

DESIGN OF COMPOUNDING FACILITIES

14

(See Section 5 in USP <800>.)

APIs of any type of HD and antineoplastic must be compounded using the containment strategies and work practices defined in <800>. An entity's Assessment of Risk may exempt specific dosage forms of those agents listed in the NIOSH hazardous list tables for non-antineoplastics and reproductive hazards if alternative containment strategies and/or work practices are identified and implemented.

14.1 GENERAL INFORMATION

14.1-1 What are the minimum facility requirements for compounding HDs?

Hazardous drugs (HDs) must be compounded in a room that is separate from compounding of non-HDs. The room must have fixed walls, be negative pressure, be vented to the outside, and have the appropriate number of air changes per hour (ACPH). Sterile compounding anterooms and buffer rooms require at least 30 ACPH. Nonsterile compounding areas and containment segregated compounding areas (C-SCAs) require at least 12 ACPH. See **Table 14-1** for minimum facility requirements.

14.1-2 What is an ACPH?

ACPH is air changes per hour. Thirty (30) ACPH means that the air in the room is turned over every 2 minutes; 12 ACPH means that the air in the room is turned over every 5 minutes. The air changes are a key element in control of a negative pressure area because it removes hazardous particles and vapors.

14.1-3 What are the significant differences between USP <797> and USP <800> regarding requirements for negative pressure rooms and hoods?

Once USP <797> is revised, there will be no differences because <797> will refer to <800> for issues of HDs. *Until <797> is revised, some differences are noted below:*

- *Negative pressure requirements*—<797> states that the negative rooms must be at least 0.01" wc negative. <800> defines a range between 0.01 to 0.03" wc.
- *Placement of primary engineering controls (PECs)*—<797> allows placement of a compounding aseptic containment isolator (CACI) outside of a negative room. <800> requires all containment PECs (biological safety cabinets [BSCs] or CACIs) to be in a negative pressure room.

14.1-4 Is there a way to look at the current (allowed by <797>) options versus the upcoming (allowed by <800>) options for placement of chemo hoods in different types of allowable rooms?

See **Table 14-2** for examples of requirements. Note that this is only an *example*; your room does not need to look exactly like it.

TABLE 14-1 Minimum Facility Requirements

See USP <795>, <797>, and <800> for details

	Storage	Sterile Compounding		Nonsterile Compounding
	May be either separate room or HDs may be stored in negative pressure buffer room, C-SCA, or nonsterile compounding room	Cleanroom Suite	C-SCA	Compounding Room
PEC	N/A	BSC or CACI		CVE
Room	Room that is separate from non-hazardous activities, with fixed walls, negative pressure between 0.01-0.03" wc to adjacent area, and externally vented			
Configuration	Single room	Positive pressure anteroom and negative pressure buffer room	Single room	Single room
HEPA-filtered ceiling air	Not required	Required	Not required	Not required
ISO classification	Not required	ISO 7	Not required	Not required
Air changes per hour	12 ACPH	30 ACPH	12 ACPH	12 ACPH

ACPH: air changes per hour; BSC: biological safety cabinet; CACI: compounding aseptic containment isolator; C-SCA: containment segregated compounding area; CVE: containment ventilated enclosure; HDs: hazardous drugs; HEPA: high-efficiency particulate air; ISO: International Standards Organization; PEC: primary engineering control; wc: water column

TABLE 14-2 What Is Currently Allowed by <797> and What Will Be Allowed by <800>

Type of PEC	Placement in Room	Allowed by <797>?	Allowed by <800>?
BSC	Cleanroom suite	Yes	Yes
BSC	C-SCA	C-SCA is not defined in <797>	Yes
BSC	Outside of cleanroom suite or C-SCA	No	No
CACI	Cleanroom suite	Yes	Yes
CACI	C-SCA	C-SCA is not defined in <797>	Yes
CACI	Negative pressure room with minimum of 12 ACPH	Yes	No (needs additional room requirements to meet the design of a C-SCA)

ACPH: air changes per hour; BSC: biological safety cabinet; CACI: compounding aseptic containment isolator; C-SCA: containment segregated compounding area; PEC: primary engineering control