

§ 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;
3,4-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-benzene, 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; 3,4-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; 3,4-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; 3,3'-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; 3,4-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]