

DECONTAMINATION AND CLEANING

21

(See Section 15 in <800>.)

APIs of any HD and antineoplastics (except those that require only counting or packaging) must comply with all containment listed in <800>, which allows the entity to perform an Assessment of Risk to evaluate exempting specific dosage forms of HDs from the containment strategies and/or work practices. Antineoplastics that require only counting or packaging, non-antineoplastic agents, and reproductive hazards may be considered for the entity's Assessment of Risk.

21.1 What is the difference between cleaning and decontamination?

There are several steps in this process:

- Deactivation and decontamination, which makes a compound inactive and removes it by transferring the residue to a disposable material (e.g., a low-lint wipe).
- Cleaning removes contaminants by use of a germicidal detergent.
- Disinfection inhibits or destroys microorganisms.

21.2 How is cleaning a chemo hood different from what's done for the regular hood?

Areas—hoods and rooms—used for handling hazardous drugs (HDs) need to be decontaminated prior to cleaning. Where surfaces used for handling non-HDs need to be cleaned and, if used for sterile compounding, disinfected, surfaces used for handling HDs have the additional preliminary step of deactivating the HD and decontaminating the surfaces. Cleaning and disinfection follows.

21.3 Do I need to wear PPE when cleaning?

Yes. In addition to the head, hair, shoe covers, gowns, and gloves, you need to wear eye protection when splashing is possible (e.g., cleaning ceilings, walls) and respiratory protection when necessary.

21.4 Is it OK for Environmental Services to clean the floors while we are compounding?

No. You cannot compound while cleaning is occurring.

21.5 What agents deactivate HDs?

Few drugs have specific deactivators. Traditionally, bleach has been used for this purpose. If the drug has a specific deactivator listed in the product labeling, use it after manipulating that drug.

21.6 What agents decontaminate HD areas?

Use a properly diluted (if required) Environmental Protection Agency (EPA)-approved oxidizing agent intended for use with HDs. Traditionally, bleach has been used in a 2% concentration, followed by sodium thiosulfate to neutralize the bleach. (Bleach left on stainless steel surfaces will corrode the surface, causing pitting and rust.) There are now commercially available agents for this purpose.

21.7 What agents clean HD areas?

Germicidal detergents are the cleaning agents for sterile compounding as defined in USP <797> and are appropriate for nonsterile areas, too. Once decontamination has been done, the cleaning and disinfection steps are the same as with non-hazardous compounding.

21.8 What agents disinfect HD areas?

Disinfecting agents for sterile compounding are defined in USP <797> and are appropriate for nonsterile areas, too. Alcohol (sterile alcohol for sterile compounding) is the predominant agent. Once decontamination has been done, the cleaning and disinfection steps are the same as with non-hazardous compounding.

21.9 Is alcohol sufficient to decontaminate and clean the HD areas?

No. Alcohol is neither a decontaminating agent nor a cleaner. Alcohol is a disinfectant and is useful only in the final step after deactivation, decontaminating, and cleaning has occurred.

21.10 Who should clean the BSC and CACI?

Only compounding personnel may decontaminate, clean, and disinfect the primary engineering controls (PECs).

21.11 Who should clean the SECs?

Either compounding personnel or Environmental Services personnel can decontaminate, clean, and disinfect the anteroom, buffer room, or containment segregated compounding area (C-SCA). Training and documented competence is required. In any case, all compounding personnel should be competent in this task in case Environmental Services is not available.

21.12 Are there specific cleaning guidelines under USP <800>?

USP <800> contains a section on Deactivation, Decontamination, Cleaning, and Disinfection. There is more detail in USP <797>. (See both the current 2008 version of USP <797>¹⁸ and the proposed revision of USP <797>.²²)