

**SUPPORTING STATEMENT FOR THE
INFORMATION COLLECTION REQUIREMENTS 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(2007))**

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

¹The purpose of this supporting statement is to analyze and describe the burden hours and costs associated with provisions of the Regulation that contain paperwork requirements; 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.

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 collection of information requirements as stated 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))*

§1910.1020(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 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

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.

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.

Purpose: Exposure-monitoring and medical records are maintained principally to protect employee health, to assist in the prevention or early diagnosis of adverse health affects, and to provide valuable information to both employees and employers. The records also assist OSHA in enforcing the Regulation. Sound public policy mandates that employers afford employees with a meaningful opportunity to detect and resolve their occupationally-related health problems. This requirement provides employers, employees and their designated representatives with the information they need to detect, treat, and prevent occupational disease, thereby permitting employees to become involved in their own health management.

B. Access to Records (§1910.1020(e))

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).

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.

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

§1910.1020(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:

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

§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

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

§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:

§1910.1020(e)(2)(i)(B)(1) - The record requested to be disclosed; and

§1910.1020(e)(2)(i)(B)(2) - The occupational health need for gaining access to these records.⁶

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

§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.

§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:

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

§1910.1020(e)(2)(ii)(C)(2) - Accept a summary of material facts and opinions in lieu of the records requested, or

§1910.1020(e)(2)(ii)(C)(3) - 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.

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

§1910.1020(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 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

Purpose: Access to exposure and medical information enables employees 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, employees and their designated representatives can use exposure-monitoring and medical-surveillance records to investigate the possible causes of employee 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 employee

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.

cooperation. Cooperation is most likely if employees 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.

Exposure-monitoring and medical-surveillance records permit an employee'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 an employee's current health status and, having the employee's exposure history available, determine if any health impairment involves the employee's occupational exposure to toxic chemicals.

Access to, and long-term maintenance of, exposure and medical records also facilitates occupational-health research. Employees 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 employee 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.

§1910.1020(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:

§1910.1020(f)(2)(i) - The claim that the information withheld is a trade secret can be supported;

§1910.1020(f)(2)(ii) - All other available information on the properties and effects of the toxic substance is disclosed;

§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.

§1910.1020(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.

§1910.1020(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:

§1910.1020(f)(4)(i) - The request is in writing;⁹

§1910.1020(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 for 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.

§1910.1020(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;

§1910.1020(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;

§1910.1020(f)(4)(iv) - The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and

§1910.1020(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.

§1910.1020(f)(5) - The confidentiality agreement authorized by paragraph (f)(4)(iv) of this section:

§1910.1020(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,

§1910.1020(f)(5)(iii) - May not include requirements for the posting of a penalty bond.

§1910.1020(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.

§1910.1020(f)(8) - If the employer denies a written request for disclosure of a specific chemical identity, the denial must:

§1910.1020(f)(8)(i) - Be provided to the health professional, employee or designated representative within thirty days of the request;

§1910.1020(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;

§1910.1020(f)(8)(iv) - State the specific reasons why the request is being denied; and,

§1910.1020(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.

Purpose: 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, and employee, 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))

§1910.1020(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:

§1910.1020(g)(1)(i) - The existence, location, and availability of any records covered by this section;

§1910.1020(g)(1)(ii) - The person responsible for maintaining and providing access to records; and

§1910.1020(g)(1)(iii) - Each employee's rights of access to these records.

§1910.1020(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

Purpose: The requirements of this provision reinforce the overall purpose of the Regulation to enable employees to use exposure-monitoring and medical-surveillance records to investigate the possible causes of health impairment and disease. These records allow employees to determine the association between occupationally-related impairments and disease, and workplace exposure to toxic chemicals and harmful physical agents. This determination will enable employees 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)(1) - Whenever an employer is ceasing to do business, the employer shall transfer all records subject to this section to the successor employer. The successor employer shall receive and maintain these records.

§1910.1020(h)(2) - Whenever an employer is ceasing to do business and there is no successor employer to receive and maintain the records subject to this standard, the employer shall notify affected current employees of their rights of access to records at least three (3) months prior to the cessation of the employer's business.

§1910.1020(h)(3) - Whenever an employer either is ceasing to do business and there is no successor employer to receive and maintain the records, or intends to dispose of any records required to be preserved for at least thirty (30) years, the employer shall:

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)).

§1910.1020(h)(3)(i) - Transfer the records to the Director of the National Institute for Occupational Safety and Health (NIOSH) if so required by a specific occupational safety and health standard; or

§1910.1020(h)(3)(ii) - Notify the Director of NIOSH in writing of the impending disposal of records at least three (3) months prior to the disposal of the records.

§1910.1020(h)(4) - Where an employer regularly disposes of records required to be preserved for at least thirty (30) years, the employer may, with at least (3) months notice, notify the Director of NIOSH on an annual basis of the records intended to be disposed of in the coming year.

Purpose: These provisions stipulate requirements for preserving exposure-monitoring and medical-surveillance records if an employer ceases to do business, thereby ensuring that these records are available for review and analysis by employees, their designated representatives, healthcare providers, and researchers. In this regard, NIOSH may use these records for assessing the medical effects of long-term employee exposure to toxic chemicals and harmful physical agents. By having NIOSH serve as a backup repository for exposure-monitoring and medical-surveillance records, these provisions ensure that these records will be available for analytic purposes and for developing treatment and prevention strategies.

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 2 above.

The requirements to maintain information are specific to each employer and employee 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 (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

The information collection 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 employees, 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 employee 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, grant-in-aid, or tax records for more than three years;
- in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

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 of 1995 (U.S.C. 3506(c)(2)(A)), OSHA published a *Federal Register* notice on February 15, 2007 (72 FR 7465, Docket No. 2007-0009) requesting public comment on its proposed extension of the information collection requirements contained in the Regulation. This notice was part of a preclearance consultation program to provide interested parties the opportunity to comment on OSHA's request for an extension by OMB of a previous approval of the information collection requirements found in the Regulation. The Agency received no comments in response to its notice.

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

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

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

To ensure that the personal information contained in medical records remains confidential, OSHA developed 29 CFR 1913.10 to regulate access to these records.

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 in Item 13 of OMB Form 83-I.
- 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.

Summary of Burden-Hour and Cost Estimates

The following table provides a summary of the burden-hours and cost estimates for the collection-of-information requirements of the Regulation, and described in Item 12 of this ICR.

Table 1
Summary of Burden Hours and Costs

| Information Collection Requirement | Current Burden Hours | Requested Burden Hours | Change (Adjustments) | Estimated Costs |
|------------------------------------|----------------------|------------------------|-----------------------|---------------------|
| A. Preservation of Records | 121,936 | 124,919 | 2,983 | \$2,640,788 |
| B. Access to Records | 120,586 | 123,386 | 2,800 | \$6,096,502 |
| C. Trade Secrets | 71,727 | 73,482 | 1,755 | \$3,630,746 |
| D. Employee Information | 244,189 | 395,461 | 151,272 | \$19,539,728 |
| E. Transfer of Records | 2,870 | 2,939 | 69 | \$145,216 |
| Totals | 561,308 | 720,187 | 158,879 | \$32,052,980 |

Estimating the Number of Employers Affected by the Regulation

Based on the *2002 Economic Census: County Business Patterns for United States*, the Agency estimates that 5,108,244 establishments are in North American Industrial Classification System (NAICS) codes that are covered by the Regulation. The Agency estimated that 18.6% (950,133) of the total number of establishments collect exposure-monitoring and/or medical information. The Agency estimated that 24% (228,038)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 of number of 722,101 employers affected by the Regulation.

¹¹“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 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 (29 CFR 1910.1096) covers an estimated 12,719 establishments. These establishments are included in this analysis, resulting in a total of 734,820 employers (722,101 (employers affected by the Regulation) + 12,719 (employers affected by the IR Standard)).

Wage Rates

The Agency adopted the mean wage rates from *Employer Costs for Employee Compensation, March 2006, U.S. Department of Labor, Bureau of Labor Statistics, Table 2, <http://stats.bls.gov/home.htm>*. Total compensation for these occupational categories includes an adjustment of 29.4 percent (*Employer Costs for Employee Compensation Summary, March 2006*) for fringe benefits; this figure represents the average level of fringe benefits in the private sector. The costs of labor used in this analysis are, therefore, estimates of total hourly compensation. These hourly wages are:

| | |
|----------------------|---------|
| Professional/Manager | \$49.41 |
| Clerical/Secretary | \$21.14 |

Burden-Hour and Cost Determinations

The following sections summarize the methodology used for estimating the number of burden hours and costs resulting from the information collection requirements 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 employee exposure-monitoring and medical-surveillance records and analyses for at least 30 years. However, for those employees 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 employee upon termination of employment. OSHA has no specific data concerning the hours required for these record-preservation activities. Therefore, OSHA assumes that a secretary (at a wage rate of \$21.14 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: 734,820 employers x .17 hour = 124,919 hours

Cost: 124,919 hours x \$21.14 = \$2,640,788

(B) Access to records (§1910.1020(e))

Access by employees and their designated representatives

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

OSHA has no data on the number of access requests made by employees 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: 734,820 employers x 2 requests x .08 hour = 117,571 hours

Cost: 117,571 hours x \$49.41 = \$5,809,183

OSHA access

Under paragraph (e)(3) of the Regulation, employers must provide OSHA with prompt access to employee exposure-monitoring and medical-surveillance records, and to any analyses associated with these records. Currently, the Agency makes a request for these records and analyses during an inspection of an employer's facility. In FY 2005, Federal OSHA and state-plan occupational safety and health agencies conducted 96,279 (Federal OSHA, 38,816 inspections, and State-plan inspections, 57,463) such inspections. OSHA takes burden hours and costs for employers providing access to these records in the Information Collection Request for each of its health standards; accordingly, OSHA subtracted 23,588 inspections from 96,279 inspections to avoid double counting the burden hours and costs. Therefore, OSHA will request access to records under the Regulation in 72,691 inspections. OSHA estimates that a manager, at a wage rate of \$49.41 an hour, takes 5 minutes (.08 hour) to provide an OSHA compliance officer with access to employee exposure-monitoring and medical-surveillance records, and associated analyses. The annual burden-hour and cost estimates for this requirement are:

Burden hours: 72,691 inspections x .08 hour = 5,815 hours

Cost: 5,815 hours x \$49.41 = \$287,319

In summary, the total burden hours and costs for employers to provide employees, their designated representatives, and OSHA with access to these records are:

Burden hours: 117,571 hours (access by employees and their designated representatives) + 5,815 hours (OSHA access) = 123,386 hours

Cost: \$5,809,183 (access by employees and their designated representatives) + \$287,319 (OSHA access) = \$6,096,502

(C) Trade secrets (§1910.1020(f))

Paragraph (f) contains several collection of information requirements addressing when employers must modify, or withhold information regarding, trade-secret information (including the specific chemical identity). Such collection of information requirements include: providing alternative information to employees 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, employees, 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 \$49.41 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: 734,820 employers x 10% x 1 hour = 73,482 hours

Cost: 73,482 hours x \$49.41 = \$3,630,746

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

When employees 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 employees' 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 employee; and 10 minutes (.17 hour) during a single session for all of an employer's existing employees (for a total of 734,820 single sessions for 734,820 employers). Based on available data regarding new employees, the Agency assumes that employers must notify 3,381,774 new employees of this information each year.¹² The annual burden-hour and cost estimates for this provision are:

¹²OSHA determined the total number of new employees each year by assuming 10.63 employees for each establishment covered by the Regulation, and multiplying this figure by the total number of covered establishments (734,820), for a total of 7,811,137 employees. To this total, the Agency added 17,073 employees for establishments covered by the Ionizing Radiation (IR) Standard, assuming 1.34 employees for each of the

Burden hours: (3,381,774 new employees x .08 hour = 270,542 hours) +
(734,820 single sessions for existing employees x .17 hour =
124,919 hours) = 395,461 hours

Cost: 395,461 hours x \$49.41 = \$19,539,728

(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 employees who have records covered by the Regulation of their right to access these records, and to do so prior to cessation of business; transfer the records to the National Institute for Occupational Safety and Health (NIOSH) if so required by another OSHA standard; and provide NIOSH with written notice of the impending disposal of records that the Regulation requires the employer to maintain for at least 30 years, and to do so at least 3 months prior to such disposal.

Employers who cease doing business within the period specified for retaining the records, and who have no successor employer, must transmit these records to NIOSH if so requested by NIOSH. Employers who remain in business for the entire retention period must, before disposing of these records, notify NIOSH in writing of the impending disposal, and transfer the records to NIOSH if it requests the records within 3 months of being so notified.

NIOSH does not request employers to transfer records to them under 29 CFR 1910.1020. Therefore, there are no burden hours or cost for transfer of records.

For purposes of informing employees of their right to access their records when the employer is ceasing business, OSHA assumes 5% of the 734,820 establishments will cease business each year, and a manager will take 5 minutes (.08 hour) to inform employees of their rights to access their medical and exposure-monitoring records.

Burden hours: 734,820 establishments x .05 x .08 hour = 2,939 hours

Cost: 2,939 hours x \$49.41 = \$145,216

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**

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 (7,828,137) by an assumed turnover rate of 43.2%, resulting in a total of 3,381,774 new employees each year.

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.

Item 12 above provides the total cost of the information collection requirements specified by 29 CFR 1910.1020.

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.

The Federal government incurs costs when, as required by paragraph (h)(3), employers who cease doing business without a successor employer transfer records covered by the Regulation to NIOSH. As noted in Item 12, NIOSH does not request employers to transfer records to them under the Regulation.

Costs to the Federal government occur when OSHA compliance officers review the exposure-monitoring and medical-surveillance records, and any analyses associated with these records, which employers must maintain under the Regulation. The Agency estimates that a compliance officer (GS-12/5), at an hourly wage rate of \$34.15, spends 10 minutes (.17 hour) during each inspection reviewing records covered by the Regulation. Other costs, such as equipment, overhead, and support-staff expenses, would occur without these collection-of-information requirements, and OSHA considers these costs to be normal operating expenses. Based on the 72,691 inspections conducted in 2005 by OSHA and state-plan occupational safety and health agencies (see Item 12), the Agency estimates that the number of hours and the cost that it expends each year on conducting inspections associated with the Regulation are:

Burden hours: 72,691 inspections x .17 hour = 12,357 hours

Cost: 12,357 hours x \$34.15 = \$421,992

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

The Agency is requesting an adjustment increase of 158,879 burden hours (from 561,308 burden hours to 720,187 hours). ~~The Agency used the latest NAICS codes to update the number of establishments from 717,268 establishments to 734,820 establishments. This increase is the result of updated data, not an expansion of the Regulation’s scope. This increase is the result of increasing the number of establishments in SIC codes covered by the Regulation from 717,268 establishments to 734,820 establishments (see the section titled “Estimating the Number of Employers Affected by the Regulation” under Item 12 above for an explanation).~~ There is also a 1 hour decrease in records since employers are not required by NIOSH to transfer their records to them.

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 are no forms on which to display the expiration date.

18. Explain each exception to the certification statement identified in Item 19, “Certification for Paperwork Reduction Act Submissions,” of OMB Form 83-1.

OSHA is not seeking an exception to the certification statement in Item 19.