

Sample Pharmacy
CLEANING AND DISINFECTING OF THE COMPOUNDING AREA
P-304.2

1.0 Definition and Purpose:

To describe, standardize and define the process by which the controlled environments (ISO Class 5, 7, and 8) and the general pharmacy preparation area are cleaned, disinfected, and maintained in a manner that ensures an environment suitable for compounding sterile preparations. Environmental contact is a major source of microbial contamination of CSPs, therefore scrupulous attention to cleaning and disinfecting of the areas used for sterile compounding is required to reduce and minimize this potential source of CSP contamination.

2.0 Applicable Documents:

- 2.1 Care and Use of Isolators (P-308)
- 2.2 Hand Hygiene and Garbing (P-404)
- 2.3 Orientation, Training and Competency Evaluation of Compounding Personnel (P-410)
- 2.4 *Competency Assessment: Hand Hygiene and Garbing (F-410.a)*
- 2.5 *Competency Assessment: Cleaning and Disinfecting (F-410.b)*
- 2.6 *Cleaning Solution Preparation Log (F-304.a)*
- 2.7 *Cleaning Log for Controlled Compounding Environments (F-304.b)*
- 2.8 *Cleaning Log for General Pharmacy Preparation Area (F-304.c)*
- 2.9 *Three Time Cleaning of Controlled Environments (F-304.d)*

3.0 Policy:

- 3.1 Since surfaces in ISO Class 5 work areas, including Laminar Air Flow Workbenches/Hoods (LAFWs), Compounding Aseptic Isolators (CAIs), Biological Safety Cabinets (BSCs), and Compounding Aseptic Containment Isolators (CACIs) are most intimate to the exposure of critical sites, they require disinfecting most frequently. These areas must be cleaned on a regular basis Includes but is not limited to:
 - 3.1.1 The beginning of each compounding shift;
 - 3.1.2 Immediately prior to each batch;
 - 3.1.3 Every 30 minutes throughout the compounding shift when ongoing compounding activities are occurring;
 - 3.1.4 After spills and
 - 3.1.5 When microbial contamination is known to have been or is suspected of having been introduced.
- 3.2 This policy is limited to cleaning and disinfection of ISO Class 7 buffer rooms, ISO Class 7/8 ante-areas, segregated compounding areas (SCAs) as well as the following PECs: LAFWs and BSCs, Refer to the Care and Use of Isolators (P-308) for specific cleaning information relative to Compounding Aseptic Isolators (CAIs) and Compounding Aseptic Containment Isolators (CACIs).
- 3.3 The Pharmacy leadership will designate an appropriate cleaning agent/s based upon careful consideration of compatibilities, effectiveness and inappropriate or toxic residues.
- 3.4 Sterile water (sterile water for injection or irrigation) must be used to dilute disinfectant solutions if they will be used inside of the ISO Class 5 areas. Though these areas are not sterile and the buckets/wipes used are not sterile, use of sterile water to dilute disinfectants reduces pyrogens and potential bioburden.
- 3.5 Though the general pharmacy preparation area is not an ISO "classed" environment it is must be kept clean and orderly and is included in the cleaning schedule in this policy.

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- 3.6 Ideally, cleaning of the general compounding area (buffer area/cleanroom and anteroom/area) should occur at the end of compounding day to prevent any component residue from sitting overnight and promoting bacterial growth.
- 3.7 If cleaning occurs at the start of the compounding day, adequate time must be given to allow all cleaned surfaces to dry PRIOR to starting any compounding activity.
- 3.8 If any compounding occurs during after-hours conditions (on-call situation), additional cleaning may occur at the start of the next business day.
- 3.9 Cleaning and disinfection of the controlled environments will not be performed while compounding is taking place.
- 3.10 Pharmacy compounding personnel must ensure that cleaning is being performed properly and by personnel who have been adequately trained on this policy as well as on Hand Hygiene and Garbing (P-404).
- 3.11 Cleaning of the buffer area/cleanroom, segregated compounding area, and anteroom/ante-area may be performed by trained custodial/housekeeping personnel.
- 3.12 Custodial/housekeeping personnel may not clean ISO Class 5 PECs.
- 3.13 All personnel who perform cleaning and disinfecting functions must successfully complete both of the following and in this order:
 - 3.13.1 *Competency Assessment: Hand Hygiene and Garbing (F-410.a)*
 - 3.13.2 *Competency Assessment: Cleaning and Disinfecting (F-410.b)*
- 3.14 Cleaning equipment and supplies
 - 3.14.1 Shall be stored in a designated area to ensure segregation from compounding supplies.
 - 3.14.2 Materials used (wipers, sponges, mops, etc.) must be non-shedding and preferable composed of synthetic micro fibers.
 - 3.14.3 Materials used must be dedicated to use in particular areas (buffer area/cleanroom, ante-area/room, segregated compounding area, etc.) and will not be moved from these areas except for disposal.
 - 3.14.4 Floor mops may be used in both the buffer area/cleanroom and the ante-area/room as long as they are used in that order.
 - 3.14.5 Ideally all cleaning tools are to be discarded after one use.
 - 3.14.6 For any reusable cleaning equipment:
 - 3.14.6.1 Hang mops vertically to promote drying when not in use
 - 3.14.6.2 Buckets must be inverted and allowed to dry.
 - 3.14.6.3 Manufacturer's instructions on the product used must be used to ensure that the effectiveness of the device is maintained and that repeated use does not add to the bioburden of the areas cleaned.
- 3.15 Since disinfectant solutions are irritants and can damage the skin and eyes, safety glasses must be worn during cleaning of ceiling and walls when there is an increased likelihood of splashing or dripping of solution.
- 3.16 Material Safety Data Sheets must be readily available for reference in the pharmacy for all disinfectants used in the cleaning and disinfecting process.
- 3.17 Tacky Mats:
 - 3.17.1 May be placed at the entrance to controlled areas within the pharmacy compounding area to remove debris from personnel and equipment as they enter these areas.

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- 3.17.2 The Pharmacy Manager or designee will determine the location of the tacky mats depending on workflow and room configuration.
- 3.17.3 Tacky mats must be changed frequently as they become soiled. Frequency of the mat change is determined by organizational policy but no less frequently than daily and change may be required more frequently depending on need.
- 3.18 Any compounding equipment (i.e. automated compounders, devices, or pumps) placed into ISO Class 5 PECs are subject to the same cleaning requirements as the LAFW, BSC, CACI or CAI itself.
- 3.19 If any equipment or device used to compound sterile preparations is removed from the ISO Class 5 buffer area/cleanroom, it must be properly cleaned and disinfected prior to being placed back into service within that environment.

Note: There is no scientific basis at the time of this policy writing to suggest that alternation of cleaning agents is necessary. The possibility of producing germicidal resistant microorganisms does not apply to cleaning of controlled pharmacy environments.

4.0 Materials and Equipment:

- 4.1 Plastic/stainless steel buckets with rounded edges into which mops fit or appropriate size sprayer bottle/s (if bucketless system is used)
- 4.2 Plastic/stainless steel mop handles suitable for mop heads used
- 4.3 Low particulate shedding cellulose mops (reusable) or disposable micro-fiber mop heads
- 4.4 Low particle shed wipes
- 4.5 Appropriate disinfectant agent
- 4.6 Sterile 70% IPA

5.0 Procedures

- 5.1 Prior to beginning cleaning
 - 5.1.1 Staff will gather supplies needed.
 - 5.1.2 Adequate amounts of the designated disinfectant are prepared by carefully mixing the cleaning solutions.
 - 5.1.3 Most disinfecting agents must be diluted. Follow manufacturer's recommendations regarding appropriate dilutions.
 - 5.1.4 Fill the bucket or sprayer with the appropriate amount of water then add the correct amount of disinfectant to the water to reduce the likelihood of splashing.
 - 5.1.5 Document the preparation of the cleaning solution on the *Cleaning Solution Preparation Log (F304.a)* immediately after preparing the solution.
- 5.2 If using traditional buckets to perform cleaning, allow the mops to soak in their respective buckets in solution for approximately five (5) minutes prior to the start of cleaning.
- 5.3 Cleaning must occur from the cleanest to the dirtiest areas. The lowest class room or environment (i.e. ISO Class 5) must be cleaned before the ISO Class 7 buffer area/cleanroom followed by the ISO Class 7/8 ante-area then general pharmacy preparation area.
- 5.4 General consideration when washing floors
 - 5.4.1 Wash floors *after* the ISO Class 5 areas, counters and other easily cleanable work surfaces have been cleaned and disinfected.

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- 5.4.2 Begin at the location farthest from the buffer area/cleanroom entrance working toward the exit to avoid walking over cleaned areas.
- 5.4.3 Move any rollable carts, shelving and chairs as cleaning is accomplished.
- 5.4.4 Perform necessary restocking or other in room activities prior to cleaning and floor washing so that buffer area/cleanroom may be exited and allowed to dry and remain at rest until the next shift.
- 5.5 No high particle shedding materials may enter the buffer area/cleanroom. This includes corrugated cardboard, paper documents (i.e. compounding worksheets and order forms are allowed, but should be kept to a minimum). No worksheets or order forms may enter the ISO Class 5 environment compounding surface at any time.
- 5.6 Document the cleaning procedure on appropriate log (Cleaning Log for Controlled Compounding Environments (F-304.b) (immediately upon completion of the task to insure proper documentation.

6.0 Cleaning LAFW / BSCs:

- 6.1 Gown and glove, in accordance with *Hand Hygiene and Garbing Procedure (P-404)*.
- 6.2 If the LAFW / BSC has been turned off, restart and allow to run a minimum of 30 minutes prior to cleaning. Ideally, PECs should never be turned off.
- 6.3 Inspect the inside of the hood/bench for any spills or puddles of crystallized compounding components. Clean the spills with sterile water prior to proceeding with the routine cleaning procedure.
- 6.4 If daily cleaning was performed the night before, at the start of each new workday, the LAFW / BSC must be wiped down with a wipe wetted with sterile 70% IPA..
- 6.5 Begin cleaning activity within the LAFW / BSC environment moving outward working from inner to outer surface. Note: Do not splash or spray the HEPA filter with disinfectant solution. Carefully clean the HEPA grills.
NOTE: *DO NOT wipe in a large circular motion across the work surface, as it is likely contaminants and particulate matter will be introduced into the rear portion of the hood as they are captured, carried, and deposited from the front edge of the LAFW.*
- 6.6 Additionally ISO Class 5 critical work areas will be cleaned with sterile 70% IPA between batches, every 30 minutes during continuous compounding, after spills and if contamination is suspected.
- 6.7 Document all cleaning activity on the appropriate cleaning log.

7.0 Daily Cleaning of Controlled Environments

- 7.1 The buffer area/cleanroom is cleaned before the ante-area/room.
- 7.2 Each compounding day the following must be cleaned in both the buffer area/cleanroom and in the ante-area/room:
 - 7.2.1 The inside surfaces of all ISO Class 5 PECs;
 - 7.2.2 Other counters and easily cleanable work surfaces (like stool tops, metro cart shelves, etc.).
 - 7.2.3 Floors
- 7.3 Cleaning is performed in this order:
 - 7.3.1 Inside surfaces of ISO Class 5 PECs
 - 7.3.2 Counters and easily cleanable work surfaces in the buffer area/clean room
 - 7.3.3 Floors in the buffer area/cleanroom from farthest point away from the door progressing toward the door to the ante-area while moving easily moveable carts and shelving.

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- 7.3.4 Counters, sink and easily cleanable work surfaces in the ante-area as long as those areas are on the “clean side” of the line of demarcation.
- 7.3.5 Counters and easily cleanable work surfaces in the ante-area/room beyond the line of demarcation (“dirty side”).
- 7.3.6 Floors of the ante-area/room.
- 7.3.7 Perform any required daily activities related to cleaning the pharmacy general preparation area as required by organizational policy.

7.4 Document the cleaning on the Cleaning Log for Controlled Environments (F-304.b).

8.0 Monthly Cleaning of Controlled Environments

8.1 Monthly cleaning includes all of the elements of the daily cleaning plus additional activities in the following order:

- 8.1.1 The buffer area/cleanroom is cleaned before the ante-area/room.
- 8.1.2 All of the daily cleaning activities defined in section 7.0 are required.
- 8.1.3 Additionally the following must be cleaned during a monthly cleaning:
 - 8.1.3.1 Ceilings and the top of PECs
 - 8.1.3.2 Walls and the horizontal surfaces of PECs (sides, back and front)
 - 8.1.3.3 All surfaces of moveable carts, storage shelving and stools (including underside, legs and feet/wheels;
 - 8.1.3.4 All storage bins must have contents removed; bins cleaned inside and out, allowed to dry and contents replaced.
 - 8.1.3.5 All surfaces in room including doors, door handles, pass throughs, permanent shelving, etc.

8.2 Document the cleaning on the Cleaning Log for Controlled Environments (F-304.b).

9.0 Routine Cleaning of the General Pharmacy Preparation Area

9.1 Though not part of the controlled environments, cleanliness and order is required in the General Pharmacy Preparation Area.

9.2 The Pharmacy Manager or designee will stipulate how and when the general pharmacy area is to be cleaned.

9.3 Document cleaning on the Cleaning Log for General Pharmacy Preparation Area (F-304.c).

10.0 Three-Time Cleaning of Controlled Environments

10.1 Three-time cleaning may be performed when the following conditions occur:

- 10.1.1 After action levels are exceeded occurring during environmental monitoring air or surface sampling procedures.
- 10.1.2 After any maintenance work performed in the cleanroom that would compromise environmental integrity.

10.2 Perform and document all required cleaning as detailed on the *Three Time Cleaning of Controlled Environments (F-304.d)*

11.0 Floor Refinishing:

11.1 The floors of the buffer area/cleanroom and ante-area shall be stripped of their existing finish (depending on floor type) and refinished by qualified personnel on an as needed basis.

11.2 The pharmacy manager or designee when this must occur.

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- 11.3 Generally stripping and refinishing is required more often on older floors. Newer materials may not need this treatment.
- 11.4 The materials utilized will be of such composition as to not compromise the integrity of the controlled environment and should be manufactured for the expressed purpose of maintenance of the type of flooring which has been installed.

NOTE: *Most states require Licensed Pharmacy Personnel to be on the premises during such activity, or while non-employees are in restricted pharmacy areas.*