



Title: Cleaning and Disinfection of the [REDACTED] Cell Therapy Areas

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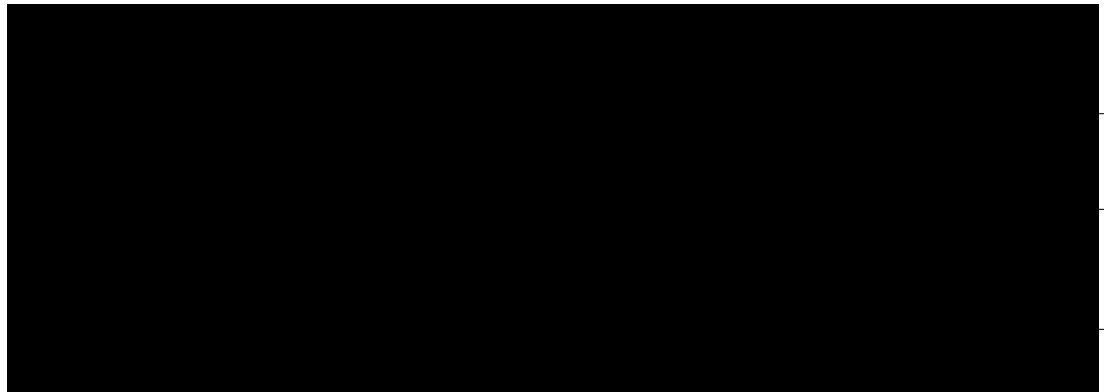


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1.0 Purpose

This document provides detailed instructions for the cleaning and disinfection of the [REDACTED] Cell Therapy Production Area in the [REDACTED].

2.0 Scope

This procedure applies to the Biopharmaceutical Development Program (BDP) [REDACTED] Cell Therapy Production Area rooms [REDACTED]. The adjoining locker room facilities are not covered by this Standard Operating Procedure (SOP) and are cleaned using general housekeeping methods. The manufacturing and support spaces on [REDACTED], and [REDACTED] within the [REDACTED] are covered in **SOP 19408 - Cleaning and Disinfection of CGMP Areas in the [REDACTED]** and the VPf is covered per **SOP 19409 – Cleaning and Disinfection of the [REDACTED] Virus Production Facility**. Manufacturing process equipment is cleaned following separate procedures. This procedure does not apply to the surrounding [REDACTED] areas within the [REDACTED].

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [REDACTED].

3.0 Authority and Responsibility

- 3.1 The Director, Technical Operations, BDP has the authority to define this procedure.
- 3.2 BDP personnel and/or BDP-directed contract cleaning personnel are responsible for the implementation of this procedure.
- 3.3 The Director, Technical Operations, or designee is responsible for training the personnel who perform this procedure and for providing documentation of this training to Biopharmaceutical Quality Assurance (BQA).
- 3.4 Persons performing cleaning of the areas defined in this procedure are responsible for complying with the steps specified in this procedure.
- 3.5 It is the responsibility of Biopharmaceutical Quality Assurance (BQA) Engineering, (BQAE) or designee, to evaluate the effectiveness of this cleaning protocol by reviewing the environmental monitoring results for the Cell Therapy areas of the [REDACTED].
- 3.6 The Cleaning Coordinator (or designee) is responsible for review of completed cleaning logs.
- 3.7 BQA is responsible for quality oversight of this procedure.

4.0 Procedure

4.1 Safety

- 4.1.1 Avoid eye and skin contact with cleaning agents. Wear proper cleanroom gowning attire as described in **SOP 19502 - Gowning Requirements for Personnel and Visitors:** [REDACTED] **Cell Therapy Areas**. Wear nitrile or other non-latex gloves that cover the wrist and hands to protect from exposure to disinfectant solution. Wear safety glasses or goggles when using disinfectants. Immediately rinse off the disinfectants using copious amounts of water from any exposed skin.
- 4.1.2 Post "Wet Floor" signs whenever the floor surface is wet due to cleaning activities. A wet floor can be slippery particularly when wearing disposable booties.
- 4.1.3 Refer to manufacturer's safety precautions and Safety Data Sheets (SDS) for appropriate protective equipment and safe handling procedures when using chemicals.
- 4.1.4 When damp mopping the walls, use extreme caution around electrical outlets and Supervisory Control and Data Acquisition (SCADA) connection points. If moisture gets inside these fixtures it can cause a short or electrical shock. Cleanroom tape may be placed securely over these fixtures to reduce (but not eliminate) the risk. Remove tape after cleaning, if applicable.
- 4.1.5 Use caution when cleaning near HEPA filters and HVAC air-intake ducts. They must never be exposed to any liquid. In order to avoid damage to the HVAC filters, **DO NOT mop or spray the HEPA filters, their protective grills or any air-intake ducts. To clean these areas, spray a wipe or pad style mop head with 70% Isopropyl Alcohol (IPA) and carefully wipe the surfaces.**

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [REDACTED].

- 4.1.6 Follow Environmental Health and Safety (EHS) Guidelines. These guidelines can be accessed by going to the NCI-Frederick Home Page on the Internet and search for desired information. EHS may also be contacted for clarification on safety pertaining to this SOP.
- 4.1.7 When using sporicidal concentrations of Decon-Spore (6.5 oz/190 mL per gallon of WFI) staff must use PAPR's equipped with a 3M GVP-443 cartridge, or a full face or half face respirator and goggles with cartridges 3M 60926 or 3M 60923. These cartridges are good for 40 hours of use or 6 months, whichever occurs first. Staff must be actively enrolled in the Respiratory Protection Program to use the equipment. Areas that have been cleaned using Decon-Spore must be posted with "Caution" signage (see attachment 20) for a minimum of 24 hours following cleaning. Ceilings are not routinely cleaned with Decon-Spore as a matter of risk versus benefit. Overspray or dripping solution from the ceiling poses a potential personnel safety risk while the likelihood of contamination to the ceiling is historically low. QA or the cleaning supervisor reserves the right to request Decon Spore use on the ceilings at sporicidal concentrations if warranted by EM data or other circumstances. For additional safety, Decon-Spore is typically used from a 13-oz. bottle to facilitate easy batching in 2 gallons of WFI.

4.2 Materials

NOTE: Only equipment, materials, and supplies that have been specifically approved are to be used in the classified areas.

4.2.1 Approved Disinfectants and Diluents

- 4.2.1.1 Decon-Ahol® or equivalent, (70% IPA, sterile), BDP PN 30129
- 4.2.1.2 Decon-Cycle®, (Low pH Phenolic, sterile), BDP PN 30119
- 4.2.1.3 Decon-Phene®, (High pH Phenolic, sterile), BDP PN 30120
- 4.2.1.4 Decon-Spore® (Peracetic Acid & H₂O₂, sterile), BDP PN 30824
- 4.2.1.5 WFI - Water for Injection

NOTE: Water for Injection (WFI) does not need to be released for cleaning purposes as long as acceptable TOC and Conductivity data is available.

- 4.2.1.6 Cavicide, BDP PN 10168
- 4.2.1.7 Simple Mix Decon-Cycle®, BDP PN 31253
- 4.2.1.8 Simple Mix Decon-Phene®, BDP PN 31254
- 4.2.1.9 Simple Mix Decon-Spore®, BDP PN 30826

4.2.2 Approved Cleaners

- 4.2.2.1 Micro-90 (Concentrated Alkaline Cleaning Solution) – BDP PN 30393

4.2.3 Approved Cleaning Equipment

- 4.2.3.1 Step Ladder

4.2.3.2 Mop Systems

- Autoclavable double bucket with wheels dedicated to the Cell Therapy Suite
- Stainless sieve
- Mop handle
- Mop head frame
- Other supplies with Manufacturing Manager approval

4.2.3.3 Volumetric Container for cleaning/disinfectant measurement

4.2.3.4 Sprayers – Hand Pump

4.2.3.5 PAPR Hood Assembly (3M PN S-655)

4.2.3.6 Belt Mounted PAPR Assembly (3M PN GVP-CB)

4.2.3.7 Air Purifying Cartridge (3M GVP-443)

4.2.3.8 Half face respirator with goggles or shield or full-face using cartridge models (3M 60926 or 60923)

4.2.3.9 Other respiratory protection equipment as approved by EHS.

4.2.4 Consumables

4.2.4.1 Cleanroom Supplies

- Mop Head Pads, BDP PN 22116 or 22120.
- Short Loop Mop Head BDP PN 22150
- Biohazard Bags, Autoclavable, Red, 38" x 48" BDP PN 21827
- Biohazard Bags, Autoclavable, Clear, 38" x 31", BDP PN 20665
- Wipes, sterile, BDP PN 20315
- Clean room wipes (9x9), BDP PN 21208

4.3 Cleaning

4.3.1 Preparation of Disinfectant Solution

4.3.1.1 Rotate the cleaning disinfectants as indicated on the Summary Sheet. (See **Attachment 1.**)

4.3.1.2 Use Decon-Spore at sporicidal concentration for the first cleaning of each month on the floors before rotation of the next cleaning disinfectant.

4.3.1.3 Simple Mix

4.3.1.3.1 Remove large top screw cap and seal.

4.3.1.3.2 Compress interior bottle to empty contents.

4.3.1.3.3 Screw cap back on and swirl to mix.

4.3.1.4 Standard Concentrated Bulk Solution

4.3.1.4.1 Water must be brought into the [REDACTED] Cell Therapy Area, as there is no WFI source within. Use a carboy or bag to transport water as the cleaning bucket is not permitted within the [REDACTED] manufacturing areas. WFI that is not sterile filtered must be used the same day it is collected.

4.3.1.4.2 Using the designated equipment for the area to be cleaned, fill the solution bucket with the proper amount of WFI.

4.3.1.4.3 Using a suitable volumetric container capable of measuring milliliters, add the appropriate amount of disinfectant concentrate to the buckets, as specified by the Disinfectant Dilution Chart in Attachment 1. Mix using the mop until the solution is visibly homogeneous, at least 30 seconds.

4.3.1.5 Document the disinfectant preparation on the Room Cleaning Log. (See Attachment 4.)

4.3.1.6 Disinfectant solutions will be prepared and disposed of daily.

4.3.2 Cleaning Techniques

NOTE: Short loop mop heads (BDP PN 22150) may only be used on floors.

4.3.2.1 Double-bucket with sieve pad-style mop technique for mopping ceilings, walls, and floors.

- Submerge the mop in the first solution bucket.
- Remove excess liquid using the sieve positioned over the second bucket.

4.3.2.2 **Mop loading:** Between submersions the mop must only be loaded in one direction and remain wet enough to ensure cleaning solution is applied on the entire surface the mop contacts. If at any point the mop is no longer sufficiently wet, it must be rewetted. Mop strokes should overlap by approximately 20% or 1/5th of the mop head length to ensure complete coverage.

4.3.2.3 **Ceilings:** The drop ceilings in this area are not conducive to mopping and shall be sprayed only to avoid unseating tiles. Detailed wiping may be used in the area close to the filters to avoid spray contact to the HEPA's.

NOTE: DO NOT mop, wipe, or spray HEPA filters. Wipe the protective grills of the HEPA filters with a cleanroom wipe or pad style mop head dampened with 70% IPA. Do not wet the HEPA filter.

- 4.3.2.4 **Walls:** Mop from the top down. Whenever cleaning around equipment and obstructions, walls may be mopped horizontally proceeding from top to bottom. Wipe the grills of the air returns with a cleanroom wipe dampened with 70% IPA.

NOTE: Ceilings and walls must be completed before floors. Once a mop head is used on the floor, it may not be used on ceilings or walls.

- 4.3.2.5 **Floors:** When mopping floors with a clean room mop, a modified technique may be used, where the mop handle is rotated 180° at each turn, so that a leading mop edge never reverses direction. Remove excess cleaning solution while mopping to avoid residue build up and puddling of cleaning solution. Floors are to be done innermost to the exit.

NOTE: Change mop heads if they become heavily soiled. Solution may be changed more frequently if heavily soiled.

- 4.3.2.6 After mopping is complete, discard the used mop head(s) (No more than 4 used mop heads may be discarded in a single bag for decontamination reasons).
- 4.3.2.7 Empty the bucket into the drain in Room [REDACTED] and wipe the buckets clean using wipes and 70% IPA.
- 4.3.2.8 **Sprayers:** Pump sprayers may be used for solution application on walls, floors, and ceilings provided no open work is in progress. Before spraying, cover any moisture sensitive equipment that may receive overspray with plastic. Following spraying, for walls and floors, use a mop head pad and the technique previously described to mechanically distribute solution and remove excess. This technique helps to ensure total coverage.

4.3.3 Cleaning Sequence

- 4.3.3.1 Perform the following tasks, as required by the frequency chart **Attachment 2**, cleaning rooms in the order as listed on the Cleaning Zone Reference Sheet **Attachment 3**. The cleaning will be performed using cleaning techniques described in Section 4.3.2.

4.3.3.2 Waste removal

NOTE: Non-BDP cleaning staff will not be responsible for handling any waste in autoclave bags or sharps containers.

- All trash within the suite is considered biohazardous and will be autoclaved out of the area.
- Non-biohazardous waste as marked by black trash bags is only within the gowning airlock and will be removed by cleaning staff.

4.3.3.3 Cleaning Sequence and Locations

- In general, clean ceilings, then walls and work surfaces, then clean the floors from the innermost areas toward the exit or the location where the used supplies and solution are discarded and supplies are stored.
- Walls include all vertical surfaces such as doors, door hardware, window frames, light and door activation switches, window, gowning mirrors, wall mounted phones, railings, and utility panels. (It is necessary to follow up cleaning of window glass with IPA to remove streaking and spotting caused by residual disinfectant).

NOTE: When a wall is indicated on a cleaning form, it is implied that all of the listed surfaces are included.

- Work surfaces include tables, carts, shelves, chairs, stools, gowning benches, trash cans, and other objects not classified as equipment or supplies.

NOTE: When a wall is indicated on a cleaning form, it is implied that all of the work surfaces are also included.

- Document the tasks and rooms disinfected on the appropriate room cleaning log form after cleaning is completed.

4.3.3.4 Wash Down/Complete Cleaning

- When performing a complete cleaning that involves cleaning of the ceilings and walls, it is recommended and acceptable to apply disinfectant using a sprayer and then use a pad style mop head to ensure even and total distribution.
- Clean work surfaces using Cavicide, BOP PN 10168, or batched disinfectant dispensed either by sprayer or wetted clean room wipes. Avoid getting liquid into or on sensitive equipment.
- The floors would then be done with a separate mop head and a bucket system. Staff may then move to the next sequential room, again using the sprayer and dedicated mop head on the ceilings and walls followed by the floor with the mop head previously used on the floor. This technique minimizes the number of solution preps and entries to an area.

4.3.3.5 Routine Floor and Surface Cleaning

- The cleaning type that occurs most often is for the floors and select surfaces. Floors are cleaned with the designated product and select surfaces are cleaned with Cavicide, BOP PN 10168. Select surfaces are to be cleaned prior to mopping floors.

- When floor cleaning is selected on the form as part of scheduled cleaning not involving the cleaning of walls, it is implied that all selected surfaces are also included.
- The select surfaces included in this cleaning are those that receive frequent contact or could otherwise impact the room environment. Surfaces may be sprayed directly or Cavicide may be sprayed first onto a clean room wipe to avoid overspray near instruments and telephones.

Door activation hardware – This includes door handles or push plates.

Tables – Staff should not move equipment to perform this activity. This does not include storage racks or carts which are the responsibility of production staff as part of production activities.

Chairs – This includes chairs, stools, and gowning benches.

Phones.

4.3.4 Frequency of Cleaning (Attachment 2 – Frequency Chart)

NOTE: Attachment 2 lists the minimum cleanings required, but frequency is not limited to these minimums.

4.3.4.1 Area disinfection is to occur whenever an area status is “in service” following the frequency guidelines in Attachment 2. Cleaning frequency may be reduced for an area if its status is “limited use” or “shutdown”. See **SOP 21554 - GMP Area Status Management** and the posted status sheets for status description details.

4.3.4.2 Production schedules may initiate special request cleanings or alter the cleaning schedule.

4.3.4.3 A complete cleaning (washdown) of the zone will occur on the schedule specified in Attachment 2 or if requested. Washdown following production includes the following tasks by manufacturing personnel prior to cleaning:

- The product removed from the area.
- Open raw materials are discarded.
- Biohazardous waste removed from the area.

4.3.4.4 Upon completion of the previous step, a single wash-down of ceilings, walls, and floors will be performed using the designated phenolic for the month (Decon-Phene or Decon-Cycle).

4.3.4.5 A rinse of floors is performed monthly prior to the application of Decon-Spore and documented. Additional rinses of surfaces including floors should be performed if a buildup of cleaning residue is observed.

- The rinsing procedure uses the same equipment, technique, and documentation as cleaning. Select “Other” for disinfectant and write in WFI.
- If WFI is insufficient to remove residue, other approved products may be used when directed by the BDP cleaning contact or BQA.

4.3.5 In-Process Cleaning

- 4.3.5.1 When work is in progress, the manager will communicate to cleaning staff if they are permitted enter the area to clean and any special instructions such as: **Cleaning Staff Entry Restricted** which means there is no entry by cleaning staff at this time, **Sprayer Use Only** see step 4.3.5.2, **Escort Required** indicating that cleaning staff may enter only if accompanied by production personnel. Communication may be done by any means including in person, email, or placing signage on the entrance to the area.
- 4.3.5.2 Mops are not permitted during production operations using Prodigy systems or other equipment with unprotected flow paths. Under these conditions, only sprayers shall be used.
- 4.3.5.2.1 If the manager deems that mopping is necessary, the cleaning staff must be escorted and supervised by production staff. Alternatively, production staff shall perform the mopping.
- 4.3.5.2.2 The monthly residue removal with WFI must be performed with a mop.
- 4.3.5.3 If cleaning staff are restricted from entry, it will become the responsibility of production personnel to perform the necessary cleaning. Arrangements may be made with the cleaning staff to make up deferred cleanings, however, the weekly frequency in Attachment 2 must be adhered to.

4.3.6 Post-Renovation, Facility Shutdown/Failure Cleaning

- 4.3.6.1 Standard requirements are described below and divided by classification. Depending on the conditions of the renovation / shutdown/failure, the number of cleanings required may be increased or decreased by the BQA Quality Engineering and Validation Manager or designee.
- 4.3.6.2 BQA Quality Engineering and Validation Manager or designee will indicate any rooms within the zone that first require detergent cleaning, including detailed wiping and a wash down with Micro 90 or approved equivalent. (This step is not required unless requested by BQA.)

4.3.6.3 Two cleanings (as described below) is standard procedure.

- The first required cleaning will include detailed wiping and a complete wash down of walls, and floors with Decon-Spore at sporicidal concentration.
- The second required cleaning will be a complete wash down of ceilings, walls, and floors with the current rotation's cleaning agent (Decon-Phene or Decon-Cycle).

4.3.6.4 Cleaning status will be communicated by the Quality Engineering and Validation Manager or designee usually via **SOP 21554 - GMP Area Status Management**.

4.4 Documentation

4.4.1 Log entries will follow documentation guidelines in **SOP 21409 - Good Documentation Practices**.

4.4.2 Record disinfectant preparations at the bottom of the cleaning form as they are formulated. (See Attachment 4.)

4.4.3 Record all cleaning and disinfection activities on the zone-cleaning log form (Attachment 4). This will include the date, initials, time completed, rooms completed, tasks completed, and any comments.

4.4.4 Cleaning entries must be reviewed regularly by the Cleaning Coordinator or designee. Loose cleaning forms should be submitted for review weekly at a minimum.

5.0 Definitions

5.1 HEPA - High Efficiency Particulate Air

5.2 IPA - Isopropyl Alcohol, sterile

5.3 PPE - Personal Protection Equipment

5.4 CGMP Area - Environmentally-controlled area with limited access

5.5 WFI - Water for Injection

5.6 Work Surfaces: Work surfaces and horizontal surfaces including, but not limited to, shelves, transfer panels, tables, stools, door handles, and telephones.

5.7 Cleaning Zones - The facility is divided into "zones" to reduce cross contamination and allow for different cleaning schedules. Clean the rooms in the order indicated for each zone in Attachment 3 unless ongoing production requires an adjusted order.

6.0 References and Related Documents

6.1 SOP 19503 *Flow of Personnel, Materials, Equipment, and Waste in [REDACTED] of [REDACTED]*

6.2 SOP 19502 *Gowning Requirements for Personnel and Visitors: [REDACTED] Cell Therapy Areas*

6.3 SOP 21409 *Good Documentation Practices*

6.4 SOP 21526 *Engineering Event Management*

6.5 SOP 21554 *GMP Area Status Management*

7.0 Attachments

7.1 Attachment 1 Summary Sheet

7.2 Attachment 2 Frequency Chart

7.3 Attachment 3 Cleaning Zone Reference Sheet

7.4 Attachment 4 Room Cleaning Log Zone 21, Cell Therapy [REDACTED], Form 19504-01

7.5 Attachment 5 Process Summary and Checklist

Attachment 1**Summary Sheet****DISINFECTANT DILUTION CHART**

Disinfectant	BOP PN*	Volume / Gallon	Volume / 5 Liter
Decon-Cycle®	30119	15 ml	20ml
Decon-Phene®	30120	30ml	40ml
Decon-Spore®	30824	6.5oz or 190ml	NIA

*Simple Mix PN's not listed as no measurement or dilution is needed for product use.

CLEANER DILUTION CHART

Cleaner	BOP PN	Volume / Gallon	Volume / 5 Liter
Micro90	30393	10ml	13ml

DISINFECTANT ROTATION CHART

Disinfectant	Month
Decon-Cycle®	January, March, May, July, September, November
Decon-Phene®	February, April, June, August, October, December
Decon-Spore®	The first cleaning of the month on the floors (between the changeover of Decon-Cycle and Decon-Phene). Special request, post-renovation, Post-facility shutdown, failure cleaning.
WFI	Used for cleaning agent residue removal. Used monthly prior to application of Decon-Spore and additionally as needed.

Attachment 2

Frequency Chart

FREQUENCY CHART						
Zone	Zone Name:	Ceilings	Walls	Curtains	Floors	Open Drains
21	Cell Therapy B2310	Quarterly (every 3 months) or by request ¹	Quarterly (every 3 months) or by request ¹	N/A	1 x Week ¹	NIA

¹ Also may be required as part of return to service.

NOTE: Cleaning frequency may be altered due to holidays, facility shutdown, inclement weather, EM results, or as directed by **SOP 21526 - Engineering Event Management**.

Attachment 3

Cleaning Zone Reference Sheet

Whenever production concerns allow, clean the rooms in the order indicated for each zone. The primary equipment storage location, water source, and frequency are listed, but subject to change as production concerns require. The zone can only be cleaned with the designated equipment sets.

Zone 21 - Cell Therapy-

Equipment Set: Cell Therapy

Equipment Storage: [REDACTED]

Water source: Remote or self-contained with Simple Mix

Room#	Room Name	Classification	ISO Classification	Cleaning Order
	Gown in Airlock	10K	7	1
	Pass Through	NA	NA	2
	Cell Therapy	10K	7	3
	Degown Airlock	100K	8	4

Attachment 4

FORM 19504-01 Room Cleaning Log

Biopharmaceutical Development Program
ROOM CLEANING LOG
Building - Zone21- Cell Therapy Room ____

FNLCR, BDP
Form 19504-01
OOP No. 1, SOT
Rev. 00: FEB 25 2020

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*Check either Scheduled or Requested

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DAILY DISINFECTANT PREPARATION LOG

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Disinfectant Dilution Schedule

Disinf t	8D?Part No.	VC>luMI Gallon	Vo1W"Mf 5 Lit.r
Decon-Cycle	30119	15 ml	20 ml
Decon-Phono	30120	30ml	,a mt.
DEcon-Spo,	30824	6.1<z or l QOm l	NIA

Summary

Disinfectant	BDP Part No.	Vo lUm@ / :;Lit.,
Micro 90	30393	10ml 13ml

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract

Attachment 5

Process Summary and Checklist

- Verify there are no entry restrictions or if mop usage is allowed.
- Use cleaning equipment dedicated to the area.
- Observe safety requirements during batching and application
- Ensure materials are within their expiration. Remove/discard expired items.
- Cleaning Sequence (note start and stop times)
 - Non-biohazardous trash removal (black bag)
 - Ceilings (when applicable)
 - Walls (when applicable). Follow spray application with a mop. Wipe windows with 70% IPA to remove streaks.
 - Work surfaces with Cavicide or batched disinfectant (tables, carts, shelves, chairs, stools, door hardware, gowning bench, trash cans)
 - Floors, working toward exit (Distribute solution evenly. Excess solution or puddles are a safety hazard and accelerates residue buildup and makes floors sticky once dry.
- Wipe buckets before storage with wipes and 70% IPA to remove any residual debris.
- Verify documentation is completed and submitted for review.