

**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 (November 2016)**

**A. JUSTIFICATION**

- 1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.**

The main objective of the Occupational Safety and Health Act (OSH Act) is to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources" (29 U.S.C. 651). To achieve this objective, the OSH Act specifically authorizes "the development and promulgation of occupational safety and health standards" (29 U.S.C. 651) to ensure that workers 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 worker health, the OSH Act authorizes the Occupational Safety and Health Administration (OSHA) to develop standards that provide for "monitoring or measuring worker 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 workers exposed to such hazards . . . to most effectively determine whether the health of such workers 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 worker 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 worker or former worker 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 worker exposures to formaldehyde (the Standard). 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 collections of information 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,<sup>1</sup> 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 a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde.

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<sup>1</sup>Paragraph (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).

§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.

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 (OMB Control Number 1218-0099).

## **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 access ways with signs bearing the following information:

DANGER  
FORMALDEHYDE  
MAY CAUSE CANCER  
CAUSES SKIN, EYE and RESPIRATORY IRRITATION  
AUTHORIZED PERSONNEL ONLY

**1910.1048(e)(1)(ii)** - Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (e)(1)(i) of this section:

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)(i))** - 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)* - The employer shall assure that protective equipment and clothing that has become contaminated with formaldehyde is cleaned or laundered before its reuse.

*§1910.1048(h)(2)(ii)(A)* - Signs. Storage areas for contaminated clothing and equipment shall have signs bearing the following information:

DANGER  
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT  
MAY CAUSE CANCER  
CAUSES SKIN, EYE AND RESPIRATORY IRRITATION  
DO NOT BREATHE VAPOR  
DO NOT GET ON SKIN

*§1910.1048(h)(2)(ii)(B)* - Labels. The employer shall ensure containers for contaminated clothing and equipment are labeled consistent with the Hazard Communication Standard, §1910.1200, and shall, as a minimum, include the following:

DANGER  
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT  
MAY CAUSE CANCER  
CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION  
DO NOT BREATHE VAPOR  
DO NOT GET ON SKIN

*§1910.1048(h)(2)(ii)(C)* - Prior to June 1, 2016, employers may use the following information in lieu of that specified in paragraph (h)(2)(ii)(A) of this section:

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

*§1910.1048(h)(2)(ii)(D)* - Prior to June 1, 2015, employers may include the following information on containers of protective clothing and equipment in lieu of the labeling requirements in paragraphs (h)(2)(ii)(B) of this section:

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.

If an employer ventilates formaldehyde-contaminated clothing and equipment, the employer must establish a storage area that minimizes worker 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 workers; therefore, employers incur no burden hours or cost for this requirement.

## **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 allow them to protect themselves from such exposure.

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 (§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 (FEV<sub>1</sub>), 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 worker has any medical condition that would place the worker at an increased risk of material impairment of health from exposure to formaldehyde;

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

§1910.1048(l)(7)(i)(C) - A statement that the worker 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's condition indicates 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) - Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§1910.1200) for formaldehyde.

§1910.1048(m)(1)(iii) - Employers shall include formaldehyde in the hazard communication program established to comply with the HCS (§1910.1200). Employers shall ensure that each employee has access to labels on containers of formaldehyde and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (n) of this section.

§1910.1048(m)(2)(i) - In addition to the requirements in paragraphs (m)(1) through (m)(1)(iv) of this section, for materials listed in paragraph (m)(1)(iv) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in paragraph (d) of §1910.1200 and Appendices A and B to §1910.1200, including cancer and respiratory sensitization, and shall contain the hazard statement "May Cause Cancer."

§1910.1048(m)(2)(ii) - As a minimum, for all materials listed in paragraph (m)(1)(i) and (iv) of this section 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 safety data sheets.

*§1910.1048(m)(2)(iii)* - Prior to June 1, 2015, employers may include the phrase "Potential Cancer Hazard" in lieu of "May Cause Cancer" as specified in paragraph (m)(2)(i) of this section.

**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.

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

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.

Employers and manufacturers, importers or distributors of formaldehyde must comply with the requirements regarding development of SDSs and hazard communication programs as specified in the OSHA Hazard Communication Standard. 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).

## **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 when 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.<sup>2</sup>

**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 take to avoid or limit such exposure. Training serves to explain and reinforce the information presented to workers on warning signs, labels, and MSDs. These written forms of information and warning will be successful and relevant only if workers understand the information, and are

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<sup>2</sup>“Director” means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

aware of the action to be taken to avoid or minimize formaldehyde exposure.

Employers must provide workers 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 workers of the location of written training materials, and make these materials readily available to the workers, as well as to OSHA compliance officers and NIOSH representatives, on request. In this regard, in previous ICRs, the Agency assumed that employers inform workers 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 workers, OSHA compliance officers, and NIOSH representatives in Item 12 of this Supporting Statement, under “Availability of records (including access to training materials) (§1910.1048(o)(6)).”

Upon further analysis, the requirement that employers provide training to workers under paragraph (n)(1)-(3) is not considered to be a collection of information. OSHA is not taking burden for this activity under Item 12 of this Supporting Statement.

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 worker 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 worker 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 worker 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 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.

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

Paragraph (h) of §1910.1020 requires employers who cease to do business to transfer medical and exposure-monitoring records to the successor employer, who then must receive and maintain the records. If no successor employer is available, the employer must, at least three months before ceasing business, notify current workers who have records of their right to access these records.<sup>3</sup>

OSHA considers the employer's transfer of records to a successor employer to be usual and customary communications during the transition from one employer to a successor employer. In this regard, the employer would communicate the location of all records, including employee exposure-monitoring and medical records, at the facility to the successor employer during the transfer of business operations, as a matter of usual and customary business practice.

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<sup>3</sup>Upon a thorough review of this ICR, the Agency determined that these provisions were not fully addressed in previous ICRs.

In addition, OSHA accounts for the burden hours and costs resulting from the employee notification requirements under the Information Collection Request (ICR) for its Access to Employee Exposure and Medical Records Standard (§1910.1020), OMB Control No. 1218-0065.

- 3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other 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 A.2 above.**

The information 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, describe any methods used to minimize burden.**

The collections of information 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)(iii) 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 (U.S.C. 3506(c)(2)(A)), OSHA published a Federal Register notice on August 1, 2016 (81 FR 50563), soliciting public comment on its proposal to extend the collections of information contained in the Formaldehyde Standard (Docket Number OSHA-2009-0041). The notice was part of a preclearance consultation program that provided interested parties with an opportunity to comment on OSHA's request for an extension by OMB of a previous approval of the collections of information found in the Standard. The Agency received no comments in response to this 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.**

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

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

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.**
- **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.**

## **Wage Rates**

The Agency determined average wage rates using average hourly earnings. For the relevant occupational categories, OSHA adjusted the mean hourly earnings according to the Bureau of Labor Statistics (BLS), U.S. Department of Labor, *Occupational Employment Statistics*, May 2015 ([www.bls.gov/oes/](http://www.bls.gov/oes/)) to allow for fringe benefits. To account for fringe benefits, we used the fringe benefit rate reported in BLS' Employer Costs for Employee Compensation (ECEC) news release for December 2015 (BLS, 2016).<sup>4</sup> BLS reported that for private industry, fringe benefits accounted for 31.3 percent of total compensation and wages accounted for the remaining 68.7 percent. To calculate the loaded hourly wage for each occupation, thus we divide the mean

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<sup>4</sup> Source: [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm).

hourly wage by 68.7 percent. The costs of labor used in this analysis are therefore estimates of total hourly compensation. These hourly wages are:

Professional/Manager	\$41.94 <sup>5</sup>
Employee	\$25.34 <sup>6</sup>
Clerical Employee	\$24.31 <sup>7</sup>
Chemical technician	\$34.11 <sup>8</sup>

### **Annual Burden-Hour and Cost Determinations**

The Agency used data from the United States Census Bureau, 2014 County Business Patterns 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 an increase in the number of establishments causing an overall increase in the number of establishments from 84,931 to 86,320 establishments. Several sectors, however, did have decreases in the number of establishments. The Census Bureau's Business Dynamics Statistics Database reports the 2013 establishment entry rate for the manufacturing sector at 5.8 new entries per year for every 100 existing establishments. OSHA used this rate to estimate the number of new establishments since 2009, the year the last ICR was completed. Given 86,320 establishments in affected sectors, new establishments can be estimated as  $86,320 \times .058 = 5,007$  establishments per year.  $5,007$  establishments per year  $\times 3$  (years) = 15,021 new establishments over the last 3 years.

The Agency reviewed the 1992 amended RIA data to determine the percentage of workers 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 workers to determine the number of workers exposed at these exposure levels. For this ICR, the Agency estimates the total number of production workers is 1,694,101.

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 worker exposures below these exposure levels.

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

##### *General (§1910.1048(d)(1))*

If employers can document using objective data that worker 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

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<sup>5</sup> The mean hourly wage for SOC 51-1011, "Production Occupations," "First-Line Supervisors of Production and Operating Workers" is \$28.81.

<sup>6</sup> The mean hourly wage for SOC 51-0000, "Production Occupations," is \$17.41.

<sup>7</sup> The mean hourly wage for SOC 43-9199 "Office and Administrative Support Occupations," "Office and Administrative Support Workers, All Other" is \$16.70.

<sup>8</sup> The mean hourly wage for "Chemical Technicians," (Occupation Code 19-4031), is \$23.43.

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 worker exposures, but instead perform initial monitoring as the most reliable and valid assessment of these exposures. As noted above, the Agency identified 15,021 new establishments over the last three years, or 5,007 new establishments annually. The Agency assumes, conservatively, that all of these establishments use formaldehyde in production. By dividing the total number of establishments (86,320) into the total number of production workers (1,694,101), the Agency estimates that each of these establishments monitors an average of 20 potentially exposed new workers per plant, for a total of 100,140 new workers potentially exposed annually (i.e., 20 workers x 5,007 establishments). The Agency also assumes from data in the 1987 RIA that these establishments will conduct representative sampling on 20% of these workers for a total of 20,028 exposure monitoring samples (100,140 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., worker identification, exposure duration) for each sample.<sup>9</sup>

**Burden hours:** 20,028 workers x .17 hour = 3,405 hours

**Cost:** 3,405 hours x \$41.94 = \$142,806

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

If the results of initial monitoring indicate that worker 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 workers at least annually. In this regard, the Agency assumes that employers conduct representative sampling on 20% of the covered workers twice a year, and no monitoring based on STEL results because semi-annual monitoring would meet the monitoring requirement for the few workers exposed above this limit. Based on data from the previous ICR and the 1992 amended RIA,<sup>10</sup> the Agency estimates that 169,410 workers require periodic monitoring (1% of 1,694,101 production workers); employers would conduct representative sampling on 33,882 of these workers (i.e., 20% of 169,410 workers). 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:** 33,882 workers x 2 samples/year x .17 hour = 11,520 hours

**Cost:** 11,520 hours x \$41.94 = \$483,149

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

If employers perform exposure monitoring, they must notify each worker included in the monitoring of the results within 15 days after receiving the results. Notification must be in

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<sup>9</sup>The badges do not interfere with worker work activities; therefore, the Agency took no burden hours or cost for lost work time.

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

writing, either by distributing copies of the results to individual workers or by posting the results. Further, if the exposure-monitoring results show that a worker's exposure exceeds the PELs,<sup>11</sup> the employer must develop and implement a written plan to reduce the worker's exposure to or below the PELs, and provide written notice to each worker 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 worker exposure to the lowest possible feasible level; therefore, there are no burden hours for written plans.

Using an updated number of affected establishments (86,320) and applying the percent of establishments that are exposed above the 0.5 ppm action level (15%) from the 1992 RIA,<sup>12</sup> OSHA determined that 12,948 establishments conduct periodic monitoring and post their monitoring results. The Agency assumes that employers notify the required workers 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:** 12,948 establishments x 2 samples/year x .08 hour = 2,072 hours  
**Cost:** 2,072 hours x \$ 24.31 = \$50,370

#### **(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 workers 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 substitutes; 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 86,320 = 863 multi-employer facilities).

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<sup>11</sup>PELs are the 8-hour TWA and the 15-minute STEL.

<sup>12</sup>See Table 1, "Number of Affected Establishments and Workers By Formaldehyde Exposure Level," at 57 FR 22300. Establishments having workers 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 workers exposed above the 0.50 AL. OSHA divided the 16,949 establishments having workers exposed above the AL by the total affected establishments (112,068), yielding 15% of the total number of establishments having workers exposed above the AL.

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

**Burden hours:** 863 multi-employer facilities/ worksites x .17 hour = 147 hours

**Cost:** 147 hours x \$41.94 = \$6,165

**(C) Respirator program (§1910.1048(g)(2)(i))**

No burden hours or costs taken. See Item 2 of this Supporting Statement.

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

No burden hours or costs taken. See Item 2 of this Supporting Statement.

**(E) Housekeeping (§1910.1048(j))**

No burden hours or costs taken. See Item 2 of this Supporting Statement.

**(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 workers: 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 workers 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 a worker 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 workers required to wear respirators to reduce formaldehyde exposure; to any worker that the physician determines, based on the worker's responses to the medical disease questionnaire, is at increased risk of health impairment from formaldehyde exposure; to all workers exposed to formaldehyde in emergencies; and when workers develop signs and symptoms of overexposure.

Using the updated total number of workers (1,694,101) and the 1992 percentage of workers exposed above the AL (10%), OSHA estimates 169,410 workers would undergo these procedures each year. The Agency assumes a worker takes one hour to complete the medical disease questionnaire and to undergo a medical examination.



**Burden hours:** 169,410 workers x 1 hour = 169,410 hours

**Cost:** 169,410 hours x \$25.34= \$4,292,849

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

Employers must provide the examining physician with specific information on each worker who receives a medical examination. OSHA estimates that physicians administer 171,704 medical examinations each year, including: 169,410 annual medical examinations (discussed above, §1910.1048(l)(1)-(l)(5)); 600 medical-removal examinations and 1,694 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 worker and provide it to the physician.

**Burden hours:** 171,704 medical examinations x .08 hour = 13,736 hours

**Cost:** 13,736 hours x \$24.31 = \$333,922

*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:** 171,704 medical examinations x .08 hour = 13,736 hours

**Cost:** 13,736 hours x \$24.31 = \$333,922

*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 \$25.34 = \$15,204

*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 1,694 medical examinations will be administered (i.e., approximately 1% of the 169,410 workers) as a result of a worker requesting multiple-physician review, and that the process will involve examinations by a second and third physician. OSHA also estimates that a worker will take one hour to complete the required medical examination. Therefore, the annual estimated burden hours and cost of this provision are:<sup>13</sup>

**Burden hours:** 1,694 medical examinations x 1 hour = 1,694 hours

**Cost:** 1,694 hours x \$25.34 = \$42,926

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

No burden hours or costs taken. See Item 2 of this Supporting Statement.

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

No burden hours or costs taken. See Item 2 of this Supporting Statement.

**(I) Recordkeeping (§1910.1048(o))**

Employers must establish and maintain worker 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 20,028 initial-monitoring records and 67,764 periodic-monitoring records (i.e., 33,882 workers sampled twice a year), for a total of 87,792 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:

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<sup>13</sup>Note that the Agency accounted for the burden hours and cost of an employer providing workers 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.”

**Burden hours:** 87,792 records x .08 hour = 7,023 hours

**Costs:** 7,023 hours x \$24.31 = \$170,729

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

Employers must establish and maintain a record of the objective data they use to determine that worker 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 \$24 (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 “(F) Medical surveillance,” the Agency estimates that this provision requires employers to establish and update (i.e., maintain) 171,704 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:** 171,704 records x .08 hour = 13,736 hours

**Cost:** 13,736 hours x \$24.31 = \$333,922

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

If an employer conducts fit testing for workers using negative-pressure respirators, the employer must establish and maintain accurate fit-testing records for these workers. 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; worker exposure-monitoring records to current and former workers covered by the Standard, and to worker representatives; and an worker’s medical-surveillance records to that worker (whether currently or formerly employed by the employer), and to anyone having that worker’s specific written consent. The requirements of paragraphs (a)-(e) and (g)-(i) of CFR 1910.1020 (“Access to worker exposure and medical records;” referred to as the “Records-Access Standard”) regulate the release of exposure-monitoring and medical-surveillance records to workers and other parties.

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% (16,941) of the 169,410 covered workers (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 workers and their designated worker representatives. Therefore, the annual estimated burden hours and cost of this provision are:

**Burden hours:** 16,941 worker-related requests x .08 = 1,355 hours  
**Cost:** 1,355 hours x \$24.31 (clerical/secretarial) = \$32,940

**Table 1 - Summary of Annual Burden Hours and Cost Estimates**

Information Collection Requirement	Responses	Current Burden Hours	Requested Burden Hours	Change	Estimated Cost
<b>A. Exposure monitoring</b>					
General	20,028	3,465	3,405	-60	\$142,806
Periodic monitoring	67,764	11,488	11,520	32	\$483,149
Worker notification of monitoring results	25,896	2,038	2,072	34	\$50,370
<b>B. Regulated areas</b>	863	144	147	3	\$6,165
<b>C. Respiratory protection (including respirator fit testing)</b>	0	0	0	0	\$0
<b>D. Maintenance of protective equipment and clothing</b>	0	0	0	0	\$0
<b>E. Housekeeping</b>	0	0	0	0	\$0
<b>F. Medical surveillance</b>					
	169,410	168,933	169,410	477	\$4,292,849

<b>Information Collection Requirement</b>	<b>Responses</b>	<b>Current Burden Hours</b>	<b>Requested Burden Hours</b>	<b>Change</b>	<b>Estimated Cost</b>
Workers covered, examination by a physician, Medical disease questionnaire, medical examinations, and examinations for Workers exposed to an emergency					
Information provided to the physician	171,704	13,698	13,736	38	\$333,922
Physician's written opinion	171,704	13,698	13,736	38	\$333,922
Medical removal	600	600	600	0	\$15,204
Multiple physician review	1,694	1,689	1,694	5	\$42,926
<b>G. Hazard communication</b>	0	0	0	0	\$0
<b>H. Employee information and training</b>	0	0	0	0	\$0
<b>I. Recordkeeping</b>					
Exposure measurements	87,792	7,037	7,023	-14	\$170,729
Exposure determinations	1	1	1	0	\$24
Medical surveillance	171,704	13,698	13,736	38	\$333,922
Respirator fit testing	0	0	0	0	\$0
Record retention	0	0	0	0	\$0
Availability of records (including access to training materials)	16,941	1,365	1,355	-10	\$32,940
<b>TOTALS</b>	<b>906,101</b>	<b>237,854</b>	<b>238,435</b>	<b>581</b>	<b>\$6,238,928</b>

**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*

The Agency estimated a cost of \$50.25 per sample to collect and analyze airborne formaldehyde using collar badges.<sup>14</sup> The determinations made under “(L) Recordkeeping” above indicate a total of 87,792 samples are taken per year. Therefore, the annual estimated cost of this requirement to employers is \$4,411,548 (\$50.25 per sample x 87,792 samples).

### *Medical surveillance*

Consistent with recent ICRs and RIAs for other standards, the Agency estimates that each medical examination costs an employer \$228.<sup>15</sup> According to the determinations made above, a total of 171,704 medical examinations are administered each year. Therefore, the annual estimated cost of this requirement to employers is \$39,148,512 (\$228 x 171,704 medical examinations). Therefore, the annual estimated cost of the medical surveillance and exposure monitoring to employers is \$43,560,060 (\$39,148,512 + \$4,411,548).

- 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.**

## **COSTS TO FEDERAL GOVERNMENT**

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<sup>14</sup> Source: To calculate the cost per sample to collect and analyze airborne formaldehyde, the Agency used the most recent OES mean hourly wage rate for SOC code 29-9011, Occupational Health and Safety Specialist, \$34.51. (See: <http://www.bls.gov/oes/current/oes299011.htm>.) The wage rate was multiplied by 1.456 to adjust for fringe benefits. The total hourly employee compensation is \$50.25 for SOC 29-9011. The 2013 ICR assumed the cost per sample to collect and analyze airborne formaldehyde to be \$50.00; the Agency calculated this cost using the Consumer Price Index (CPI) to inflate the estimate from the 2010 ICR. However, the Agency has now determined that using the most recent OES wage data is a better source for estimating this exposure monitoring cost to employers.

<sup>15</sup> Average price of an office-based visit with a physician. (Source: Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey (MEPS) 2015, [http://meps.ahrq.gov/mepsweb/data\\_files/publications/st484/stat484.pdf](http://meps.ahrq.gov/mepsweb/data_files/publications/st484/stat484.pdf) .)

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

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

OSHA is requesting an adjustment increase in the burden hours of these collections of information from 237,854 to 238,435 hours, for a total increase of 581 hours. The increase is due to the overall estimated increase in the number of covered establishments and workers. Table 1 above provides a summary of the burden hour and costs.

The costs to conduct a medical examination increased (from \$218 to \$228) and for contract industrial hygiene services to conduct exposure-monitoring sampling increased (from \$50 to \$50.25). Total capital costs increased, from \$41,724,296 to \$43,560,060, an increase of \$1,835,764. The increase is due to the estimated increase in the number of covered workers undergoing exposure monitoring and medical exams.

**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.**

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

**B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS.**

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