

**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) (September 2015)**

A. JUSTIFICATION

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

The 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 worker health, the OSH Act authorizes the Occupational Safety and Health Administration (“OSHA” or “Agency”) to develop standards that provide for “monitoring or measuring worker 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 workers exposed to such hazards . . . to most effectively determine whether the health of such workers 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 worker 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 workers 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 worker 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 workers 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, workers use small quantities of numerous hazardous chemicals³ 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 workers have better knowledge of the hazardous chemicals with which they work than do workers involved in typical industrial operations; based on the high level of training they receive, laboratory workers 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 workers 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. Worker exposure determination (§1910.1450(d))

Initial monitoring (§1910.1450(d)(1))

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

3 ³For the purposes of this Supporting Statement, the term “hazardous chemical” means a chemical for which acute or chronic health effects may occur in exposed workers 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 ⁴Employers institute these practices not only to protect their workers from exposure to the toxic substances, but also to ensure the reliability of the analytic or clinical results.

The employer shall measure the worker'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 worker 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 worker 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 workers of the need to protect workers 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 a worker's exposure to the hazardous chemical(s) for use in assessing the worker's medical condition.

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

Monitoring may be terminated in accordance with the relevant standard.

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

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

Purpose: Notification provides workers 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 workers 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, and employee representatives;*

§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 worker 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 worker 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 worker 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 worker 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 worker 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 worker overexposures. Employers are required to develop a written Chemical Hygiene Plan and ensure that they carry out the provisions.

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

§1910.1450(f)(1) - The employer shall provide workers 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 worker'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) - Workers 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, Safety Data Sheets, (SDSs) received from the chemical supplier.

Training (§1910.1450(f)(4))

§1910.1450(f)(4)(i) - Worker 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 workers can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect workers 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 worker shall be trained on the applicable details of the employer's written Chemical Hygiene Plan.

Purpose: This requirement is essential to inform workers 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 workers on signs, labels, and SDSs; however, this information will be effective only if workers understand the information and can take the actions necessary to avoid or minimize hazardous chemical

exposure. Training also enables workers 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 workers 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 worker develops signs or symptoms associated with a hazardous chemical to which the worker may have been exposed in the laboratory, the worker 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 worker 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 worker 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 worker, without loss of pay and at a reasonable time and place.

Purpose: The requirements specified by these paragraphs provide for medical attention under these circumstances to prevent the development of serious illnesses among workers 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 worker 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 worker is experiencing, if any.

Purpose: The examining physician is provided this information to assist him in evaluating the worker's exposure to a hazardous chemical. 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 worker at increased risk as a result of exposure to a hazardous workplace; and

§1910.1450(g)(4)(i)(D) - A statement that the worker 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 worker 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. Workers 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 worker 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 workers.

§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 workers, 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 workers 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 worker, 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 workers select, use, and maintain appropriate respirators if respirators are necessary to protect workers from hazardous chemical exposures.

G. Recordkeeping (§1910.1450(j))

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

Purpose: This requirement provides both employers and workers 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 workers and their physicians in determining the need for, and effectiveness of, medical treatment and other interventions implemented in response to the workers' 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: Workers and their designated representatives may use these records to evaluate worker 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.⁵

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. This paragraph also requires that whenever an employer ceases 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 workers of their rights of access to records at least three (3) months prior to the cessation of the employer's business. OSHA considers the employer's transfer of records to a successor to be usual and customary communications during the transition from one employer to a successor employer. In this regard, the employer would communicate the location of all records, including worker exposure-monitoring and medical records, at the facility to the successor employer during the transfer of business operations, as a matter of usual and customary business practice. In addition, OSHA accounts for the burden hours and costs resulting from the worker notification requirements under the Information Collection Request (ICR) for its Access to Worker Exposure and Medical Records Standard (§ 1910.1020), OMB Control No. 1218-0065.

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

⁵Upon a thorough review of this ICR, the Agency determined that these provisions were not fully addressed in previous ICRs.

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 what information to provide, not how 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 A.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, 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, workers 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 worker of their exposure monitoring results within 15 working days after receiving these results. Employers may notify workers either individually in writing or by posting the monitoring results in an appropriate location that is accessible to the workers. 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.

Pursuant to the Paperwork Reduction Act (the PRA) (44 U.S.C. 3506(c)(2)(A)), OSHA published a notice in the Federal Register on December 15, 2014 (79 FR 74113) soliciting comments on its proposal to extend the Office of Management and Budget's approval of the information collection requirements contained in the Standard on Occupational Exposure to Hazardous Chemicals in Laboratories (the Lab Standard; 29 CFR 1910.1450). The notice was part of a preclearance consultation program that provided the general public and government with an opportunity to comment. The Agency received one comment from Mr. Aaron Adamczyk who stated "To reduce burden on employers update Appendix B to accept current national standards and reference documents."

OSHA recognizes that its regulations do not reflect the latest editions of consensus standards and has undertaken a multi-year project to update these standards. A notice describing the project was published in November 2004 (69 FR 68283). Additional information about this project may be found in the spring 2014 Regulatory Agenda (Regulatory Action Titled: Updating OSHA Standards Based on National Consensus Standards Eye and Face Protection, RIN: 1218-AC87).

The outdated consensus standards do not impact the collection of information requirements contained in the Standard; therefore, the Agency will retain its estimated burden hours and cost estimates.

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

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

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

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 Worker 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.**
- **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 workers to hazardous chemicals and the number of workers so exposed.

Table 1. Number of Laboratory Facilities and Workers for Each Type of Laboratory

Type of Laboratory	No. of Facilities	No. of Workers
Industrial		
Independent testing[a]	6,730	125,608
Research and development[b]	51,736	1,471,000
<i>Subtotals</i>	<i>58,466</i>	<i>1,596,608</i>
Clinical		
Hospital[c]	14,200	322,170
Independent-medical[d]	6,648	162,081
<i>Subtotals</i>	<i>20,848</i>	<i>484,251</i>
Academic (Private)		
Post-secondary[e]	4,294	173,665
Secondary[f]	51,590	240,620
Professional and Research Institutes[g]	313	182,160
<i>Subtotals</i>	<i>56,197</i>	<i>596,445</i>
Totals	135,511	2,677,304

^[a]Source: County Business Patterns (CBP), 2013. County Business Patterns (CBP). U.S. Census. Available at <http://www.census.gov/econ/cbp/download/> (Accessed June 23, 2015).

The number of Testing Laboratories (ITLs) and workers in those ITLs is assumed to be equal to the number of establishments and the number of employees in NAICS 541380 Testing Laboratories.

^[b]Source: National Science Foundation (NSF), 2014. Business Research and Development and Innovation - 2011. National Center for Science and Engineering Statistics (NCSES). Table 5: Companies with worldwide, domestic, or foreign R&D paid for by the company and others and performed by the company, by source of funds,

industry, and company size: 2011 and Table 31: Worldwide, domestic, and foreign total and R&D employment, by industry and company size: 2011. Available at <http://www.nsf.gov/statistics/2015/nsf15307/pdf/nsf15307.pdf> (Accessed June 26, 2015).

^[c]Source: Bureau of Labor and Statistics (BLS), 2014. Occupational Employment Statistics (OES) - National, May 2014. Available at <http://www.bls.gov/oes/tables.htm> (Accessed June 9, 2015).

The sum of employees in Occupational Codes 29-2011 Medical and Clinical Laboratory Technologists (161,710) and 29-2012 Medical and Clinical Laboratory Technicians (160,460) was used to estimate the number of workers in the hospital-based labs. The percent change in employees from the previous ICR (199,205) to 322,170 (161,710 + 160,460) in 2014 was 61.7 percent which was then applied to the number of hospital labs from the previous ICR (8,782) to obtain 14,200 (8,782 * (1 + 61.7%).

^[d] County Business Patterns (CBP), 2013. County Business Patterns (CBP). U.S. Census. Available at <http://www.census.gov/econ/cbp/download/> (Accessed June 23, 2015).

The number of establishments and employees in NAICS 621511 Medical Laboratories were used to estimate the number of Independent-Medical facilities and the number of workers there respectively.

^[e]Source: National Center For Education Statistics (NCES), 2014. Table 305.30. Number and percentage of degree-granting postsecondary institutions with first-year undergraduates using various selection criteria for admission, by control and level of institution: Selected years, 2000-01 through 2013-14. Digest of Education

Statistics. *Table 305.30. Number and percentage of degree-granting postsecondary institutions with first-year undergraduates using various selection criteria for admission, by control and level of institution: Selected years, 2000-01 through 2013-14.* Available at https://nces.ed.gov/programs/digest/d14/tables/dt14_305.30.asp (Accessed June 26, 2015). Used the number of degree-granting postsecondary institutions (4,294) to estimate the number of facilities in post-secondary labs. That was a 31.9 percent increase from the estimate from the previous ICR (3,256). The 31.9 percent was applied to the previous number of workers in post-secondary labs (131,664) which resulted in 173,665 workers.

^[f]Source: National Center For Education Statistics (NCES), 2014. Table 214.40. Public elementary and secondary school enrollment, number of schools, and other selected characteristics, by locale: 2009-10 through 2012-13. Digest of Education Statistics. Available at https://nces.ed.gov/programs/digest/d14/tables/dt14_214.40.asp (Accessed June 26, 2015). National Center For Education Statistics (NCES), 2013. Table 205.50. Private elementary and secondary enrollment, number of schools, and average tuition, by school level, orientation, and tuition- Selected years, 1999-2000 through 2011-12. Digest of Education Statistics. Available at https://nces.ed.gov/programs/digest/d13/tables/dt13_205.50.asp (Accessed June 23, 2015). According to NCES, 2014, there was a total of 98,454 public elementary and secondary schools. In order to obtain the updated number of secondary schools, the agency multiplied this number by 52.4 percent (which is the percentage of secondary school enrollment as a percent of total school enrollment (NCES, 2013).

^[g]Source: County Business Patterns (CBP), 2011, 2013. County Business Patterns (CBP). U.S. Census. Available at <http://www.census.gov/econ/cbp/download/> (Accessed June 23, 2015). The number of establishments and employees increased by 39.1 percent and 65.6 percent respectively between 2001 (for 1997 NAICS 541710 Research and Development in the Physical, Engineering, and Life Sciences - biotechnology research and development) and 2013 (for 2012 NAICS 541711 Research and Development in Biotechnology and NAICS 541712 Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)). The number from the previous ICR (which was retained since 2001 ICR – 225 establishments and 110,000 workers for Professional and Research Institutes) was adjusted with the 39.1 percent (for facilities) and 65.6 percent (for workers) to estimate updated numbers.

Burden Hour and Cost Determinations

The Agency adopted the mean wage rates for the relevant occupational categories from the May 2014 National Industry-Specific Occupational Employment and Wage Estimates published by the Bureau of Labor Statistics⁶. These wages have been adjusted to reflect the fact that fringe benefits comprise roughly 31.7 percent of total worker compensation for civilian workers⁷. The total hourly compensation costs of labor used in this analysis are:

Administrative Service Manager	\$64.93
Worker	\$33.35
Office Clerk	\$25.01

(A) Worker 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 workers 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 as gloves and goggles, laboratory hoods). Therefore, overexposure of laboratory workers 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: 135,511 facilities x .17 hour = 23,037 hours
Cost: 23,037 hours x \$64.93 = \$1,495,792

⁶ Bureau of Labor and Statistics (BLS), 2014. Occupational Employment Statistics (OES) - National, May 2014. Available at <http://www.bls.gov/oes/tables.htm> or http://www.bls.gov/oes/current/oes_nat.htm (Accessed June 9, 2015).

The agency assumed the wage rates for the labor categories to be the same as these BLS occupation codes (Administrative Service Manager – 10-3011 Administrative Services Managers; Worker – 19-4030 Chemical Technicians; Office Clerk – 43-0000 Office and Administrative Support Occupations).

⁷Bureau of Labor and Statistics (BLS), 2015. Employer Costs for Employee Compensation - March 2015. Available at http://www.bls.gov/news.release/archives/ecec_06102015.pdf or <http://www.bls.gov/news.release/pdf/ecec.pdf> (Accessed June 15, 2015).

Worker 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: 135,511 facilities x .08 hour = 10,841 hours

Cost: 10,841 hours x \$25.01 = \$271,133

(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.⁸ The Agency estimates that the number of laboratory facilities increased by 5,314 annually during the past three years (64,404 existing CHPs – 48,461 CHPs = 15,943/3 = 5,314, 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: [(5,314 new CHPs x 8 hours) = 42,512] + [(135,511 existing CHPs x .5 = 67,756 hours)] = 110,268 hours

Cost: 110,268 hours x \$64.93 = \$7,159,701

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

Upon further analysis, the requirements that employers provide training to workers under paragraphs (f)(1) through (f)(4), are not considered to be collections of information. OSHA is not taking burden for these activities under Item 12 of this Supporting Statement.

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

General (§1910.1450(g)(1) and (g)(2))

OSHA believes that 8% (214,184) of the workers covered by the Standard receive medical attention. Of these workers, the Agency assumes that: half (107,092) obtain a medical consultation, which OSHA estimates takes 45 minutes (.75 hour) to administer;⁹ one-fourth (53,546) 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

⁸ This paragraph also specifies that employers must, as appropriate, establish designated areas to provide workers with additional protection. This provision does not require employers to establish records or maintain information, therefore the Agency is not taking any burden to perform these functions. This provision does not require employers to establish records or maintain information.

⁹Estimates of administration time include 30 minutes of travel time.

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: [(107,092 workers x .75 hour) = 80,319] + [(53,546 workers x 1.5
= 80,319 hours)] + [(53,546 workers x 2.25 hours)] = 120,479
hours

Cost: 120,479hours x \$33.35 = \$4017,975

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: 214,184 x .08 hour = 17,135 hours

Cost: 17,135 hours x \$25.01 = \$428,546

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 214,184 written opinions annually), and that an office clerk takes five minutes (.08 hour) to distribute the written opinion to a worker.¹⁰ Thus, the estimated burden hours and cost of this requirement each year are:

Burden hours: 214,184 written opinions x .08 hour = 17,135 hours

Cost: 17,135 hours x \$25.01 = \$428,546

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

OSHA's Hazard Communication (HC) Standard (§1910.1200) applies to the requirements regarding labels and Safety Data Sheets specified by this provision of the Standard.¹¹ 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))

¹⁰The five minutes does not include the annual burden for maintaining a record of each written opinion as required by paragraph (j) of the Standard.

¹¹Paragraph (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.

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 135,511 records.¹² In addition, the determinations made above in section (D) ("Medical Consultation and Medical Examinations") show that employers administer 214,184 medical consultations and medical examinations annually, developing 214,184 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:

$$\begin{aligned} \text{Burden hours: } & [(135,511 \text{ exposure monitoring records}) + (214,184 \text{ medical} \\ & \text{records})] \times .08 \text{ hour} = 27,976 \text{ hours} \\ \text{Cost: } & 27,976 \text{ hours} \times \$25.01 = \$699,680 \end{aligned}$$

Worker access

For this determination, OSHA estimates that the exposure monitoring requirements of the Standard cover all workers (2,677,304) in laboratory facilities, while 214,184 of these workers have medical records (see previous determinations in this section). Additionally, the Agency assumes that 10% (289,149 of the workers covered by these records request access to them each year (2,677,305 workers + 214,184 workers) \times 10% = 289,149 workers).¹³ 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:

$$\begin{aligned} \text{Burden hours: } & 289,149 \text{ workers} \times .08 \text{ hours} = 23,132 \text{ hours} \\ \text{Cost: } & 23,132 \text{ hours} \times \$25.01 = \$578,531 \end{aligned}$$

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**

¹² OSHA assumes that the record is the list of exposure-monitoring results used for posting.

¹³ The Agency believes that employers receive minimal requests for exposure monitoring and medical records from former workers, workers' legal representatives, individuals and organizations to whom workers give written authorization to exercise a right of access, and designated worker representatives; therefore, it did not include these requests in this determination.

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 workers with exposure monitoring, medical consultations, and medical examinations is \$72,499,536. The following sections describe the cost determinations.

(A) Exposure monitoring

The Agency estimates that employers pay \$64¹⁴ to analyze an exposure monitoring sample. According to the information provided above in section (A) (“Exposure Monitoring”) under Item 12, employers collect 135,511 exposure monitoring samples each year. Thus, the annual cost associated with obtaining exposure monitoring samples is:

$$\text{Cost: } 135,511 \text{ samples} \times \$64 = \$8,672,704$$

(B) Medical consultation and medical examinations

OSHA identified the following costs for providing medical attention to workers: Medical consultation (med consult), \$158; medical examination (med exam), \$359; and a combined medical consultation and med examination (med consult-med exam), \$517.¹⁵ In addition, the

¹⁴ The Consumer Price Index (CPI) indicated a 6.7% increase in the price of professional medical services from December 2011 to 2014. The previous ICR estimated that the cost for exposure monitoring sample analysis was \$60; given the 6.7% increase in the price of professional medical services, it was assumed that the cost of exposure monitoring increased by 6.7% as well. Source: *CPI Detailed Report - February 2014* (<http://www.bls.gov/cpi/cpid1402.pdf>.)

¹⁵ The previous ICR assumed that each medical consultation cost \$148, each medical examination \$336, and each combined medical consultation and medical examination \$484. The Consumer Price Index (CPI) indicated a 6.7% increase in the

determinations made above in section (D) (“Medical consultation and medical examinations”) show that each year employers administer 107,092 med consults, 53,546 med exams, and 53,546 med consults-med exams to workers. Accordingly, the yearly cost of providing medical attention to workers is:

$$\text{Cost: } [(107,092 \text{ med consults} \times \$158 = \$16,920,536) + [(53,546 \text{ med exams} \times \$359 = \$19,223,014) + [(53,546 \text{ (med consults-med exams)} \times \$517 = \$27,683,282)] = \$63,826,832$$

- 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.**

There is no cost to the Federal Government associated with this information collection request.

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

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 **293,373** to **350,003** hours, a total adjustment of **56,630** hours.

Additionally, the capital cost estimate has increased from **\$41,267,950** to **\$72,499,536** a total increase of **\$31,231,586**. This increase is a result of an increase in the number of workers requiring medical consultations, medical exams, and medical consultations and medical examinations.

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.

- 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.**

price of professional medical services from December 2011 to 2014; the cost of a medical consultation or examination was assumed to have increased by 6.7% as well.

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

18. Explain each exception to the certification statement.

OSHA is not requesting an exception to the certification statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

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

Table 2¹⁶

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Adjustment	Estimated Cost (\$) Item 12	Responses	Explanation of Adjustment
A. Worker exposure determination (§1910.1450(d))						
Initial monitoring and periodic monitoring	8,238	23,037	14,799	\$1,495,792	135,511	There was an increase in the number of facilities being monitored from 64,404 to 135,511.
Worker notification of monitoring results	3,877	10,841	6,964	\$271,133	135,511	There was an increase in the number of facilities being monitored from 64,404 to 135,511.
B. Chemical hygiene plan (§1910.1450(e))	31,815	110,268	78,453	\$7,159,701	140,825	There was an increase in the number of facilities being monitored from 64,404 to 135,511.
C. Worker information and training (§1910.1450(f))	0	0	0	\$0	0	Upon further analysis, the requirements that employers provide training to workers under paragraphs (f)(1) through (f)(4) are not considered to be collections of information. OSHA is no longer taking burden for these activities.
D. Medical consultation and medical examinations (§1910.1450(g))						
General	180,474	120,479	59,995	\$9,375,252	214,184	There was an increase in the number of workers covered by the Standard from 1,780,807 to 2,677,304.
Information provided to the physician	11,000	17,135	6,135	\$428,546	214,184	There was an increase in the number of workers covered by the Standard from 1,780,807 to 2,677,304 which increased the number of workers providing information to the physician from 142,465 to 214,184.
Physician's written opinion	11,000	17,135	6,135	\$428,546	214,184	There was an increase in the number of

16 The increase in the number of facilities and workers is based upon using updated data from previous sources and newly identified data sources as referenced in *Table 1. Number of Laboratory Facilities and Workers for Each Type of Laboratory*. To illustrate, for labs in Professional and Research Institutes, OSHA previously relied on a 2001 ICR for a total of 225 labs. In this submission, OSHA used the County Business Patterns (CBP), 2011, 2013 that resulted in an increase of 88 labs for a total 313 labs. Previously, OSHA did not identify any new resources to update the 13,000 Research and Development Labs. In this submission, using the National Science Foundation (NSF), 2014. Business Research and Development and Innovation - 2011. National Center for Science and Engineering Statistics (NCSES) data, the Agency updated the number of labs in Research and development as 51,736 labs.

OCCUAPTIONAL EXPOSURE TO HAZARDOUS
 CHEMICALS IN LABORATORIES
 1218-0131
 September 2015

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Adjustment	Estimated Cost (\$) Item 12	Responses	Explanation of Adjustment
						workers covered by the Standard from 1,780,807 to 2,677,304 which increased the number of written opinions from 142,465 to 214,184.
E. Hazard identification (§1910.1450(h))	0	0	0	\$0	0	
F. Use of respirators (§1910.1450(i))	0	0	0	\$0	0	
G. Recordkeeping (§1910.1450(j))						
General	14,877	27,976	13,099	\$699,680	349,695	There was an increase in the number of facilities being monitored from 64,404 to 135,511 and an increase in the number of workers covered by the standard from 1,780,807 to 2,677,304.
Access to records	14,904	23,132	8,228	\$578,531	289,149	There was an increase in the number of facilities being monitored from 64,404 to 135,511 and an increase in the number of workers covered by the standard from 1,780,807 to 2,677,304.
Totals	293,373	350,003	56,630	\$20,437,181	1,693,243	