum requirements for medical evaluation that employers must implement to determine the employee'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.

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 employee 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 employee 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 employees. For example, wearing protective clothing while performing heavy work can be highly stressful. Also, specific medical conditions can compromise an employee's ability to tolerate the physiological burdens imposed by respirator use, thereby placing the employee 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 employees who are at high risk for cardiopulmonary disease.

Follow-up medical examination (§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 employees 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 employee'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 an employee's ability to use the respirator. This information also allows the PLHCP to limit the conditions under which the employee uses a respirator.

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

Additional medical evaluations (§1910.134(e)(7))

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

> §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 an employee remains medically eligible to use a respirator during exposure to atmospheric contaminants in the workplace.

C. Fit testing (§1910.134(f))

This paragraph requires that, before an employee may be required to use any respirator with a negative or positive pressure tight-fitting facepiece, the employee 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)(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: Please insert a purpose.

[5] After a fit test, employers must record the employee'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.

D. Maintenance and care of respirators (§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 employees.

> §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 employees that emergency-use respirators will operate properly when needed.

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

This paragraph requires the employer to provide employees 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 employees and employers that the purchased breathing air used in atmosphere-supplying respirators is safe. In addition, the tag requirement provides assurance to employees 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 (§1910.134(k))

This paragraph requires the employer to provide effective training to employees who are required to use respirators. The training must be comprehensive, understandable, and recur annually, and more often if necessary. This paragraph also requires the employer to provide the basic information on respirators in Appendix D of this section to employees who wear respirators when not required by this section or by the employer to do so.

§1910.134(k)(1) - The employer shall ensure that each employee can demonstrate knowledge of at least the following:

> §1910.134(k)(1)(i) - Why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator;
>
> §1910.134(k)(1)(ii) - What the limitations and capabilities of the respirator are;
>
> §1910.134(k)(1)(iii) - How to use the respirator effectively in emergency situations, including situations in which the respirator malfunctions;
>
> §1910.134(k)(1)(iv) - How to inspect, put on and remove, use, and check the seals of the respirator;
>
> §1910.134(k)(1)(v) - What the procedures are for maintenance and storage of the respirator;
>
> §1910.134(k)(1)(vi) - How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators; and
>
> §1910.134(k)(1)(vii) - The general requirements of this section.

§1910.134(k)(2) - The training shall be conducted in a manner that is understandable to the employee.

§1910.134(k)(3) - The employer shall provide the training prior to requiring the employee to use a respirator in the workplace.

§1910.134(k)(4) - An employer who is able to demonstrate that a new employee has received training within the last 12 months that addresses the elements specified in paragraph (k)(1)(i) through (vii) is not required to repeat such training provided that, as required by paragraph

(k)(1), the employee can demonstrate knowledge of those element(s). Previous training not repeated initially by the employer must be provided no later than 12 months from the date of the previous training.

§1910.134(k)(5) - Retraining shall be administered annually, and when the following situations occur:

> §1910.134(k)(5)(i) - Changes in the workplace or the type of respirator render previous training obsolete;
>
> §1910.134(k)(5)(ii) - Inadequacies in the employee's knowledge or use of the respirator indicate that the employee has not retained the requisite understanding or skill; or
>
> §1910.134(k)(5)(iii) - Any other situation arises in which retraining appears necessary to ensure safe respirator use.

§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.

Purpose: Training ensures that employees understand that proper fit, use, and maintenance of respirators is critical to proper respirator protection. Inadequate attention to any of the training elements may impair employees' effective use of respirators.

G. Recordkeeping (§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 employee 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.

§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.

Purpose: Employers may use an employee'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 an employee prior to initial respirator use, administered the appropriate test, and performed the test correctly; and the employee passed the test and is using the proper respirator model and size.

Making the information ensures that employees 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 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 for the purposes described in Item 2 above.

The information collection requirements in the Standard are specific to each employer and employee 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 (Item 5 of OMB Form 83-I), 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.

6. Describe the consequence 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 employees 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 date 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 3 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.

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), OSHA will publish a notice in the **Federal Register** requesting public comment on its extension of the information collection requirements contained in the Respiratory Protection Standard (29 CFR 1910.134). The notice is part of a preclearance consultation program intended to provide those interested parties the opportunity to comment on OSHA's request for an extension by the Office of Management and Budget (OMB) of a previous approval of the information collection requirements found in the above standard.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration 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 §1913.10, which governs its access to employee 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 form whom the information is requested, and any steps to be taken to obtain their consent.

None of the provisions in the Standard require an employer to collect sensitive information.

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 in Item 13 of OMB Form 83-I.**

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of**

information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

Burden Hour and Cost Determinations

The following sections summarize the methodology used for estimating the number of burden hours and costs resulting from the information-collection requirements of the Standard.

Wage Rates

The Agency adopted the mean wage rates from *"Employer Costs for Employee Compensation, September 2007", U.S. Department of Labor, Bureau of Labor Statistics http://stats.bls.gov/home.htm.* Total compensation for these occupational categories includes an adjustment of 29.4 percent (*Employer Costs for Employee Compensation, September 2007, pp.4)* for fringe benefits; this figure represents the average level of fringe benefits in the private sector. The costs of labor used in this analysis are, therefore, estimates of total hourly compensation. These hourly wages are:

Supervisor	$43.80
Worker (Employee)	$35.04
Secretary	$21.44

(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 4 and 8 hours, respectfully, to develop the written program. Of the estimated 639,623[6] employers covered by the Standard in 2005, OSHA believes that each year 11.6%[7] (74,196) are new employers who must develop new programs. The Agency assumes that 9% (72,712) of the new employers are small firms,[8] and that the remaining 2% (1,484) 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 and maintain a written respiratory-protection program are:

Burden hours: (72,712 x 4 hours) + (1,484 x 8 hours) = 302,720 hours
Cost: 302,720 hours x $43.80 = $13,259,136

[6] 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 compared the estimated number of establishments covered under the previous ICR with 2001 County Business Patterns (CBP) survey data to determine the percentage of establishments within each industry using respirators. These percentages were applied to 2005 CBP data to determine the total number of establishments within each industry division currently using respirators.
[7] The United States Census Bureau, http://www2.census.gov/csd/susb/dynamic/0304/us4dn03_04.xls.
[8] Small firms are defined as those employers employing less than 500 employees per facility.

Existing employers[9] must update their programs to accommodate changes in workplace conditions that affect respirator use. OSHA assumes that 20% of existing employers (113,085) update their programs every year, and that supervisors for small firms (113,085 x 98% = 110,823 firms) would take 2 hours, and supervisors for larger firms (113,085 x 2% = 2,262 firms) would take 4 hours, to update the programs. The annual burden hour and cost estimates for existing employers to update their programs are:

Burden hours: (110,823 x 2 hours) + (2,262 x 4 hours) = 230,694 hours
Cost: 230,694 hours x $43.80 = $10,104,397

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

Total burden hours: 302,720 hours + 230,694 hours = 533,414 hours
Total cost: $13,259,136 + $10,104,397 = $23,363,533

(B) Medical Evaluation (§1910.134(e))

Paragraph (e)(2) of the Standard specifies that employers must medically evaluate employees 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 an employee takes 15 minutes (.25 hour) to complete the questionnaire. Based on assumptions used in the 2001 NIOSH/BLS survey of respirator use and practices and employment data from the U.S. Census Bureau's County Business Patterns survey, it is estimated that in 2005 the Standard covered 5,412,000 employees.[10] The 2005 BLS Job Openings and Labor Turnover survey estimated an average total separations rate of 40.5% in industries covered by the Standard. The burden hours and cost to administer the questionnaire to the 2,191,860 (5,412,000 x 40.5%) new employees (with an hourly wage rate of $35.04) each year are:

Burden hours: 2,191,860 questionnaires x .25 hour = 547,965 hours
Cost: 547,965 hours x $35.04 = $19,200,694

According to paragraph (e)(3) of the Standard, employers must provide follow-up medical examinations to employees who respond positively to specific items in the questionnaire (or to the initial medical examination). OSHA estimates that 23%[11] of the 2,191,860 new employees (504,128) require follow-up medical examinations each year, and that it takes 1 hour for them to receive a follow-up medical examination. Therefore, the annual burden hours and cost of this provision are:

Burden hours: 504,128 employees x 1 hour = 504,128 hours
Cost: 504,128 hours x $35.04 = $17,664,645

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9 Existing employers do not include the 74,196 employer's who have developed new initial written respirator programs.

[10] 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. To determine the current number of affected employees, OSHA used CBP data to compare total employment in each industry division covered by the Standard; total employment in these industries declined by 1.6% (0.016) from 2001 to 2005. This 1.6% decrease was then applied to the existing estimate contained in the previous ICR to determine updated employment figures (5,500,000 x 0.984 = 5,412,000)

[11]The FEA initially 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.

Paragraph (e)(5) of the Standard requires employers to provide PLHCPs with information about an employee's respirator and work conditions before the PLHCP makes a recommendation concerning an employee's eligibility to use the respirator. Employers provide this information to PLHCPs prior to an employee's initial medical evaluation and any additional medical examination.[12] OSHA estimates that employers provide 2,191,860 initial medical evaluations and 504,128 additional medical evaluations each year and that, for each medical evaluation, a secretary takes 15 minutes (.25 hour) 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: 2,695,988 medical evaluations x .25 hour = 673,997 hours
Cost: 673,997 hours x $21.44 = $14,450,496

Paragraph (e)(7) of the Standard requires employers to provide an additional medical evaluation to employees under specific conditions. However, the Agency believes that most employees who use respirators do not need additional medical evaluations. Therefore, OSHA assumes that 5% of all employees (5% x 5,412,000 = 270,600) will require additional medical evaluations each year, and that each of these employees takes .50 hour to undergo the additional medical evaluation. The yearly burden hours and cost of this provision are:

Burden hours: 270,600 employees x .50 hour = 135,300 hours
Cost: 135,300 hours x $35.04 = $4,740,912

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: 547,965 hours + 504,128 hours + 673,997 hours + 135,300 hours = 1,861,390 hours
Total cost: $19,200,694 + $17,664,645 + $14,450,496 + $4,740,912 = $56,056,747

C. Fit testing (§1910.134(f))

Based on the FEA, of the 5,412,000 employees covered by this provision, 13% (705,560) were receiving annual fit tests when the Standard became effective. Therefore, the additional paperwork requirement associated with annual fit testing applies only to the remaining 87% (4,708,440). From percentages used in the FEA, OSHA finds that outside contractors provide quantitative fit tests to 8% (376,675) of these employees, while respirator manufacturers administer qualitative fit tests to about 20% (941,688) of the remaining employees at no cost to their employers, and employers conduct in-house fit testing on the final group of 3,390,077 employees. The Agency believes that each employee takes about 30 minutes (.50 hour) to complete a fit test, and that a supervisor requires about 30 minutes (.50 hour) to administer an in-house fit test. The annual burden hour and cost estimates for fit testing are:

[12]Employers do not need to provide supplemental information regarding an employee 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 an employee receives a follow-up examination because the PLHCP usually receives the information prior to the initial medical evaluation.

Quantitative Fit Testing by Outside Contractors

Burden hours: 376,675 tests x .50 hour (employee time) = 188,338 hours
Cost: 188,338 hours x $35.04 = $6,599,364

Qualitative Fit Testing by Respirator Manufacturers

Burden hours: 941,688 tests x .50 hour (employee time) = 470,844 hours
Cost: 470,844 hours x $35.04 = $16,498,374

In-House Fit Testing by Supervisors

Burden hours:	Supervisors:	3,390,077 tests x .50 hour = 1,695,039 hours
	Employees:	3,390,077 tests x .50 hour = 1,695,039 hours
	Total:	1,695,039 hours + 1,695,039 hours = 3,390,078 hours
Cost:	Supervisors:	1,695,039 hours x $43.80 = $74,242,708
	Employees:	1,695,039 hours x $35.04 = $59,394,167
	Total:	$74,242,708 + $59,394,167 = $133,636,875

Total burden hours and costs for fit testing by outside contractors, respirator manufacturers, and in-house supervisors are:

Total burden hours: 188,338 hours + 470,844 hours + 3,390,078 hours = 4,049,260 hours
Total cost: $6,599,364 + $16,498,374 + $133,636,875 = $156,734,613

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. Applying this percentage to the total number of employers who use respirators (639,623) results in 12,792 employers who would be affected by this provision. OSHA assumes that 10% of these employers (1,279) 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 2,558 respirators. In addition, the Agency estimates that an employee takes 5 minutes (.08 hour) 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: 2,558 respirators x .08 hour = 205 hours
Cost: 205 hours x $35.04 = $7,183

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 an employee takes 10 minutes (.17 hour) 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 12,792 employers each have 2 emergency-use respirators (for a total of 25,586 respirators). Accordingly, the yearly burden-hour and cost estimates for this provision are:

Burden hours: 25,586 respirators x 12 inspections/year x .17 hour = 52,195 hours
Cost: 52,195 hours x $35.04 = $1,828,913

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 3 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 24,331 compressors[13], and that an employee takes 5 minutes (.08 hour) to enter this information on a tag. Therefore, the annual burden hours and cost of this provision are:

Burden hours: 24,331 compressors x 3 changes/year x .08 hour = 5,839 hours
Cost: 5,839 hours x $35.04 = $204,599

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

This provision requires employers to provide employees with specific knowledge and skills, and to retrain them under defined conditions. Employers can comply with this provision by reviewing with the employee, orally or using written material, the information provided under the training program and how the employee uses the respirator.

OSHA believes that this provision is performance oriented because employers assess employees' knowledge and skills by observing how they use respirators; in addition, the provision does not specify an hourly training requirement, require training records, training format, or how the employer is to conduct the training. Therefore, the Agency will incur no burden hours or cost for these information-collection requirements in this Summary Statement.

(G) Recordkeeping (§1910.134(m))

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

[13] OSHA assumes that compressors are used in forced air respirators and that the number of compressors declined at the same rate as total employment. OSHA has updated the value contained in the original ICR to update this 1.6% decline (24,727 x 0.984 = 24,331)

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 2,966,588 medical records each year (i.e., 2,191,860 initial medical evaluations + 504,128 follow-up medical examinations + 270,600 additional medical evaluations). In addition, the Agency estimates that a secretary takes 5 minutes (.08 hour) to maintain each medical record. Accordingly, the annual burden hours and cost of this recordkeeping requirement are:

Burden hours: 2,966,588 records x .08 hour = 237,327 hours
Cost: 237,327 hours x $21.44 = $5,088,291

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 employees. As noted under section (C) above, employers collect 4,708,440 fit-testing records annually. OSHA estimates that a secretary spends 5 minutes (.08 hour) annually establishing and maintaining each of these records. The burden hours and cost associated with this provision are:

Burden hours: 4,708,440 records x .08 hour = 376,675 hours
Cost: 376,675 hours x $21.44 = $8,075,912

Employee Access (§1910.134(m)(4))

OSHA assumes that each year 10% of the employees 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 (.08 hour) to process each of these requests. Therefore, this provision results in the following burden hours and cost:

Burden hours: 5,412,000 employees x 10% x .08 hour = 43,296 hours
Cost: 43,296 hours x $21.44 = $928,266

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 of 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**

collection services should be a 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 total cost for employers to provide medical examinations and fit testing is $164,751,553 determined as follows:

Medical Examinations

Assuming that each medical examination costs $266.50[14], the total cost of administering the 504,128 medical examinations (see section (B) above (§1910.134(e)(3)) is $134,350,112 (504,128 medical examinations x $266.50).

Fit-Testing Materials

As noted under section (C) above, employers administer in-house fit tests to 3,390,077 employees each year. Estimating that the materials for each fit test cost $1.07[15], OSHA determined that the total cost of these materials is $3,627,382 (3,390,077 tests x $1.07).[16]

Quantitative Fit Tests

Section (C) above shows that contractors administer quantitative fit tests to 376,675 employees. Having determined that the price of each of these fit tests is $71.08[17], the Agency found that the total cost of this testing was $26,774,059 (376,675 tests x $71.08).

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

The Agency estimates that a compliance officer (GS-12, step 5), with an hourly rate of $37.89, would spend 10 minutes (.17 hour) during an inspection reviewing the paperwork requirements specified by the

[14] The previous ICR assumed that each medical examination cost $250. The Consumer Price Index (CPI) indicated a 6.6% increase in the price of professional medical services from 2004 to 2006; the cost of a medical examination was assumed to have increased by 6.6% as well.
[15] The previous ICR assumed that materials for each fit test cost $1.00. Given an increase in the CPI of 6.6% from 2004 to 2006, it was assumed that the cost of materials increased by 6.6% as well.
[16] 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.
[17] The previous ICR determined that the price of quantitative fit test was $66.68. Given an increase in the CPI of 6.6% from 2004 to 2006, it was assumed that the cost of quantitative fit tests increased by 6.6% as well.

Standard, especially medical-evaluation and fit-testing records. OSHA determined that its compliance officers would conduct 8,955 inspections during 2004.[18] The Agency considers other expenses, such as equipment, overhead, and support-staff salaries, to be normal operating expenses that would occur without the collection-of-information requirements specified by the Standard. Therefore, the total cost of these paperwork requirements to the Federal government is:

Cost: 8,955 inspections x $37.89 x .17 hour = $57,682

15. Explain the reasons for any program changes or adjustments reporting in Items 13 or 14 of the OMB Form 83-I.

OSHA is requesting to increase the burden hours of these paperwork requirements from 6,551,314 burden hours to 7,159,601 hours, for a total increase of 608,287 hours. Table 1 attached describes each of the requested burden hour adjustments.

The cost to respondents is $164,751,553; this is an increase of $66,206,249 from the current estimate of $98,545,304. The cost of medical examinations has increased from $250.00 to $266.50. With 504,128 being performed at $266.50 per examination, the total cost is $134,350,112; this is an increase of $65,600,112. The cost of fit-testing materials has increased from $1.00 to $1.07. With 3,390,077 fit-test being administered at $1.07, the total cost is $3,627,382; this is an increase of $182,182. The cost of quantitative test has increased from $66.68 to $71.08. With 376,675 quantitative examinations being performed at $71.08 per exam, the total cost is $26,774,059; this is an increase of $1,248,955.

16. For collections 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 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 appropriate.

There are no forms on which to display the expiration date.

18. Explain each exception to the certification statement identified in Item 19 per "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.

OSHA is not seeking such an exception.

[18]OSHA estimated the number of inspections by determining an overall inspection rate of 1.4% (0.014) for all employers under its jurisdiction, then applying this percentage to the number of employers (639,623) covered by the Standard.

Table 1

Description of Requested Burden-Hour Adjustments

Information-Collection Requirement	Responses	Current Burden Hours	Requested Burden Hours	Burden Hour Change	Estimated Cost	Description of Change
Respiratory Protection Program						
Respiratory Protection Program	191,886	505,455	533,414	27,959	$23,363,533	The number of affected employers increased from 619,430 to 639,623 as a result of updating the existing number of covered employees using the 2005 County Business Patterns see footnote 7 for source information). This is an additional 20,193 covered employees.
Medical Evaluation						
Medical Evaluation: Initial Medical Evaluations, Follow-up Medical Examinations, Additional Medical Evaluations, and Information Provided to the PLHCP	5,662,576	1,089,550	1,861,390	771,840	$56,056,747	There is an increase in burden hours although the number of covered employees has decreased. This is a result of an increase in the percentage of separations rate or job turnover rate (from 22% to 40.5%).
Fit Testing						
Fit Testing	8,098,517	4,115,100	4,049,260	-65,840	$156,734,613	The decrease is due to a reduction in the number of covered employees (from 5,500,000 to 5,412,000). A total reduction of 88,000 covered employees.
Maintenance and Care of Respirators:						
Storing and Marking		198	205	7	$7,183	The number of employers covered by the standard

Information-Collection Requirement	Responses	Current Burden Hours	Requested Burden Hours	Burden Hour Change	Estimated Cost	Description of Change
Emergency-Use Respirator						increased from 619,430 to 639,623 as a result of updating the existing number of covered employees using the 2005 County Business Patterns see footnote 7 for source information). This is an additional 20,193 covered employers.
Certification of Emergency-Use Respirator	307,032	50,547	52,195	-1,648	$1,828,913	The number of employers covered by the standard increased from 619,430 to 639,623 as a result of updating the existing number of covered employees using the 2005 County Business Patterns see footnote 7 for source information). This is an additional 20,193 covered employers.
Breathing air quality and use						
Certificate of Analysis of Cylinders	0	0	0	0	0	
Sorbent Beds and Filters	72,993	5,934	5,839	-95	$204,599	The -95 hours decrease is a result of the number of air compressors decreased by 1.6%, from 24,727 to 24,331.
Training and Information						
Recordkeeping						
Medical-Evaluation Records	2,966,588	141,064	237,327	96,263	$5,088,291	There is an increase in burden hours although the number of covered employees has decreased. This is a result of an increase in the percentage of separations rate or job turnover rate (from 22% to 40.5%).
Fit-Testing Records	4,708,440	382,800	376,675	-6,125	$8,075,912	The decrease is due to a reduction in the number of covered employees (from 5,500,000 to 4,412,000).

Information-Collection Requirement	Responses	Current Burden Hours	Requested Burden Hours	Burden Hour Change	Estimated Cost	Description of Change
Employee Access	541,200	44,000	43,296	-704	$928,266	The decrease is due to a reduction in the number of covered employees (from 5,500,000 to 4,412,000).
TOTALS	22,547,185	6,551,314	7,159,601	608,287	$252,288,056	

SEC. 2. Congressional Findings and Purpose

29 USC 651

(a) The Congress finds that personal injuries and illnesses arising out of work situations impose a substantial burden upon, and are a hindrance to, interstate commerce in terms of lost production, wage loss, medical expenses, and disability compensation payments.

(b) The Congress declares it to be its purpose and policy, through the exercise of its powers to regulate commerce among the several States and with foreign nations and to provide for the general welfare, 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 --

(1) by encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions; (2) by providing that employers and employees have separate but dependent responsibilities and rights with respect to achieving safe and healthful working conditions;

(3) by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under the Act;

(4) by building upon advances already made through employer and employee initiative for providing safe and healthful working conditions;

(5) by providing for research in the field of occupational safety and health, including the psychological factors involved, and by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems;

(6) by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety;

(7) by providing medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience;

(8) by providing for training programs to increase the number and competence of personnel engaged in the field of occupational safety and health; affecting the OSH Act since its passage in 1970 through January 1, 2004.

(9) by providing for the development and promulgation of occupational safety and health standards;

(10) by providing an effective enforcement program which shall include a prohibition against giving advance notice of any inspection and sanctions for any individual violating this prohibition;

(11) by encouraging the States to assume the fullest responsibility for the administration and enforcement of their occupational safety and health laws by providing grants to the States to assist in identifying their needs and responsibilities in the area of occupational safety and health, to develop plans in accordance with the provisions of this Act, to improve the administration and enforcement of State occupational safety and health laws, and to conduct experimental and demonstration projects in connection therewith;

(12) by providing for appropriate reporting procedures with respect to occupational safety and health which procedures will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem;

(13) by encouraging joint labor-management efforts to reduce injuries and disease arising out of employment.

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6. Occupational Safety and Health Standards

29 USC 655:

(a) Without regard to chapter 5 of title 5, United States Code, or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this Act and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees.

(b) The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:

(1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health and Human Services, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this Act, the Secretary may request the recommendations of an advisory committee appointed under section 7 of this Act. The Secretary shall provide such an advisory committee with any proposals of his own or of the Secretary of Health and Human Services, together with all pertinent factual information developed by the Secretary or the Secretary of Health and Human Services, or otherwise available, including the results of research, demonstrations, and experiments. An advisory committee shall submit to the Secretary its recommendations regarding the rule to be promulgated within ninety days from the date of its appointment or within such longer or shorter period as may be prescribed by the Secretary, but in no event for a period which is longer than two hundred and seventy days.

(2) The Secretary shall publish a proposed rule promulgating, modifying, or revoking an occupational safety or health standard in the Federal Register and shall afford interested persons a period of thirty days after publication to submit written data or comments. Where an advisory committee is appointed and the Secretary determines that a rule should be issued, he shall publish the proposed rule within sixty days after the submission of the advisory committee's recommendations or the expiration of the period prescribed by the Secretary for such submission.

(3) On or before the last day of the period provided for the submission of written data or comments under paragraph (2), any interested person may file with the Secretary written objections to the proposed rule, stating the grounds therefore and requesting a public hearing on such objections. Within thirty days after the last day for filing such objections, the Secretary shall publish in the Federal Register a notice specifying the occupational safety or health standard to which objections have been filed and a hearing requested, and specifying a time and place for such hearing.

(4) Within sixty days after the expiration of the period provided for the submission of written data or comments under paragraph (2), or within sixty days after the completion of any hearing held under paragraph (3), the Secretary shall issue a rule promulgating, modifying, or revoking an occupational safety or health standard or make a determination that a rule should not be issued. Such a rule may contain a provision delaying its effective date for such period (not in excess of ninety days) as the Secretary determines may be necessary to insure that affected employers and employees will be informed of the existence of the standard and of its terms and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the requirements of the standard.

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

(6) (A) Any employer may apply to the Secretary for a temporary order granting a variance from a standard or any provision thereof promulgated under this section. Such temporary order shall be granted only if the employer files an application which meets the requirements of clause (B) and establishes

that --

(i) he is unable to comply with a standard by its effective date because of unavailability of professional or technical personnel or of materials and equipment needed to come into compliance with the standard or because necessary construction or alteration of facilities cannot be completed by the effective date,

(ii) he is taking all available steps to safeguard his employees against the hazards covered by the standard, and

(iii) he has an effective program for coming into compliance with the standard as quickly as practicable.

Any temporary order issued under this paragraph shall prescribe the practices, means, methods, operations, and processes which the employer must adopt and use while the order is in effect and state in detail his program for coming into compliance with the standard. Such a temporary order may be granted only after notice to employees and an opportunity for a hearing: *Provided,* That the Secretary may issue one interim order to be effective until a decision is made on the basis of the hearing. No temporary order may be in effect for longer than the period needed by the employer to achieve

compliance with the standard or one year, whichever is shorter, except that such an order may be renewed not more that twice (I) so long as the requirements of this paragraph are met and (II) if an application for renewal is filed at least 90 days prior to the expiration date of the order. No interim renewal of an order may remain in effect for longer than 180 days.

(B) An application for temporary order under this paragraph (6) shall contain:

(i) a specification of the standard or portion thereof from which the employer seeks a variance,

(ii) a representation by the employer, supported by representations from qualified persons having firsthand knowledge of the facts represented, that he is unable to comply with the standard or portion thereof and a detailed statement of the reasons therefor,

(iii) a statement of the steps he has taken and will take (with specific dates) to protect employees against the hazard covered by the standard,

(iv) a statement of when he expects to be able to comply with the standard and what steps he has taken and what steps he will take (with dates specified) to come into compliance with the standard, and

(v) a certification that he has informed his employees of the application by giving a copy thereof to their authorized representative, posting a statement giving a summary of the application and specifying where a copy may be examined at the place or places where notices to employees are normally posted, and by other appropriate means.

A description of how employees have been informed shall be contained in the certification. The information to employees shall also inform them of their right to petition the Secretary for a hearing.

(C) The Secretary is authorized to grant a variance from any standard or portion thereof whenever he determines, or the Secretary of Health and Human Services certifies, that such variance is necessary to permit an employer to participate in an experiment approved by him or the Secretary of Health and Human Services designed to demonstrate or validate new and improved techniques to safeguard the health or safety of workers.

(7) Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. In the event such medical examinations are in the nature of research, as determined by the Secretary of

Health and Human Services, such examinations may be furnished at the expense of the Secretary of Health and Human Services. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health and Human Services, and, at the request of the employee, to his physician. The Secretary, in consultation with the Secretary of Health and Human Services, may by rule promulgated pursuant to section 553 of title 5, United States Code, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

(8) Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard.

(c) (1) The Secretary shall provide, without regard to the requirements of chapter 5, title 5, Unites States Code, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines --

(A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and

(B) that such emergency standard is necessary to protect employees from such danger.

(2) Such standard shall be effective until superseded by a standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

(3) Upon publication of such standard in the Federal Register the Secretary shall commence a proceeding in accordance with section 6 (b) of this Act, and the standard as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a standard under this paragraph no later than six months after publication of the emergency standard as provided in paragraph (2) of this subsection.

(d) Any affected employer may apply to the Secretary for a rule or order for a variance from a standard promulgated under this section. Affected employees shall be given notice of each such application and an opportunity to participate in a hearing. The Secretary shall issue such rule or order if he determines on the record, after opportunity for an inspection where appropriate and a hearing, that the proponent of the variance has demonstrated by a preponderance of the evidence that the conditions, practices, means, methods, operations, or processes used or proposed to be used by an employer will provide employment and places of employment to his employees which are as safe and healthful as those which would prevail if he complied with the standard. The rule or order so issued shall prescribe the conditions the employer must maintain, and the practices, means, methods, operations, and

processes which he must adopt and utilize to the extent they differ from the standard in question. Such a rule or order may be modified or revoked upon application by an employer, employees, or by the Secretary on his own motion, in the manner prescribed for its issuance under this subsection at any time after six months from its issuance.

(e) Whenever the Secretary promulgates any standard, makes any rule, order, or decision, grants any exemption or extension of time, or compromises, mitigates, or settles any penalty assessed under this Act, he shall include a statement of the reasons for such action, which shall be published in the Federal Register.

(f) Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

(g) In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments. The Secretary shall also give due regard to the recommendations of the Secretary of Health and Human Services regarding the need for mandatory standards in determining the priority for establishing such standards.

SEC. 8. Inspections, Investigations, and Recordkeeping

(a) In order to carry out the purposes of this Act, the Secretary, upon presenting appropriate credentials to the owner, operator, or agent in charge, is authorized -- 29 USC 657

(1) to enter without delay and at reasonable times any factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by an employee of an employer; and

(2) to inspect and investigate during regular working hours and at other reasonable times, and within reasonable limits and in a reasonable manner, any such place of employment and all pertinent conditions, structures, machines, apparatus, devices, equipment, and materials therein, and to question privately any such employer, owner, operator, agent or employee.

(b) In making his inspections and investigations under this Act the Secretary may require the attendance and testimony of witnesses and the production of evidence under oath. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In case of a contumacy, failure, or refusal of any person to obey such an order, any district court of the United States or the United States courts of any territory or possession, within the jurisdiction of which such person is found, or resides or transacts business, upon the application by the Secretary, shall have jurisdiction to issue to such person an order requiring such person to appear to produce evidence if, as, and when so ordered, and to give testimony relating to the matter under investigation or in question, and any failure to obey such order of the court may be punished by said court as a contempt thereof.

(c) (1) Each employer shall make, keep and preserve, and make available to the Secretary or the Secretary of Health and Human Services, such records regarding his activities relating to this Act as the Secretary, in cooperation with the Secretary of Health and Human Services, 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. In order to carry out the provisions of this paragraph such regulations may include provisions requiring employers to conduct periodic inspections. The Secretary shall also issue regulations requiring that employers, through posting of notices or other appropriate means, keep their employees informed of their protections and obligations under this Act, including the provisions of applicable standards.

(2) The Secretary, in cooperation with the Secretary of Health and Human Services, shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.

(3) The Secretary, in cooperation with the Secretary of Health and Human Services, shall issue regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6. Such regulations shall provide employees or their representatives with an opportunity to observe such monitoring or measuring, and to have access to the records thereof. Such regulations shall also make appropriate provision for each employee or former employee to have access to such records as will indicate his own exposure to toxic materials or harmful physical agents. Each employer shall promptly notify any employee who has been or is being exposed to toxic materials or harmful physical agents in concentrations or at levels which exceed those prescribed by an applicable occupational safety and health standard promulgated under section 6, and shall inform any employee who is being thus exposed of the corrective action being taken.

(d) Any information obtained by the Secretary, the Secretary of Health and Human Services, or a State agency under this Act shall be obtained with a minimum burden upon employers, especially those operating small businesses. Unnecessary duplication of efforts in obtaining information shall be reduced to the maximum extent feasible.

(e) Subject to regulations issued by the Secretary, a representative of the employer and a representative authorized by his employees shall be given an opportunity to accompany the Secretary or his authorized representative during the physical inspection of any workplace under subsection (a) for the purpose of aiding such inspection. Where there is no authorized employee representative, the Secretary or his authorized representative shall consult with a reasonable number of employees concerning matters of health and safety in the workplace.

(f) (1) Any employees or representative of employees who believe that a violation of a safety or health standard exists that threatens physical harm, or that an imminent danger exists, may request an inspection by giving notice to the Secretary or his authorized representative of such violation or danger. Any such notice shall be reduced to writing, shall set forth with reasonable particularity the grounds for the notice, and shall be signed by the employees or representative of employees, and a copy shall be provided the employer or his agent no later than at the time of inspection, except that, upon the request of the person giving such notice, his name and the names of individual employees referred to therein shall not appear in such copy or on any record published, released, or made available pursuant to subsection (g) of this section. If upon receipt of such notification the Secretary determines there are reasonable grounds to believe that such violation or danger exists, he shall make a special inspection in accordance with the provisions of this section as soon as practicable, to determine if such violation or danger exists. If the Secretary determines there are no reasonable grounds to believe that a violation or danger exists he shall notify the employees or representative of the employees in writing of such determination.

(2) Prior to or during any inspection of a workplace, any employees

or representative of employees employed in such workplace may notify the Secretary or any representative of the Secretary responsible for conducting the inspection, in writing, of any violation of this Act which they have reason to believe exists in such workplace. The Secretary shall, by regulation, establish procedures for informal review of any refusal by a representative of the Secretary to issue a citation with respect to any such alleged violation and shall furnish the employees or representative of employees requesting such review a written statement of the reasons for the Secretary's final disposition of the case.

(g) (1) The Secretary and Secretary of Health and Human Services are authorized to compile, analyze, and publish, either in summary or detailed form, all reports or information obtained under this section.

(2) The Secretary and the Secretary of Health and Human Services shall each prescribe such rules and regulations as he may deem necessary to carry out their responsibilities under this Act, including rules and regulations dealing with the inspection of an employer's establishment.

(h) The Secretary shall not use the results of enforcement activities, such as the number of citations issued or penalties assessed, to evaluate employees directly involved in enforcement activities under this Act or to impose quotas or goals with regard to the results of such activities.

Pub. L. 105-198 added subsection (h).

(b) *Criteria for protective eye and face devices.* (1) Protective eye and face devices purchased after July 5, 1994 shall comply with ANSI Z87.1–1989, ''American National Standard Practice for Occupational and Educational Eye and Face Protection,'' which is incorporated by reference as specified in § 1910.6, or shall be demonstrated by the employer to be equally effective.

(2) Eye and face protective devices purchased before July 5, 1994 shall comply with the ANSI ''USA standard for Occupational and Educational Eye and Face Protection,'' Z87.1–1968, which is incorporated by reference as specified in § 1910.6, or shall be demonstrated by the employer to be equally effective.

[59 FR 16360, Apr. 6, 1994; 59 FR 33911, July 1, 1994, as amended at 61 FR 9238, Mar. 7, 1996; 61 FR 19548, May 2, 1996]

§ 1910.134 Respiratory protection.

This section applies to General Industry (part 1910), Shipyards (part 1915), Marine Terminals (part 1917), Longshoring (part 1918), and Construction (part 1926).

(a) *Permissible practice.* (1) In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to this section.

(2) Respirators shall be provided by the employer when such equipment is necessary to protect the health of the 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.

(b) *Definitions.* The following definitions are important terms used in the respiratory protection standard in this section.

Air-purifying respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

Assigned protection factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section.

Atmosphere-supplying respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

Canister or cartridge means a container with a filter, sorbent, or catalyst, or combination of these items, which removes specific contaminants from the air passed through the container.

Demand respirator means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Emergency situation means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of an airborne contaminant.

Employee exposure means exposure to a concentration of an airborne contaminant that would occur if the employee were not using respiratory protection.

End-of-service-life indicator (ESLI) means a system that warns the respirator user of the approach of the end of adequate respiratory protection, for example, that the sorbent is approaching saturation or is no longer effective.

Escape-only respirator means a respirator intended to be used only for emergency exit.

Filter or air purifying element means a component used in respirators to remove solid or liquid aerosols from the inspired air.

Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium.

Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual. (See also Qualitative fit test QLFT and Quantitative fit test QNFT.)

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

High efficiency particulate air (HEPA) filter means a filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter. The equivalent NIOSH 42 CFR 84 particulate filters are the N100, R100, and P100 filters.

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Immediately dangerous to life or health (IDLH) means an atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual's ability to escape from a dangerous atmosphere.

Interior structural firefighting means the physical activity of fire suppression, rescue or both, inside of buildings or enclosed structures which are involved in a fire situation beyond the incipient stage. (See 29 CFR 1910.155)

Loose-fitting facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The MUC can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the required OSHA permissible exposure limit, short-term exposure limit, or ceiling limit. When no OSHA exposure limit is available for a hazardous substance, an employer must determine an MUC on the basis of relevant available information and informed professional judgment.

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Oxygen deficient atmosphere means an atmosphere with an oxygen content below 19.5% by volume.

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all of the health care services required by paragraph (e) of this section.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Respiratory inlet covering means that portion of a respirator that forms the protective barrier between the user's respiratory tract and an air-purifying device or breathing air source, or both. It may be a facepiece, helmet, hood,

suit, or a mouthpiece respirator with nose clamp.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Service life means the period of time that a respirator, filter or sorbent, or other respiratory equipment provides adequate protection to the wearer.

Supplied-air respirator (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

This section means this respiratory protection standard.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

User seal check means an action conducted by the respirator user to determine if the respirator is properly seated to the face.

(c) *Respiratory protection program.* This paragraph requires the employer to develop and implement a written respiratory protection program with required worksite-specific procedures and elements for required respirator use. The program must be administered by a suitably trained program administrator. In addition, certain program elements may be required for voluntary use to prevent potential hazards associated with the use of the respirator. The Small Entity Compliance Guide contains criteria for the selection of a program administrator and a sample program that meets the requirements of this paragraph. Copies of the Small Entity Compliance Guide will be available on or about April 8, 1998 from the Occupational Safety and Health Administration's Office of Publications, Room N 3101, 200 Constitution Avenue, NW, Washington, DC, 20210 (202–219–4667).

(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:

(i) Procedures for selecting respirators for use in the workplace;

(ii) Medical evaluations of employees required to use respirators;

(iii) Fit testing procedures for tight-fitting respirators;

(iv) Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;

(v) Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators;

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

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

(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

(ix) Procedures for regularly evaluating the effectiveness of the program.

(2) Where respirator use is not required:

(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

(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).

(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.

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

(d) *Selection of respirators.* This paragraph requires the employer to evaluate respiratory hazard(s) in the workplace, identify relevant workplace and user factors, and base respirator selection on these factors. The paragraph also specifies appropriately protective respirators for use in IDLH atmospheres, and limits the selection and use of air-purifying respirators.

(1) *General requirements.* (i) The employer shall select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is exposed and workplace and user factors that affect respirator performance and reliability.

(ii) The employer shall select a NIOSH-certified respirator. The respirator shall be used in compliance with the conditions of its certification.

(iii) The employer shall identify and evaluate the respiratory hazard(s) in the workplace; this evaluation shall include a reasonable estimate of employee exposures to respiratory hazard(s) and an identification of the contaminant's chemical state and physical form. Where the employer cannot identify or reasonably estimate the employee exposure, the employer shall consider the atmosphere to be IDLH.

(iv) The employer shall select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

(2) *Respirators for IDLH atmospheres.* (i) The employer shall provide the following respirators for employee use in IDLH atmospheres:

(A) A full facepiece pressure demand SCBA certified by NIOSH for a minimum service life of thirty minutes, or

(B) A combination full facepiece pressure demand supplied-air respirator (SAR) with auxiliary self-contained air supply.

(ii) Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

(iii) All oxygen-deficient atmospheres shall be considered IDLH. Exception: If the employer demonstrates that, under all foreseeable conditions, the oxygen concentration can be maintained within the ranges specified in Table II of this section (i.e., for the altitudes set out in the table), then any atmosphere-supplying respirator may be used.

(3) *Respirators for atmospheres that are not IDLH.* (i) The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements, under routine and reasonably foreseeable emergency situations.

(A) *Assigned Protection Factors (APFs).* Employers must use the assigned protection factors listed in Table 1 to select a respirator that meets or exceeds the required level of employee protection. When using a combination respirator (e.g., airline respirators with an air-purifying filter), employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.

TABLE 1—ASSIGNED PROTECTION FACTORS[5]

Type of respirator[1,2]	Quarter mask	Half mask	Full facepiece	Helmet/hood	Loose-fitting facepiece
1. Air-Purifying Respirator	5	[3]10	50	.....	.....
2. Powered Air-Purifying Respirator (PAPR)	.....	50	1,000	[4]25/1,000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator.					
• Demand mode	.....	10	50	.....	.....
• Continuous flow mode	.....	50	1,000	[4]25/1,000	25
• Pressure-demand or other positive-pressure mode	.....	50	1,000	.....	.....

TABLE 1—ASSIGNED PROTECTION FACTORS [5]—Continued

Type of respirator [1,2]	Quarter mask	Half mask	Full face-piece	Helmet/ hood	Loose-fitting facepiece
4. Self-Contained Breathing Apparatus (SCBA).					
• Demand mode	.....	10	50	50	.....
• Pressure-demand or other positive-pressure mode (e.g., open/closed circuit)	.....	.....	10,000	10,000	.....

Notes:
[1] Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for use at lower concentrations of that substance, or when required respirator use is independent of concentration.
[2] The assigned protection factors in Table 1 are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.
[3] This APF category includes filtering facepieces, and half masks with elastomeric facepieces.
[4] The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.
[5] These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR 1910 subpart Z, employers must refer to the appropriate substance-specific standards in that subpart. Escape respirators for other IDLH atmospheres are specified by 29 CFR 1910.134 (d)(2)(ii).

(B) *Maximum Use Concentration (MUC).* (*1*) The employer must select a respirator for employee use that maintains the employee's exposure to the hazardous substance, when measured outside the respirator, at or below the MUC.

(*2*) Employers must not apply MUCs to conditions that are immediately dangerous to life or health (IDLH); instead, they must use respirators listed for IDLH conditions in paragraph (d)(2) of this standard.

(*3*) When the calculated MUC exceeds the IDLH level for a hazardous substance, or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.

(ii) The respirator selected shall be appropriate for the chemical state and physical form of the contaminant.

(iii) For protection against gases and vapors, the employer shall provide:

(A) An atmosphere-supplying respirator, or

(B) An air-purifying respirator, provided that:

(*1*) The respirator is equipped with an end-of-service-life indicator (ESLI) certified by NIOSH for the contaminant; or

(*2*) If there is no ESLI appropriate for conditions in the employer's workplace, the employer implements a change schedule for canisters and cartridges that is based on objective information or data that will ensure that canisters and cartridges are changed before the end of their service life. The employer shall describe in the respirator program the information and data relied upon and the basis for the canister and cartridge change schedule and the basis for reliance on the data.

(iv) For protection against particulates, the employer shall provide:

(A) An atmosphere-supplying respirator; or

(B) An air-purifying respirator equipped with a filter certified by NIOSH under 30 CFR part 11 as a high efficiency particulate air (HEPA) filter, or an air-purifying respirator equipped with a filter certified for particulates by NIOSH under 42 CFR part 84; or

(C) For contaminants consisting primarily of particles with mass median aerodynamic diameters (MMAD) of at least 2 micrometers, an air-purifying respirator equipped with any filter certified for particulates by NIOSH.

TABLE I—ASSIGNED PROTECTION FACTORS [RESERVED]

TABLE II

Altitude (ft.)	Oxygen deficient Atmospheres (% 0_2) for which the employer may rely on atmosphere-supplying respirators
Less than 3,001	16.0–19.5
3,001–4,000	16.4–19.5
4,001–5,000	17.1–19.5
5,001–6,000	17.8–19.5
6,001–7,000	18.5–19.5
7,001–8,000[1]	19.3–19.5.

[1] Above 8,000 feet the exception does not apply. Oxygen-enriched breathing air must be supplied above 14,000 feet.

(e) *Medical evaluation.* Using a respirator may place a physiological burden on employees 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 employee. Accordingly, this paragraph specifies the minimum requirements for medical evaluation that employers must implement to determine the employee's ability to use a respirator.

(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.

(2) *Medical evaluation procedures.* (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.

(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.

(3) *Follow-up medical examination.* (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.

(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.

(4) *Administration of the medical questionnaire and examinations.* (i) The medical questionnaire and examinations shall be administered confidentially during the employee's normal working hours or at a time and place convenient to the employee. The medical questionnaire shall be administered in a manner that ensures that the employee understands its content.

(ii) The employer shall provide the employee with an opportunity to discuss the questionnaire and examination results with the PLHCP.

(5) *Supplemental information for the PLHCP.* (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:

(A) The type and weight of the respirator to be used by the employee;

(B) The duration and frequency of respirator use (including use for rescue and escape);

(C) The expected physical work effort;

(D) Additional protective clothing and equipment to be worn; and

(E) Temperature and humidity extremes that may be encountered.

(ii) Any supplemental information provided previously to the PLHCP regarding an employee need not be provided for a subsequent medical evaluation if the information and the PLHCP remain the same.

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

NOTE TO PARAGRAPH (e)(5)(iii): When the employer replaces a PLHCP, the employer must ensure that the new PLHCP obtains this information, either by providing the documents directly to the PLHCP or having the documents transferred from the former PLHCP to the new PLHCP. However, OSHA does not expect employers to have employees medically reevaluated solely because a new PLHCP has been selected.

(6) *Medical determination.* In determining the employee's ability to use a respirator, the employer shall:

(i) Obtain a written recommendation regarding the employee's ability to use the respirator from the PLHCP. The recommendation shall provide only the following information:

(A) Any limitations on respirator use related to the medical condition of the employee, or relating to the workplace conditions in which the respirator will be used, including whether or not the employee is medically able to use the respirator;

(B) The need, if any, for follow-up medical evaluations; and

(C) A statement that the PLHCP has provided the employee with a copy of the PLHCP's written recommendation.

(ii) If the respirator is a negative pressure respirator and the PLHCP finds a medical condition that may place the employee's health at increased risk if the respirator is used, the employer shall provide a PAPR if the PLHCP's medical evaluation finds that the employee can use such a respirator; if a subsequent medical evaluation finds that the employee is medically able to use a negative pressure respirator, then the employer is no longer required to provide a PAPR.

(7) *Additional medical evaluations.* At a minimum, the employer shall provide additional medical evaluations that comply with the requirements of this section if:

(i) An employee reports medical signs or symptoms that are related to ability to use a respirator;

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

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

(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.

(f) *Fit testing.* This paragraph requires that, before an employee may be required to use any respirator with a negative or positive pressure tight-fitting facepiece, the employee 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.

(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.

(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.

(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.

(4) If after passing a QLFT or QNFT, the employee subsequently notifies the employer, program administrator, supervisor, or PLHCP that the fit of the respirator is unacceptable, the employee shall be given a reasonable opportunity to select a different respirator facepiece and to be retested.

(5) The fit test shall be administered using an OSHA-accepted QLFT or QNFT protocol. The OSHA-accepted QLFT and QNFT protocols and procedures are contained in Appendix A of this section.

(6) QLFT may only be used to fit test negative pressure air-purifying respirators that must achieve a fit factor of 100 or less.

(7) If the fit factor, as determined through an OSHA-accepted QNFT protocol, is equal to or greater than 100 for tight-fitting half facepieces, or equal to or greater than 500 for tight-fitting full facepieces, the QNFT has been passed with that respirator.

(8) Fit testing of tight-fitting atmosphere-supplying respirators and tight-fitting powered air-purifying respirators shall be accomplished by performing quantitative or qualitative fit testing in the negative pressure mode, regardless of the mode of operation (negative or positive pressure) that is used for respiratory protection.

(i) Qualitative fit testing of these respirators shall be accomplished by temporarily converting the respirator user's actual facepiece into a negative pressure respirator with appropriate filters, or by using an identical negative pressure air-purifying respirator

facepiece with the same sealing surfaces as a surrogate for the atmosphere-supplying or powered air-purifying respirator facepiece.

(ii) Quantitative fit testing of these respirators shall be accomplished by modifying the facepiece to allow sampling inside the facepiece in the breathing zone of the user, midway between the nose and mouth. This requirement shall be accomplished by installing a permanent sampling probe onto a surrogate facepiece, or by using a sampling adapter designed to temporarily provide a means of sampling air from inside the facepiece.

(iii) Any modifications to the respirator facepiece for fit testing shall be completely removed, and the facepiece restored to NIOSH-approved configuration, before that facepiece can be used in the workplace.

(g) *Use of respirators.* This paragraph requires employers to establish and implement procedures for the proper use of respirators. These requirements include prohibiting conditions that may result in facepiece seal leakage, preventing employees from removing respirators in hazardous environments, taking actions to ensure continued effective respirator operation throughout the work shift, and establishing procedures for the use of respirators in IDLH atmospheres or in interior structural firefighting situations.

(1) *Facepiece seal protection.* (i) The employer shall not permit respirators with tight-fitting facepieces to be worn by employees who have:

(A) Facial hair that comes between the sealing surface of the facepiece and the face or that interferes with valve function; or

(B) Any condition that interferes with the face-to-facepiece seal or valve function.

(ii) If an employee wears corrective glasses or goggles or other personal protective equipment, the employer shall ensure that such equipment is worn in a manner that does not interfere with the seal of the facepiece to the face of the user.

(iii) For all tight-fitting respirators, the employer shall ensure that employees perform a user seal check each time they put on the respirator using the procedures in Appendix B–1 or procedures recommended by the respirator manufacturer that the employer demonstrates are as effective as those in Appendix B–1 of this section.

(2) *Continuing respirator effectiveness.* (i) Appropriate surveillance shall be maintained of work area conditions and degree of employee exposure or stress. When there is a change in work area conditions or degree of employee exposure or stress that may affect respirator effectiveness, the employer shall reevaluate the continued effectiveness of the respirator.

(ii) The employer shall ensure that employees leave the respirator use area:

(A) To wash their faces and respirator facepieces as necessary to prevent eye or skin irritation associated with respirator use; or

(B) If they detect vapor or gas breakthrough, changes in breathing resistance, or leakage of the facepiece; or

(C) To replace the respirator or the filter, cartridge, or canister elements.

(iii) If the employee detects vapor or gas breakthrough, changes in breathing resistance, or leakage of the facepiece, the employer must replace or repair the respirator before allowing the employee to return to the work area.

(3) *Procedures for IDLH atmospheres.* For all IDLH atmospheres, the employer shall ensure that:

(i) One employee or, when needed, more than one employee is located outside the IDLH atmosphere;

(ii) Visual, voice, or signal line communication is maintained between the employee(s) in the IDLH atmosphere and the employee(s) located outside the IDLH atmosphere;

(iii) The employee(s) located outside the IDLH atmosphere are trained and equipped to provide effective emergency rescue;

(iv) The employer or designee is notified before the employee(s) located outside the IDLH atmosphere enter the IDLH atmosphere to provide emergency rescue;

(v) The employer or designee authorized to do so by the employer, once notified, provides necessary assistance appropriate to the situation;

(vi) Employee(s) located outside the IDLH atmospheres are equipped with:

(A) Pressure demand or other positive pressure SCBAs, or a pressure demand or other positive pressure supplied-air respirator with auxiliary SCBA; and either

(B) Appropriate retrieval equipment for removing the employee(s) who enter(s) these hazardous atmospheres where retrieval equipment would contribute to the rescue of the employee(s) and would not increase the overall risk resulting from entry; or

(C) Equivalent means for rescue where retrieval equipment is not required under paragraph (g)(3)(vi)(B).

(4) *Procedures for interior structural firefighting.* In addition to the requirements set forth under paragraph (g)(3), in interior structural fires, the employer shall ensure that:

(i) At least two employees enter the IDLH atmosphere and remain in visual or voice contact with one another at all times;

(ii) At least two employees are located outside the IDLH atmosphere; and

(iii) All employees engaged in interior structural firefighting use SCBAs.

NOTE 1 TO PARAGRAPH (g): One of the two individuals located outside the IDLH atmosphere may be assigned to an additional role, such as incident commander in charge of the emergency or safety officer, so long as this individual is able to perform assistance or rescue activities without jeopardizing the safety or health of any firefighter working at the incident.

NOTE 2 TO PARAGRAPH (g): Nothing in this section is meant to preclude firefighters from performing emergency rescue activities before an entire team has assembled.

(h) *Maintenance and care of respirators.* This paragraph requires the employer to provide for the cleaning and disinfecting, storage, inspection, and repair of respirators used by employees.

(1) *Cleaning and disinfecting.* The employer shall provide each respirator user with a respirator that is clean, sanitary, and in good working order. The employer shall ensure that respirators are cleaned and disinfected using the procedures in Appendix B–2 of this section, or procedures recommended by the respirator manufacturer, provided that such procedures are of equivalent effectiveness. The respirators shall be cleaned and disinfected at the following intervals:

(i) Respirators issued for the exclusive use of an employee shall be cleaned and disinfected as often as necessary to be maintained in a sanitary condition;

(ii) Respirators issued to more than one employee shall be cleaned and disinfected before being worn by different individuals;

(iii) Respirators maintained for emergency use shall be cleaned and disinfected after each use; and

(iv) Respirators used in fit testing and training shall be cleaned and disinfected after each use.

(2) *Storage.* The employer shall ensure that respirators are stored as follows:

(i) All respirators shall be stored to protect them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and they shall be packed or stored to prevent deformation of the facepiece and exhalation valve.

(ii) In addition to the requirements of paragraph (h)(2)(i) of this section, emergency respirators shall be:

(A) Kept accessible to the work area;

(B) Stored in compartments or in covers that are clearly marked as containing emergency respirators; and

(C) Stored in accordance with any applicable manufacturer instructions.

(3) *Inspection.* (i) The employer shall ensure that respirators are inspected as follows:

(A) All respirators used in routine situations shall be inspected before each use and during cleaning;

(B) All respirators maintained for use in emergency situations shall be inspected at least monthly and in accordance with the manufacturer's recommendations, and shall be checked for proper function before and after each use; and

(C) Emergency escape-only respirators shall be inspected before being carried into the workplace for use.

(ii) The employer shall ensure that respirator inspections include the following:

(A) A check of respirator function, tightness of connections, and the condition of the various parts including, but not limited to, the facepiece, head

straps, valves, connecting tube, and cartridges, canisters or filters; and

(B) A check of elastomeric parts for pliability and signs of deterioration.

(iii) In addition to the requirements of paragraphs (h)(3)(i) and (ii) of this section, self-contained breathing apparatus shall be inspected monthly. Air and oxygen cylinders shall be maintained in a fully charged state and shall be recharged when the pressure falls to 90% of the manufacturer's recommended pressure level. The employer shall determine that the regulator and warning devices function properly.

(iv) For respirators maintained for emergency use, the employer shall:

(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

(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.

(4) *Repairs.* The employer shall ensure that respirators that fail an inspection or are otherwise found to be defective are removed from service, and are discarded or repaired or adjusted in accordance with the following procedures:

(i) Repairs or adjustments to respirators are to be made only by persons appropriately trained to perform such operations and shall use only the respirator manufacturer's NIOSH-approved parts designed for the respirator;

(ii) Repairs shall be made according to the manufacturer's recommendations and specifications for the type and extent of repairs to be performed; and

(iii) Reducing and admission valves, regulators, and alarms shall be adjusted or repaired only by the manufacturer or a technician trained by the manufacturer.

(i) *Breathing air quality and use.* This paragraph requires the employer to provide employees using atmosphere-supplying respirators (supplied-air and SCBA) with breathing gases of high purity.

(1) The employer shall ensure that compressed air, compressed oxygen, liquid air, and liquid oxygen used for respiration accords with the following specifications:

(i) Compressed and liquid oxygen shall meet the United States Pharmacopoeia requirements for medical or breathing oxygen; and

(ii) Compressed breathing air shall meet at least the requirements for Grade D breathing air described in ANSI/Compressed Gas Association Commodity Specification for Air, G–7.1–1989, to include:

(A) Oxygen content (v/v) of 19.5–23.5%;

(B) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(C) Carbon monoxide (CO) content of 10 ppm or less;

(D) Carbon dioxide content of 1,000 ppm or less; and

(E) Lack of noticeable odor.

(2) The employer shall ensure that compressed oxygen is not used in atmosphere-supplying respirators that have previously used compressed air.

(3) The employer shall ensure that oxygen concentrations greater than 23.5% are used only in equipment designed for oxygen service or distribution.

(4) The employer shall ensure that cylinders used to supply breathing air to respirators meet the following requirements:

(i) Cylinders are tested and maintained as prescribed in the Shipping Container Specification Regulations of the Department of Transportation (49 CFR part 173 and part 178);

(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

(iii) The moisture content in the cylinder does not exceed a dew point of −50 °F (−45.6 °C) at 1 atmosphere pressure.

(5) The employer shall ensure that compressors used to supply breathing air to respirators are constructed and situated so as to:

(i) Prevent entry of contaminated air into the air-supply system;

(ii) Minimize moisture content so that the dew point at 1 atmosphere pressure is 10 degrees F (5.56 °C) below the ambient temperature;

(iii) Have suitable in-line air-purifying sorbent beds and filters to further ensure breathing air quality. Sorbent beds and filters shall be maintained and replaced or refurbished periodically following the manufacturer's instructions.

(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.

(6) For compressors that are not oil-lubricated, the employer shall ensure that carbon monoxide levels in the breathing air do not exceed 10 ppm.

(7) For oil-lubricated compressors, the employer shall use a high-temperature or carbon monoxide alarm, or both, to monitor carbon monoxide levels. If only high-temperature alarms are used, the air supply shall be monitored at intervals sufficient to prevent carbon monoxide in the breathing air from exceeding 10 ppm.

(8) The employer shall ensure that breathing air couplings are incompatible with outlets for nonrespirable worksite air or other gas systems. No asphyxiating substance shall be introduced into breathing air lines.

(9) The employer shall use breathing gas containers marked in accordance with the NIOSH respirator certification standard, 42 CFR part 84.

(j) *Identification of filters, cartridges, and canisters.* The employer shall ensure that all filters, cartridges and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible.

(k) *Training and information.* This paragraph requires the employer to provide effective training to employees who are required to use respirators. The training must be comprehensive, understandable, and recur annually, and more often if necessary. This paragraph also requires the employer to provide the basic information on respirators in Appendix D of this section to employees who wear respirators when not required by this section or by the employer to do so.

(1) The employer shall ensure that each employee can demonstrate knowledge of at least the following:

(i) Why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator;

(ii) What the limitations and capabilities of the respirator are;

(iii) How to use the respirator effectively in emergency situations, including situations in which the respirator malfunctions;

(iv) How to inspect, put on and remove, use, and check the seals of the respirator;

(v) What the procedures are for maintenance and storage of the respirator;

(vi) How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators; and

(vii) The general requirements of this section.

(2) The training shall be conducted in a manner that is understandable to the employee.

(3) The employer shall provide the training prior to requiring the employee to use a respirator in the workplace.

(4) An employer who is able to demonstrate that a new employee has received training within the last 12 months that addresses the elements specified in paragraph (k)(1)(i) through (vii) is not required to repeat such training provided that, as required by paragraph (k)(1), the employee can demonstrate knowledge of those element(s). Previous training not repeated initially by the employer must be provided no later than 12 months from the date of the previous training.

(5) Retraining shall be administered annually, and when the following situations occur:

(i) Changes in the workplace or the type of respirator render previous training obsolete;

(ii) Inadequacies in the employee's knowledge or use of the respirator indicate that the employee has not retained the requisite understanding or skill; or

(iii) Any other situation arises in which retraining appears necessary to ensure safe respirator use.

(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.

(l) *Program evaluation.* This section requires the employer to conduct evaluations of the workplace to ensure that the written respiratory protection program is being properly implemented, and to consult employees to ensure that they are using the respirators properly.

(1) The employer shall conduct evaluations of the workplace as necessary to ensure that the provisions of the current written program are being effectively implemented and that it continues to be effective.

(2) The employer shall regularly consult employees required to use respirators to assess the employees' views on program effectiveness and to identify any problems. Any problems that are identified during this assessment shall be corrected. Factors to be assessed include, but are not limited to:

(i) Respirator fit (including the ability to use the respirator without interfering with effective workplace performance);

(ii) Appropriate respirator selection for the hazards to which the employee is exposed;

(iii) Proper respirator use under the workplace conditions the employee encounters; and

(iv) Proper respirator maintenance.

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

(1) *Medical evaluation.* Records of medical evaluations required by this section must be retained and made available in accordance with 29 CFR 1910.1020.

(2) *Fit testing.* (i) The employer shall establish a record of the qualitative and quantitative fit tests administered to an employee including:

(A) The name or identification of the employee tested;

(B) Type of fit test performed;

(C) Specific make, model, style, and size of respirator tested;

(D) Date of test; and

(E) The pass/fail results for QLFTs or the fit factor and strip chart recording or other recording of the test results for QNFTs.

(ii) Fit test records shall be retained for respirator users until the next fit test is administered.

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

(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.

(n) *Effective date.* Paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) of this section become effective November 22, 2006.

(o) *Appendices.* (1) Compliance with Appendix A, Appendix B–1, Appendix B–2, and Appendix C of this section is mandatory.

(2) Appendix D of this section is nonmandatory and is not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

APPENDIX A TO § 1910.134—FIT TESTING PROCEDURES (MANDATORY)

PART I. OSHA-ACCEPTED FIT TEST PROTOCOLS

A. Fit Testing Procedures—General Requirements

The employer shall conduct fit testing using the following procedures. The requirements in this appendix apply to all OSHA-accepted fit test methods, both QLFT and QNFT.

1. The test subject shall be allowed to pick the most acceptable respirator from a sufficient number of respirator models and sizes

so that the respirator is acceptable to, and correctly fits, the user.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine an acceptable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. This instruction may not constitute the subject's formal training on respirator use, because it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those that obviously do not give an acceptable fit.

5. The more acceptable facepieces are noted in case the one selected proves unacceptable; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in the following item A.6. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include a review of the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) Position of the mask on the nose

(b) Room for eye protection

(c) Room to talk

(d) Position of mask on face and cheeks

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;

(b) Adequate strap tension, not overly tightened;

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip;

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct a user seal check, either the negative and positive pressure seal checks described in Appendix B–1 of this section or those recommended by the respirator manufacturer which provide equivalent protection to the procedures in Appendix B–1. Before conducting the negative and positive pressure checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the user seal check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache or sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician or other licensed health care professional, as appropriate, to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. The fit test shall be performed while the test subject is wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with respirator fit.

14. Test Exercises. (a) Employers must perform the following test exercises for all fit testing methods prescribed in this appendix, except for the CNP quantitative fit testing protocol and the CNP REDON quantitative fit testing protocol. For these two protocols, employers must ensure that the test subjects (*i.e.,* employees) perform the exercise procedure specified in Part I.C.4(b) of this appendix for the CNP quantitative fit testing protocol, or the exercise procedure described in Part I.C.5(b) of this appendix for the CNP REDON quantitative fit-testing protocol. For the remaining fit testing methods, employers must ensure that employees perform the test exercises in the appropriate test environment in the following manner:

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) Moving head up and down. Standing in place, the subject shall slowly move his/her

head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(6) Grimace. The test subject shall grimace by smiling or frowning. (This applies only to QNFT testing; it is not performed for QLFT)

(7) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT or QLFT units that do not permit bending over at the waist.

(8) Normal breathing. Same as exercise (1).

(b) Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds. The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried. The respirator shall not be adjusted once the fit test exercises begin. Any adjustment voids the test, and the fit test must be repeated.

B. Qualitative Fit Test (QLFT) Protocols

1. General

(a) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

NOTE: This protocol is not appropriate to use for the fit testing of particulate respirators. If used to fit test particulate respirators, the respirator must be equipped with an organic vapor filter.

(a) Odor Threshold Screening

Odor threshold screening, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate at low levels.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor-free water (e.g., distilled or spring water) at approximately 25 °C (77 °F) shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 ml of pure IAA to 800 ml of odor-free water in a 1 liter jar, closing the lid and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well-ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 ml of the stock solution into 500 ml of odor-free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor-free water.

(7) The odor test and test blank jar lids shall be labeled (e.g., 1 and 2) for jar identification. Labels shall be placed on the lids so that they can be peeled off periodically and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): ''The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil.''

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl Acetate Fit Test

(1) The fit test chamber shall be a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. If no drum liner is available, a similar chamber shall be constructed using plastic sheeting. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well-ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 ml of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber. An IAA test swab or ampule may be substituted for the IAA wetted paper towel provided it has been demonstrated that the alternative IAA source will generate an IAA test atmosphere with a concentration equivalent to that generated by the paper towel method.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana-like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (b) (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait at least 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) If the subject passes the test, the efficiency of the test procedure shall be demonstrated by having the subject break the respirator face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so that there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self-sealing plastic bag to keep the test area from being contaminated.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾-inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a sweet taste.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the threshold check solution into the enclosure. The nozzle is directed away from the nose and mouth of the person. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The threshold check solution is prepared by dissolving 0.83 gram of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted. If the test subject reports tasting the sweet taste during the ten squeezes, the screening test is completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the

test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes actually completed.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject is unable to taste saccharin and may not perform the saccharin fit test.

NOTE TO PARAGRAPH 3(a): If the test subject eats or drinks something sweet before the screening test, he/she may be unable to taste the weak saccharin solution.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in 3. (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I. A. of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended, and report if he/she tastes the sweet taste of saccharin.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of saccharin fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test. A minimum of 10 squeezes is required.

(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the original number of squeezes used initially (e.g., 5, 10 or 15).

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected. If the test subject does not report tasting the saccharin, the test is passed.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).

(12) Since the nebulizer has a tendency to clog during use, the test operator must make periodic checks of the nebulizer to ensure that it is not clogged. If clogging is found at the end of the test session, the test is invalid.

4. Bitrex™ (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex™ (Denatonium benzoate) solution aerosol QLFT protocol uses the published saccharin test protocol because that protocol is widely accepted. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste Threshold Screening.

The Bitrex taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of Bitrex.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches (30.5 cm) in diameter by 14 inches (35.6 cm) tall. The front portion of the enclosure shall be clear from the respirator and allow free movement of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾ inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through

his or her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a bitter taste.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the Threshold Check Solution into the enclosure. This Nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The Threshold Check Solution is prepared by adding 13.5 milligrams of Bitrex to 100 ml of 5% salt (NaCl) solution in distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that the bulb collapses completely, and is then released and allowed to fully expand.

(7) An initial ten squeezes are repeated rapidly and then the test subject is asked whether the Bitrex can be tasted. If the test subject reports tasting the bitter taste during the ten squeezes, the screening test is completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted. If the test subject reports tasting the bitter taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted. If the test subject reports tasting the bitter taste during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes actually completed.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the Bitrex is not tasted after 30 squeezes (step 10), the test subject is unable to taste Bitrex and may not perform the Bitrex fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken to dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Bitrex Solution Aerosol Fit Test Procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure as that described in 4. (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected according to section I. A. of this appendix. The respirator shall be properly adjusted and equipped with any type particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 337.5 mg of Bitrex to 200 ml of a 5% salt (NaCl) solution in warm water.

(6) As before, the test subject shall breathe through his or her slightly open mouth with tongue extended, and be instructed to report if he/she tastes the bitter taste of Bitrex.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of the fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test.

(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes used initially (e.g., 5, 10 or 15).

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of Bitrex is detected. If the test subject does not report tasting the Bitrex, the test is passed.

(11) If the taste of Bitrex is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).

5. Irritant Smoke (Stannic Chloride) Protocol

This qualitative fit test uses a person's response to the irritating chemicals released in the ''smoke'' produced by a stannic chloride ventilation smoke tube to detect leakage into the respirator.

(a) General Requirements and Precautions

(1) The respirator to be tested shall be equipped with high efficiency particulate air (HEPA) or P100 series filter(s).

(2) Only stannic chloride smoke tubes shall be used for this protocol.

(3) No form of test enclosure or hood for the test subject shall be used.

(4) The smoke can be irritating to the eyes, lungs, and nasal passages. The test conductor shall take precautions to minimize the test subject's exposure to irritant smoke. Sensitivity varies, and certain individuals may respond to a greater degree to irritant smoke. Care shall be taken when performing

the sensitivity screening checks that determine whether the test subject can detect irritant smoke to use only the minimum amount of smoke necessary to elicit a response from the test subject.

(5) The fit test shall be performed in an area with adequate ventilation to prevent exposure of the person conducting the fit test or the build-up of irritant smoke in the general atmosphere.

(b) Sensitivity Screening Check

The person to be tested must demonstrate his or her ability to detect a weak concentration of the irritant smoke.

(1) The test operator shall break both ends of a ventilation smoke tube containing stannic chloride, and attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute, or an aspirator squeeze bulb. The test operator shall cover the other end of the smoke tube with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

(2) The test operator shall advise the test subject that the smoke can be irritating to the eyes, lungs, and nasal passages and instruct the subject to keep his/her eyes closed while the test is performed.

(3) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties and to determine if he/she can detect the irritating properties of the smoke. The test operator shall carefully direct a small amount of the irritant smoke in the test subject's direction to determine that he/she can detect it.

(c) Irritant Smoke Fit Test Procedure

(1) The person being fit tested shall don the respirator without assistance, and perform the required user seal check(s).

(2) The test subject shall be instructed to keep his/her eyes closed.

(3) The test operator shall direct the stream of irritant smoke from the smoke tube toward the faceseal area of the test subject, using the low flow pump or the squeeze bulb. The test operator shall begin at least 12 inches from the facepiece and move the smoke stream around the whole perimeter of the mask. The operator shall gradually make two more passes around the perimeter of the mask, moving to within six inches of the respirator.

(4) If the person being tested has not had an involuntary response and/or detected the irritant smoke, proceed with the test exercises.

(5) The exercises identified in section I.A. 14. of this appendix shall be performed by the test subject while the respirator seal is being continually challenged by the smoke, directed around the perimeter of the respirator at a distance of six inches.

(6) If the person being fit tested reports detecting the irritant smoke at any time, the test is failed. The person being retested must repeat the entire sensitivity check and fit test procedure.

(7) Each test subject passing the irritant smoke test without evidence of a response (involuntary cough, irritation) shall be given a second sensitivity screening check, with the smoke from the same smoke tube used during the fit test, once the respirator has been removed, to determine whether he/she still reacts to the smoke. Failure to evoke a response shall void the fit test.

(8) If a response is produced during this second sensitivity check, then the fit test is passed.

C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable: Quantitative fit testing using a non-hazardous test aerosol (such as corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator; Quantitative fit testing using ambient aerosol as the test agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit; Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

1. General

(a) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QNFT equipment is kept clean, and is maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated Aerosol Quantitative Fit Testing Protocol

(a) Apparatus.

(1) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS] or sodium chloride) as test aerosols shall be used for quantitative fit testing.

(2) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the test agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the test agent is effectively isolated from

the ambient air, yet uniform in concentration throughout the chamber.

(3) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high efficiency particulate air (HEPA) or P100 series filter supplied by the same manufacturer.

(4) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the test agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers that integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(5) The combination of substitute air-purifying elements, test agent and test agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the test agent at any time during the testing process, based upon the length of the exposure and the exposure limit duration.

(6) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g., where the respirator is probed), a free air flow is allowed into the sampling line at all times, and there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least 1/4 inch.

(7) The test setup shall permit the person administering the test to observe the test subject inside the chamber during the test.

(8) The equipment generating the test atmosphere shall maintain the concentration of test agent constant to within a 10 percent variation for the duration of the test.

(9) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(10) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(11) The exhaust flow from the test chamber shall pass through an appropriate filter (i.e., high efficiency particulate filter) before release.

(12) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(13) The limitations of instrument detection shall be taken into account when determining the fit factor.

(14) Test respirators shall be maintained in proper working order and be inspected regularly for deficiencies such as cracks or missing valves and gaskets.

(b) Procedural Requirements.

(1) When performing the initial user seal check using a positive or negative pressure check, the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these pressure checks.

(2) The use of an abbreviated screening QLFT test is optional. Such a test may be utilized in order to quickly identify poor fitting respirators that passed the positive and/or negative pressure test and reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another optional method to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(3) A reasonably stable test agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain types of test units, the determination of the test agent's stability may be established after the test subject has entered the test environment.

(4) Immediately after the subject enters the test chamber, the test agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(5) A stable test agent concentration shall be obtained prior to the actual start of testing.

(6) Respirator restraining straps shall not be over-tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonably comfortable fit typical of normal use. The respirator shall not be adjusted once the fit test exercises begin.

(7) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(8) Calculation of fit factors.

(i) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(ii) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e., 7 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(iii) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(*A*) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers that calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(*B*) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(*C*) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise. This includes computerized integration.

(*D*) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_7 + 1/ff_8}$$

Where ff_1, ff_2, ff_3, etc. are the fit factors for exercises 1, 2, 3, etc.

(9) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(10) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media.

3. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol.

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (Portacount™) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, style, model, and size that the employer uses and can be obtained from the respirator manufacturer or distributor. The CNC instrument manufacturer, TSI Inc., also provides probe attachments (TSI sampling adapters) that permit fit testing in an employee's own respirator. A minimum fit factor pass level of at least 100 is necessary for a half-mask respirator and a minimum fit factor pass level of at least 500 is required for a full facepiece negative pressure respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Portacount Fit Test Requirements. (1) Check the respirator to make sure the sampling probe and line are properly attached to the facepiece and that the respirator is fitted with a particulate filter capable of preventing significant penetration by the ambient particles used for the fit test (e.g., NIOSH 42 CFR 84 series 100, series 99, or series 95 particulate filter) per manufacturer's instruction.

(2) Instruct the person to be tested to don the respirator for five minutes before the fit test starts. This purges the ambient particles trapped inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual shall already have been trained on how to wear the respirator properly.

(3) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendency of the respirator to slip; Self-observation in a mirror to evaluate fit and respirator position.

(4) Have the person wearing the respirator do a user seal check. If leakage is detected, determine the cause. If leakage is from a poorly fitting facepiece, try another size of the same model respirator, or another model of respirator.

(5) Follow the manufacturer's instructions for operating the Portacount and proceed with the test.

(6) The test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(7) After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

(b) Portacount Test Instrument.

(1) The Portacount will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The Pass or Fail message will indicate whether or not the test was successful. If the test was a Pass, the fit test is over.

(2) Since the pass or fail criterion of the Portacount is user programmable, the test operator shall ensure that the pass or fail criterion meet the requirements for minimum respirator performance in this Appendix.

(3) A record of the test needs to be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style, and size of respirator used; and date tested.

4. Controlled negative pressure (CNP) quantitative fit testing protocol.

The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator. The CNP fit test method measures leak rates through the facepiece as a method for determining the facepiece fit for negative pressure respirators. The CNP instrument manufacturer Occupational Health Dynamics of Birmingham, Alabama also provides attachments (sampling manifolds) that replace the filter cartridges to permit fit testing in an employee's own respirator. To perform the test, the test subject closes his or her mouth and holds his/her breath, after which an air pump removes air from the respirator facepiece at a pre-selected constant pressure. The facepiece fit is expressed as the leak rate through the facepiece, expressed as milliliters per minute. The quality and validity of the CNP fit tests are determined by the degree to which the in-mask pressure tracks the test pressure during the system measurement time of approximately five seconds. Instantaneous feedback in the form of a real-time pressure trace of the in-mask pressure is provided and used to determine test validity and quality. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) CNP Fit Test Requirements.

(1) The instrument shall have a non-adjustable test pressure of 15.0 mm water pressure.

(2) The CNP system defaults selected for test pressure shall be set at −15 mm of water (-0.58 inches of water) and the modeled inspiratory flow rate shall be 53.8 liters per minute for performing fit tests.

NOTE: CNP systems have built-in capability to conduct fit testing that is specific to unique work rate, mask, and gender situations that might apply in a specific workplace. Use of system default values, which were selected to represent respirator wear with medium cartridge resistance at a low-moderate work rate, will allow inter-test comparison of the respirator fit.)

(3) The individual who conducts the CNP fit testing shall be thoroughly trained to perform the test.

(4) The respirator filter or cartridge needs to be replaced with the CNP test manifold. The inhalation valve downstream from the manifold either needs to be temporarily removed or propped open.

(5) The employer must train the test subject to hold his or her breath for at least 10 seconds.

(6) The test subject must don the test respirator without any assistance from the test administrator who is conducting the CNP fit test. The respirator must not be adjusted once the fit-test exercises begin. Any adjustment voids the test, and the test subject must repeat the fit test.

(7) The QNFT protocol shall be followed according to section I. C. 1. of this appendix with an exception for the CNP test exercises.

(b) CNP Test Exercises.

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, being careful not to hyperventilate. After the deep breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during test measurement.

(3)Turning head side to side. Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side. After the turning head side to side exercise, the subject needs to hold head full left and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to

hold head full right and hold his or her breath for 10 seconds during test measurement.

(4) Moving head up and down. Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling). After the moving head up and down exercise, the subject shall hold his or her head full up and hold his or her breath for 10 seconds during test measurement. Next, the subject shall hold his or her head full down and hold his or her breath for 10 seconds during test measurement.

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute. After the talking exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(6) Grimace. The test subject shall grimace by smiling or frowning for 15 seconds.

(7) Bending Over. The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud-type QNFT units that prohibit bending at the waist. After the bending over exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(8) Normal Breathing. The test subject shall remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement. After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of a respirator shall be tried.

(c) CNP Test Instrument.

(1) The test instrument must have an effective audio-warning device, or a visual-warning device in the form of a screen tracing, that indicates when the test subject fails to hold his or her breath during the test. The test must be terminated and restarted from the beginning when the test subject fails to hold his or her breath during the test. The test subject then may be refitted and retested.

(2) A record of the test shall be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style and size of respirator used; and date tested.

5. Controlled negative pressure (CNP) REDON quantitative fit testing protocol.

(a) When administering this protocol to test subjects, employers must comply with the requirements specified in paragraphs (a) and (c) of Part I.C.4 of this appendix (''Controlled negative pressure (CNP) quantitative fit testing protocol''), as well as use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in paragraph (b) of Part I.C.4 of this appendix.

(b) Employers must ensure that each test subject being fit tested using this protocol follows the exercise and measurement procedures, including the order of administration, described below in Table A–1 of this appendix.

TABLE A–1—CNP REDON QUANTITATIVE FIT TESTING PROTOCOL

Exercises[1]	Exercise procedure	Measurement procedure
Facing Forward	Stand and breathe normally, without talking, for 30 seconds.	Face forward, while holding breath for 10 seconds.
Bending Over	Bend at the waist, as if going to touch his or her toes, for 30 seconds.	Face parallel to the floor, while holding breath for 10 seconds
Head Shaking	For about three seconds, shake head back and forth vigorously several times while shouting.	Face forward, while holding breath for 10 seconds
REDON 1	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask.	Face forward, while holding breath for 10 seconds.
REDON 2	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask again.	Face forward, while holding breath for 10 seconds.

[1] Exercises are listed in the order in which they are to be administered.

(c) After completing the test exercises, the test administrator must question each test subject regarding the comfort of the respirator. When a test subject states that the respirator is unacceptable, the employer must ensure that the test administrator repeats the protocol using another respirator model.

(d) Employers must determine the overall fit factor for each test subject by calculating the harmonic mean of the fit testing exercises as follows:

$$\text{Overall Fit Factor} = \frac{N}{\left[1/FF_1 + 1/FF_2 + \ldots\ 1/FF_N\right]}$$

Where:

N = The number of exercises;
FF_1 = The fit factor for the first exercise;
FF_2 = The fit factor for the second exercise; and
FF_N = The fit factor for the nth exercise.

PART II. NEW FIT TEST PROTOCOLS

A. Any person may submit to OSHA an application for approval of a new fit test protocol. If the application meets the following criteria, OSHA will initiate a rulemaking proceeding under section 6(b)(7) of the OSH Act to determine whether to list the new protocol as an approved protocol in this Appendix A.

B. The application must include a detailed description of the proposed new fit test protocol. This application must be supported by either:

1. A test report prepared by an independent government research laboratory (e.g., Lawrence Livermore National Laboratory, Los Alamos National Laboratory, the National Institute for Standards and Technology) stating that the laboratory has tested the protocol and had found it to be accurate and reliable; or

2. An article that has been published in a peer-reviewed industrial hygiene journal describing the protocol and explaining how test data support the protocol's accuracy and reliability.

C. If OSHA determines that additional information is required before the Agency commences a rulemaking proceeding under this section, OSHA will so notify the applicant and afford the applicant the opportunity to submit the supplemental information. Initiation of a rulemaking proceeding will be deferred until OSHA has received and evaluated the supplemental information.

APPENDIX B–1 TO § 1910.134: USER SEAL CHECK PROCEDURES (MANDATORY)

The individual who uses a tight-fitting respirator is to perform a user seal check to ensure that an adequate seal is achieved each time the respirator is put on. Either the positive and negative pressure checks listed in this appendix, or the respirator manufacturer's recommended user seal check method shall be used. User seal checks are not substitutes for qualitative or quantitative fit tests.

I. Facepiece Positive and/or Negative Pressure Checks

A. *Positive pressure check.* Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

B. *Negative pressure check.* Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. The design of the inlet opening of some cartridges cannot be effectively covered with the palm of the hand. The test can be performed by covering the inlet opening of the cartridge with a thin latex or nitrile glove. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

II. Manufacturer's Recommended User Seal Check Procedures

The respirator manufacturer's recommended procedures for performing a user seal check may be used instead of the positive and/or negative pressure check procedures provided that the employer demonstrates that the manufacturer's procedures are equally effective.

APPENDIX B–2 TO § 1910.134: RESPIRATOR CLEANING PROCEDURES (MANDATORY)

These procedures are provided for employer use when cleaning respirators. They are general in nature, and the employer as an alternative may use the cleaning recommendations provided by the manufacturer of the respirators used by their employees, provided such procedures are as effective as those listed here in Appendix B–2. Equivalent effectiveness simply means that the procedures used must accomplish the objectives set forth in Appendix B–2, i.e., must ensure that the respirator is properly cleaned and disinfected in a manner that prevents damage to the respirator and does not cause harm to the user.

I. Procedures for Cleaning Respirators

A. Remove filters, cartridges, or canisters. Disassemble facepieces by removing speaking diaphragms, demand and pressure-demand valve assemblies, hoses, or any components recommended by the manufacturer. Discard or repair any defective parts.

B. Wash components in warm (43 °C [110 °F] maximum) water with a mild detergent or with a cleaner recommended by the manufacturer. A stiff bristle (not wire) brush may be used to facilitate the removal of dirt.

C. Rinse components thoroughly in clean, warm (43 °C [110 °F] maximum), preferably running water. Drain.

D. When the cleaner used does not contain a disinfecting agent, respirator components should be immersed for two minutes in one of the following:

1. Hypochlorite solution (50 ppm of chlorine) made by adding approximately one milliliter of laundry bleach to one liter of water at 43 °C (110 °F); or,

2. Aqueous solution of iodine (50 ppm iodine) made by adding approximately 0.8 milliliters of tincture of iodine (6–8 grams ammonium and/or potassium iodide/100 cc of 45% alcohol) to one liter of water at 43 °C (110 °F); or,

3. Other commercially available cleansers of equivalent disinfectant quality when used as directed, if their use is recommended or approved by the respirator manufacturer.

E. Rinse components thoroughly in clean, warm (43 °C [110 °F] maximum), preferably running water. Drain. The importance of thorough rinsing cannot be overemphasized. Detergents or disinfectants that dry on facepieces may result in dermatitis. In addition, some disinfectants may cause deterioration of rubber or corrosion of metal parts if not completely removed.

F. Components should be hand-dried with a clean lint-free cloth or air-dried.

G. Reassemble facepiece, replacing filters, cartridges, and canisters where necessary.

H. Test the respirator to ensure that all components work properly.

APPENDIX C TO §1910.134: OSHA RESPIRATOR MEDICAL EVALUATION QUESTIONNAIRE (MANDATORY)

To the employer: Answers to questions in Section 1, and to question 9 in Section 2 of Part A, do not require a medical examination.

To the employee:

Can you read (circle one): Yes/No

Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.

Part A. Section 1. (Mandatory) The following information must be provided by every employee who has been selected to use any type of respirator (please print).

1. Today's date: _____
2. Your name: _____
3. Your age (to nearest year): _____
4. Sex (circle one): Male/Female
5. Your height: ____ft. ____in.
6. Your weight: ____ lbs.
7. Your job title: _____
8. A phone number where you can be reached by the health care professional who reviews this questionnaire (include the Area Code): _____
9. The best time to phone you at this number: ____
10. Has your employer told you how to contact the health care professional who will review this questionnaire (circle one): Yes/No
11. Check the type of respirator you will use (you can check more than one category):
    a. ____ N, R, or P disposable respirator (filter-mask, non-cartridge type only).
    b. ____ Other type (for example, half- or full-facepiece type, powered-air purifying, supplied-air, self-contained breathing apparatus).
12. Have you worn a respirator (circle one): Yes/No

7 If ''yes,'' what type(s): _____

Part A. Section 2. (Mandatory) Questions 1 through 9 below must be answered by every employee who has been selected to use any type of respirator (please circle ''yes'' or ''no'').

1. Do you *currently* smoke tobacco, or have you smoked tobacco in the last month: Yes/No
2. Have you *ever had* any of the following conditions?
    a. Seizures (fits): Yes/No
    b. Diabetes (sugar disease): Yes/No
    c. Allergic reactions that interfere with your breathing: Yes/No
    d. Claustrophobia (fear of closed-in places): Yes/No
    e. Trouble smelling odors: Yes/No
3. Have you *ever had* any of the following pulmonary or lung problems?
    a. Asbestosis: Yes/No
    b. Asthma: Yes/No
    c. Chronic bronchitis: Yes/No
    d. Emphysema: Yes/No
    e. Pneumonia: Yes/No
    f. Tuberculosis: Yes/No
    g. Silicosis: Yes/No
    h. Pneumothorax (collapsed lung): Yes/No
    i. Lung cancer: Yes/No
    j. Broken ribs: Yes/No
    k. Any chest injuries or surgeries: Yes/No
    l. Any other lung problem that you've been told about: Yes/No
4. Do you *currently* have any of the following symptoms of pulmonary or lung illness?
    a. Shortness of breath: Yes/No
    b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline: Yes/No
    c. Shortness of breath when walking with other people at an ordinary pace on level ground: Yes/No
    d. Have to stop for breath when walking at your own pace on level ground: Yes/No

e. Shortness of breath when washing or dressing yourself: Yes/No
f. Shortness of breath that interferes with your job: Yes/No
g. Coughing that produces phlegm (thick sputum): Yes/No
h. Coughing that wakes you early in the morning: Yes/No
i. Coughing that occurs mostly when you are lying down: Yes/No
j. Coughing up blood in the last month: Yes/No
k. Wheezing: Yes/No
l. Wheezing that interferes with your job: Yes/No
m. Chest pain when you breathe deeply: Yes/No
n. Any other symptoms that you think may be related to lung problems: Yes/No

5. Have you *ever had* any of the following cardiovascular or heart problems?
a. Heart attack: Yes/No
b. Stroke: Yes/No
c. Angina: Yes/No
d. Heart failure: Yes/No
e. Swelling in your legs or feet (not caused by walking): Yes/No
f. Heart arrhythmia (heart beating irregularly): Yes/No
g. High blood pressure: Yes/No
h. Any other heart problem that you've been told about: Yes/No

6. Have you *ever had* any of the following cardiovascular or heart symptoms?
a. Frequent pain or tightness in your chest: Yes/No
b. Pain or tightness in your chest during physical activity: Yes/No
c. Pain or tightness in your chest that interferes with your job: Yes/No
d. In the past two years, have you noticed your heart skipping or missing a beat: Yes/No
e. Heartburn or indigestion that is not related to eating: Yes/No
f. Any other symptoms that you think may be related to heart or circulation problems: Yes/No

7. Do you *currently* take medication for any of the following problems?
a. Breathing or lung problems: Yes/No
b. Heart trouble: Yes/No
c. Blood pressure: Yes/No
d. Seizures (fits): Yes/No

8. If you've used a respirator, have you *ever had* any of the following problems? (If you've never used a respirator, check the following space and go to question 9:)
a. Eye irritation: Yes/No
b. Skin allergies or rashes: Yes/No
c. Anxiety: Yes/No
d. General weakness or fatigue: Yes/No
e. Any other problem that interferes with your use of a respirator: Yes/No

9. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire: Yes/No

Questions 10 to 15 below must be answered by every employee who has been selected to use either a full-facepiece respirator or a self-contained breathing apparatus (SCBA). For employees who have been selected to use other types of respirators, answering these questions is voluntary.

10. Have you *ever lost* vision in either eye (temporarily or permanently): Yes/No

11. Do you *currently* have any of the following vision problems?
a. Wear contact lenses: Yes/No
b. Wear glasses: Yes/No
c. Color blind: Yes/No
d. Any other eye or vision problem: Yes/No

12. Have you *ever had* an injury to your ears, including a broken ear drum: Yes/No

13. Do you *currently* have any of the following hearing problems?
a. Difficulty hearing: Yes/No
b. Wear a hearing aid: Yes/No
c. Any other hearing or ear problem: Yes/No

14. Have you *ever had* a back injury: Yes/No

15. Do you *currently* have any of the following musculoskeletal problems?
a. Weakness in any of your arms, hands, legs, or feet: Yes/No
b. Back pain: Yes/No
c. Difficulty fully moving your arms and legs: Yes/No
d. Pain or stiffness when you lean forward or backward at the waist: Yes/No
e. Difficulty fully moving your head up or down: Yes/No
f. Difficulty fully moving your head side to side: Yes/No
g. Difficulty bending at your knees: Yes/No
h. Difficulty squatting to the ground: Yes/No
i. Climbing a flight of stairs or a ladder carrying more than 25 lbs: Yes/No
j. Any other muscle or skeletal problem that interferes with using a respirator: Yes/No

Part B Any of the following questions, and other questions not listed, may be added to the questionnaire at the discretion of the health care professional who will review the questionnaire.

1. In your present job, are you working at high altitudes (over 5,000 feet) or in a place that has lower than normal amounts of oxygen: Yes/No
If ''yes,'' do you have feelings of dizziness, shortness of breath, pounding in your chest, or other symptoms when you're working under these conditions: Yes/No

2. At work or at home, have you ever been exposed to hazardous solvents, hazardous airborne chemicals (*e.g.*, gases, fumes, or dust), or have you come into skin contact with hazardous chemicals: Yes/No

If ''yes,'' name the chemicals if you know them: _____

3. Have you ever worked with any of the materials, or under any of the conditions, listed below:
a. Asbestos: Yes/No
b. Silica (*e.g.*, in sandblasting): Yes/No
c. Tungsten/cobalt (*e.g.*, grinding or welding this material): Yes/No
d. Beryllium: Yes/No
e. Aluminum: Yes/No
f. Coal (for example, mining): Yes/No
g. Iron: Yes/No
h. Tin: Yes/No
i. Dusty environments: Yes/No
j. Any other hazardous exposures: Yes/No
If ''yes,'' describe these exposures: _____

4. List any second jobs or side businesses you have: _____

5. List your previous occupations: _____

6. List your current and previous hobbies: _____

7. Have you been in the military services? Yes/No
If ''yes,'' were you exposed to biological or chemical agents (either in training or combat): Yes/No
8. Have you ever worked on a HAZMAT team? Yes/No
9. Other than medications for breathing and lung problems, heart trouble, blood pressure, and seizures mentioned earlier in this questionnaire, are you taking any other medications for any reason (including over-the-counter medications): Yes/No
If ''yes,'' name the medications if you know them: _____
10. Will you be using any of the following items with your respirator(s)?
a. HEPA Filters: Yes/No
b. Canisters (for example, gas masks): Yes/No
c. Cartridges: Yes/No
11. How often are you expected to use the respirator(s) (circle ''yes'' or ''no'' for all answers that apply to you)?:
a. Escape only (no rescue): Yes/No
b. Emergency rescue only: Yes/No
c. Less than 5 hours *per week:* Yes/No
d. Less than 2 hours *per day:* Yes/No
e. 2 to 4 hours *per day:* Yes/No
f. Over 4 hours *per day:* Yes/No
12. During the period you are using the respirator(s), is your work effort:
a. *Light* (less than 200 kcal per hour): Yes/No
If ''yes,'' how long does this period last during the average shift:_____hrs._____mins.

Examples of a light work effort are *sitting* while writing, typing, drafting, or performing light assembly work; or *standing* while operating a drill press (1–3 lbs.) or controlling machines.

b. *Moderate* (200 to 350 kcal per hour): Yes/No
If ''yes,'' how long does this period last during the average shift:_____hrs._____mins.

Examples of moderate work effort are *sitting* while nailing or filing; *driving* a truck or bus in urban traffic; *standing* while drilling, nailing, performing assembly work, or transferring a moderate load (about 35 lbs.) at trunk level; *walking* on a level surface about 2 mph or down a 5-degree grade about 3 mph; or *pushing* a wheelbarrow with a heavy load (about 100 lbs.) on a level surface.

c. *Heavy* (above 350 kcal per hour): Yes/No
If ''yes,'' how long does this period last during the average shift:_____hrs._____mins.

Examples of heavy work are *lifting* a heavy load (about 50 lbs.) from the floor to your waist or shoulder; *working* on a loading dock; *shoveling; standing* while bricklaying or chipping castings; *walking* up an 8-degree grade about 2 mph; *climbing* stairs with a heavy load (about 50 lbs.).

13. Will you be wearing protective clothing and/or equipment (other than the respirator) when you're using your respirator: Yes/No
If ''yes,'' describe this protective clothing and/or equipment: _____
14. Will you be working under hot conditions (temperature exceeding 77 °F): Yes/No
15. Will you be working under humid conditions: Yes/No
16. Describe the work you'll be doing while you're using your respirator(s):
17. Describe any special or hazardous conditions you might encounter when you're using your respirator(s) (for example, confined spaces, life-threatening gases):
18. Provide the following information, if you know it, for each toxic substance that you'll be exposed to when you're using your respirator(s):
Name of the first toxic substance: _____
Estimated maximum exposure level per shift: _____
Duration of exposure per shift _____
Name of the second toxic substance: _____
Estimated maximum exposure level per shift: _____

Duration of exposure per shift: _____

Name of the third toxic substance: _____

Estimated maximum exposure level per shift: _____

Duration of exposure per shift: _____

The name of any other toxic substances that you'll be exposed to while using your respirator:

_____

_____

_____

19. Describe any special responsibilities you'll have while using your respirator(s) that may affect the safety and well-being of others (for example, rescue, security):

_____

APPENDIX D TO § 1910.134 (MANDATORY) INFORMATION FOR EMPLOYEES USING RESPIRATORS WHEN NOT REQUIRED UNDER THE STANDARD

Respirators are an effective method of protection against designated hazards when properly selected and worn. Respirator use is encouraged, even when exposures are below the exposure limit, to provide an additional level of comfort and protection for workers. However, if a respirator is used improperly or not kept clean, the respirator itself can become a hazard to the worker. Sometimes, workers may wear respirators to avoid exposures to hazards, even if the amount of hazardous substance does not exceed the limits set by OSHA standards. If your employer provides respirators for your voluntary use, or if you provide your own respirator, you need to take certain precautions to be sure that the respirator itself does not present a hazard.

You should do the following:

1. Read and heed all instructions provided by the manufacturer on use, maintenance, cleaning and care, and warnings regarding the respirators limitations.

2. Choose respirators certified for use to protect against the contaminant of concern. NIOSH, the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services, certifies respirators. A label or statement of certification should appear on the respirator or respirator packaging. It will tell you what the respirator is designed for and how much it will protect you.

3. Do not wear your respirator into atmospheres containing contaminants for which your respirator is not designed to protect against. For example, a respirator designed to filter dust particles will not protect you against gases, vapors, or very small solid particles of fumes or smoke.

4. Keep track of your respirator so that you do not mistakenly use someone else's respirator.

[63 FR 1270, Jan. 8, 1998; 63 FR 20098, 20099, Apr. 23, 1998, as amended at 69 FR 46993, Aug. 4, 2004; 71 FR 16672, Apr. 3, 2006; 71 FR 50187, Aug. 24, 2006]

§ 1910.135 Head protection.

(a) *General requirements.* (1) The employer shall ensure that each affected employee wears a protective helmet when working in areas where there is a potential for injury to the head from falling objects.

(2) The employer shall ensure that a protective helmet designed to reduce electrical shock hazard is worn by each such affected employee when near exposed electrical conductors which could contact the head.

(b) *Criteria for protective helmets.* (1) Protective helmets purchased after July 5, 1994 shall comply with ANSI Z89.1–1986, ''American National Standard for Personnel Protection—Protective Headwear for Industrial Workers-Requirements,'' which is incorporated by reference as specified in § 1910.6, or shall be demonstrated to be equally effective.

(2) Protective helmets purchased before July 5, 1994 shall comply with the ANSI standard ''American National Standard Safety Requirements for Industrial Head Protection,'' ANSI Z89.1–1969, which is incorporated by reference as specified in § 1910.6, or shall be demonstrated by the employer to be equally effective.

[59 FR 16362, Apr. 6, 1994, as amended at 61 FR 9238, Mar. 7, 1996; 61 FR 19548, May 2, 1996]

§ 1910.136 Foot protection.

(a) *General requirements.* The employer shall ensure that each affected employee uses protective footwear when working in areas where there is a danger of foot injuries due to falling or rolling objects, or objects piercing the sole, and where such employee's feet are exposed to electrical hazards.

(b) *Criteria for protective footwear.* (1) Protective footwear purchased after July 5, 1994 shall comply with ANSI Z41–1991, ''American National Standard for Personal Protection—Protective Footwear,'' which is incorporated by reference as specified in § 1910.6, or

§ 1912a.14 Petitions for changes in the rules; complaints.

(a) Any interested person shall have the right to petition for the issuance, amendment, or repeal of rules published in this part. Any such petition will be considered in a reasonable time. Prompt notice shall be given of the denial in whole or in part of any petition. Except in affirming a prior denial or when the denial is self-explanatory the notice shall be accompanied by a brief statement of the reasons therefor.

(b) Any advisory committee member or any other aggrieved person may file a written complaint with the Assistant Secretary alleging noncompliance with the rules in this part. Any complaint must be timely filed, but in no case shall any complaint be filed later than thirty (30) days following the day on which the act of alleged noncompliance occurred. Any complaint shall be acted upon promptly and a written notice of the disposition of the complaint shall be provided to the complainant.

(c) Complaints and petitions should make reference to this §1912a.14 and be filed and addressed as follows:

Assistant Secretary of Labor for Occupational Safety and Health
United States Department of Labor
Washington, D.C. 20210.

PART 1913—RULES OF AGENCY PRACTICE AND PROCEDURE CONCERNING OSHA ACCESS TO EMPLOYEE MEDICAL RECORDS

AUTHORITY: Sec. 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 657); Sec. e, Privacy Act (5 U.S.C. 552a(e); 5 U.S.C. 301); Secretary of Labor's Order No. 8–76 (41 FR 25059), or 5–2002 (67 FR 65008) as applicable.

§ 1913.10 Rules of agency practice and procedure concerning OSHA access to employee medical records.

(a) *General policy.* OSHA access to employee medical records will in certain circumstances be important to the agency's performance of its statutory functions. Medical records, however, contain personal details concerning the lives of employees. Due to the substantial personal privacy interests involved, OSHA authority to gain access to personally identifiable employee medical information will be exercised only after the agency has made a careful determination of its need for this information, and only with appropriate safeguards to protect individual privacy. Once this information is obtained, OSHA examination and use of it will be limited to only that information needed to accomplish the purpose for access. Personally identifiable employee medical information will be retained by OSHA only for so long as needed to accomplish the purpose for access, will be kept secure while being used, and will not be disclosed to other agencies or members of the public except in narrowly defined circumstances. This section establishes procedures to implement these policies.

(b) *Scope and application.* (1) Except as provided in paragraphs (b) (3) through (6) below, this section applies to all requests by OSHA personnel to obtain access to records in order to examine or copy personally identifiable employee medical information, whether or not pursuant to the access provisions of 29 CFR 1910.1020(e).

(2) For the purposes of this section, ''personally identifiable employee medical information'' means employee medical information accompanied by either direct identifiers (name, address, social security number, payroll number, etc.) or by information which could reasonably be used in the particular circumstances indirectly to identify specific employees (e.g., exact age, height, weight, race, sex, date of initial employment, job title, etc.).

(3) This section does not apply to OSHA access to, or the use of, aggregate employee medical information or medical records on individual employees which is not in a personally identifiable form. This section does not apply to records required by 29 CFR part 1904, to death certificates, or to employee exposure records, including biological monitoring records treated by 29 CFR 1910.1020(c)(5) or by specific occupational safety and health standards as exposure records.

(4) This section does not apply where OSHA compliance personnel conduct an examination of employee medical records solely to verify employer compliance with the medical surveillance

recordkeeping requirements of an occupational safety and health standard, or with 29 CFR 1910.1020. An examination of this nature shall be conducted onsite and, if requested, shall be conducted under the observation of the recordholder. The OSHA compliance personnel shall not record and take offsite any information from medical records other than documentation of the fact of compliance or non-compliance.

(5) This section does not apply to agency access to, or the use of, personally identifiable employee medical information obtained in the course of litigation.

(6) This section does not apply where a written directive by the Assistant Secretary authorizes appropriately qualified personnel to conduct limited reviews of specific medical information mandated by an occupational safety and health standard, or of specific biological monitoring test results.

(7) Even if not covered by the terms of this section, all medically related information reported in a personally identifiable form shall be handled with appropriate discretion and care befitting all information concerning specific employees. There may, for example, be personal privacy interests involved which militate against disclosure of this kind of information to the public (*See*, 29 CFR 70.26 and 70a.3).

(c) *Responsible persons*—(1) *Assistant Secretary*. The Assistant Secretary of Labor for Occupational Safety and Health (Assistant Secretary) shall be responsible for the overall administration and implementation of the procedures contained in this section, including making final OSHA determinations concerning:

(i) Access to personally identifiable employee medical information (paragraph (d)), and

(ii) Inter-agency transfer or public disclosure of personally identifiable employee medical information (paragraph (m)).

(2) *OSHA Medical Records Officer*. The Assistant Secretary shall designate an OSHA official with experience or training in the evaluation, use, and privacy protection of medical records to be the OSHA Medical Records Officer. The OSHA Medical Records Officer shall report directly to the Assistant Secretary on matters concerning this section and shall be responsible for:

(i) Making recommendations to the Assistant Secretary as to the approval or denial of written access orders (paragraph (d)),

(ii) Assuring that written access orders meet the requirements of paragraphs (d) (2) and (3) of this section,

(iii) Responding to employee, collective bargaining agent, and employer objections concerning written access orders (paragraph (f)),

(iv) Regulating the use of direct personal identifiers (paragraph (g)),

(v) Regulating internal agency use and security of personally identifiable employee medical information (paragraphs (h) through (j)),

(vi) Assuring that the results of agency analyses of personally identifiable medical information are, where appropriate, communicated to employees (paragraph (k)),

(vii) Preparing an annual report of OSHA's experience under this section (paragraph (l)), and

(viii) Assuring that advance notice is given of intended inter-agency transfers or public disclosures (paragraph (m)).

(3) *Principal OSHA Investigator*. The Principal OSHA Investigator shall be the OSHA employee in each instance of access to personally identifiable employee medical information who is made primarily responsible for assuring that the examination and use of this information is performed in the manner prescribed by a written access order and the requirements of this section (paragraphs (d) through (m). When access is pursuant to a written access order, the Principal OSHA Investigator shall be professionally trained in medicine, public health, or allied fields (epidemiology, toxicology, industrial hygiene, biostatistics, environmental health, etc.).

(d) *Written access orders*—(1) *Requirement for written access order*. Except as provided in paragraph (d)(4) below, each request by an OSHA representative to examine or copy personally identifiable employee medical information contained in a record held by an employer or other recordholder shall be made pursuant to a written access

order which has been approved by the Assistant Secretary upon the recommendation of the OSHA Medical Records Officer. If deemed appropriate, a written access order may constitute, or be accompanied by, an administrative subpoena.

(2) *Approval criteria for written access order.* Before approving a written access order, the Assistant Secretary and the OSHA Medical Records Officer shall determine that:

(i) The medical information to be examined or copied is relevant to a statutory purpose and there is a need to gain access to this personally identifiable information,

(ii) The personally identifiable medical information to be examined or copied is limited to only that information needed to accomplish the purpose for access, and

(iii) The personnel authorized to review and analyze the personally identifiable medical information are limited to those who have a need for access and have appropriate professional qualifications.

(3) *Content of written access order.* Each written access order shall state with reasonable particularity:

(i) The statutory purposes for which access is sought,

(ii) A general description of the kind of employee medical information that will be examined and why there is a need to examine personally identifiable information,

(iii) Whether medical information will be examined on-site, and what type of information will be copied and removed off-site,

(iv) The name, address, and phone number of the Principal OSHA Investigator and the names of any other authorized persons who are expected to review and analyze the medical information.

(v) The name, address, and phone number of the OSHA Medical Records Officer, and

(vi) The anticipated period of time during which OSHA expects to retain the employee medical information in a personally identifiable form.

(4) *Special situations.* Written access orders need not be obtained to examine or copy personally identifiable employee medical information under the following circumstances:

(i) *Specific written consent.* If the specific written consent of an employee is obtained pursuant to 29 CFR 1910.1020(e)(2)(ii), and the agency or an agency employee is listed on the authorization as the designated representative to receive the medical information, then a written access order need not be obtained. Whenever personally identifiable employee medical information is obtained through specific written consent and taken off-site, a Principal OSHA Investigator shall be promptly named to assure protection of the information, and the OSHA Medical Records Officer shall be notified of this person's identity. The personally identifiable medical information obtained shall thereafter be subject to the use and security requirements of paragraphs (h) through (m) of this section.

(ii) *Physician consultations.* A written access order need not be obtained where an OSHA staff or contract physician consults with an employer's physician concerning an occupational safety or health issue. In a situation of this nature, the OSHA physician may conduct on-site evaluation of employee medical records in consultation with the employer's physician, and may make necessary personal notes of his or her findings. No employee medical records, however, shall be taken offsite in the absence of a written access order or the specific written consent of an employee, and no notes of personally identifiable employee medical information made by the OSHA physician shall leave his or her control without the permission of the OSHA Medical Records Officer.

(e) *Presentation of written access order and notice to employees.* (1) The Principal OSHA Investigator, or someone under his or her supervision, shall present at least two (2) copies each of the written access order and an accompanying cover letter to the employer prior to examining or obtaining medical information subject to a written access order. At least one copy of the written access order shall not identify specific employees by direct personal identifier. The accompanying cover letter shall summarize the requirements

of this section and indicate that questions or objections concerning the written access order may be directed to the Principal OSHA Investigator or to the OSHA Medical Records Officer.

(2) The Principal OSHA Investigator shall promptly present a copy of the written access order (which does not identify specific employees by direct personal identifier) and its accompanying cover letter to each collective bargaining agent representing employees whose medical records are subject to the written access order.

(3) The Principal OSHA Investigator shall indicate that the employer must promptly post a copy of the written access order which does not identify specific employees by direct personal identifier, as well as post its accompanying cover letter (*See*, 29 CFR 1910.1020(e)(3)(ii)).

(4) The Principal OSHA Investigator shall discuss with any collective bargaining agent and with the employer the appropriateness of individual notice to employees affected by the written access order. Where it is agreed that individual notice is appropriate, the Principal OSHA Investigator shall promptly provide to the employer an adequate number of copies of the written access order (which does not identify specific employees by direct personal identifier) and its accompanying cover letter to enable the employer either to individually notify each employee or to place a copy in each employee's medical file.

(f) *Objections concerning a written access order*. All employee, collective bargaining agent, and employer written objections concerning access to records pursuant to a written access order shall be transmitted to the OSHA Medical Records Officer. Unless the agency decides otherwise, access to the records shall proceed without delay notwithstanding the lodging of an objection. The OSHA Medical Records Officer shall respond in writing to each employee's and collective bargaining agent's written objection to OSHA access. Where appropriate, the OSHA Medical Records Officer may revoke a written access order and direct that any medical information obtained by it be returned to the original recordholder or destroyed. The Principal OSHA Investigator shall assure that such instructions by the OSHA Medical Records Officer are promptly implemented.

(g) *Removal of direct personal identifiers*. Whenever employee medical information obtained pursuant to a written access order is taken off-site with direct personal identifiers included, the Principal OSHA Investigator shall, unless otherwise authorized by the OSHA Medical Records Officer, promptly separate all direct personal identifiers from the medical information, and code the medical information and the list of direct identifiers with a unique identifying number for each employee. The medical information with its numerical code shall thereafter be used and kept secured as though still in a directly identifiable form. The Principal OSHA Investigator shall also hand deliver or mail the list of direct personal identifiers with their corresponding numerical codes to the OSHA Medical Records Officer. The OSHA Medical Records Officer shall thereafter limit the use and distribution of the list of coded identifiers to those with a need to know its contents.

(h) *Internal agency use of personally identifiable employee medical information*. (1) The Principal OSHA Investigator shall in each instance of access be primarily responsible for assuring that personally identifiable employee medical information is used and kept secured in accordance with this section.

(2) The Principal OSHA Investigator, the OSHA Medical Records Officer, the Assistant Secretary, and any other authorized person listed on a written access order may permit the examination or use of personally identifiable employee medical information by agency employees and contractors who have a need for access, and appropriate qualifications for the purpose for which they are using the information. No OSHA employee or contractor is authorized to examine or otherwise use personally identifiable employee medical information unless so permitted.

(3) Where a need exists, access to personally identifiable employee medical information may be provided to attorneys in the Office of the Solicitor of Labor, and to agency contractors who

are physicians or who have contractually agreed to abide by the requirements of this section and implementing agency directives and instructions.

(4) OSHA employees and contractors are only authorized to use personally identifiable employee medical information for the purposes for which it was obtained, unless the specific written consent of an employee is obtained as to a secondary purpose, or the procedures of paragraphs (d) through (g) of this section are repeated with respect to the secondary purpose.

(5) Whenever practicable, the examination of personally identifiable employee medical information shall be performed on-site with a minimum of medical information taken off-site in a personally identifiable form.

(i) *Security procedures.* (1) Agency files containing personally identifiable employee medical information shall be segregated from other agency files. When not in active use, files containing this information shall be kept secured in a locked cabinet or vault.

(2) The OSHA Medical Records Officer and the Principal OSHA Investigator shall each maintain a log of uses and transfers of personally identifiable employee medical information and lists of coded direct personal identifiers, except as to necessary uses by staff under their direct personal supervision.

(3) The photocopying or other duplication of personally identifiable employee medical information shall be kept to the minimum necessary to accomplish the purposes for which the information was obtained.

(4) The protective measures established by this section apply to all worksheets, duplicate copies, or other agency documents containing personally identifiable employee medical information.

(5) Intra-agency transfers of personally identifiable employee medical information shall be by hand delivery, United States mail, or equally protective means. Inter-office mailing channels shall not be used.

(j) *Retention and destruction of records.* (1) Consistent with OSHA records disposition programs, personally identifiable employee medical information and lists of coded direct personal identifiers shall be destroyed or returned to the original recordholder when no longer needed for the purposes for which they were obtained.

(2) Personally identifiable employee medical information which is currently not being used actively but may be needed for future use shall be transferred to the OSHA Medical Records Officer. The OSHA Medical Records Officer shall conduct an annual review of all centrally-held information to determine which information is no longer needed for the purposes for which it was obtained.

(k) *Results of an agency analysis using personally identifiable employee medical information.* The OSHA Medical Records Officer shall, as appropriate, assure that the results of an agency analysis using personally identifiable employee medical information are communicated to the employees whose personal medical information was used as a part of the analysis.

(l) *Annual report.* The OSHA Medical Records Officer shall on an annual basis review OSHA's experience under this section during the previous year, and prepare a report to the Assistant Secretary which shall be made available to the public. This report shall discuss:

(1) The number of written access orders approved and a summary of the purposes for access,

(2) The nature and disposition of employee, collective bargaining agent, and employer written objections concerning OSHA access to personally identifiable employee medical information, and

(3) The nature and disposition of requests for inter-agency transfer or public disclosure of personally identifiable employee medical information.

(m) *Inter-agency transfer and public disclosure.* (1) Personally identifiable employee medical information shall not be transferred to another agency or office outside of OSHA (other than to the Office of the Solicitor of Labor) or disclosed to the public (other than to the affected employee or the original recordholder) except when required by law or when approved by the Assistant Secretary.

(2) Except as provided in paragraph (m)(3) of this section, the Assistant Secretary shall not approve a request for an inter-agency transfer of personally identifiable employee medical information, which has not been consented to by the affected employees, unless the request is by a public health agency which:

(i) Needs the requested information in a personally identifiable form for a substantial public health purpose,

(ii) Will not use the requested information to make individual determinations concerning affected employees which could be to their detriment,

(iii) Has regulations or established written procedures providing protection for personally identifiable medical information substantially equivalent to that of this section, and

(iv) Satisfies an exemption to the Privacy Act to the extent that the Privacy Act applies to the requested information (*See*, 5 U.S.C. 552a(b); 29 CFR 70a.3).

(3) Upon the approval of the Assistant Secretary, personally identifiable employee medical information may be transferred to:

(i) The National Institute for Occupational Safety and Health (NIOSH) and

(ii) The Department of Justice when necessary with respect to a specific action under the Occupational Safety and Health Act.

(4) The Assistant Secretary shall not approve a request for public disclosure of employee medical information containing direct personal identifiers unless there are compelling circumstances affecting the health or safety of an individual.

(5) The Assistant Secretary shall not approve a request for public disclosure of employee medical information which contains information which could reasonably be used indirectly to identify specific employees when the disclosure would constitute a clearly unwarranted invasion of personal privacy (*See*, 5 U.S.C. 552(b)(6); 29 CFR 70.26).

(6) Except as to inter-agency transfers to NIOSH or the Department of Justice, the OSHA Medical Records Officer shall assure that advance notice is provided to any collective bargaining agent representing affected employees and to the employer on each occasion that OSHA intends to either transfer personally identifiable employee medical information to another agency or disclose it to a member of the public other than to an affected employee. When feasible, the OSHA Medical Records Officer shall take reasonable steps to assure that advance notice is provided to affected employees when the employee medical information to be transferred or disclosed contains direct personal identifiers.

[45 FR 35294, May 23, 1980; 45 FR 54334, Aug. 15, 1980, as amended at 71 FR 16674, Apr. 3, 2006]

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

Subpart A—General Provisions

Sec.

Subpart B—Confined and Enclosed Spaces and Other Dangerous Atmospheres in Shipyard Employment

Subpart C—Surface Preparation and Preservation

poisoning are due to severe inflammation of the mucous membranes and greatly increased permeability of the blood capillaries.

Chronic arsenical poisoning due to ingestion is rare and generally confined to patients taking prescribed medications. However, it can be a concomitant of inhaled inorganic arsenic from swallowed sputum and improper eating habits. Symptoms are weight loss, nausea and diarrhea alternating with constipation, pigmentation and eruption of the skin, loss of hair, and peripheral neuritis. Chronic hepatitis and cirrhosis have been described. Polyneuritis may be the salient feature, but more frequently there are numbness and parasthenias of ''glove and stocking'' distribution. The skin lesions are usually melanotic and keratotic and may occasionally take the form of an intradermal cancer of the squamous cell type, but without infiltrative properties. Horizontal white lines (striations) on the fingernails and toenails are commonly seen in chronic arsenical poisoning and are considered to be a diagnostic accompaniment of arsenical polyneuritis.

Inhalation of inorganic arsenic compounds is the most common cause of chronic poisoning in the industrial situation. This condition is divided into three phases based on signs and symptoms.

First Phase: The worker complains of weakness, loss of appetite, some nausea, occasional vomiting, a sense of heaviness in the stomach, and some diarrhea.

Second Phase: The worker complains of conjunctivitis, a catarrhal state of the mucous membranes of the nose, larynx, and respiratory passage. Coryza, hoarseness, and mild tracheobronchitis may occur. Perforation of the nasal septum is common, and is probably the most typical lesion of the upper respiratory tract in occupational exposure to arsenical dust. Skin lesions, eczematoid and allergic in type, are common.

Third Phase: The worker complains of symptoms of peripheral neuritis, initially of hands and feet, which is essentially sensory. In more severe cases, motor paralyses occur; the first muscles affected are usually the toe extensors and the peronei. In only the most severe cases will paralysis of flexor muscles of the feet or of the extensor muscles of hands occur.

Liver damage from chronic arsenical poisoning is still debated, and as yet the question is unanswered. In cases of chronic and acute arsenical poisoning, toxic effects to the myocardium have been reported based on EKG changes. These findings, however, are now largely discounted and the EKG changes are ascribed to electrolyte disturbances concomitant with arsenicalism. Inhalation of arsenic trioxide and other inorganic arsenical dusts does not give rise to radiological evidence or pneumoconiosis. Arsenic does have a depressant effect upon the bone marrow, with disturbances of both erythropoiesis and myelopoiesis.

BIBLIOGRAPHY

Dinman, B. D. 1960. Arsenic; chronic human intoxication. J. Occup. Med. 2:137.

Elkins, H. B. 1959. The Chemistry of Industrial Toxicology, 2nd ed. John Wiley and Sons, New York.

Holmquist, L. 1951. Occupational arsenical dermatitis; a study among employees at a copper-ore smelting works including investigations of skin reactions to contact with arsenic compounds. Acta. Derm. Venereol. (Supp. 26) 31:1.

Pinto, S. S., and C. M. McGill. 1953. Arsenic trioxide exposure in industry. Ind. Med. Surg. 22:281.

Pinto, S. S., and K. W. Nelson. 1976. Arsenic toxicology and industrial exposure. Annu. Rev. Pharmacol. Toxicol. 16:95.

Vallee, B. L., D. D. Ulmer, and W. E. C. Wacker. 1960. Arsenic toxicology and biochemistry. AMA Arch. Indust. Health 21:132.

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§ 1910.1020 Access to employee exposure and medical records.

(a) *Purpose.* The purpose of this section is to provide employees and their designated representatives a right of access to relevant exposure and medical records; and to provide representatives of the Assistant Secretary a right of access to these records in order to fulfill responsibilities under the Occupational Safety and Health Act. Access by employees, their representatives, and the Assistant Secretary is necessary to yield both direct and indirect improvements in the detection, treatment, and prevention of occupational disease. Each employer is responsible for assuring compliance with this section, but the activities involved in complying with the access to medical records provisions can be carried out, on behalf of the employer, by the physician or other health care personnel in charge of employee medical records. Except as expressly provided, nothing in this section is intended to affect existing legal and ethical obligations

concerning the maintenance and confidentiality of employee medical information, the duty to disclose information to a patient/employee or any other aspect of the medical-care relationship, or affect existing legal obligations concerning the protection of trade secret information.

(b) *Scope and application.* (1) This section applies to each general industry, maritime, and construction employer who makes, maintains, contracts for, or has access to employee exposure or medical records, or analyses thereof, pertaining to employees exposed to toxic substances or harmful physical agents.

(2) This section applies to all employee exposure and medical records, and analyses thereof, of such employees, whether or not the records are mandated by specific occupational safety and health standards.

(3) This section applies to all employee exposure and medical records, and analyses thereof, made or maintained in any manner, including on an in-house of contractual (e.g., fee-for-service) basis. Each employer shall assure that the preservation and access requirements of this section are complied with regardless of the manner in which the records are made or maintained.

(c) *Definitions.* (1) *Access* means the right and opportunity to examine and copy.

(2) *Analysis using exposure or medical records* means any compilation of data or any statistical study based at least in part on information collected from individual employee exposure or medical records or information collected from health insurance claims records, provided that either the analysis has been reported to the employer or no further work is currently being done by the person responsible for preparing the analysis.

(3) *Designated representative* means any individual or organization to whom an employee gives written authorization to exercise a right of access. For the purposes of access to employee exposure records and analyses using exposure or medical records, a recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

(4) *Employee* means a current employee, a former employee, or an employee being assigned or transferred to work where there will be exposure to toxic substances or harmful physical agents. In the case of a deceased or legally incapacitated employee, the employee's legal representative may directly exercise all the employee's rights under this section.

(5) *Employee exposure record* means a record containing any of the following kinds of information:

(i) Environmental (workplace) monitoring or measuring of a toxic substance or harmful physical agent, including personal, area, grab, wipe, or other form of sampling, as well as related collection and analytical methodologies, calculations, and other background data relevant to interpretation of the results obtained;

(ii) Biological monitoring results which directly assess the absorption of a toxic substance or harmful physical agent by body systems (e.g., the level of a chemical in the blood, urine, breath, hair, fingernails, etc) but not including results which assess the biological effect of a substance or agent or which assess an employee's use of alcohol or drugs;

(iii) Material safety data sheets indicating that the material may pose a hazard to human health; or

(iv) In the absence of the above, a chemcial inventory or any other record which reveals where and when used and the identity (e.g., chemical, common, or trade name) of a toxic substance or harmful physical agent.

(6)(i) *Employee medical record* means a record concerning the health status of an employee which is made or maintained by a physician, nurse, or other health care personnel or technician, including:

(A) Medical and employment questionnaires or histories (including job description and occupational exposures),

(B) The results of medical examinations (pre-employment, pre-assignment, periodic, or episodic) and laboratory tests (including chest and other X-

ray examinations taken for the purposes of establishing a base-line or detecting occupational illness, and all biological monitoring not defined as an ''employee exposure record''),

(C) Medical opinions, diagnoses, progress notes, and recommendations,

(D) First aid records,

(E) Descriptions of treatments and prescriptions, and

(F) Employee medical complaints.

(ii) ''Employee medical record'' does not include medical information in the form of:

(A) Physical specimens (e.g., blood or urine samples) which are routinely discarded as a part of normal medical practice; or

(B) Records concerning health insurance claims if maintained separately from the employer's medical program and its records, and not accessible to the employer by employee name or other direct personal identifier (e.g., social security number, payroll number, etc.); or

(C) Records created solely in preparation for litigation which are privileged from discovery under the applicable rules of procedure or evidence; or

(D) Records concerning voluntary employee assistance programs (alcohol, drug abuse, or personal counseling programs) if maintained separately from the employer's medical program and its records.

(7) *Employer* means a current employer, a former employer, or a successor employer.

(8) *Exposure* or *exposed* means that an employee is subjected to a toxic substance or harmful physical agent in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), and includes past exposure and potential (e.g., accidental or possible) exposure, but does not include situations where the employer can demonstrate that the toxic substance or harmful physical agent is not used, handled, stored, generated, or present in the workplace in any manner different from typical nonoccupational situations.

(9) *Health Professional* means a physician, occupational health nurse, industrial hygienist, toxicologist, or epidemiologist, providing medical or other occupational health services to exposed employees.

(10) *Record* means any item, collection, or grouping of information regardless of the form or process by which it is maintained (e.g., paper document, microfiche, microfilm, X-ray film, or automated data processing).

(11) *Specific chemical identity* means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

(12)(i) *Specific written consent* means a written authorization containing the following:

(A) The name and signature of the employee authorizing the release of medical information,

(B) The date of the written authorization,

(C) The name of the individual or organization that is authorized to release the medical information,

(D) The name of the designated representative (individual or organization) that is authorized to receive the released information,

(E) A general description of the medical information that is authorized to be released,

(F) A general description of the purpose for the release of the medical information, and

(G) A date or condition upon which the written authorization will expire (if less than one year).

(ii) A written authorization does not operate to authorize the release of medical information not in existence on the date of written authorization, unless the release of future information is expressly authorized, and does not operate for more than one year from the date of written authorization.

(iii) A written authorization may be revoked in writing prospectively at any time.

(13) *Toxic substance or harmful physical agent* means any chemical substance, biological agent (bacteria, virus, fungus, etc.), or physical stress (noise, heat, cold, vibration, repetitive motion, ionizing and non-ionizing radiation, hypo-or hyperbaric pressure, etc.) which:

(i) Is listed in the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS), which is incorporated by reference as specified in §1910.6; or

(ii) Has yielded positive evidence of an acute or chronic health hazard in testing conducted by, or known to, the employer; or

(iii) Is the subject of a material safety data sheet kept by or known to the employer indicating that the material may pose a hazard to human health.

(14) *Trade secret* means any confidential formula, pattern, process, device, or information or compilation of information that is used in an employer's business and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it.

(d) *Preservation of records.* (1) Unless a specific occupational safety and health standard provides a different period of time, each employer shall assure the preservation and retention of records as follows:

(i) *Employee medical records.* The medical record for each employee shall be preserved and maintained for at least the duration of employment plus thirty (30) years, except that the following types of records need not be retained for any specified period:

(A) Health insurance claims records maintained separately from the employer's medical program and its records,

(B) First aid records (not including medical histories) of one-time treatment and subsequent observation of minor scratches, cuts, burns, splinters, and the like which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job, if made on-site by a non-physician and if maintained separately from the employer's medical program and its records, and

(C) The medical records of employees who have worked for less than (1) year for the employer need not be retained beyond the term of employment if they are provided to the employee upon the termination of employment.

(ii) *Employee exposure records.* Each employee exposure record shall be preserved and maintained for at least thirty (30) years, except that:

(A) Background data to environmental (workplace) monitoring or measuring, such as laboratory reports and worksheets, need only be retained for one (1) year as long as the sampling results, the collection methodology (sampling plan), a description of the analytical and mathematical methods used, and a summary of other background data relevant to interpretation of the results obtained, are retained for at least thirty (30) years; and

(B) Material safety data sheets and paragraph (c)(5)(iv) records concerning the identity of a substance or agent need not be retained for any specified period as long as some record of the identity (chemical name if known) of the substance or agent, where it was used, and when it was used is retained for at least thirty (30) years;[1] and

(C) Biological monitoring results designated as exposure records by specific occupational safety and health standards shall be preserved and maintained as required by the specific standard.

(iii) *Analyses using exposure or medical records.* Each analysis using exposure or medial records shall be preserved and maintained for at least thirty (30) years.

(2) Nothing in this section is intended to mandate the form, manner, or process by which an employer preserves a record as long as the information contained in the record is preserved and retrievable, except that chest X-ray films shall be preserved in their original state.

(e) *Access to records*—(1) *General.* (i) Whenever an employee or designated representative requests access to a record, the employer shall assure that access is provided in a reasonable time, place, and manner. If the employer cannot reasonably provide access to the record within fifteen (15) working days, the employer shall within the fifteen (15) working days apprise the employee or designated representative requesting the record of the reason for

[1] Material safety data sheets must be kept for those chemicals currently in use that are effected by the Hazard Communication Standard in accordance with 29 CFR 1910.1200(g).

the delay and the earliest date when the record can be made available.

(ii) The employer may require of the requester only such information as should be readily known to the requester and which may be necessary to locate or identify the records being requested (e.g. dates and locations where the employee worked during the time period in question).

(iii) Whenever an employee or designated representative requests a copy of a record, the employer shall assure that either:

(A) A copy of the record is provided without cost to the employee or representative,

(B) The necessary mechanical copying facilities (e.g., photocopying) are made available without cost to the employee or representative for copying the record, or

(C) The record is loaned to the employee or representative for a reasonable time to enable a copy to be made.

(iv) In the case of an original X-ray, the employer may restrict access to on-site examination or make other suitable arrangements for the temporary loan of the X-ray.

(v) Whenever a record has been previously provided without cost to an employee or designated representative, the employer may charge reasonable, non-discriminatory administrative costs (i.e., search and copying expenses but not including overhead expenses) for a request by the employee or designated representative for additional copies of the record, except that

(A) An employer shall not charge for an initial request for a copy of new information that has been added to a record which was previously provided; and

(B) An employer shall not charge for an initial request by a recognized or certified collective bargaining agent for a copy of an employee exposure record or an analysis using exposure or medical records.

(vi) Nothing in this section is intended to preclude employees and collective bargaining agents from collectively bargaining to obtain access to information in addition to that available under this section.

(2) *Employee and designated representative access*—(i) *Employee exposure records.* (A) Except as limited by paragraph (f) of this section, each employer shall, upon request, assure the access to each employee and designated representative to employee exposure records relevant to the employee. For the purpose of this section, an exposure record relevant to the employee consists of:

(*1*) A record which measures or monitors the amount of a toxic substance or harmful physical agent to which the employee is or has been exposed;

(*2*) In the absence of such directly relevant records, such records of other employees with past or present job duties or working conditions related to or similar to those of the employee to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents to which the employee is or has been subjected, and

(*3*) Exposure records to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents at workplaces or under working conditions to which the employee is being assigned or transferred.

(B) Requests by designated representatives for unconsented access to employee exposure records shall be in writing and shall specify with reasonable particularity:

(*1*) The records requested to be disclosed; and

(*2*) The occupational health need for gaining access to these records.

(ii) *Employee medical records.* (A) Each employer shall, upon request, assure the access of each employee to employee medical records of which the employee is the subject, except as provided in paragraph (e)(2)(ii)(D) of this section.

(B) Each employer shall, upon request, assure the access of each designated representative to the employee medical records of any employee who has given the designated representative specific written consent. Appendix A to this section contains a sample form which may be used to establish specific written consent for access to employee medical records.

(C) Whenever access to employee medical records is requested, a physician representing the employer may

recommend that the employee or designated representative:

(*1*) Consult with the physician for the purposes of reviewing and discussing the records requested,

(*2*) Accept a summary of material facts and opinions in lieu of the records requested, or

(*3*) Accept release of the requested records only to a physician or other designated representative.

(D) Whenever an employee requests access to his or her employee medical records, and a physician representing the employer believes that direct employee access to information contained in the records regarding a specific diagnosis of a terminal illness or a psychiatric condition could be detrimental to the employee's health, the employer may inform the employee that access will only be provided to a designated representative of the employee having specific written consent, and deny the employee's request for direct access to this information only. Where a designated representative with specific written consent requests access to information so withheld, the employer shall assure the access of the designated representative to this information, even when it is known that the designated representative will give the information to the employee.

(E) A physician, nurse, or other responsible health care personnel maintaining medical records may delete from requested medical records the identity of a family member, personal friend, or fellow employee who has provided confidential information concerning an employee's health status.

(iii) *Analyses using exposure or medical records.* (A) Each employee shall, upon request, assure the access of each employee and designated representative to each analysis using exposure or medical records concerning the employee's working conditions or workplace.

(B) Whenever access is requested to an analysis which reports the contents of employee medical records by either direct identifier (name, address, social security number, payroll number, etc.) or by information which could reasonably be used under the circumstances indirectly to identify specific employees (exact age, height, weight, race, sex, date of initial employment, job title, etc.), the employer shall assure that personal identifiers are removed before access is provided. If the employer can demonstrate that removal of personal identifiers from an analysis is not feasible, access to the personally identifiable portions of the analysis need not be provided.

(3) *OSHA access.* (i) Each employer shall, upon request, and without derogation of any rights under the Constitution or the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.*, that the employer chooses to exercise, assure the prompt access of representatives of the Assistant Secretary of Labor for Occupational Safety and Health to employee exposure and medical records and to analyses using exposure or medical records. Rules of agency practice and procedure governing OSHA access to employee medical records are contained in 29 CFR 1913.10.

(ii) Whenever OSHA seeks access to personally identifiable employee medical information by presenting to the employer a written access order pursuant to 29 CFR 1913.10(d), the employer shall prominently post a copy of the written access order and its accompanying cover letter for at least fifteen (15) working days.

(f) *Trade secrets.* (1) Except as provided in paragraph (f)(2) of this section, nothing in this section precludes an employer from deleting from records requested by a health professional, employee, or designated representative any trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in mixture, as long as the health professional, employee, or designated representative is notified that information has been deleted. Whenever deletion of trade secret information substantially impairs evaluation of the place where or the time when exposure to a toxic substance or harmful physical agent occurred, the employer shall provide alternative information which is sufficient to permit the requesting party to identify where and when exposure occurred.

(2) The employer may withhold the specific chemical identity, including the chemical name and other specific

identification of a toxic substance from a disclosable record provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) All other available information on the properties and effects of the toxic substance is disclosed;

(iii) The employer informs the requesting party that the specific chemical identity is being withheld as a trade secret; and

(iv) The specific chemical identity is made available to health professionals, employees and designated representatives in accordance with the specific applicable provisions of this paragraph.

(3) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity of a toxic substance is necessary for emergency or first-aid treatment, the employer shall immediately disclose the specific chemical identity of a trade secret chemical to the treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (f)(4) and (f)(5), as soon as circumstances permit.

(4) In non-emergency situations, an employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under paragraph (f)(2) of this section, to a health professional, employee, or designated representative if:

(i) The request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity is essential and that, in lieu thereof, the disclosure of the following information would not enable the health professional, employee or designated representative to provide the occupational health services described in paragraph (f)(4)(ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, employee, or designated representative and the employer or contractor of the services of the health professional or designated representative agree in a written confidentiality agreement that the health professional, employee or designated representative will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (f)(7) of this section, except as authorized by the terms of the agreement or by the employer.

(5) The confidentiality agreement authorized by paragraph (f)(4)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(6) Nothing in this section is meant to preclude the parties from pursuing

non-contractual remedies to the extent permitted by law.

(7) If the health professional, employee or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the employer who provided the information shall be informed by the health professional prior to, or at the same time as, such disclosure.

(8) If the employer denies a written request for disclosure of a specific chemical identity, the denial must:

(i) Be provided to the health professional, employee or designated representative within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the specific chemical identity.

(9) The health professional, employee, or designated representative whose request for information is denied under paragraph (f)(4) of this section may refer the request and the written denial of the request to OSHA for consideration.

(10) When a heath professional employee, or designated representative refers a denial to OSHA under paragraph (f)(9) of this section, OSHA shall consider the evidence to determine if:

(i) The employer has supported the claim that the specific chemical identity is a trade secret;

(ii) The health professional employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and

(iii) The health professional, employee or designated representative has demonstrated adequate means to protect the confidentiality.

(11)(i) If OSHA determines that the specific chemical identity requested under paragraph (f)(4) of this section is not a *bona fide* trade secret, or that it is a trade secret but the requesting health professional, employee or designated representatives has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means for complying with the terms of such agreement, the employer will be subject to citation by OSHA.

(ii) If an employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health needs are met without an undue risk of harm to the employer.

(12) Notwithstanding the existence of a trade secret claim, an employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process or percentage of mixture information which is trade secret.

(g) *Employee information.* (1) Upon an employee's first entering into employment, and at least annually thereafter, each employer shall inform current employees covered by this section of the following:

(i) The existence, location, and availability of any records covered by this section;

(ii) The person responsible for maintaining and providing access to records; and

(iii) Each employee's rights of access to these records.

(2) Each employer shall keep a copy of this section and its appendices, and make copies readily available, upon request, to employees. The employer

shall also distribute to current employees any informational materials concerning this section which are made available to the employer by the Assistant Secretary of Labor for Occupational Safety and Health.

(h) *Transfer of records.* (1) Whenever an employer is ceasing to do business, the employer shall transfer all records subject to this section to the successor employer. The successor employer shall receive and maintain these records.

(2) Whenever an employer is ceasing to do business and there is no successor employer to receive and maintain the records subject to this standard, the employer shall notify affected current employees of their rights of access to records at least three (3) months prior to the cessation of the employer's business.

(3) Whenever an employer either is ceasing to do business and there is no successor employer to receive and maintain the records, or intends to dispose of any records required to be preserved for at least thirty (30) years, the employer shall:

(i) Transfer the records to the Director of the National Institute for Occupational Safety and Health (NIOSH) if so required by a specific occupational safety and health standard; or

(ii) Notify the Director of NIOSH in writing of the impending disposal of records at least three (3) months prior to the disposal of the records.

(4) Where an employer regularly disposes of records required to be preserved for at least thirty (30) years, the employer may, with at least (3) months notice, notify the Director of NIOSH on an annual basis of the records intended to be disposed of in the coming year.

(i) *Appendices.* The information contained in appendices A and B to this section is not intended, by itself, to create any additional obligations not otherwise imposed by this section nor detract from any existing obligation.

APPENDIX A TO §1910.1020—SAMPLE AUTHORIZATION LETTER FOR THE RELEASE OF EMPLOYEE MEDICAL RECORD INFORMATION TO A DESIGNATED REPRESENTATIVE (NON-MANDATORY)

I, _____ (full name of worker/patient), hereby authorize _____ (individual or organization holding the medical records) to release to _____ (individual or organization authorized to receive the medical information), the following medical information from my personal medical records:

_____

_____

(Describe generally the information desired to be released)

I give my permission for this medical information to be used for the following purpose:

_____

_____

but I do not give permission for any other use or re-disclosure of this information.

NOTE: Several extra lines are provided below so that you can place additional restrictions on this authorization letter if you want to. You may, however, leave these lines blank. On the other hand, you may want to (1) specify a particular expiration date for this letter (if less than one year); (2) describe medical information to be created in the future that you intend to be covered by this authorization letter; or (3) describe portions of the medical information in your records which you do not intend to be released as a result of this letter.)

_____

_____

_____

_____

_____

Full name of Employee or Legal Representative

_____

Signature of Employee or Legal Representative

_____

_____

Date of Signature

APPENDIX B TO §1910.1020—AVAILABILITY OF NIOSH REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES (RTECS) (NON-MANDATORY)

The final regulation, 29 CFR 1910.20, applies to all employee exposure and medical records, and analyses thereof, of employees exposed to toxic substances or harmful physical agents (paragraph (b)(2)). The term *toxic substance or harmful physical agent* is defined by paragraph (c)(13) to encompass chemical substances, biological agents, and physical stresses for which there is evidence of harmful health effects. The regulation uses the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS) as one of the chief sources of information as to whether evidence of harmful health effects exists. If a substance is listed in the latest printed RTECS, the regulation applies to exposure and medical records (and analyses of these

records) relevant to employees exposed to the substance.

It is appropriate to note that the final regulation does not require that employers purchase a copy of RTECS, and many employers need not consult RTECS to ascertain whether their employee exposure or medical records are subject to the rule. Employers who do not currently have the latest printed edition of the NIOSH RTECS, however, may desire to obtain a copy. The RTECS is issued in an annual printed edition as mandated by section 20(a)(6) of the Occupational Safety and Health Act (29 U.S.C. 669(a)(6)).

The Introduction to the 1980 printed edition describes the RTECS as follows:

''The 1980 edition of the Registry of Toxic Effects of Chemical Substances, formerly known as the Toxic Substances list, is the ninth revision prepared in compliance with the requirements of Section 20(a)(6) of the Occupational Safety and Health Act of 1970 (Public Law 91–596). The original list was completed on June 28, 1971, and has been updated annually in book format. Beginning in October 1977, quarterly revisions have been provided in microfiche. This edition of the Registry contains 168,096 listings of chemical substances: 45,156 are names of different chemicals with their associated toxicity data and 122,940 are synonyms. This edition includes approximately 5,900 new chemical compounds that did not appear in the 1979 Registry. (p. xi)

''The Registry's purposes are many, and it serves a variety of users. It is a single source document for basic toxicity information and for other data, such as chemical identifiers ad information necessary for the preparation of safety directives and hazard evaluations for chemical substances. The various types of toxic effects linked to literature citations provide researchers and occupational health scientists with an introduction to the toxicological literature, making their own review of the toxic hazards of a given substance easier. By presenting data on the lowest reported doses that produce effects by several routes of entry in various species, the Registry furnishes valuable information to those responsible for preparing safety data sheets for chemical substances in the workplace. Chemical and production engineers can use the Registry to identify the hazards which may be associated with chemical intermediates in the development of final products, and thus can more readily select substitutes or alternative processes which may be less hazardous. Some organizations, including health agencies and chemical companies, have included the NIOSH Registry accession numbers with the listing of chemicals in their files to reference toxicity information associated with those chemicals. By including foreign language chemical names, a start has been made toward providing rapid identification of substances produced in other countries. (p. xi)

''In this edition of the Registry, the editors intend to identify ''all known toxic substances'' which may exist in the environment and to provide pertinent data on the toxic effects from known doses entering an organism by any route described. (p xi)

''It must be reemphasized that the entry of a substance in the Registry does not automatically mean that it must be avoided. A listing does mean, however, that the substance has the documented potential of being harmful if misused, and care must be exercised to prevent tragic consequences. Thus, the Registry lists many substances that are common in everyday life and are in nearly every household in the United States. One can name a variety of such dangerous substances: prescription and non-prescription drugs; food additives; pesticide concentrates, sprays, and dusts; fungicides; herbicides; paints; glazes, dyes; bleaches and other household cleaning agents; alkalies; and various solvents and diluents. The list is extensive because chemicals have become an integral part of our existence.''

The RTECS printed edition may be purchased from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402 (202–783–3238).

Some employers may desire to subscribe to the quarterly update to the RTECS which is published in a microfiche edition. An annual subscription to the quarterly microfiche may be purchased from the GPO (Order the ''Microfiche Edition, Registry of Toxic Effects of Chemical Substances''). Both the printed edition and the microfiche edition of RTECS are available for review at many university and public libraries throughout the country. The latest RTECS editions may also be examined at the OSHA Technical Data Center, Room N2439—Rear, United States Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (202–523–9700), or at any OSHA Regional or Area Office (*See,* major city telephone directories under United States Government-Labor Department).

[53 FR 38163, Sept. 29, 1988; 53 FR 49981, Dec. 13, 1988, as amended at 54 FR 24333, June 7, 1989; 55 FR 26431, June 28, 1990; 61 FR 9235, Mar. 7, 1996. Redesignated at 61 FR 31430, June 20, 1996, as amended at 71 FR 16673, Apr. 3, 2006]

§ 1910.1025 Lead.

(a) *Scope and application.* (1) This section applies to all occupational exposure to lead, except as provided in paragraph (a)(2).