

**SUPPORTING STATEMENT FOR THE  
INFORMATION COLLECTION REQUIREMENTS IN  
THE 13 CARCINOGENS STANDARD (29 CFR 1910.1003<sup>1</sup>)  
OFFICE OF MANAGEMENT BUDGET (OMB)  
CONTROL NO. 1218-0085 (January 2025)**

The agency is seeking an extension of a currently approved data collection.

**A. JUSTIFICATION**

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

The Occupational Safety and Health Act's (OSH Act) main objective 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 *et seq.*). As one means in achieving this objective, the OSH Act specifically authorizes "the development and promulgation of occupational safety and health standards" to ensure that workers will be furnished "employment and a place of employment which are free from recognized hazards that are causing or likely to cause death or serious physical harm."

For toxic substances, the OSH Act contains specific statutory language. Thus, as appropriate, health standards must include provisions for monitoring and measuring worker exposure, medical examinations and other tests, control and other technological procedures, suitable protective equipment, labels and other appropriate forms of warning, and precautions for safe use or exposure (29 U.S.C. 655(b)(7)). In addition, the OSH Act specifically mandates issuing "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 requires that workers exposed to concentrations over prescribed limits be notified of this fact, and of the corrective action being taken (29 U.S.C. 657(c)(1) and (c)(3)).

The 13 Carcinogens Standard covers the following carcinogens: 4-Nitrobiphenyl (§1910.1003), alpha-Naphthylamine (§1910.1004), Methyl chloromethyl ether (§1910.1006), 3,3'-Dichlorobenzidine (and its salts) (§1910.1007), bis-Chloromethyl ether (§1910.1008), beta-

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<sup>1</sup>Reference to 29 CFR 1910.1003 also incorporates the 13 Carcinogens Standards for Shipyards (29 CFR 1915.1003-.1016) and Construction (29 CFR 1926.1103-.1116), which have requirements identical to those contained in §1910.1003.

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Naphthylamine (§1910.1009), Benzidine (§1910.1010), 4-Aminodiphenyl (§1910.1011), Ethyleneimine (§1910.1012), beta-Propiolactone (§1910.1013), 2-Acetylaminofluorene (§1910.1014), 4-Dimethylaminoazobenzene (§1910.1015), and N-Nitrosodimethylamine (§1910.1016).

The standard provides protection for workers from adverse health effects associated with occupational exposure to these substances. Items 2 and 12 below describe in detail 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.**

**A. General regulated area requirements (§1910.1003(d))**

**Respirator program §1910.1003(d)(1)** - The employer must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b), (c), (d) (except (d)(1)(iii) and (iv), and (d) (3)), and (e) through (m), which covers each employee required by this section to use a respirator.

**Purpose:** To ensure that employers establish a standardized procedure for selecting, using, and maintaining respirators for each workplace where respirators will be used. Developing written procedures ensures that employers develop a respirator program that meets the needs of their workers.

**Emergencies §1910.1003(d)(2)** - In an emergency, immediate measures including, but not limited to, the requirements of paragraphs (d)(2)(i) through (v) of this section shall be implemented.

**§1910.1003(d)(2)(iii)** - Requires employers to provide special medical surveillance by a physician within 24 hours for employees present in the potentially affected area at the time of the emergency.

**Purpose:** The emergency medical surveillance is necessary to ensure that no worker has suffered adverse effects as a result of the emergency.

**Decontamination procedures §1910.1003(d)(4)(iii)** - Decontamination procedures shall be established and implemented to remove carcinogens addressed by this section from the surfaces of materials, equipment, and the decontamination facility.

**Purpose:** Implementation of these procedures will remove carcinogens from materials, equipment, and the decontamination facility.

**Communication of hazards §1910.1003(e)(1) - Hazard communication.** (i) Chemical manufacturers, importers, distributors, and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§1910.1200) for each carcinogen listed in paragraph (e)(1)(iv) of this section.

(ii) In classifying the hazards of carcinogens listed in paragraph (e)(1)(iv) of this section, at least the hazards listed in paragraph (e)(1)(iv) are to be addressed.

(iii) Employers shall include the carcinogens listed in paragraph (e)(1)(iv) of this section 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 the carcinogens listed in paragraph (e)(1)(iv) and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (e)(4) of this section.

(iv) List of Carcinogens:

(A) 4-Nitrobiphenyl: Cancer.

(B) alpha-Naphthylamine: Cancer; skin irritation; and acute toxicity effects.

(C) Methyl chloromethyl ether: Cancer; skin, eye, and respiratory effects; acute toxicity effects; and flammability.

(D) 3,3'-Dichlorobenzidine (and its salts): Cancer and skin sensitization.

(E) bis-Chloromethyl ether: Cancer; skin, eye, and respiratory tract effects; acute toxicity effects; and flammability.

(F) beta-Naphthylamine: Cancer and acute toxicity effects.

(G) Benzidine: Cancer and acute toxicity effects.

(H) 4-Aminodiphenyl: Cancer.

(I) Ethyleneimine: Cancer; mutagenicity; skin and eye effects; liver effects; kidney effects; acute toxicity effects; and flammability.

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(J) beta-Propiolactone: Cancer; skin irritation; eye effects; and acute toxicity effects.

(K) 2-Acetylaminofluorene: Cancer.

(L) 4-Dimethylaminoazo-benzene: Cancer; skin effects; and respiratory tract irritation.

(M) N-Nitrosodimethylamine: Cancer; liver effects; and acute toxicity effects.

(2) *Signs.* (i) The employer shall post entrances to regulated areas with signs bearing the legend:

DANGER  
(CHEMICAL IDENTIFICATION)  
MAY CAUSE CANCER  
AUTHORIZED PERSONNEL ONLY

(ii) The employer shall post signs at entrances to regulated areas containing operations covered in paragraph (c)(5) of this section. The signs shall bear the legend:

DANGER  
(CHEMICAL IDENTIFICATION)  
MAY CAUSE CANCER  
WEAR AIR-SUPPLIED HOODS, IMPERVIOUS SUITS, AND PROTECTIVE EQUIPMENT  
IN THIS AREA  
AUTHORIZED PERSONNEL ONLY

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

CANCER-SUSPECT AGENT  
AUTHORIZED PERSONNEL ONLY

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

CANCER-SUSPECT AGENT EXPOSED IN THIS AREA  
IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD  
REQUIRED AT ALL TIMES  
AUTHORIZED PERSONNEL ONLY

(v) Appropriate signs and instructions shall be posted at the entrance to, and exit from, regulated areas, informing employees of the procedures that must be followed in entering and leaving a regulated area.

(3) *Prohibited statements.* No statement shall appear on or near any required sign, label, or instruction that contradicts or detracts from the effect of any required warning, information, or instruction.

(4) *Training and indoctrination.* (i) Each employee prior to being authorized to enter a regulated area, shall receive a training and indoctrination program including, but not necessarily limited to:

(A) The nature of the carcinogenic hazards of a carcinogen addressed by this section, including local and systemic toxicity;

(B) The specific nature of the operation involving a carcinogen addressed by this section that could result in exposure;

(C) The purpose for and application of the medical surveillance program, including, as appropriate, methods of self-examination;

(D) The purpose for and application of decontamination practices and purposes;

(E) The purpose for and significance of emergency practices and procedures;

(F) The employee's specific role in emergency procedures;

(G) Specific information to aid the employee in recognition and evaluation of conditions and situations which may result in the release of a carcinogen addressed by this section;

(H) The purpose for and application of specific first aid procedures and practices;

(I) A review of this section at the employee's first training and indoctrination program and annually thereafter.

(ii) Specific emergency procedures shall be prescribed, and posted, and employees shall be familiarized with their terms, and rehearsed in their application.

(iii) All materials relating to the program shall be provided upon request to authorized representatives of the Assistant Secretary and the Director.

**Purpose:** Such signs warn workers that entry is permitted only if they are authorized to do so, and there is a specific need to enter the area. Warning signs also supplement the training workers receive under this standard.

Posting emergency procedures provides a continuing reminder to workers of what actions they need to take if an emergency occurs.

### **Medical Surveillance (§1910.1003(g))**

At no cost to the worker, a program of medical surveillance shall be established and implemented for workers considered for assignment to enter regulated areas, and for authorized workers.

**Examinations §1910.1003(g)(1)(i)** - Before an employee is assigned to enter a regulated area, a preassignment physical examination by a physician shall be provided. The examination shall include the personal history of the worker, family, and occupational background, including genetic and environmental factors.

**§1910.1003(g)(1)(ii)** - Authorized employees shall be provided periodic physical examinations, not less often than annually, following the preassignment examination.

**§1910.1003(g)(1)(iii)** - In all physical examinations, the examining physician shall consider whether there exist conditions of increased risk, including reduced immunological competence, those undergoing treatment with steroids or cytotoxic agents, pregnancy, and cigarette smoking.

**Purpose:** Worker health must be documented periodically so that a physician can determine whether workers have experienced adverse health effects over the course of their exposure to the carcinogenic chemicals regulated by this standard. In addition, if symptoms of organic damage

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appear, the physician often needs information about the patient's previous medical conditions to make an accurate diagnosis of the new problem, its apparent cause, and the course of treatment required. Further, these medical records will aid workers and their physicians in determining whether treatment or other interventions are needed for occupational exposure to any of the carcinogens.

**Records §1910.1003(g)(2)(i)** - Employers of employees examined pursuant to this paragraph shall cause to be maintained complete and accurate records of all such medical examinations. Records shall be maintained for the duration of the employee's employment.

§1910.1003(g)(2)(ii) - Records required by this paragraph shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.1020 (a) through (e) and (g) through (i). These records shall also be provided upon request to the Director<sup>2</sup>.

§1910.1003(g)(2)(iii) - Any physician who conducts a medical examination required by this paragraph shall furnish to the employer a statement of the employee's suitability for employment in the specific 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 burdens.**

Employers may use improved information technology as appropriate when making, keeping, and preserving the required records. The standard is written in performance-oriented language, that is, in terms of what data must be collected and maintained, rather than how the data must be collected and maintained.

**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 by this standard is specific to each employer and worker involved and is not available or duplicated by another source. This information is available only from employers. Currently, there is no indication that any alternate source is available.

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<sup>2</sup> *Director* means the Director, National Institute for Occupational Safety and Health, or any person directed by him or the Secretary of Health and Human Services to act for the Director.

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

The information collections do not have a significant impact on a substantial number of small entities.

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

The information collection frequencies specified by this standard are the minimum OSHA believes are necessary to ensure that employers and OSHA can effectively monitor the health status of workers working with any of the 13 carcinogens.

**7. Explain any special circumstances that would cause an information collection to be conducted in a manner:**

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which**

**unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

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

No special circumstances exist that require employers to collect information in the manner or using the procedure specified by this item; the paperwork requirements in the Standard conform to the guidelines set forth in 5 CFR 1320.5.

- 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.**

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), OSHA published a notice in the Federal Register on October 30, 2024, (89 FR 86374) OSHA Docket No -2011-0860 soliciting comments on its proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified by The 13 Carcinogens Standard. This notice was a part of a preclearance consultation program that provides the general public and government agencies with an opportunity to comment.

The agency received one comment from an anonymous commenter under docket number OSHA-

2010-0047 in response to this notice. The commenter states:

*I believe that the Office of Management and Budget's approval of information collection requirements extension should be granted. Since they are only asking for less than one hundred additional hours and a cost below \$400,000, I believe that the price is relatively low in contrast to the benefit that will arise from a thorough and well done study. Carcinogens have no place in any workplace, so it is vital that they are eliminated and that we better understand where they are in our current workplace.*

OSHA appreciates your support in regards for OMB to extend the approval of the collection of information requirements contained in the 13 Carcinogens Standard. This standard and its information collection requirements provides protection for employees from the adverse effects associated with the occupational exposure to the following carcinogens: 4-Nitrobiphenyl, alpha-Naphthylamine, methyl chloromethyl ether, 3,3-Dichlorobenzidine (and its salts), bis-chloromethyl ether, beta-Naphthylamine, Benzidine, 4-Aminodiphenyl, Ethylenimine, beta-Propiolactone, 2-Acetylaminofluorene, 4-Dimethylaminoazo-benzene, and Nnitrosodimethylamine. Thank you for your support in keeping employer's safe.

**9. Explain any decision to provide any payment or gift to respondents, other than remuneration 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.**

Agency files containing personally identifiable employee medical information shall be segregated from other agency files. When not in active use, files containing this information shall be kept secured in a locked cabinet or vault. The OSHA Medical Records Officer and the Principal OSHA Investigator shall each maintain a log of uses and transfers of personally identifiable employee medical information and lists of coded direct personal identifiers, except as to necessary uses by staff under their direct personal supervision.

The photocopying or other duplication of personally identifiable employee medical information shall be kept to the minimum necessary to accomplish the purposes for which the information was obtained. The protective measures established by this section apply to all worksheets, duplicate copies, or other agency documents containing personally identifiable employee medical information. Intra-agency transfers of personally identifiable employee medical information shall be by hand delivery, United States mail, or equally protective means.

Consistent with OSHA records disposition programs, personally identifiable employee medical information and lists of coded direct personal identifiers shall be destroyed or returned to the original record holder when no longer needed for the purposes for which they were obtained. Personally identifiable employee medical information which is currently not being used actively but may be needed for future use shall be transferred to the OSHA Medical Records Officer. The OSHA Medical Records Officer shall conduct an annual review of all centrally held information to determine which information is no longer needed for the purposes for which it was obtained.

Since employee medical records contain information that may be considered private, OSHA has taken steps to ensure that the data are kept private to the extent allowed by law. Rules of Agency practice and procedure governing OSHA access to worker medical records are contained in 29 CFR 1913.10 and 29 CFR 1910.1020. The legal authority for these procedural regulations is found in sections 8(c)(1) and 8(g)(2) of the Occupational Safety and Health, 29 U.S.C. 657.

**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 Standard requires that worker pre-assignment medical examinations include a personal history of the worker and a family background, including “genetic and environmental factors” (§1910.1003(g)(1)(i)). In addition, in all physical examinations (pre-assignment, periodic, emergency) the physician must consider whether conditions exist that pose increased risk to the worker. The Standard specifically mentions the following conditions: reduced immunological competence, pregnancy, cigarette smoking, and treatment involving steroids or cytotoxic agents. This information is necessary to ensure that workers will not be at increased risk of harm if they enter or work in a regulated area or have not been harmed due to a workplace emergency. Regarding pregnant workers, obtaining such information will also help to ensure that entering or working in a regulated area will not result in adverse developmental health effects.

**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.**
- **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 14.**

### **Respondent Burden Hour and Cost Determination**

Table 1 summarizes the number of establishments and number of exposed workers based on previous ICR estimates. In attempting to update these figures, the agency examined the quires Protection Agency (EPA) Toxic Release Inventory (TRI) program data reporting years (RY) 2013- 2023. By expanding the number of RY searched, the agency could identify establishments that may have had a single release in preceding years and would not appear in quires of past few years. In previous ICRs, the agency also searched the *Directory of Chemical Producers* (DCP) and found no domestic U.S. production of any of the 13 carcinogens. TRI data indicates that releases of these chemicals are often limited to just a few establishments.<sup>3</sup> Given this, OSHA believes the number of establishments may be overestimated, and, thus, the burden hours and costs are overestimated. However, the *DCP* only includes production establishments, while the TRI database only identifies Establishments releasing chemicals in quantities greater than reporting thresholds. Because of these limitations, it is unclear the total number of establishments covered by the Standard that might be engaged in processing, repackaging, releasing, handling, or storing a particular chemical. The agency maintains the existing establishment and exposed workers estimates unless the TRI database identifies additional establishments.

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<sup>3</sup>For previous ICRs, the agency searched the *Directory of Chemical Producers* by chemical name listed in the Standard, commonly used alternate names, and Chemical Abstract Service (CAS) Registry Numbers (<http://www.sriconsulting.com/DCP/Public/index.html>). Generally, EPA TRI data for each chemical is discussed below in Table 1. Environmental Protection Agency (EPA), 2023. Toxic Releases Inventory (TRI) Basic Data Files: Calendar Years 1987 - 2023. Available at <https://www.epa.gov/toxics-release-inventory-tri-program/tri-basic-data-files-calendar-years-1987-2016> (Accessed September 16, 2024).

**Table 1. Establishments and Exposure Data**

Previous CFR Citation	Title	OMB Inventory Number	CAS Number	Number of Establishments	Number of Exposed Workers
1910.1003	4-Nitrobiphenyl <sup>1</sup>	1218-0085	92-93-3	0	0
1910.1004	$\alpha$ -Naphthylamine <sup>2</sup>	1218-0084	134-32-7	38	200
1910.1006	Methyl Chloromethyl ether <sup>3</sup>	1218-0086	107-30-2	12	169
1910.1007	3,3'-Dichlorobenzidine (and its salts) <sup>4</sup>	1218-0083	91-94-1	12	127
1910.1008	bis-Chloromethyl ether <sup>5</sup>	1218-0087	542-88-1	2	16
1910.1009	$\beta$ -Naphthylamine <sup>6</sup>	1218-0089	91-59-8	10	43
1910.1010	Benzidine <sup>7</sup>	1218-0082	92-87-5	7	41
1910.1011	4-Aminobiphenyl <sup>8</sup>	1218-0090	92-67-1	2	14
1910.1012	Ethyleneimine <sup>9</sup>	1218-0080	151-56-4	11	82
1910.1013	$\beta$ -Propiolactone <sup>10</sup>	1218-0079	57-57-8	10	20
1910.1014	2-Acetylaminofluorene <sup>11</sup>	1218-0088	53-96-3	3	10
1910.1015	4-Dimethylaminoazobenzene <sup>12</sup>	1218-0044	60-11-7	2	20
1910.1016	N-Nitrosodimethylamine <sup>13</sup>	1218-0081	62-75-9	4	28
<b>Totals</b>				<b>113</b>	<b>770</b>

<sup>1</sup> EPA reported that 4-Nitrobiphenyl is no longer manufactured or used in the United States (<https://www.epa.gov/sites/production/files/2016-09/documents/4-nitrobiphenyl.pdf>). Additionally, the EPA TRI database reported found no matches for 4-Nitrobiphenyl in Reporting Years (RY) 2013-2022. TRI Toxics Tracker ([epa.gov](http://epa.gov)).

<sup>2</sup> EPA TRI database reported three establishments that released  $\alpha$ -Naphthylamine for RY 2013-2022. As in previously submitted ICRs, the agency maintains the currently approved number of establishments and exposed workers.

<sup>3</sup> The EPA TRI database reported five establishments with releases of Methyl chloromethyl for RY 2013-2022. EPA reports different uses for Methyl chloromethyl but does not provide current usage statistics (<https://www.epa.gov/sites/production/files/2016-09/documents/chloromethyl-methyl-ether.pdf>). As in previously submitted ICRs, the agency maintains the currently approved number of establishments and exposed workers.

<sup>4</sup> The TRI tracker identified three 3,3'-Dichlorobenzidine (and its salts) establishments in the RY 2013-2022. EPA reports that, while this chemical was used in the past in the production of dyes and pigments, it is no longer used to manufacture dyes in the United States (<https://www.epa.gov/sites/production/files/2016-09/documents/3-3-dichlorobenzidine.pdf>). As in previously submitted ICRs, the agency maintains the currently approved number of establishments and exposed workers.

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<sup>5</sup> EPA reports that BCME is used only as a research chemical and lab reagent and is no longer used commercially in the United States (<https://www.epa.gov/sites/production/files/2016-09/documents/bis-chloromethyl-ether.pdf>). The TRI tracker identified two establishments in the RY 2018-2022. The agency added **one new facility** to the number of establishments and kept the assumption of eight exposed workers per establishment; for a total of sixteen employees.

<sup>6</sup>Department of Health and Human Services, National Toxicology Program, *15<sup>th</sup> Report on Carcinogens* reports that the commercial manufacture and use of  $\beta$ -Naphthylamine was banned in the early 1970s. Today, this chemical is available in small quantities for laboratory research; as of 2009, there were ten U.S. suppliers of  $\beta$ -Naphthylamine <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/naphthylamine.pdf> EPA TRI database reported three establishments reporting  $\beta$ -Naphthylamine for RY 2018-2022. The agency **added two previous establishments** making the total 10.

<sup>7</sup>EPA TRI database identified seven establishments reporting Benzidine for RY 2013 - 2022. “Benzidine is no longer produced in the United States, although benzidine-based dyes maybe imported into this country” <https://www.epa.gov/sites/production/files/2016-09/documents/benzidine.pdf>. The agency added **one new facility**.

<sup>8</sup>EPA TRI database identified two establishments reporting release of 4-Aminobiphenyl for RY 2013-2022. According to EPA 4-Aminobiphenyl is no longer produced commercially (<https://www.epa.gov/sites/production/files/2016-08/documents/4-aminobiphenyl.pdf>). As in previously submitted ICRs, the agency maintains the currently approved number of establishments and exposed workers.

<sup>9</sup>The EPA TRI database reported five establishments reporting release of Ethyleneimine for RY 2013-2022 and reports a number of uses for Ethyleneimine, but does not provide current usage statistics (<https://www.epa.gov/sites/production/files/2016-09/documents/ethyleneimine.pdf>). As in previously submitted ICRs, the agency maintains the currently approved number of establishments and exposed workers.

<sup>10</sup>The EPA TRI database has no reported data of  $\beta$ -Propiolactone for RY2013-2022. EPA reports a number of uses for  $\beta$ -Propiolactone, but does not provide current usage statistics (<https://www.epa.gov/sites/production/files/2016-09/documents/beta-propiolactone.pdf>). As in previously submitted ICRs, the agency maintains the currently approved number of establishments and exposed workers.

<sup>11</sup> The EPA TRI database (RY 2013 -2022) identified three establishments with releases of 2-Acetylaminofluorene. EPA reports that 2-Acetylaminofluorene is “frequently used in the laboratory by biochemists and technicians as a positive control in the study of liver enzymes and the carcinogenesis and mutagenicity of aromatic amines.” <https://www.epa.gov/sites/production/files/2016-08/documents/2-acetylaminofluorene.pdf>. As in previously submitted ICRs, the agency maintains the currently approved number of establishments and exposed workers.

<sup>12</sup>EPA TRI database identifies two establishments with releases, 4-Dimethylaminoazobenzene for RY(2013-2022). EPA reports that the chemical was “used as a dye for coloring polishes and other wax products, polystyrene, soap, and as a pH indicator.” EPA also reports that “4-Dimethylaminoazobenzene is not currently produced or used commercially in the U.S. (<https://www.epa.gov/sites/production/files/2016-09/documents/4-dimethylaminoazobenzene.pdf>). **The agency is adding one new establishment.**

<sup>13</sup>EPA TRI database lists **four**

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**abishments** with releases of N-Nitrosodimethylamine for RY (2013-2022); releases were in 2021 and 2022. EPA reports that “NDMA is not produced in pure form or commercially used, except for research purposes” ([https://www.epa.gov/sites/production/files/2014-03/documents/ffrofactsheet\\_contaminant\\_ndma\\_january2014\\_final.pdf](https://www.epa.gov/sites/production/files/2014-03/documents/ffrofactsheet_contaminant_ndma_january2014_final.pdf)). The agency assumes these are new establishments.

**Wage Rates**

The agency determined the wage rates from mean hourly wage earnings to represent the cost of employees’ time. For the relevant standard occupational classification category, OSHA used the wage rates reported in the Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Wage Statistics (OEWS), May 2023. (OEWS data is available at [May 2023 National Occupational Employment and Wage Estimates \(bls.gov\)](https://www.bls.gov/news.release/oeos2.toc). To access a wage rate, select the, “Occupation profiles,” and the Standard Occupational Classification (SOC) code.) [May 2023 National Occupational Employment and Wage Estimates \(bls.gov\)](https://www.bls.gov/news.release/oeos2.toc)

To account for fringe benefits, the agency used the [Employer Costs for Employee Compensation – December 2023 \(bls.gov\)](https://www.bls.gov/news.release/comp2.toc). Fringe markup is from the following BLS release: [Employer Costs for Employee Compensation Summary - 2024 Q02 Results \(bls.gov\)](https://www.bls.gov/news.release/comp2.toc) news release text; For release, September 10, 2024 [Employer Costs for Employee Compensation – June 2024](https://www.bls.gov/news.release/comp2.toc). BLS reported that private sector workers, fringe benefits accounted for accounted for 29.7 percent of total compensation and wages accounted for the remaining 70.3 percent.

**Table 2. Wage Rate Estimates with Fringe Benefits**

<b>WAGE HOUR ESTIMATES</b>				
<b>Occupational Title</b>	<b>SOC Code</b>	<b>Mean Hourly Wage Rate (A)</b>	<b>Fringe Benefits (B)</b>	<b>Loaded Hourly Wage Rate C=[A/(1-B)]</b>
Professional /Manager/Supervisors	51-1011	\$34.48	.297	\$49.05
Worker /Production Workers	51-0000	\$22.90	.297	\$32.57
Secretaries and Administrative Assistants	43-6014	\$21.87	.297	\$31.11

**(A) General regulated areas (§1910.1003(d))**

**Respirator Program (§1910.1003(d)(1))**

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The information collection requirements pertaining to the respiratory protection requirements in the 13 Carcinogens Standard and burden associated with those requirements are included in the Respiratory Protection standard (29 CFR 1910.134) (OMB Control Number 1218-0099) and, therefore, are not included in this ICR.

### **Emergencies (§1910.1003(d)(2))**

The standard requires that employers implement certain measures in an emergency, including providing special medical surveillance for workers present in the potentially affected area at the time of the emergency. The burden hours and costs associated with emergency medical surveillance is included in the medical surveillance provision discussed in (C) below.

### **Decontamination Procedures (§1910.1003(d)(4))**

Newly identified establishments must establish decontamination procedures to remove carcinogens regulated by the standard from the surfaces of materials, equipment, and the decontamination facility. OSHA estimates a professional takes one hour to develop the decontamination procedures.

#### **New Establishments**

Burden hours:	$7 \text{ new employers} \times 1 \text{ hour} = 7 \text{ hours}$
Costs:	$7 \text{ hours} \times \$49.05 = \$343$

For existing establishments, OSHA estimates that a professional takes 15 minutes (15/60 hours) to review and update decontamination procedures.

#### **Existing Establishments**

Burden hours:	$106 \text{ existing establishments} \times 15/60 \text{ hours} = 27 \text{ hours}$
Costs:	$27 \text{ hours} \times \$49.05 = \$1,324$

### **(B) Signs, information, and training (§1910.1003(e))**

The standard requires that establishments post signs and instructions at regulated area entrances and exits. The standard also specifies how containers must be labeled. Labeling requirements for containers vary depending on whether workers are authorized to be in regulated areas (i.e., authorized workers). In addition, the standard requires specific emergency procedures to be posted.

The standard provides specific language for many of the required signs and labels; therefore, no burden has been taken for this requirement since the government is providing information. (See the final rule on Controlling Paperwork Burden on the Public (5 CFR 1320.3(c)(2)). Burden associated with generating any other required label or sign is attributed to the Information Collection Request for OSHA's Hazard Communication Standard, OMB Control Number 1218-0072.

The training required under §1910.1003(e)(4) is not considered to be subject to the PRA, therefore, no burden is associated with this requirement.

The agency identified seven new establishments covered by this ICR. For these new establishments, OSHA estimates that a professional takes 30 minutes to develop and post the instructions for the entry and exit procedures for regulated areas and one hour to develop and post emergency procedures (90/60 hours)

#### **New Establishments**

Burden hours:	$7 \text{ new establishments} \times 1.5 \text{ hours} = 11 \text{ hours}$
Costs:	$11 \text{ hours} \times \$49.05 = \$540$

The agency estimates that 106 existing establishments are using the 13 carcinogens. For existing establishments, OSHA assumes a professional would take 15 minutes (15/60 hours) to review, update and post existing instructions for the entry and exit procedures for regulated areas, and existing emergency procedures.

#### **Existing Establishments**

Burden hours:	$106 \text{ existing employers} \times 15/60 \text{ hours} = 27 \text{ hours}$
Costs:	$27 \text{ hours} \times \$49.05 = \$1,324$

#### **(C) Medical surveillance (§1910.1003(g)(2)(i))**

OSHA estimates that 770 workers receive pre-assignment, periodic or emergency medical exams. Of the 770 workers, OSHA estimates that one supervisor per establishment, 113 supervisors, receive medical examinations. The remaining 657 are workers receiving a medical examination. OSHA estimates that supervisors and workers spend two hours away from the job per medical exam, and that a clerk would expend 5 minutes (5/60 hours) to update/maintain the corresponding medical records.

### **Update and Maintain Medical Records**

Burden hours: 770 exams  $\times$  5/60 hours = 64 hours  
Cost: 64 hours  $\times$  \$31.11 = \$1,991

### **Medical Exams**

**Workers:** Burden hours: 657 workers  $\times$  2 hours = 1,314  
Cost: 1,314 hours  $\times$  \$32.57 = \$42,797

**Supervisors:** Burden hours: 113 medical exams  $\times$  2 hours = 226  
Cost: 226 hours  $\times$  \$49.05 = \$11,085

### **(D) Records Access (§1910.1003(g)(2)(ii))**

OSHA assumes that all workers who receive medical examinations will request records access to their medical records since the standard does not require employers to provide a physician's written opinion to the worker. Each request takes 5 minutes (5/60 hours) of clerical time to process.

Burden hours: 770 workers  $\times$  5/60 hours = 64 hours  
Cost: 64 hours  $\times$  \$31.11 = \$1,991

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<b>Table 3 Estimated Annualized Respondent Hour and Cost Burden</b>								
<b>Information Collection Requirement</b>	<b>Type of Respondent*</b>	<b>Respondents</b>	<b>Responses per Respondent</b>	<b>Total Responses</b>	<b>Time per Response</b>	<b>Burden Hours</b>	<b>Loaded Hourly Wage</b>	<b>Burden Cost</b>
<b>A. General regulated areas (§1910.1003(d))</b>								
<b>Respirator Program §1910.1003(d)(1)</b>	N/A	0	0	0	0	0	\$0.00	\$0
<b>Emergencies §1910.1003(d)(2)</b>	N/A	0	0	0	0	0	\$0.00	\$0
<i>Decontamination procedures §1910.1003(d)(4)(iii)</i>								
<b>New Establishments</b>	<b>Professional</b>	7	1	7	1	7	\$49.05	\$343
<b>Existing Employers</b>	<b>Professional</b>	106	1	106	0.25	27	\$49.05	\$1,324
<b>B. Signs, information, and training §1910.1003(e)</b>								
<b>New Establishments</b>	<b>Professional</b>	7	1	7	1.5	11	\$49.05	\$540
<b>Existing Employers</b>	<b>Professional</b>	106	1	106	0.25	27	\$49.05	\$1,324
<b>C. Medical surveillance §1910.1003(g)(1) and (g)(2)(i)</b>								
<b>Clerical Time to Maintain Records</b>	<b>Clerical</b>	770	1	770	0.083	64	\$31.11	\$1,991

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<b>Worker Exam Time</b>	<b>Worker</b>	<b>657</b>	<b>1</b>	<b>657</b>	<b>2</b>	<b>1,314</b>	<b>\$32.57</b>	<b>\$42,797</b>
<b>Professional Exam Time</b>	<b>Professional</b>	<b>113</b>	<b>1</b>	<b>113</b>	<b>2</b>	<b>226</b>	<b>\$49.05</b>	<b>\$11,085</b>
<b>Records Access</b>	<b>Clerical</b>	<b>770</b>	<b>1</b>	<b>770</b>	<b>0.083</b>	<b>64</b>	<b>\$31.11</b>	<b>\$1,991</b>
<b>Total</b>								
<b>Total</b>	<b>—</b>		<b>—</b>	<b>2,536</b>	<b>—</b>	<b>1,740</b>	<b>—</b>	<b>\$61,395</b>

\*Respondents are private sector establishments—business or other for profit. The number of respondents is 770.

**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.**

**Medical exams**

OSHA estimates that each worker's medical exam, which includes the physician's written opinion, costs the employer \$444.<sup>4</sup> Approximately 770 medical exams will be given annually for a total cost of \$341,880.

**Costs:** 770 exams x \$444 = \$341,880

- 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.**

There is no cost to the Federal Government associated with this information collection request. The disclosure of records during an inspection is not subject to the PRA under 5 CFR 1320.4(a) (2). OSHA would only review records in the context of an open investigation of a particular employer to determine compliance with the Standard. Therefore, OSHA takes no burden or cost in this Supporting Statement for disclosing information during an inspection.

- 15. Explain the reasons for any program changes or adjustments reporting in Item 12 or 13 of this Supporting Statement.**

OSHA is requesting an adjustment increase of 131 hours (from 1,609 hours to 1,740 hours). The increase is a result of a slight increase in the number of establishments affected by the Standard from 104 to 113 establishments. The agency is also requesting an adjustment cost increase of \$34,716 from \$307,164 to \$341,880. The increase results from an increase in the number of workers receiving medical examinations, from 716 to 770 and an increase in the cost of medical examinations from \$429 to \$444.

- 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.**

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<sup>4</sup>The information source for this estimate has changed from the previous ICR. The \$444 used for this ICR comes from <https://www.fairhealthconsumer.org/medical/results>. FAIRHealth Consumer reports that a physician's fee would cost \$168, and the hospital fee would cost \$276 for an out-of-network/uninsured patient in St. Louis, Missouri. The Agency base the increase on the CPI of 10.759%.

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The collection of information will not be published.

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

OSHA lists current valid control numbers in §§1910.8, 1915.8, 1917.4, 1918.4, and 1926.5 and publishes the expiration date in the Federal Register notice announcing OMB approval of the information collection requirement (See 5 CFR 1320.3(f)(3)). OSHA believes that this is the most appropriate and accurate mechanism to inform interested parties of these expiration dates.

**18. Explain each exception to the certification statement.**

OSHA is not seeking such exceptions.

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

This collection of information does not employ statistical methods.