

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).

Safety data sheet (SDS) 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.

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.

AMENDATORY SECTION (Amending WSR 12-02-053, filed 1/3/12, effective 1/1/14 and (2) effective 1/1/15)

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 or barrier isolators 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))~~ worker exposure.

(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)) Hazardous drugs that volatilize must be handled only in a ventilated cabinet that captures the volatilized material to prevent employee exposure, or in a ventilated cabinet that does not recirculate air inside the cabinet or exhausts air back into the room environment.~~

~~(c) Install and maintain the ventilation equipment determined by your hazard assessment in accordance with:~~

~~(i) The ventilation equipment manufacturer's design, instructions, and precautions;~~

~~(ii) Appropriate and most current national safety and industry standards.~~

~~Note: The following are examples of industry standards related to installing and maintaining ventilation equipment. There may be other industry standards in addition to those listed below:~~

~~(A) Center for Disease Control/National Institute for Health: Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets (CDC/NIH).~~

~~(B) National Sanitation Foundation/American National Standards Institute Standard 49, (NSF/ANSI) Class II (laminar flow) Biosafety Cabinetry.~~

(C) U.S. Pharmacopeial Convention (USP).

(D) American Glove Box Standards.

(iii) National Institute of Occupational Safety and Health (NIOSH) "Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings"; and

(iv) Applicable state, federal, and local regulations.

(d) 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 Glove-box 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.*

AMENDATORY SECTION (Amending WSR 12-02-053, filed 1/3/12, effective 1/1/14)

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~~) per glove manufacturer's instruction, type of occupational exposure, 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)) appropriate respiratory protection 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.

AMENDATORY SECTION (Amending WSR 14-07-086, filed 3/18/14, effective 5/1/14)

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

(a) Label hazardous drug containers in accordance with WAC 296-901-140((7)) Hazard communication.

(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.))~~ Hand-washing.
 - (i) Prior to donning gloves, if hands are contaminated, wash with soap and water; and
 - (ii) Wash hands with soap and water immediately after removal, and whenever hands become contaminated.

AMENDATORY SECTION (Amending WSR 12-02-053, filed 1/3/12, effective 1/1/14)

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))~~ in accordance with chapter 296-824 WAC Emergency response and WAC 296-800-150, first-aid summary for emergency washing requirements.

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.

AMENDATORY SECTION (Amending WSR 12-02-053, filed 1/3/12, effective 7/1/14)

WAC 296-62-50050 Training. (1) Provide effective hazardous drugs training to all employees with occupational exposure at the time of their initial job assignment and (~~on a regularly scheduled basis thereafter~~) whenever a new hazardous drug or a new process related to handling a hazardous drug that the employees have not previously been trained about is introduced into their work area.

(2) Include the training elements listed in WAC (~~296-800-17030~~) 296-901-14016, Inform and train your employees about hazardous chemicals in your workplace.