

USP <795> Cleaning Requirements

Site	Minimum Frequency	Cleaning Agent
Work Surfaces	At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected Between compounding CNSPs with different components	Specific cleaning agent not required, reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, isopropyl alcohol 70% may be used as a sanitizing agent
Floors	Daily on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected	Specific cleaning agent not required, reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, isopropyl alcohol 70% may be used as a sanitizing agent
Walls	When visibly soiled, after spills, and when surface contamination (e.g., from splashes) is known or suspected	Specific cleaning agent not required, reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, isopropyl alcohol 70% may be used as a sanitizing agent
Ceilings	When visibly soiled and when surface contamination (e.g., from splashes) is known or suspected	Specific cleaning agent not required, reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, isopropyl alcohol 70% may be used as a sanitizing agent
Storage Shelving	Every 3 months, after spills, and when surface contamination (e.g., from splashes) is known or suspected	Specific cleaning agent not required, reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, isopropyl alcohol 70% may be used as a sanitizing agent
CVE (Containment ventilated enclosures) and BSCs (biological safety cabinets)	At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected Clean and sanitize the horizontal work surface of the CVE between compounding CNSPs with different components Additionally, BSCs should also be cleaned and sanitized at least monthly	Specific cleaning agent not required, reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, isopropyl alcohol 70% may be used as a sanitizing agent
Other devices and equipment	Before first use and thereafter in accordance with the manufacturer's recommendations, if no recommendation is available, between compounding CNSPs with different components	Specific cleaning agent not required, reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, isopropyl alcohol 70% may be used as a sanitizing agent

USP 800 Deactivation/Decontamination/Cleaning Recommendations

Per current USP 800 guidelines, all areas where hazardous drugs (HDs) are handled and all reusable equipment and devices that come into contact with HDs must be deactivated, decontaminated, and cleaned. For sterile compounding with hazardous drugs, in addition to these steps, you must also disinfect sterile compounding areas, equipment, and devices. See below that expands upon table 5 from current USP 800 guidelines.

Cleaning Step	Purpose	Example Agents
Deactivation	This step is intended to render HDs inert or inactive	The guideline specifies agents as listed in HD labeling and references peroxide formulations or sodium hypochlorite. Consider using a product that notes it has been studied and found effective for deactivation. Examples commonly recommend include: PeridoxRTU (Contec) ¹ Sodium Hypochlorite (Clorox) ² Hydrogen Peroxide (Clorox) ²
Decontamination	This step is intended to remove HD residue	The guideline specifies that this must be a material that has been validated to be effective for HD decontamination or proved effective through testing. Examples include: PeridoxRTU (Contec) ¹ Isopropyl Alcohol 70% Peroxide Sodium hypochlorite
Cleaning	This step is intended to remove organic and inorganic material	The guideline just specifies that this be a germicidal detergent. Examples include: Soap and water PeridoxRTU ¹
Disinfection (required for sterile hazardous compounding)	This step is intended to destroy microorganisms	The guideline specifies EPA registered disinfectant and/or sterile alcohol. Examples include: Sterile Isopropyl Alcohol 70%

Various concentrations are available for use for sodium hypochlorite and hydrogen peroxide. Sodium hypochlorite has been studied at a range of 0.5-2%. One study of sodium hypochlorite at 2% found it effective at removing cyclophosphamide from BSC contaminated workbenches.³ Another study evaluating the efficacy of several agents as decontamination solutions found sodium hypochlorite 0.5% to be effective for 23 tested antineoplastic drugs, as well as hydrogen peroxide 5%. The study concluded that sodium hypochlorite is the best decontaminant after standard application.⁴

1. Contec offers information stating that PeridoxRTU (hydrogen peroxide 4.4% among other ingredients) as an EPA registered product that is a cleaner and disinfectant. It meets the definition of a germicidal detergent
2. Clorox offers information stating that some of their products, for example, Clorox Healthcare Bleach Germicidal Wipes (sodium hypochlorite 0.55% among other ingredients) and Clorox HealthCare Hydrogen Peroxide Cleaner Disinfectant Wipes are EPA-registered as disinfectants and oxidizers and also meet criteria for germicidal detergents
3. Adé A, Chauchat L, Frève JO, Gagné S, Caron N, Bussièrès JF. Comparison of Decontamination Efficacy of Cleaning Solutions on a Biological Safety Cabinet Workbench Contaminated by Cyclophosphamide. *Can J Hosp Pharm*. 2017;70(6):407-414. doi:10.4212/cjhp.v70i6.1708
4. Simon N, Guichard N, Odou P, Decaudin B, Bonnabry P, Fleury-Souverain S. Efficiency of four solutions in removing 23 conventional antineoplastic drugs from contaminated surfaces. *PLoS One*. 2020;15(6):e0235131. Published 2020 Jun 22. doi:10.1371/journal.pone.0235131

USP 797 Cleaning Requirements

Site	Minimum Frequency	Cleaning Agent
Primary Engineering Control (i.e. hood) and equipment contained	Cleaned and disinfected on days when compounding occurs and when surface contamination is known or suspected. Entities making Category 1 and 2 CSPs must apply a sporicidal monthly, entities making Category 3 CSPs must apply a sporicidal weekly	Reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, sterile isopropyl alcohol may be used as a disinfection agent, sporicidal may include products such as sterile PeridoxRTU or sterile sodium hypochlorite solution
Removable Work Tray of PEC, if applicable	The work surface is cleaned and disinfected daily on days when compounding occurs, all surfaces and areas underneath the work tray are cleaned monthly	Reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, sterile isopropyl alcohol may be used as a disinfection agent, sporicidal may include products such as sterile PeridoxRTU or sterile sodium hypochlorite solution
Pass-through Chambers	Cleaned and disinfected daily on days when compounding occurs. Entities making Category 1 and 2 CSPs must apply a sporicidal monthly, entities making Category 3 CSPs must apply a sporicidal weekly	Reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, sterile isopropyl alcohol may be used as a disinfection agent, sporicidal may include products such as sterile PeridoxRTU or sterile sodium hypochlorite solution
Work Surfaces Outside the Primary Engineering Control (i.e. hood)	Cleaned and disinfected daily on days when compounding occurs. Entities making Category 1 and 2 CSPs must apply a sporicidal monthly, entities making Category 3 CSPs must apply a sporicidal weekly	Reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, sterile isopropyl alcohol may be used as a disinfection agent, sporicidal may include products such as sterile PeridoxRTU or sterile sodium hypochlorite solution
Floors	Cleaned and disinfected daily on days when compounding occurs. Entities making Category 1 and 2 CSPs must apply a sporicidal monthly, entities making Category 3 CSPs must apply a sporicidal weekly	Reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, sterile isopropyl alcohol may be used as a disinfection agent, sporicidal may include products such as sterile PeridoxRTU or sterile sodium hypochlorite solution
Walls, Doors, Door Frames, Ceilings, Storage Shelving and Bins, and Equipment Outside PEC	Cleaned, disinfected, and a sporicidal applied on a monthly basis	Reference SOP for specifics, typically a cleaning agent would be a surfactant containing solution like a soap, sterile isopropyl alcohol may be used as a disinfection agent, sporicidal may include products such as sterile PeridoxRTU or sterile sodium hypochlorite solution

A note on sterile vs non-sterile cleaning solutions, USP <797> notes that cleaning, disinfecting, and sporicidal agents used inside the Primary Engineering Control (PEC) MUST be sterile whereas cleaning and disinfecting agents used in classified areas outside of the PEC SHOULD be sterile.

Sporicidal: You may use an existing sporicidal commercially available product such as PeridoxRTU or you may use sodium hypochlorite or hydrogen peroxide. Existing data suggests sodium hypochlorite is effective between 0.6-3.65% as a sporicidal agent after a 5-minute application. Hydrogen peroxide products at 4.5% have also demonstrated efficacy but tend to require longer contact times such as 10 minutes.¹ PeridoxRTU states a 3 minute application time is necessary for sporicidal activity.

Disinfectant: Sterile Isopropyl Alcohol 70% may be considered as a disinfectant, but does not qualify as a sporicidal.

Cleaning Agent: Typically, a detergent or surfactant, some agents fulfill more than one purpose, sterile PeridoxRTU may also serve as a cleaning agent

1. Uwamahoro MC, Massicotte R, Hurtubise Y, Gagné-Bourque F, Mafu AA, Yahia L. Evaluating the Sporocidal Activity of Disinfectants against *Clostridium difficile* and *Bacillus amyloliquefaciens* Spores by Using the Improved Methods Based on ASTM E2197-11. *Front Public Health*. 2018;6:18. Published 2018 Feb 5. doi:10.3389/fpubh.2018.00018