Personnel Training	
SC Practice Act	USP 800
Training must include: • Safe aseptic manipulation practices • Negative pressure techniques when utilizing a BSC or CACI • Correct use of CSTD devices • Containment, cleanup and disposal procedures for breakages and spills • Treatment of personnel contact and inhalation	Training must include: • Overview of entity's list of HDs and their risks • Review of the entity's SOPs related to handling of HDs • Proper use of PPE • Proper use of equipment and devices • Response to known or suspected HD exposure • Spill management • Proper disposal of HDs and trace-contaminated materials Requires designated person responsible Hazardous Communication Plan
Documentation/compliance must be updated annually.	Competency must be reassessed annually.

C-PEC	
SC Practice Act	USP 800
• Must maintain ISO Class 5 or better conditions while compounding • HEPA-filtered air must be supplied in critical areas at a velocity sufficient to sweep particles away from the compounding area • PEC must be placed out of the traffic flow in a manner to avoid conditions that could adversely affect its operation	• Must maintain ISO Class 5 or better air quality while sterile hazardous drug compounding • Placed in an ISO Class 7 buffer room that has fixed walls, HEPA-filtered supply air, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas, and a minimum if 30 ACPH

Buffer Area	
SC Practice Act	USP 800
• Must maintain at least ISO Class 7 conditions • Surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets must be smooth, impervious, and nonshedding • Shall not contain sources of water or floor drains with the exception of emergency safety devices • Pressure between the positive ISO Class 7 or better buffer area, the ante area and the general pharmacy may not be less than a 0.02 inch water column	• Must maintain air quality of ISO Class 7 or better • Surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets must be smooth, impervious, free from cracks and crevices, and non-shedding • Must have a minimum of 30 ACPH of HEPA-filtered supply air • Must maintain a positive pressure of a least 0.02 inches of water column relative to all adjacent unclassified areas

PPE	
SC Practice Act	USP 800
• Appropriate personal protective equipment must be worn by personnel compounding hazardous drugs	• Appropriate personal protective equipment must be worn when handling hazardous drugs including during receipt, storage, transport, compounding, administration, deactivation, cleaning, disinfecting, spill control, and waste disposal • Gowns, head, hair, shoe covers, and two pairs chemotherapy gloves required for compounding • Second pair of shoe coverings donned when enter C-SEC • All personnel performing deactivating, decontaminating, cleaning, and disinfecting activities must wear appropriate PPE resistant to the cleaning agents used, including two pairs of chemotherapy gloves and impermeable disposable gowns • Eye protection and face shields must be used if splashing is likely • If warranted by the activity, respiratory protection must be used

Environmental Quality and Control Practices	
SC Practice Act	USP 800
• Environmental Quality performance verification procedures must be performed by a qualifies individual no less than every 6 months and when the device or room is relocated or altered • Certification documents must be retained for 2 years	• Environmental wipe sampling for hazardous drugs surface residue should be performed initially as a benchmark and at least every 6 months to verify containment (C-PEC and contained equipment, pass-through chambers, surfaces in staging/work areas, all areas adjacent to C-PEC, areas immediately outside HD buffer room or C-SCA, pt admin areas)

Hazardous Drug Spill Control	
SC Practice Act	USP 800
• Written procedures for disposal and handling spills of hazardous agents must be developed • Must be immediate access to emergency spill supplies wherever hazardous drugs are prepared	• Standard of Operations must address prevention of accidental exposures or spills, personnel training on response to exposure, and use of spill kit • Spills must be contained and cleaned immediately only by qualified personnel with appropriate PEE • All spill materials must be disposed of as hazardous waste • Spill kits containing all of the materials needed to clean hazardous drugs spills must be readily available in all areas where hazardous drugs are routinely handled

Hazardous Drug Labeling, Packaging, and Handling	
SC Practice Act	USP 800
• Hazardous CSP must be identified with warning labels in accordance with state and federal requirements • Hazardous CSP must be packaged for handling and delivery in a manner that minimizes the risk of rupture of	• Written SOPs specific to labeling, packaging, transport, disposal, exposure/spill prevention, personnel response, spill kit usage

the primary container and ensures the stability, sterility, and potency of the solution • Hazardous drugs must be handled with caution at all times during the receiving, distribution, stocking, inventorying, preparation for administration, and disposal	• Hazardous drugs identified by the entity as requiring special hazardous drug handling precautions must be clearly labeled at all times during their transport • APIs and other powdered HDs must be handled in C-PEC • Antineoplastic hazardous drugs and all hazardous drugs APIs must be unpacked in an area that is neutral/normal or negative pressure relative to the surrounding areas (not in sterile cmpd area or positive pressure area) • Stored separately from non-HDs • Personnel must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility of the hazardous drugs during transport • Hazardous drugs should be received from the supplier in impervious plastic to segregate them from other drugs and to allow for safety in the receiving and internal transfer process • Hazardous drugs must be stored in a manner that prevents spillage or breakage if the container falls • Disposal of all hazardous drug waste, including, but not limited to, unused hazardous drugs and trace-contaminated PPE and other materials, must comply with all applicable federal, state, and local regulations

Hazardous Drug Compounding	
SC Practice Act	USP 800
• If hazardous drugs are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous cleaning of contaminated equipment before its use for the preparation of other drugs, must be utilized in order to prevent cross-contamination	• Sterile and nonsterile hazardous drugs must be compounded within a C-PEC located in a C-SEC that is externally ventilated, physically separated, appropriate air exchange, neg pressure b/t 0.01 and 0.03 inches water column relative to adjacent areas • A laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) must not be used for the compounding of an antineoplastic hazardous drug

• All hazardous CSPs must be compounded and prepared in an ISO Class 5 environment in a BSC or CACI with the exception of radiopharmaceuticals • Hazardous drugs may not be prepared in a laminar airflow workbench or a compounding aseptic isolator • A sink with hot and cold running water readily accessible to the sterile preparations preparation area with immediate availability of germicidal skin cleanser and either an air blower or nonshedding single-use towels for hand drying must be available to all personnel preparing sterile pharmaceuticals	• A BSC or CACI used for the preparation of hazardous drugs must not be used for the preparation of a non-hazardous drug unless the non-hazardous drug preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions • A hand-washing sink must be placed in the ante-room at least 1 meter from the entrance to the hazardous drug buffer room to avoid contamination migration into the negative pressure hazardous drug buffer room (should this go under Buffer?)

USP <800>

Requires each facility maintain a list of Hazardous Drugs which must include ANY item on the current NIOSH list that the facility/entity handles. Must be reviewed every 12 months or when new agent or dosage form is used. Use NIOSH criteria to identify HDs. Also use for those that enter after current NIOSH list published.

Requires Assessment of Risk for alternative containment strategies