**SUPPORTING STATEMENT FOR THE
INFORMATION COLLECTION REQUIREMENTS IN
THE 13 CARCINOGENS STANDARD (29 CFR 1910.1003[1])
OFFICE OF MANAGEMENT BUDGET (OMB)
CONTROL NO. 1218-0085 (October 2024)**

This is a request to extend/revise (select one) 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-Naphthylamine (§1910.1009), Benzidine (§1910.1010), 4-Aminodiphenyl (§1910.1011), Ethyleneimine (§1910.1012), beta-Propiolactone (§1910.1013), 2-Acetylaminofluorene (§1910.1014), 4-Dimethylaminoazo-benzene (§1910.1015), and N-Nitrosodimethylamine

(§1910.1016). The standard provides protection for workers from adverse health effects

[1]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.

associated with occupational exposure to these substances.

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 employer 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.

B. Signs, information, and training (§1910.1003(e))

(e) *Communication of hazards*— (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.

(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 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.

§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 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.

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.

As required by 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) requesting public comments on its proposed extension of the information collection requirements specified by the 13 Carcinogens Standard (29 CFR 1910.1003) under docket number OSHA 2011-0860. This notice is part of a preclearance consultation program intended to provide those interested parties the opportunity to comment on OSHA's request for an extension by OMB of previous approval of the information collection requirements found in the above Standard. The agency will respond to any public comments received in response to this notice.

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

No payments or gifts will be provided 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. With regard to 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.**

Wage Rates

The agency determined the wage rates from mean hourly wage earnings to represent the cost of employee 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. (OES data is available at May 2023 National Occupational Employment and Wage Estimates (bls.gov). 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)

To account for fringe benefits, the agency used the Employer Costs for Employee Compensation – December 2023 (bls.gov) Fringe markup is from the following BLS release: Employer Costs for Employee Compensation Summary - 2024 Q02 Results (bls.gov) news release text; For release, September 10, 2024 Employer Costs for Employee Compensation – June 2024. 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.

- Professional/Manager/Supervisor $45.63[2]
- Worker $28.52[3]

[2] Occupation Code: 51-1011, First-line supervisors of production and operating workers.

[3] Occupation Code: 51-0000, Production occupations.

- Clerical/Secretary $27.60[4]

Table 1. Wage Estimates

Occupational Title	Standard Occupation Code (SOC)	Mean Hourly Wage Rate A	Fringe Benefits B	Loaded Hourly Wage Rate C=A* /1/1-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

Table 2 summarizes the number of establishments and number of exposed workers based on previous ICR estimates updated with new information where possible. In attempting to update these figures, the Agency examined the Environmental Protection Agency (EPA) Toxic Release Inventory (TRI) program data (TRI data) for 2023. For 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 facilities.[5] Given this, OSHA believes the number of facilities may be overestimated, and, thus, the burden hours and costs are overestimated. However, the *DCP* only includes production facilities, while the TRI database only identifies facilities releasing chemicals in quantities greater than reporting thresholds. Because of these limitations, it is unclear the total number of facilities covered by the Standard that might be engaged in processing, repackaging, releasing, handling, or storing a particular chemical. As indicated in Table 2, the Agency now estimates that 100 establishments and 667 exposed workers are now affected the Standard. The Agency believes the main reason for the slight reduction in burden is that TRI exposes less data.

[4] Occupation Code 43-6014, Secretaries and administrative assistants, except legal, medical and executive.

[5]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). 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 2. Establishments and Exposure Data

Previous CFR Citation	Title	OMB Inventory Number	CAS Number	Number of Establishments	Number of Exposed Workers
1910.1003	4-Nitrobiphenyl[1]	1218-0085	92-93-3	0	0
1910.1004	α-Naphthylamine[2]	1218-0084	134-32-7	38	200
1910.1006	Methyl chloromethyl ether[3]	1218-0086	107-30-2	12	169
1910.1007	3,3'-Dichlorobenzidine (and its salts)[4]	1218-0083	91-94-1	12	127
1910.1008	bis-Chloromethyl ether[5]	1218-0087	542-88-1	1	8
1910.1009	β-Naphthylamine[6]	1218-0089	91-59-8	7	27
1910.1010	Benzidine[7]	1218-0082	92-87-5	4	14
1910.1011	4-Aminobiphenyl[8]	1218-0090	92-67-1	2	0
1910.1012	Ethyleneimine[9]	1218-0080	151-56-4	10	82
1910.1013	β-Propiolactone[10]	1218-0079	57-57-8	10	20
1910.1014	2-Acetylaminofluorene[11]	1218-0088	53-96-3	3	10
1910.1015	4-Dimethylaminoazobenzene[12]	1218-0044	60-11-7	1	10
1910.1016	N-Nitrosodimethylamine[13]	1218-0081	62-75-9	0	0
Total				**100**	**667**

[1] EPA reports 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 no releases of 4-Nitrobiphenyl for Reporting Year (RY) 2019.

[2] EPA TRI database reported two facilities that released α-Naphthylamine for RY2019. However, these facilities were also reported in the TRI database in previous reporting years.

[3] The EPA TRI database reported no release of Methyl chloromethyl ether for RY2019. 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 l

[4]The EPA TRI database reported no release of 3,3'-Dichlorobenzidine for RY2019. 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).

[5]The EPA TRI database reported no release of bis-Chloromethyl ether (BCME) for RY2019. 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).

[6]Department of Health and Human Services, National Toxicology Program reports that the commercial manufacture and use of β-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 β-Naphthylamine (https://ntp.niehs.nih.gov/ntp/roc/content/profiles/naphthylamine.pdf). EPA TRI database reported one facility reporting β-Naphthylamine for RY2019. However, this was the same facility as reported in the TRI database for RY2016.

[7]EPA TRI database included five facilities reporting Benzidine for RY2019. Three of the five facilities reported also appeared in the TRI database for RY2016. EPA also reports that "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). OSHA included two new facilities and estimates fourteen exposed workers based on an average of seven workers per establishment as used in previous ICRs.

[8]EPA TRI database included two facilities reporting release of 4-Aminobiphenyl for RY2019. However, these facilities were also recorded in the TRI database for RY2016. According to EPA4-Aminobiphenyl is no longer produced commercially (https://www.epa.gov/sites/production/files/2016-08/documents/4-aminobiphenyl.pdf 1).

[9]The EPA TRI database reported two facilities reporting release of Ethyleneimine for RY2019. One of the two facilities reported also appeared in the TRI database for RY2016. OSHA included the one new facility and estimates seven exposed workers based on an average of seven workers per establishment as used in previous ICRs. EPA also 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 1).

[10]The EPA TRI database has no reported data of β-Propiolactone for RY2019. EPA reports a number of uses for β-Propiolactone, but does not provide current usage statistics (https://www.epa.gov/sites/production/files/2016-09/documents/beta-propiolactone.pdf)

[11]The EPA TRI database has no reported data of 2-Acetylaminofluorene for RY2019. 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).

[12]EPA TRI database lists one facility reporting 4-Dimethylaminoazobenzene for RY2019. This facility is the same as the one that was reported in the EPA TRI for RY2016. 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-Dimethylaminoazobenzeneis not currently produced or used commercially in the U.S (https://www.epa.gov/sites/production/files/2016-09/documents/4-dimethylaminoazobenzene.pdf).

[13]EPA TRI database reports no release of N-Nitrosodimethylamine for RY2019. EPA also 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/ffrrofactsheet_contaminant_ndma_january2014_final.pdf).

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

Respirator Program (§1910.1003(d)(1))

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))

Employers must establish decontamination procedures to remove carcinogens regulated by the standard from the surfaces of materials, equipment, and the decontamination facility. OSHA assumes that a professional would take 15 minutes (15/60 hour) to review and update decontamination procedures. In addition, after conducting extensive research, the Agency deduced that there were four less covered by this ICR. For these new establishments, OSHA assumes that a professional would take 1 hour to develop the decontamination procedures.

Burden hours: 100 existing employers × 15/60 hour = 25 hours
Costs: 25 hours × $49.05 = $1,226

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

The standard requires that employers 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 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 estimates that 100 existing establishments are using the 13 carcinogens. For existing establishments, OSHA assumes a professional would take 15 minutes (15/60 hour) to review, update and post existing instructions for the entry and exit procedures for regulated areas, and existing emergency procedures. The Agency identified three new establishments covered by this ICR. For these new establishments, OSHA assumes that a professional would take one hour and 30 minutes (90/60 hours) to develop and post the instructions for the entry and exit procedures for regulated areas and 1 hour to develop and post emergency procedures.

Burden hours: 100 existing employers × 15/60 hour = 25. hours
Costs: 25 hours × $49.05 = $1,2266

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

OSHA estimates that 667 workers will receive pre-assignment, periodic or emergency medical exams. Of the 667, OSHA estimates that 1 supervisor per plant or 100 supervisors will receive medical examinations. The remaining 567 are workers receiving a medical examination. OSHA estimates that a worker spends 2 hours away from the job per medical exam, and that a clerk would expend 5 minutes (5/60 hour) to update/maintain the corresponding medical records.

Burden hours: (667 workers × 2 hours) + (667 exams × 5/60 hour) = 1,390 hours
Costs: Clerical: 667 medical exams × 5/60 hour × $31.11 = $1,742
Supervisors: 100 medical exams × 2 hours × $49.05 = $9,810
Workers: 567 medical exams × 2 hours × $32.57 = $

Burden hours: 667 clerical × 5/60 hour = 56 hours
Costs: 56 hours × $31.11 = $1,742

Burden hours: 100 supervisors x 2 hours = 200hours
Cost: 200 hours x $49.05 = $9,810

Burden hours: 567 workers x 2 hours = 1,134 hours
Cost: 1,134 hours x $32.572 = $36,934

(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 will take 5 minutes (5/60 hour) of clerical time to process.

Burden hours: 667 workers × 5/60 hour = 56hours
Cost: 56 hours × $31.11 = $1,742

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 .[6] Approximately 667 medical exams will be given annually for a total cost of $296,148 .

[6]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%.

Costs: 667 exams x $444 = $296,148

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.

OSHA would only review records in the context of an open investigation of a particular employer to determine compliance with the Standard.

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 decrease of 114 hours (from 1,610 hours to 1,496 hours). The decrease is a result of a slight decline in the number of establishments affected by the Standard from 104 to 100 establishments. This results in a decrease in the number of workers receiving medical examinations, from 716 to 667. The Agency is also requesting an adjustment cost decrease of $11,016. There was an increase in the cost of medical examinations from $429 to $444, but the number of exposed workers is now 667 vs 716 during the prior Information Request. The cost of the physical exam is $168, and the hospital fee for out-of-network/uninsured patient is $276. The last ICR was in 2018 so estimated the increase in price from 2018 to 2023. It seems that the updated medical cost should use the preceding ICR not the original medical cost of 130. That is what was done here. The cost is now $168. The out-of-network fee increased 10.759% to $276, based on the CPI from 2018-2023.

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.

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.

Table 3. Respondents, Responses, Burden Hours, and Annual Burden Hours and Annual Burden Cost for Private Sector

Information Collection Requirement	Type of Respondent*	No. of Respondents	No. of Responses per Respondent	Total No. of Responses	Avg. Burden per Response (In Hrs.)	Total Burden Hours	Avg. Hourly Wage Rate**	Total Burden Costs
A. General regulated areas (§1910.1003(d))								
Respirator Program §1910.1003(d)(1)	N/A	0	0	0	0	0	$0.00	$0.00
Emergencies §1910.1003(d)(2)	N/A	0	0	0	0	0	$0.00	$0.00
Decontamination procedures §1910.1003(d)(4)(iii)								
Existing Employers	Professional	100	1	100	15/60	25	$49.05	$1,226
New Employers	Professional		1		1	3	$49.05	$
B. Signs, information, and training §1910.1003(e)								
Existing Employers	Professional	100	1	100	15/60	25.25	$49.05	$1,226
New Employers	Professional		1					$2
C. Medical surveillance §1910.1003(g)(1) and (g)(2)(i)								
Clerical Time to Maintain Records	Clerical	667	1	667	5/60	56	$31.11	$1,742
Worker Exam Time	Worker	567	1	567	2	1,134	$32.57	$36,934
Supervisor Exam Time	Supervisor	100	1	100	2	200	$49.05	$9,810
D. Access to records §1910.1003(g)(2)(ii)								
Exam Records	Clerical	667	1	667	5/60	56	$31.110	$1,742 9
Total								
Total	**—**		**—**	**2,201**	**—**	**1,496**	**—**	**$52,680**

*Respondents are private sector establishments—business or other for profit.
**See Table 1 for an explanation of the wage rate calculations.

SEC. 2. Congressional Findings and Purpose

(a) The Congress finds that personal injuries and illnesses arising out of work situations impose a substantial burden upon, and are a hindrance to, interstate commerce in terms of lost production, wage loss, medical expenses, and disability compensation payments. (b) The Congress declares it to be its purpose and policy, through the exercise of its powers to regulate commerce among the several States and with foreign nations and to provide for the general welfare, 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 USC 651
(1) by encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions; (2) by providing that employers and employees have separate but dependent responsibilities and rights with respect to achieving safe and healthful working conditions; (3) by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under the Act; (4) by building upon advances already made through employer and employee initiative for providing safe and healthful working conditions; (5) by providing for research in the field of occupational safety and health, including the psychological factors involved, and by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems; (6) by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety; (7) by providing medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience; (8) by providing for training programs to increase the number and competence of personnel engaged in the field of occupational safety and health; affecting the OSH Act since its passage in 1970 through January 1, 2004. (9) by providing for the development and promulgation of occupational safety and health standards; (10) by providing an effective enforcement program which shall include a prohibition against giving advance notice of any inspection and sanctions for any individual violating this prohibition;
(11) by encouraging the States to assume the fullest responsibility for the administration and enforcement of their occupational safety and health laws by providing grants to the States to assist in identifying their needs and responsibilities in the area of occupational safety and health, to develop plans in accordance with the provisions of this Act, to improve the administration and enforcement of State occupational safety and health laws, and to conduct experimental and demonstration projects in connection therewith; (12) by providing for appropriate reporting procedures with respect to occupational safety and health which procedures will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem; (13) by encouraging joint labor-management efforts to reduce injuries and disease arising out of employment.

6. Occupational Safety and Health Standards

29 USC 655:
(a) Without regard to chapter 5 of title 5, United States Code, or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this Act and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees. (b) The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:

(1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health and Human Services, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this Act, the Secretary may request the recommendations of an advisory committee appointed under section 7 of this Act. The Secretary shall provide such an advisory committee with any proposals of his own or of the Secretary of Health and Human Services, together with all pertinent factual information developed by the Secretary or the Secretary of Health and Human Services, or otherwise available, including the results of research, demonstrations, and experiments. An advisory committee shall submit to the Secretary its recommendations regarding the rule to be promulgated within ninety days from the date of its appointment or within such longer or shorter period as may be prescribed by the Secretary, but in no event for a period which is longer than two hundred and seventy days. (2) The Secretary shall publish a proposed rule promulgating, modifying, or revoking an occupational safety or health standard in the Federal Register and shall afford interested persons a period of thirty days after publication to submit written data or comments. Where an advisory committee is appointed and the Secretary determines that a rule should be issued, he shall publish the

proposed rule within sixty days after the submission of the advisory committee's recommendations or the expiration of the period prescribed by the Secretary for such submission. (3) On or before the last day of the period provided for the submission of written data or comments under paragraph (2), any interested person may file with the Secretary written objections to the proposed rule, stating the grounds therefore and requesting a public hearing on such objections. Within thirty days after the last day for filing such objections, the Secretary shall publish in the Federal Register a notice specifying the occupational safety or health standard to which objections have been filed and a hearing requested, and specifying a time and place for such hearing.

SEC. 8. Inspections, Investigations, and Recordkeeping

(a) In order to carry out the purposes of this Act, the Secretary, upon presenting appropriate credentials to the owner, operator, or agent in charge, is authorized -- 29 USC 657

(1) to enter without delay and at reasonable times any factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by an employee of an employer; and

(2) to inspect and investigate during regular working hours and at other reasonable times, and within reasonable limits and in a reasonable manner, any such place of employment and all pertinent conditions, structures, machines, apparatus, devices, equipment, and materials therein, and to question privately any such employer, owner, operator, agent or employee.

(b) In making his inspections and investigations under this Act the Secretary may require the attendance and testimony of witnesses and the production of evidence under oath. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In case of a contumacy, failure, or refusal of any person to obey such an order, any district court of the United States or the United States courts of any territory or possession, within the jurisdiction of which such person is found, or resides or transacts business, upon the application by the Secretary, shall have jurisdiction to issue to such person an order requiring such person to appear to produce evidence if, as, and when so ordered, and to give testimony relating to the matter under investigation or in question, and any failure to obey such order of the court may be punished by said court as a contempt thereof.

(c) (1) Each employer shall make, keep and preserve, and make available to the Secretary or the Secretary of Health and Human Services, such records regarding his activities relating to this Act as the Secretary, in cooperation with the Secretary of Health and Human Services, 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. In order to carry out the provisions of this paragraph such regulations may include provisions requiring employers to conduct periodic inspections. The Secretary shall also issue regulations requiring that employers, through posting of notices or other appropriate means, keep their employees informed of their protections and obligations under this Act, including the provisions of applicable standards.

(2) The Secretary, in cooperation with the Secretary of Health and Human Services, shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.

(3) The Secretary, in cooperation with the Secretary of Health and Human Services, shall issue regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6. Such regulations shall provide employees or their representatives with an opportunity to observe such monitoring or measuring, and to have access to the records thereof. Such regulations shall also make appropriate provision for each employee or former employee to have access to such records as will indicate his own exposure

to toxic materials or harmful physical agents. Each employer shall promptly notify any employee who has been or is being exposed to toxic materials or harmful physical agents in concentrations or at levels which exceed those prescribed by an applicable occupational safety and health standard promulgated under section 6, and shall inform any employee who is being thus exposed of the corrective action being taken.

(d) Any information obtained by the Secretary, the Secretary of Health and Human Services, or a State agency under this Act shall be obtained with a minimum burden upon employers, especially those operating small businesses. Unnecessary duplication of efforts in obtaining information shall be reduced to the maximum extent feasible.

(e) Subject to regulations issued by the Secretary, a representative of the employer and a representative authorized by his employees shall be given an opportunity to accompany the Secretary or his authorized representative during the physical inspection of any workplace under subsection (a) for the purpose of aiding such inspection. Where there is no authorized employee representative, the Secretary or his authorized representative shall consult with a reasonable number of employees concerning matters of health and safety in the workplace.

(f) (1) Any employees or representative of employees who believe that a violation of a safety or health standard exists that threatens physical harm, or that an imminent danger exists, may request an inspection by giving notice to the Secretary or his authorized representative of such violation or danger. Any such notice shall be reduced to writing, shall set forth with reasonable particularity the grounds for the notice, and shall be signed by the employees or representative of employees, and a copy shall be provided the employer or his agent no later than at the time of inspection, except that, upon the request

of the person giving such notice, his name and the names of individual employees referred to therein shall not appear in such copy or on any record published, released, or made available pursuant to subsection (g) of this section. If upon receipt of such notification the Secretary determines there are reasonable grounds to believe that such violation or danger exists, he shall make a special inspection in accordance with the provisions of this section as soon as practicable, to determine if such violation or danger exists. If the Secretary determines there are no reasonable grounds to believe that a violation or danger exists he shall notify the employees or representative of the employees in writing of such determination.

(2) Prior to or during any inspection of a workplace, any employees or representative of employees employed in such workplace may notify the Secretary or any representative of the Secretary responsible for conducting the inspection, in writing, of any violation of this Act which they have reason to believe exists in such workplace. The Secretary shall, by regulation, establish procedures for informal review of any refusal by a representative of the Secretary to issue a citation with respect to any such alleged violation and shall furnish the employees or representative of employees requesting such review a written statement of the reasons for the Secretary's final disposition of the case.

(g) (1) The Secretary and Secretary of Health and Human Services are authorized to compile, analyze, and publish, either in summary or detailed form, all reports or information obtained under this section.

(2) The Secretary and the Secretary of Health and Human Services shall each prescribe such rules and regulations as he may deem necessary to carry out their responsibilities under this Act, including rules and

regulations dealing with the inspection of an employer's establishment.

(h) The Secretary shall not use the results of enforcement activities, such as the number of citations issued or penalties assessed, to evaluate employees directly involved in enforcement activities under this Act or to impose quotas or goals with regard to the results of such activities.

Pub. L. 105-198 added subsection (h).

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§ 1910.1003 13 Carcinogens (4-Nitrobiphenyl, etc.).
(a) ***Scope and application.***
(1) This section applies to any area in which the 13 carcinogens addressed by this section are manufactured, processed, repackaged, released, handled, or stored, but shall not apply to transshipment in sealed containers, except for the labeling requirements under paragraphs (e)(2), (3) and (4) of this section. The 13 carcinogens are the following:
4-Nitrobiphenyl, Chemical Abstracts Service Register Number (CAS No.) 92933;
alpha-Naphthylamine, CAS No. 134327;
methyl chloromethyl ether, CAS No. 107302;
3,′-Dichlorobenzidine (and its salts) CAS No. 91941;
bis-Chloromethyl ether, CAS No. 542881;
beta-Naphthylamine, CAS No. 91598;
Benzidine, CAS No. 92875;
4-Aminodiphenyl, CAS No. 92671;
Ethyleneimine, CAS No. 151564;
beta-Propiolactone, CAS No. 57578;
2-Acetylaminofluorene, CAS No. 53963;
4-Dimethylaminoazo-benezene, CAS No. 60117; and

N-Nitrosodimethylamine, CAS No. 62759.
(2) This section shall not apply to the following:
(i) Solid or liquid mixtures containing less than 0.1 percent by weight or volume of 4-Nitrobiphenyl; methyl chloromethyl ether; bis-chloromethyl ether; beta-Naphthylamine; benzidine or 4-Aminodiphenyl; and
(ii) Solid or liquid mixtures containing less than 1.0 percent by weight or volume of alpha-Naphthylamine; 3,′-Dichlorobenzidine (and its salts); Ethyleneimine; beta-Propiolactone; 2-Acetylaminofluorene; 4-Dimethylaminoazobenzene, or N-Nitrosodimethylamine.
(b) ***Definitions.*** For the purposes of this section:
Absolute filter is one capable of retaining 99.97 percent of a mono disperse aerosol of 0.3 μm particles.
Authorized employee means an employee whose duties require him to be in the regulated area and who has been specifically assigned by the employer.
Clean change room means a room where employees put on clean clothing and/or protective equipment in an environment free of the 13 carcinogens addressed by this section. The clean change room shall be contiguous to and have an entry from a shower room, when the shower room facilities are otherwise required in this section.
Closed system means an operation involving a carcinogen addressed by this section where containment prevents the release of the material into regulated areas, non-regulated areas, or the external environment.
Decontamination means the inactivation of a carcinogen addressed by this section or its safe disposal.
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.
Disposal means the safe removal of the carcinogens addressed by this section from the work environment.
Emergency means an unforeseen circumstance or set of circumstances resulting in the release of a carcinogen addressed by this section that may result in exposure to or contact with the material.
External environment means any environment external to regulated and nonregulated areas.
Isolated system means a fully enclosed structure other than the vessel of containment of a carcinogen addressed by this section that is impervious to the passage of the material and would prevent the entry of the carcinogen addressed by this section into regulated areas, nonregulated areas, or the external environment, should leakage or spillage from the vessel of containment occur.
Laboratory-type hood is a device enclosed on the three sides and the top and bottom, designed and maintained so as to draw air inward at an average linear face velocity of 150 feet per minute with a minimum of 125 feet per minute; designed, constructed, and maintained in such a way that an operation involving a carcinogen addressed by this section within the hood does not require the insertion of any portion of any employee's body other than his hands and arms.
Nonregulated area means any area under the control of the employer where entry and exit is neither restricted nor controlled.
Open-vessel system means an operation involving a carcinogen addressed by this section in an open vessel that is not in an isolated system, a laboratory-

type hood, nor in any other system affording equivalent protection against the entry of the material into regulated areas, non-regulated areas, or the external environment.
Protective clothing means clothing designed to protect an employee against contact with or exposure to a carcinogen addressed by this section.
Regulated area means an area where entry and exit is restricted and controlled.
(c) ***Requirements for areas containing a carcinogen addressed by this section.*** A regulated area shall be established by an employer where a carcinogen addressed by this section is manufactured, processed, used, repackaged, released, handled or stored. All such areas shall be controlled in accordance with the requirements for the following category or categories describing the operation involved:
(1) ***Isolated systems.*** Employees working with a carcinogen addressed by this section within an isolated system such as a "glove box" shall wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.
(2) ***Closed system operation.***
(i) Within regulated areas where the carcinogens addressed by this section are stored in sealed containers, or contained in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens addressed by this section are contained within, access shall be restricted to authorized employees only.
(ii) Employees exposed to 4-Nitrobiphenyl; alpha-Naphthylamine; 3,′-Dichlorobenzidine (and its salts); beta-Naphthylamine; benzidine; 4-Aminodiphenyl; 2-Acetylaminofluorene; 4-Dimethylaminoazo-benzene; and N-Nitrosodimethylamine shall be required to wash hands, forearms, face, and neck upon each exit from the regulated areas, close to the point of exit, and before engaging in other activities.
(3) ***Open-vessel system operations.*** Open-vessel system operations as defined in paragraph (b)(13) of this section are prohibited.
(4) ***Transfer from a closed system, charging or discharging point operations, or otherwise opening a closed system.*** In operations involving "laboratory-type hoods," or in locations where the carcinogens addressed by this section are contained in an otherwise "closed system," but is transferred, charged, or discharged into other normally closed containers, the provisions of this paragraph shall apply.
(i) Access shall be restricted to authorized employees only.
(ii) Each operation shall be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation. Exhaust air shall not be discharged to regulated areas, nonregulated areas or the external environment unless decontaminated. Clean makeup air shall be introduced in sufficient volume to maintain the correct operation of the local exhaust system.
(iii) Employees shall be provided with, and required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), shoe covers and gloves prior to entering the regulated area.
(iv) Employers must provide each employee engaged in handling operations involving the carcinogens 4-Nitrobiphenyl, alpha-Naphthylamine, 3,3′-Dichlorobenzidine (and its salts), beta-Naphthylamine, Benzidine, 4-Aminodiphenyl, 2-Acetylaminofluorene, 4-Dimethylaminoazo-benzene, and N-Nitrosodimethylamine, addressed by this section, with, and ensure that each of these employees wears and uses, a NIOSH-certified air-purifying, half-mask respirator with particulate filters. Employers also must provide each employee engaged in handling operations involving the carcinogens methyl

chloromethyl ether, bis-Chloromethyl ether, Ethyleneimine, and beta-Propiolactone, addressed by this section, with, and ensure that each of these employees wears and uses any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode, or any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained positive-pressure breathing apparatus. Employers may substitute a respirator affording employees higher levels of protection than these respirators.
(v) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers shall be identified, as required under paragraph (e) of this section.
(vi) Drinking fountains are prohibited in the regulated area.
(vii) Employees shall be required to wash hands, forearms, face, and neck on each exit from the regulated area, close to the point of exit, and before engaging in other activities and employees exposed to 4-Nitrobiphenyl; alpha-Naphthylamine; 3,′-Dichlorobenzidine (and its salts); beta-Naphthylamine; Benzidine; 4-Aminodiphenyl; 2-Acetylaminofluorene; 4-Dimethylaminoazo-benzene; and N-Nitrosodimethylamine shall be required to shower after the last exit of the day.
(5) ***Maintenance and decontamination activities.*** In cleanup of leaks of spills, maintenance, or repair operations on contaminated systems or equipment, or any operations involving work in an area where direct contact with a carcinogen addressed by this section could result, each authorized employee entering that area shall:
(i) Be provided with and required to wear clean, impervious garments, including gloves, boots, and continuous-air supplied hood in accordance with § 1910.134;
(ii) Be decontaminated before removing the protective garments and hood;
(iii) Be required to shower upon removing the protective garments and hood.
(d) ***General regulated area requirements*** —
(1) ***Respiratory program.*** The employer must implement a respiratory protection program in accordance with § 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.
(2) ***Emergencies.*** 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.
(i) The potentially affected area shall be evacuated as soon as the emergency has been determined.
(ii) Hazardous conditions created by the emergency shall be eliminated and the potentially affected area shall be decontaminated prior to the resumption of normal operations.
(iii) Special medical surveillance by a physician shall be instituted within 24 hours for employees present in the potentially affected area at the time of the emergency.

(iv) Where an employee has a known contact with a carcinogen addressed by this section, such employee shall be required to shower as soon as possible, unless contraindicated by physical injuries.
(v) Emergency deluge showers and eyewash fountains supplied with running potable water shall be located near, within sight of, and on the same level with locations where a direct exposure to Ethyleneimine or beta-Propiolactone only would be most likely as a result of equipment failure or improper work practice.
(3) ***Hygiene facilities and practices.***
(i) Storage or consumption of food, storage or use of containers of beverages, storage or application of cosmetics, smoking, storage of smoking materials, tobacco products or other products for chewing, or the chewing of such products are prohibited in regulated areas.
(ii) Where employees are required by this section to wash, washing facilities shall be provided in accordance with § 1910.141(d) (1) and (2) (ii) through (vii).
(iii) Where employees are required by this section to shower, shower facilities shall be provided in accordance with § 1910.141(d)(3).
(iv) Where employees wear protective clothing and equipment, clean change rooms shall be provided for the number of such employees required to change clothes, in accordance with § 1910.141(e).
(v) Where toilets are in regulated areas, such toilets shall be in a separate room.
(4) ***Contamination control.***
(i) Except for outdoor systems, regulated areas shall be maintained under pressure negative with respect to nonregulated areas. Local exhaust ventilation may be used to satisfy this requirement. Clean makeup air in equal volume shall replace air removed.
(ii) Any equipment, material, or other item taken into or removed from a regulated area shall be done so in a manner that does not cause contamination in nonregulated areas or the external environment.
(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.
(iv) Dry sweeping and dry mopping are prohibited for 4-Nitrobiphenyl; alpha-Naphthylamine; 3,′-Dichlorobenzidine (and its salts); beta-Naphthylamine; Benzidine; 4-Aminodiphenyl; 2-Acetylaminofluorene; 4-Dimethylaminoazo-benzene and N-Nitrosodimethylamine.
(e) ***Communication of hazards*** —
(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.
(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.
(f) [Reserved]
(g) ***Medical surveillance.*** At no cost to the employee, a program of medical surveillance shall be established and implemented for employees considered for assignment to enter regulated areas, and for authorized employees.
(1) ***Examinations.***
(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 employee, family and occupational background, including genetic and environmental factors.
(ii) Authorized employees shall be provided periodic physical examinations, not less often than annually, following the preassignment examination.
(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.
(2) ***Records.***
(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.
(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.
(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.
[61 FR 9242, Mar. 7, 1996, as amended at 63 FR 1286, Jan. 8, 1998; 63 FR 20099, Apr. 23, 1998; 70 FR 1141, Jan. 5, 2005; 71 FR 16672, Apr. 3, 2006; 73 FR 75584, Dec. 2, 2008; 76 FR 33608, June 8, 2011; 76 FR 80740, Dec. 27, 2011; 77 FR 17779, Mar. 26, 2012]