# Clean Up Your Act: Maintaining a clean environment for sterile compounding

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No actual or potential conflicts of interest



## Goals and Objectives

- Outline required USP 797 cleaning practices and their significance in assuring a safe compounding environment.
- Discuss the importance of having written policies and procedures for the cleaning of facilities where compounded sterile products are made.
- Discuss the development of a USP 797 cleaning program.



## USP 797

"The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility)…"

"Environmental contact is a major source of microbial contamination of CSPs. Consequently, scrupulous attention to cleaning and disinfecting the sterile compounding areas is required to minimize this as a source of CSP contamination."



## Definitions

- Clean Room - A room in which the concentration of airborne particles is controlled to meet a specified class
- Direct Compounding Area (DCA) – Area within PEC where IV admixture occurs
- Buffer Area – Area where PEC is physically located
- Ante Area – Area where higher particle generating activities occur
- PEC – Primary engineering control (i.e., laminar flow hood, biological safety cabinet)



## Definitions (continued)

- Sterilizing – Destruction/removal of *all* forms of microbial life
- Cleaning – Removal of loose material and residue
- Disinfecting – A process that eliminates many or all pathogenic microorganisms
- Sanitizing agent – Product that removes bacterial microorganisms
- Sporicidal agent – Product that is active against spores



## Who Cleans?

- Properly trained personnel
- Pharmacy staff
- Environmental services
- Policies and procedures – specified personnel should be identified in policies and procedures as responsible for certain areas

## Disinfecting Agents

Appendix I

Appendix B. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties[1]

| | | Chemical Category of Disinfectant | | | | | |
|---|---|---|---|---|---|---|---|
| | | Isopropyl alcohol | Accelerated hydrogen peroxide | Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride) | Phenolics | Chlorine (e.g., sodium hypochlorite) | Iodophors (e.g., povidone-iodine) |
| Concentration Used | | 60–95% | 0.5%[2] | 0.4–1.6% aq | 0.4–1.6% aq | 100–6000 ppm | 30–50 ppm |
| Microbial Inactivation[3] | Bacteria | + | + | + | + | + | + |
| | Lipophilic viruses | + | + | + | + | + | + |
| | Hydrophilic viruses | ± | + | ± | ± | + | ± |
| | M.tuberculosis | + | + | ± | + | + | ? |
| | Mycotic agents (fungi) | + | + | + | + | + | ± |
| | Bacterial Spores | – | + | – | – | + | – |
| Important Chemical & Physical Properties | Shelf life >1 week | + | + | + | + | – | + |
| | Corrosive or deleterious effects | ± | – | – | – | ± | ± |
| | Non-evaporable residue | – | – | + | + | – | + |
| | Inactivated by organic matter | + | ± | + | ± | + | + |
| | Skin irritant | ± | – | + | + | + | ± |
| | Eye irritant | + | – | + | + | + | + |
| | Respiratory irritant | – | – | – | – | + | – |
| | Systemic toxicity | + | – | + | + | + | + |

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; – = no; ± = variable results.



## Disinfecting Agent Considerations

- Documentation of correct dilution is crucial
- Determination of necessary contact time
- Storage considerations
- Follow manufacturer instructions



## Avoiding Microbial Resistance

- From USP Chapter <1072> Disinfectants and Antiseptics – "The development of microbial resistance to disinfectants is less likely, as disinfectants are more powerful biocidal agents than antibiotics and are applied in high concentrations against low populations of microorganisms usually not growing actively…"
- Cleaning program should still include weekly/monthly use of a sporicidal agent



## Cleaning Equipment

- Mops and (if needed) buckets
- Non-shedding and non-linting wipes
  - Pre-wetted and dry options
  - Nylon fabrics
  - Polyester knit fabrics
- Specialized Equipment
  - Isolator Cleaning tools, Clean Room Vacuum/Steamer



## Cleaning Equipment – Mops

- Consider the benefits of a bucket-less system
- Identify potential points of microbial contamination
- Identify medical grade mops that can withstand use with strong disinfectants
- Identify appropriate storage areas
- Consider the need for dedicated equipment in buffer area and ante area



## Cleaning Technique

- Clean from cleanest to dirtiest; from top to bottom
- Wipe in a unidirectional motion and avoid circular action
- Regardless of the type of cleaning be sure to overlap wiping motion
- Rewet and replace wipes/mop frequently

## Cleaning Technique

- If using a mop bucket consider using a clean bucket and "dirty" bucket
- Consider the need for disinfectant dwell time and the type of surface you are cleaning
- Consider the activities being performed



## Frequency of Cleaning

| Daily or More | Daily | Monthly |
|---|---|---|
| **DCA**<br>• Beginning of day/shift<br>• Prior to each batch<br>• Every 30 min<br>• When visibly soiled<br>• As spills occur<br>• Suspected contamination | • Easily cleanable horizontal surfaces in ante and buffer rooms (including passthrough surface)<br>• Floors from furthest location in buffer area out into the anteroom | • Ceiling<br>• Walls<br>• Surfaces outside of PECs<br>• All carts (top, bottom, wheels, etc.)<br>• Supply bins<br>• Doors, handles, vents<br>• Floors (same as daily)<br>• Refrigerators, freezers, incubators, etc. |



## Establishing a Cleaning Program

- Work with infection control department if possible
- If building a new facility consider cleaning in the design process
- Develop standard operating procedures (SOP)
- Document cleaning activities performed
- Train personnel and document the type of training received



## Standard Operating Procedures

- Be extremely clear when outlining who, when, and where
- Identify the specific equipment that is to be used
- If you are rotating cleaning agents specify when/how they are to be changed
- Work with other departments involved to ensure policies and procedures overlap



## Approaches to Documentation

- Electronic methods
- Paper methods
  - See USP 797 Appendix
  - Audits
- "Oral history" is not acceptable



## Know Your Equipment

- Identify a certifier who will work **with** you
- If you don't understand your equipment you can't clean it properly
- Ask them to help you identify problem areas
- Ask them for recommendations of products and/or cleaning services

## Monitoring your cleaning program

- Even the most diligent cleaning practices require objective monitoring
- Environmental sampling promotes early detection of the source of contamination
- Decreases the potential for contamination to reach patients
- Required for USP 797 compliance



## Environmental Sampling

- Required every six months for USP 797 compliance
- Best practice is monthly environmental sampling
- Should include surface contamination as well as airborne contamination
- Should be performed with new equipment and after equipment maintenance
- Requires specialized equipment



## Viable Air Testing

- Growth media – Must support microbial and fungal growth
- Volumetric air sampling is required; settling plates are not sufficient
- Develop a sampling plan that includes:
  - Equipment
  - Frequency
  - Volume of air sampled
  - Specify locations for testing



## Surface Sampling

- Should be performed under the worst possible conditions
- Should be done in multiple areas (i.e., DCA, ante area, buffer room)
- Sampling areas should be included in sampling plan



## Surface Sampling

- Action levels should be defined in sampling plan
- Procedures to be carried out when action levels are exceeded should also be included in policies and procedures
- Procedures should vary based on the source of contamination
- Consider recent modifications to engineering controls



## Patient Safety

- All of these steps are carried out to ensure patient safety
- Thanks to recent contaminated CSPs, compounding pharmacies are in the spotlight
- Would you want a CSP for your own family member prepared in a "dirty" environment?

# References


- Images used with permission Copyright Criticalpoint 2008-2014 – All Rights Reserved
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# Questions?

Illinois Council of Health-System Pharmacists 2014 Annual Meeting

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## Self-Assessment Questions

1. Cleaning is defined as:
   a. The destruction or removal of microbial contamination
   b. The removal of loose material and residue
   c. The removal of spores
   d. The removal of all forms of microbial life

2. Who is responsible for cleaning a pharmacy clean room?
   a. Pharmacy staff
   b. Environmental services
   c. Outside vendor
   d. Trained personnel as outlined in policies and procedures

3. Which of the following is a sporicidal sanitizing agent?
   a. Sterile 70% Isopropyl Alcohol
   b. 2% Sodium Hypochlorite
   c. 3% Hydrogen Peroxide
   d. Povidone-iodine

4. Your cleaning program policies and procedures should be as _____ as possible.
   a. Specific
   b. Vague
   c. Flexible
   d. Simple

5. The ultimate goal of maintaining a clean facility is to safeguard:
   a. Institutional liability
   b. Against fines
   c. Patient care
   d. Board of pharmacy oversight

Answer Key: 1. B, 2. D, 3. B, 4. A, 5. C

**Appendix II. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties[1]**

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| **Concentration Used** | | **60–95%** | **0.5%[3]** | **0.4–1.6% aq** | **0.4–1.6% aq** | **100–5000 ppm** | **30–50 ppm** |
| Microbial Inactivation[2] | Bacteria | + | + | + | + | + | + |
| | Lipophilic viruses | + | + | + | + | + | + |
| | Hydrophilic viruses | ± | + | ± | ± | + | ± |
| | M.tuberculosis | + | + | ± | + | + | ± |
| | Mycotic agents (fungi) | + | + | + | + | + | ± |
| | Bacterial Spores | – | – | – | – | + | – |
| Important Chemical & Physical Properties | Shelf life >1 week | + | + | + | + | + | + |
| | Corrosive or deleterious effects | ± | – | – | – | ± | ± |
| | Non-evaporable residue | – | – | + | + | – | + |
| | Inactivated by organic matter | + | ± | + | ± | + | + |
| | Skin irritant | ± | – | + | + | + | ± |
| | Eye irritant | + | – | + | + | + | + |
| | Respiratory irritant | – | – | – | – | + | – |
| | Systemic toxicity | + | – | + | + | + | + |

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; – = no; ± = variable results.

[1] Modified from World Health Organization, Laboratory Bio Safety Manual 1983 and Rutala WA, "Antisepsis, disinfection and sterilization in the hospital and related institutions," *Manual of Clinical Microbiology,* American Society for Microbiology, Washington, DC, 1995, pages 227-245.

[2] Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of ≤1 minute; inactivation of spores requires longer contact times (e.g., 5-10 minutes for 5,000 ppm chlorine solution against *C. difficile spores). Reference: Perez J, Springthorpe VS, Sattar SA, "Activity of selected oxidizing microbicides against the spores of Clostridium difficile: Relevance to environmental control," American Journal of Infection Control, August 2005, pages 320-325.*

[3] *Accelerated* hydrogen peroxide is a new generation of hydrogen peroxide-based germicides in which the potency and performance of the active ingredient have been enhanced and accelerated through the use of appropriate acids and detergents.