



DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

OCCUPATIONAL HEALTH STANDARDS

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(By authority conferred on the director of the department of licensing and regulatory affairs by sections 14 and 24 of 1974 PA 154 and Executive Reorganization Orders Nos. 1996-2, 2003-1, 2008-4, and 2011-4, MCL 445.2001, 445.2011, 445.2025, and 445.2030

R 325.35001, R 325.35002, R 325.35003, R 325.35004, R 325.35005, R 325.35007, R 325.35008, R 325.35009, and R 325.35011, of the Michigan Administrative Code are amended and R 325.35002a and R 325.35006a are added, R 325.35010 is rescinded, as follows:

PART 350. CARCINOGENS

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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-benezene, CAS No. 60117.
- (m) N-Nitrosodimethylamine, CAS No. 62759.

(2) These rules shall not apply to any of 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.

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 carcinogens listed in R 325.135001(1).

(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) "Director" means the director of the Michigan department of licensing and regulatory affairs or his or her designee.

(h) "Disposal" means the safe removal of the carcinogens from the work environment.

(i) "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.

(j) "External environment" means any environment external to regulated and nonregulated areas.

(k) "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.

(l) "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.

(m) "Nonregulated area" means any area under the control of the employer where entry and exit is neither restricted nor controlled.

(n) "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.

(o) "Protective clothing" means clothing designed to protect an employee against contact with or exposure to a carcinogen.

(p) "Regulated area" means an area where entry and exit is restricted and controlled.

R 325.35002a MIOSHA standards by reference.

Rule 2a. The following Michigan occupational safety and health administration (MIOSHA) standards are referenced in these rules. Up to 5 copies of these standards may be obtained at no charge from the Michigan Department of Licensing and Regulatory Affairs, MIOSHA Standards Section, 7150 Harris Drive, P.O. Box 30643, Lansing, MI, 48909-8143 or via the internet at website:

www.michigan.gov/mioshastandards. For quantities greater than 5, the cost, at the time of adoption of these rules, is 4 cents per page.

(a) Occupational Health Part 430 "Hazard Communication," R 325.77001 to R 325.77003.

(b) Occupational Health Part 451 "Respiratory Protection," R 325.60051 to R 325.60052.

(c) Occupational Health Part 470 "Employee Medical Records and Trade Secrets," R 325.3451 to R 325.3476.

(d) Occupational Health Part 474 "Sanitation," R 325.47401 to R 325.47425.

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.

(3) 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.

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

(5) 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) An employer shall provide each employee engaged in handling operations involving carcinogens addressed by this rule, with, and ensure that each of these employees wears and uses, a NIOSH-certified air-purifying, half-mask respirator with particulate filters for all of the following:

- (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-

(e) An employer shall provide each employee engaged in handling operations involving the carcinogens addressed by this rule, 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 for all of the following:

- (i) Methyl chloromethyl ether.
- (ii) Bis-Chloromethyl ether.
- (iii) Ethyleneimine.
- (iv) Beta-Propiolactone.

(f) An employer may substitute a respirator affording employees higher levels of protection than the respirators specified in subrule (6) (d) and (e).

(g) 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 325.35006a, R 325.35007, and R 325.35008.

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

(i) 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.

(6) 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 with all of the following requirements:

(a) Be provided with and required to wear clean, impervious garments, including gloves, boots, and a continuous air-supplied hood in accordance with Occupational Health Standard Part 451 "Respiratory Protection," as referenced in R 325.35002a.

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

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

(7) 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) 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.

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

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

(k) 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.

R 325.35004 General regulated area requirements.

Rule 4. (1) An employer shall implement a respiratory protection program in accordance with Occupational Health Standard Part 451 "Respiratory Protection," 29 C.F.R. Rules 1910.134 (b), (c), (d), (except (d)(1)(iii) and (iv), and (d)(3)), and (e) through (m), as referenced in R 325.35002a, which covers each employee required by these rules to use a respirator.

(2) 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.

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

(e) 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

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 Standard Part 474 "Sanitation," as referenced in R 325.35002a.

(3) If employees are required by these rules to shower, then shower facilities shall be provided in accordance with Occupational Health Standard Part 474 "Sanitation," as referenced in R 325.35002a.

(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 Standard Part 474 "Sanitation," as referenced in R 325.35002a.

(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.

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.

HAZARD COMMUNICATION

R 325.35006a Hazard communication, generally.

Rule 6a. (1) Chemical manufacturers, importers, distributors and employers shall comply with Occupational Health Standard Part 430 "Hazard Communication," as referenced in R 325.35002a, for each carcinogen listed in subrule (4) of this rule.

(2) In classifying the hazards of carcinogens listed in subrule (4) of this rule, at a minimum the hazards listed in subrule (4) of this rule are to be addressed.

(3) Employers shall include the carcinogens listed in subrule (4) of this rule in the hazard communication program established to comply with Occupational Health Standard Part 430 "Hazard Communication." Employers shall ensure that each employee has access to labels on containers of the carcinogens listed in subrule (4) of this rule, and to safety data sheets, and is trained in accordance with the requirements of subrule (4) of this rule and Occupational Health Standard Part 430 "Hazard Communication," as referenced in R 325.35002a.

(4) All of the following carcinogens are included:

- (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.

R 325.35007 Signs.

Rule 7. (1) An employer shall ensure that entrances to regulated areas are posted with signs bearing the following legend:

DANGER
(CHEMICAL IDENTIFICATION)
MAY CAUSE CANCER
AUTHORIZED PERSONNEL ONLY

(2) The employer shall post signs at entrances to regulated areas containing operations covered in R 325.35003(7). The signs shall bear the following legend:

DANGER
(CHEMICAL IDENTIFICATION)
MAY CAUSE CANCER

WEAR AIR-SUPPLIED HOODS,
IMPERVIOUS SUITS, AND PROTECTIVE
EQUIPMENT IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(3) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in subrule (1) of this rule:

CANCER-SUSPECT AGENT
AUTHORIZED PERSONNEL ONLY

(4) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in subrule (2) of this rule:

CANCER-SUSPECT AGENT
EXPOSED IN THIS AREA

IMPERVIOUS SUIT INCLUDING GLOVES,
BOOTS, AND AIR-SUPPLIED HOOD
REQUIRED AT ALL TIMES
AUTHORIZED PERSONNEL ONLY

(5) 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.

R 325.35008 Container labeling.

Rule 8. An employer shall ensure that 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.

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 licensing and regulatory affairs or his or her authorized representative.

R 325.35010 Rescinded.

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.

(6) An employer shall ensure that records required by this rule be provided upon request in compliance with Occupational Health Standard Part 470, "Employee Medical Records and Trade Secrets," as referenced in R 325.35002a. The records shall also be provided, upon request, to the director of the department of licensing and regulatory affairs.

(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.



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