WAC 296-62-50010 Definitions. Biological safety cabinet. 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. 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. 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. Inactivation, neutralization, or removal of toxic agents, usually by chemical means.

Engineering controls. 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. 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:

(a) Carcinogenicity.

(b) Teratogenicity or developmental toxicity.

(c) Reproductive toxicity in humans.

(d) Organ toxicity at low doses in humans or animals.

(e) Genotoxicity.

(f) New drugs that mimic existing hazardous drugs in structure and toxicity.

Health care facilities. 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. A high-efficiency particulate air filter rated 99.97% efficient in capturing 0.3-micron-diameter particles.

• **Isolator.** 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.

Occupational exposure. 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). 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. 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:

(a) The full or partial enclosure of a potential contaminant source.

(b) The use of airflow capture velocities to capture and remove airborne contaminants near their point of generation.

(c) 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.

[Statutory Authority: RCW 49.17.010, 49.17.040, 49.17.050, and 49.17.060. WSR 19-01-094, § 296-62-50010, filed 12/18/18, effective 1/18/19; WSR 16-10-083, § 296-62-50010, filed 5/3/16, effective 6/3/16. Statutory Authority: RCW 49.17.010, 49.17.040, 49.17.050, 49.17.060, and 2011 c 39. WSR 12-02-053, § 296-62-50010, filed 1/3/12, effective 1/1/14.]