DESIGN OF COMPOUNDING FACILITIES 11

11.1 FACILITY DESIGN

11.1-1 What are the minimum facility requirements for compounding nonhazardous nonsterile preparations (CNSPs)?

CNSPs must be compounded in an area that is specifically designated for nonsterile compounding. A perimeter should be defined to distinguish the space, and it should not be used for other purposes when compounding is occurring. The surfaces in the area need to be able to withstand the cleaning and sanitizing agents required following compounding. The floor should not be carpeted. Temperature must be controlled to meet manufacturers' requirements for drug storage and for the comfort of personnel. Your state regulations may have additional requirements.

Although not required in <795>, consider the finishes required for a segregated compounding area in <797>[3]:

- Smooth, impervious, non-shedding surfaces of ceilings, walls, floors, doors, shelving and other fixtures, counter, and other spaces
- Overhangs and ledges should be avoided, but if present, need to be kept clean
- Area needs to be kept clean and uncluttered
- Sink should be dedicated to compounding (if possible) and not within 1 meter of the containment ventilated enclosure (CVE) or biological safety cabinet (BSC)

11.1-2 What are the minimum facility requirements for compounding hazardous CNSPs?

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 <800>[4] and *The Chapter <800> Answer Book*[8] for more information.

DOI 10.37573/9781585286782.011

11.1-3 Does the nonsterile compounding area need to be a separate room?

No, as long as you are not compounding HDs. It can be a designated area that is defined by a visible perimeter. If you are compounding HDs, the compounding area needs to be a separate room. See <800>[4] and *The Chapter <800> Answer Book*[8] for details.

11.1-4 What does *designated area* mean?

An area for nonsterile compounding. Ideally, it is a separate room, but that is not required. It could be as simple as a dedicated countertop area, as long as that meets the requirements of your state board regulations. It should be away from high traffic areas and accessible only to authorized personnel.

11.1-5 Can non-compounding activities occur in the compounding area?

The requirement in <795> is for the area to be defined. Other activities should not be allowed in the area when compounding is occurring.

11.1-6 Can I use plastic curtains or drapes to define the compounding area?

<795> does not prohibit this, but it is not a good idea. Dividers made of these materials are very difficult to keep clean.

11.1-7 Does the nonsterile compounding area need to meet a particular ISO standard?

No. The ISO classifications are requirements of <797>[3] for sterile compounding rooms.

11.1-8 Does the nonsterile compounding area need to be positive pressure?

There is no requirement for pressure gradients for nonsterile compounding in <795>.

11.1-9 Does the nonsterile compounding area need to have a certain number of air changes per hour?

No. The ACPH requirements are part of <797>[3] and <800>.[4] There is no requirement in <795> for ACPH for nonhazardous nonsterile compounding.

11.1-10 We are in the process of building a pharmacy compounding room for nonsterile compounding only (no sterile compounding). Is it possible to compound both nonhazardous and hazardous mixtures in one compounding room?

No, unless you want to treat all your compounds as hazardous. That is not practical from either a personnel or work flow perspective or appropriate for patients. Why