Cleaning and Disinfecting Practices and Frequencies

Recommended "Detergent" Cleaning Materials & Equipment:

- 1:10 bleach and water solution
- Microfiber terry wipes
- Particulate pickup with HEPA vacuum

Recommended Disinfectant/Sterilization Materials & Equipment:

- Isopropyl alcohol with USP Isopropyl Alcohol formulated with Water for Injection.
- Sterile Wipe
- Tacky film mop

Replacement Cleaning Products:

Company Information
BENCHMARK PRODUCTS
1665 WAUKEGAN ROAD
WAUKEGAN, IL. 60085
(847) 689-9600

Item No	***Item Description***
Y-PR18,	*MOP,TACKYFILM,18",40SH/RL*
Y-EP-1,	*HANDLE, EXTENSION 4-8'*
Y-PH-18,	*HANDLE,18" ROLLER*
C-DECTR-08,	*IPA,70%TRIGRSPRAY,ST,160Z,12/C CASE*
W-1212NS,	*WIPER, POLY/CELL12X12,150/B10/C CASE*

Per USP 797: ***Cleaning and Disinfecting the Sterile Compounding Areas***

The cleaning and disinfecting practices and frequencies in this section apply to direct and contiguous compounding areas (DCCAs), which include ISO Class 5, compounding areas for exposure of critical sites as well as buffer rooms, anterooms, and ante-areas. ***Trained compounding personnel are responsible for developing and practicing written procedures for cleaning and disinfecting the DCCAs***. ***These procedures shall be conducted at the beginning of each work shift and when there are spills or environmental quality breaches***. Before compounding is performed, all items are removed from the DCCA and all surfaces are cleaned of loose material and residue from spills, followed by an application of a residue-free disinfecting -agent (e.g., IPA), that is left on for a time sufficient to exert its antimicrobial effect. Work surfaces in the ISO Class 7 buffer areas and ISO Class anterooms or ante-areas are cleaned and disinfected at least daily, and dust and debris are removed when necessary from storage sites for compounding ingredients and supplies, using a method that does not degrade the ISO Class 7 or 8 air quality.

Minimum Frequency of Cleaning and Disinfecting Sterile Compounding Areas Site	Minimum Frequency
ISO Class 5 (see *Table 1*) Primary Engineering Control (e.g., LAFW, BSC, CAI)	At the beginning of each shift
Counters and easily cleanable work surfaces	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage shelving	Monthly

Floors in the buffer or clean area are cleaned by mopping once daily when no aseptic operations are in progress. Mopping may be performed by trained and supervised custodial personnel using approved agents described in the written procedures. Only approved cleaning and disinfecting agents are used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues. Their schedules of use and methods of application are in accord with written procedures. All cleaning tools, such as wipers, sponges, and mops, are nonshedding and dedicated to use in the buffer or clean area. Floor mops may be used in both the buffer or clean area and anteroom area, but only in that order. Most wipers are discarded after one use. If cleaning tools are reused, their cleanliness is maintained by thorough rinsing and disinfecting after use and by storing in a clean environment between uses. Trash is collected in suitable plastic bags and removed with minimal agitation.

In the anteroom area, walls, ceilings, and shelving shall be cleaned monthly. Supplies and equipment removed from shipping cartons are wiped with a disinfecting agent, such as IPA. The IPA shall be delivered from a wash or spray bottle, the discharge opening of which must not contact any objects or materials before contacting the surfaces to be disinfected. Wiping with small IPA swabs that are commercially available in individual foil-sealed packages is preferred for disinfecting stoppers on bags and vials before they are pierced with sterile needles and for necks of ampuls before they are broken. The surface of IPA swabs for disinfecting stoppers must not contact any other object before contacting the stoppers. After IPA is sprayed or wiped on a surface to be disinfected, allow the IPA to remain for at least 30 seconds before the surface is contacted to prepare CSPs. Alternatively, if supplies are received in sealed pouches, the pouches can be removed as the supplies are introduced into the buffer or clean area without the need to disinfect the individual supply items. No shipping or other external cartons may be taken into the buffer or clean area.

Cleaning and disinfecting of counters and other easily cleanable surfaces of the anteroom area is performed at least daily by trained and supervised custodial personnel, in accordance with written procedures. However, floors are cleaned and disinfected daily, always proceeding from the buffer or clean area to the anteroom area. Storage shelving, emptied of all supplies, walls, and ceilings are cleaned and disinfected at planned intervals, monthly if not more frequently.

USP 797: Personnel Cleansing and Garbing

The careful cleansing of hands and arms, and correct donning of personal protective equipment (PPE) by compounding personnel, constitute the first major step in preventing microbial contamination in CSPs. Personnel must also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs. Squamous cells are normally shed from the human body at a rate of 10^6 or more per hour, and those skin particles are laden with microorganisms.**10**,[11] When persons are afflicted with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear sheddable cosmetics, they shed these particles at even higher rates. Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. Therefore, compounding personnel with such afflictions as mentioned above shall be excluded from working in ISO Class 5 and ISO Class 7 (see *Table 1*) compounding areas until their condition is remedied. Personnel wearing cosmetics that may shed and could contact critical sites shall not be permitted to prepare CSPs until the cosmetics are sufficiently removed from the skin.

Before entering the clean area, compounding personnel must remove the following: personal outer garments (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics, because they shed flakes and particles; and all hand, wrist, and other body jewelry that can interfere with the effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves, or visible body piercing above the neck). The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails must also be kept neat and trimmed. Personnel must don the following PPE and perform hand hygiene in an order that proceeds from the dirtiest to cleanest activities. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents.

After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Wash hands and arms to the elbows for at least 30 seconds with either a plain (nonantimicrobial) soap, or antimicrobial soap, and water while in the anteroom/ante-area. The use of antimicrobial scrub brushes is not recommended as they can cause skin irritation and skin damage. Hands and forearms will be completely dried using either a lint-free disposable towels or an electronic hand dryer. After completion of hand washing, don nonshedding disposable gowns with sleeves that fit snugly around the wrists.

Once inside the clean area, prior to donning sterile, powder-free gloves, antiseptic hand cleansing must be performed using an alcohol-based surgical hand scrub with persistent activity12 (e.g., alcohol-based preparations containing either 0.5% or 1.0% chlorhexidine gluconate) following manufacturers' recommendations. Allow hands to dry thoroughly before donning sterile gloves.

Sterile gloves shall be the last item donned before compounding begins. Gloves become contaminated when they contact nonsterile surfaces during compounding activities. Disinfection of contaminated gloves may be accomplished by applying 70% IPA to all contact surface areas of the gloves and letting the gloves dry thoroughly. Only use gloves that have been tested for compatibility with alcohol disinfection by the manufacturer. Routine application of 70% IPA should occur throughout the compounding day and whenever nonsterile surfaces (e.g. vials, counter tops, chairs, and carts) are touched. Gloved hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if detected, along with performing antiseptic hand cleansing as indicated above. Compounding personnel must be trained and evaluated in the avoidance of touching critical sites with contaminated gloves.

When compounding personnel must temporarily exit the ISO Class 7 (see *Table 1*) environment during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ISO Class 8 (see *Table 1*) anteroom/ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and gloves must be replaced with new ones before re-entering the ISO Class 7 (see *Table 1*) clean environment along with performing proper hand hygiene.

During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 (see *Table 1*) environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 8 (see *Table 1*) must re-garb PPE along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-based surgical scrub, and donning sterile gloves upon re-entering the ISO Class 7 (see *Table 1*) clean area. When CAIs[2] are the source of the ISO Class 5 (see *Table 1*) environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.

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10 Agalloco J, Akers JE. Aseptic Processing: A Vision of the Future. *Pharmaceutical Technology,* 2005. Aseptic Processing supplement, s16.

11 Eaton T. Microbial Risk Assessment for Aseptically Prepared Products. *Am Pharm Rev.* 2005; 8 (5, Sep/Oct): 46–51.

12 *Guideline for Hand Hygiene in Health care Settings,* MMWR, October 25, 2002, vol. 51, No. RR-16 available on the Internet at http://www.cdc.gov/handhygiene/.

FAQ

What should I use to clean and disinfect my biological safety cabinet?

Consult your lab director or local safety officer on the appropriate disinfectant. Many people use liquid Lysol, isopropyl alcohol or a 10% bleach solution. However, when using any disinfectant, after using, then rinse thoroughly with water as soon as possible. Although chlorine bleach is a known corrosive on stainless steel, the thorough wash down will help to remove residue.

Baker https://www.bakerco.com/faqs?page=2

NuAire - http://www.nuaire.com/sales-support/technical-papers/10-steps-to-cleaning-a-bsc-spill.php

Ten Easy Steps for Cleaning a Spill in the Biosafety Cabinet

There are several different models of BSCs, which are differentiated by the user's experimental focus and the degree of bio-containment required. The primary purpose of a BSC is to protect the laboratory worker and the surrounding environment from pathogens such as bacteria and viruses being used within the cabinet. All exhaust air is filtered through HEPA-filters as it exits the biosafety cabinet, removing the harmful pathogens. Most classes of BSCs have a secondary purpose that is to maintain the sterility of materials inside the cabinet.

It happens at some point to even the most seasoned laboratory user that a spill occurs within the BSC. Taking precautionary measures before and during your work with hazardous materials could help keep you and others safe. Remember, if a spill occurs, don't panic. Here are some simple steps to keep you and your laboratory safe. Please check with your EHS office or Biosafety Officer to ensure you have proper steps in place in case of a spill based of standard Biosafety in Microbiological and Biomedical Laboratories (BMBL).

Sources of Contamination
This is a partial list of some of the commonly known contaminants that can cause problems in some cleanroom environments. It has been found that many of these contaminants are generated from five basic sources. The facilities, people, tools, fluids and the product being manufactured can all contribute to contamination. Review this list to gain a better understanding of where contamination originates.

1. Facilities
    - Walls, floors and ceilings
    - Paint and coatings
    - Construction material (sheet rock, saw dust etc.)
    - Air conditioning debris
    - Room air and vapors
    - Spills and leaks
2. People
    - Skin flakes and oil
    - Cosmetics and perfume
    - Spittle
    - Clothing debris (lint, fibers etc.)
    - Hair
3. Tool Generated
    - Friction and wear particles
    - Lubricants and emissions
    - Vibrations
    - Brooms, mops and dusters
4. Fluids
    - Particulates floating in air
    - Bacteria, organics and moisture
    - Floor finishes or coatings
    - Cleaning chemicals
    - Plasticizers (outgasses)
    - Deionized water