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. **1218–0131** 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. Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450)

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

9. Keywords:

10. Abstract: The Standard requires that employers monitor employee exposure to hazardous chemicals in laboratories, to provide medical consultation and examinations, to train employees about the hazards of chemicals in their working areas, and to establish and maintain accurate records of employee exposure to hazardous chemicals.

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	45,616
b. Total annual responses	911,446
1. Percentages of these responses collected electronically	%
c. Total annual hours requested	281,419
d. Current OMB inventory	270,636
e. Difference	10,783
f. Explanation of difference	
1. Program change	10,783
2. Adjustments	

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

a. Total annualized capital/startup costs	
b. Total annual costs (O&M)	35,978
c. Total annualized cost requested	
d. Current OMB inventory	32,616
e. Difference	3,362
f. Explanation of difference	
1. Program change	3,362
2. Adjustment	

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

a. __ Application for benefits
b. __ Program evaluation
c. __ General purpose statistics
d. __ Audit
e. __ 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 STANDARD ENTITLED "OCCUPATIONAL EXPOSURE TO HAZARDOUS CHEMICALS IN LABORATORIES" (29 CFR 1910.1450)[1] (OMB CONTROL NO. 1218-0131 (January 2008))

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 main purpose of the Occupational Safety and Health Act ("OSH Act" or "Act") 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 standards" (29 U.S.C. 651). The Act states further that "[t]he Secretary . . . shall prescribe such rules and regulations as [he/she] may deem necessary to carry out [his/her] responsibilities under this Act, including rules and regulations dealing with the inspection of an employer's establishment" (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 . . . to most effectively determine whether the health of such employees is adversely affected by such exposure" (29 U.S.C. 655). Moreover, the Act directs OSHA to "issue regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or other harmful physical agents which are required to be monitored and measured . . . " (29 U.S.C. 657). 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 [the employer's] activities relating to this Act as the Secretary . . . may prescribe by regulation as necessary or appropriate for the enforcement of this Act . . . " (29 U.S.C. 657).

The Act authorizes the Agency to issue standards that "prescribe 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" (29 U.S.C. 655). Additionally, the OSH Act mandates that "[e]ach employer shall make, keep and preserve, and make available to

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

the Secretary . . . such records . . . as the Secretary . . . may prescribe by regulation as necessary or appropriate for the enforcement of this Act . . . " (29 U.S.C. 657).

Beginning in the early 1970s, OSHA published numerous health standards to control employee exposure to toxic substances in 29 CFR part 1910, subpart Z (the "subpart Z standards").[2] However, OSHA developed the subpart Z standards primarily to protect employees exposed to toxic substances during industrial operations. These operations typically involve exposure to a few toxic substances emitted during a standardized and continuous or repetitive process that uses large quantities of the toxic substances. In laboratories, employees use small quantities of numerous hazardous chemicals[3] in a variety of analytic and clinical procedures and operations, each of which they perform infrequently or periodically. In addition, standard laboratory practices often require techniques that control the release of, and exposure to, hazardous chemicals (e.g., extensive labeling, sealed containers, protective clothing, fume hoods).[4] Moreover, laboratory employees have better knowledge of the hazardous chemicals with which they work than do employees involved in typical industrial operations; based on the high level of training they receive, laboratory employees usually have a thorough understanding of the chemical properties of these substances, as well as the safety and health problems associated with them.

Based on this evidence, OSHA concluded that, in general, laboratory employees have minimal exposures to hazardous chemicals in the workplace (i.e., below the action level (i.e., "AL") or, in the absence of an AL, the permissible exposure limit ("PEL") specified by subpart Z for any of these substances). Therefore, under the authority granted by the OSH Act, the Agency published a health standard governing occupational exposure to hazardous chemicals in laboratories (29 CFR 1910.1450; 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 Standard contains a number of paperwork requirements. The following paragraphs describe these requirements, specify who uses them, and what purpose they serve.

A. Employee exposure determination (§1910.1450(d))

Initial monitoring (§1910.1450(d)(1))

[2]Employers also have an obligation to protect employees from exposure to toxic substances under the general-duty clause of the Act at 29 U.S.C. 654.

[3]For the purposes of this Supporting Statement, the term "hazardous chemical" means a chemical for which acute or chronic health effects may occur in exposed employees as demonstrated by statistically significant evidence based upon at least one study conducted in accordance with established scientific principles. (See paragraph (b) of § 1910.1450).

[4]Employers institute these practices not only to protect their employees from exposure to the toxic substances, but also to ensure the reliability of the analytic or clinical results.

The employer shall measure the employee's exposure to any substance regulated by a standard which requires monitoring if there is reason to believe that exposure levels for that substance routinely exceed the action level (or in the absence of an action level, the PEL).

Purpose: Initial monitoring assists employers in identifying procedures and operations that require modification to reduce exposures to the AL or PEL specified by the appropriate subpart Z standard. In this regard, initial monitoring results enable employers to determine the need for engineering controls, institute new (or modify existing) work practices, and select appropriate respiratory protection to prevent employee overexposure. This information also determines whether or not the employer must perform periodic monitoring.

Periodic monitoring (§1910.1450(d)(2))

§1910.1450(d)(2) - If the initial monitoring prescribed by paragraph (d)(1) of this section discloses employee exposure over the action level (or in the absence of an action level, the PEL), the employer shall immediately comply with the exposure monitoring provisions of the relevant standard.

Purpose: Employers use periodic monitoring results to evaluate the effectiveness of selected control methods. In addition, these measurements remind both the employer and employees of the need to protect employees against the effects of overexposure to hazardous chemicals in laboratory facilities. These monitoring data will also inform the examining physician of the existence and extent of an employee's exposure to the hazardous chemical(s) for use in assessing the employee's medical condition.

Termination of monitoring (§1910.1450(d)(3))

Monitoring may be terminated in accordance with the relevant standard.

Employee notification of monitoring results (§1910.1450(d)(4))

The employer shall, within 15 working days after the receipt of any monitoring results, notify the employee of these results in writing either individually or by posting the results in an appropriate location that is accessible to employees.

Purpose: Notification provides employees with information they can use to assess the effectiveness of the controls their employer implement to reduce their exposures to hazardous laboratory chemicals, and to determine if any medical signs and symptoms they may be experiencing could be the result of their exposure to these chemicals.

B. Chemical Hygiene Plan (CHP) (§1910.1450(e))

§1910.1450(e)(1) - Where hazardous chemicals as defined by this standard are used in the workplace, the employer shall develop and carry out the provisions of a written Chemical Hygiene Plan which is:

§1910.1450(e)(1)(i) - Capable of protecting employees from health hazards associated with hazardous chemicals in that laboratory, and

§1910.1450(e)(1)(ii) - Capable of keeping exposures below the limits specified in paragraph (c) of this section.

§1910.1450(e)(3) - The Chemical Hygiene Plan shall include each of the following elements and shall indicate specific measures that the employer will take to ensure laboratory employee protection:

§1910.1450(e)(3)(i) - Standard operating procedures relevant to safety and health considerations to be followed when laboratory work involves the use of hazardous chemicals;

§1910.1450(e)(3)(ii) - Criteria that the employer will use to determine and implement control measures to reduce employee exposure to hazardous chemicals including engineering controls, the use of personal protective equipment and hygiene practices; particular attention shall be given to the selection of control measures for chemicals that are known to be extremely hazardous;

§1910.1450(e)(3)(iii) - A requirement that fume hoods and other protective equipment are functioning properly and specific measures that shall be taken to ensure proper and adequate performance of such equipment;

§1910.1450(e)(3)(iv) - Provisions for employee information and training as prescribed in paragraph (f) of this section;

§1910.1450(e)(3)(v) - The circumstances under which a particular laboratory operation, procedure or activity shall require prior approval from the employer or the employer's designee before implementation;

§1910.1450(e)(3)(vi) - Provisions for medical consultation and medical examinations in accordance with paragraph (g) of this section;

§1910.1450(e)(3)(vii) - Designation of personnel responsible for implementation of the Chemical Hygiene Plan including the assignment of a Chemical Hygiene Officer, and, if appropriate, establishment of a Chemical Hygiene Committee; and

§1910.1450(e)(3)(viii) - Provisions for additional employee protection for work with particularly hazardous substances. These include "select carcinogens," reproductive toxins and substances which have a high degree of acute toxicity. Specific consideration shall be given to the following

provisions which shall be included where appropriate:

§1910.1450(e)(3)(viii)(A) - Establishment of a designated area;

§1910.1450(e)(3)(viii)(B) - Use of containment devices such as fume hoods or glove boxes;

§1910.1450(e)(3)(viii)(C) - Procedures for safe removal of contaminated waste; and

§1910.1450(e)(3)(viii)(D) - Decontamination procedures.

§1910.1450(e)(4) - The employer shall review and evaluate the effectiveness of the Chemical Hygiene Plan at least annually and update it as necessary.

Purpose: This requirement commits employers to evaluate employee exposures to hazardous laboratory chemicals and establish an organized and complete program for reducing these exposures to the PEL specified for these chemicals. The requirement to review and update the CHP ensures that employers continue to evaluate workplace conditions, including hazardous-chemical exposures, and to implement the controls required to reduce employee overexposures. Employers are required to develop a written Chemical Hygiene Plan and ensure that they carry out the provisions.

C. Employee Information and Training (§1910.1450(f))

§1910.1450(f)(1) - The employer shall provide employees with information and training to ensure that they are apprised of the hazards of chemicals present in their work area.

§1910.1450(f)(2) - Such information shall be provided at the time of an employee's initial assignment to a work area where hazardous chemicals are present and prior to assignments involving new exposure situations. The frequency of refresher information and training shall be determined by the employer.

§1910.1450(f)(3) - Employees shall be informed of:

§1910.1450(f)(3)(i) - The contents of this standard and its appendices which shall be made available to them;

§1910.1450(f)(3)(ii) - the location and availability of the employer's Chemical Hygiene Plan;

§1910.1450(f)(3)(iii) - The permissible exposure limits for OSHA regulated substances or recommended exposure limits for other hazardous chemicals where there is no applicable OSHA standard;

§1910.1450(f)(3)(iv) - Signs and symptoms associated with exposures to hazardous chemicals used in the laboratory; and

§1910.1450(f)(3)(v) - The location and availability of known reference material on the hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory including, but not limited to, Material Safety Data Sheets, (MSDSs) received from the chemical supplier.

Training (§1910.1450(f)(4))

§1910.1450(f)(4)(i) - Employee training shall include:

> §1910.1450(f)(4)(i)(A) - Methods and observations that may be used to detect the presence or release of a hazardous chemical (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);
>
> §1910.1450(f)(4)(i)(B) - The physical and health hazards of chemicals in the work area; and
>
> §1910.1450(f)(4)(i)(C) - The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

§1910.1450(f)(4)(ii) - The employee shall be trained on the applicable details of the employer's written Chemical Hygiene Plan.

Purpose: This requirement is essential to inform employees of the health hazards resulting from hazardous chemical exposure and to provide them with the understanding necessary to minimize these hazards. Training serves to explain and reinforce the information presented to employees on signs, labels, and MSDSs; however, this information will be effective only if employees understand the information and can take the actions necessary to avoid or minimize hazardous chemical exposure. Training also enables employees to recognize operations and locations associated with hazardous chemical exposures, thereby permitting them to limit exposure from these sources.

D. Medical Consultation and Medical Examinations (§1910.1450(g))

General (§1910.1450(g)(1) and (g)(2))

§1910.1450(g)(1) - The employer shall provide all employees who work with hazardous chemicals an opportunity to receive medical attention, including any follow-up examinations which the examining physician determines to be necessary, under the following circumstances:

§1910.1450(g)(1)(i) - Whenever an employee develops signs or symptoms associated with a hazardous chemical to which the employee may have been exposed in the laboratory, the employee shall be provided an opportunity to receive an appropriate medical examination.

§1910.1450(g)(1)(ii) - Where exposure monitoring reveals an exposure level routinely above the action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring and medical surveillance requirements, medical surveillance shall be established for the affected employee as prescribed by the particular standard.

§1910.1450(g)(1)(iii) - Whenever an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a hazardous exposure, the affected employee shall be provided an opportunity for a medical consultation. Such consultation shall be for the purpose of determining the need for a medical examination.

§1910.1450(g)(2) - All medical examinations and consultations shall be performed by or under the direct supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.

Purpose: The requirements specified by these paragraphs prevent the development of serious illnesses among employees overexposed or potentially overexposed to hazardous chemicals used in their work areas.

Information provided to the physician (§1910.1450(g)(3))

The employer shall provide the following information to the physician:

§1910.1450(g)(3)(i) - The identity of the hazardous chemical(s) to which the employee may have been exposed;

§1910.1450(g)(3)(ii) - A description of the conditions under which the exposure occurred including quantitative exposure data, if available; and

§1910.1450(g)(3)(iii) - A description of the signs and symptoms of exposure that the employee is experiencing, if any.

Purpose: The examining physicians are provided this information to assist them in evaluating the employee's health and fitness for specific job assignments involving hazardous chemical exposure. The physician also uses this information to determine if an observed health condition is contributed to occupational exposure to hazardous chemicals in the laboratory work area.

Physician's written opinion (§1910.1450(g)(4))

§1910.1450(g)(4)(i) - For examination or consultation required under this standard, the employer shall obtain a written opinion from the examining physician which shall include the following:

§1910.1450(g)(4)(i)(A) - Any recommendation for further medical follow-up;

§1910.1450(g)(4)(i)(B) - The results of the medical examination and any associated tests;

§1910.1450(g)(4)(i)(C) - Any medical condition which may be revealed in the course of the examination which may place the employee at increased risk as a result of exposure to a hazardous workplace; and

§1910.1450(g)(4)(i)(D) - A statement that the employee has been informed by the physician of the results of the consultation or medical examination and any medical condition that may require further examination or treatment.

§1910.1450(g)(4)(ii) - The written opinion shall not reveal specific findings of diagnoses unrelated to occupational exposure.

Purpose: The purpose of requiring the employer to obtain a physician's written opinion is to provide the employer with medical information on whether or not the employee has a condition indicating overexposure to hazardous chemicals. If such a condition exists, the employer can implement additional controls to prevent overexposure. The information also allows the employer to plan necessary medical follow-up and treatment. The requirement that the physician's opinion be in writing ensures that the information is available for future reference. Employees are given a copy of the physician's written opinion to determine the need for treatments and other interventions. The written opinion allows the physician to make recommendations to remove the employee from the contaminated area or to make recommendations for control measures.

E. Hazard Identification (§1910.1450(h))

§1910.1450(h)(1) - With respect to labels and material safety data sheets:

§1910.1450(h)(1)(i) - Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced.

§1910.1450(h)(1)(ii) - Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory employees.

§1910.1450(h)(2) - The following provisions shall apply to chemical substances developed in the laboratory:

§1910.1450(h)(2)(i) - If the composition of the chemical substance which is produced

exclusively for the laboratory's use is known, the employer shall determine if it is a hazardous chemical as defined in paragraph (b) of this section. If the chemical is determined to be hazardous, the employer shall provide appropriate training as required under paragraph (f) of this section.

§1910.1450(h)(2)(ii) - If the chemical produced is a byproduct whose composition is not known, the employer shall assume that the substance is hazardous and shall implement paragraph (e) of this section.

§1910.1450(h)(2)(iii) - If the chemical substance is produced for another user outside of the laboratory, the employer shall comply with the Hazard Communication Standard (29 CFR 1910.1200) including the requirements for preparation of material safety data sheets and labeling.

Purpose: The provision ensures that employees, whether in a laboratory facility or at a downstream facility, receive adequate notice and, if necessary, other information regarding chemicals that are hazardous or potentially hazardous.

OSHA believes that this provision protects employees by alerting them to potential hazardous chemical exposures, thereby allowing them to take appropriate actions to control these exposures. In addition, this provision supplements the information and training requirements contained in paragraph (f) of the Standard.

F. Use of Respirators (§1910.1450(i))

Where the use of respirators is necessary to maintain exposure below permissible exposure limits, the employer shall provide, at no cost to the employee, the proper respiratory equipment. Respirators shall be selected and used in accordance with the requirements of 29 CFR 1910.134.

Purpose: The purpose of this requirement is to ensure that employers and employees select, use, and maintain appropriate respirators if respirators are necessary to protect employees from hazardous chemical exposures.

G. Recordkeeping (§1910.1450(j))

§1910.1450(j)(1) - The employer shall establish and maintain for each employee an accurate record of any measurements taken to monitor employee exposures and any medical consultation and examinations including tests or written opinions required by this standard.

Purpose: This requirement provides both employers and employees with useful information. The information alerts employers to routine overexposures to hazardous chemicals, thereby enabling them to modify controls or take other actions necessary to reduce these exposures. The exposure monitoring and medical information contained in these records assists employees and their physicians in determining the need for, and effectiveness of, medical treatment and other

interventions implemented in response to the employees' exposure to hazardous chemicals in a laboratory facility.

§1910.1450(j)(2) - The employer shall assure that such records are kept, transferred, and made available in accordance with 29 CFR 1910.1020.

Purpose: Employees and their designated representatives may use these records to evaluate employee medical status over the course of employment, to determine the effectiveness of the employer's exposure reduction program, and for other reasons. An OSHA compliance officer reviews the records to assess the employer's compliance with the medical and exposure control provisions of the Standard.

Paragraph (h) of § 1910.1020 requires employers who cease to do business to transfer medical and exposure-monitoring records to the successor employer, who then must receive and maintain the records. If no successor employer is available, the employer must: At least three months before ceasing business, notify current employees who have records of their right to access these records; and provide the National Institute for Occupational Safety and Health (NIOSH) with written notice of the impending disposal of these records at least three months prior to such disposal. NIOSH may use these records for research purposes (e.g., assessing the medical effects of long-term exposure to hazardous chemicals); in addition, serving as a repository for medical and exposure monitoring records, it provides employees with continuous access to their records if needed for health or other reasons.

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 any available technology to meet the paperwork requirements specified by the Standard. The Agency wrote these provisions in performance-oriented language, i.e., in terms of <u>what</u> information to provide, not <u>how</u> to provide 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 involved, and no other sources or agencies duplicate these requirements or can make the required information available to OSHA, 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 specified by 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 Agency believes that the information collection frequencies required by the Standard are the minimum frequencies necessary to fulfill its mandate "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" as specified in the OSH Act at 29 U.S.C. 651. Accordingly, if employers do not perform the information collections required by the Standard, or delay in providing this information, employees are at risk of developing serious illnesses resulting from overexposure to hazardous chemicals used in laboratory facilities.

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.**

Paragraph (d)(4) of the Standard requires that employers notify each employee of their exposure monitoring results within 15 working days after receiving these results. Employers may notify employees either individually in writing or by posting the monitoring results in an appropriate location that is accessible to the employees. Except for this provision, the information collection requirements of the Standard are consistent with 5 CFR 1320.5.

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 Standard on Hazardous Chemicals in Laboratories (29 CFR §1910.1450). 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 <u>not</u> 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.

To ensure that the personal information in the medical records required by the Standard remains confidential, the Agency developed §1913.10 ("Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records') to regulate its access to these records.

11. Provide additional justification for any question of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

The paperwork requirements specified by the Standard do not involve 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.**

Table 1 below presents information for the different types of laboratories covered by the Standard. For each type of laboratory, the table provides an estimate of the number of facilities that expose employees to hazardous chemicals and the number of employees so exposed.

Table 1: Number of Laboratory Facilities and Employees for Each Type of Laboratory

Type of Laboratory	No. of Facilities	No. of Employees
Industrial		
Independent testing[a]	6,213	100,679
Research and development[b]	13,000	1,000,000
Subtotals	*19,213*	*1,100,679*
Clinical		
Hospital[c]	7,356	166,867
Independent-medical[d]	5,179	134,547
Subtotals	*12,535*	*301,414*
Academic (Private)		
Post-secondary[e]	2,583	107,274
Secondary[f]	11,060	41,041
Professional and Research Institutes[g]	225	110,000
Subtotals	*13,868*	*258,315*
Totals	**45,616**	**1,660,408**

[a] Source: County Business Patterns 2005. U.S. Department of Commerce, Bureau of the Census. Total number of Independent Testing Laboratories (ITLs) calculated as the sum of taxable establishments (6,003 establishments, NAICS 54138) and tax-exempt establishments (210 establishments). The number of tax-exempt establishments estimated as 3.5 percent of total number of ITLs, based on data from 2002 Census. Number of Employees calculated as the sum of employees in taxable establishments (93,049 employees) and employees in tax-exempt establishments (7,630 employees). The number of employees in tax-exempt establishments estimated as 8.2 percent of total number of employees in ITLs, based on data from 2002 Census.

[b] Source: Supporting Statement for the Information Collection Requirements of the Standard Entitled "Occupational Exposure to Hazardous Chemicals in Laboratories" (29 CFR 1910.1450) [ICR 1218-0131 (2005)], based on analysis by DynCorp I&ET of *The Directory of American Research and Technology; Industrial Research Labs of the United States*; and "Survey of Industrial Research and Development," National Science Foundation/Division of Science Resources Studies. Because original sources appear to not have been updated, OSHA has no basis to revise 2005 figures.

[c]Source: Supporting Statement for the Information Collection Requirements of the Standard Entitled "Occupational Exposure to Hazardous Chemicals in Laboratories" (29 CFR 1910.1450) [ICR 1218-0131 (2005)] and Occupational Outlook Handbook, 2008-2009 ed., Bureau of Labor Statistics. Estimate of hospital-based labs derived by adjusting the 2005 ICR estimate by the percentage increase in lab employees reported in BLS.

[d] Source: County Business Patterns 2005. U.S. Department of Commerce, Bureau of the Census (NAICS 621511).

[e]Source: U.S. Department of Education, National Center for Education Statistics, Digest of Education Statistics, 2006. Table 248: Degree-granting institutions, by control and type of institution. Estimated number of employees in 2006 based on percentage change in post-secondary labs from 2005 ICR to 2006, applied to estimate of employees in 2005 ICR.

[f]Source: U.S. Department of Education, National Center for Education Statistics, Digest of Education Statistics, 2006. Table 56: Private elementary and secondary enrollment, number of schools, and average tuition, by school level, orientation, and tuition. Estimated number of employees in 2006 based on percentage change in private secondary labs from 2005 ICR to 2006, applied to estimate of employees in 2005 ICR.

[g]Source: 2001 ICR. As OSHA was unable to identify updated establishment and employment figures, estimates from previous ICR updates have been retained.

Burden Hour and Cost Determinations

The Agency determined average wage rates using average hourly earnings. For the relevant occupational categories, OSHA adjusted the mean hourly earnings from the National Compensation Survey, June 2005, Supplementary Tables. U.S. Department of Labor, Bureau of Labor Statistics, July 2006. Supplementary Table 2.1 to allow for fringe benefits, which comprise about 29.4% of total compensation in the private sector. With wages comprising 70.6% of employee compensation, the Agency multiplied wages by 1.4 (1/0.706) to derive total hourly employee compensation. Therefore, the costs of labor used in this analysis are estimates of total hourly compensation. These estimates are:

Administrative Service Manager:	$41.29
Employee	$20.21
Office Clerk	$16.95

(A) Employee exposure determination (§1910.1450(d))

Initial monitoring (§1910.1450(d)(1) and periodic monitoring (§1910.1450(d)(2) and (d)(3))

As noted above in Item 1, laboratory employees typically use small quantities of numerous hazardous chemicals in a variety of procedures and operations, each of which they perform infrequently or periodically. In addition, standard laboratory practices require techniques that control the release of, and exposure to, hazardous chemicals (e.g., extensive labeling, sealed containers, protective clothing such a gloves and goggles, laboratory hoods). Therefore, overexposure of laboratory employees to hazardous chemicals is rare. Accordingly, OSHA assumes that only a minimal need exists to conduct initial and periodic exposure monitoring (i.e., once a year per laboratory facility), and that a laboratory supervisor takes, on average, 10 minutes (.17 hour) to distribute and collect exposure-monitoring samples and mail them for analysis. Thus, the estimated burden hours and cost for these requirements each year are:

Burden hours: 45,616 facilities x .17 hour = 7,755 hours
Cost: 7,755 hours x $41.29 = $320,204

Employee notification of monitoring results (§1910.1450(d)(4))

Assuming that employers post exposure monitoring results in an appropriate location, the Agency estimates that an office clerk spends five minutes (.08 hour) developing and posting these results for each facility once a year. Therefore, the estimated annual burden hours and cost of this provision are:

Burden hours: 45,616 facilities x .08 hour = 3,649 hours
Cost: 3,649 hours x $16.95 = $61,851

(B) Chemical hygiene plan (§1910.1450(e))

This paragraph requires new laboratory facilities to develop a chemical hygiene plan (CHP), while existing facilities must review their CHPs at least annually.[5] The Agency estimates that the number of laboratory facilities increases by 750 each year, and that a laboratory supervisor (acting as the Chemical Hygiene Officer) takes 8 hours to develop a new CHP and one-half (.5) hour to update an existing CHP. The burden hour and cost estimate for this requirement are:

Burden hours: (750 new CHPs x 8 hours) + (45,616 existing CHPs x .5 hours) = 28,808 hours
Costs: 28,808 hours x $41.29 = $1,189,482

[5] This paragraph also specifies that employers must, as appropriate, establish designated areas to provide employees with additional protection. This provision does not require employers to establish records or maintain information, so the Agency is not taking any burden for this requirement.

(C) Employee information and training (§1910.1450(f))

The Agency assumes that 20% (332,082) of the employees covered by the Standard require information and training as specified by this provision; of this 20%, half consist of new or replacement (turnover) employees who are assuming new assignments, while the remaining half include existing employees who are receiving new exposures.[6] OSHA estimates that a laboratory supervisor can deliver the required training to 20 employees in a single session, for a total of 16,604 sessions to train 332,082 employees annually (i.e., 332,082 employees ÷ 20 employees per session). In addition, the Agency believes that, for each session, the laboratory supervisor requires 15 minutes (.25 hour) to prepare the training material and 45 minutes (.75 hour) to deliver it, for a total of one hour. Accordingly, the estimated yearly burden hours and cost of this information collection requirement are:

Burden hours: 16,604 sessions x 1 hour = 16,604 hours
Cost: 16,604 hours x $41.29 = $685,579

(D) Medical consultation and medical examinations (§1910.1450(g))

General (§1910.1450(g)(1) and (g)(2))

OSHA believes that 8% (132,833) of the employees covered by the Standard receive medical attention. Of these employees, the Agency assumes that: half (66,417) obtain a medical consultation, which OSHA estimates takes 45 minutes (.75 hour) to administer;[7] one-fourth (33,208) receive a medical examination, which the Agency finds takes 1.5 hours to administer; and the remaining one-fourth get both a medical consultation and medical examination, requiring an estimated total of 2.25 hours to administer. Thus, the estimated annual burden hour and cost to employers of the lost productivity resulting from these provisions are:

Burden hours: (66,417 employees x .75 hour) + (33,208 employees x 1.5 hours) +
(33,208 employees x 2.25 hours) = 174,343 hours
Cost: 174,343 hours x $20.21 = $3,523,472

Information provided to the physician (§1910.1450(g)(3))

OSHA estimates that an office clerk spends five minutes (.08 hour) compiling and sending the required information to the physician prior to each medical consultation or medical examination. Therefore, the yearly burden hour and cost estimates for this paperwork requirement are:

Burden hours: 132,833 employees x .08 hour = 10,627 hours
Cost: 10,627 hours x $16.95 = $180,128

[6] OSHA believes that employers do not repeat this training after the employees have been working in these assignments.
[7] Estimates of administration time include 30 minutes of travel time.

Physician's written opinion (§1910.1450(g)(4))

The Agency assumes that the physician writes an opinion for each medical consultation and medical examination administered (for a total of 132,833 written opinions annually), and that an office clerk takes five minutes (.08 hour) to distribute the written opinion to an employee.[8] Thus, the estimated burden hours and cost of this requirement each year are:

Burden hours: 132,833 written opinions x .08 hour = 10,627 hours
Cost: 10,627 hours x $16.95 = $180,128

(E) Hazard identification (§1910.1450(h))

OSHA's Hazard Communication (HC) Standard (§ 1910.1200) applies to the requirements regarding labels and MSDSs specified by this provision of the Standard.[9] Therefore, the Agency is accounting for the burden hours and cost resulting from these requirements under the Information Collection Request (ICR) for the HC Standard, OMB Control Number 1218-0072.

(F) Use of respirators (§1910.1450(i))

The Agency accounts for the burden hours and cost resulting from this paragraph (including the selection, use, and maintenance of respirators, and the development of a written respirator protection program) under the Information Collection Request (ICR) for OSHA's Respiratory Protection Standard (§1910.134), OMB Control Number 1218-0099.

(G) Recordkeeping (§1910.1450(j))

General (§1910.1450(j)(1))

As noted above in section (A) ("Exposure Monitoring") of this item, each laboratory facility covered by the Standard develops a record of exposure monitoring results, for an annual total of 45,616 records.[10] In addition, the determinations made above in section (D) ("Medical Consultation and Medical Examinations") show that employers administer 132,833 medical consultations and medical examinations annually, developing 132,833 medical records. Under the requirements of this recordkeeping provision, the Agency estimates that an office clerk spends five minutes (.08 hour) each year establishing and maintaining each of these records. Therefore, the annual burden hours and cost associated with this recordkeeping requirement are:

[8] The five minutes does not include the annual burden for maintaining a record of each written opinion as required by paragraph (j) of the Standard.

[9] Paragraph (h)(2)(i) of the Standard requires employers to provide training in accordance with paragraph (f), while paragraphs (h)(2)(ii) mandates CHPs specified by paragraph (e); the Agency included the burden-hour and cost estimates for paragraphs (h)(2)(i) and (h)(2)(ii) in the determinations made under sections (C) and (B), respectively, of this item.

[10] OSHA assumes that the record is the list of exposure-monitoring results used for posting.

Burden hours: [(45,616 exposure monitoring records) + (132,833 medical records)] x .08 hour = 14,276 hours
Cost: 14,276 hours x $16.95 = $241,978

Access to records and transfer of records (§1910.1450(j)(2))

The determinations for this provision show that employers spend a total of 14,276 burden hours at a cost of $241,978 providing access to exposure monitoring and medical records to employees, their designated representatives, and OSHA compliance officers, as well as transferring these records to NIOSH as required by paragraph (h) of §1910.1020 ("Access to employee exposure and medical records"). The following sections describe in detail the burden hour and cost determinations for this provision.

1. Employee access

For this determination, OSHA estimates that the exposure monitoring requirements of the Standard cover all employees (1,660,408) in laboratory facilities, while 132,833 of these employees have medical records (see previous determinations in this section). Additionally, the Agency assumes that 10% (179,324) of the employees covered by these records request access to them each year ((1,660,408 employees + 132,833 employees) x 10% = 179,324 employees).[11] OSHA estimates that an office clerk takes five minutes (.08 hour) to retrieve and re-file each requested record, resulting in the following annual burden hour and cost estimates:

Burden hours: 179,324 employees x .08 hours = 14,346 hours
Cost: 14,346 hours x $16.95 = $243,165

2. Federal access

The Agency determined that employers receive 639 requests annually for exposure monitoring and medical records during inspections conducted by its compliance officers (see Item 14 below). In addition, OSHA finds that a laboratory supervisor spends five minutes (.08 hour) informing a compliance officer of the location of the requested records. Accordingly, the estimated yearly burden hours and cost of this provision are:

Burden hours: 639 requests x .08 hours = 51 hours
Cost: 51 hours x $41.29 = $2,106

[11] The Agency believes that employers receive minimal requests for exposure monitoring and medical records from former employees, employees' legal representatives, individuals and organizations to whom employees give written authorization to exercise a right of access, and designated employee representatives; therefore, it did not include these requests in this determination.

Paragraph (h) of § 1910.1020 specifies the conditions for transferring exposure monitoring and medical records to NIOSH. Based on information from the previous ICR, OSHA estimates that four employers will send 333 sets of employee records to NIOSH each year during the period covered by this ICR. The Agency assumes that an office clerk requires one hour to prepare and send a set of records to NIOSH. Therefore, the annual estimated burden hours and cost of this provision are:

Burden hours: 333 sets of records x 1 hour = 333 hours
Cost: 333 hours x $16.95 = $5,644

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 service 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 respondent (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.

Capital Cost Determinations

Annual Medical Cost Determinations

OSHA found that the annual cost of providing employees with exposure monitoring, medical consultations, and medical examinations is $35,978,301. The following sections describe the cost determinations.

(A) Exposure monitoring

The Agency estimates that employers pay $60 to analyze an exposure monitoring sample. According to the information provided above in section (A) (“Exposure Monitoring”) under Item 12, employers collect 45,616 exposure monitoring samples each year. Thus, the annual cost

associated with obtaining exposure monitoring samples is:

Cost: 45,616 samples x $60 = $2,736,960

(B) Medical consultation and medical examinations

OSHA identified the following costs for providing medical attention to employees: Medical consultation (med consult), $133; medical examination (med exam), $301; and a combined medical consultation and med examination (med consult-med exam), $434.[12] In addition, the determinations made above in section (D) ("Medical consultation and medical examinations") show that each year employers administer 66,417 med consults, 33,208 med exams, and 33,208 med consults-med exams to employees. Accordingly, the yearly cost of providing medical attention to employees is:

Cost: (66,417 med consults x $133) + (33,208 med exams x $301) + (33,208 med consults-med exams x $434) = $33,241,341

OSHA found that the capital cost of providing employees with exposure monitoring, medical consultations, and medical examinations is $32,615,952. The following sections describe the capital-cost determinations.

(A) Exposure monitoring

The Agency estimates that employers pay $60 to analyze an exposure monitoring sample. According to the information provided above in section (A) ("Exposure monitoring") under Item 12, employers collect 43,300 exposure monitoring samples each year. Thus, the annual capital cost associated with obtaining exposure monitoring samples is:

Cost: 43,300 samples x $60 = $2,598,000

(B) Medical consultation and medical examinations

OSHA identified the following capital costs for providing medical attention to employees: Medical consultation (med consult), $125; medical examination (med exam), $282; and a combined medical consultation and med examination (med consult-med exam), $407. In addition, the determinations made above in section (D) ("Medical consultation and medical examinations") show that each year employers administer 63,936 med consults, 31,968 med exams, and 31,968 med consults-med exams to employees. Accordingly, the yearly capital cost of providing medical attention to employees is:

[12] The previous ICR assumed that each medical consultation cost $125, each medical examination $282, and each combined medical consultation and medical examination $408. 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 consultation or examination was assumed to have increased by 6.6% as well.

Cost: (63,936 med consults x $125) + (31,968 med exams x $282) +
(31,968 med consults-med exams x $407) = $30,017,952

14. Provide estimates of annualized cost of 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 paperwork requirements specified by the Standard cost the Federal government an estimated $2,055 each year. The following sections provide the basis for this cost determination.

1. Transfer of records

The determination made above under section (G) ("Recordkeeping") in Item 12 shows that employers send 333 sets of exposure monitoring and medical records to NIOSH annually. The Agency estimates that a NIOSH clerical/secretary (at a wage rate of $19.09 per hour) will spend five minutes (.08 hour) processing each set of records. Therefore, the estimated annual cost of this requirement to the Federal government is:

Cost: 333 set of records x .08 hour x $19.09 = $509

2. OSHA enforcement

The Agency estimates that a compliance officer (GS-12, step 5), at an hourly wage rate of $37.89, spends five minutes (.08 hour) during an inspection reviewing the documents required by the Standard. OSHA determines that its compliance officers will conduct 606 such inspections during each year covered by this ICR.[13] In making this cost determination, the Agency does not account for other occupational costs (e.g., equipment, overhead, and support staff expenses) because it considers these costs to be normal expenses that would occur without the collection of information requirements specified by the Standard. Thus, the estimated yearly cost of these paperwork requirements to the Federal government is:

Cost: 639 inspections x .08 hour x $37.89 = $1,937

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB form 83-1.

OSHA is requesting to increase the existing burden hour estimate for the collection of information requirements in the Standard. In this regard, the Agency is requesting to increase the current burden hour estimate from 270,636 hours to 281,419 hours, a total increase of 10,783

[13]The Agency estimated the number of inspections by determining the inspection rate (1.4%) for all facilities under the jurisdiction of the OSH Act (including both Federal OSHA and approved state-plan agencies) and then multiplying the total number of laboratory facilities (i.e., 45,616) by this percentage (i.e., 45,616 facilities x 1.4% = 639 inspections).

hours.

Additionally, the capital cost estimate has increased from $32,615,952 to $35,978,301 a total increase of $3,362,349. This increase is a result of an increase in the cost of medical consultations from $125 to $133, medical exams increasing from $282 to $301.

Table 2 below lists the current and requested burden hours of the information collection requirements specified by the Standard, and describes each of the requested burden hour adjustments.

Table 2

Requested Burden Hours and Adjustments

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Estimated Cost ($)	Adjustment	Explanation of Adjustment
A. Employee exposure determination (§1910.1450(d))					
Initial monitoring and periodic monitoring	7,361	7,755	$320,204	394	There was an increase in the number of facilities being monitored (from 43,300 to 45,616).
Employee notification of monitoring results	3,464	3,649	$61,851	185	There was an increase in the number of facilities being monitored (from 43,300 to 45,616).
B. Chemical hygiene plan (§1910.1450(e))	27,650	28,808	$1,189,482	1,158	There was an increase in the number of facilities being monitored (from 43,300 to 45,616).
C. Employee information and training (§1910.1450(f))	15,984	16,604	$685,579	620	There was an increase in the number of employees covered by the Standard (from 1,598,385 to 1,660,408) which increased the number of training sessions (from 15,984 to 16,604).
D. Medical consultation and medical examinations (§1910.1450(g))					
General	167,832	174,343	$3,523,472	6,511	There was an increase in the number of employees

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Estimated Cost ($)	Adjustment	Explanation of Adjustment
					covered by the Standard (from 1,598,385 to 1,660,408).
Information provided to the physician	10,230	10,627	$180,128	397	There was an increase in the number of employees covered by the Standard (from 1,598,385 to 1,660,408) which increases the number of employees providing information to the physician from 127,871 to 132,833).
Physician's written opinion	10,230	10,627	$180,128	397	There was an increase in the number of employees covered by the Standard (from 1,598,385 to 1,660,408) which increases the number of written opinions 127,871 to 132,833).
E. Hazard identification (§1910.1450(h))	0	0	0	0	
F. Use of respirators (§1910.1450(i))	0	0	0	0	
G. Recordkeeping (§1910.1450(j))					
General	13,694	14,276	$241,978	582	There was an increase in the number of facilities being monitored (from 43,300 to 45,616) and an increase in the number of employees covered by the Standard (from 1,598,385 to 1,660,408).
Access to records and transfer of records	14,191	14,730	$250,915	539	There was an increase in the number of facilities being monitored (from 43,300 to 45,616) and an increase in the number of employees covered by the Standard (from 1,598,385 to 1,660,408).
Totals	**270,636**	**281,419**	**$6,633,737**	**10,783**	

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.

No forms are available for the Agency 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 requesting an exception to the certification statement in Item 19 of the OMB 83-I.

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.

TITLE 29 - LABOR

CHAPTER 15 - OCCUPATIONAL SAFETY AND HEALTH

Sec. 654. Duties of employers and employees

-STATUTE-

(a) Each employer -

(1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;

(2) shall comply with occupational safety and health standards promulgated under this chapter.

(b) Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this chapter which are applicable to his own actions and conduct.

(Pub. L. 91-596, Sec. 5, Dec. 29, 1970, 84 Stat. 1593.)

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).

Occupational exposure to hazardous chemicals in laboratories. - 1910.1450

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• **Part Number:**	1910
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• **Subpart:**	Z
• **Subpart Title:**	Toxic and Hazardous Substances
• **Standard Number:**	1910.1450
• **Title:**	Occupational exposure to hazardous chemicals in laboratories.
• **Appendix:**	A , B

1910.1450(a)

Scope and application.

1910.1450(a)(1)

This section shall apply to all employers engaged in the laboratory use of hazardous chemicals as defined below.

1910.1450(a)(2)

Where this section applies, it shall supersede, for laboratories, the requirements of all other OSHA health standards in 29 CFR part 1910, subpart Z, except as follows:

1910.1450(a)(2)(i)

For any OSHA health standard, only the requirement to limit employee exposure to the specific permissible exposure limit shall apply for laboratories, unless that particular standard states otherwise or unless the conditions of paragraph (a)(2)(iii) of this section apply.

1910.1450(a)(2)(ii)

Prohibition of eye and skin contact where specified by any OSHA health standard shall be observed.

1910.1450(a)(2)(iii)

Where the action level (or in the absence of an action level, the permissible exposure limit) is routinely exceeded for an OSHA regulated substance with exposure monitoring and medical surveillance requirements paragraphs (d) and (g)(1)(ii) of this section shall apply.

1910.1450(a)(3)

This section shall not apply to:

1910.1450(a)(3)(i)

Uses of hazardous chemicals which do not meet the definition of laboratory use, and in such cases, the employer shall comply with the relevant standard in 29 CFR part 1910, subpart Z, even if such use occurs in a laboratory.

1910.1450(a)(3)(ii)

Laboratory uses of hazardous chemicals which provide no potential for employee exposure. Examples of such conditions might include:

1910.1450(a)(3)(ii)(A)

Procedures using chemically-impregnated test media such as Dip-and-Read tests where a reagent strip is dipped into the specimen to be tested and the results are interpreted by comparing the color reaction to a color chart supplied by the manufacturer of the test strip; and

1910.1450(a)(3)(ii)(B)

Commercially prepared kits such as those used in performing pregnancy tests in which all of the reagents needed to conduct the test are contained in the kit.

1910.1450(b)

Definitions --

Action level means a concentration designated in 29 CFR part 1910 for a specific substance,

calculated as an eight (8)-hour time-weighted average, which initiates certain required activities such as exposure monitoring and medical surveillance.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Carcinogen (***see select carcinogen***).

Chemical Hygiene Officer means an employee who is designated by the employer, and who is qualified by training or experience, to provide technical guidance in the development and implementation of the provisions of the Chemical Hygiene Plan. This definition is not intended to place limitations on the position description or job classification that the designated individual shall hold within the employer's organizational structure.

Chemical Hygiene Plan means a written program developed and implemented by the employer which sets forth procedures, equipment, personal protective equipment and work practices that (i) are capable of protecting employees from the health hazards presented by hazardous chemicals used in that particular workplace and (ii) meets the requirements of paragraph (e) of this section.

Combustible liquid means any liquid having a flashpoint at or above 100 deg. F (37.8 deg. C), but below 200 deg. F (93.3 deg. C), except any mixture having components with flashpoints of 200 deg. F (93.3 deg. C), or higher, the total volume of which make up 99 percent or more of the total volume of the mixture.

Compressed gas means:

(i) A gas or mixture of gases having, in a container, an absolute pressure exceeding 40 psi at 70 deg. F (21.1 deg. C); or

(ii) A gas or mixture of gases having, in a container, an absolute pressure exceeding 104 psi at 130 deg. F (54.4 deg C) regardless of the pressure at 70 deg. F (21.1 deg. C); or

(iii) A liquid having a vapor pressure exceeding 40 psi at 100 deg. F (37.8 C) as determined by ASTM D-323-72.

Designated area means an area which may be used for work with "select carcinogens," reproductive toxins or substances which have a high degree of acute toxicity. A designated area may be the entire laboratory, an area of a laboratory or a device such as a laboratory hood.

Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers or failure of control equipment which results in an uncontrolled release of a hazardous chemical into the workplace.

Employee means an individual employed in a laboratory workplace who may be exposed to hazardous chemicals in the course of his or her assignments.

Explosive means a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

Flammable means a chemical that falls into one of the following categories:

(i) ***Aerosol, flammable*** means an aerosol that, when tested by the method described in 16 CFR 1500.45, yields a flame protection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening;

(ii) ***Gas, flammable*** means:

(A) A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of 13 percent by volume or less; or

(B) A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than 12 percent by volume, regardless of the lower limit.

(iii) ***Liquid, flammable*** means any liquid having a flashpoint below 100 deg F (37.8 deg. C), except any mixture having components with flashpoints of 100 deg. C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.

(iv) ***Solid, flammable*** means a solid, other than a blasting agent or explosive as defined in § 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

Flashpoint means the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

(i) Tagliabue Closed Tester (See American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24 - 1979 (ASTM D 56-79)) - for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100 deg. F (37.8 deg. C), that do not contain suspended solids and do not have a tendency to form a surface film under test; or

(ii) Pensky-Martens Closed Tester (See American National Standard Method of Test for Flashpoint by Pensky-Martens Closed Tester, Z11.7 - 1979 (ASTM D 93-79)) - for liquids with a viscosity equal to or greater than 45 SUS at 100 deg. F (37.8 deg. C), or that contain suspended solids, or that have a tendency to form a surface film under test; or

(iii) Setaflash Closed Tester (see American National Standard Method of test for Flash Point by Setaflash Closed Tester (ASTM D 3278-78)).

Organic peroxides, which undergo autoaccelerating thermal decomposition, are excluded from any of the flashpoint determination methods specified above.

Hazardous chemical means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic systems, and agents which damage the lungs, skin, eyes, or mucous membranes.

Appendices A and B of the Hazard Communication Standard (29 CFR 1910.1200) provide further guidance in defining the scope of health hazards and determining whether or not a chemical is to be considered hazardous for purposes of this standard.

Laboratory means a facility where the "laboratory use of hazardous chemicals" occurs. It is a workplace where relatively small quantities of hazardous chemicals are used on a non-production basis.

Laboratory scale means work with substances in which the containers used for reactions, transfers, and other handling of substances are designed to be easily and safety manipulated by one person. "Laboratory scale" excludes those workplaces whose function is to produce commercial quantities of materials.

Laboratory-type hood means a device located in a laboratory, enclosure on five sides with a movable sash or fixed partial enclosed on the remaining side; constructed and maintained to draw air from the laboratory and to prevent or minimize the escape of air contaminants into the laboratory; and allows chemical manipulations to be conducted in the enclosure without insertion of any portion of the employee's body other than hands and arms.

Walk-in hoods with adjustable sashes meet the above definition provided that the sashes are adjusted during use so that the airflow and the exhaust of air contaminants are not compromised and employees do not work inside the enclosure during the release of airborne hazardous chemicals.

Laboratory use of hazardous chemicals means handling or use of such chemicals in which all of the following conditions are met:

(i) Chemical manipulations are carried out on a "laboratory scale;"

(ii) Multiple chemical procedures or chemicals are used;

(iii) The procedures involved are not part of a production process, nor in any way simulate a production process; and

(iv) "Protective laboratory practices and equipment" are available and in common use to minimize the potential for employee exposure to hazardous chemicals.

Medical consultation means a consultation which takes place between an employee and a licensed physician for the purpose of determining what medical examinations or procedures, if any, are appropriate in cases where a significant exposure to a hazardous chemical may have taken place.

Organic peroxide means an organic compound that contains the bivalent -O-O- structure and which may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

Oxidizer means a chemical other than a blasting agent or explosive as defined in § 1910.109(a), that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

Physical hazard means a chemical for which there is scientifically valid evidence tat it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer pyrophoric, unstable (reactive) or water-reactive.

Protective laboratory practices and equipment means those laboratory procedures, practices and equipment accepted by laboratory health and safety experts as effective, or that the employer can show to be effective, in minimizing the potential for employee exposure to hazardous chemicals.

Reproductive toxins means chemicals which affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis).

Select carcinogen means any substance which meets one of the following criteria:

(i) It is regulated by OSHA as a carcinogen; or

(ii) It is listed under the category, "known to be carcinogens," in the Annual Report on Carcinogens published by the National Toxicology Program (NTP)(latest edition); or

(iii) It is listed under Group 1 ("carcinogenic to humans") by the International Agency for research on Cancer Monographs (IARC)(latest editions); or

(iv) It is listed in either Group 2A or 2B by IARC or under the category, "reasonably anticipated to be carcinogens" by NTP, and causes statistically significant tumor incidence in experimental animals in accordance with any of the following criteria:

(A) After inhalation exposure of 6-7 hours per day, 5 days per week, for a significant portion of a lifetime to dosages of less than 10 mg/m(3);

(B) After repeated skin application of less than 300 (mg/kg of body weight) per week; or

(C) After oral dosages of less than 50 mg/kg of body weight per day.

Unstable (reactive) means a chemical which is the pure state, or as produced or transported, will vigorously polymerize, decompose, condense, or will become self-reactive under conditions of shocks, pressure or temperature.

Water-reactive means a chemical that reacts with water to release a gas that is either flammable or presents a health hazard.

1910.1450(c)

Permissible exposure limits. For laboratory uses of OSHA regulated substances, the employer shall assure that laboratory employees' exposures to such substances do not exceed the permissible exposure limits specified in 29 CFR part 1910, subpart Z.

1910.1450(d)

Employee exposure determination --

1910.1450(d)(1)

Initial monitoring. The employer shall measure the employee's exposure to any substance regulated by a standard which requires monitoring if there is reason to believe that exposure levels for that substance routinely exceed the action level (or in the absence of an action level, the PEL).

1910.1450(d)(2)

Periodic monitoring. If the initial monitoring prescribed by paragraph (d)(1) of this section discloses employee exposure over the action level (or in the absence of an action level, the PEL), the employer shall immediately comply with the exposure monitoring provisions of the relevant standard.

1910.1450(d)(3)

Termination of monitoring. Monitoring may be terminated in accordance with the relevant standard.

1910.1450(d)(4)

Employee notification of monitoring results. The employer shall, within 15 working days after the receipt of any monitoring results, notify the employee of these results in writing either individually or by posting results in an appropriate location that is accessible to employees.

1910.1450(e)

Chemical hygiene plan -- General. (Appendix A of this section is non-mandatory but provides guidance to assist employers in the development of the Chemical Hygiene Plan).

1910.1450(e)(1)

Where hazardous chemicals as defined by this standard are used in the workplace, the employer shall develop and carry out the provisions of a written Chemical Hygiene Plan which is:

1910.1450(e)(1)(i)

Capable of protecting employees from health hazards associated with hazardous chemicals in

that laboratory and

1910.1450(e)(1)(ii)

Capable of keeping exposures below the limits specified in paragraph (c) of this section.

1910.1450(e)(2)

The Chemical Hygiene Plan shall be readily available to employees, employee representatives and, upon request, to the Assistant Secretary.

1910.1450(e)(3)

The Chemical Hygiene Plan shall include each of the following elements and shall indicate specific measures that the employer will take to ensure laboratory employee protection;

1910.1450(e)(3)(i)

Standard operating procedures relevant to safety and health considerations to be followed when laboratory work involves the use of hazardous chemicals;

1910.1450(e)(3)(ii)

Criteria that the employer will use to determine and implement control measures to reduce employee exposure to hazardous chemicals including engineering controls, the use of personal protective equipment and hygiene practices; particular attention shall be given to the selection of control measures for chemicals that are known to be extremely hazardous;

1910.1450(e)(3)(iii)

A requirement that fume hoods and other protective equipment are functioning properly and specific measures that shall be taken to ensure proper and adequate performance of such equipment;

1910.1450(e)(3)(iv)

Provisions for employee information and training as prescribed in paragraph (f) of this section;

1910.1450(e)(3)(v)

The circumstances under which a particular laboratory operation, procedure or activity shall require prior approval from the employer or the employer's designee before implementation;

1910.1450(e)(3)(vi)

Provisions for medical consultation and medical examinations in accordance with paragraph (g) of this section;

1910.1450(e)(3)(vii)

Designation of personnel responsible for implementation of the Chemical Hygiene Plan including the assignment of a Chemical Hygiene Officer, and, if appropriate, establishment of a Chemical Hygiene Committee; and

1910.1450(e)(3)(viii)

Provisions for additional employee protection for work with particularly hazardous substances. These include "select carcinogens," reproductive toxins and substances which have a high degree of acute toxicity. Specific consideration shall be given to the following provisions which shall be included where appropriate:

1910.1450(e)(3)(viii)(A)

Establishment of a designated area;

1910.1450(e)(3)(viii)(B)

Use of containment devices such as fume hoods or glove boxes;

1910.1450(e)(3)(viii)(C)

Procedures for safe removal of contaminated waste; and

1910.1450(e)(3)(viii)(D)

Decontamination procedures.

1910.1450(e)(4)

The employer shall review and evaluate the effectiveness of the Chemical Hygiene Plan at least annually and update it as necessary.

1910.1450(f)

Employee information and training.

1910.1450(f)(1)

The employer shall provide employees with information and training to ensure that they are apprised of the hazards of chemicals present in their work area.

1910.1450(f)(2)

Such information shall be provided at the time of an employee's initial assignment to a work area where hazardous chemicals are present and prior to assignments involving new exposure situations. The frequency of refresher information and training shall be determined by the employer.

1910.1450(f)(3)

Information. Employees shall be informed of:
1910.1450(f)(3)(i)
The contents of this standard and its appendices which shall be made available to employees;
1910.1450(f)(3)(ii)
the location and availability of the employer's Chemical Hygiene Plan;
1910.1450(f)(3)(iii)
The permissible exposure limits for OSHA regulated substances or recommended exposure limits for other hazardous chemicals where there is no applicable OSHA standard;
1910.1450(f)(3)(iv)
Signs and symptoms associated with exposures to hazardous chemicals used in the laboratory; and
1910.1450(f)(3)(v)
The location and availability of known reference material on the hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory including, but not limited to, Material Safety Data Sheets received from the chemical supplier.
1910.1450(f)(4)
Training.
1910.1450(f)(4)(i)
Employee training shall include:
1910.1450(f)(4)(i)(A)
Methods and observations that may be used to detect the presence or release of a hazardous chemical (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);
1910.1450(f)(4)(i)(B)
The physical and health hazards of chemicals in the work area; and
1910.1450(f)(4)(i)(C)
The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.
1910.1450(f)(4)(ii)
The employee shall be trained on the applicable details of the employer's written Chemical Hygiene Plan.
1910.1450(g)
Medical consultation and medical examinations.
1910.1450(g)(1)
The employer shall provide all employees who work with hazardous chemicals an opportunity to receive medical attention, including any follow-up examinations which the examining physician determines to be necessary, under the following circumstances:
1910.1450(g)(1)(i)
Whenever an employee develops signs or symptoms associated with a hazardous chemical to which the employee may have been exposed in the laboratory, the employee shall be provided an opportunity to receive an appropriate medical examination.
1910.1450(g)(1)(ii)
Where exposure monitoring reveals an exposure level routinely above the action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring and medical surveillance requirements, medical surveillance shall be established for the affected employee as prescribed by the particular standard.
1910.1450(g)(1)(iii)
Whenever an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a hazardous exposure, the affected employee shall be provided an opportunity for a medical consultation. Such consultation shall be for the purpose of determining the need for a medical examination.
1910.1450(g)(2)
All medical examinations and consultations shall be performed by or under the direct supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.
1910.1450(g)(3)
Information provided to the physician. The employer shall provide the following

information to the physician:
1910.1450(g)(3)(i)
The identity of the hazardous chemical(s) to which the employee may have been exposed;
1910.1450(g)(3)(ii)
A description of the conditions under which the exposure occurred including quantitative exposure data, if available; and
1910.1450(g)(3)(iii)
A description of the signs and symptoms of exposure that the employee is experiencing, if any.
1910.1450(g)(4)
Physician's written opinion.
1910.1450(g)(4)(i)
For examination or consultation required under this standard, the employer shall obtain a written opinion from the examining physician which shall include the following:
1910.1450(g)(4)(i)(A)
Any recommendation for further medical follow-up;
1910.1450(g)(4)(i)(B)
The results of the medical examination and any associated tests;
1910.1450(g)(4)(i)(C)
Any medical condition which may be revealed in the course of the examination which may place the employee at increased risk as a result of exposure to a hazardous workplace; and
1910.1450(g)(4)(i)(D)
A statement that the employee has been informed by the physician of the results of the consultation or medical examination and any medical condition that may require further examination or treatment.
1910.1450(g)(4)(ii)
The written opinion shall not reveal specific findings of diagnoses unrelated to occupational exposure.
1910.1450(h)
Hazard identification.
1910.1450(h)(1)
With respect to labels and material safety data sheets:
1910.1450(h)(1)(i)
Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced.
1910.1450(h)(1)(ii)
Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory employees.
1910.1450(h)(2)
The following provisions shall apply to chemical substances developed in the laboratory:
1910.1450(h)(2)(i)
If the composition of the chemical substance which is produced exclusively for the laboratory's use is known, the employer shall determine if it is a hazardous chemical as defined in paragraph (b) of this section. If the chemical is determined to be hazardous, the employer shall provide appropriate training as required under paragraph (f) of this section.
1910.1450(h)(2)(ii)
If the chemical produced is a byproduct whose composition is not known, the employer shall assume that the substance is hazardous and shall implement paragraph (e) of this section.
1910.1450(h)(2)(iii)
If the chemical substance is produced for another user outside of the laboratory, the employer shall comply with the Hazard Communication Standard (29 CFR 1910.1200) including the requirements for preparation of material safety data sheets and labeling.
1910.1450(i)
Use of respirators. Where the use of respirators is necessary to maintain exposure below permissible exposure limits, the employer shall provide, at no cost to the employee, the proper respiratory equipment. Respirators shall be selected and used in accordance with the requirements of 29 CFR 1910.134.
1910.1450(j)
Recordkeeping.
1910.1450(j)(1)

The employer shall establish and maintain for each employee an accurate record of any measurements taken to monitor employee exposures and any medical consultation and examinations including tests or written opinions required by this standard.

1910.1450(j)(2)

The employer shall assure that such records are kept, transferred, and made available in accordance with 29 CFR 1910.1020.

1910.1450(k)

[Reserved]

1910.1450(l)

Appendices. The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

[55 FR 3327, Jan. 31, 1990; 55 FR 7967, March, 6, 1990; 55 FR 12777, March 30, 1990; 61 FR 5507, Feb. 13, 1996; 71 FR 16674, April 3, 2006]

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.

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[39 FR 23502, June 27, 1974, as amended at 43 FR 19624, May 5, 1978; 43 FR 28472, June 30, 1978; 45 FR 35282, May 23, 1980; 54 FR 24334, June 7, 1989; 58 FR 35310, June 30, 1993; 61 FR 5508, Feb. 13, 1996; 61 FR 9245, Mar. 7, 1996; 63 FR 1286, Jan. 8, 1998; 63 FR 33468, June 18, 1998]

§ 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 non-occupational 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 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

[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).

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)(9) 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]

§ 1910.1025 Lead.

(a) *Scope and application.* (1) This section applies to all occupational exposure to lead, except as provided in paragraph (a)(2).

(2) This section does not apply to the construction industry or to agricultural operations covered by 29 CFR Part 1928.

(b) *Definitions. Action level* means employee exposure, without regard to the use of respirators, to an airborne concentration of lead of 30 micrograms per cubic meter of air (30 μg/m^3) averaged over an 8-hour period.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Director means the Director, National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health, Education, and Welfare, or designee.

Lead means metallic lead, all inorganic lead compounds, and organic lead soaps. Excluded from this definition are all other organic lead compounds.

(c) *Permissible exposure limit (PEL).* (1) The employer shall assure that no employee is exposed to lead at concentrations greater than fifty micrograms per cubic meter of air (50 μg/m^3) averaged over an 8-hour period.

(2) If an employee is exposed to lead for more than 8 hours in any work day, the permissible exposure limit, as a time weighted average (TWA) for that day, shall be reduced according to the following formula:

$$\text{Maximum permissible limit (in } \mu g/m^3) = 400 \div \text{hours worked in the day.}$$

(3) When respirators are used to supplement engineering and work practice controls to comply with the PEL and all the requirements of paragraph (f) have been met, employee exposure, for the purpose of determining whether the employer has complied with the PEL, may be considered to be at the level provided by the protection factor of the respirator for those periods the respirator is worn. Those periods may be averaged with exposure levels during periods when respirators are not worn to determine the employee's daily TWA exposure.

§ 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

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