

PART R--HAZARDOUS DRUGS

NEW SECTION

WAC 296-62-500 Hazardous drugs. This rule provides minimum requirements for developing a hazardous drugs control program; enabling employers to provide effective, assessment-based precautions designed to minimize or eliminate occupational exposure.

IMPORTANT:

Hazardous drugs are covered under WAC 296-800-170, Employer chemical hazard communication--Introduction. In addition the employer must follow the requirements in WAC 296-800-160 and chapter 296-842 WAC as related to the provision of personal protective equipment and respiratory protection. Whenever there is a conflict between rule requirements the most protective requirement will take precedent.

NEW SECTION

WAC 296-62-50005 Scope. (1) This chapter applies to all health care settings that have employees with occupational exposure to hazardous drugs.

(2) The following lists jobs that may involve occupational exposure to hazardous drugs. This is not an exhaustive list and there may be other jobs that fall within the scope of this chapter:

- Physicians and physician assistants;
- Nurses (ARNPs, RNs, LPNs, nurses aids);
- Patient care assistive personnel (nurses aides or technicians);
- Operating room personnel;
- Employees in research laboratories;
- Home health care workers;
- Veterinarians and veterinary technicians;
- Pharmacists and pharmacy technicians;
- Environmental services employees (e.g., housekeeping, laundry, and waste disposal) in health care settings;
- Employees who ship, or receive hazardous drugs from the manufacturer or distributor.

Exemption: This chapter does not apply to the drug manufacturing sector.

NEW SECTION

WAC 296-62-50010 Definitions. Biological safety cabinet means a ventilated cabinet for compounding pharmaceutical ingredients, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. For a complete description of the different types of biologic safety cabinets see the Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) document *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets*.

Chemotherapy glove means a medical glove that has been approved by the Food and Drug Administration (FDA) and that meets the permeability standards of the American Society for Testing Materials (ASTM) Standard D6978 - 05.

Closed system drug-transfer device means a drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside of the system.

Compounding aseptic containment isolator means a compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA at a minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

Compounding aseptic isolator means a form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum).

Contaminated means materials or surfaces that have been in direct contact with a hazardous drug. Urine, fecal matter, vomit, blood, or bodily fluids from patients receiving certain hazardous drugs are considered contaminated for a minimum of forty-eight hours after administration. Containers that have held contaminated

urine, fecal matter, vomit, blood, or other bodily fluids are considered contaminated until cleaned and decontaminated.

Deactivation means treating a chemical agent (such as a hazardous drug) with another chemical, heat, ultraviolet light, or other agent to create a less hazardous agent.

Decontamination means inactivation, neutralization, or removal of toxic agents, usually by chemical means.

Engineering controls means devices designed to eliminate or reduce worker exposure to hazards. Examples include biological safety cabinets, containment isolators, safer sharps devices, and safety interlocks.

Hazardous drugs means any drug identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control or any drug that meets at least one of the following six criteria:

- Carcinogenicity;
- Teratogenicity or developmental toxicity;
- Reproductive toxicity in humans;
- Organ toxicity at low doses in humans or animals;
- Genotoxicity;
- New drugs that mimic existing hazardous drugs in structure and toxicity.

Health care settings means all hospitals, medical clinics, outpatient facilities, physicians' offices, retail pharmacies, home health care, veterinary clinics, and similar settings dedicated to the care of patients.

HEPA filter means a high-efficiency particulate air filter rated ninety-nine and ninety-seven percent efficient in capturing 0.3-micron-diameter particles.

Material safety data sheet (MSDS) means a summary provided by the manufacturer to describe the chemical properties and hazards of specific chemicals and ways in which workers can protect themselves from exposure to these chemicals.

Occupational exposure means reasonably anticipated inhalation, skin, ingestion, or injection contact with hazardous drugs as a result of the performance of an employee's duties.

Factors that affect worker exposure include:

- Drug handling circumstances (preparation, administration, or disposal);
- Amount of drug prepared;
- Frequency and duration of drug handling;
- Potential for absorption;
- Use of ventilated cabinets;
- Personal protective equipment;
- Work practices.

The likelihood that a worker will experience adverse effects from hazardous drugs increases with the amount and frequency of exposure and the lack of proper work practices.

Ventilated cabinet means a type of engineering control designed for purposes of worker protection. These devices are designed to minimize worker exposures by controlling emissions of airborne contaminants through the following:

- The full or partial enclosure of a potential contaminant source;
- The use of airflow capture velocities to capture and remove airborne contaminants near their point of generation;
- The use of air pressure relationships that define the direction of airflow into the cabinet.

Examples of ventilated cabinets include biological safety cabinets and containment isolators.

NEW SECTION

WAC 296-62-50015 Hazardous drugs control program. (1) By July 1, 2012 each health care setting shall develop and implement a written hazardous drugs control program specific to the workplace. The hazardous drugs control program must, at a minimum, include the following:

- (a) A current hazard assessment;
- (b) A written inventory of hazardous drugs in the workplace;
- (c) A description of the hazardous drugs training program;
- (d) Hazardous drugs policies and procedures including, but not limited to:
 - (i) Personal protective equipment;
 - (ii) Engineering controls (equipment use and maintenance);
 - (iii) Safe handling practices (receiving and storage, labeling, preparing, administering, and disposing of hazardous drugs);
 - (iv) Cleaning, housekeeping, and waste handling;
 - (v) Spill control;
 - (vi) Medical surveillance;
 - (vii) Personnel issues (such as exposure of pregnant workers);
 - (viii) Training;
 - (ix) Recordkeeping.

Note: Elements of the hazardous drugs control program may be located in other documents such as the employer's accident prevention program or other policies and procedures as long as they are referenced in the program.

Reference: Refer to the most current **NIOSH list of antineoplastic and other hazardous drugs in healthcare settings** for guidance on developing and maintaining a hazardous drugs list.

(2) Review and update the written hazardous drugs control program on at least an annual basis and whenever changes that affect occupational exposure occur, such as introduction of a new hazardous drug, or a change in handling practices.

(3) Seek input from employees who handle hazardous drugs and from other employees who may be exposed to hazardous drugs as a result of the performance of their duties regarding the quality and effectiveness of the hazardous drugs control program.

NEW SECTION

WAC 296-62-50020 Hazard assessment. (1) Each health care setting must conduct initial and at least annual hazard assessments in order to determine the appropriate protective actions to be taken.

(2) The assessment must include, but is not limited to, the following:

- (a) Total working environment;
- (b) Equipment (i.e., ventilated cabinets, closed-system drug transfer devices, glovebags, needleless systems, and personal protective equipment);
- (c) Physical layout of work areas;
- (d) Types of drugs being handled;
- (e) Volume, frequency, and form of drugs handled (tablets, coated versus uncoated, powder versus liquid);
- (f) Equipment maintenance;
- (g) Decontamination and cleaning;
- (h) Waste handling;
- (i) Potential exposures during work, including hazardous drugs, bloodborne pathogens, and chemicals used to deactivate hazardous drugs or to clean drug-contaminated surfaces;
- (j) Routine operations;
- (k) Spill response;
- (l) Waste segregation, containment, and disposal.

NEW SECTION

WAC 296-62-50025 Personal protective equipment (PPE). (1) Conduct a PPE hazard assessment and provide appropriate PPE at no cost to employees.

(2) Gloves.

(a) Wear appropriate gloves when handling hazardous drugs or when there is potential contact with hazardous drug contaminated materials or surfaces.

(b) Use powder-free chemotherapy gloves when handling chemotherapy drugs or when there is potential contact with chemotherapy contaminated items or surfaces.

Note: Consider using chemotherapy gloves for hazardous drugs that are not chemotherapy drugs or for which no information is available.

(c) Provide latex-free gloves to employees with latex sensitivities.

(d) Wear two pairs of gloves whenever there is a risk of exposure to hazardous drugs, e.g., during compounding, administering, handling contaminated bodily fluids and linens, and cleaning up hazardous drug spills.

(e) Make sure that the outer glove extends over the cuff of the gown.

(f) Instruct all employees to inspect gloves for physical defects before use.

(g) Change gloves every thirty minutes or when torn, punctured, or contaminated.

Note: Glove thickness cannot be relied upon as the sole determination of protection. It is important to evaluate test information provided by the glove manufacturer and other research that demonstrates permeation resistance to the specific hazardous drug being handled.

(3) Protective clothing.

(a) Wear gowns whenever there is the possibility of a splash or spill, or contact with contaminated materials or surfaces, including opening drug packages, handling vials or finished products, labeling hazardous drug containers, disposal of waste and all activities associated with drug administration.

(b) Wear gowns made of polyethylene-coated polypropylene or other protective material as determined by the PPE hazard assessment. Make sure the gown has a closed front, long sleeves, and elastic or knit cuffs.

(c) Remove and dispose of gowns at the end of drug handling activities, when leaving the drug handling area and as soon as possible when damaged or contaminated.

(d) If no permeation information is available, change gowns every two to three hours.

(4) Face protection. Wear a full-face shield when splashes to the eyes, nose, or mouth may occur. Examples include cleaning a spill or performing a procedure such as bladder instillation.

(5) Respiratory protection.

(a) Use N95 or equivalent respiratory protection during spill clean up and whenever there is risk of exposure to hazardous drug particulates.

(b) Use an appropriate full-facepiece chemical cartridge-type respirator whenever there is a significant risk of exposure to hazardous drug vapors or gases (e.g., for events such as large spills when an intravenous (IV) bag breaks or a line disconnects and leaks).

(6) Dispose of PPE immediately after use or whenever contaminated.

NEW SECTION

WAC 296-62-50030 Engineering controls. (1) Use engineering controls to eliminate or minimize employee exposure to hazardous drugs. Examples of engineering controls include, but are not limited to:

- (a) Biologic safety cabinets;
- (b) Containment isolators;
- (c) Closed system transfer devices;
- (d) Safer sharps devices;
- (e) Safety interlocks.

(2) Develop a written safety plan for all routine maintenance activities performed on equipment that could be contaminated with hazardous drugs.

(3) General ventilation. Make sure that storage areas have sufficient general exhaust ventilation to dilute and remove airborne contaminants.

Note: Depending on the physical nature and quantity of the stored drugs, consider installing a dedicated emergency exhaust fan that is large enough to quickly purge airborne contaminants from the storage room in the event of a spill and prevent contamination in adjacent areas.

(4) Ventilated cabinets.

(a) Prepare (mix, compound, crush, pour liquid) hazardous drugs inside an appropriate ventilated cabinet designed to prevent release into the work environment.

(b) When selecting ventilated cabinets based on the need for aseptic processing make sure to use ventilated cabinets designed for both hazardous drug containment and aseptic processing. When asepsis is not required, a Class I biosafety cabinet or isolator intended for containment applications may be sufficient.

(c) Do not use supplemental engineering or process controls (such as needleless systems, glovebags, and closed system drug transfer devices) as a substitution for ventilated cabinets.

(d) Equip ventilated cabinets with a continuous monitoring device to confirm adequate airflow before each use.

(e) Use a high-efficiency particulate air filter (HEPA filter) for exhaust, and where feasible, exhaust one hundred percent of the filtered air to the outside.

(f) Install the outside exhaust so that the exhausted air is not pulled back into the building by the heating, ventilating, and air conditioning systems or by the windows, doors, or other points of entry.

(g) Place fans downstream of the HEPA filter so that contaminated ducts are maintained under negative pressure.

(h) Do not use a ventilated cabinet that recirculates air inside the cabinet or exhausts air back into the room environment unless the hazardous drug(s) in use will not volatilize while they are being handled or after they are captured by the HEPA filter.

(i) Develop and implement maintenance and cleaning procedures that ensure the effectiveness and safety of the ventilated cabinet.

(i) Field-certify biosafety cabinet performance, in accordance with National Sanitation Foundation/American National Standards Institute Standard 49, after installation, relocation, maintenance, repairs to internal components, HEPA filter replacement, and every six months thereafter.

(ii) Select appropriate performance and test methods for containment isolators, at a minimum, conduct leak and containment integrity tests in accordance with current American Glovebox Society guidelines. In addition perform a HEPA filter leak test for those containment isolators that utilize HEPA filtration.

(iii) Prominently display a current field-certification label on the ventilated cabinet.

(iv) Make sure that workers performing maintenance are familiar with applicable safety procedures, warned about hazards,

and trained in appropriate work techniques and PPE needed to minimize exposure.

(v) Remove all hazardous drugs and chemicals, and decontaminate the ventilated cabinet before beginning maintenance activities.

(vi) Notify occupants in the affected areas immediately before the maintenance activity begins, and place warning signs on all affected equipment.

(vii) Deenergize the ventilated cabinet in accordance with chapter 296-803 WAC, Lockout/Tagout (control of hazardous energy).

(viii) Decontaminate and bag equipment parts removed for replacement or repair before they are taken outside the facility.

(ix) Seal used filtration media in plastic immediately upon removal, and dispose as contaminated waste.

(5) Institution of effective ventilation controls must be accomplished by December 1, 2012.

Note: Consult the following documents for performance test methods and selection criteria for ventilated cabinets:
(a) *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets (CDC/NIH)*.
(b) *NSF/ANSI 49, Class II (laminar flow) Biosafety Cabinetry*.

NEW SECTION

WAC 296-62-50035 Safe handling practices. (1) Receiving and storage.

(a) Make sure that all hazardous drug containers received from the manufacturer, distributor, another pharmacy, or medical clinic are labeled.

(b) At a minimum wear appropriate gloves when opening and unpacking shipping containers, and transporting hazardous drugs.

(c) Store hazardous drugs separately from other drugs, and in a manner that minimizes the potential for spills.

(d) Prohibit the use of unventilated areas for drug storage.

(e) Transport hazardous drugs in closed containers that minimize the risk of breakage.

(2) Labeling.

(a) Label hazardous drug containers in accordance with WAC 296-800-170, Employer chemical hazard communication.

(b) Label pharmaceutical waste containers in accordance with WAC 173-303-200, Accumulating dangerous waste on-site. See the Washington state department of ecology pharmaceutical waste web site for more information.

(3) Preparing.

(a) Provide work areas that are devoted solely to preparing hazardous drugs and limited to authorized personnel.

(b) Coordinate tasks associated with preparing and administering hazardous drugs to minimize exposure risks.

(c) Use engineering controls such as closed-system transfer devices, glovebags, and needleless systems when transferring

hazardous drugs from primary packaging (such as vials) to dosing equipment (such as infusion bags, bottles, or pumps).

(d) Spike and prime the IV tubing and syringes inside an appropriate ventilated cabinet, never in the patient's room.

(e) When drug preparation is complete, seal the final product in a clear plastic bag or other sealable container for transport before removing it from the ventilated cabinet.

(f) Seal and decontaminate all waste containers inside the ventilated cabinet before removing them from the ventilated cabinet.

(g) Remove outer gloves and sleeve covers (if used) and bag them for disposal while inside the ventilated cabinet.

(4) Administering.

(a) Ensure that staff has been trained and follow policies and procedures regarding the safe administration of hazardous drugs and related patient care. Examples include, but are not limited to; oral, intravenous, intramuscular or subcutaneous injections, topical, intracavitary, and aerosol administration.

(b) Use engineering controls to transfer and administer hazardous drugs.

(c) Wear appropriate personal protective equipment when administering hazardous drugs.

(d) Spike and prime administration sets prior to adding the drug to the bag.

(e) Do not remove tubing from an IV bag containing a hazardous drug.

(f) Do not disconnect tubing at other points in the system until the tubing has been thoroughly flushed.

(g) Place contaminated waste and other disposable items directly into a designated waste container.

(h) Personal hygiene. Prohibit eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses in work areas where hazardous drugs may be found.

(5) Handwashing. Wash hands with soap and water before donning gloves, immediately after removal, and whenever hands become contaminated.

(6) Laundry. Place contaminated laundry in leakproof, labeled or color-coded containers.

NEW SECTION

WAC 296-62-50040 Cleaning, housekeeping, and waste handling.

(1) Establish procedures for cleaning and decontamination of areas and equipment where hazardous drugs are present.

(2) Perform cleaning and decontamination work in areas that are sufficiently ventilated to prevent buildup of hazardous airborne concentrations.

(3) Clean work surfaces with an appropriate deactivation agent and cleaning agent before and after each continuous activity and at

the end of the work shift.

(4) Wear appropriate gloves for cleaning and decontamination work.

(5) Wear a gown and face protection whenever splashing or contact with contaminated materials or surfaces is possible.

(6) Wear appropriate gloves and gown when handling linens, feces, or urine from patients who have received hazardous drugs within the last forty-eight hours that may be excreted in the urine or feces. In some cases handling precautions may need to be extended beyond forty-eight hours; e.g., Cisplatin may be excreted in urine for up to seven days.

(7) Place hazardous drug contaminated waste in designated pharmaceutical waste containers and dispose of in accordance with Washington state department of ecology dangerous waste requirements, chapter 173-303 WAC.

(8) Waste containers must be:

(a) Leakproof and appropriate for intended use, e.g., containers holding sharps must be puncture resistant;

(b) Color-coded or labeled;

(c) Located as close as feasible to the immediate area where contaminated waste is generated or can be anticipated to be found;

(d) Maintained upright throughout use;

(e) Not allowed to overfill;

(f) Closed except when in use, and prior to removal or replacement.

NEW SECTION

WAC 296-62-50045 Spill control. (1) Develop written spill response procedures based on the hazardous drugs present and potential spill or release conditions.

(2) Spill procedures must include, at a minimum:

(a) Description of who is authorized to respond and under what circumstances;

(b) PPE (including respiratory protection) for various drugs and spill sizes;

(c) Location and use of spill kits or clean-up materials, and personal protective equipment;

(d) Possible spreading of material, and area containment and signage;

(e) Reporting and evaluating the circumstances surrounding spills and releases;

(f) Restricted access to hazardous drug spills.

(3) Provide spill kits or clean-up materials near all potential spill sources.

(4) Dispose of all clean-up materials in an appropriate pharmaceutical waste container.

Note: See chapter 296-824 WAC, Emergency response for requirements regarding response to spills that create significant safety and health risks. See the scope of chapter 296-824 WAC for further guidance.

NEW SECTION

WAC 296-62-50050 Medical surveillance. (1) Make confidential medical evaluations available to employees who directly handle hazardous drugs, and others who may come directly into contact with patient wastes within forty-eight hours after receiving a hazardous drug (e.g., nurses aides, laundry workers) under the following schedule:

- (a) Upon hire and on a scheduled basis thereafter;
- (b) Following acute exposures;
- (c) At the time of job termination or transfer (exit evaluation).

(2) Ensure that all medical evaluations are performed by or under the supervision of a licensed health care provider (LHCP), and are provided at no cost to the employee and at a reasonable time and place.

(3) The medical evaluations must include:

(a) A health questionnaire that includes reproductive and occupational information.

(b) Baseline and periodic laboratory work as indicated based on the health hazards of the hazardous drugs the employee is exposed to or reasonably likely to be exposed to.

(c) A physical examination at the time of hire and as indicated based on the health questionnaire, changes in health status or laboratory work findings.

(d) Additional testing and examinations as recommended by the LHCP.

Note: Many hazardous drugs may affect the production of blood cells and may cause bladder damage. Because of this many authoritative bodies (e.g., NIOSH, the Occupational Health and Safety Administration, and the Oncology Nursing Society) recommend a complete blood count with differential, and examination for blood in the urine. Additional laboratory work, such as liver function testing, may be indicated.

(4) Provide the LHCP the following information:

(a) A description of the employee's duties as they relate to the employee's exposure;

(b) The employee's exposure levels or anticipated exposure levels;

(c) A description of the personal protective equipment and respiratory protection used or to be used;

(d) Information available from previous medical examinations of the employee, which is not readily available to the LHCP.

NEW SECTION

WAC 296-62-50055 Training. (1) Provide hazardous drugs training to all employees with occupational exposure at the time of their initial job assignment, on a regular basis, and whenever changes in the workplace occur that may affect occupational exposure.

(2) Employee training includes, but is not limited to, the following elements:

(a) A review of the hazardous drugs control program and how to access a copy of the program;

(b) An explanation of and how to access material safety data sheets (MSDSs);

(c) Sources of exposure to hazardous drugs;

(d) Health hazards of the hazardous drugs in the work area, including the possible physical symptoms or effects of exposure;

(e) Steps employees can take to protect themselves from exposure to hazardous drugs in the workplace, including specific procedures to protect employees from exposure to hazardous chemicals. Specific procedures may include:

(i) Personal protective equipment;

(ii) Engineering controls;

(iii) Safe handling practices;

(iv) Cleaning, housekeeping, and waste disposal;

(v) Spill control;

(vi) System for reporting exposure incidents and hazardous conditions.

(f) Medical surveillance.

(3) Initial and periodic assessments of preparation and administration technique.

(4) The training must be conducted in a manner which the employees are able to understand.

Note: This training will suffice for the training on hazardous drugs required under WAC 296-800-170, Employer chemical hazard communication--Introduction.

NEW SECTION

WAC 296-62-50060 Recordkeeping. (1) Training records.

(a) Maintain current training records for each employee.

(b) Training records must include the following:

(i) Dates of training sessions;

(ii) Contents or a summary of the training sessions;

(iii) Names and job titles of employees taking the training.

(2) Medical and exposure records. Establish and maintain employee medical and exposure records in accordance with chapter 296-802 WAC, Employee medical and exposure records.

(3) Spill records. Maintain spill records and evaluation

findings for at least one year from the date of the spill or release.