

**SUPPORTING STATEMENT FOR THE  
INFORMATION COLLECTION REQUIREMENTS IN THE  
LEAD IN GENERAL INDUSTRY STANDARD (29 CFR 1910.1025)<sup>1</sup>  
OFFICE OF MANAGEMENT AND BUDGET  
(OMB) CONTROL NO. 1218-0092 (February 2016)**

**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 objective of the Occupational Safety and Health Act (OSH 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 regulations" (29 U.S.C. 651).

To protect worker health, the OSH Act authorizes the Occupational Safety and Health Administration (OSHA) to develop standards that provide for "monitoring or measuring employee exposure" to occupational hazards and "prescribe the type and frequency of medical examinations and other tests which shall be made available [by the employer] to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure" (29 U.S.C. 655). In addition, the OSH Act mandates that "[e]ach employer shall make, keep and preserve, and make available to the Secretary [of Labor] . . . such records regarding [his/her] activities relating to this Act as the Secretary . . . may prescribe by regulation as necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses" (29 U.S.C. 657). In addition, the OSH Act directs OSHA to "issue regulations requiring employers to maintain accurate records of employee exposure to potentially toxic materials or other harmful physical agents which are required to be monitored and measured," and further specifies that such regulations provide "for each employee or former employee to have access to such records as will indicate [their] own exposure to toxic materials or harmful physical agents" (29 U.S.C. 657). The OSH Act states further that "[t]he Secretary . . . shall . . . prescribe such rules and regulations as [he/she] may deem necessary to carry out [his/her]

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<sup>1</sup>The purpose of this supporting statement is to analyze and describe the burden hours and costs associated with provisions of the Lead in General Industry 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.

responsibilities under this Act, including rules and regulations dealing with the inspection of an employer's establishment" (29 U.S.C. 651).

Pursuant to its statutory authority, OSHA promulgated a health standard governing worker exposure to lead for general industry (29 CFR 1910.1025). The standard applies to all operations where exposure to lead may occur, except the construction and agricultural sectors. The purpose of this regulation is to provide protection for workers from the health effects associated with occupational exposure to lead. In general, the standard requires employers to monitor worker exposure to lead, to take action to reduce worker exposure to the permissible exposure limit (PEL), to monitor worker health, to train workers about lead hazards, and to provide workers with information about their exposures and the health effects of lead. The specific information collection activities necessary to fulfill the above requirements are described in items 2 and 12.

**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.**

### **Exposure Monitoring (§1910.1025(d))**

The exposure monitoring and worker notification requirements of this standard protect the health and safety of workers who work with lead by providing both the employer and the worker with information regarding exposures to this toxic substance.

#### Exposure Measurement (§1910.1025(d)(1)-(7))

Employers covered by the standard must determine if any worker may be exposed to lead at or above the action level ("AL")<sup>2</sup>. Employers must monitor worker exposures and base initial determinations on the worker exposure monitoring results and any of the following relevant considerations: (A) any information, observations, or calculations which would indicate worker exposure to lead; (B) any previous measurements of airborne lead; and (C) any worker complaints of symptoms which may be attributable to exposure to lead. Employers may use representative sampling.

If the employer makes an initial determination that no worker is exposed to lead at or above the action level, the employer must make a written record of the determination. The records must include information specified in paragraph (d)(3), and include the date of determination, location within the worksite, and the name and social security number of each worker monitored.

The standard requires worker monitoring at least every 6 months when 8-hour time-weighted (TWA) average exposures are at or above the action level but below the permissible exposure limit (PEL) of 50 micrograms per cubic meter of air (50 ug/m<sup>3</sup>). When worker exposures are in excess of the PEL, monitoring must be performed quarterly. When worker exposures are reduced to below the action level, monitoring may be discontinued. In the event of a production,

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<sup>2</sup>Action level means worker exposure, without regard to the use of respirators, to an airborne concentration of lead of 30 micrograms per cubic meter of air (30ug/m<sup>3</sup>) averaged over an 8-hour period.

process, control, or personnel change which may result in new or additional exposures to lead, or whenever the employer has another reason to suspect a change that may result in new or additional exposures to lead, additional monitoring in accordance with the standard must be conducted by the employer.

### **Employee Notification of Monitoring Results (§1910.1025(d)(8))**

After employers conduct exposure monitoring for lead, they must 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. In addition, if the exposure monitoring results show that a worker's exposure exceeds the PEL, the employer must inform the exposed worker of the corrective action the employer is taking to prevent such overexposure, and the schedule for completion of this action. Notification provides workers with information about the efforts the employer is taking to lower their lead exposures and to furnish them with a safe and healthful workplace in accordance with section 8(c)(3) of the Act.

### **Compliance Program (§1910.1025(e)(3))**

#### Written Compliance Program (§1910.1025(e)(3)(i)-(iv))

The standard requires that employers establish and implement a written compliance program to reduce worker exposures to or below the PEL solely by means of engineering and work practice controls. These written plans must be revised and updated annually to reflect the current status of the program.

The compliance plans must include at least the following information: (1) a description of each operation in which lead is emitted, e.g., machinery used, material processed, controls in place, crew size, worker job responsibilities, operating procedures, and maintenance practices; (2) a description of the specific means that will be employed to achieve compliance with the lead standard, including engineering plans and studies used to determine methods selected for controlling exposure to lead; (3) a report of the technology considered in meeting the PEL; (4) air monitoring data that document the source of lead emissions; (5) a detailed schedule for implementation of the program, including documentation such as copies of purchase orders for equipment, construction contracts, etc.; (6) a work practice program that includes items required under paragraphs (g) "Protective Work Clothing and Equipment", (h) "Housekeeping", and (i) "Hygiene facilities and practices" of this regulation; (7) an administrative control schedule, if applicable; and (8) other relevant information.

Written compliance plans must be submitted upon request to OSHA and to the National Institute for Occupational Safety and Health (NIOSH), and must be available at the worksite for

examination and copying by representatives of these government officials, workers, and authorized worker representatives.

The purpose of requiring an employer to establish a written compliance program is to effectively promote required compliance with the standard's Permissible Exposure Limits. The written program requirement commits the employer to evaluating worker exposure and setting down an organized and complete plan of reducing worker exposure to the permissible exposure limits. The plan also provides workers, and their designated representatives, a resource to ensure that all appropriate protective steps will be taken to protect them from hazardous exposure.

#### Administrative Controls (§1910.1025(e)(5)(i)-(iii))

If administrative controls are used as a means of reducing workers' TWA exposure to lead, the employer must establish and implement a job rotation schedule that includes the following information: (1) name or identification number of each affected worker; (2) duration and exposure levels at each job or work station where each affected worker is located; and (3) any other information that may be useful in assessing the reliability of administrative controls to reduce exposure to lead.

#### **Respirator Program (§1910.1025(f)(2))**

Where the use of respiratory protective equipment is required or permitted under the provisions of the lead standard, the employer must institute a respirator program in accordance with 29 CFR 1910.134(b) through (d) (except (d)(1)(iii)), and (f) through (m). 29 CFR 1910.134 (b) and (e) require that written standard operating procedures governing the selection and use of respirators be established. The purpose of these requirements is to ensure that employers establish a standardized procedure for selecting, using, and maintaining respirators for each workplace where respirators will be used. Developing written procedures requires employers to think through just how all of their requirements of the respiratory standard will be met in their workplace.

#### **Notifying the Laundry (§1910.1025(g)(2)(vi))**

The standard requires employers to inform, in writing, any person who launders or cleans protective clothing or equipment of the potentially harmful effects of exposure to lead. By providing this information to the person doing the laundry, they are informed of the presence and potentially harmful effects of lead.

#### **Labeling of Contaminated Protective Clothing and Equipment (§1910.1025(g)(2)(vii))**

**1910.1025(g)(2)(vii)(A):** Employers must ensure that labels of bags or containers of contaminated protective clothing and equipment required by paragraph (g)(2)(v). As required by paragraph (g)(2)(vii)(A), the labels must state: "DANGER: CLOTHING AND EQUIPMENT CONTAMINATED WITH LEAD. MAY DAMAGE FERTILITY OR THE UNBORN CHILD."

CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM. DO NOT EAT, DRINK OR SMOKE WHEN HANDLING. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.”

**1910.1025(g)(2)(vii)(B):** Prior to June 1, 2015, employers may include the following information on bags or containers of contaminated protective clothing and equipment in lieu of the labeling requirements in paragraphs (g)(2)(vii)(A): CAUTION: CLOTHING CONTAMINATED WITH LEAD. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.

Warning labels inform downstream workers and employers of the hazards associated with lead, and that they may need to implement special practices to prevent or reduce lead exposure. Furthermore, the labels alert downstream employers that they may have an obligation to protect their workers under the Standard.

**1910.1025(g)(2)(viii):** The employer shall prohibit the removal of lead from protective clothing or equipment by blowing, shaking, or any other means which disperses lead into the air.

### **Medical Surveillance (§§1910.1025(j) and (j)(1)(i))**

The standard requires that the employer institute a medical surveillance program for all workers who are or may be exposed to lead at or above the action level (30 ug/m<sup>3</sup>) for more than 30 days per year. The employer must institute a medical surveillance program for all employees who are or may be exposed at or above the action level for more than 30 days per year.

#### Biological Monitoring (§§1910.1025(j)(2)(i), (ii), (iv))

##### (1) Initial Blood Lead and ZPP Level Sampling and Analysis (§1910.1025(j)(2)(i))

The employer must make available at least every 6 months biological monitoring in the form of blood sampling and analysis for lead and zinc protoporphyrin (ZPP) levels to each worker who is or may be exposed to lead at or above the action level (30 ug/m<sup>3</sup>) for more than 30 days per year.

At least every 2 months, such lead and ZPP monitoring must be made available to each worker whose last blood sampling and ZPP analysis indicates a blood lead level at or above 40 micrograms lead per 100 grams of whole blood (40 ug/100 g). This frequency of sampling must continue until two consecutive blood samples and ZPP analyses indicate a blood lead level below 40 ug/100 g. Lead and ZPP monitoring must be conducted at least monthly during the removal period for each worker removed from exposure to lead due to an elevated blood lead level.

(2) Follow-up Blood Sampling Tests (§1910.1025(j)(2)(ii))

Whenever the results of a blood lead level test indicate that a worker's blood lead level at or above the numerical criterion for medical removal under paragraph (k)(1)(i)(A), the employer must provide a second (follow-up) blood sampling test within 2 weeks after the employer receives the results of the first blood sampling test.

(3) Employee Notification of Biological Monitoring Results (§1910.1025(j)(2)(iv))

Within 5 working days after the receipt of biological monitoring results, the employer must notify in writing each worker whose blood lead level is at or above 40 ug/100 g. The employer must inform the affected worker of that worker's blood lead level, and of the fact that the standard requires temporary medical removal with Medical Removal Protection benefits when a worker's blood lead level meets or exceeds the numerical criterion for medical removal.

Medical Examinations and Consultations (§1910.1025(j)(3))

The employer must provide medical examinations and consultations to each worker who is or may be exposed to lead at or above the action level (30 ug/m<sup>3</sup>) for more than 30 days per year. Such medical examinations and consultations must be provided in accordance with the following schedule: (1) at least annually for each worker for whom blood sampling tests, conducted at any time during the preceding 12 months, indicated a blood lead level at or above 40 ug/100 g; (2) prior to assigning the worker, for the first time, to an area in which airborne concentrations of lead are at or above the action level; (3) as soon as possible upon notification, by a worker, either that the worker has developed signs or symptoms associated with lead intoxication, that the worker desires medical advice concerning the effects of current or past exposure to lead on the worker's ability to produce a healthy child, or that the worker has demonstrated difficulty in breathing during a respirator fit test or during respirator use; and (4) as medically appropriate for each worker who is either removed from exposure to lead due to a risk of sustaining material impairment to health or is otherwise limited pursuant to a final medical determination.

Medical examinations conducted pursuant to the standard must include the following elements:

- (1) A detailed work history and a medical history, with particular attention to past lead exposure, personal habits (smoking and hygiene), and past gastrointestinal, hematologic, renal, cardiovascular, reproductive, and neurological problems.
- (2) A thorough physical examination, with particular attention to teeth, gums, and hematologic, gastrointestinal, renal, cardiovascular, and neurological systems. Pulmonary status should be evaluated if respirators will be used.
- (3) A blood pressure measurement.
- (4) A blood sample and analysis which determines blood lead level; hemoglobin and

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hematocrit determinations, red cell indices, and examination of peripheral smear morphology; zinc protoporphyrin; blood urea nitrogen; and serum creatinine.

- (5) A routine urinalysis with microscopic examination.
- (6) Any laboratory or other test that the examining physician deems necessary by sound medical practice.
- (7) If requested by a worker, the medical examination shall include pregnancy testing or laboratory evaluation of male fertility.

(1) Multiple Physician Review Mechanism (§1910.1025(j)(3)(iii))

Under the standard's multiple physician review provisions, if the employer selects the initial physician who conducts any medical examination or consultation provided to a worker, the worker may designate a second physician: (a) to review any findings, determinations, or recommendations of the initial physician; and (b) to conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review.

The employer must promptly notify a worker of the right to seek a second medical opinion after each occasion on which an initial physician conducts a medical examination or consultation.

Information Provided to Examining and Consulting Physicians (§1910.1025(j)(3)(iv))

The lead standard requires that the employer provide the following information to the initial physician conducting a medical examination or consultation: (a) a copy of the lead standard, including all appendices; (b) a description of the affected worker's duties as they relate to the worker's exposure; (c) the worker's exposure level or anticipated exposure level to lead and to any other toxic substance (if applicable); (d) a description of any personal protective equipment used or to be used; (e) prior blood lead determinations; and (f) all prior written medical opinions concerning the worker in the employer's possession or control.

The standard further requires that the employer must also provide the aforementioned information to the second and third physician conducting a medical examination or consultation in accordance with the standard's multiple physician review provisions, upon request of the second or third physician or the worker.

Written Medical Opinions (§1910.1025(j)(3)(v))

(§ 1910.1025(j)(3)(v)(A)(1) – (A)(4)): From each examining or consulting physician, the employer must obtain and furnish to the worker a copy of a written medical opinion that contains the following information: (a) the physician's opinion as to whether the worker has any detected medical condition that would place the worker at increased risk of material impairment of health from exposure to lead; (b) any recommended special protective measures to be provided to the

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worker, or limitations to be placed upon the worker's exposure to lead; (c) any recommended limitation upon the worker's use of respirators, including a determination of whether the worker can wear a powered air-purifying respirator if a physician determines that the worker cannot wear a negative-pressure respirator; and (d) the results of the blood lead determinations.

### Instructing Examining and Consulting Physician (§1910.1025(j)(3)(v)(B))

The employer must instruct each examining and consulting physician to: not reveal either in the written opinion, or in any other means of communication with the employer, findings, including laboratory results or diagnoses unrelated to a worker's occupational exposure to lead; and to advise the worker of any medical condition, occupational or nonoccupational, which dictates further medical examination or treatment.

### Chelation (§1910.1025(j)(4)(ii))

If therapeutic or diagnostic chelation is to be performed on any person whom the employer retains, employs, supervises, or controls, the employer must ensure that it is performed under the supervision of a licensed physician, in a clinical setting, with thorough and appropriate medical monitoring, and that the worker is notified, in writing, prior to its performance.

### Employees Whose Blood Lead Levels Do Not Adequately Decline Within 18 Months of Removal. (§1910.1025 (k)(2)(vi))

The standard requires the employer to take the following measures with respect to any employee removed from exposure to lead due to an elevated blood lead level whose blood lead level has not declined within the past eighteen (18) months of removal so that the employee has been returned to his or her former job status:

(A) The employer shall make available to the employee a medical examination pursuant to this section to obtain a final medical determination with respect to the employee;

(B) The employer shall assure that the final medical determination obtained indicates whether or not the employee may be returned to his or her former job status, and if not, what steps should be taken to protect the employee's health; . . .

(D) Where the employer acts pursuant to a final medical determination which permits the return of the employee to his or her former job status despite what would otherwise be an unacceptable blood lead level, later questions concerning removing the employee again shall be decided by a final medical determination. The employer need not automatically remove such an employee pursuant to the blood lead level removal criteria provided by this section.

## **Employee Information and Training (§1910.1025(l))**

### Training Program (§1910.1025(l)(1))



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The standard requires each employer who has a workplace in which there is potential exposure to airborne lead to inform workers of the contents of Appendices A and B of the lead standard. The employer shall train each worker and ensure the participation of all workers who are subject to lead exposure at or above the action level or for whom the possibility of skin or eye irritation exists. Training must be provided prior to initial job assignment and must be repeated at least annually thereafter for all covered workers.

The employer is responsible for informing workers of the following: (1) the content of the lead standard and its appendices; (2) the specific nature of the operations that could result in exposure to lead above the action level; (3) the purpose, proper selection, fitting, use and limitations of respirators; (4) the purpose and a description of the medical surveillance program and the medical removal protection program, including information concerning the adverse health effects associated with excessive exposure to lead (with particular attention to the adverse reproductive effects on both males and females); (5) the engineering controls and work practices associated with the worker's job assignment; (6) the contents of any compliance plan in effect; and (7) instructions to workers that chelating agents should not be used routinely to remove lead from their bodies, and should not be used at all except under the direction of a licensed physician.

Upon further analysis, the requirement that employers provide training to workers under (l)(1) is not considered to be a collection of information.

### Access to Information and Training Materials (§1910.1025(l)(2))

As required by (l)(2)(i) and (l)(2)(iii), the employer must make readily available to all affected workers a copy of the standard and its appendices and distribute to employees training and information materials which are made available to the employer by OSHA. These requirements are not collections of information, because they are public disclosures of information originally provided by the Federal government to the recipient for the purpose of disclosure to the public. Therefore, these requirements do not fall within the definition of a collection of information under 5 CFR 1320.3(c)(2).

As directed by the standard under (l)(2)(ii), the employer must provide to OSHA and NIOSH, upon request, all materials relating to the worker information and training program.

### **Communication of Hazards (§1910.1025(m)(1))**

(m) *Communication of hazards*—(1) *Hazard communication—general*. (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§1910.1200) for lead. (ii) In classifying the hazards of lead at least the following hazards are to be addressed: Reproductive/developmental toxicity; central nervous system effects; kidney effects; blood effects; and acute toxicity effects. (iii) Employers shall include lead in the hazard communication program established to comply with the HCS (§1910.1200). Employers shall ensure that each employee has access to labels on

containers of lead and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (l).<sup>3</sup>

**Signs (§1910.1025(m)(2))**

(m)(2) *Signs.* (i) The employer shall post the following warning signs in each work area where the PEL is exceeded:

DANGER

LEAD

MAY DAMAGE FERTILITY OR THE UNBORN CHILD

CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM

DO NOT EAT, DRINK OR SMOKE IN THIS AREA

(v) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (m)(2)(ii):

WARNING

LEAD WORK AREA

POISON

NO SMOKING OR EATING

Posting warning signs serve to warn workers, who may otherwise not know, that they are entering a hazardous area. Warning signs also supplement the training which workers receive under this standard.

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<sup>3</sup> The Agency accounts for the burden hours and costs associated with compliance with the HCS, such as the development of a hazard communication program, under the Information Collection Request (ICR) for the HCS. OMB Control No. 1218-0072.

## **Recordkeeping (§1910.1025(n))**

### Exposure Monitoring Records (§1910.1025(n)(1))

The standard requires that the employer establish and maintain an accurate record of all monitoring required by the standard. The exposure monitoring records must include the following information: (1) the date(s), number, duration, location, and results of each of the samples taken, including a description of the sampling procedure used to determine representative worker exposure where applicable; (2) a description of the sampling and analytical methods used and evidence of their accuracy; (3) the type of respiratory protective devices worn, if any; name, social security number, and job classification of the worker monitored and of all other workers whose exposure the measurement is intended to represent; and (4) the environmental variables that could affect the measurement of worker exposure.

In accordance with the standard, the employer must maintain these exposure monitoring records for at least 40 years or for the duration of employment plus 20 years, whichever is longer.

### Medical Surveillance Records (§1910.1025(n)(2))

The standard requires that the employer establish and maintain an accurate record for each worker subject to medical surveillance as required by this standard. Medical surveillance records must include the following information: (1) the name, social security number, and description of the duties of the worker; (2) a copy of the physician's written opinions; (3) results of any airborne exposure monitoring done for that worker and the representative exposure levels supplied to the physician; and (4) any worker medical complaints related to exposure to lead.

As directed by the standard, the employer must keep, or ensure that the examining physician keeps, the following medical records: (1) a copy of the medical examination results, including required medical and work histories; (2) a description of the laboratory procedures and a copy of any standards or guidelines used to interpret the test results or references to that information; and (3) a copy of the results of the biological monitoring.

The employer must maintain or ensure that the physician maintains these medical surveillance records for at least 40 years, or for the duration of employment plus 20 years, whichever is longer.

### Medical Removal Records (§1910.1025(n)(3))

The lead standard requires that the employer establish and maintain an accurate record for each worker removed from current exposure to lead. Each medical removal record must include the following information: (1) the name and social security number of the worker; (2) the date of each occasion on which the worker was removed from current exposure to lead as well as the corresponding date on which the worker was returned to his or her former job status; (3) a brief explanation of how each removal was or is being accomplished; and (4) a statement with respect

to each removal, indicating whether or not the reason for the removal was an elevated blood lead level.

In accordance with the standard, the employer must maintain each medical removal record for at least the duration of a worker's employment.

#### Records Access (§1910.1025(n)(4))

As directed by the standard, the employer must make all records required to be maintained available, upon request, to the Assistant Secretary and the Director for examination and copying. Usually, OSHA requests access to records during a compliance inspection. Information collected by the Agency during the investigation is not subject to the PRA under 5 CFR 1320.4(a)(2). Therefore, OSHA takes no burden or cost in Items 12 and 14 of this Supporting Statement.

In addition, the employer must make environmental monitoring, medical removal, and medical surveillance records available, upon request, for examination and copying to workers, their designated representatives, and the Assistant Secretary, in accordance with OSHA's Access to Employee Exposure and Medical Records Standard (29 CFR 1910.1020).

#### Records Transfer (§ 910.1025(n)(5)(i) and (ii))

Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by paragraph (n) of this standard. The employer must comply with requirements involving the transfer of records set forth in 29 CFR 1910.1020(h).

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 workers who have records of their right to access these records.

OSHA considers the employer's transfer of records to a successor employer 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 Employee 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 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 burdens.**

Employers may use improved information technology when establishing and maintaining exposure-monitoring and medical-surveillance records. OSHA wrote the paperwork requirements of the standard in performance-oriented language (i.e., in terms of what data to maintain, not how to maintain the data).

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

The information required to be collected and maintained is specific to each employer and worker involved and is not available or duplicated by another source. The information required by this standard is available only from employers. At this time, there is no indication that any alternate source is available.

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

The information collection requirements of the Standard do not have a significant impact on a substantial number of small entities.

**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.**

OSHA's recordkeeping requirements are designed to ensure that employers are complying with applicable standards and that protection of workers exposed to lead is provided to the full extent required. Occupational safety and health compliance officers examine the records for this purpose when conducting inspections. Additionally, the data contained in exposure measurement records are useful to employers in pinpointing areas of their operations that may require additional efforts to reduce exposure.

Records of previous medical examinations are used by physicians who must periodically examine workers exposed to lead. Without records of previous medical examinations, the physician may not be able to determine whether a worker has suffered an adverse health effect since his or her last examination. Further, when symptoms of organic damage appear, the physician often needs information as to the patient's previous medical condition to make an accurate diagnosis of the new problem, its apparent cause, and the course of treatment required.

The information collection frequencies specified by this standard are the minimum OSHA believes necessary to ensure that the employer and OSHA can effectively monitor the exposure and health status of workers working with or exposed to lead.

**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)(8)) requires employers to notify workers of their exposure monitoring results, individually, in writing or by posting, within 15 working days after the employer's receipt of the results. Also paragraph (j)(2)(iv) requires employers to notify workers of their biological monitoring results within five working days after the employers' receipt of the results.

In addition, under OSHA's Access to Employee Exposure and Medical Records Standard (§1910.1020), employers must maintain the exposure monitoring results for 30 years.

**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, 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 specific situations. These circumstances should be explained.**

As required by the Paperwork Reduction Act (44 U.S.C. 3506(c)(2)(A)), OSHA published a notice in the Federal Register on September 25, 2015 (80 FR 57878, Docket No. OSHA-2012-0013) requesting public comment on its proposed extension of the collections of information

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contained in the Lead in General Industry Standard at 29 CFR 1910.1025. This notice was 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 collections of information found in the above Standard. The Agency received no public comments in response to this notice.

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

No payments or gifts will be provided to the respondents.

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

Since employee medical records contain information that may be considered private, OSHA has taken steps to ensure that the data are kept private to the extent allowed by law. Rules of Agency practice and procedure governing OSHA access to worker medical records are contained in 29 CFR 1913.10. The legal authority for these procedural regulations is found in sections 8(c)(1) and 8(g)(2) of the Occupational Safety and Health, 29 U.S.C. 657; in section (e) of the Privacy Act, 5 U.S.C. 552a(e); in 29 CFR Part 70a; and in 5 U.S.C. 301.

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

There are no provisions in this standard requiring that questions of a sensitive nature be asked; therefore, this question is not applicable to this clearance request.

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

## **BURDEN HOUR AND COST DETERMINATIONS**

Estimates of the number of establishments and exposed workers covered by the Standard have been revised to reflect the most recent available data. Table A contains updated figures from the U.S. Census Bureau, the Bureau of Labor Statistics and other sources cited below

### **Wage Rates**

The following hourly wage rates for the relevant occupational categories have been derived from the May 2014 National Industry-Specific Occupational Employment and Wage Estimates published by the Bureau of Labor Statistics<sup>4</sup>. These wages have been adjusted to reflect the fact that fringe benefits comprise roughly 31.7 percent of total worker compensation for civilian workers<sup>5</sup>. The costs of labor used in this analysis are therefore estimates of total hourly compensation. These hourly wages are:

- Worker \$35.51
- Clerical/Secretary \$25.01
- Professional/Manager \$59.72

### **Exposure Monitoring (§1910.1025 (d))**

The cost of exposure monitoring is based on the cost per sample and the number of samples that must be taken. Also, employers would have in-house industrial hygiene technicians take the samples and send them to a lab to be analyzed.

#### Initial Exposure Measurement

Employers must determine if any workers are exposed to lead at or above the action level. As evidenced in Table A, we have identified no new secondary smelter facilities since the last ICR was prepared; therefore, there are 0 burden hours and costs are estimated for initial monitoring

#### Periodic Exposure Measurement

Based on the initial monitoring results, periodic monitoring is required every six months if workers are exposed at or above the action level but below the PEL, and quarterly if workers are exposed to lead above the PEL. For purposes of estimating burden hours and costs in this Information Collection Request (ICR), no employers are exposing their workers to lead levels above the PEL, and therefore, there are no burden hours and costs for quarterly monitoring.

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<sup>4</sup> May 2014 National Occupational Employment and Wage Estimates United States. Available at <http://www.bls.gov/oes/tables.htm> or [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)

<sup>5</sup> Employer Costs for Employee Compensation – March 2015. Available at [http://www.bls.gov/news.release/archives/ecec\\_06102015.pdf](http://www.bls.gov/news.release/archives/ecec_06102015.pdf) or <http://www.bls.gov/news.release/pdf/ecec.pdf>



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OSHA estimates 331,304 workers may be exposed to lead at levels between the action level and the PEL, requiring employers to conduct periodic monitoring at six-month intervals.

Approximately one in four workers is actually sampled. One technician takes eight samples per day, thus OSHA assumes it takes one hour of a technician's time to sample and document results. Hours involved in periodic exposure monitoring are estimated as follows:

**Burden hours:**  $(331,304 \div 4) \times 1 \text{ hour} \times 2 \text{ samples/year} = 165,652 \text{ hours}$   
**Costs:**  $165,652 \text{ hours} \times \$35.51 = \$5,882,303$

Periodic monitoring is also required whenever there is a production, process, control, or personnel change that may result in new or additional exposures to lead. OSHA has not included any burden estimate for such additional monitoring since it is likely that the estimates given for periodic monitoring above are too high because they do not take into consideration whether employers have reduced some worker exposures to below the action level since 1978, so that they could discontinue periodic monitoring. The hours estimated above represent total periodic and additional monitoring burdens.

### Employee Notification of Monitoring Results

The standard requires that employers notify workers of monitoring results, individually in writing or by posting the results, within 15 working days of the employer's receipt of the results. A clerk takes 5 minutes (.08 hour) to notify workers of their exposure-monitoring results. OSHA assumes 53,935 existing employers conduct periodic semiannual monitoring, taking 5 minutes (.08 hour) to post the results.

**Burden hours:**  $(53,935 \text{ employers}) \times 2 \text{ (semiannual)} \times .08 \text{ hour} = 8,630 \text{ hours}$   
**Costs:**  $8,630 \text{ hours} \times \$25.01 = \$215,836$

### **Written Compliance Program (§1910.1025 (e))**

The standard requires that each employer establish and implement a written compliance program to reduce worker exposures to or below the PEL (and interim levels, if applicable) solely by means of engineering and work practice controls. Such plans must be revised and updated annually to reflect the current status of the program until all worker exposures are reduced to or below the PEL solely by engineering and work practice control methods. The standard required that compliance with this provision be achieved no later than the compliance dates in the implementation table (1996 or earlier, depending on the industry). Therefore, all firms that were in existence prior to 1996 have already prepared their written plans. In addition, existing firms that have successfully reduced worker exposure below the PEL are not required to maintain their written compliance plans. The Agency has not identified any new firms since the last ICR, thus, this ICR assumes that there are no new firms.<sup>6</sup>

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<sup>6</sup> New firms started after these compliance dates may not expose their employees to lead levels in excess of the PEL. For purposes of this ICR, when new firms are identified, they are assumed to have worker lead exposure levels below the PEL; therefore, these new firms would not be required to develop compliance plans.

### **Administrative Controls (§1910.1025 (e)(6))**

Although the standard permits the use of worker rotation to control exposure to lead, OSHA assumes that the establishment and implementation of such job rotation schedules are not widely used because of the administrative difficulties inherent in such a practice. There may be some operations where such practice is feasible; however, OSHA has no indication of the number of employers or workers who will be involved. OSHA has, therefore, included one hour of supervisory time as the burden of this requirement at a cost of \$60.

### **Respiratory Protection (§1910.1025(f)(2))**

The standard requires the employer to institute a respiratory protection program in accordance with 29 CFR 1910.134. No burden is taken for this requirement. The burden is taken in the Respiratory Protection paperwork package for §1910.134 (OMB Control Number 1218-0099).

### **Notifying the Laundry (§1910.1025 (g)(vi))**

This ICR assumes no employers have workers exposed over the PEL; therefore there are no burden hours and no costs associated with this provision.

### **Labeling of Contaminated Protective Clothing and Equipment (§1910.1025(g)(2)(vii))**

Since this provision provides specific language for labels of contaminated protective clothing and equipment, the Agency is exempted from taking burden hours and costs for these provisions. (See 5 CFR 1320.2(c)(2) (“Controlling paperwork burden on the public”)).

### **Signs (§1910.1025(m))**

This ICR assumes no employers have workers exposed over the PEL; therefore, there are no burden hours and no costs associated with this provision. Furthermore, since this provision provides specific language for warning signs, the Agency is exempted from taking burden hours and costs for these provisions. (See 5 CFR 1320.2(c)(2) (“Controlling paperwork burden on the public”)).

### **Medical Surveillance (§1910.1025 (j))**

Employers must institute a medical surveillance program for all workers who are or may be exposed to lead at or above the action level for more than 30 days each year. OSHA estimates that 24,129 workers in the five major industrial sectors are exposed to levels of lead at or above the action level for more than 30 days per year and 292,582 workers in the miscellaneous industry sectors are assumed to be exposed at this level.

Biological Monitoring

The employer must make available biological monitoring in the form of blood sampling and analysis for lead and zinc protoporphyrin (ZPP) levels to each worker who may be exposed to lead at or above the action level for more than 30 days per year. Such monitoring must be made available at least every six months. OSHA assumes that all of the 331,304 workers exposed at or above the action level in existing industries (see Table A) require such monitoring. OSHA has estimated that blood sampling requires approximately 15 minutes (.25 hour) of the worker's time and of the occupational health nurse's time.

**Burden hours:** 331,304 workers × 2 samples per year × .25 hours = 165,652 hours  
**Costs:** 165,652 hours × \$35.51 = \$5,882,303

The standard requires blood sampling and analysis every two months for workers found to have blood lead levels at or above 40 µg/100 g and at least monthly for workers who are removed from exposure to lead due to elevated blood lead levels (in excess of 50 µg/100 g). According to information gathered by OSHA during the rulemaking process for lead, even achievement of the PEL of 50 µg/m<sup>3</sup> will not result in maintaining the blood lead levels of all occupationally exposed workers below 40 µg/100 g. Even in those industries achieving compliance with the PEL, OSHA predicts that 0.5 percent of worker blood leads will meet or exceed 60 µg/100 g; 5.5 percent will have blood leads between 50-60 µg/100 g; and 23.3 percent will be between 40-50 µg/100 g. Overall, 29.3 percent of exposed workers will have blood lead levels at or above 40 µg/100 g at any one time.

With the above estimates in mind, OSHA estimates 6 percent (or 19,878 workers) of the 331,304 workers may have blood lead levels which would require removal from further lead exposure and monthly biological monitoring. Since two months of sampling have been accounted for under the biological monitoring estimates discussed above, only 10 additional blood samples must be taken for these workers.

**Burden hours:** 19,878 workers × 10 samples × .25 hour = 49,695 hours  
**Costs:** 49,695 worker hours × \$35.51 = \$1,764,669

Approximately 23.3 percent (or 77,194) of the 331,304 workers employed in those industries may have blood lead levels which would require biological monitoring every two months. Since OSHA has already accounted for two months of such monitoring above, only 4 additional blood samples must be taken for these workers:

**Burden hours:** 77,194 workers × 4 samples × .25 hour = 77,194 hours  
**Costs:** 77,194 × \$35.51 = \$2,741,159

Employee Notification of Biological Monitoring Results

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The lead standard requires that the employer notify, in writing, within 5 working days after the receipt of biological monitoring results, each worker whose blood lead level exceeds 40 µg/100 g of whole blood. Based on the above information, OSHA estimates 19,878 workers require monthly notification and approximately 77,194 workers require bi-monthly notifications. On the basis of these estimates, 97,072 (19,878 monthly notifications + 77,194 bi-monthly notification) of the 331,304 workers assumed to be exposed at levels at or above 40 µg/100g of whole blood, will require notification of biological monitoring results.

Such notification takes five minutes (.08 hour) of supervisor time (\$59.72 supervisor wage rate per hour). Total burden hours of this requirement are shown below.

**Burden hours:**  $(19,878 \times 12 \text{ notifications} \times .08 \text{ hour}) + (77,194 \times 6 \text{ notifications} \times .08 \text{ hour}) = 56,136 \text{ hours}$   
**Costs:**  $56,136 \text{ hours} \times \$59.72 = \$3,352,442$

### Medical Examinations and Consultations

The lead standard requires that employers make medical examinations and consultations available to each worker who may be exposed at or above the action level for more than 30 days per year. Such examinations and consultations must be provided annually for each worker for whom a blood sampling test conducted at any time during the preceding 12 months indicates a blood lead level at or above 40 µg/100 g of whole blood. Based on the discussion above, OSHA assumes 97,072 workers will experience blood levels at or above 40 µg/100 g, thus, requiring medical examination. Medical examinations are assumed to require 2 hours of worker time which includes time away from their work station.

**Burden hours:**  $97,072 \text{ exams} \times 2 \text{ hours worker time} = 194,144 \text{ hours}$   
**Costs:**  $194,144 \text{ worker hours} \times \$35.51 = \$6,894,053$

OSHA estimates a worker turn-over rate of approximately 30 percent, therefore 78,850 workers at or above the action level but below the PEL in the existing lead-using/producing industries will require an initial medical examination.

**Burden hours:**  $78,850 \text{ exams} \times 2 \text{ hours worker time} = 157,700 \text{ hours}$   
**Costs:**  $157,700 \text{ worker hours} \times \$35.51 = \$5,599,927$

In accordance with the lead standard, each employer must also make medical examinations available to those worker who have developed signs or symptoms commonly associated with lead intoxication, to those worker who desire medical advice concerning the effects of current or past exposures to lead on the worker's ability to produce healthy children or to those worker who demonstrate difficulty in breathing during respirator fit testing or during respirator use. OSHA estimates that no more than 5 percent (or 16,565) of worker exposed at or above the action level in each industrial sector will receive medical examinations as a result of these specified circumstances.

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**Burden hours:** 16,565 exams × 2 hours worker time = 33,130 hours  
**Costs:** 33,130 worker hours × \$35.51 = \$1,176,446

In accordance with the lead standard, each employer must provide a medical examination as medically appropriate for each worker either removed from exposure to lead due to a risk of sustaining material impairment to health, or otherwise limited pursuant to a final medical determination. Based on the information collected during the rulemaking proceedings for this standard, OSHA has estimated that approximately 19,878 workers may require some additional medical examinations as a result of their being removed from lead exposure because of their high blood lead levels. OSHA has estimated that approximately five percent (or 994) of these workers may require additional medical examinations.

**Burden hours:** 994 exams × 2 hours worker time = 1,988 hours  
**Costs:** 1,988 worker hours × \$35.51 = \$70,594

### Multiple Physician Review Mechanism

The lead standard requires that each employer promptly notify each worker of his or her right to seek a second medical opinion after each occasion during which a physician conducts a medical examination or consultation. This requirement can be fulfilled by including a photocopy of such notification with the physician's written medical opinion that the employer must provide to each worker after each medical examination. OSHA estimates that inclusion of this notification form will require no more than 1 minute (.02 hour) of supervisor time. According to the estimates made above, employers will provide approximately 193,481 medical examinations (97,072 + 78,850 + 16,565 + 994) each year which will require the insertion of this notification in each worker's medical opinion.

**Burden hours:** 193,481 exams × 0.02 hour = 3,870 hours  
**Costs:** 3,870 hours × \$59.72 = \$231,116

### Information Provided to Examining and Consulting Physicians

Information must be provided to physicians who will conduct medical examinations of worker under the requirements of the lead standard. A supervisor or worker takes 5 minutes (.08 hour) to provide the required information to physicians. Based on the analysis above there are 193,481 examinations to be performed annually.

**Burden hours:** 193,481 exams × .08 hours = 15,478 hours  
**Costs:** 15,478 hours × \$59.72 = \$924,346

### Physician's Written Opinion

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OSHA estimates five minutes (.08 hour) of supervisor time is needed to give each examined worker a copy of the physician's written opinion.

**Burden hours:** 193,481 exams × .08 hour = 15,478 hours  
**Costs:** 15,478 hours × \$59.72 = \$924,346

### Chelation Notification

In accordance with the lead standard, each employer must notify each worker in writing prior to therapeutic or diagnostic chelation. OSHA has prohibited the use of prophylactic chelation and permits diagnostic and therapeutic only under the supervision of a licensed physician with appropriate medical monitoring in an acceptable clinical setting. In general, chelation is only performed in severe cases of lead intoxication. Unless severe symptoms are present, therapeutic chelation is not recommended given the opportunity to remove a worker from exposure and to allow the body to naturally excrete accumulated lead. For this reason, OSHA does not anticipate much use of chelation and, consequently, does not foresee the need for large scale notification of worker. Therefore, we have estimated that one hour of supervisor time at a cost of \$60 supervisor wage rate.

### **Recordkeeping**

#### Exposure Monitoring Records

OSHA estimates that employers take 5 minutes (.08 hour) to update and maintain each worker's exposure monitoring record annually, and that a secretary fulfills this requirement. The number of workers exposed who must be monitored periodically in existing facilities totals 331,304.

**Burden hours:** 331,304 × .08 hour = 26,504 hours  
**Costs:** 26,504 hours × \$25.01 = \$662,865

#### Medical Surveillance Records

OSHA estimates employers take 10 minutes (.17 hour) to establish, update, and maintain worker medical surveillance records. The number of records to be created and maintained in each industrial sector is based on the number of workers exposed who must be provided medical examinations due to their occupational exposure to lead.

**Burden hours:** 331,304 workers × .17 hour = 56,322 hours  
**Costs:** 56,322 hours × \$59.72 = \$3,363,550

#### Medical Removal Records

Approximately five percent of the 19,878 workers are removed from lead exposure as a result of their being found to have blood lead levels in excess of 50 µg / 100 g. OSHA estimates that

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approximately 5 minutes (.08 hour) will be required to establish and maintain medical removal records.

**Burden hours:** 19,878 records × 5% × .08 hour = 80 hours

**Costs:** 80 hours × \$59.72 = \$4,778

Employee Access

OSHA has no information that permits any confident determination of the number of workers who will request access to their exposure monitoring, medical, and/or medical removal records each year. OSHA therefore assumes that approximately 10 percent of workers exposed to lead at or above the action level will annually request access to these records. Providing access will require approximately 5 minutes (.08 hour) per request.

**Burden hours:** 331,304 workers × 10% × .08 hour = 2,650 hours

**Costs:** 2,650 hours × \$25.01 = \$66,277

**Table 1**  
**Summary of Burden Hours and Costs for the Collections of Information contained in the Lead in General Industry Standard**

Information Collection Requirement	Responses	Current Burden Hours	Proposed Burden Hours	Change	Estimated Cost	
EXPOSURE MONITORING						
Initial Exposure Measurement	0	43	0	-43	\$0	
Periodic Exposure Measurement	165,652	170,422	165,652	-4,770	\$5,882,303	
Employee Notification of Monitoring Results	107,870	9,113	8,630	-483	\$215,836	
COMPLIANCE PROGRAM	0	0	0	0	\$0	
ADMINISTRATIVE CONTROLS	1	1	1	0	\$60	
RESPIRATOR PROGRAM	0	0	0	0	\$0	
NOTIFY THE LAUNDRY	0	0	0	0	\$0	
LABELING CONTAMINATED PROTECTIVE CLOTHING AND EQUIPMENT	0	0	0	0	\$0	
SIGNS	0	0	0	0	\$0	
MEDICAL SURVEILLANCE		0		0		
Biological Monitoring		0		0		
	<i>Biannual</i>	662,608	170,422	165,652	-4,770	\$5,882,303
	<i>Monthly</i>	198,780	51,128	49,695	-1,433	\$1,764,669

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Information Collection Requirement	Responses	Current Burden Hours	Proposed Burden Hours	Change	Estimated Cost
<i>Every Two Months</i>	308,776	79,416	77,194	-2,222	\$2,741,159
Employee Notification	701,700	57,753	56,136	-1,617	\$3,352,442
Medical Examinations		0		0	
<i>At or Above the AL</i>	97,072	199,734	194,144	-5,590	\$6,894,053
<i>Initial</i>	78,850	204,506	157,700	-46,806	\$5,599,927
<i>Employee Signs and Symptoms</i>	16,565	34,084	33,130	-954	\$1,176,446
<i>Removal</i>	994	2,046	1,988	-58	\$70,594
Physician Review	193,481	3,523	3,870	347	\$231,116
Information to the Physician	193,481	17,615	15,478	-2,137	\$924,346
Physician's Opinion	193,481	17,615	15,478	-2,137	\$924,346
Chelation Notification	1	1	1	0	\$60
EMPLOYEE INFORMATION AND TRAINING				0	
Training Program Development	0	16	0	-16	\$0
Provide Training (New Employers)	0	0	0	0	\$0
Provide Training (Existing Employers)	0	0	0	0	\$0
Access to Training Materials	0	0	0	0	\$0
RECORDKEEPING				0	
Exposure Records	331,304	27,281	26,504	-777	\$662,865
Medical Records	331,304	57,943	56,322	-1,621	\$3,363,550
Removal Records	994	82	80	-2	\$4,778
Access to Records	33,130	2,727	2,650	-77	\$66,277
<b>TOTAL</b>	<b>3,616,044</b>	<b>1,105,397*</b>	<b>1,030,305</b>	<b>-75,092</b>	<b>\$39,757,130</b>

\*Upon careful review of this ICR, the Agency identified an administrative error. There is a discrepancy of 74 burden hours between the estimated current burden hours in the previous ICR Supporting Statement (1,105,471) and in the ROCIS database (1,105,397). This chart has been adjusted to show the ROCIS database figure.

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

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



**purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**

- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or Private practices.**

### **Exposure Monitoring**

The agency assumes that employers will incur costs for analyzing the samples taken for exposure monitoring. The Agency assumes that it will cost \$29 per sample, including supplies used and analysis of the sample taken.<sup>7</sup> The costs are as follows:

**Costs:**

$$165,652 \text{ periodic samples} \times \$29 \text{ per sample} = \$4,803,908$$

### **Biological Monitoring**

The Agency assumes that the cost for a blood lead and ZPP test is \$29.85.<sup>8</sup> The total number of biological monitoring tests, as described under “Biological Monitoring” section is 1,170,164 samples ((331,304 × 2) + (19,878 × 10) + (77,194 × 4)). Therefore, the cost is \$34,929,395.

### **Medical Examinations**

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<sup>7</sup> Galson Laboratories, 2015. Sampling & Analysis Guide. Available at <http://www.galsonlabs.com/samplinganalysis/sampling-analysis-guide/> (Accessed June 12, 2015). Used the average cost of Analytical Technique – ICP/AES (\$33), Analytical Technique – ICP/MS (\$40) and Analytical Technique – FAA (\$15).

<sup>8</sup>FAIR Health, 2015. Consumer Cost Lookup. Available at [http://fairhealthconsumer.org/medical\\_cost.php](http://fairhealthconsumer.org/medical_cost.php) (Accessed June 12, 2015). Out-of-pocket costs by CPT Code were obtained from FAIR Health webpage. The cost used is the average of \$31.79 for CPT Code 84202 Protoporphyrin (metabolism substance level) and \$27.91 for CPT Code 83655 Lead Level.

The total number of medical examinations is 193,481 (see “Medical Surveillance” item 12). The Agency estimates the cost of a medical examination to be \$273.<sup>9</sup> Therefore, the total cost for medical examinations is \$52,903,510.

**Cost Summary for Monitoring and Examinations**

<b>Provision</b>	<b>Cost</b>
Exposure Monitoring	\$ 4,803,908
Biological Monitoring	\$ 34,929,395
Medical Examinations	\$ 52,903,510
<b>Total</b>	<b>\$92,636,813</b>

**14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.**

Usually, OSHA requests access to records during an inspection. Information collected by the Agency during the investigation is not subject to the PRA under 5 CFR 1320.4(a)(2). Therefore, OSHA takes no burden or cost in Items 12 and 14 of this Supporting Statement

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

The Agency is requesting a 75,092 hour adjustment decrease, from 1,105,397 hours to 1,030,305 hours. The decrease is primarily due to the estimated reduction in the number of facilities (from 56,949 to 53,935) and exposed workers (from 804,507 to 775,551), based on updated data.

Additionally, due to the reduction in the number of facilities and exposed workers as stated above, as well as a decrease in the estimated cost to perform biological medical surveillance, there is a decrease in total operation and maintenance costs of \$50,554,871 (from \$143,191,684 to \$92,636,813). The decrease in operation and maintenance costs is due to the Agency’s identification of a new data source which indicates a lower cost for biological monitoring tests than previously assumed; the estimated cost to perform biological medical surveillance decreased, from \$70.86 to \$29.85. The estimated cost to perform exposure monitoring has

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<sup>9</sup>The previous ICR estimated that the cost of a medical examination was \$242; given the 13% increase in the CPI price of medical care services from 2010 to 2014, it is assumed that the cost of a medical examination increased by 13% as well. Source: Bureau of Labor Statistics (BLS), 2014. Consumer Price Index - All Urban Consumers - Medical care services (Not-seasonally adjusted). Available at <http://www.bls.gov/data/> (Accessed June 22, 2015).

increased from \$27 to \$29, and to perform medical examinations increased from \$242 to \$273.

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

The information required to be collected by the Lead in General Industry Standard will not have results that will be published for statistical use.

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

OSHA lists current valid control numbers in §§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. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS.**

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

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**Table A. Estimated Number of Facilities and Exposed Workers**

Industrial Sector	2012 ICR Estimates			New Estimates		
	Estimated # Facilities	Estimated # Exposed Employees	Estimated # Employees Exposed Above the Action Level, but Below the PEL	Estimated # Facilities	Estimated # of Exposed Employees [i]	Estimated # Employees Exposed Above the Action Level, but Below the PEL [ii]
Primary Smelting	1	291	259	0[iii]	0	0
Secondary Smelting	22	1,880	912	22[iv]	1,880	912
Battery Manufacture	66	8,926	5,891	68[v]	9,196	6,070
Nonferrous Foundries	267	11,469	6,422	703[vi]	30,197	16,909
Lead Pigment Manufacture	8	280	238	8[vii]	280	238
Additional 5 Sector Estimates from 1987 ICR	19	1,290	787	18[viii]	1,222	746
Miscellaneous Sectors	53,873	737,918	310,793	50,587[viii]	692,908	291,836
Additional Miscellaneous Sector Estimates from 1987 ICR	2,693	42,453	15,539	2,529[viii]	39,868	14,593
<b>Total</b>	<b>56,949</b>	<b>804,507</b>	<b>340,841</b>	<b>53,935</b>	<b>775,551</b>	<b>331,304</b>

[i] The ratio of estimated number of exposed workers to the estimated number of facilities has been retained from the previous ICR. Values presented in this column reflect this original ratio and updated facility data.

[ii] The ratio of estimated number of workers exposed at or above the action level, but below the permissible exposure limit has been retained from the previous ICR.

[iii] Source: U.S. Geological Survey (USGS), “Mineral Commodity Summaries 2015.” The USGS reports that as per the U.S. Environmental Protection Agency, the Herculaneum, Missouri lead smelter, the only domestic primary lead smelter, closed at year end 2013. (See: USGS’s “Mineral Commodity Summaries 2015,” (<http://minerals.usgs.gov/minerals/pubs/mcs/2015/mcs2015.pdf>.)

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<sup>[iv]</sup> The USGS’s “Mineral Commodity Summaries 2015” did not report the total number of plants producing secondary lead. (See: <http://minerals.usgs.gov/minerals/pubs/mcs/2015/mcs2015.pdf>.) The USGS’s “Mineral Commodity Summaries 2011,” as cited in the previous ICR, is the most recent report with data on plants producing secondary lead that the Agency could identify. The USGS 2011 report indicates that there were 20 plants producing secondary lead in the United States in 2010. (See: USGS’s “Mineral Commodity Summaries 2011,” <http://minerals.usgs.gov/minerals/pubs/mcs/2011/mcs2011.pdf> .) Also, as noted in the previous ICR, in response to a comment from NIOSH, OSHA added 2 additional secondary smelter facilities to the 20 plant estimate for a total of 22 facilities. The NIOSH comment suggested that there were 2 new facilities based on narrative text in the USGS’s “Mineral Commodities Summaries 2012,” page 91, second paragraph (See: USGS’s “Mineral Commodity Summaries 2012,” <http://minerals.usgs.gov/minerals/pubs/mcs/2012/mcs2012.pdf> .)

<sup>[v]</sup> Source: U.S. Geological Survey (USGS), “Mineral Commodity Summaries 2015.” The USGS 2015 report indicates that lead was consumed in more than 70 manufacturing plants. Since the exact total is not reported, the Agency continues to assume that, as reported by the USGS in 2011, there were approximately 76 manufacturing plants consuming lead in the U.S. The lead-acid battery industry accounted for approximately 90 percent of the reported domestic lead consumption in 2014. The Agency assumed that 90 percent of these manufacturing facilities were in the lead-acid battery industry. . (See: <http://minerals.usgs.gov/minerals/pubs/mcs/2015/mcs2015.pdf> and <http://minerals.usgs.gov/minerals/pubs/mcs/2011/mcs2011.pdf> .)

<sup>[vi]</sup> According to the U.S. Census County Business Pattern (CBP) data for 2013, the total number of establishments in NAICS 331523 Nonferrous Metal Die-Casting Foundries and NAICS 331529 Other Nonferrous Metal Foundries (except Die-Casting) 727. This represents a 163.4 percent increase in the number of establishments from 2009 data. The Agency applied this increase to the 2012 ICR facilities estimate. The reason for the high percent increase in the number of establishments in those NAICS is because, the current CBP data uses 2012 NAICS (vs the 2007 NAICS) whereby NAICS 331523 Nonferrous Metal Die-Casting Foundries now combines NAICS 331521 Aluminum Die-Casting Foundries and 331522 Nonferrous (except Aluminum) Die-Casting Foundries. Similarly, NAICS 331529 Other Nonferrous Metal Foundries (except Die-Casting) now includes NAICS 331525 Copper Foundries (except Die-Casting) and NAICS 331528 Other Nonferrous Foundries (except Die-Casting).

<sup>[vii]</sup> Source: U.S. Geological Survey (USGS), “Mineral Commodity Summaries 2009” (see: <http://minerals.usgs.gov/minerals/pubs/mcs/2009/mcs2009.pdf> ) and U.S. Census County Business Pattern, 2013: 2012 NAICS325130 – Inorganic dye and pigment manufacturing (includes 2007 NAICS 325131 Inorganic dye and pigment manufacturing industry and 2007 NAICS 325132 Synthetic Organic Dye and Pigment Manufacturing). According to the U.S. Census Bureau, there were 162 total establishments in the Inorganic dye and pigment manufacturing industry in 2013. The Agency is unable to locate data regarding the number of firms manufacturing lead-containing pigment (or the extent to which this pigment is used today, if at all), however, assumes that manufacturing and use have declined significantly in recent years given government regulation and public health concerns. The USGS reported that in 2008 about 10 percent of lead was used in ammunition; casting material; sheets (including radiation shielding), pipes, traps and extruded products; cable covering, caulking lead, and building construction; solder; and oxides for glass, ceramics, pigments, and chemicals. Conservatively, if all ten percent of lead used in manufacturing plants consuming lead was used in lead oxide pigment manufacturing, the Agency estimates that this industry would be comprised of 8 firms (10 percent of 76).

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<sup>[viii]</sup> Based on available documentation, the Agency was unable to determine from which industries and/or occupations these estimates were derived. According to the U.S. Census Bureau, the total number of establishments in NAICS 31-33 (Manufacturing) in 2013 was 535,935. This represents a 6.1 percent decrease in the number of establishments from 2009 data. The Agency applied this decrease to the 2012 ICR facilities estimate.