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SUPPORTING STATEMENT FOR THE INFORMATION COLLECTION REQUIREMENTS IN THE LEAD IN GENERAL INDUSTRY STANDARD (29 CFR 1910.1025)¹ OFFICE OF MANAGEMENT AND BUDGET (OMB) CONTROL NO. 1218-0092 (July 2025)

The agency is seeking an extension of the currently approved information collection.

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 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).

To protect worker health, the OSH Act authorizes the Occupational Safety and Health Administration (OSHA or agency) to develop standards that provide for "monitoring or measuring employee exposure" to occupational hazards and that "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). Moreover, 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). In addition, the OSH Act mandates that "[e]ach employer shall make, keep and preserve, and make available to the Secretary [of Labor] . . . such records regarding [their] activities relating to this Act as the Secretary . . . may prescribe by regulation as necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses" (29 U.S.C. 657). The Act states further that "[t]he Secretary . . . shall . . . prescribe such rules and regulations as [they] may deem necessary to carry out [their] responsibilities under this Act, including rules and regulations dealing with the inspection of an employer's establishment" (29 U.S.C. 651).

Pursuant to its statutory authority, OSHA promulgated a health standard governing worker

¹ 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.

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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 protect workers from the health effects associated with occupational exposure to lead. Such exposure may cause lead poisoning, anemia, heart disease, kidney disease, reduced fertility, and death. Items 2 and 12 below list and describe the specific information collection requirements of the standard.

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

The following collection of information requirements will help employers to monitor worker exposure to lead, to take action to reduce worker exposure to the permissible exposure limit (PEL), to monitor worker health, and to provide workers with information about their exposures and the health effects of lead.

A. Exposure Monitoring (§ 1910.1025(d))

General (§ 1910.1025(d)(1)(i-iii))

For the purposes of paragraph (d), employee exposure is that exposure which would occur if the employee were not using a respirator. With the exception of monitoring under paragraph (d)(3), the employer shall collect full shift (for at least 7 continuous hours) personal samples including at least one sample for each shift for each job classification in each work area. Full shift personal samples shall be representative of the monitored employee's regular, daily exposure to lead.

Purpose: 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.

Initial Determination (§ 1910.1025(d)(2))

Each employer who has a workplace or work operation covered by this standard shall determine if any employee may be exposed to lead at or above the action level.

Basis of Initial Determination (§ 1910.1025(d)(3))

§ 1910.1025(d)(3)(i)

The employer shall monitor employee exposures and shall base initial determinations on the employee exposure monitoring results and any of the following, relevant considerations:

(A) any information, observations, or calculations which would indicate employee exposure to lead;

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(B) any previous measurements of airborne lead;

(C) any employee complaints of symptoms which may be attributable to exposure to lead. $\S 1910.1025(d)(3)(ii)$

Monitoring for the initial determination may be limited to a representative sample of the exposed employees who the employer reasonably believes are exposed to the greatest airborne concentrations of lead in the workplace.

§ 1910.1025(d)(3)(iii)

Measurements of airborne lead made in the preceding 12 months may be used to satisfy the requirement to monitor under paragraph (d)(3)(i) if the sampling and analytical methods used meet the accuracy and confidence levels of paragraph (d)(9) of this section.

Positive Initial Determination and Initial Monitoring (§ 1910.1025(d)(4)(i-ii))

Where a determination conducted under paragraphs (d)(2) and (3) of this section shows the possibility of any employee exposure at or above the action level, the employer shall conduct monitoring which is representative of the exposure for each employee in the workplace who is exposed to lead. Measurements of airborne lead made in the preceding 12 months may be used to satisfy this requirement if the sampling and analytical methods used meet the accuracy and confidence levels of paragraph (d)(9) of this section.

Negative Initial Determination (§ 1910.1025(d)(5))

Where a determination, conducted under paragraphs (d)(2) and (3) of this section is made that no employee is exposed to airborne concentrations of lead at or above the action level, the employer shall make a written record of such determination. The record shall include at least the information specified in paragraph (d)(3) of this section and shall also include the date of determination, location which the worksite, and the name of each employee monitored.

Frequency (§ 1910.1025(d)(6)(i-iii))

If the initial monitoring reveals employee exposure to be below the action level the measurements need not be repeated except as otherwise provided in paragraph (d)(7) of this section. If the initial determination or subsequent monitoring reveals employee exposure to be at or above the action level but below the permissible exposure limit the employer shall repeat monitoring in accordance with this paragraph at least every 6 months. The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are below the action level at which time the employer may discontinue monitoring for that employee except as otherwise provided in paragraph (d)(7) of this section. If the initial monitoring reveals that employee exposure is above the permissible exposure limit the employer shall repeat monitoring quarterly. The employer shall continue monitoring at the required frequency until at least two consecutive measurements, taken at least 7 days apart, are

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below the PEL but at or above the action level at which time the employer shall repeat monitoring for that employee at the frequency specified in paragraph (d)(6)(ii), except as otherwise provided in paragraph (d)(7) of this section.

Additional Monitoring (§ 1910.1025(d)(7))

Whenever there has been a production, process, control, or personnel change which may result in new or additional exposure to lead, or whenever the employer has any other reason to suspect a change which may result in new or additional exposures to lead, additional monitoring in accordance with this paragraph shall be conducted.

Employee Notification (§ 1910.1025(d)(8)(i-ii))

The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to affected employees. Whenever the results indicate that the representative employee exposure, without regard to respirators, exceeds the permissible exposure limit, the employer shall include in the written notice a statement that the permissible exposure limit was exceeded and a description of the corrective action taken or to be taken to reduce exposure to or below the permissible exposure limit.

Purpose: 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.

B. Compliance Program (§ 1910.1025(e)(3))

§ 1910.1025(e)(3)(i)

Each employer shall establish and implement a written compliance program to reduce exposures to or below the permissible exposure limit, and interim levels if applicable, solely by means of engineering and work practice controls in accordance with the implementation schedule in paragraph (e)(1).

§ 1910.1025(e)(3)(ii)

Written plans for these compliance programs shall include at least the following: (A) a description of each operation in which lead is emitted e.g. machinery used, material processed, controls in place, crew size, employee job responsibilities, operation procedures and maintenance practices; (B) a description of the specific means that will be employed to achieve compliance, including engineering plans and studies used to determine methods selected for controlling exposure to lead; (C) a report of the technology considered in meeting the permissible exposure limit; (D) air monitoring data which documents the source of lead emissions; (E) a detailed schedule for implementation of the program, including documentation such as copies of purchase

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orders for equipment, construction contracts, etc.; (F) a work practice program which includes items required under paragraphs (g), (h), and (i) of this regulation; (G) an administrative control schedule required by paragraph (e)(5) of this section, if applicable; (H) other relevant information.

Purpose: Requiring an employer to establish a written compliance program effectively promotes required compliance with the standard's permissible exposure limits. The written program requirement commits the employer to evaluate worker exposure and set 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.

C. 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: (i) name or identification number of each affected worker; (ii) duration and exposure levels at each job or work station where each affected worker is located; and (iii) any other information that may be useful in assessing the reliability of administrative controls to reduce exposure to lead.

D. Respirator Program (§ 1910.1025(f)(2))

The employer must implement a respiratory protection program in accordance with 1910.134(b) through (d) (except (d)(1)(iii), and (f) through (m), which covers each employee required by this section to use a respirator. If an employee has difficulty during fit testing or respirator use, the employer must provide the employee with a medical examination in accordance with paragraph (j)(3)(i)(C) of this section to determine whether the employee can use a respirator while performing the required duty.

Purpose: These requirements ensure that employers have 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 how all requirements of the respiratory standard will be met in their workplace.

E. Notifying Laundry Services (§ 1910.1025(g)(2)(vi))

The employer shall inform in writing any person who cleans or launders protective clothing or equipment of the potentially harmful effects of exposure to lead.

Purpose: Providing this information to the person doing the laundry, they are informed of the presence and potentially harmful effects of lead.

F. Labeling of Contaminated Protective Clothing and Equipment (§ 1910.1025(g)(2)(vii))

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§ 1910.1025(g)(2)(vii)(A)

The employer shall ensure that labels of bags or containers of contaminated protective clothing and equipment include the following information:

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(q)(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) of this section:

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.

G. Medical Surveillance, General (§ 1910.1025(j)(1)(i))

The employer shall 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.

(1) Biological Monitoring. Blood Lead and ZPP Level Sampling and Analysis (§ 1910.1025(j)(2)(i))

The employer shall make available biological monitoring in the form of blood sampling and analysis for lead and zinc protoporphyrin levels to each employee covered under paragraph (j)(1) (i) of this section on the following schedule: (A) at least every 6 months to each employee covered under paragraph (j)(1)(i) of this section; (B) at least every two months for each employee whose last blood sampling and analysis indicated a blood lead level at or above 40 μ g/100 g of whole blood. This frequency shall continue until two consecutive blood samples and analyses indicate a blood lead level below 40 μ g/100 g of whole blood; and (C) at least monthly during the removal period of each employee removed from exposure to lead due to an elevated blood lead level.

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

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

(2) Employee Notification (§ 1910.1025(j)(2)(iv))

Within five working days after the receipt of biological monitoring results, the employer shall notify in writing each worker whose blood lead level is at or above 40 μ g/100 g above: (A) of that employee's blood lead level; and (B) that the standard requires temporary medical removal with Medical Removal Protection benefits when a worker's blood lead level is at or above the numerical criterion for medical removal under paragraph (k)(1)(i) of this section.

(3) Medical Examinations and Consultations, Frequency (§ 1910.1025(j)(3)(i))

The employer shall make available medical examinations and consultations to each employee covered under paragraph (j)(1)(i) of this section on the following schedule: (A) at least annually for each employee for whom a blood sampling test is conducted at any time during the preceding 12 months indicated a blood lead level at or above 40 ug/100 g; (B) prior to assignment for each employee being assigned for the first time to an area in which airborne concentrations of lead are at or above the action level; (C) as soon as possible, upon notification by an employee either that the employee has developed signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice concerning the effects of current or past exposure to lead on the employee's ability to procreate a healthy child, or that the employee has demonstrated difficulty in breathing during a respirator fitting test or during use; and (D) as medically appropriate for each employee 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.

Content (§ 1910.1025(j)(3)(ii))

Medical examinations made available pursuant to paragraph (j)(3)(i)(A)(B) of this section shall include the following elements: (A) a detailed work history and a medical history, with particular attention to past lead exposure (occupational and non-occupational), personal habits (smoking, hygiene), and past gastrointestinal, hematologic, renal, cardiovascular, reproductive, and neurological problems; (B) a thorough physical examination, with particular attention to teeth, gums, hematologic, gastrointestinal, renal, cardiovascular, and neurological systems. Pulmonary status should be evaluated if respiratory protection will be used; (C) a blood pressure measurement; (D) a blood sample and analysis which determines: (1) blood lead level; (2) hemoglobin and hematocrit determinations, red cell indices, and examination of peripheral smear morphology; (3) zinc protoporphyrin; (4) blood urea nitrogen; and (5) serum creatinine; (E) a routine urinalysis with microscopic examination; (F) any laboratory or other test that the examining physician deems necessary by sound medical practice. The content of medical examinations made available pursuant to paragraph (j)(3)(i)(C)-(D) of this section shall be

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determined by an examining physician and, if requested by an employee, shall include pregnancy testing or laboratory evaluation of male fertility.

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

§ 1910.1025(e)(3)(iii)(A)

If the employer selects the initial physician who conducts any medical examination or consultation provided to an employee under this section, the employee may designate a second physician: (1) to review any findings, determinations, or recommendations of the initial physician; and (2) to conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review.

§ 1910.1025(e)(3)(iii)(B)

The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation pursuant to this section. The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the foregoing notification, or receipt of the initial physician's written opinion, whichever is later: (1) the employee informing the employer that he or she intends to seek a second medical opinion, and (2) the employee initiating steps to make an appointment with a second physician.

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

§ 1910.1025(e)(3)(iv)(A)

The employer shall provide an initial physician conducting a medical examination or consultation under this section with the following information: (1) a copy of this regulation for lead including all Appendices; (2) a description of the affected employee's duties as they relate to the employee's exposure; (3) the employee's exposure level or anticipated exposure level to lead and to any other toxic substance (if applicable); (4) a description of any personal protective equipment used or to be used; (5) prior blood lead determinations; and (6) all prior written medical opinions concerning the employee in the employer's possession or control.

§ 1910.1025(j)(3)(iv)(B)

The employer shall provide the foregoing information to a second or third physician conducting a medical examination or consultation under this section upon request of the second or third physician, or by the employee.

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

§ 1910.1025(j)(3)(v)(A)

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The employer shall obtain and furnish to the employee a copy of a written medical opinion from each examining or consulting physician which contains the following information: (1) the physician's opinion as to whether the employee has any detected medical condition that would place the employee at increased risk of material impairment of employee's health from exposure to lead; (2) any recommended special protective measures to be provided to the employee, or limitations to be placed upon the employee's exposure to lead; (3) any recommended limitation upon the employee's use of respirators, including a determination of whether the employee can wear a powered air purifying respirator if a physician determines that the worker cannot wear a negative pressure respirator; and (4) the results of the blood lead determinations.

§ 1910.1025(j)(3)(v)(B)

The employer must instruct each examining and consulting physician to: (1) 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 an employee's occupational exposure to lead; and (2) to advise the employee of any medical condition, occupational or nonoccupational, which dictates further medical examination or treatment.

(7) Chelation (§ 1910.1025(j)(4)(ii))

If therapeutic or diagnostic chelation is to be performed by any person in paragraph (j)(4)(i), the employer shall assure that it be done 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.

Medical Removal Protection Benefits, Employees Whose Blood Lead Levels Do Not Adequately Decline Within 18 Months of Removal (§ 1910.1025(k)(2)(vi))

The employer shall 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

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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)(i-iv))

Each employer who has a workplace in which there is potential exposure to airborne lead at any level shall inform employees of the contents of Appendices A and B of this regulation. The employer shall train each employee who is subject to exposure to lead at or above the action level, or for whom the possibility of skin or eye irritation exists, in accordance with the requirements of this section. The employer shall institute a training program and ensure employee participation in the program. The employer shall provide initial training by 180 days from the effective date for those employees covered by paragraph (l)(1)(ii) on the standard's effective date and prior to the time of initial job assignment for those employees subsequently covered by this paragraph. The training program shall be repeated at least annually for each employee.

§ 1910.1025(l)(1)(v)

The employer shall assure that each employee is informed of the following: (A) the content of this standard and its appendices; (B) the specific nature of the operations which could result in exposure to lead above the action level; (C) the purpose, proper selection, fitting, use, and limitations of respirators; (D) 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); (E) the engineering controls and work practices associated with the worker's job assignment; (F) the contents of any compliance plan in effect; and (G) instructions to employees that chelating agents should not routinely be used to remove lead from their bodies and should not be used at all except under the direction of a licensed physician.

Note: Training is not considered to be a collection of information.

Access to Information and Training Materials (§ 1910.1025(l)(2)(i-iii))

The employer shall make readily available to all affected employees a copy of this standard and its appendices. The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director. In addition to the information required by paragraph (l)(1)(v), the employer shall include as part of the training program, and shall distribute to employees, any materials pertaining to the Occupational Safety and Health Act, the regulations issued pursuant to that Act, and this lead standard, which are made available to the employer by the Assistant Secretary.

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Note: These requirements are not collections of information because they are public disclosures of information originally provided by the Federal government to the recipient for 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. OSHA would only review these records in the context of an investigation of a particular employer to determine compliance with the Standard. These activities are outside the scope of the PRA. See 5 CFR 1320.4(a)(2).

Communication of Hazards, General (§ 1910.1025(m)(1))

§ 1910.1025(m)(1)(i-iii)

Chemical manufacturers, importers, distributors, and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for lead. 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. 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) of this section.²

Burden hours and costs for employers to comply with HCS information collection requirements are included in the paperwork package for Hazard Communication, OMB Control Number 1218-0072.

H. Signs (§ 1910.1025(m)(2))

§ 1910.1025(m)(2)(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

² 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.

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§ 1910.1025(m)(2)(v)

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

WARNING LEAD WORK AREA POISON NO SMOKING OR EATING

Purpose: 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 that workers receive under this standard.

I. Recordkeeping (§ 1910.1025(n))

Exposure Monitoring Records (§ 1910.1025(n)(1)(i-iii))

The employer shall establish and maintain an accurate record of all monitoring required in paragraph (d) of this section. This record shall include: (A) 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 employee exposure where applicable; (B) a description of the sampling and analytical methods used and evidence of their accuracy; (C) the type of respiratory protective devices worn, if any; (D) name and job classification of the employee monitored and of all other workers whose exposure the measurement is intended to represent; and (E) the environmental variables that could affect the measurement of employee exposure.

The employer shall maintain these 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))

§ 1910.1025(n)(2)(i)

The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (j) of this section.

§ 1910.1025(n)(2)(ii)

This record shall include: (A) the name, and description of the duties of the employee; (B) a copy of the physician's written opinions; (C) results of any airborne exposure monitoring done for that employee and the representative exposure levels supplied to the physician; and (D) any employee medical complaints related to exposure to lead.

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§ 1910.1025(n)(2)(iii)

The employer shall keep, or assure that the examining physician keeps, the following medical records: (A) a copy of the medical examination results including medical and work history required under paragraph (j) of this section; (B) 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 (C) a copy of the results of the biological monitoring.

§ 1910.1025(n)(2)(iv)

The employer shall maintain or assure that the physician maintains these medical 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)(i-iii))

§ 1910.1025(n)(3)(i)

The employer shall establish and maintain an accurate record for each employee removed from current exposure to lead pursuant to paragraph (k) of this section.

Each record shall include: (A) the name of the employee; (B) the date on each occasion that the employee was removed from current exposure to lead as well as the corresponding date on which the employee was returned to his or her former job status; (C) a brief explanation of how each removal was or is being accomplished; and (D) a statement with respect to each removal indicating whether or not the reason for the removal was an elevated blood lead level.

Availability (§ 1910.1025(n)(4)(i-ii))

The employer shall make available upon request all records required to be maintained by paragraph (n) of this section to the Assistant Secretary and the Director for examination and copying. Environmental monitoring, medical removal, and medical records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020(a)-(e) and (2)-(i). Medical removal records shall be provided in the same manner as environmental monitoring records.

Transfer of Records (§ 1910.1025(n)(5)(i-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 section. The employer shall also comply with any additional requirements involving the transfer of records set forth in 29 CFR 1910.1020(h).³

³ 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

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Note: 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.

Therefore, the agency is not taking a burden for the transfer of records.

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, including electronic recording, when establishing and maintaining exposure-monitoring and performance-oriented records. OSHA wrote the paperwork requirements of the standard in performance-oriented language (i.e., in terms of <a href="https://www.what.edu/wh

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 requirements to collect and maintain information are specific to each employer and worker involved and no other agency duplicates these requirements or can make the required information available to OSHA. Currently, there is no indication that any alternate source is available (i.e., the information is only available from employers).

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.

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, thereby, fulfilling its mandate "to assure so far as possible every working man and woman in the Nation safe and healthful working

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

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conditions and to preserve our human resources" as specified by the OSH Act at 29 U.S.C. 651.

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 occupational 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 their 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.

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

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confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

Under section (d)(8) of the standard, employers must notify workers of their exposure monitoring results, individually, and in writing or by posting in an appropriate location, within 15 working days after obtaining the results. Also, paragraph (j)(2)(iv) requires employers to notify workers of their biological monitoring results within five working days of obtaining the results. If these results indicate that a worker's exposures are above the PEL, the notification must state this fact and describe what corrective actions the employer is taking to reduce the worker's exposure to or below the PEL.

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. OSHA accounts for the burden hours and costs related to the retention of these records under the Information Collection Request (ICR) for § 1910.1020, OMB Control No. 1218-0065.

8. If applicable, provide a copy and identify the date and page number of publication in the <u>Federal Register</u> 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 of 1995 (44 U.S.C. 3506(c)(2)(A)), OSHA published a notice in the Federal Register on April 14, 2025 (90 FR 15591) soliciting public comments on its proposed extension of the information collection requirements specified by the Lead Standard for General Industry (29 CFR 1910.1025) under the docket number OSHA-2012-0013. 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 OMB of a previous approval of the collection of information requirements found in the above Standard.

The agency received two comments on its proposed extension of the data collection for the Lead in General Industry standard. One commenter, a private citizen, expressed general support for federal efforts to control lead exposure (Document ID 0017). The other, Battery Council

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International (BCI) (Document ID 0016), questioned the accuracy of OSHA's burden estimates. BCI, an international trade association representing manufacturers, distributors, and recyclers of rechargeable batteries, questioned two aspects of OSHA's analysis. First, questioning OSHA's estimate that employers would expend 20.6 hours per employee on average to comply with the standard, they stated that each of their members "invest nearly 4,000 man hours per year to complete the administrative work required to comply with the biological monitoring requirements of the Lead Standard alone." They further state that their members spend \$320 per employee per year to comply with the standard's biological monitoring provisions.

The agency thanks BCI for their comments on the burden hour estimates associated with this information collection. OSHA's burden estimates are intended to reflect average compliance time across all affected entities, recognizing that actual burdens may vary depending on organization size, complexity, and industry-specific factors. Although BCI contends OSHA's estimates do not reflect the experience of their members, the comment does not provide sufficient information for the agency to revise its current estimates. For example, because BCI does not indicate how many covered employees their individual members employ, the agency has no context to evaluate the claimed 4,000 man hours per employer resulting from the standard's biological monitoring requirements.⁴

BCI also does not indicate what specific aspects of OSHA's estimates are incorrect and why. As required by the PRA, OSHA has estimated the average amount of time it will take for an employer to comply with each information collection and the associated costs. For example, OSHA estimates that obtaining a blood sample for biological monitoring takes 15 minutes of an employee's and an occupational nurse's time and that written notification of the monitoring results takes 5 minutes per sample of a supervisor's time. Although BCI indicates that OSHA's ultimate conclusion on the costs of these provisions does not represent the cost to its members, they provide no information or data demonstrating where OSHA has miscalculated (for example, by demonstrating that notification in fact takes 10 minutes per sample). Without this information, OSHA cannot effectively evaluate BCI's survey results or determine whether their members' experience would apply to other industries and employers as well, such that a revision to the agency's estimates is warranted.

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

The agency will <u>not</u> provide payments or gifts to the respondents.

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

⁴ Although BCI states that their members "employ 106,000 direct jobs in the U.S.," the organization's website indicates the industry "directly employs 28,050 workers" and "supports 29,600 supplier jobs in a variety of industries and an additional 38,150 jobs from worker spending in different sectors" (see Economic Impact of the U.S. Battery Industry | Battery Council International, last accessed 7/28/25). In any event, BCI does not indicate the percentage of these employees that are subject to the standard because of their occupational exposure to lead or how many exposed employees work for each of their individual members.

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As 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. 552(a)-(e); in 29 CFR Part 70(a); 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.

While this standard does not require questions of a sensitive nature, questions perceived as such may be included in medical questionnaires. Information from medical questionnaires is necessary for the physician, licensed health care provider (PLHCP), or employer to determine what protections an employer must take to ensure that the employee will have minimal occupational exposure to hazards.

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 burdens.
- Provide estimates of annualized cost to respondents for the hour burden for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 13.

Burden Hour and Cost Determinations

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The agency determined the wage rate from mean hourly wage earnings to represent the cost of employee time. For the relevant standard occupational classification category, OSHA used the wage rates reported in the Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics (OEWS), May 2023 [date accessed: February 13, 2025]. (OEWS data is available at https://www.bls.gov/oes/tables.htm. To access a wage rate, select the year, "Occupation profiles," and the Standard Occupational Classification (SOC) code.)

To derive the loaded hourly wage rate presented in the table below, the agency used wage rates, as determined in the paragraph above, and applied a fringe benefit from the following BLS release: *Employer Costs for Employee Compensation News Release* text, released 10:00 AM (EDT), December 17, 2024 (https://www.bls.gov/news.release/archives/ecec_12172024.htm). BLS reported that for private industry workers, fringe benefits accounted for 29.6 percent of total compensation and wages accounted for the remaining 70.4 percent. To calculate the loaded hourly wage for each occupation, the agency divided the mean hourly wage rate by 1 minus the fringe benefits.

Table A, below, summarizes how the loaded hourly wage rate estimates were derived for the information collection requirements specified in the standard.

Table A – Wage Rate Estimates						
Occupational Title	SOC Code	Mean Hourly Wage Rate (A)	Fringe Benefits (B)	Loaded Hourly Wage Rate (C) = (A/(1-B))		
Health and Safety Engineers, Except Mining Safety Engineers and Inspectors (Manager)	17-2111	\$52.28	29.60%	\$74.26		
Industrial Machinery Mechanics (Worker)	49-9041	\$30.62	29.60%	\$43.49		
Office and Administrative Support Occupations (Clerical)	43-0000	\$23.05	29.60%	\$32.74		

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

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Table B – Estimated Number of Employers and Exposed Workers							
	2	022 ICR Esti	mates	2025 New Estimates			
Industrial Sector	Estimated # of Facilities (Employers)	Estimated # Exposed Employee s	Estimated # Employees Exposed Above the Action Level, but Below the PEL	Estimated # Facilities (Employers)	Estimated # of Exposed Employees [i]	Estimated # Employees Exposed Above the Action Level, but Below the PEL [ii]	
Primary Smelting [iii]	0	0	0	0	0	0	
Secondary Smelting [iv]	22	1,880	912	22	1,880	912	
Battery Manufacture [v]	70	9,467	6,249	65	8,775	5,785	
Nonferrous Foundries [vi]	609	26,159	14,648	558	23,994	13,392	
Lead Pigment Manufacture [vii]	8	280	238	8	280	238	
Additional 5 Sector [viii]	18	1,222	746	18	1,222	746	
Miscellaneou s Sectors [viii]	53,504	732,864	308,665	57,046	781,380	329,099	
Additional Miscellaneou s Sector Estimates [viii]	2,675	42,171	15,436	2,852	44,963	16,458	
Total	56,906	814,043	346,894	60,569	862,493	366,629	

[[]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 2025." The USGS report estimated the U.S. apparent consumption of refined lead decreased by 7% from that in 2023, and the net import reliance decreased to 28% from 33%. The last primary lead smelter closed in 2013 and a secondary smelter, in South Carolina, in 2021. (See USGS's "Mineral Commodity Summaries 2022," (https://minerals.usgs.gov/minerals/pubs/mcs/2022/mcs2022.pdf)) and mcs2025.pdf - Mineral Commodity Summaries 2025.

[[]iv] The USGS's "Mineral Commodity Summaries 2025" did not report any changes to the number of a secondary lead refineries. Therefore, this ICR maintains the previous ICR of 22. (See mcs2025.pdf - Mineral Commodity Summaries 2025

[[]v] Source: U.S. Geological Survey (USGS), "Mineral Commodity Summaries 2025." The USGS 2025 does not indicate the number of manufacturing plants that use lead. The agency continues to assume that, as reported by the USGS in 2011, there are approximately 76 manufacturing plants consuming lead in the U.S. The lead-acid battery industry accounted for more than 86 percent of the reported domestic lead consumption during 2024 (USGS, 2025). The agency assumed that 86 percent of the 76 manufacturing facilities are in the lead-acid battery industry. (See http://minerals.usgs.gov/minerals/pubs/mcs/2011/mcs2011.pdf and mcs2025.pdf - Mineral Commodity Summaries 2025.

[[]vi] According to the U.S. Census County Business Pattern (CBP) data for 2021, there were 343 establishments in NAICS 331523 Nonferrous Metal Die-Casting Foundries and 234 establishments in NAICS 331529 Other Nonferrous Metal Foundries (except Die-Casting), for a total of 577 establishments. This represents an approximate 8.41 percent decrease in the number of establishments from 2019 data (630 establishments). The Agency applied the 8.41% decrease to the 2023 ICR facilities estimate (609). (See https://www.census.gov/programs-surveys/cbp/data/tables.All.List_1592946817.html)

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[vii] According to the U.S. Census County Business Pattern, 2021, there were 135 total establishments in the NAICS 325130 Synthetic dye and pigment manufacturing industry in 2021. 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, it is assumed that manufacturing and use have declined significantly in recent years given government regulation and public health concerns. The U.S. Geological Survey (USGS), "Mineral Commodity Summaries 2009" 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. The 2009 Mineral Commodity Summary was the last Summary that contained the 10% breakout.

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 the 76 manufacturing plants that consume lead). (See https://minerals.usgs.gov/minerals/pubs/mcs/2009/mcs/2009/mcs/2009.pdf, and https://www.census.gov/programs-surveys/cbp/data/tables.All.List_1592946817.html)

[viii] According to the U.S. Census Bureau, the total number of establishments in NAICS 31-33 (Manufacturing in 2020 was 567,048. This represents a 6.62% increase in the number of establishments from the 2016 NAICS 31-33 (531,836). The agency applied this increase to the facilities estimate from the previous ICR. Source: https://data.census.gov/cedsci/table?q=NAICS%2031-338tid=CBP2020,CB2000CBP

A. 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. Costs also consider that employers would have in-house industrial hygiene technicians take the samples and then send them to an external lab to be analyzed.

(1) Initial Exposure Measurement

Employers must determine if any workers are exposed to lead at or above the action level. In Table B above, there were no new secondary smelter facilities identified since the last ICR was prepared. Therefore, no new workers will be accounted for, and no burden will be taken for initial exposure measurements.

(2) 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 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.

OSHA estimates 366,629 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 (91,657 workers) are sampled. One technician takes eight samples per day; thus, OSHA assumes a technician takes one hour to sample and document the representative exposure monitoring results. Hours involved in periodic exposure monitoring are estimated as follows:

Burden hours: 91,657 workers x 2 samples/year \times 1 hour = 183,314 hours

Costs: 183,314 hours × \$43.49 = \$7,972,326

Periodic monitoring is also required whenever a production, process, control, or personnel change 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 the AL are too high. The exposure monitoring calculation does not account for

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employers who may have stopped exposure monitoring for those workers whose exposures are below the action level since 1978. The hours estimated above represent total periodic and additional monitoring burdens.

(3) 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 five minutes (5/60 hours) to notify workers of their exposure-monitoring results. OSHA assumes 60,569 existing employers conduct periodic semiannual monitoring, taking five minutes (5/60 hour) to post the results.

Burden hours: $(60,569 \text{ employers}) \times 2 \text{ (semiannual)}) \times 5/60 \text{ hour}$

= 10,095 hours

Costs: $10,095 \text{ hours} \times \$32.74 = \$330,510$

B. 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 utilizing engineering and work practice controls. Such plans must be revised and updated annually to reflect the program's current status until all worker exposures are reduced to or below the PEL solely by engineering and work practice control methods. The standard required 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 before 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 identified new firms since the last ICR. However, new firms started after these compliance dates may not expose their employees to lead levels in excess of the PEL. Therefore, they are assumed to have worker lead exposure levels below the PEL and are not required to develop compliance plans.

C. 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.

Therefore, OSHA has included one hour of supervisory time at a cost of \$74.26 as the burden of this requirement.

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Burden hours: 1 estimated establishment x 1 hour = 1 hour

Costs: 1 hour x \$74.26 = \$74

D. 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).

E. Notifying the Laundry (§ 1910.1025(g)(2)(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.

F. 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")).

G. Medical Surveillance (§ 1910.1025(j))

(1) 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 the 366,629 workers exposed at or above the action level in existing industries (*See* Table B) require such monitoring. OSHA has estimated that blood sampling requires approximately 15 minutes (15/60 hours) of the worker's time and of the occupational health nurse's time.

Burden hours: 366,629 workers \times 2 annual samples \times 15/60 hours

= 183,315 hours

Costs: $183,315 \text{ hours} \times \$43.49 = \$7,972,369$

The standard requires blood sampling and analysis every two months for workers found to have blood lead levels at or above 40 μ g/100 g and at least monthly for workers who are removed from exposure to lead due to elevated blood lead levels (more than 50 μ g/100 g). According to information gathered by OSHA during the rulemaking process for lead, even achievement of the PEL of 50 μ g/m³ will not result in maintaining the blood lead levels of all occupationally exposed workers below 40 μ g/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 μ g/100 g; 5.5 percent will have blood leads between 50-60 μ g/100 g; and 23.3 percent will be between 40-50

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 μ g/100 g. Overall, 29.3 percent of exposed workers will have blood lead levels at or above 40 μ g/100 g at any one time.

With the above estimates in mind, OSHA estimates 6 percent (or 21,998 workers) of the 366,629 workers may have blood lead levels which would require removal from further lead exposure and monthly biological monitoring. As two months of sampling have already been accounted for under the biological monitoring estimates discussed above, only 10 additional blood samples must be taken for these workers.

Burden hours: 21,998 workers \times 10 samples \times 15/60 hours = 54,996 hours

Costs: 54,996 hours × \$43.49 = \$2,391,776

Approximately 23.3 percent of the 366,629 (or 85,425 workers) workers employed in those industries may have blood lead levels that 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: 85,425 workers \times 4 samples \times 15/60 hours = 85,425 hours

Costs: 85,425 hours × \$43.49 = \$3,715,133

(2) Employee Medical Notification

The lead standard requires the employer to notify, in writing, within five working days after the receipt of biological monitoring results, each worker whose blood lead level exceeds 40 μ g/100 g of whole blood. Based on the above information, OSHA estimates 21,998 workers require monthly notification, and 85,425 workers require bi-monthly notifications. Based on these estimates, 107,423 (21,998 monthly notifications + 85,425 bi-monthly notifications) workers are assumed to be exposed at levels at or above 40 μ g/100g of whole blood, will require notification of biological monitoring results.

Such notification takes five minutes (5/60 hours) of supervisor time. The total burden hours for this requirement are shown below.

Burden hours: 21,998 x 12 monthly notifications \times 5/60 hours = 21,998 hours

Costs: $21,998 \text{ hours} \times \$74.26 = \$1,633,571$

Burden hours: 85,425 workers x 6 bi-monthly notifications \times 5/60 hour

= 42,712 hours

Costs: 42,712 hours x \$74.26 = \$3,171,793

Subtotal of Burden hours: 21,998 hours + 42,712 hours = 64,710 hours

Subtotal of Costs: \$1,633,571 + \$3,171,793 = \$4,805,364

(3) Medical Examinations and Consultations

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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 $40 \,\mu\text{g}/100 \,\text{g}$ of whole blood.

Based on the discussion above, OSHA assumes 107,423 workers experience blood levels at or above 40 μ g/100 g, thus requiring a medical examination. Medical examinations are assumed to require two hours of worker time, including time away from their workstation.

Burden hours: $107,423 \text{ exams} \times 2 \text{ hours worker time} = 214,846 \text{ hours}$

Costs: 214,846 hours × \$43.49 = \$9,343,653

OSHA estimates a worker turnover rate of approximately 39 percent,⁵ therefore, 142,985 workers at or above the action level but below the PEL in the existing lead using/producing industries require an initial medical examination.

Burden hours: 142,985 exams × 2 hours = 285,971 hours **Costs**: 285,791 hours × \$43.49 = \$12,436,879

In accordance with the lead standard, each employer must also make medical examinations available to those workers who have developed signs or symptoms commonly associated with lead intoxication, to those workers 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 workers who demonstrate difficulty in breathing during respirator fit testing or during respirator use. OSHA estimates that no more than five percent (or 18,331) of workers exposed at or above the action level in each industrial sector receive medical examinations because of these specified circumstances.

Burden hours: 18,331 exams × 2 hours = 36,663 hours **Costs**: 36,663 worker hours × \$43.49 = \$1,594,474

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 under a final medical determination. Based on the information collected during the rulemaking proceedings for this standard, OSHA estimates 21,998 workers may require some additional medical examinations because of their being removed from lead exposure because of their high blood lead levels. OSHA estimates that approximately five percent (or 1,100) of these workers may require additional medical examinations.

⁵ Source: Bureau of Labor Statistics (BLS), 2024. Job Openings and Labor Turnover Survey, Total Separations Rate for the General Industry. Available at http://www.bls.gov/jlt/data.htm (Accessed November 2024.).

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Burden hours: $1,100 \text{ exams} \times 2 \text{ hours} = 2,200 \text{ hours}$

Costs: 2,200 worker hours \times \$43.49 = \$95,678

(4) Multiple Physician Review

The lead standard requires that each employer promptly notify each worker of their right to seek a second medical opinion after each occasion 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 including this notification form will require no more than one minute (1/60 hour) of supervisor time. According to the estimates made above, employers will provide approximately 269,840 medical examinations (107,423 + 142,985 + 18,331+ 1,100) each year which will require the insertion of this notification in each worker's medical opinion.

Burden hours: $269,840 \text{ exams} \times 1/60 \text{ hour} = 4,497 \text{ hours}$

Costs: $4,497 \text{ hours} \times \$74.26 = \$333,947$

(5) Information Provided to Examining and Consulting Physicians

Information must be provided to physicians who will conduct medical examinations of workers under the requirements of the lead standard. A supervisor takes five minutes (5/60 hour) to provide the required information to physicians. Based on the analysis above there are 269,840 examinations to be performed annually.

Burden hours: $269,840 \text{ exams} \times 5/60 \text{ hours} = 22,487 \text{ hours}$

Costs: 22,487 hours × \$74.26 = \$1,669,885

(6) Physician's Written Opinion

OSHA estimates that five minutes (5/60 hours) of supervisor time is needed to give each examined worker a copy of the physician's written opinion.

Burden hours: $269,840 \text{ exams} \times 5/60 \text{ hour} = 22,487 \text{ hours}$

Costs: $22,487 \text{ hours} \times \$74.26 = \$1,669,885$

(7) <u>Chelation Notification</u>

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 care 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

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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 workers. Therefore, we have estimated that one hour of supervisor time.

Burden hours: 1 estimated establishment x 1 hour = 1 hour

Costs: 1 hour x \$74.26 = \$74

H. 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")).

I. Recordkeeping

(1) Exposure Monitoring Records

OSHA estimates a secretary takes five minutes (5/60 hour) annually to update and maintain worker's representative exposure monitoring records. The number of representative employee exposure monitoring records in existing facilities totals 183,320.

Burden hours: $183,320 \text{ records} \times 5/60 \text{ hours} = 15,277 \text{ hours}$

Costs: $15,277 \text{ hours} \times \$32.74 = \$500,169$

(2) Medical Surveillance Records

OSHA estimates s supervisor takes 10 minutes (10/60 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: $366,629 \text{ records} \times 10/60 \text{ hour} = 61,105 \text{ hours}$

Costs: $61,105 \text{ hours} \times \$74.26 = \$4,537,657$

(3) Medical Removal Records

Approximately five percent ($\underline{1,100 \text{ workers}}$) of the 21,998 workers were removed from lead exposure because their blood lead levels were more than 50 μg /100 g. OSHA estimates that approximately five minutes (5/60 hours) will be required to establish and maintain medical removal records.

Burden hours: $1,100 \text{ records} \times 5/60 \text{ hour} = 92 \text{ hours}$

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Costs: 92 hours × \$74.26 = \$6,832

(4) Employee Access to Records

OSHA has no information that permits a confident determination of the number of workers who request access to their exposure monitoring, medical, and/or medical removal records each year. Therefore, OSHA assumes that approximately 10 percent of 366,629 workers (36,663 workers) exposed to lead at or above the action level will annually request access to these records. Providing access requires approximately five minutes (5/60 hour) per request.

Burden hours: 36,663 workers 5/60 hour = 3,055 hours

Costs: $3,055 \text{ hours} \times \$43.49 = \$132,876$

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	Table	C - Summary of	Estimated Ann	ualized Respo	ondent Hour a	nd Cost Burd	len	
Collection of Information	Type of Respondent (Employer)	No. of Respondents*	Responses per Respondent	Total Responses	Time per Response (hours)	Burden Hours	Loaded Hourly Wage	Burden Costs
Exposure Monitoring								
Initial Exposure Measurement	Worker	0	1	0	1	0	\$43.49	\$0
Periodic Exposure Measurement	Worker	91,657	2	183,314	1	183,314	\$43.49	\$7,972,326
Employee Notification of Monitoring Results	Clerical	60,569	2	121,138	1/12	10,095	\$32.74	\$330,510
Administrative Controls	Supervisor	1	1	1	1	1	\$74.26	\$74
S	Subtotal - Expos	sure Monitoring		304,453		193,410		\$8,302,910
Medical Surveillance								
Biological Monitoring								
Biannual (ZPP)	Worker	366,629	2	733,258	1/4	183,315	\$43.49	\$7,972,369
Monthly	Worker	21,998	10	219,983	1/4	54,996	\$43.49	\$2,391,776
Bi-Monthly	Worker	85,425	4	341,698	1/4	85,425	\$43.49	\$3,715,133
	Subtotal - Medi	cal Surveillance		1,294,940		323,736		\$14,079,278
Employee Notification								
Monthly	Supervisor	21,998	12	263,976	1/12	21,998	\$74.26	\$1,633,571
Bi-Monthly	Supervisor	85,425	6	512,547	1/12	42,712	\$74.26	\$3,171,793
	Subtotal- Emplo	yee Notification		776,523		64,710		\$4,805,364
9		cal Surveillance yee Notification		2,071,463		388,446		\$18,884,642
Medical Examina	tions							
At or Above the AL	Worker	107,423	1	107,423	2	214,846	\$43.49	\$9,343,653
Initial	Worker	142,985	1	142,985	2	285,971	\$43.49	\$12,436,879
Employee Signs and Symptoms	Worker	18,331	1	18,331	2	36,663	\$43.49	\$1,594,474
Additional	Worker	1,100	1	1,100	2	2,200	\$43.49	\$95,678
Multiple Physician Review	Supervisor	269,840	1	269,840	1/60	4,497	\$74.26	\$333,947

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Table C - Summary of Estimated Annualized Respondent Hour and Cost Burden								
Collection of Information	Type of Respondent (Employer)	No. of Respondents*	Responses per Respondent	Total Responses	Time per Response (hours)	Burden Hours	Loaded Hourly Wage	Burden Costs
Information to the Physician	Supervisor	269,840	1	269,840	1/12	22,487	\$74.26	\$1,669,885
Physician's Written Opinion	Supervisor	269,840	1	269,840	1/12	22,487	\$74.26	\$1,669,885
Chelation Notification	Supervisor	1	1	1	1	1	\$74.26	\$74
Su	ıbtotal - Medico	al Examinations		1,079,360		589,152		\$27,144,475
Recordkeeping								
Exposure Records	Clerical	183,320	1	183,320	1/12	15,277	\$32.74	\$500,169
Medical Records	Supervisor	366,629	1	366,629	1/6	61,105	\$74.26	\$4,537,657
Removal Records	Supervisor	1,100	1	1,100	1/12	92	\$74.26	\$6,832
Access to Records	Worker	36,663	1	36,663	1/12	3,055	\$43.49	\$132,862
	Subtotal - Recordkeeping					79,529		\$5,177,520
GRAND TOTA	GRAND TOTAL 4,042,988 1,250,537 \$59,509,542						\$59,509,547	

^{*=}not cumulative. A total of 60,569 employers are the total respondents.

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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.

Capital Cost Determinations

In determining the capital cost of these paperwork requirements, OSHA used the information and data from Item 12 above. From these determinations, the agency estimates that the total capital cost of these requirements is \$210,232,946.

(A) Exposure Monitoring

The agency assumes that employers incur no costs for analyzing the samples taken for initial (0 samples) and \$8,799,072 for periodic (91,657 workers x 2 samples per year =183,314 samples)

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representative exposure monitoring. The agency estimates it costs \$48 (rounded) per sample to analyze lead. The cost is as follows:

Cost: 183,314 samples × \$48 per sample = \$8,799,072

(B) Biological Monitoring

The agency assumes that blood sampling and analysis of lead and zinc protoporphyrin (ZPP) levels cost \$93.⁷

Cost: 366,629 workers \times 2 annual samples \times \$93 = \$68,192,994

The agency assumes that the cost for blood sampling and analysis tests, as discussed under "Biological Monitoring" is \$105. The total number of samples is $561,688 (21,998 \times 10) + (85,425 \times 4)$). Therefore, the cost is as follows:

Cost: 561,688 samples x \$105 = \$36,098,480

(C) Medical Examinations

The total number of medical examination records is 269,840 (*See* "Medical Surveillance" item 12). The agency estimates the cost of a medical examination to be \$360.⁸ Therefore, the total cost for medical examinations are as follows:

Costs: 269,840 records x \$360 = \$97,142,400

Table D - Cost Summary for Monitoring and Examinations					
Provision	Cost				
Exposure Monitoring \$8,799,072					
Biological Monitoring					
Lead and Zinc protoporphyrin levels	\$68,192,994				

⁶ Galson Laboratories, 2022. Sampling & Analysis Guide. Available at https://www.sgsgalson.com/sagdetail/std/Lead/7439-92-1/ (Accessed February 11, 2025). Averaged the cost of the five lead methods (Fee Per Sample) Analytical Technique – ICP/AES and Analytical Technique – ICP/MS.

⁷ FAIR Health, 2025. Medical Costs (Lead and Protoporphyrin (metabolism substance) for zip code 22201 Arlington, VA); available at https://www.fairhealthconsumer.org/medical# (Accessed February 15, 2025). For calculation purposes, the agency uses in-network service costs including doctor's fee and Hospital Outpatient Facility (HOSPF) estimates for each procedure code. In-Network Price for Lead Level (search CPT Code: 83655) is \$93.00 and for Protoporphyrin (metabolism substance) (search CPT Code 84202), the cost is \$105.00.

⁸ Upon further review of the 2023 ICR, the agency identified a miscalculation in the inflation rate for the CPI medical care services. The correct estimate for the inflation indicates a 13.1% increase between 2017 and 2021 in medical examination costs from \$298 to \$337, not the deflated by 3.3% to \$288. Based on this information, the current cost of medical exams is \$360 given inflation of 6.9% from 2021 to 2024 instead of the estimated rate of \$308.

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Table D - Cost Summary for Monitoring and Examinations					
Provision	Cost				
Blood sampling and analysis tests	\$36,098,480				
Medical Examinations	\$97,142,400				
Total \$210,232,946					

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

The agency has no annualized cost associated with enforcing the standard. OSHA would only review records in the context of an investigation of a particular employer to determine compliance with the standard. These activities are outside the scope of the PRA. *See* 5 CFR 1320.4(a)(2).

Furthermore, while NIOSH may use information collected from employers for research purposes, the agency does not anticipate that NIOSH will request employers to make available information during the approval period. Therefore, the burden for the employer to make this information available to NIOSH is zero.

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

The agency is requesting a burden hour adjustment increase of 116,099 hours (from 1,134,438 hours to 1,250,537 hours). The adjustment increase is due to an overall increase in the number of employers (56,906 to 60,569 employers) and an increase in the number of exposed workers (346,894 to 366,629 exposed workers), based on updated data.

The agency is requesting an adjustment cost increase of \$65,152,826 (from \$145,080,120 to \$210,232,946). The increase is mainly due to two factors: first, an increase in the number of employees receiving exposure monitoring, biological monitoring, and medical examinations; and second, an increase in costs to perform these exposure, biological, monitoring's and medical examinations as required by the standard.

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Table E – Summary of Burden Hours for the Collections of Information					
Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Adjustment		
A. Exposure Monitoring					
(1) Initial Exposure Measurement	0	0	0		
(2) Periodic Exposure Measurement	173,448	183,314	9,866		
(3) Employee Notification of Monitoring Results	9,934	10,095	161		
B. Written Compliance Programs	0	0	0		
C. Administrative Controls	1	1	0		
D. Respiratory Programs	0	0	0		
E. Notifying the Laundry	0	0	0		
F. Labeling of Contaminated Protective Clothing and Equipment	0	0	0		
G. Medical Surveillance					
(1) Biological Monitoring					
Biannual	173,448	183,315	9,867		
Monthly	52,035	54,996	2,961		
Every Two Months	80,826	85,425	4,599		
(2) Employee Notification					
Monthly	20,814	21,998	1,184		
Every Two Months	40,413	42,712	2,299		
(3) Medical Examinations and Consultat	tions				
At or Above the AL	203,280	214,846	11,566		
Initial	212,300	285,971	12,077		
Employee Signs and Symptoms	34,690	36,663	1,973		
Additional	2,082	2,200	118		
(4) Additional Physician Review	3,770	4,497	214		
(5) Information Provided to the Physician	18,848	22,487	1,072		
(6) Physician's Written Opinion	18,848	22,487	1,072		
(7) Chelation Notification	1	1	0		
H. Signs					
I. Recordkeeping	1				
(1) Exposure Monitoring Records	28,908	15,277	-13,631		
(2) Medical Surveillance Records	57,816	61,105	3,289		
(3) Medical Removal Records	87	92	5		
(4) Employee Access to Records	2,891	3,055	164		
TOTAL	1,134,438	1,250,537	116,099		

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

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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, 1914.4, 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.

There are no collections of information employing statistical methods.