SUPPORTING STATEMENT FOR THE COLLECTIONS OF INFORMATION IN THE REGULATION TITLED ACCESS TO EMPLOYEE EXPOSURE AND MEDICAL RECORDS (29 CFR 1910.1020)^{1, 2} Office of Management and Budget (OMB) Control No. 1218-0065 (February 2017)

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]

¹The purpose of this supporting statement is to analyze and describe the burden hours and costs associated with provisions of the Regulation that contain collections of information; this supporting statement does not provide information or guidance on how to comply with, or how to enforce the Regulation.

²The Construction, Shipyard Employment, Marine Terminals and Longshoring versions of this Regulation (29 CFR 1926.33, 29 CFR 1915.1020, 29 CFR 1917.1, 29 CFR 1918.1, respectively) incorporate 29 CFR 1910.1020 by reference.

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

Under the authority granted by the OSH Act, OSHA published a health regulation governing access to employee exposure-monitoring³ data and medical records⁴ at 29 CFR 1910.1020 (the "Regulation"). The Regulation does not require employers to collect any information or to establish any new systems of records. Rather, the Regulation requires that employers provide employers and their designated representatives with access to exposure-monitoring and medical records. In this regard, the Regulation specifies record-retention periods, record-access procedures, and employee-information requirements. The Agency attributes the burden hours and costs associated with conducting exposure monitoring and providing medical surveillance to the toxic-chemical standards that specify these activities; therefore, OSHA did not include these burden hours and costs in this information collection request (ICR).

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

The following are the collections of information contained in the Regulation, followed by discussions indicating how, by whom, and for what purpose the information is used for each of these requirements.

A. Preservation of Employee Records (§1910.1020(d))

 $\S1910.1020(d)(1)$ - Unless a specific occupational safety and health standard provides a different period of time, each employer shall assure the preservation and retention of records as follows:

§1910.1020(d)(1)(i) - Employee medical records. The medical record for each employee shall be preserved and maintained for at least the duration of employment plus thirty (30) years, except that the following types of records need not be retained for any specified period:

§1910.1020(d)(1)(i)(A) — Health insurance claims records maintained separately

³Paragraph (c)(5) of the Regulation defines an employee exposure record as: environmental (workplace) monitoring or measurement of a toxic substance or harmful physical agent; biological monitoring results; and material safety data sheets. In the absence of these items, exposure records include a chemical inventory or any other record that provides the identity of the toxic chemical or harmful physical agent (i.e., its chemical, common, or trade name), as well as the location and time of its use.

⁴Paragraph (c)(6) of the Regulation specifies that an employee medical record documents an employee's health status and includes the following items: medical and employment questionnaires or histories; the results of medical examinations and laboratory tests; medical opinions, diagnoses, progress notes, and recommendations; first-aid records; descriptions of treatments and prescriptions; and employee medical complaints. A physician, nurse, or other healthcare personnel or technician makes or maintains the record.

from the employer's medical program and its records,

§1910.1020(d)(1)(i)(B) — First aid records (not including medical histories) of one-time treatment and subsequent observation of minor scratches, cuts, burns, splinters, and the like which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job, if made on-site by a non-physician and if maintained separately from the employer's medical program and its records, and

§1910.1020(d)(1)(i)(C) - The medical records of employees who have worked for less than (1) year for the employer need not be retained beyond the term of employment if they are provided to the employee upon the termination of employment.

*§*1910.1020(*d*)(1)(*ii*) - Employee exposure records. Each employee exposure record shall be preserved and maintained for at least thirty (30) years, except that:

§1910.1020(d)(1)(ii)(A) - Background data to environmental (workplace) monitoring or measuring, such as laboratory reports and worksheets, need only be retained for one (1) year as long as the sampling results, the collection methodology (sampling plan), a description of the analytical and mathematical methods used, and a summary of other background data relevant to interpretation of the results obtained, are retained for at least thirty (30) years; and

§1910.1020(d)(1)(ii)(B) - Material safety data sheets and paragraph (c)(5)(iv) records concerning the identity of a substance or agent need not be retained for any specified period as long as some record of the identity (chemical name if known) of the substance or agent, where it was used, and when it was used is retained for at least thirty (30) years;⁵ and

§1910.1020(d)(1)(ii)(C) - Biological monitoring results designated as exposure records by specific occupational safety and health standards shall be preserved and maintained as required by the specific standard.

§1910.1020(d)(1)(iii) - Analyses using exposure or medical records. Each analysis using exposure or medical records shall be preserved and maintained for at least thirty (30) years.

§1910.1020(d)(2) - Nothing in this section is intended to mandate the form, manner, or process

⁵Material safety data sheets must be kept for those chemicals currently in use that are effected by the Hazard Communication Standard in accordance with 29 CFR 1910.1200(g).

by which an employer preserves a record as long as the information contained in the record is preserved and retrievable, except that chest X-ray films shall be preserved in their original state. **Purpose:** Exposure-monitoring and medical records are maintained principally to protect worker health, to assist in the prevention or early diagnosis of adverse health effects, and to provide valuable information to both workers and employers. The records also assist OSHA in enforcing the Regulation. Sound public policy mandates that employers afford workers with a meaningful opportunity to detect and resolve their occupationally-related health problems. This requirement provides employers, workers and their designated representatives with the information they need to detect, treat, and prevent occupational disease; thereby, permitting workers to become involved in their own health management.

B. Access to Records (§1910.1020(e))

General (§1910.1020(e)(1))

§1910.1020(e)(1)(i) - Whenever an employee or designated representative requests access to a record, the employer shall assure that access is provided in a reasonable time, place, and manner. If the employer cannot reasonably provide access to the record within fifteen (15) working days, the employer shall within the fifteen (15) working days apprise the employee or designated representative requesting the record of the reason for the delay and the earliest date when the record can be made available.

 $\S 1910.1020(e)(1)(iii)$ - Whenever an employee or designated representative requests a copy of a record, the employer shall assure that either:

§1910.1020(e)(1)(iii)(A) - A copy of the record is provided without cost to the employee or representative,

§1910.1020(e)(1)(iii)(B) - The necessary mechanical copying facilities (e.g., photocopying) are made available without cost to the employee or representative for copying the record, or

§1910.1020(e)(1)(iii)(C) - The record is loaned to the employee or representative for a reasonable time to enable a copy to be made.

Employee and designated representative access (§1910.1020(e)(2))

 $\S1910.1020(e)(2)(i)$ Employee exposure records.

\$1910.1020(e)(2)(i)(A) - Except as limited by paragraph (f) of this section, each employer shall, upon request, assure the access to each employee and designated

representative to employee exposure records relevant to the employee. For the purpose of this section, an exposure record relevant to the employee consists of:

<u>§1910.1020(e)(2)(i)(A)(1)</u> - A record which measures or monitors the amount of a toxic substance or harmful physical agent to which the employee is or has been exposed;

§1910.1020(e)(2)(i)(A)(2) - In the absence of such directly relevant records, such records of other employees with past or present job duties or working conditions related to or similar to those of the employee to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents to which the employee is or has been subjected, and

<u>§1910.1020(e)(2)(i)(A)(3)</u> - Exposure records to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents at workplaces or under working conditions to which the employee is being assigned or transferred.

§1910.1020(e)(2)(i)(B) - Requests by designated representatives for unconsented access to employee exposure records shall be in writing and shall specify with reasonable particularity:

 $\underline{\$1910.1020(e)(2)(i)(B)(1)}$ - The record requested to be disclosed; and

 $\underline{\$1910.1020(e)(2)(i)(B)(2)}$ - The occupational health need for gaining access to these records.

§1910.1020(e)(2)(ii) - Employee medical records

§1910.1020(e)(2)(ii)(A) - Each employer shall, upon request, assure the access of each employee to employee medical records of which the employee is the subject, except as provided in paragraph (e)(2)(ii)(D) of this section.

§1910.1020(e)(2)(ii)(B) - Each employer shall, upon request, assure the access of each designated representative to the employee medical records of any employee who has given the designated representative specific written consent. Appendix A to this section contains a sample form which may be used to establish specific written consent for access to employee medical records.

⁶This provision imposes no burden on employers since employers are not developing this information.

§1910.1020(e)(2)(ii)(C) - Whenever access to employee medical records is requested, a physician representing the employer may recommend that the employee or designated representative:

<u>§1910.1020(e)(2)(ii)(C)(1)</u> - Consult with the physician for the purposes of reviewing and discussing the records requested,

 $\underline{\$1910.1020(e)(2)(ii)(C)(2)}$ - Accept a summary of material facts and opinions in lieu of the records requested, or

<u>§1910.1020(e)(2)(ii)(C)(3)</u> - Accept release of the requested records only to a physician or other designated representative.⁷

§1910.1020(e)(2)(ii)(D) - Whenever an employee requests access to his or her employee medical records, and a physician representing the employer believes that direct employee access to information contained in the records regarding a specific diagnosis of a terminal illness or a psychiatric condition could be detrimental to the employee's health, the employer may inform the employee that access will only be provided to a designated representative of the employee having specific written consent, and deny the employee's request for direct access to this information only. Where a designated representative with specific written consent requests access to information so withheld, the employer shall assure the access of the designated representative to this information, even when it is known that the designated representative will give the information to the employee.

§1910.1020(e)(2)(iii) - Analyses using exposure or medical records.

 $\S1910.1020(e)(2)(iii)(A)$ - Each employer shall, upon request, assure the access of each employee and designated representative to each analysis using exposure or medical records concerning the employee's working conditions or workplace.

§1910.1020(e)(2)(iii)(B) - Whenever access is requested to an analysis which reports the contents of employee medical records by either direct identifier (name, address, social security number, payroll number, etc.) or by information which could reasonably be used under the circumstances indirectly to identify specific employees (exact age, height, weight, race, sex, date of initial employment, job title, etc.), the employer shall assure that personal identifiers are removed before access is provided. If the employer can demonstrate that removal of personal

⁷It is usual and customary for physicians to discuss medical records with workers or their representatives when disclosing medical records. The information in this paragraph would be part of the usual and customary discussions.

identifiers from an analysis is not feasible, access to the personally identifiable portions of the analysis need not be provided.

OSHA Access (§1910.1020(e)(3))

§1910.1020(e)(3)(i) - Each employer shall, upon request, and without derogation of any rights under the Constitution or the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.*, that the employer chooses to exercise, assure the prompt access of representatives of the Assistant Secretary of Labor for Occupational Safety and Health to employee exposure and medical records and to analyses using exposure or medical records. Rules of agency practice and procedure governing OSHA access to employee medical records are contained in 29 CFR 1913.10.

§1910.1020(e)(3)(ii) - Whenever OSHA seeks access to personally identifiable employee medical information by presenting to the employer a written access order pursuant to 29 CFR 1913.10(d), the employer shall prominently post a copy of the written access order and its accompanying cover letter for at least fifteen (15) working days.⁸

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 for disclosing information during an inspection.

Purpose: Access to exposure and medical information enables workers and their designated representatives to become directly involved in identifying and controlling occupational health hazards, as well as managing and preventing occupationally-related health impairment and disease. Accordingly, workers and their designated representatives can use exposure-monitoring and medical-surveillance records to investigate the possible causes of worker health impairment and disease. These records allow them to determine the association between specific adverse health effects and occupational exposure to toxic chemicals. If they find such an association, they can take action to control their exposure to toxic chemicals and harmful physical agents through the use of respirators, protective work clothing, hygiene measures (i.e., showers, hand and face washing before eating), and work practices that minimize dispersal of these hazards in the workplace (i.e., immediately storing dust-laden scrap material in closed containers). Implementing these controls also depends in large measure on worker cooperation. Cooperation is most likely if workers know the identity of toxic chemicals or harmful physical agents in the workplace, the magnitude of their exposure to these hazards, and the possible health effects of such exposure.

⁸Posting a copy of the written access order is not considered a collection of information requirement since "the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure is not included in this definition" (5 CFR 1320.3(c)(1)). The term "definition" used in this statement refers to a collection of information.

Exposure-monitoring and medical-surveillance records permit a worker's physician to diagnose, treat, and possibly prevent permanent health impairment. Accordingly, a physician can compare medical information collected at the start of employment with a worker's current health status and, having the worker's exposure history available, determine if any health impairment involves the worker's occupational exposure to toxic chemicals.

Access to, and long-term maintenance of, exposure and medical records also facilitates occupational-health research. Workers and their designated representative can make the exposure and medical information in these records available to public and private organizations and to scientists for epidemiological research. This research can determine if a significant relationship exists between worker exposure to toxic chemicals and harmful physical agents and health impairments and disease.

C. Trade Secrets (§1910.1020(f))

\$1910.1020(f)(1) - Except as provided in paragraph (f)(2) of this section, nothing in this section precludes an employer from deleting from records requested by a health professional, employee, or designated representative any trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in mixture, as long as the health professional, employee, or designated representative is notified that information has been deleted. Whenever deletion of trade secret information substantially impairs evaluation of the place where or the time when exposure to a toxic substance or harmful physical agent occurred, the employer shall provide alternative information which is sufficient to permit the requesting party to identify where and when exposure occurred.

 $\S1910.1020(f)(2)$ - The employer may withhold the specific chemical identity, including the chemical name and other specific identification of a toxic substance from a disclosable record provided that:

 $\S1910.1020(f)(2)(i)$ - The claim that the information withheld is a trade secret can be supported;

 $\S1910.1020(f)(2)(ii)$ - All other available information on the properties and effects of the toxic substance is disclosed;

 $\S 1910.1020(f)(2)(iii)$ - The employer informs the requesting party that the specific chemical identity is being withheld as a trade secret; and

§1910.1020(f)(2)(iv) - The specific chemical identity is made available to health professionals, employees and designated representatives in accordance with the specific

applicable provisions of this paragraph.

 $\S1910.1020(f)(3)$ - Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity of a toxic substance is necessary for emergency or first-aid treatment, the employer shall immediately disclose the specific chemical identity of a trade secret chemical to the treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (f)(4) and (f)(5), as soon as circumstances permit.

 $\S1910.1020(f)(4)$ - In non-emergency situations, an employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under paragraph (f)(2) of this section, to a health professional, employee, or designated representative if:

 $\S1910.1020(f)(4)(i)$ - The request is in writing;

 $\S1910.1020(f)(4)(ii)$ - The request describes with reasonable detail one or more of the following occupational health needs for the information:

§1910.1020(f)(4)(ii)(A) - To assess the hazards of the chemicals to which employees will be exposed;

§1910.1020(f)(4)(ii)(B) - To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

\$1910.1020(f)(4)(ii)(C) - To conduct pre-assignment or periodic medical surveillance of exposed employees;

§1910.1020(f)(4)(ii)(D) - To provide medical treatment to exposed employees;

§1910.1020(f)(4)(ii)(E) - To select or assess appropriate personal protective equipment exposed employees;

§1910.1020(f)(4)(ii)(F) - To design or assess engineering controls or other protective measures for exposed employees; and

§1910.1020(f)(4)(ii)(G) - To conduct studies to determine the health effects of exposure.

 $\S1910.1020(f)(4)(iii)$ - The request explains in detail why the disclosure of the specific

⁹This request is being provided to the employer, not generated by the employer; therefore the collection of information is not applicable to the respondents in this ICR; the only burden is for the employer to maintain the request.

chemical identity is essential and that, in lieu thereof, the disclosure of the following information would not enable the health professional, employee or designated representative to provide the occupational health services described in paragraph (f)(4) (ii) of this section;

§1910.1020(f)(4)(iii)(A) - The properties and effects of the chemical;

§1910.1020(f)(4)(iii)(B) - Measures for controlling workers' exposure to the chemical;

 $\S1910.1020(f)(4)(iii)(C)$ - Methods of monitoring and analyzing worker exposure to the chemical; and

§1910.1020(f)(4)(iii)(D) - Methods of diagnosing and treating harmful exposures to the chemical;

 $\S1910.1020(f)(4)(iv)$ - The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and

 $\S1910.1020(f)(4)(v)$ - The health professional, employee, or designated representative and the employer or contractor of the services of the health professional or designated representative agree in a written confidentiality agreement that the health professional, employee or designated representative will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (f)(7) of this section, except as authorized by the terms of the agreement or by the employer.

 $\S1910.1020(f)(5)$ - The confidentiality agreement authorized by paragraph (f)(4)(iv) of this section:

 $\S1910.1020(f)(5)(i)$ - May restrict the use of the information to the health purposes indicated in the written statement of need;

§1910.1020(f)(5)(ii) - May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

 $\S1910.1020(f)(5)(iii)$ - May not include requirements for the posting of a penalty bond.

 $\S1910.1020(f)(7)$ - If the health professional, employee or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the employer

who

provided the information shall be informed by the health professional prior to, or at the same time as, such disclosure.

 $\S1910.1020(f)(8)$ - If the employer denies a written request for disclosure of a specific chemical identity, the denial must:

 $\S1910.1020(f)(8)(i)$ - Be provided to the health professional, employee or designated representative within thirty days of the request;

 $\S1910.1020(f)(8)(ii)$ - Be in writing;

§1910.1020(f)(8)(iii) - Include evidence to support the claim that the specific chemical identity is a trade secret;

 $\S1910.1020(f)(8)(iv)$ - State the specific reasons why the request is being denied; and,

 $\S1910.1020(f)(8)(v)$ - Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the specific chemical identity.

§1910.1020(f)(11)(ii) - If an employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health needs are met without an undue risk of harm to the employer.

§1910.1020(f)(12) - Notwithstanding the existence of a trade secret claim, an employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

<u>**Purpose**</u>: The basic need for information on a chemical is to better assist a physician to diagnose a medical condition. Trade secret claims have long been used in industry where information, if disclosed, could jeopardize the competitive edge the manufacturer may have.

The provisions regarding trade secrets in 1910.1020 state that trade secrets must be revealed whenever it is requested by a health professional, a worker, and a designated representative.

Both in emergencies and non-emergencies it may be necessary to gain this information. These provisions provide the means to request this information from the manufacturer or the employer.

D. Employee Information (§1910.1020(g))

 $\S1910.1020(g)(1)$ - Upon an employee's first entering into employment, and at least annually thereafter, each employer shall inform current employees covered by this section of the following:

 $\S1910.1020(g)(1)(i)$ - The existence, location, and availability of any records covered by this section;

 $\S1910.1020(g)(1)(ii)$ - The person responsible for maintaining and providing access to records; and

 $\S1910.1020(g)(1)(iii)$ - Each employee's rights of access to these records.

 $\S1910.1020(g)(2)$ - Each employer shall keep a copy of this section and its appendices, and make copies readily available, upon request, to employees. The employer shall also distribute to current employees any informational materials concerning this section which are made available to the employer by the Assistant Secretary of Labor for Occupational Safety and Health. ¹⁰

<u>Purpose</u>: The requirements of this provision reinforce the overall purpose of the Regulation to enable workers to use exposure-monitoring and medical-surveillance records to investigate the possible causes of health impairment and disease. These records allow workers to determine the association between occupationally-related impairments and disease, and workplace exposure to toxic chemicals and harmful physical agents. This determination will enable workers to effectively treat these effects and to prevent such effects by controlling their exposure to these hazards.

E. Transfer of Records (§1910.1020(h))

§1910.1020(h)

¹⁰Employers maintaining a copy of the Regulation, and making copies readily available, upon request, to employees, and distributing to current employees any informational materials concerning this Regulation which are made available to the employer by the Assistant Secretary of Labor for Occupational Safety and Health are exempt from the definition of a collection of information since "the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure is not included in this definition" (5 CFR 1320.3(c)(1)).

The employer shall comply with the requirements involving 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.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Employers may use improved information technology when establishing and maintaining exposure-monitoring and medical-surveillance records. Given the length of time employers must maintain employee exposure-monitoring and medical records, and changing technology, employers must ensure that electronic records can always be accessed and copied. OSHA wrote the paperwork requirements of the Regulation 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 used or modified for use for the purposes described in Item A.2 above.

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

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

The collection of information requirements of the Regulation 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 regulation only controls preservation of, and access to, exposure-monitoring and medical-surveillance records; it does not directly require the collection of the exposure and medical information. Providing workers, their designated representatives, healthcare providers, and occupational-health researchers with access to these historical records enables them to: identify toxic chemicals and harmful physical agents used in the workplace; control worker exposure to these health hazards; and treat and prevent the occupationally-related health impairment and disease that result from hazardous exposures. Accordingly, the regulation helps to fulfill the principal objective of the OSH Act (i.e., "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions") by augmenting the requirements of its substance-specific standards. Therefore, the Agency believes that any reduction in the requirements of the regulation would seriously interfere with the stated objective of the OSH Act.

- 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, grantin-aid, or tax records for more than three years;
 - in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
 - requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
 - that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent

with

the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

• requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

No special circumstances exist that require employers to collect information in the manner, or using the procedures, described in this item.

8. If applicable, provide a copy and identify the data and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8 (d), soliciting comments on the information

collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years, even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

As required by the Paperwork Reduction Act (44 U.S.C. 3506(c)(2)(A)), OSHA published a notice in the Federal Register soliciting comments from the public and other interested parties on the collections of information contained in the Access to Employee Exposure and Medical Records Standard (29 CFR 1910.1020) (Docket No. OSHA-2009-0043). The notice was part of a preclearance consultation program that provided interested parties with 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 Standard. The Agency received no public comments on the notice.

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

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

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

Since 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 Act, 29 U.S.C. 657.

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.

None of the provisions in the regulation require the collection of sensitive information.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- Indicate the number of respondents, frequency of response, annual hour burden, and an
 explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct
 special surveys to obtain information on which to base hour burden estimates.
 - Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.
 - If this request for approval covers more than one form, provide separate hour burden estimate for estimates for each form and aggregate the hour burdens.
- Provide estimates of annualized cost to respondents for the hour burdens for collection of information, identifying and using appropriate wage rate categories. The cost of contracting out of paying outside parties for information should not be included here. Instead this cost should be included in Item 13.

Summary of Burden-Hour and Cost Estimates

Estimating the Number of Employers Affected by the Regulation

Based on the U.S. Census Bureau's 2013 County Business Patterns, the Agency estimates that 5,140,864 establishments are in North American Industrial Classification System (NAICS) codes that are covered by the Regulation. The Agency estimated that 18.6% (956,201) of the total number of establishments collect exposure-monitoring and/or medical information. The Agency estimated that 24% (229,488)¹¹ of these employers developed their medical-surveillance programs and exposure monitoring records to comply with OSHA's substance-specific standards. Burden hours and costs for medical surveillance and exposure monitoring contained in substance-specific standards are accounted for in their corresponding information collection requests. Accordingly, the Agency removed these employers from further analysis, resulting in an estimated total number of 726,713 employers affected by the Regulation.

The Ionizing Radiation (IR) Standard (29 CFR 1910.1096) does not specify access requirements in the Standard; therefore, burden hours and costs were not included in the Information Collection Request (OMB Control Number 1218-0103). The IR Standard covers an estimated 12,719 establishments. These establishments are included in this analysis, resulting **in a total of 739,432 employers covered by this ICR** (726,713 employers affected by the Regulation) + (12,719 employers affected by the IR Standard).

Wage Rates

^{11&}quot;The Description and Evaluation of Medical Surveillance Programs in General Industry and Construction Final Report," prepared by OSHA's Office of Regulatory Analysis, July 1993.

The following mean wage rates from the *Occupational Employment Statistics May 2015 National Industry-Specific Occupational Employment and Wage Estimates.* To account for fringe benefits, we used the fringe benefit rate reported in BLS' Employer Costs for Employee Compensation (ECEC) news release for December 2015 (BLS, 2016). BLS reported that for private industry, fringe benefits accounted for 31.3 percent of total compensation and wages accounted for the remaining 68.7 percent. To calculate the loaded hourly wage for each occupation, thus we divide the mean hourly wage by 68.7 percent. The cost of labor used in this analysis is, therefore, an estimate of total hourly compensation.

Professional/Manager \$83.61 (11-1021)¹³ Clerical/Secretary \$24.63 (43-6014)¹³

Burden-Hour and Cost Determinations

The following sections summarize the methodology used for estimating the number of burden hours and costs resulting from the collections of information of the Regulation. The Regulation applies to employers whether or not other OSHA standards mandate preservation of, and access to, exposure-monitoring and medical-surveillance records. The Agency accounts for the burden hours and costs associated with the record-preservation and record-access requirements of these other standards in the ICRs for those standards; the exception is the burden hours and costs of the recordkeeping and record-access provisions of the IR Standard, which OSHA includes with this ICR.

(A) Preservation of records (§1910.1020(d))

The Regulation requires employers to maintain worker exposure-monitoring and medical-surveillance records and analyses for at least 30 years. However, for those workers who work less than one year for an employer, the employer is not required to retain the medical records if they are provided to the worker upon termination of employment. OSHA has no specific data concerning the hours required for these record-preservation activities. Therefore, OSHA

¹² Source: http://www.bls.gov/oes/current/oes nat.htm.

¹³ This mean hourly wage rate corresponds to SOC code 11-1021,"General and Operations Managers." (Source: *May 2015 National Occupational Employment and Wage Estimates, United States*, U.S. Department of Labor, Bureau of Labor Statistics; http://www.bls.gov/oes/current/oes_nat.htm.)

¹³ This mean hourly wage rate corresponds to SOC code 43-6014,"Secretaries and Administrative Assistants Except Legal, Medical and Executive."(Source: *May 2015 National Occupational Employment and Wage Estimates, United States*, U.S. Department of Labor, Bureau of Labor Statistics; http://www.bls.gov/oes/current/oes nat.htm.)

assumes that a clerical employee (at a wage rate of \$24.63 per hour) spends 10 minutes (.17 hour) each year maintaining these records for each employer. The annual burden hour and cost estimates for this provision are:

Burden hours: 739,432 employers x .17 hour = 125,703 hours

Cost: 125,703 hours x \$24.63 = \$3,096,065

(B) Access to records (§1910.1020(e))

Access by employees and their designated representatives

Paragraph (e) requires that employers provide workers and their designated representatives, on request, with access to worker exposure-monitoring and medical-surveillance records, as well as any analyses of these records. If an employer cannot provide workers or their designated representatives' access to records within 15 days, the employer must provide the reasons for the delay to workers, or their designated representatives. Also, employers may need to remove worker identifiers from analytical medical records. Finally, under certain circumstances, employers may inform workers that access will only be provided to a designated representative of the worker having specific written consent.

OSHA has no data on the number of access requests made by workers and their designated representatives and, therefore, assumes that each employer will receive two such requests each year, and that a manager takes 5 minutes (.08 hour) to appropriately respond to the request, including retrieving and, if necessary, copying the records. The annual burden hour and cost estimates for this paragraph are:

Burden hours: 739,432 employers x 2 requests x .08 hour = 118,309 hours

Cost: 118,309 hours x \$83.61 = \$9,891,815

Written Authorization

Appendix A, "Sample Authorization Letter for the Release of Employee Medical Record Information to a Designated Representative (Non-Mandatory)" of the standard contains a sample letter which may be used by workers to establish specific written consent for access to employee medical records. OSHA has no data on the number of workers who would provide written consent for this purpose. Therefore, the Agency assumes that 1% of access requests (calculated in the equation above) would involve written authorization consent documentation.

Burden hours: $(739,432 \text{ employers } \times 2 \text{ requests}) \times 1\% \times .08 \text{ hour} = 1,183 \text{ hours}$

Cost: 1,183 hours x \$83.61 = \$98,911

(C) Trade secrets (§1910.1020(f))

Paragraph (f) contains several collections of information addressing when employers must modify, or withhold, information regarding trade-secret information (including the specific chemical identity). Such collections of information include: providing alternative information to workers or the designated representative when trade-secret information is not provided; an explanation of why trade-secret information or specific information is being withheld; information denying a written request for disclosure; written confidentiality agreements between employers and/or health professionals, workers, or designated representatives; and disclosing the information to OSHA.

OSHA assumes that 10% of employers must respond to a trade-secret request, and estimates that a manager (at a wage rate of \$83.61 per hour) requires one hour to prepare the necessary documentation, depending upon the circumstances involved in developing or disclosing the trade-secret information. The annual burden hour and cost estimates for this provision are:

Burden hours: 739,432 employers x 10% x 1 hour = 73,943 hours

Cost: 73,943 hours x \$83.61 = \$6,182,374

(D) Employee information (§1910.1020(g))

When workers first enter employment, and at least annually thereafter, employers must notify them of: the existence, location, and availability of any records covered by the regulation; who is responsible for maintaining and providing access to these records; and the workers' right to access their personnel records. OSHA estimates that a professional takes the following times to provide the required information: 5 minutes (.08 hour) for each new worker; and 10 minutes (.17 hour) during a single session for all of an employer's existing workers (for a total of 739,432 single sessions for 739,432 employers). Based on available data regarding new workers, the Agency assumes that employers must notify 3,367,771 new workers of this information each year, or to 4.554537 new employees per employer. The annual burden hour and cost estimates for this provision are:

Burden hours: (739,432 employers x 4.554537 new workers) x .08 hour = 269,422 hours) + <math>(739,432 single sessions for existing workers x .17 hour = 269,422 hours)

125,703 hours) = 392,125 hours

Cost: 392,125 hours x \$83.61 = \$33,036,401

(E) Transfer of records (§1910.1020(h))

Whenever an employer ceases to do business, paragraph (h)(1) of the Regulation requires the employer to transfer all records covered by the Regulation to the successor employer. This

paragraph requires employers who cease doing business and have no successor employer to: notify current workers who have records covered by the Regulation of their right to access these records, and to do so prior to cessation of business.

For purposes of informing workers of their right to access their records when the employer is ceasing business, OSHA assumes 5% of the 739,432 establishments will cease business each year, and a manager will take 5 minutes (.08 hour) to inform workers of their rights to access their medical and exposure-monitoring records.

Burden hours: 739,432 establishments x .05 x .08 hour = 2,958 hours **Cost**: 2,958 hours x \$83.61 = \$247,318

The following table provides a summary of the burden hours and cost estimates for the collections of information of the Regulation, and described above.

¹⁴ Based on ratios of employees to establishments in earlier ICRs, OSHA estimates there are 10.63 employees per establishment covered by the Regulation. Multiplying this figure by the total number of covered establishments (726,713), yields a total of 7,724,959 employees. To this total, the Agency added 17,043 employees for establishments covered by the Ionizing Radiation (IR) Standard, assuming 1.34 employees for each of the 12,719 establishments covered by the IR Standard. OSHA then multiplied the total number of employees covered by both the Regulation and the IR Standard (7,742,002) by an assumed turnover rate of 43.5% (Hires Rate, total Nonfarm—JOLTS, Bureau of Labor Statistics, 2015), resulting in a total of 3,367,771 new employees each year.

Table A12 - Estimated Annualized Respondent Burden Hours and Costs

Collections of Information	No. of Respondents	No. of Responses per Respondent		Avg, Burden per Response (in Hrs.)	Total Burden Hours	Mean Wage Rate ⁽¹³⁾	Total Burden Costs
RECORDKEEPING							
A. Preservation of Records	739,432	1	739,432	.17	125,703	24.63	\$3,096,065
3 RD PARTY NOTIFICATION							
B. Access to Records							
B.1. Access by employees/ designated representatives	739,432	2	1,478,864	.08	118,309	83.61	\$9,891,815
B.2. Written Authorization	7,394	2	1,183	.08	1,183	83.61	\$98,911
Total for B.			1,480,047		119,492		9,990,726
C. Trade Secrets	73,943	1	73,943	1	73,943	83.61	\$6,182,374
D. Employee Information							
D.1. New	739,432	4.554537	3,367,771	.08	269,422	83.61	\$22,526,373
D.2. Existing	739,432	1	739,432	.17	125,703	83.61	\$10,510,028
Total for D.			4,107,203		395,125	83.61	\$33,036,401
E. Transfer of Records	36,972	1	36,972	.08	2,958	83.61	\$247,318
Grand Totals			6,437,597		717,221		\$52,552,884

- 13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14.)
- The cost estimate should be split into two components: (a) A total capital and start-up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparation 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.

There are no additional costs to the respondents other than their time. . .

14. Provide estimates of the 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 Item 14 of this Supporting Statement for disclosing information during an inspection.

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

Table 1
Summary of Burden Hours and Costs Adjustments

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Total Adjusted Burden Hours
A. Preservation of Records	129,144	125,703	-3,441
B. Access to Records	127,146	119,492	-7,654
C. Trade Secrets	75,967	73,943	-2,024
D. Employee Information	395,219	395,125	-94
E. Transfer of Records	3,039	2,958	-81
Totals	730,515	717,221	-13,294

The Agency is requesting an adjustment decrease of 13,294 burden hours from 730,515 to 717,221 hours. This decrease is the result of an adjustment of the number of establishments used in this analysis based on updated data. The total estimated number of establishments affected by the regulation decreased from 759,668 to 739,432, a total adjustment of 20,236 less establishments. The Agency identified 1,183 burden hours associated with employees who choose to use the Sample Authorization Letter for the Release of Employee Medical Record Information to a Designated Representative (Non-Mandatory Appendix A), or other written means. The total burden hour decrease is partially offset by the newly-identified written authorization burden hours.

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

OSHA will not publish the information collected under the Regulation.

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.

There is a sample letter displaying the OMB Control Number and burden statement.

18. Explain each exception to the certification statement.

OSHA is not seeking an exception to the certification statement.

B. COLLECTIONS OF INFORMATON EMPLOYING STATISTICAL METHODS

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