SOP Title:	**Title Use, Cleaning and Disinfection of Equipment and Laboratories in PA/QC**
SOP Number:	**22909**
Revision:	**06**

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1. PURPOSE

This Standard Operating Procedure (SOP) outlines the cleaning and disinfection procedures for laboratories and equipment in use by Process Analytics/Quality Control (PA/QC) and Biopharmaceutical Development Program (BDP) personnel.

2. SCOPE

This standard operating procedure applies to PA/QC and BDP personnel when using, cleaning and disinfecting equipment [Biological Safety Cabinets (BSC's) incubators, centrifuges] and laboratories. Refer to **SOP 21533 Policies for Operation, Cleaning, and Routine Maintenance of Controlled Temperature Equipment**, for use and maintenance of refrigerators and freezers and forms for documentation.

3. RESPONSIBILITIES

3.1 Director / PA/QC

- Defines procedure

3.2 PA/QC/BDP Managers

- Provides training to laboratory personnel
- Reviews data

3.3 PA/QC/BDP Personnel

- Performs procedure

3.4 BQA

- Provides quality oversight

4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
10163	Spor-Klenz® (Hydrogen peroxide and Peroxyacetic acid). Ready to use.	☒ YES ☐ NO
10167	Dispatch® (stabilized bleach). Ready to use. For use with enveloped and non-enveloped viruses.	☒ YES ☐ NO
10168	CaviCide® (Disobutylphenoxyethoxyethy dimethyl benzyl ammonium chloride). Ready to use. For use with enveloped viruses only.	☒ YES ☐ NO
20295	Clorox® bleach. Supplied as a 6.15% sodium hypochlorite solution. For use with enveloped and non-enveloped viruses.	☒ YES ☐ NO
30129	Sterile 70% Isopropyl alcohol. Ready to use.	☒ YES ☐ NO
30135	Sporicidin®, (phenol 1.56%, sodium phenate 0.06%). For use with enveloped viruses and Simian Virus 40.	☒ YES ☐ NO
30968	Conflikt®, (n-alkyl dimethylbenzyl ammonium chlorides 0.105%, n-alkyl ethylbenzyl ammonium chlorides 0.105%). For use with enveloped viruses, adenoviruses and simian virus 40.	☐ YES ☒ NO

5. USE

5.1 Approved Disinfectants/Sanitants for PA/QC/BDP Use

NOTE: Before each use make sure that the expiration date of the bottle of disinfectant has not passed. 70% isopropyl alcohol and Spor-Klenz® are sanitants and are not for virus disinfection. Note the restrictions for Cavicide®, Sporicidin® and Conflikt® when used as disinfectants for virus work. Dispatch® and bleach may be used for any virus work.

5.1.1 Clorox® bleach, BDP PN 20295, is supplied as a 6.15% solution; therefore, make a 1:10 dilution with RODI water or BDP approved equivalent. Due to its instability when exposed to light, store all Clorox® solutions in an opaque or amber bottle. Label the bottle and record the dilution of the bleach per **SOP 22702 Solutions Used in Process Analytics**.

NOTE: Make the prepared solution fresh daily.

5.1.2 If Clorox® bleach (1:10 dilution) or Dispatch® is used as the cleaning agent, it is recommended that the surface be wiped with sterile 70% isopropyl alcohol afterward to remove any residual disinfectant from the surface.

5.2 Before and after working in the BSC, sanitize all exposed surfaces, including all interior surfaces of the BSC. Clean the BSC under the working surface at least once per year. This is done by Safety, just prior to recertification, but may be done by personnel using the BSC as well. **Form 22909-01** is for the BSC. Fill in the additional information requested on the log sheets, as appropriate.

NOTE: Log sheets must be bound into a book by QA. Request a book and record requested information, as appropriate to the piece of equipment. Books of bound log sheets are reviewed as each page is completed or at least once per month.

NOTE: When working with infectious agents, all items in the BSC must be disinfected prior to removal. See contact times for disinfection (5.2.1).

5.2.1 Allow sufficient contact time to maximize effectiveness.

- CaviCide® 3 minutes
- Dispatch® 1 minute
- Sterile 70% isopropyl alcohol* 15-20 minutes*
- Spor-Klenz® 15 minutes
- Sporicidin® 10 minutes
- 1:10 dilution of Clorox bleach 30 minutes
- Conflikt® 5 minutes

*Sterile 70% isopropyl alcohol is quite volatile and will evaporate too quickly to be effective as a virucidal (enveloped viruses) and/or bactericidal agent. Use only as a secondary disinfectant and/or sanitant.

5.2.2 To avoid creating toxic Chlorine gas fumes, **never** mix any solution containing Sodium Hypochlorite (i.e., Dispatch® Clorox®) or Spor-Klenz® with any other listed disinfectant.

5.2.3 To prevent growth of resistant microorganisms, rotate the primary disinfectant used on a daily basis. If sterile 70% isopropyl alcohol is used after another agent such as Dispatch® to remove residues, it may be used again the following day as a primary sanitizing agent for clean cell culture or media preparation.

5.3 When working with viral agents in the BSC, follow **SOP 17109 Procedures for Safe Handling, Decontamination, and Spill Cleanup of Infectious or Potentially Infectious Materials**. Only Dispatch® is an approved disinfectant for all virus work [enveloped and non-enveloped viruses (see above).]

5.4 Clean bench tops at least weekly. For virus laboratories, use an approved disinfectant listed in section 5.2.1.

5.5 Centrifuge cleaning is outlined in **SOP 19102 Routine Use and Disinfection of Biological Safety Cabinet, Incubators, Shakers and Centrifuges** for centrifuges that are currently being used in the PA/QC, as well as in any additional procedures pertinent to centrifuges that are acquired. As necessary, refer to **SOP 17109 Procedures for Safe Handling, Decontamination, and Spill Cleanup of Infectious or Potentially Infectious Materials**. The disinfectants recommended for most centrifuges Sporicidin® and Conflikt® , for certain non-enveloped viruses (see above) clean with Dispatch followed by sterile 70% isopropyl alcohol. Centrifuges and rotors are cleaned following each use or when deemed necessary by the Laboratory Manager and prior to calibration (at least annually). Document using **Form 22909-02**.

5.6 For routine cleaning of incubators use Conflikt® or Sporicidin® followed by sterile 70% isopropyl alcohol. Incubators may be cleaned following use with a specific product and/or when deemed necessary by the Laboratory Manager. Incubators are always cleaned prior to calibration (at least annually). Clean any calibrated thermometers associated with the incubator. If an incubator is not used routinely, temperatures, etc., are recorded only during the period of use.

NOTE: Due to its corrosive nature, use Dispatch® or any other disinfectant containing active Chlorine on the interior surfaces of centrifuges and/or incubators only when working with certain non-enveloped viruses. Chlorine is highly corrosive and will compromise the integrity of the instrument.

5.6.1 Daily (weekends, holidays, and facility closures excluded) monitor and record the temperature, CO_2, and percent humidity of the incubator as appropriate to the incubator. If the incubator has a humidity readout record that reading. Document in **Form 22909-04** (CO_2 incubators). For the current CO_2 incubators in the labs, connected to the SCADA (Supervisory Control and Data Acquisition) system, the suggested frequency of temperature, % CO_2 and humidity levels monitoring/recording in the logbook is on a weekly basis.

5.6.2 For CO_2 incubators (e.g., Thermo CO_2/Incubator/HERA Cell 150i, currently in use) fill fresh RODI water in the bottom reservoir of the incubator to maintain the humidity. Replenish the water to keep level half full always.

5.6.3 Prior to calibration, or at least once a year, remove, clean, and disinfect all shelves, support brackets, and associated hardware in the incubator. Clean and disinfect the newly exposed interior surfaces, replace the HEPA filter in the exhaust fan (if so equipped) and any other filters associated with the air filtration system. If the incubator is self-sanitizing, the system is activated at least once per year prior to calibration and filters are replaced as appropriate. Record yearly maintenance in the incubator logbook.

5.7 Empty, Clean, disinfect, and replenish water baths with fresh RO or DI water or BDP approved equivalent at least once a month, or when visible evidence of contamination (clouding, “floaters,” or odors) is noted. If water baths are not used on a regular basis, they should be cleaned after use and not refilled until needed. Clean calibrated thermometers associated with the water bath. Record temperatures of the water bath on the day of use and record cleaning of the water bath in the logbook. When water baths are used infrequently, usage may instead be recorded on study-associated paperwork. Clean water baths with Cavicide®, Sporicidin® or Conflikt® followed by sterile 70% isopropyl alcohol.

For virus laboratories, clean floors with an approved disinfectant (Section 5.2.1) or with a Clorox® mop kit, or BDP approved equivalent, weekly. Cleaning is documented in a laboratory notebook.

NOTE: To avoid any potential airborne contamination, **NEVER** use a bristle type brush or any type of vacuum cleaner that creates an exhaust in an actively operating cell culture or virus laboratory. **In a virus laboratory, the room must be cleaned and disinfected by laboratory staff prior to entry of housekeeping staff, Security/Protective Services, or FME**. Schedule floors for stripping and waxing by FME/housekeeping at least once a year.

5.8 All equipment must be cleaned, decontaminated and documented with FME (Safety Tag) prior to performing any routine and/or emergency maintenance and/or calibration procedures.

5.9 Clean other equipment following the manufacturer's recommendations with an approved disinfectant from the list in section 5.2.1.

6. DOCUMENTATION AND RECORDS

Document the following in the appropriate books of bound log sheets: cleaning of the BSC, cleaning of incubators, cleaning of centrifuges.

7. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
17109	Procedures for Safe Handling, Decontamination, and Spill Cleanup of Infectious or Potentially Infectious Materials
19102	Routine Use and Disinfection of Biological Safety Cabinet, Incubators, Shakers and Centrifuges
21533	Policies for Operation, Cleaning, and Routine Maintenance of Controlled Temperature Equipment
22702	Solutions Used in Process Analytics
22909-01	Biological Safety Cabinet Use, Maintenance, Disinfection, and Calibration
22909-02	Centrifuge Use, Maintenance, Cleaning, Calibration and Disinfection
22909-03	Incubator Use, Disinfection, Maintenance, and Calibration (For Non-CO2 Incubators)
22909-04	Incubator Use, Disinfection, Maintenance, and Calibration (For CO2 Incubators)
7013307	Steri-Cult Model 3307 and 3310 Series CO2 Incubator Controlled RH and Sterilization Cycle. Operating and Maintenance Manual, current revision.

8. ATTACHMENTS

Attachment 1 Cleaning a Humidity System Instruction Diagram

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Attachment 1 Cleaning a Humidity System Instruction Diagram

7.3 Cleaning the Humidity System

Make sure power is on and the RH setpoint has been changed from factory default.

1. Open outer chamber door.
2. Open the access door located on the front of the unit, below the control panel.
3. Locate the humidity system drain fitting attached to the bottom of this door. See Figure 1-11.
4. Install the hose barb end of this fitting to the supplied tubing and route to a drain or suitable 1.5 gallon container.
5. Connect the other end of the fitting to the quick-connect drain located below the fold-down storage door. See Figure 7-1. Allow water to drain. This may take a few minutes.

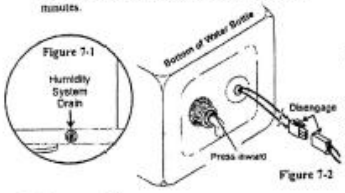

Figure 7-2

6. Turn power off.
7. Attached to the bottom of the water bottle is a length of tubing and low voltage wiring (Figure 7-2). Disconnect the tubing by pressing inward on the collar where the tubing connects to the bottle. Pull the tubing free. Disengage the wiring at the connector.
8. Lift the water bottle from the bottle platform. Empty any water out of the bottle.
9. Replace the filter in the lid by first unscrewing the clear plastic nut on the outside of the lid. Catch the filter as it loosens from the inside of the lid. Remove the small black o-ring from the filter and discard the filter. Assemble this o-ring onto the new filter and install as previously. Tighten the plastic nut only finger-tight to prevent stripping.

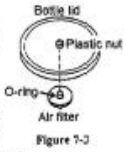

Figure 7-3

9. Clean the humidity bottle and lid with soap and water and a general-use laboratory disinfectant. Rinse with sterile water and spray with 70% alcohol.

10. Also behind the access door is the humidifier. See Figure 7-4. Lift the latches on both sides of this small unit.

Figure 7-4

11. Separate the top and bottom sections. Carefully clean the inside of both sections and spray with 70% alcohol.

Do not touch the metal disk in the bottom of the humidifier with bare fingers as any fingerprints or other residue can affect humidity recovery.

14. Reinstall the top section of the humidifier. Fasten the latches on each side.
15. Reconnect the tubing and wiring to the water bottle as previously.

7.4 HEPA Filter Maintenance

Replace the HEPA filter when the REPLACE HEPA reminder is displayed, or after each Sterilization cycle. The REPLACE HEPA reminder can be set to alarm after a specified time from 1 to 12 months. The reminder default is the factory recommended setting of 6 months. For details on setting the reminder, see Sections 4.1c.

Replace the HEPA filter (Figure 7-5) using the steps below.

1. Locate and loosen the two large wingnuts in the top of the inner chamber. Slide the filter bracket toward the chamber opening until the filter swings down.
2. Lift the back edge of the HEPA filter until it unhooks from the metal lip in the back of the chamber. Discard the filter.
3. Install a new HEPA by first hooking the back edge of the filter as previously.
4. After the back edge is hooked, lift the front of the HEPA to the top of the chamber. Slide the filter bracket over the HEPA frame to secure it. Tighten the two wingnuts.

Model 3307/3308

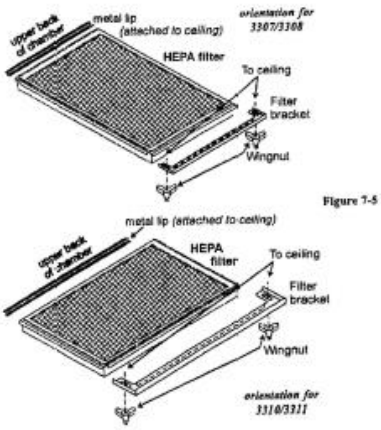

Figure 7-5