TYPES OF ENGINEERING CONTROLS 12

(See <800> Section 5, Appendix 2, and Appendix 3 in USP <800>.)

Engineering controls are used to contain hazards. <800> describes three types of engineering controls: *primary* (the hood), *secondary* (the room in which the primary control is placed), and *supplemental* (closed system drug-transfer devices used for compounding and administration). If alternative containment strategies and/or work practices are defined in the Assessment of Risk, the entity may exempt specific dosage forms of non-antineoplastic agents and reproductive hazards and dosage forms of antineoplastics that are only counted or packaged from some engineering control requirements.

12.1 GENERAL INFORMATION

12.1-1 What are the types of engineering controls?

Three types of engineering controls are defined in <800>:

1. *Containment primary engineering control* (C-PEC)—the device in which compounds are mixed, including a containment ventilated enclosure (CVE) commonly called *powder hoods*, a biological safety cabinet (BSC), and a compounding aseptic containment isolator (CACI).
2. *Containment secondary engineering control* (C-SEC)—the room in which the C-PEC is placed, including the anteroom/buffer room suite or a containment segregated compounding area (C-SCA).
3. *Supplemental engineering controls*—closed system drug-transfer devices (CSTDs), which are devices that mechanically prohibit the transfer of environmental contaminants into the system and the escape of hazardous drug (HD) or vapor concentrations outside the system.

12.1-2 How do the PECs in <800> differ from those in <797>?

The PECs for compounding sterile HDs are the same. <800> also requires PECs for nonsterile HD compounding. The *containment* term is added to designate use with HDs.

12.1-3 How do the SECs in <800> differ from those in <797>?

A cleanroom suite as a SEC has the same structure as in <797>, but <800> adds in some additional requirements. The *containment* term is added to designate use with HDs. (*See Section 14, Design of Compounding Facilities*.) <797> allows placement of a BSC or CACI in a positive pressure room if only a low volume of hazardous compounding is done; <800> does not allow that. <800> allows a C-SCA, which is a new configuration not permitted by <797>.

12.1-4 How do the supplemental engineering controls in <800> differ from those in <797>?

The term *supplemental engineering control* does not appear in <797>, although CSTDs are included. In <797>, CSTDs are required if you have a BSC or CACI in a positive pressure buffer room. In <800>, that configuration is not permitted. In <800>, CSTDs are recommended for use when compounding and required for use during administration of HDs if the dosage form allows.

12.1-5 What is a *C-PEC*?

A *C-PEC* is the hood where the preparations are compounded. USP <800> defines a C-PEC as a

> "ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants through a full or partial enclosure of a potential contaminant source, the use of airflow capture velocities to trap and remove airborne contaminants near their point of generation, the use of air pressure relationships that define the direction of airflow into the cabinet, and the use of HEPA filtration on all potentially contaminated exhaust streams."[8]

12.1-6 Do certain drugs require use of a CACI instead of a BSC?

No. Either a CACI or a BSC can be used as your PEC; there is no distinction between them based on what drugs you are compounding.

12.1-7 What are the basic requirements for a BSC for sterile compounding?

Only Class II BSCs are appropriate for sterile compounding. Class II BSCs provide worker, preparation, and environmental protection. Be sure to get a BSC that is on the list of NSF Certified Biosafety Cabinetry (http://info.nsf.org/Certified/Biosafety/), which has been independently performance-verified. Standard Class II BSCs that you can purchase will be on this list. If you need a special order BSC for some reason, ask the manufacturer to perform the biological test that they would use for certification of the unit.

12.1-8 What is a *containment ventilated enclosure*?

A *CVE* is a type of C-PEC used for nonsterile compounding, commonly called a *powder hood*.

12.1-9 What additional items should be considered if my CVE will have redundant HEPA filters instead of being vented to the outside?

External venting is preferred; but if you will have a CVE that has redundant high-efficiency particulate air (HEPA) filters, be sure that both filters will be able to be leak tested. If the CVE is used to protect against drugs that volatilize at room temperature, it needs to be externally vented.

12.1-10 What is a *containment secondary engineering control*?

A *C-SEC* is a room with fixed walls in which the C-PEC is placed. The room is under negative pressure, is vented to the outside, and has an appropriate number of air changes per hour (ACPH). Ideally, for sterile compounding, this is a suite of rooms (positive pressure anteroom