

PART R--HAZARDOUS DRUGS

NEW SECTION

WAC 296-62-500 Hazardous drugs. This chapter provides minimum requirements for developing a hazardous drugs control program when occupational exposure to hazardous drugs is reasonably anticipated. It is designed to provide effective, assessment-based precautions to minimize or eliminate occupational exposure to hazardous drugs.

IMPORTANT:

Occupational exposure to hazardous drugs is also covered under WAC 296-800-170, Employer chemical hazard communication--Introduction. In addition the employer must follow the requirements in WAC 296-800-160, personal protective equipment (PPE) and chapter 296-842 WAC, Respirators. 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 employers in health care facilities regardless of the setting that have employees with occupational exposure to hazardous drugs.

(2) Chapter application.

(a) The requirements in this rule only apply to the hazardous drugs being used in the workplace.

(b) If hazardous drugs are being used in the workplace the requirements in this rule only apply if there is reasonably anticipated occupational exposure as defined in WAC 296-62-50010.

(c) If there is reasonably anticipated occupational exposure to one or more hazardous drugs, the employer must develop a hazardous drugs control program as required in section WAC 296-62-50015.

(d) For purposes of making the determinations in this section about scope and application, occupational exposure is that exposure which would be reasonably anticipated in the absence of engineering controls or PPE.

(3) 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:

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

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.

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, laboratory fume hoods, 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 (CDC) 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 facilities means all hospitals, clinics, nursing homes, laboratories, offices or similar places where a health care provider provides health care to patients. For purposes of this chapter this includes veterinary medicine, retail pharmacies, home health care agencies and also those research laboratories in settings where a health care provider provides health care to patients. It does not include the drug manufacturing sector or research laboratories where health care providers do not provide health care to patients.

HEPA filter means a high-efficiency particulate air filter rated 99.97% efficient in capturing 0.3-micron-diameter particles.

● **Isolator** means a device that is sealed or is supplied with air through a microbially retentive filtration system (HEPA minimum) and may be reproducibly decontaminated. When closed, an isolator uses only decontaminated interfaces (when necessary) or rapid transfer ports (RTPs) for materials transfer. When open, it allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contaminants or unfiltered air to adjacent environments. An isolator can be used for aseptic processing, for containment of potent compounds, or for simultaneous asepsis and containment. Some isolator designs allow operations within the isolator to be conducted through attached rubber gloves without compromising asepsis and/or containment.

● **Aseptic isolator:** A ventilated isolator designed to exclude external contamination from entering the critical zone inside the isolator.

● **Aseptic containment isolator:** A ventilated isolator designed to meet the requirements of both an aseptic isolator and a containment isolator.

● **Containment isolator:** A ventilated isolator designed to prevent the toxic materials processed inside it from escaping to the surrounding environment.

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. Some drugs defined as hazardous may not pose a significant risk of occupational exposure because of their dosage formulation (for example, coated tablets or capsules that are administered to patients without modifying the formulation). However, they may pose a risk if altered (for example, if tablets are crushed or dissolved, or if capsules are pierced or opened).

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) Each health care facility covered under the scope of this chapter must develop and implement a written hazardous drugs control program. 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. The hazardous drugs control program must, at a minimum, include the following:

- (a) A written inventory of hazardous drugs in the workplace.
- (b) A current hazard assessment for hazardous drugs for which there is reasonably anticipated occupational exposure.
- (c) Hazardous drugs policies and procedures including, but not limited to:
 - (i) Engineering controls (equipment use and maintenance).
 - (ii) Personal protective equipment.
 - (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) Personnel issues (such as exposure of pregnant workers).
 - (vii) Training.

(2) A standard or universal precautions approach to managing occupational exposure to hazardous drugs is recommended by NIOSH; however, due to the variety of factors that affect occupational exposure some health care facilities may find it more effective to institute precautions based on exposure risk. For example a tiered approach that effectively matches precautions to the nature of exposure may be used including, but not limited to, handling, storing, cleaning, preparing and engineering controls.

(3) Review and update the written hazardous drugs control program annually and whenever changes that affect occupational exposure occur, such as introduction of a new hazardous drug, or a change in handling practices.

- (4) Seek and consider input from 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 facility covered under the scope of this chapter must conduct hazard assessments in order to determine the appropriate precautions to be taken. These assessments may be limited to the hazardous drugs for which there is reasonably anticipated occupational exposure.

(2) Assessments must include the following elements as appropriate:

- (a) Personal protective equipment.
- (b) Engineering controls (e.g., ventilated cabinets, closed-system drug transfer devices, glovebags, and needleless systems).
- (c) Physical layout of work areas.
- (d) Types of hazardous drugs being handled.
- (e) Volume, frequency, packaging, and form of hazardous drugs handled (tablets, coated versus uncoated, powder versus liquid).
- (f) Equipment maintenance.
- (g) Decontamination and cleaning.
- (h) Waste handling.
- (i) Potential hazardous drug exposures during work operations, such as drug preparation and administration.
- (j) Spill response.

(3) Conduct a hazard assessment as part of the hazardous drugs control program update and whenever changes that affect occupational exposure occur, such as introduction of a new hazardous drug or a change in handling practices.

Note: The likelihood that a worker will experience adverse effects from exposure to hazardous drugs varies depending upon the relative toxicity and absorptive properties of a drug, the amount, duration and frequency of contact, and the lack of proper work precautions.

NEW SECTION

WAC 296-62-50025 Engineering controls. (1) Evaluate and implement appropriate engineering controls to eliminate or minimize employee exposure. Examples of engineering controls include, but are not limited to:

- (a) Closed system transfer devices.
- (b) Safer sharps devices.
- (c) Safety interlocks.

(d) Ventilated cabinets.

(2) Ventilated cabinets.

(a) Prepare (e.g., mix, compound, crush) hazardous drugs inside an appropriate ventilated cabinet designed to prevent release into the work environment. When asepsis is not required, a Class I biosafety cabinet or isolator intended for containment applications may be sufficient.

(i) Alternate precautions may be used where the hazard assessment determines a low occupational exposure risk while preparing hazardous drugs other than chemotherapy agents (e.g., crushing and splitting tablets, drawing medication into a syringe). These may include, but are not limited to, temporarily designating a preparation area, use of appropriate personal protective equipment, and instituting cleaning procedures.

(ii) Chemotherapy drugs must be prepared in an appropriate ventilated cabinet with the exception of circumstances where the employer can document evidence of a clinical need (e.g., there is a nonroutine need to provide chemotherapy treatment, compounding services are not readily available, and it is in the best interest of the patient to provide local care). In such circumstances alternate precautions must be instituted as described above.

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

(c) Use filtering media that is approved by the cabinet manufacturer and is appropriate for the agent being captured, such as a high-efficiency particulate air filter (HEPA filter) for exhaust, and where feasible, exhaust one hundred percent of the filtered air to the outside unless the employer can provide an evidence-based justification to do otherwise.

(d) 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.

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

(f) 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 filter.

(g) 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 or as recommended by the manufacturer.

(ii) Select appropriate performance and test methods for isolators, depending on the type (containment only or aseptic containment), the operating pressure (positive or negative and designed magnitude), and toxicity of the hazardous drug. 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 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 (e.g., through the provision of material safety data sheet or other equivalent information resources), 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.

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

NEW SECTION

WAC 296-62-50030 Personal protective equipment (PPE). (1) When there is reasonably anticipated exposure to hazardous drugs each health care facility must conduct a PPE assessment and provide and ensure use of appropriate PPE in accordance with WAC 296-800-160, personal protective equipment (PPE), and chapter 296-842 WAC, Respirators.

(2) Use appropriate PPE whenever handling body fluids and contaminated laundry.

(3) Gloves.

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

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

(c) Wear two pairs of gloves when there is a significant risk of breakage or contamination or permeation, e.g., during compounding, extended handling periods, and cleaning up large hazardous drug spills.

(d) Change gloves every thirty to sixty minutes or when torn, punctured, or contaminated.

(4) Protective clothing.

(a) Wear gowns whenever there is a reasonable possibility of

a hazardous drug splash or spill such as in compounding, preparing and administering hazardous drugs.

(b) Wear gowns made of polyethylene-coated polypropylene or other nonabsorbent, nonlinting 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 hazardous drug handling activities, when leaving the hazardous 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 or when contaminated after a splash or spill.

(5) Face protection. Wear a full-face shield or a mask and eye protection as appropriate when splashes to the eyes, nose, or mouth may occur; examples include cleaning a spill, or performing a procedure such as bladder instillation.

(6) Respiratory protection.

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

(b) Use an appropriate chemical cartridge-type respirator for events such as large spills of volatile hazardous drugs, e.g., when an intravenous (IV) bag breaks or a line disconnects.

(7) Disposable PPE must be discarded into appropriate containers immediately after use or as soon as feasible after contamination. Reusable PPE must be properly cleaned and decontaminated after use or contamination.

NEW SECTION

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

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

(b) Store and transport hazardous drugs in a manner that minimizes the risk of breakage.

(2) Preparation and administration.

(a) Provide designated work areas for the preparation of hazardous drugs and limit access during preparation.

(b) Coordinate tasks associated with preparing and administering hazardous drugs for the most effective control of worker exposure.

(c) Spike and prime the IV tubing and prepare syringes in a manner that most effectively limits occupational exposure.

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

(e) When drug preparation is completed in a ventilated cabinet:

(i) Seal the final product in a plastic bag or other sealed

container for transport before taking it out of the cabinet.

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

(iii) Remove all outer gloves and sleeve covers and bag them for disposal while inside the cabinet.

(3) Waste handling.

(a) Dispose of pharmaceutical waste in accordance with applicable state and federal regulations.

(b) Place disposable items in designated containers.

(4) Personal hygiene.

(a) Prohibit eating or drinking in areas where hazardous drugs are handled.

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

NEW SECTION

WAC 296-62-50040 Cleaning and housekeeping. (1) Establish procedures for cleaning and decontamination of areas and equipment where hazardous drugs are present.

(2) Do not clean contaminated equipment in unventilated areas.

(3) Clean work surfaces before and after each continuous activity and at the end of the work shift.

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 for various hazardous drugs and spill sizes.

(c) Location and use of spill kits or clean-up materials.

(d) Possible spreading of contamination, and area containment and signage.

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

(f) Restricted access to hazardous drug spills.

(g) Waste disposal.

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

Note: See chapter 296-824 WAC, Emergency response for requirements regarding response to spills that create significant safety and health risks, and WAC 296-800-150, first-aid summary for emergency washing requirements.

NEW SECTION

WAC 296-62-50050 Training. (1) Provide hazardous drugs training to all employees with occupational exposure at the time of their initial job assignment and on a regularly scheduled basis thereafter.

(2) Include the training elements listed in WAC 296-800-17030, Inform and train your employees about hazardous chemicals in your workplace.

NEW SECTION

WAC 296-62-50055 Implementation plan. (1) Effective dates.

(a) The written hazardous drugs control program must be completed and implemented by January 1, 2014, with the exception of (b) and (c) of this subsection.

(b) Employee training must be implemented by July 1, 2014.

(c) Installation of appropriate ventilated cabinets must be completed by January 1, 2015.

(2) The department will work with stakeholders to implement this chapter by doing the following:

(a) Establish a hazardous drugs advisory committee to discuss new NIOSH recommendations, scientific and technological developments and other unanticipated issues related to rule implementation. This committee will include employer and employee representatives of the health care industry and representatives of affected state agencies. It may provide recommendations to the department regarding appropriate actions.

(b) Work with trade associations, labor unions and other representatives from the health care industry to develop model programs for implementation of these rules in a variety of health care facilities and settings. The department will provide education, training and consultation services to ensure that these model programs are widely distributed and can be effectively utilized.

(c) Establish a hazardous drugs web page, and post relevant resources, sample programs and forms.