

DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES

DIRECTOR'S OFFICE

OCCUPATIONAL HEALTH STANDARDS--CARCINOGENS

(By authority conferred on the director of the department of consumer and industry services by sections 14 and 24 of 1974 PA 154 and Executive Reorganization Orders Nos. 1996-1 and 1996-2, MCL 408.1014, 408.1024, 330.3101, and 445.2001)

CARCINOGENS

R 325.35001 Scope and application.

Rule 1. (1) These rules apply to any area in which the following 13 carcinogens are manufactured, processed, repackaged, released, handled, or stored, but shall not apply to transshipment in sealed containers, except for the labeling requirements under R 325.35008:

- (a) 4-Nitrobiphenyl, chemical abstracts service register number (CAS No.) 92933.
- (b) alpha-Naphthylamine, CAS No. 134327.
- (c) methyl chloromethyl ether, CAS No. 107302.
- (d) 3,3'-Dichlorobenzidine (and its salts) CAS No. 91941.
- (e) bis-Chloromethyl ether, CAS No. 542881.
- (f) beta-Naphthylamine, CAS No. 91598.
- (g) Benzidine, CAS No. 92875.
- (h) 4-Aminodiphenyl, CAS No. 92671.
- (i) Ethyleneimine, CAS No. 151564.
- (j) beta-Propiolactone, CAS No. 57578.
- (k) 2-Acetylaminofluorene, CAS No. 53963.
- (l) 4-Dimethylaminoazo-benzene, CAS No. 60117.
- (m) N-Nitrosodimethylamine, CAS No. 62759.

(2) These rules shall not apply to the following:

- (a) Solid or liquid mixtures containing less than 0.1% by weight or volume of any of the following:
  - (i) 4-Nitrobiphenyl.
  - (ii) Methyl chloromethyl ether.
  - (iii) Bis-chloromethyl ether.
  - (iv) Beta-Naphthylamine.
  - (v) Benzidine.
  - (vi) 4-Aminodiphenyl.
- (b) Solid or liquid mixtures containing less than 1.0% by weight or volume of any of the following:
  - (i) Alpha-Naphthylamine.
  - (ii) 3,3'-Dichlorobenzidine (and its salts).
  - (iii) Ethyleneimine.
  - (iv) Beta-Propiolactone.
  - (v) 2-Acetylaminofluorene.
  - (vi) 4-Dimethylaminoazobenzene.
  - (vii) N-Nitrosodimethylamine.

(3) These rules replace OH rules 2301 and 2302.

History: 2002 AACCS.

R 325.35002 Definitions.

Rule 2. As used in these rules:

- (a) "Absolute filter" means a filter capable of retaining 99.97% of a mono disperse aerosol of 0.3 um particles.

- (b) "Authorized employee" means an employee whose duties require him or her to be in the regulated area and who has been specifically assigned by the employer.
- (c) "Carcinogens" means all materials covered in the scope of these rules as described in R 325.35001.
- (d) "Clean change room" means a room where employees put on clean clothing, protective equipment, or both, in an environment free of the 13 carcinogens.
- (e) "Closed system" means an operation involving a carcinogen where containment prevents the release of the material into regulated areas, non-regulated areas, or the external environment.
- (f) "Decontamination" means the inactivation of a carcinogen or its safe disposal.
- (g) "Disposal" means the safe removal of the carcinogens from the work environment.
- (h) "Emergency" means an unforeseen circumstance or set of circumstances resulting in the release of a carcinogen that may result in exposure to or contact with the material.
- (i) "External environment" means any environment external to regulated and nonregulated areas.
- (j) "Isolated system" means a fully enclosed structure other than the vessel of containment of a carcinogen that is impervious to the passage of the material and would prevent the entry of the carcinogen into regulated areas, nonregulated areas, or the external environment if leakage or spillage from the vessel of containment occurs.
- (k) "Laboratory-type hood" means a device which is enclosed on the 3 sides and the top and bottom, which is 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, and which is designed, constructed, and maintained so that an operation involving a carcinogen within the hood does not require the insertion of any portion of any employee's body other than his or her hands and arms.
- (l) "Nonregulated area" means any area under the control of the employer where entry and exit is neither restricted nor controlled.
- (m) "Open-vessel system" means an operation involving a carcinogen 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.
- (n) "Protective clothing" means clothing designed to protect an employee against contact with or exposure to a carcinogen.
- (o) "Regulated area" means an area where entry and exit is restricted and controlled.

History: 2002 AACS.

#### R 325.35003 Requirements for areas containing a carcinogen.

Rule 3. (1) An employer shall ensure that a regulated area be established where a carcinogen is manufactured, processed, used, repackaged, released, handled, or stored.

(2) All areas shall be controlled in accordance with the requirements for the following category or categories describing the operation involved:

(a) Isolated systems. An employer shall ensure that if an isolated system is used, the employees working with a carcinogen within an isolated system such as a "glove box" wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.

(b) Closed system operation. An employer shall ensure that access to regulated areas be restricted to authorized employees where the carcinogens are stored in sealed containers, or contained in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens are contained within.

(4) If employees are exposed to any of the following then employers shall ensure that employees 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:

- (a) 4-Nitrobiphenyl.
- (b) Alpha-Naphthylamine.
- (c) 3,3'-Dichlorobenzidine (and its salts).
- (d) Beta-Naphthylamine.
- (e) Benzidine.
- (f) 4-Aminodiphenyl.

- (g) 2-Acetylaminofluorene.
- (h) 4-Dimethylaminoazo-benzene.
- (i) N-Nitrosodimethylamine.

(5) An employer shall ensure that open-vessel system operations as defined in R 325.35002(1) are prohibited.

(6) An employer shall ensure compliance with all of the following provisions when operations involve "laboratory-type hoods" or are in locations where carcinogens are contained in an otherwise "closed system," but are transferred, charged, or discharged into other normally closed containers:

(a) Access shall be restricted to authorized employees only.

(b) 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.

(c) Employees shall be provided with, and required to wear, clean, full body protective clothing, such as smocks, coveralls, or long-sleeved shirt and pants, shoe covers, and gloves before entering a regulated area.

(d) Employees engaged in handling operations involving carcinogens shall be provided with, and required to wear and use, a half-face filter-type respirator with filters for dusts, mists, and fumes, or air-purifying canisters or cartridges. A respirator affording higher levels of protection than a half-face filter-type respirator may be substituted.

(e) Before each exit from a regulated area, an employer shall require employees to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day and to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of the impervious containers shall be identified in accordance with R 325.35008.

(f) Drinking fountains are prohibited in a regulated area.

(g) 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. An employer shall require employees exposed to any of the following to shower after the last exit of the day:

- (i) 4-Nitrobiphenyl.
- (ii) Alpha-Naphthylamine.
- (iii) 3,3'-Dichlorobenzidine (and its salts).
- (iv) Beta-Naphthylamine.
- (v) Benzidine.
- (vi) 4-Aminodiphenyl.
- (vii) 2-Acetylaminofluorene.
- (viii) 4-Dimethylaminoazo-benzene.
- (ix) N-Nitrosodimethylamine.

(7) If 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 could result, then an employer shall ensure that each authorized employee entering that area comply to all of the following requirements:

(a) Wear clean, impervious garments, including gloves, boots, and a continuous air-supplied hood in accordance with 29 C.F.R. §1910.134 as adopted by reference in occupational health standard R 325.60051 et seq. being Part 451. Respiratory Protection.

(b) Be decontaminated before removing the protective garments and hood.

(c) Shower upon removing the protective garments and hood.

(8) Laboratory activities. All of the following requirements apply to research and quality control activities involving the use of a carcinogen:

(a) Mechanical pipetting aids shall be used for all pipetting procedures.

(b) Experiments, procedures, and equipment that could produce aerosols shall be confined to laboratory-type hoods or glove boxes.

(c) Surfaces on which a carcinogen is handled shall be protected from contamination.

(d) Contaminated wastes and animal carcasses shall be collected in impervious containers that are closed and decontaminated before removal from the work area. The wastes and carcasses shall be incinerated in a manner so that carcinogenic products are not released.

(e) All other forms of carcinogens shall be inactivated before disposal.

(f) Laboratory vacuum systems shall be protected with high-efficiency scrubbers or with disposable absolute filters.

(g) An employer shall ensure that all of the following provisions are met for employees engaged in animal support activities:

(i) Employees shall be provided, and required to wear, a complete protective clothing change, clean each day, including coveralls, or pants and shirt, foot covers, head covers, gloves, and appropriate respiratory protective equipment or devices.

(ii) Employees shall remove and leave protective clothing and equipment at the point of exit before each exit from a regulated area and at the last exit of the day and place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. Containers shall comply with requirements set forth in R 325.35008.

(iii) Employees shall wash hands, forearms, face, and neck upon each exit from a regulated area close to the point of exit and before engaging in other activities.

(iv) Employees shall shower after the last exit of the day.

(h) An employer shall ensure that all of the following provisions are met for employees engaged in animal support activities:

(i) Provide, and require employees to wear, a clean change of appropriate laboratory clothing, such as a solid front gown, surgical scrub suit, or fully buttoned laboratory coat.

(ii) Employees shall remove and leave protective clothing and equipment at the point of exit before each exit from a regulated area and at the last exit of the day and place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. Containers shall comply with the requirements set forth in R 325.35008.

(iii) Employees shall wash hands, forearms, face, and neck upon each exit from the regulated area close to the point of exit and before engaging in other activities.

(i) Air pressure in laboratory areas and animal rooms where a carcinogen is handled and bioassay studies are performed shall be negative in relation to the pressure in surrounding areas. Exhaust air shall not be discharged to regulated areas, nonregulated areas, or the external environment unless decontaminated.

(j) There shall not be a connection between regulated areas and any other areas through the ventilation system.

(k) An employer shall maintain a current inventory of carcinogens.

(l) Ventilated apparatus, such as laboratory-type hoods, shall be tested at least semiannually or immediately after ventilation modification or maintenance operations, by personnel who are fully qualified to certify correct containment and operation.

History: 2002 AACS.

#### R 325.35004 General regulated area requirements.

Rule 4. (1) A daily roster of employees entering regulated areas shall be established and maintained. The rosters or a summary of the rosters shall be retained for a period of 20 years. The rosters or summaries shall be provided upon request to the director or his or her authorized representative. If an employer ceases business without a successor, then rosters shall be forwarded by registered mail to the director.

(2) An employer shall implement a respiratory protection program in accordance with 29 C.F.R. 1910.134 (b), (c), (d), (except (d)(1)(iii) and (iv), and (d)(3)), and (e) through (m) as adopted by reference in R 325.60051 et seq. being Part 451. Respiratory Protection.

(3) An employer shall ensure that in an emergency, immediate measures are implemented, including, but not limited to, all of the following measures:

(a) Evacuate the potentially affected area as soon as the emergency has been determined.

(b) Eliminate the hazardous conditions created by the emergency and decontaminate the potentially affected area before resuming normal operations.

(c) 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. A report of the medical surveillance and any treatment shall be included in the incident report in accordance with R 325.35010.

(d) Employees shall shower as soon as possible, unless contraindicated by physical injuries, when an employee has a known contact with a carcinogen.

(e) An incident report on the emergency shall be reported in accordance with R 325.35010.

(f) Emergency deluge showers and eyewash fountains supplied with running potable water shall be located near, within sight of, and on the same level as, 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.

History: 2002 AACS.

#### R 325.35005 Hygiene facilities and practices.

Rule 5. (1) An employer shall take measures to prevent all of the following in regulated areas:

(a) The storage or consumption of food.

(b) The storage or use of containers of beverages.

(c) The storage or application of cosmetics.

(d) Smoking.

(e) The storage of smoking materials, tobacco products, or other products for chewing.

(f) The chewing of the items specified in subdivision (e) of this subrule.

(2) If employees are required by these rules to wash, then washing facilities shall be provided in accordance with occupational health rule 4201(4), being Part 474. Sanitation.

(3) If employees are required by these rules to shower, then shower facilities shall be provided in accordance with occupational health rule 4201(4), being Part 474. Sanitation.

(4) If employees wear protective clothing and equipment, then clean change rooms shall be provided for the number of employees who are required to change clothes in accordance with occupational health rule 4201(5), being Part 474. Sanitation.

(5) Clean change room shall be contiguous to and have an entry from a shower room.

(6) If toilets are in regulated areas, then the toilets shall be in a separate room.

History: 2002 AACS.

#### R 325.35006 Contamination control.

Rule 6. (1) An employer shall ensure that regulated areas are maintained under pressure negative with respect to nonregulated areas, except for outdoor systems. Local exhaust ventilation may be used to satisfy this requirement. Clean makeup air in equal volume shall replace air that is removed.

(2) Equipment, material, or other items shall be taken into, or removed from, a regulated area in a manner that does not cause contamination in nonregulated areas or the external environment.

(3) Decontamination procedures shall be established and implemented to remove carcinogens from the surfaces of materials, equipment, and the decontamination facility.

(4) Dry sweeping and dry mopping are prohibited for all of the following:

(a) 4-Nitrobiphenyl.

(b) Alpha-Naphthylamine.

(c) 3,3'-Dichlorobenzidine (and its salts).

(d) Beta-Naphthylamine.

(e) Benzidine.

(f) 4-Aminodiphenyl.

(g) 2-Acetylaminofluorene.

(h) 4-Dimethylaminoazo-benzene.

(i) N-Nitrosodimethylamine.

History: 2002 AACS.

R 325.35007 Signs.

Rule 7. (1) An employer shall ensure that entrances to regulated areas are posted with signs bearing the following legend: CANCER-SUSPECT AGENT AUTHORIZED PERSONNEL ONLY

(2) An employer shall ensure that entrances to regulated areas containing operations covered in R 325.35003(7) be posted with signs bearing the following legend:

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

(3) An employer shall ensure that appropriate signs and instructions are 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.

(4) An employer shall ensure that lettering on signs and instructions is a minimum letter height of 2 inches (5 cm).

History: 2002 AACS.

R 325.35008 Container labeling.

Rule 8. (1) An employer shall ensure that all of the following labeling requirements are complied with:

(a) Containers of a carcinogen and containers required in R 325.35003(6)(e) and (8)(g)(ii) and (h)(ii) that are accessible only to and handled only by authorized employees or by other employees trained in compliance with R 325.35009 may have labeling limited to a generic or proprietary name or other proprietary identification of the carcinogen and percent.

(b) Containers of a carcinogen and containers required in R 325.35003(6)(e) and (8)(g)(ii) and (h)(ii) that are accessible to or handled by employees other than authorized employees or employees trained in compliance with R 325.35009 shall have contents identification that includes the full chemical name and chemical abstracts service registry number as listed in R 325.35001(1).

(c) Containers shall have the warning words "CANCER-SUSPECT AGENT" displayed immediately under or adjacent to the contents identification.

(d) Containers that have contents which are carcinogens with corrosive or irritating properties shall have label statements warning of the hazards noting, if appropriate, particularly sensitive or affected portions of the body.

(e) Labels on containers shall be not less than 1/2 the size of the largest lettering on the package and be not less than 8-point type if the lettering is not required to be more than 1 inch (2.5 cm) in height.

(f) Nothing 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.

History: 2002 AACS.

R 325.35009 Training and indoctrination.

Rule 9. (1) An employer shall ensure that each authorized employee, before entering a regulated area and annually, receives training that includes, but is not limited to, all of the following:

(a) The nature of the carcinogenic hazards of a carcinogen to include local and systemic toxicity.

(b) The specific nature of the operation involving a carcinogen 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.

- (h) The purpose for and application of specific first aid procedures and practices.
- (2) An employer shall ensure that specific emergency procedures are prescribed, and posted and that employees are familiarized with emergency procedures terminology, and that the procedures are rehearsed.
- (3) All materials relating to the program shall be provided upon request to the director of the department of consumer and industry services or his or her authorized representative.

History: 2002 AACS.

#### R 325.35010 Reports.

Rule 10. (1) An employer shall report, in writing, all of the following to the director of the department of consumer and industry services:

- (a) A brief description and in-plant location of the area or areas regulated and the address of each regulated area.
- (b) The name or names and other identifying information of a carcinogen in each regulated area.
- (c) The number of employees in each regulated area, during normal operations, including maintenance activities.
- (d) The manner in which carcinogens are present in each regulated area, whether it is manufactured, processed, used, repackaged, released, stored, or otherwise handled. Any changes in the information specified in this subrule shall be similarly reported, in writing, within 15 calendar days of the change.

(2) An employer shall ensure that incidents that result in the release of a carcinogen into any area where employees may be potentially exposed are reported in accordance with all of the following provisions:

- (a) A report of the occurrence of the incident and the facts obtainable at that time, including a report on any medical treatment of affected employees, shall be made within 24 hours to the director of the department of consumer and industry services.
- (b) A written report shall be filed with the director of the department of consumer and industry services within 15 calendar days. The report shall contain all of the following information:
  - (i) A specification of the amount of material released, the amount of time involved, and an explanation of the procedure used in determining the amount of material released.
  - (ii) A description of the area involved and the extent of known and possible employee exposure and area contamination.
  - (iii) A report of any medical treatment of affected employees and any medical surveillance program implemented.
  - (iv) An analysis of the circumstances of the incident and measures taken or to be taken, with specific completion dates, to avoid further similar releases.

History: 2002 AACS.

#### R 325.35011 Medical surveillance, examinations, and medical records.

Rule 11. (1) An employer shall establish and implement, at no cost to employees, a medical surveillance program for employees considered for assignment to enter regulated areas.

(2) An employer shall ensure that a preassignment physical examination by a physician is provided before an employee is assigned to enter a regulated area. The examination shall include the personal history of the employee, family, and occupational background, including genetic and environmental factors.

(3) An employer shall provide periodic physical examinations, at least annually, for authorized employees after the preassignment examination.

(4) For all physical examinations, an employer shall ensure that the examining physician consider whether there exist conditions of increased risk, including reduced immunological competence, treatment with steroids or cytotoxic agents, pregnancy, or cigarette smoking.

(5) Employers of employees examined pursuant to this rule shall maintain complete and accurate records of all medical examinations. Records shall be maintained for the duration of the employee's employment. Upon termination of the employee's employment, including retirement or death,

or if the employer ceases business without a successor, records, or notarized true copies of records shall be forwarded, by registered mail, to the director of the department of consumer and industry services.

(6) An employer shall ensure that records required by this rule be provided upon request in compliance with R 325.3451 et seq., except R 325.3472 and R 325.3472a, being Part 470. Medical Records and Trade Secrets. The records shall also be provided, upon request, to the director of the department of consumer and industry services.

(7) A physician who conducts a medical examination required by this rule shall furnish, to the employer, a statement of the employee's suitability for employment in the specific exposure.

History: 2002 AACS.

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