

**SUPPORTING STATEMENT FOR THE
INFORMATION COLLECTION REQUIREMENTS CONTAINED
IN THE FORMALDEHYDE STANDARD (29 CFR 1910.1048)
(Office of Management and Budget (OMB) Control No. 1218-0145(2010))^{1,2}**

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 standards" (29 U.S.C. 651) to ensure that employees will be furnished "employment and a place of employment . . . free from recognized hazards that are causing or likely to cause death or serious physical harm."

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 . . . 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 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 the Agency to "issue regulations requiring employers to maintain accurate records of employee exposures 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).

Under the authority granted by the OSH Act, the Agency published a General Industry health standard at 29 CFR 1910.1048 regulating employee exposure to formaldehyde (the Standard).

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

²The Construction and Shipyard Employment Formaldehyde Standards (29 CFR 1926.1148 and 29 CFR 1915.1048, respectively) incorporate 29 CFR 1910.1048 by reference.

OSHA based the Standard on a determination that occupational exposure to formaldehyde poses a hazard to exposed workers. This determination showed that breathing formaldehyde may cause: an itchy, runny, and stuffy nose; a dry or sore throat; eye irritation; headache; and cancer of the lung, buccal cavity, and pharynx. In addition, the determination indicated that formaldehyde solutions can damage the skin and burn the eyes. Items 2 and 12 below describe the specific information collection requirements of the Standard.

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

The following are the collection of information requirements as stated in the Standard, followed by discussions indicating how, by whom, and for what purpose the information is used.

A. Exposure monitoring (§1910.1048(d))

General (§1910.1048(d)(1))

§1910.1048(d)(1)(i) - Each employer who has a workplace covered by this standard shall monitor employees to determine their exposure to formaldehyde.

(§1910.1048(d)(1)(ii)) – Exception. Where the employer documents, using objective data, that the presence of formaldehyde or formaldehyde-releasing products in the workplace cannot result in airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use,³ the employer will not be required to measure employee exposure to formaldehyde.

Purpose: Requiring employers to record this determination permits OSHA to ascertain whether or not an employer is complying with the Standard, thereby ensuring that workers are receiving adequate protection from formaldehyde exposures.

Initial monitoring (§1910.1048(d)(2)) - The employer shall identify all workers who may be exposed at or above the action level or at or above the STEL and accurately determine the exposure of each employee so identified.

§1910.1048(d)(2)(i) - Unless the employer chooses to measure the exposure of each employee potentially exposed to formaldehyde, the employer shall develop a representative sampling strategy and measure sufficient exposures within each job classification for each workshift to correctly characterize and not underestimate the exposure of any employee within each exposure group.

§1910.1048(d)(2)(ii) - The initial monitoring process shall be repeated each time there is

³Paragraph (b) of the Standard specifies an action level (AL) of 0.50 parts of formaldehyde per million parts of air (0.50 ppm). Paragraph (c) specifies two permissible exposure levels (PELs): An 8-hour, time-weighted average (TWA) of 0.75 parts of formaldehyde per million parts of air (0.75 ppm), and a 15-minute, short-term exposure level (STEL) of two parts of formaldehyde per million parts of air (2.0 ppm).

a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde.

§1910.1048(d)(2)(iii) - If the employer receives reports of signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the employer shall promptly monitor the affected employee's exposure.

Purpose: Employers must perform initial monitoring to determine the extent of formaldehyde exposure in their workplace. Initial monitoring allows employers to identify areas of operation that may require additional reduction in airborne formaldehyde to meet the PELs. Initial monitoring also provides information regarding the effectiveness of engineering and work-practice controls, including the need to implement or revise these controls, and the selection of appropriate respirators to prevent worker overexposure to formaldehyde.

Periodic monitoring (§1910.1048(d)(3))

§1910.1048(d)(3)(ii) - If the last monitoring results reveal employee exposure at or above the action level, the employer shall repeat monitoring of the employees at least every 6 months.

§1910.1048(d)(3)(iii) - If the last monitoring results reveal employee exposure at or above the STEL, the employer shall repeat monitoring of the employees at least once a year under worst conditions.

Termination of monitoring (§1910.1048(d)(4)) - The employer may discontinue periodic monitoring for employees if results from two consecutive sampling periods taken at least 7 days apart show that employee exposure is below the action level and the STEL. The results must be statistically representative and consistent with the employer's knowledge of the job and work operation.

Purpose: Periodic exposure monitoring allows employers to determine if changes in processes, materials, or environmental conditions result in increased levels of airborne formaldehyde. Periodic monitoring also enables employers to evaluate the effectiveness of selected control methods.

Employee notification of monitoring results (§1910.1048(d)(6)) - The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees. If employee exposure is above the PEL, affected employees shall be provided with a description of the corrective actions being taken by the employer to decrease exposure.

Purpose: Consistent with section 8(c)(3) of the Act, every worker has the right to know what their exposure level is and whether it is above or below the AL. Moreover, since the PEL is one that also considers feasibility and, therefore, is not necessarily a “safe” level, it is necessary for workers to know the level of formaldehyde to which they were exposed. Additionally, when

exposures are above the PEL, the employer must also state in the notification what corrective action the employer is going to take to reduce the exposure level. This requirement is necessary to assure workers that the employer is making every effort to furnish them with a safe and healthful work environment as required by section 8(c)(3) of the OSH Act.

B. Regulated areas (§1910.1048(e))

§1910.1048(e)(1) - The employer shall establish regulated areas where the concentration of airborne formaldehyde exceeds either the TWA or the STEL and post all entrances and accessways with signs bearing the following information:

DANGER
FORMALDEHYDE
IRRITANT AND POTENTIAL CANCER HAZARD
AUTHORIZED PERSONNEL ONLY

§1910.1048(e)(3) - An employer at a multiemployer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite.

C. Respiratory protection (§1910.1048(g)(1))

General §1910.1048(g)(1) - For employers who use respirators required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respirators must be used during:

§1910.1048(g)(1)(i) - Periods necessary to install or implement feasible engineering and work-practice controls.

§1910.1048(g)(1)(ii) - Work operations, such as maintenance and repair activities or vessel cleaning, for which the employer establishes that engineering and work-practice controls are not feasible.

§1910.1048(g)(1)(iii) - Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the PELs.

§1910.1048(g)(1)(iv) - Emergencies.

Respirator program (§1910.1048(g)(2)) - The employer must implement a respiratory protection program in accordance with § 1910.134(b) through (d) (except (d)(1)(iii), (d)(3)(iii)(b)(1), and (2)), and (f) through (m), which covers each employee required by this section to use a respirator.

Purpose: The Respiratory Protection Standard assists employers in protecting the health of workers exposed to airborne contaminants and biological agents. The Respiratory Protection

Standard collections of information are contained in the Respiratory Protection Standard ICR, OMB control number 1218-0099. The Respiratory Protection Standard ICR provides the justification, purpose, and burden hours and cost estimates for these provisions.

D. Protective equipment and clothing (§1910.1048(h))

Maintenance of protective equipment and clothing (§1910.1048(h)(2))

§1910.1048(h)(2)(ii) - When ventilating formaldehyde-contaminated clothing and equipment, the employer shall establish a storage area so that employee exposure is minimized. Containers for contaminated clothing and equipment and storage areas shall have labels and signs containing the following information:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT
AVOID INHALATION AND SKIN CONTACT

Purpose: These signs and labels warn workers of the formaldehyde hazard, and how to prevent exposure to the hazard. In addition, warning labels assure that downstream employers and workers are informed of the hazards of formaldehyde, and that these employers may need to implement special practices to prevent exposure. Furthermore, hazard labels alert other employers who, in the absence of such labels, might not know that formaldehyde is present in their workplace and, consequently, that they must comply with the Standard.

§1910.1048(h)(2)(vi) - The employer shall inform any person who launders, cleans, or repairs such clothing or equipment of formaldehyde's potentially harmful effects and of procedures to safely handle the clothing and equipment.

Purpose: This information allows laundry personnel to protect themselves from formaldehyde exposure.

E. Housekeeping (§1910.1048(j))

§1910.1048(j)(4) - Formaldehyde-contaminated waste and debris resulting from leaks or spills shall be placed for disposal in sealed containers bearing a label warning of formaldehyde's presence and of the hazards associated with formaldehyde.

Purpose: These labels warn workers of the dangers associated with formaldehyde exposure, and allows them to protect themselves from such exposure.

F. Medical surveillance (§1910.1048(l))

Employees covered (§1910.1048(l)(1))

§1910.1048(l)(1)(i) - The employer shall institute medical surveillance programs for all employees exposed to formaldehyde at concentrations at or exceeding the action level or

exceeding the STEL.

§1910.1048(l)(1)(ii) - The employer shall make medical surveillance available for employees who develop signs and symptoms of overexposure to formaldehyde and for all employees exposed to formaldehyde in emergencies. When determining whether an employee may be experiencing signs and symptoms of possible overexposure to formaldehyde, the employer may rely on the evidence that signs and symptoms associated with formaldehyde exposure will occur only in exceptional circumstances when airborne exposure is less than 0.1 ppm and when formaldehyde is present in material in concentrations less than 0.1 percent.

Examination by a physician (§1910.1048(l)(2)) - All medical procedures, including administration of medical disease questionnaires, shall be performed by or under the supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay, and at a reasonable time and place.

Medical disease questionnaire (§1910.1048(l)(3)) - The employer shall make the following medical surveillance available to employees prior to assignment to a job where formaldehyde exposure is at or above the action level or above the STEL and annually thereafter. The employer shall also make the following medical surveillance available promptly upon determining that an employee is experiencing signs and symptoms indicative of possible overexposure to formaldehyde.

§1910.1048(l)(3)(i) - Administration of a medical disease questionnaire, such as in Appendix D, which is designed to elicit information on work history, smoking history, any evidence of eye, nose, or throat irritation; chronic airway problems or hyperreactive airway disease: allergic skin conditions or dermatitis; and upper or lower respiratory problems.

Medical examinations (§1910.1048(l)(4)) - Medical examinations shall be given to any employee who the physician feels, based on information in the medical disease questionnaire, may be at increased risk from exposure to formaldehyde and at the time of initial assignment and at least annually thereafter to all employees required to wear a respirator to reduce exposure to formaldehyde. The medical examination shall include:

§1910.1048(l)(4)(i) - A physical examination with emphasis on evidence of irritation or sensitization of the skin and respiratory system, shortness of breath, or irritation of the eyes.

§1910.1048(l)(4)(ii) - Laboratory examinations for respirator wearers consisting of baseline and annual pulmonary function tests. As a minimum, these tests shall consist of forced vital capacity (FVC), forced expiratory volume in one second (FEV₁), and forced expiratory flow (FEF).

§1910.1048(l)(4)(iii) - Any other test which the examining physician deems necessary to complete the written opinion.

§1910.1048(l)(4)(iv) - Counseling of employees having medical conditions that would be directly or indirectly aggravated by exposure to formaldehyde on the increased risk of impairment of their health.

Examinations for employees exposed in an emergency (§1910.1048(l)(5)) - The employer shall make medical examinations available as soon as possible to all employees who have been exposed to formaldehyde in an emergency.

§1910.1048(l)(5)(i) - The examination shall include a medical and work history with emphasis on any evidence of upper or lower respiratory problems, allergic conditions, skin reaction or hypersensitivity, and any evidence of eye, nose, or throat irritation.

§1910.1048(l)(5)(ii) - Other examinations shall consist of those elements considered appropriate by the examining physician.

Purpose: The principal purpose of medical surveillance is the prevention or detection of abnormalities that may occur in some formaldehyde-exposed workers early enough to prevent future or progressive adverse health effects. Documentation and maintenance of the medical-examination results required by the Standard provide a continuous record of worker health. Physicians use these records to determine the extent to which workers, since their last examination, experience health effects related to formaldehyde exposure. Additionally, if signs and symptoms of potential formaldehyde overexposure appear, the physician often needs information about a worker's previous medical conditions to make an accurate diagnosis of the present condition, ascertain its apparent cause, and identify a course of treatment. Medical records also permit workers to determine whether or not they need treatment, or to evaluate the effectiveness of their employer's exposure-reduction program.

Information provided to the physician (§1910.1048(l)(6)) - The employer shall provide the following information to the examining physician:

§1910.1048(l)(6)(i) - A copy of this standard and Appendix A, C, D, and E;

§1910.1048(l)(6)(ii) - A description of the affected employee's job duties as they relate to the employee's exposure to formaldehyde;

§1910.1048(l)(6)(iii) - The representative exposure level for the employee's job assignment;

§1910.1048(l)(6)(iv) - Information concerning any personal protective equipment and respiratory protection used or to be used by the employee; and

§1910.1048(l)(6)(v) - Information from previous medical examinations of the affected employee within the control of the employer.

§1910.1048(l)(6)(vi) - In the event of a nonroutine examination because of an emergency, the employer shall provide to the physician as soon as possible: A description of how the

emergency occurred and the exposure the victim may have received.

Purpose: Making this information available to physicians assists them in evaluating a worker's health and fitness for specific job assignments involving formaldehyde exposure. In the case of medical examinations administered in response to emergency exposures, the physician can use the exposure information to devise an appropriate treatment.

Physician's written opinion (§1910.1048(l)(7))

§1910.1048(l)(7)(i) - For each examination required under this standard, the employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination except that it shall not reveal specific findings or diagnoses unrelated to occupational exposure to formaldehyde. The written opinion shall include:

§1910.1048(l)(7)(i)(A) - The physician's opinion as to whether the employee has any medical condition that would place the employee at an increased risk of material impairment of health from exposure to formaldehyde;

§1910.1048(l)(7)(i)(B) - Any recommended limitations on the employee's exposure or changes in the use of personal protective equipment, including respirators;

§1910.1048(l)(7)(i)(C) - A statement that the employee has been informed by the physician of any medical conditions which would be aggravated by exposure to formaldehyde, whether these conditions may have resulted from past formaldehyde exposure or from exposure in an emergency, and whether there is a need for further examination or treatment.

§1910.1048(l)(7)(ii) - The employer shall provide for retention of the results of the medical examination and tests conducted by the physician.

§1910.1048(l)(7)(iii) - The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days of its receipt.

Purpose: The purpose of requiring the employer to obtain a written opinion from the examining physician is to provide the employer with medical information to aid in determining the initial placement of workers, and to assess the worker's ability to use protective clothing and equipment. The physician's written opinion will also provide information to the employer about whether or not the worker condition indicating overexposure to formaldehyde. The requirement that the physician's opinion be in writing will ensure that the information is available for future reference. Providing workers with a copy of the physician's written opinion will inform them of the medical-examination results so that they can determine the need for, and evaluate the effectiveness of, treatment or other interventions.

Medical removal (§1910.1048(l)(8))

§1910.1048(l)(8)(ii) - An employee's report of signs or symptoms of possible overexposure to formaldehyde shall be evaluated by a physician selected by the employer pursuant to paragraph (l)(3). If the physician determines that a medical examination is not necessary under paragraph (l)(3)(ii), there shall be a two-week evaluation and remediation period to permit the employer to ascertain whether the signs or symptoms subside untreated or with the use of creams, gloves, first aid treatment or personal protective equipment. Industrial hygiene measures that limit the employee's exposure to formaldehyde may also be implemented during this period. The employee shall be referred immediately to a physician prior to expiration of the two-week period if the signs or symptoms worsen. Earnings, seniority and benefits may not be altered during the two-week period by virtue of the report.

§1910.1048(l)(8)(iii) - If the signs or symptoms have not subsided or been remedied by the end of the two-week period, or earlier if signs or symptoms warrant, the employee shall be examined by a physician selected by the employer. The physician shall presume, absent contrary evidence, that observed dermal irritation or dermal sensitization are not attributable to formaldehyde when products to which the affected employee is exposed contain less than 0.1 percent formaldehyde.

§1910.1048(l)(8)(iv) - Medical examinations shall be conducted in compliance with the requirements of paragraph (l)(5)(i) and (ii). Additional guidelines for conducting medical exams are contained in appendix C.

§1910.1048(l)(8)(v) - If the physician finds that significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization result from workplace formaldehyde exposure and recommends restrictions or removal, the employer shall promptly comply with the restrictions or recommendation of removal. In the event of a recommendation of removal, the employer shall remove the affected employee from the current formaldehyde exposure and if possible, transfer the employee to work having no or significantly less exposure to formaldehyde.

§1910.1048(l)(8)(vii) - The employer shall arrange for a follow-up medical examination to take place within six months after the employee is removed pursuant to this paragraph. This examination shall determine if the employee can return to the original job status, or if the removal is to be permanent. The physician shall make a decision within six months of the date the employee was removed as to whether the employee can be returned to the original job status, or if the removal is to be permanent.

Purpose: Medical removal is an integral and essential part of medical surveillance. Medical removal prevents medical impairments induced or exacerbated by formaldehyde from becoming worse. In addition, medical removal allows workers who have these impairments an opportunity to recuperate and return to their jobs.

Multiple physician review (§1910.1048(l)(9))

§1910.1048(l)(9)(i) - After the employer selects the initial physician who conducts any medical examination or consultation to determine whether medical removal or restriction is appropriate, the employee may designate a second physician to review any findings, determinations or recommendations of the initial physician and to conduct such examinations, consultations, and laboratory tests as the second physician deems necessary and appropriate to evaluate the effects of formaldehyde exposure and to facilitate this review.

§1910.1048(l)(9)(ii) - The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation for the purpose of medical removal or restriction.

§1910.1048(l)(9)(iv) - If the findings, determinations or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve the disagreement. If the two physicians are unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician who shall be a specialist in the field at issue:

§1910.1048(l)(9)(iv)(A) - To review the findings, determinations or recommendations of the prior physicians; and

§1910.1048(l)(9)(iv)(B) - To conduct such examinations, consultations, laboratory tests and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

§1910.1048(l)(9)(v) - In the alternative, the employer and the employee or authorized employee representative may jointly designate such third physician.

§1910.1048(l)(9)(vi) - The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

Purpose: OSHA believes that multiple-physician review improves worker participation for an employer's medical-surveillance program, thereby increasing early detection and treatment for formaldehyde-related medical conditions. In this regard, participation in the medical-surveillance program is strictly voluntary on the part of workers. If the medical opinion provided by the employer's physician could result in job removal or restriction, and no opportunity existed for workers to obtain a second medical opinion, OSHA believes that many of them would refuse to participate in the medical-surveillance program; such refusal could jeopardize their health and well-being.

G. Hazard communication (§1910.1048(m))

General (§1910.1048(m)(1))

§1910.1048(m)(1)(i) - The following shall be subject to the hazard communication requirements of this paragraph: Formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and materials capable of releasing formaldehyde into the air, under reasonably foreseeable conditions of use, at concentrations reaching or exceeding 0.1 ppm.

§1910.1048(m)(1)(ii) - As a minimum, specific health hazards that the employer shall address are: Cancer, irritation and sensitization of the skin and respiratory system, eye and throat irritation, and acute toxicity.

§1910.1048(m)(2) - Manufacturers and importers who produce or import formaldehyde or formaldehyde-containing products shall provide downstream employers using or handling these products with an objective determination through the required labels and MSDSs if these items may constitute a health hazard within the meaning of 29 CFR 1910.1200(d) under normal conditions of use.

Labels (§1910.1048(m)(3))

§1910.1048(m)(3)(i) - The employer shall assure that hazard warning labels complying with the requirements of 29 CFR 1910.1200(f) are affixed to all containers of materials listed in paragraph (m)(1)(i), except to the extent that 29 CFR 1910.1200(f) is inconsistent with this paragraph.

§1910.1048(m)(3)(ii) - Information on labels. As a minimum, for all materials listed in paragraph (m)(1)(i) capable of releasing formaldehyde at levels of 0.1 ppm to 0.5 ppm, labels shall identify that the product contains formaldehyde; list the name and address of the responsible party; and state that physical and health hazard information is readily available from the employer and from material safety data sheets.

§1910.1048(m)(3)(iii) - For materials listed in paragraph (m)(1)(i) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in 29 CFR 1910.1200 (d) and 29 CFR 1910.1200 Appendices A and B, including respiratory sensitization, and shall contain the words "Potential Cancer Hazard."

§1910.1048(m)(3)(v) - *Substitute warning labels.* The employer may use warning labels required by other statutes, regulations, or ordinances which impart the same information as the warning statements required by this paragraph.

Purpose: Warning labels assure that downstream employers and workers are informed of the hazards of formaldehyde, and that these employers may need to implement special practices to prevent exposure. Furthermore, hazard labels alert other employers, who in the absence of such labels, might not know that formaldehyde is present in their workplace, and, consequently, that they must comply with the Standard.

Material safety data sheets (§1910.1048(m)(4))

§1910.1048(m)(4)(i) - Any employer who uses formaldehyde-containing materials listed in paragraph (m)(1)(i) shall comply with the requirements of 29 CFR 1910.1200(g) with regard to the development and updating of material safety data sheets.

§1910.1048(m)(4)(ii) - Manufacturers, importers, and distributors of formaldehyde-containing materials listed in paragraph (m)(1)(i) shall assure that material safety data sheets and updated information are provided to all employers purchasing such materials at the time of the initial shipment and at the time of the first shipment after a material safety data sheet is updated.

Purpose: Material safety data sheets (MSDSs) serve as the main source of information to workers and downstream employers about the hazards of exposure to formaldehyde. In addition, MSDSs provide information about formaldehyde that is essential to the training requirements of the Standard.

Written hazard communication program (§1910.1048(m)(5)) - The employer shall develop, implement, and maintain at the workplace, a written hazard communication program for formaldehyde exposures in the workplace, which at a minimum describes how the requirements specified in this paragraph for labels and other forms of warning and material safety data sheets, and paragraph (n) for employee information and training, will be met. Employers in multi-employer workplaces shall comply with the requirements of 29 CFR 1910.1200(e)(2).

Purpose: A written program provides a structure upon which to evaluate programs. Employers develop criteria they use in developing their programs, as well as the means used to meet those criteria. The written program serves as a useful reference for workers. Having the program in writing makes it easier to determine if the intent of the Standard is being met. Employers need not update their hazard communication programs as long as they meet the criteria established in 29 CFR 1910.1200(e) of the Standard.

H. Employee information and training (§1910.1048(n))

Participation (§1910.1048(n)(1)) - The employer shall assure that all employees who are assigned to workplaces where there is exposure to formaldehyde participate in a training program, except that where the employer can show, using objective data, that employees are not exposed to formaldehyde at or above 0.1 ppm, the employer is not required to provide training.

Frequency (§1910.1048(n)(2)) - Employers shall provide such information and training to employees at the time of initial assignment, and whenever a new exposure to formaldehyde is introduced into the work area. The training shall be repeated at least annually.

Training program (§1910.1048(n)(3)) - The training program shall be conducted in a manner which the employee is able to understand and shall include:

§1910.1048(n)(3)(i) - A discussion of the contents of this regulation and the contents of the Material Safety Data Sheet.

§1910.1048(n)(3)(ii) - The purpose for and a description of the medical surveillance program required by this standard, including:

§1910.1048(n)(3)(ii)(A) - A description of the potential health hazards associated with exposure to formaldehyde and a description of the signs and symptoms of exposure to formaldehyde.

§1910.1048(n)(3)(ii)(B) - Instructions to immediately report to the employer the development of any adverse signs or symptoms that the employee suspects is attributable to formaldehyde exposure.

§1910.1048(n)(3)(iii) - Description of operations in the work area where formaldehyde is present and an explanation of the safe work practices appropriate for limiting exposure to formaldehyde in each job;

§1910.1048(n)(3)(iv) - The purpose for, proper use of, and limitations of personal protective clothing and equipment;

§1910.1048(n)(3)(v) - Instructions for the handling of spills, emergencies, and clean-up procedures;

§1910.1048(n)(3)(vi) - An explanation of the importance of engineering and work practice controls for employee protection and any necessary instruction in the use of these controls; and

§1910.1048(n)(3)(vii) - A review of emergency procedures including the specific duties or assignments of each employee in the event of an emergency.

Access to training materials (§1910.1048(n)(4))

§1910.1048(n)(4)(i) - The employer shall inform all affected employees of the location of written training materials and shall make these materials readily available, without cost, to the affected employees.

§1910.1048(n)(4)(ii) - The employer shall provide, upon request, all training materials relating to the employee training program to the Assistant Secretary and the Director.⁴

Purpose: Training is essential to inform workers of the physical and health hazards of formaldehyde exposure, and to provide them with an understanding of the degree to which they can minimize the health-hazard potential. In addition, training provides information to workers that enable them to recognize how and where formaldehyde exposure occurs, and what steps to

⁴“Director” means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

take to avoid or limit such exposure. Training serves to explain and reinforce the information presented to workers on warning signs, labels, and material safety data sheets. These written forms of information and warning will be successful and relevant only if workers understand the information, and are aware of the action to be taken to avoid or minimize formaldehyde exposure.

The requirement to provide the training materials to OSHA compliance officers ensures that the training materials are correct and meet the requirements of the provision. NIOSH may review the training materials for research and evaluation purposes, and to develop additional training materials.

I. Recordkeeping (§1910.1048(o))

Exposure measurements (§1910.1048(o)(1)) - The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to formaldehyde. This record shall include:

§1910.1048(o)(1)(i) - The date of measurement;

§1910.1048(o)(1)(ii) - The operation being monitored;

§1910.1048(o)(1)(iii) - The methods of sampling and analysis and evidence of their accuracy and precision;

§1910.1048(o)(1)(iv) - The number, durations, time, and results of samples taken;

§1910.1048(o)(1)(v) - The types of protective devices worn; and

§1910.1048(o)(1)(vi) - The names, job classifications, social security numbers, and exposure estimates of the employees whose exposures are represented by the actual monitoring results.

Exposure determinations (§1910.1048(o)(2)) - Where the employer has determined that no monitoring is required under this standard, the employer shall maintain a record of the objective data relied upon to support the determination that no employee is exposed to formaldehyde at or above the action level.

Medical surveillance (§1910.1048(o)(3)) - The employer shall establish and maintain an accurate record for each employee subject to medical surveillance under this standard. This record shall include:

§1910.1048(o)(3)(i) - The name and social security number of the employee;

§1910.1048(o)(3)(ii) - The physician's written opinion;

§1910.1048(o)(3)(iii) - A list of any employee health complaints that may be related to

exposure to formaldehyde; and

§1910.1048(o)(3)(iv) - A copy of the medical examination results, including medical disease questionnaires and results of any medical tests required by the standard or mandated by the examining physician.

Respirator fit testing (§1910.1048(o)(4))

§1910.1048(o)(4)(i) - The employer shall establish and maintain accurate records for employees subject to negative pressure respirator fit testing required by this standard.

§1910.1048(o)(4)(ii) - This record shall include:

§1910.1048(o)(4)(ii)(A) - A copy of the protocol selected for respirator fit testing.

§1910.1048(o)(4)(ii)(B) - A copy of the results of any fit testing performed.

§1910.1048(o)(4)(ii)(C) - The size and manufacturer of the types of respirators available for selection.

§1910.1048(o)(4)(ii)(D) - The date of the most recent fit testing, the name and social security number of each tested employee, and the respirator type and facepiece selected.

Record retention (§1910.1048(o)(5)) - The employer shall retain records required by this standard for at least the following periods:

§1910.1048(o)(5)(i) - Exposure records and determinations shall be kept for at least 30 years.

§1910.1048(o)(5)(ii) - Medical records shall be kept for the duration of employment plus 30 years.

§1910.1048(o)(5)(iii) - Respirator fit testing records shall be kept until replaced by a more recent record.

Availability of records (§1910.1048(o)(6))

§1910.1048(o)(6)(i) - Upon request, the employer shall make all records maintained as a requirement of this standard available for examination and copying to the Assistant Secretary and the Director.

§1910.1048(o)(6)(ii) - The employer shall make employee exposure records, including estimates made from representative monitoring and available upon request for examination, and copying to the subject employee, or former employee, and employee representatives in accordance with 29 CFR 1910.1020 (a)-(e) and (g)-(i).

§1910.1048(o)(6)(iii) - Employee medical records required by this standard shall be

provided upon request for examination and copying, to the subject employee or former employee or to anyone having the specific written consent of the subject employee or former employee in accordance with 29 CFR 1910.1020 (a)-(e) and (g)-(i).

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 associated with formaldehyde exposure, and to provide valuable information to both workers and employers about the effectiveness of methods used to control exposure to formaldehyde. The records also assist OSHA in enforcing the Standard. The exposure-monitoring records required by this Standard will aid workers and their physicians in determining whether or not treatment or other interventions are needed for formaldehyde exposure.

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 the required records. The Agency wrote the paperwork requirements of the Standard in performance-oriented language, i.e., in terms of what data to collect, not how to record 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 information collection required to be collected and maintained are specific to each employer and worker involved, and is not available from, or duplicated by another source. The information required by the Standard is available only from employers. At this time there is no alternate information source available.

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 Standard do not have a significant impact on a substantial number of small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The information collection frequencies specified by this Standard are the minimum frequencies that the Agency believes are necessary to ensure that employers and OSHA can effectively monitor the exposure and health status of workers, and that housekeeping, hazard communication, and training are preventing hazardous worker exposures to formaldehyde.

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.**
- **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.**

Under paragraph (d)(6) of the Standard, employers must inform workers of their exposure-monitoring results in writing or by posting the results in an appropriate location that is accessible to workers, and do so within 15 working days after obtaining the results. If these results indicate that a worker's exposures are above either of the PELs, the notification must state this fact and describe what corrective actions the employer is taking to reduce the worker's exposure to or below the PEL. Additionally, paragraph (l)(7) of the Standard requires employers to provide a copy of the physician's written opinion to the worker within 15 working days of receiving the opinion. Also, if the medical examination is in response to an emergency exposure, paragraph (l)(6)(vi) requires that employers provide the physician, as soon as possible, with a description of how the emergency occurred and the worker's likely formaldehyde exposure.

- 8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.**

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

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

As required by the Paperwork Reduction Act of 1995 (44 U.S.C.2506 (c)(2)(A)), OSHA published a notice in the *Federal Register* on April 5, 2010 (75 FR 17163, Docket No. OSHA - 2009-0041) requesting public comment on its proposal to extend the Office of Management and

Budget's approval of the information collection requirements specified by the Formaldehyde Standard (29 CFR 1910.1048). This notice was part of a preclearance consultation program that provided the general public and government agencies with an opportunity to comment. 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 required by the Standard remains confidential, the Agency developed 29 CFR 1913.10 ("Rules of Agency Practice and Procedure Concerning OSHA Access to Worker Medical Records") 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.

The paperwork requirements specified by the Standard do not 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 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 collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead this cost should be included in Item 13.**

Table 1 - Summary of Annual Burden Hours and Cost Estimates

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Change	Estimated Cost
A. Exposure monitoring				
General	1,459	5,420	3,961	\$200,323
Periodic monitoring	25,201	13,963	-11,238	\$516,072
Employee notification of monitoring results	2,703	2,484	-219	\$51,468
B. Regulated areas	19	176	157	\$6,505
C. Respiratory protection (including respirator fit testing)	0	0	0	0
D. Maintenance of protective equipment and clothing	0	0	0	\$0
E. Housekeeping	0	0	0	\$0
F. Medical surveillance				
Employees covered, examination by a physician, Medical disease questionnaire, medical examinations, and examinations for Employees exposed to an emergency	370,610	205,333	-165,277	\$5,995,724
Information provided to the physician	29,993	16,639	-13,354	\$344,760
Physician's written opinion	29,993	16,639	-13,354	\$344,760
Medical removal	600	600	0	\$17,520
Multiple physician review	3,706	2,053	-1,653	\$59,948
G. Hazard communication	0	0	0	\$0
H. Employee information and training	9,266	36,805	27,539	\$1,360,313
I. Recordkeeping				
Exposure measurements	12,546	9,121	-3,425	\$188,987
Exposure determinations	1	1	0	\$21
Medical surveillance	29,993	16,639	-13,354	\$344,760
Respirator fit testing	0	0	0	0
Record retention	0	0	0	0
Availability of records (Including Access to training materials)	2,984	1,660	-1,324	34,671
Transfer of records	2	2	0	\$41
TOTALS	519,076	327,535	-191,541	\$9,465,836

Wage Rates

The Agency determined average wage rates using average hourly earnings. For the relevant occupational categories, OSHA adjusted the mean hourly earnings from the May 2008 *National Compensation Survey by the Bureau of Labor Statistics* to allow for fringe benefits, which comprise about 30.4% of total compensation in the private sector. With wages comprising 69.6% of employee compensation, the Agency multiplied wages by 1.437 (1/0.696) to derive total hourly employee compensation. Therefore, the costs of labor used in this analysis are estimates of total hourly compensation. These estimates are:

Professional/Manager	\$36.96
Clerical/Secretary	\$20.72
Chemical technician	\$30.21
Employee	\$29.20

Annual Burden-Hour and Cost Determinations

The Agency used data from the U.S. Department of Commerce report, *2007 Economic Census, Bureau of Census* to develop annual burden hours and costs for this ICR. Using the North American Industrial Classification System (NAICS) codes, OSHA identified those sectors likely to be affected by the Standard. Most sectors had a decrease in the number of establishments causing an overall reduction in the number of establishments from 112,638 to 103,511 establishments. Several sectors, however, did have increases in the number of establishments. The Census Bureau's Business Dynamics Statistics Database reports the establishment entry rate for the manufacturing sector at 7.7 new entries per year for every 100 existing establishments. OSHA used this rate to estimate the number of new establishments since 2006, the year the last ICR was completed. Given 103,511 establishments in affected sectors, new establishments can be estimated as $103,511 \times .077 \times 3$ (years) = 23,911 new establishments over the last 3 years.

The Agency reviewed the 1992 amended RIA data to determine the percentage of employees that were exposed above 0.5-0.75 ppm and between 0.75 and 1 ppm. OSHA applied these percentages to the new number of total affected employees to determine the number of employees exposed at these exposure levels. The Agency believes the burden hours and costs for this ICR are overestimated as a result of using these percentages since most employers, especially new employers, are likely to have measures in place to keep employee exposures below these exposure levels.

(A) Exposure monitoring (§1910.1048(d))

General (§1910.1048(d)(1))

If employers can document using objective data that employee exposure to formaldehyde or formaldehyde-releasing products are below the AL and STEL under foreseeable conditions of formaldehyde use, they are exempt from the monitoring requirements of the Standard. However, other employers must perform initial monitoring to determine the extent of formaldehyde

exposure in their workplace. In estimating the burden hours and costs for this provision, the Agency assumes that establishments will not rely on objective data for determining employee exposures, but instead perform initial monitoring as the most reliable and valid assessment of these exposures. While there was an overall decrease in the total number of establishments, OSHA did identify certain industries that had an increase in the number of establishments.

As noted above, the Agency identified 23,911 new establishments over the last three years, or 7,970 new establishments annually. The Agency assumes, conservatively, that all of these establishments use formaldehyde in production. By dividing the total number of establishments (103,511) into the total number of production employees (2,053,330), the Agency estimates that each of these establishments monitors an average of 20 potentially exposed new employees per plant, for a total of 159,400 new employees potentially exposed annually (i.e., 20 employees x 7,970 establishments). The Agency also assumes from data in the 1987 RIA that these establishments will conduct representative sampling on 20% of these employees for a total of 31,880 exposure monitoring samples (159,400 x 20%). In addition, the Agency believes that these establishments use a collar-badge procedure for sampling, and estimates that a professional will take 10 minutes (.17 hour) to implement the procedure, and then collect and record the necessary information (e.g., employee identification, exposure duration) for each sample.⁵

Burden hours: 31,880 employees x .17 hour = 5,420 hours

Cost: 5,420 hours x \$36.96 = \$200,323

Periodic monitoring (§1910.1048(d)(3))

If the results of initial monitoring indicate that employee exposure is at or above the action level, employers must perform periodic monitoring at least semi-annually; if the initial results are at or above the STEL, employers must monitor their employees at least annually. In this regard, the Agency assumes that employers conduct representative sampling on 20% of the covered employees twice a year, and no monitoring based on STEL results because semi-annual monitoring would meet the monitoring requirement for the few employees exposed above this limit. Based on data from the previous ICR and the 1992 amended RIA,⁶ the Agency estimates that 205,333 employees require periodic monitoring; employers would conduct representative sampling on 41,067 of these employees (i.e., 20% of 205,333 employees). Additionally, OSHA assumes that a professional takes 10 minutes (.17 hour) to implement the collar-badge procedure and collect and record the necessary information for each sample.

Burden hours: 41,067 employees x 2 samples/year x .17 hour = 13,963 hours

Cost: 13,963 hours x \$36.96 = \$516,072

Employee notification of monitoring results (§1910.1048(d)(6))

⁵The badges do not interfere with employee work activities; therefore, the Agency took no burden hours or cost for lost work time.

⁶See Table 1, "Number of Affected Establishments and Employees by Formaldehyde Exposure Level," at 57 FR 22300. Employees exposed between .75 – 1.0 ppm (83,818) and between 0.5 and .75 ppm (122,554) totaled 206,372 employees exposed above the 0.50 AL. The 206,372 exposed employees were divided by the total number of affected employees, 1,472,174, yielding .096; therefore, 370,610 employees are exposed to formaldehyde above the AL (i.e., 10% x 3,706,101 total employees).

If employers perform exposure monitoring, they must notify each employee included in the monitoring of the results within 15 days after receiving the results. Notification must be in writing, either by distributing copies of the results to individual employees or by posting the results. Further, if the exposure-monitoring results show that an employee's exposure exceeds the PELs,⁷ the employer must develop and implement a written plan to reduce the employee's exposure to or below the PELs, and provide written notice to each employee of the corrective action the employer is taking to prevent overexposure to formaldehyde.

Since engineering controls and work practices were to be in place by June 26, 1993, OSHA assumes employers already have developed and implemented the written plan to reduce employee exposure to the lowest possible feasible level; therefore, there are no burden hours for written plans.

Using an updated number of affected establishments (103,511) and applying the percent of establishments that are exposed above the 0.5 ppm (15%) from the 1992 RIA,⁸ OSHA determined that 15,527 establishments conduct periodic monitoring and post their monitoring results. The Agency assumes that employers notify the required employees by posting their exposure results; accordingly, OSHA estimates that an employer uses about five minutes (.08 hour) of clerical/secretarial time to post the notice in each of these establishments.

Burden hours: 15,527 establishments x 2 samples/year x .08 hour = 2,484 hours

Cost: 2,484 hours x \$ 20.72 = \$ 51,468

(B) Regulated areas (§1910.1048(e))

Employers must post signs at the entrances and access ways to regulated areas. If an employer establishes a regulated area at a multi-employer worksite, that employer must communicate the location of, as well as any access restrictions to, the regulated area to the other employers conducting operations at the worksite.

The Agency is unaware of any reliable data to determine the number of multi-employer worksites where the employer must inform other employers about regulated areas. Most likely, such sites would involve the use of particle board, hardwood plywood, or fiberboard where employees may be exposed by off-gassing from formaldehyde in these products. OSHA staff indicated that manufacturers of particle board, hardwood plywood, and fiberboard are modifying the formaldehyde mixture used in these products or are using substitutions, thereby reducing the number of exposures at such worksites. The Agency assumes that such notification will occur in less than 1% of the affected facilities (i.e., 1% x 103,511 = 1,035 multi-employer facilities).

For purposes of estimating the burden hours and costs for this provision, the Agency assumes that a manager will take 10 minutes (.17 hour) to inform other employers at the 1,035 multi-

⁷PELs are the 8-hour TWA and the 15-minute STEL.

⁸See Table 1, "Number of Affected Establishments and Employees By Formaldehyde Exposure Level," at 57 FR 22300. Establishments having employees exposed between 0.75 – 1.0 ppm (5,453 establishments) and between 0.5 and .75 ppm (11,496 establishments) totaled 16,949 establishments having employees exposed above the 0.50 AL. OSHA divided the 16,949 establishments having employees exposed above the AL by the total affected establishments (112,068), yielding 15% of the total number of establishments having employees exposed above the AL.

employer facilities of the location and access restriction to the regulated areas.

Burden hours: 1,035 multi employer facilities/ worksites x .17 hour = 176 hours

Cost: 176 hours x \$36.96 = \$6,505

(C) Respiratory program (§1910.1048(g)(2))

The Standard requires employers to implement a respiratory-protection program, including fit-testing, as specified by the Agency's Respiratory Protection Standard (29 CFR 1910.134). OSHA accounts for the burden hours and cost of this requirement under the ICR for the Respiratory Protection Standard (Control Number 1218-0099).

(D) Maintenance of protective equipment and clothing (§1910.1048(h)(2))

If an employer ventilates formaldehyde-contaminated clothing and equipment, the employer must establish a storage area that minimizes employee exposure. The storage area, as well as any containers used for contaminated clothing and equipment, must have warning labels and signs. This provision also requires employers to notify laundry personnel who clean or repair formaldehyde-contaminated protective clothing or equipment of the potentially harmful effects of formaldehyde, and of procedures for safely handling this clothing and equipment.

The Agency took no burden hours or cost for the requirement to provide warning labels and signs for storage areas and containers used to hold formaldehyde-contaminated clothing and equipment because the Standard provides specific language for the required labels and signs. (See 5 CFR 1320.3(c)(2).) Regarding notification of laundry personnel, OSHA assumes, based on information in the 1987 RIA, that employers provide disposable protective clothing for their employees; therefore, employers incur no burden hours or cost for this requirement.

(E) Housekeeping (§1910.1048(j))

The Standard requires employers to place formaldehyde-contaminated waste and debris resulting from leaks or spills in sealed containers. These containers must have labels that provide the following information: the containers hold formaldehyde-contaminated materials; and the hazards associated with formaldehyde exposure. Therefore, the Agency took no burden hours or cost for this requirement because employers can use the labels specified by paragraph (h)(2)(ii) of the Standard for this purpose. (See 5 CFR 1320.3(c)(2).)

(F) Medical surveillance (§1910.1048(l))

Employees covered; examination by a physician; medical disease questionnaire; medical examinations; and examinations for employees exposed in an emergency (§1910.1048(l)(1)-(l)(5))

Employers must implement a medical-surveillance program for employees: who are exposed to formaldehyde at concentrations at or above the AL or above the STEL; during emergencies; and who develop signs and symptoms of overexposure to formaldehyde. In addition, a physician

must perform or supervise the required medical procedures, including administration of the medical disease questionnaire.

Employers must ensure that employees complete a medical disease questionnaire: prior to assignment to jobs having formaldehyde exposures at or above the AL or above the STEL, and annually thereafter for the duration of such an assignment; and promptly after determining that an employee experiences signs and symptoms of potential formaldehyde overexposure. Employers must also provide medical examinations having a specified content: prior to the initial job assignment and annually thereafter to employees required to wear respirators to reduce formaldehyde exposure; to any employee that the physician determines, based on the employee's responses to the medical disease questionnaire, is at increased risk of health impairment from formaldehyde exposure; to all employees exposed to formaldehyde in emergencies; and when employees develop signs and symptoms of overexposure.

Using the updated total number of employees (2,053,330) and the 1992 percentage of employees exposed above the AL (10%), OSHA estimates 205,333 employees would undergo these procedures each year. The Agency assumes an employee takes one hour to complete the medical disease questionnaire and to undergo a medical examination.

Burden hours: 205,333 employees x 1 hour = 205,333 hours
Cost: 205,333 hours x \$29.20 = \$ 5,995,724

Information provided to the physician (§1910.1048(l)(6))

Employers must provide the examining physician with specific information on each employee who receives a medical examination. OSHA estimates that physicians administer 207,986 medical examinations each year, including: 205,333 annual medical examinations (discussed above, §1910.1048(l)(1)-(l)(5)); 600 medical-removal examinations and 2,053 multiple physician examinations (discussed below in the *Medical removal* (§1910.1048(l)(8) and *Multiple physician review* (§1910.1048(l)(9)) sections).

The Agency assumes that, for each of these medical examinations, an employer uses about five minutes (.08 hour) of clerical/secretarial time to compile the information for each employee and provide it to the physician.

Burden hours: 207,986 medical examinations x .08 hour = 16,639 hours
Cost: 16,639 hours x \$20.72 = \$344,760

Physician's written opinion (§1910.1048(l)(7))

Within 15 days of receiving the physician's written opinion, the employer must provide a copy of it to the employee who was the subject of the medical examination. Additionally, the Agency assumes that employers, to reduce the paperwork burden, will include on each copy a written statement that the employee has a right to seek a second opinion if the first physician conducted the medical examination for the purpose of medical removal or restriction; this statement would meet the notification requirement of paragraph (l)(9)(ii) of the Standard. OSHA further assumes

that an employer uses about five minutes (.08 hour) of clerical/secretarial time to deliver a copy of the physician's written opinion to each employee who received a medical examination.

Burden hours: 207,986 medical examinations x .08 hour = 16,639 hours
Cost: 16,639 hours x \$20.72 = \$344,760

Medical removal (§1910.1048(l)(8))

An employer bases the decision to medically remove an employee from a job, or to restrict an employee's exposure to formaldehyde, on a written recommendation provided by the examining physician, which the physician makes following a medical examination. According to the 1992 RIA, OSHA expected the number of employees requiring medical examinations for this purpose to be small (57 FR 22304); as noted above in the determinations made for "Information provided to the physician," the Agency estimates this number to be 600. For the purpose of determining the burden hours and cost of the physician evaluations and medical examinations associated with medical removal, OSHA assumes that each employee takes one hour to complete the required procedures. Therefore, the annual estimated burden hours and cost of this provision are:

Burden hours: 600 employees x 1 hour = 600 hours
Cost: 600 hours x \$29.20 = \$17,520

Multiple physician review (§1910.1048(l)(9))

The Agency is unaware of any reliable data that would estimate the number of instances when an employee may request a second or third physician to review the findings and determinations made by previous physicians. For purposes of calculating burden hours and costs, the Agency assumes that an additional 2,053 medical examinations will be administered (i.e., approximately 1% of the 205,333 employees) as a result of an employee requesting multiple-physician review, and that the process will involve examinations by a second and third physician. OSHA also estimates that an employee will take one hour to complete the required medical examination. Therefore, the annual estimated burden hours and cost of this provision are:⁹

Burden hours: 2,053 medical examinations x 1 hour = 2,053 hours
Cost: 2,053 hours x \$29.20 = \$59,948

(G) Hazard communication (§1910.1048(m))

General; Labels; Material safety data sheets; and Written hazard communication program (§§ (m)(1)-(m)(5))

OSHA accounts for the burden hours and cost of paperwork requirements in paragraph (m) of the Standard under the ICR for its Hazard Communication Standard (29 CFR 1910.1200; OMB Control Number 1218-0072).

⁹Note that the Agency accounted for the burden hours and cost of an employer providing employees with notification of their right to multiple-physician review, as specified in paragraph (l)(9)(ii) of the Standard, under the determinations made above for "Physician's written opinion."

(H) Employee information and training (§1910.1048(n))

Employers must provide employees with training: prior to assigning them to work areas with airborne formaldehyde concentrations at or above 0.1 ppm, and at least annually thereafter; and if the employer introduces a new exposure to formaldehyde to the work area. In addition, employers must inform the employees of the location of written training materials, and make these materials readily available to the employees, as well as to OSHA compliance officers and NIOSH representatives, on request. In this regard, the Agency assumes that employers inform employees of the location and availability of training materials during the training sessions; therefore, OSHA made no burden-hour and cost determinations for this paperwork requirement. In addition, the Agency included the burden hours and cost associated with making these materials available to employees, OSHA compliance officers, and NIOSH representatives in the determinations made below under “Availability of records (including access to training materials) (§ 1910.1048(o)(6)).”

The Agency estimates 1,472,174 employees have formaldehyde exposures at or above 0.1 ppm and, additionally, that a professional can administer the required training during a session lasting one-half (.50 hour). The Agency further assumes that a training session consists of 20 employees, for a total of 73,609 sessions (i.e., 1,472,174 employees ÷ 20 employees).

Burden hours: 73,609 sessions x .50 hour = 36,805 medical examinations

Cost: 36,805 hours x \$36.96 = \$1,360,313

(I) Recordkeeping (§1910.1048(o))

Employers must establish and maintain employee exposure-monitoring, medical-surveillance, and respirator-fit-testing records, retain these records for specific periods, and make the records available to designated parties. The following paragraphs provide the burden-hour and cost determinations for these paperwork requirements.

Exposure measurements (§1910.1048(o)(1))

Under this provision, employers must establish and maintain an accurate record of the exposure measurements taken under the Standard. Based on data from the burden-hour and cost determinations performed above under “(A) Exposure monitoring,” the Agency estimates that these records include 31,880 initial-monitoring records and 82,134 periodic-monitoring records (i.e., 41,067 employees sampled twice a year), for a total of 114,014 records. OSHA further estimates that establishing and maintaining these records requires about five minutes (.08 hour) of clerical/secretarial time. Therefore, the annual estimated burden hours and cost of this provision are:

Burden hours: 114,014 records x .08 hour = 9,121 hours

Costs: 9,121 hours x \$20.72 = \$188,987

Exposure determinations (§1910.1048(o)(2))

Employers must establish and maintain a record of the objective data they use to determine that employee exposures to formaldehyde are below the AL and STEL. The Agency assumes that employers made these determinations previously (i.e., employers will not make additional determinations during this ICR period), and that they will not review or update the determinations because the data continue to accurately represent current workplace conditions. Therefore, the only paperwork burden associated with this provision is the requirement to maintain the records, which is negligible. Accordingly, OSHA estimates that this provision results in a total of one burden hour at a cost of \$21 (rounded) for clerical/secretarial time for all employers to maintain the required paperwork.

Medical surveillance (§1910.1048(o)(3))

This provision requires employers to establish and maintain an accurate record of the medical-surveillance information obtained under the Standard. Using data from the burden-hour and cost determinations performed above under “(G) Medical surveillance,” the Agency estimates that this provision requires employers to establish and update (i.e., maintain) 207,986 medical-surveillance records each year using about five minutes (.08 hour) of clerical/secretarial time for each record. Therefore, the annual estimated burden hours and cost of this provision are:

Burden hours: 207,986 records x .08 hour = 16,639 hours

Cost: 16,639 hours x \$20.72 = \$344,760

Respirator fit testing (§1910.1048(o)(4))

If an employer conducts fit testing for employees using negative-pressure respirators, the employer must establish and maintain accurate fit-testing records for these employees. The Agency accounts for the burden hours and cost resulting from this requirement under the ICR for its Respiratory Protection Standard (29 CFR 1910.134; OMB Control Number 1218-0099).

Record retention (§1910.1048(o)(5))

Employers must maintain exposure-monitoring records for at least 30 years, medical-surveillance records for the duration of employment plus 30 years, and respirator fit-testing records until replaced by more recent records. OSHA accounts for the paperwork burden of maintaining exposure-monitoring and medical-surveillance records in the burden-hour and cost determinations performed above under “Exposure measurements (§1910.1048(o)(1))(A),” “Exposure determinations (§1910.1048(o)(2)),” and “Medical surveillance (§1910.1048(o)(3)).”

Availability of records (including access to training materials) (§1910.1048(o)(6))

On request, employers must provide for examination and copying: all records required by the Standard, including training materials specified in paragraph (n)(4), to the Agency’s compliance officers and NIOSH representatives; employee exposure-monitoring records to current and former employees covered by the Standard, and to employee representatives; and an employee’s

medical-surveillance records to that employee (whether currently or formerly employed by the employer), and to anyone having that employee's specific written consent. The requirements of paragraphs (a)-(e) and (g)-(i) of CFR 1910.1020 ("Access to employee exposure and medical records;" referred to as the "Records-Access Standard") regulate the release of exposure-monitoring and medical-surveillance records to employees and other parties.

The Agency estimates that each year its compliance officers make requests for formaldehyde-related records during inspections conducted at 217 facilities,¹⁰ and that a professional takes about five minutes (.08 hour) during the inspection to inform an OSHA compliance officer of the location of the requested records. In addition, the Agency assumes that each year requests are made for access to exposure-monitoring and medical-surveillance records, as well as training materials (as specified by paragraph (n)(4)(i) of the Standard), by about 10% (20,533) of the 205,333 covered employees (see "Periodic monitoring (§1910.1048(d)(3))" above), which includes their representatives and anyone having their specific written consent (regarding medical-surveillance records). OSHA estimates that an employer uses about five minutes (.08 hour) of clerical/secretarial time to make these records available to the employees and their designated employee representatives. Therefore, the annual estimated burden hours and cost of this provision are:

Burden hours: $((217 \text{ inspections} \times .08 \text{ hours}) = 17 \text{ hours}) + ((20,533 \text{ employee-related requests} \times .08) = 1,643) = 1,660 \text{ hours}$

Cost: $((17 \text{ hours} \times \$36.96 \text{ (professional)}) = \$628) + ((1,643 \text{ hours} \times \$20.72 \text{ (clerical/secretarial)}) = \$34,043) = \$34,671$

Transfer of records (§1910.1048(o)(6)(ii), (iii))

As noted above, paragraphs (o)(6)(i) and (o)(6)(ii) of the Standard specify that the requirements of paragraphs (a)-(e) and (g)-(i) of the Records-Access Standard regulate the release of exposure-monitoring and medical-surveillance records to employees and other parties. Paragraph (h) of the Records-Access Standard requires employers to transmit exposure-monitoring and medical-surveillance records to NIOSH if they cease doing business within the period specified for retaining these records and have no successor employer. Employers who remain in business for the entire retention period must, before disposing of the records, notify NIOSH in writing of the impending disposal, and transfer the records to NIOSH if it requests them within three months of being so notified.

Based on previous NIOSH estimates, NIOSH received employee exposure-monitoring and/or medical-surveillance records from two employers during the period covered by the last ICR (i.e., about one set of records each year). The Agency assumes that an employer uses about one hour of clerical/secretarial time to prepare and send each set of records to NIOSH. Therefore, the annual estimated burden hours and cost of this provision are:

¹⁰The Agency estimated the number of inspections by determining the inspection rate (1.4%) for all facilities under the jurisdiction of the OSH Act (including both Federal OSHA and approved state-plan agencies) for 1999, and then multiplied the total number of facilities regulated by the Standard (15,527; see the determinations made above under "Employee notification of monitoring results (§1910.1048(d)(6))" by this percentage (i.e., .014% inspection rate x 15,527 facilities = 217 inspections).

Burden hours: 2 sets of records x 1 hour = 2 hours

Cost: 2 hours x \$20.72 = \$41

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

Exposure monitoring

Based on recent discussions with OSHA's Salt Lake City Laboratory, the Agency estimated a cost of \$45 per sample to collect and analyze airborne formaldehyde using collar badges.¹¹ The determinations made under "(A) Exposure monitoring" above indicate a total of 114,014 samples are taken per year. Therefore, the annual estimated cost of this requirement to employers is \$5,130,630 (\$45 per sample x 114,014 samples).

Medical surveillance

Consistent with recent ICRs and RIAs for other standards, the Agency estimates that each medical examination costs an employer \$180.28.¹² According to the determinations made above under a total of 207,986 medical examinations are administered each year. Therefore, the annual estimated cost of this requirement to employers is \$ 37,495,716 (\$180.28 x 207,986 medical examinations). Therefore, the annual estimated cost of the medical surveillance and exposure monitoring to employers is \$42,626,346 (\$37,495,716 + \$5,130,630).

¹¹ Inflated from 2006 to 2009 prices. CPI inflation rate: 7.1%

¹² Average price of an office-based visit with a physician, MEPS 2004,

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

The total cost to the Federal government of the Standard's information collection requirements is \$678. This cost results from the information collection requirements specified in paragraph (o)(6) ("Availability of records (including access to training materials") of the Standard, and consists of \$675 for the Agency to access employers' records during an inspection, and \$3.00 for NIOSH to receive exposure-monitoring and medical-surveillance records when employers cease to do business or send these records to NIOSH at the end of the respective retention period. Other occupational expenses, such as equipment, overhead, and support-staff expenses, would occur without the collection of information requirements, and the Agency considers these to be normal operating expenses.

OSHA access to records

Based on the determinations made above under "Availability of records (including access to training materials) (§1910.1048(o)(6)),” employers covered by the Standard receive 217 inspections each year. The Agency estimates that a compliance officer (GS-12/5), with an hourly wage rate of \$39.70, spends about five minutes (.08 hour) reviewing requested information during an inspection. Therefore, the estimated annual hours and cost of this requirement to the Federal government are:

Burden hours: 217 inspections x .08 hour = 17 hours
Cost: 17 hours x \$39.70 = \$675

Transfer of records NIOSH

Employers must transmit exposure-monitoring and medical-surveillance records to NIOSH if they cease doing business within the period specified for retaining these records and have no successor employer. Employers who remain in business for the entire retention period must, before disposing of the records, notify NIOSH in writing of the impending disposal, and transfer the records to NIOSH if requested to do so.

The determinations made above under "Transfer of records (§1910.1048(o)(6)(ii), (iii))” showed that NIOSH received about one set of employee exposure-monitoring and/or medical-surveillance records each year during the period covered by the last ICR. The Agency estimates that NIOSH spends about five minutes (.08 hour) of clerical/secretarial time (at a wage rate of \$20.44 per hour) to process a set of records. Therefore, the estimated annual hours and cost of this requirement to the Federal government are:

Burden hours: 2 sets of records x .08 hours = .16 hour
Cost: .16 hour x \$20.44 = \$3

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

The Agency is requesting an adjustment decrease of 191,541 hours (from 519,076 hours to 327,535 hours). The primary reason for the reduction is due to Agency decreasing the overall number of establishments, from 112,638 to 103,511. The establishment decrease resulted in fewer medical examinations, training sessions, and exposure measurements.

The Agency is also requesting a cost decrease of \$12,699,342, from \$55,325,688 to \$42,626,346. The cost decrease is primarily the result of reducing the number of establishments, and thus the number of exposed workers. Although the number of establishments and workers has decreased, the cost of medical examinations increased from \$130 to \$180. Additionally, the cost for monitoring samples has increased from \$42 to \$45.

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

OSHA will not publish the information collected under this Standard.

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

No forms are available for the Agency 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 83-I.

The Agency is not seeking an exception to the certification statement in item 19.