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### 1.0 Purpose

This SOP describes the procedure for use and disinfection of biological safety cabinets, incubators, shakers, and centrifuges.

### 2.0 Scope

This SOP applies to Biopharmaceutical Development Program (BDP) personnel using biological safety cabinets, incubators, shakers, and centrifuges.

**NOTE:** Process Analytics\Quality Control staff should refer to **SOP 22909 - Use, Cleaning, and Disinfection of Equipment and Laboratories in PA/QC**

### 3.0 Authority and Responsibility

- 3.1 The Program and Technical Director, Biopharmaceutical Development Program (BDP), has the authority to define this procedure.
- 3.2 The Supervisors/Managers of the work areas are responsible for training personnel in this procedure and for submitting documentation of the training to Biopharmaceutical Quality Assurance (BQA).
- 3.3 Production personnel are responsible for following this procedure.
- 3.4 The Supervisor/Manager is responsible for review of forms and submissions of forms to Biopharmaceutical Quality Assurance (BQA).
- 3.5 BQA is responsible for quality oversight and approval of this procedure.

### 4.0 Procedure

#### 4.1 Materials

- 4.1.1 Wear gloves, gowning, and laboratory jacket as required for the area and safety eyewear during all procedures.
- 4.1.2 Aquaguard-1 Solution (for water baths in CO2 incubators), BDP PN 31373 or equivalent
- 4.1.3 Aqua-tech Preservation Cell (BDP PN 22723 or equivalent)

4.1.4 7.5% Sodium Bicarbonate Solution (BDP PN 31498 or equivalent)

4.1.5 The following are approved disinfectants.

- 70% IPA (Decon-ahol), sterile, BDP PN 30129 or equivalent.
- Clorox Bleach Germicidal Cleaner, BDP PN 10167 or equivalent (sporicide)
- Cavicide, BDP PN 10168 or equivalent
- Steri-Perox 6%, BDP PN 10665 or equivalent (sporicide)

**NOTE:** Do not use Cavicide with Clorox Bleach Germicidal Cleaner. If Clorox Bleach Germicidal Cleaner is used on stainless steel surfaces, use 70% IPA to wipe residue left from this disinfectant.

Only Steri-Perox 6% and Clorox are effective sporicidal agents.

4.1.6 Rotate disinfectants daily or between campaigns. Further rotational information may be provided based on EM results.

4.1.7 Low lint sterile disposable wipes, BDP PN 20315 or equivalent.

**NOTE:** All forms listed for the equipment are incorporated into logbooks.

#### 4.2 Incubators/Shakers

**NOTE:** Institute a new Incubator Use and Disinfection Log sheet (**Form 19102-01** or **Form 19102-04**) each time the parameters of the incubator are changed.

4.2.1 Monitor the temperature using the calibrated digital readouts once daily when the equipment is in use (weekends, holidays, and facility closures excluded) or review the Supervisory Control and Data Acquisition (SCADA) System data and/or alarm history for proper operation. Refer to the log sheet or batch production record for correct parameters.

4.2.2 Clean the interior before and after each process by wiping with disinfectant (refer to Section 4.1.2). Incubator shelves may also be autoclaved before the start of a process and noted in the comments column of the Incubator Use and Disinfection Log Sheet.

4.2.3 If necessary, adjustment to incubator setpoints should be made at the front display. Using the soft touch buttons, select the incubator settings and adjust the temperature, humidity, and CO<sub>2</sub> percentage as directed by the area supervisor or BPR.

4.2.4 Record the following information on **Form 19102-01** or **-04** or in the equipment logbook: date, time, temperature, disinfectant used, disinfectant release number, product, or lot number, and initials.

4.2.5 Incubator humidity reservoirs should be routinely maintained at the specified interval, depending on the batching method used below.

4.2.5.1 If using Aquaguard preservative (PN 31373), add the preservative at a concentration of 10ml/L of carbon bed water from the CUP. This water should be changed monthly.

4.2.5.2 If using sodium bicarbonate (PN 31498) and WFI, add 4mL of diluted (0.1ml 7.5% bicarb/10ml WFI) 7.5% sodium bicarbonate per L of WFI. This sterile filtered solution will be pre-made and stored at room temperature with an

expiration date of one year. After adding the water, add an Aqua-tech Preservation Cell (PN 22723) to the incubator reservoir. Change out the water and preservation cell every six months. If the process is shorter than 6 months, drain the water and preservation cell once the incubators are no longer used for the process, as in step 4.2.6 below.

- 4.2.6 Any incubators not in use (or expected to be in use) for more than a month should be cleaned, drained of water, humidity system cleaned, and powered off. Any SCADA alarms should also be modified accordingly.

#### 4.3 Biological Safety Cabinet (BSC)

- 4.3.1 Keeping the internal air intake blowers on at all times is required for Type B2 (exhaust) and recommended for Type A2 (recirculated). If a Type A2 BSC is shut down, allow it to operate for at least 30 minutes before using it to ensure a clean, filtered environment. Do not use the BSC if an alarm is active. Keep the sash at the recommended height, and the drain valve (if present) closed during use. Do not block airflow by placing objects or arms on the front air grill or positioning supplies to block the rear grill.
- 4.3.2 Wear gloves, sterile sleeve covers, or appropriate covering over arms such as Tyvek®, throughout this procedure.
- 4.3.3 Prior to beginning work in the BSC, spray down the hood interior with disinfectant (refer to Section 4.1.2). Then wipe down the hood using low-lint, disposable sterile packaged wipes. Wipe the hood from top to bottom and back to front, finishing with the work surface and front grill.
- 4.3.4 When operations are complete, remove equipment, components, and materials from the hood. Spray down the hood interior with disinfectant allowing the required contact time. Then wipe down the hood using low-lint, disposable sterile packaged wipes. Wipe the hood from top to bottom and back to front, finishing with the work surface and front grill.
- 4.3.5 Once a month, during periods of use, clean the entire hood including all removable parts such as the screens and plenum with disinfectant. For Esco Biological Safety Cabinets refer to the Esco User and Service Manual, Class II Type A2 Biological Safety Cabinet for directions. Record the following information on **Form 19102-02**: date, time in, time out, disinfectant used, disinfectant release number, product or lot number, and initials.

**NOTE:** BSCs will be cleaned as part of area RTS following certification/service/or prolonged outage prior to environmental monitoring being performed.

- 4.3.6 Facilities, Maintenance and Engineering (FME) or a contracted vendor shall certify and perform preventive maintenance of BSC's according to National Sanitation Foundation/American National Standards Institute (NSF/ANSI) 49. BSCs are certified at least annually, with consideration for more frequent testing to occur after repair, relocation, or significant maintenance, or when BSCs are used for critical applications such as aseptic filling or cell banking. The BDP maintains records of certification and basic certification information. A certification label that includes the date of certification is placed on the front of the BSC by the technician performing the certification. The

due date for the next certification (effectively the certification expiration) may also be displayed.

4.3.7 All non-routine maintenance procedures, such as replacement of filters, blower motors, fans, belts, etc., will be handled by a vendor, contractor, or FME.

#### 4.4 Centrifuges

4.4.1 At the end of the centrifugation process, wipe off the interior and exterior of the rotor lid, the interior compartments of the rotor, and the interior and exterior of the centrifuge with disinfectant.

4.4.2 In case of a spill, remove the large O-ring from the rotor lid and wipe it off with disinfectant. Wipe off the O-ring space on the rotor lid. Apply fresh vacuum grease to the O-ring. Replace the O-ring on the rotor lid, return the lid to the rotor, and secure the centrifuge door.

4.4.3 Dispose of all waste using guidelines established by Environmental Health Safety Program (EHS).

4.4.4 Record the following information on **Form 19102-03**: date, time in, time out, disinfectant used, disinfectant release number, product or lot number, and initials.

4.4.5 Subject each ultracentrifuge rotor to an annual inspection by a qualified vendor to verify continued suitability for safe use.

### 5.0 Abbreviations

- 5.1 [REDACTED]
- 5.2 **BDP** – Biopharmaceutical Development Program
- 5.3 **BSC** – Biological Safety Cabinet
- 5.4 **EHS** – Environmental Health and Safety Program
- 5.5 **FME** – Facilities, Maintenance, and Engineering
- 5.6 **PN** – Part Number

### 6.0 Documentation Requirements

- 6.1 Document the routine monitoring and disinfection of lab incubators on **Form 19102-01 or -04**, Incubator Use, and Disinfection Log Sheet.
- 6.2 Document the use and decontamination of the BSC on **Form 19102-02**, Biological Safety Cabinet Use, and Disinfection Log Sheet.
- 6.3 Document routine cleaning/disinfection of centrifuge on **Form 19102-03**, Centrifuge Use, and Disinfection Log Sheet.
- 6.4 Logbooks should be kept for equipment listed in this SOP to record any other activities involving the equipment such as repairs or preventative maintenance as per **SOP 21531 - Equipment Logbooks**.
- 6.5 If equipment should fail, submit an Engineering Event Form, (**Form 21526-01**), as per **SOP 21526 - Engineering Event Management**, to BQA documentation.

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6.6 Document annual inspection of ultracentrifuge rotors in the equipment log for the centrifuge with which the rotor is presently being used.

## **7.0 References and Related Documents**

**SOP 21404** *Abbreviations Used in the Biopharmaceutical Development Program*

**SOP 21507** *Monitoring Temperatures with Chart Recorders*

**SOP 21526** *Engineering Event Management*

**SOP 21531** *Equipment Logs*

**SOP 22909** *Use, Cleaning and Disinfection of Equipment and Laboratories in PA/QC*

Esco User and Service Manual, Class II Type A2 Biological Safety Cabinet, Version A 2010

**Form 19102-01** Incubator Use, Disinfection, Maintenance, and Calibration (For CO<sub>2</sub> Incubators)

**Form 19102-04** Incubator Use, Disinfection, Maintenance, and Calibration (For Non- CO<sub>2</sub> Incubators)

**Form 19102-02** Biological Safety Cabinet Use, Maintenance, Disinfection, and Certification

**Form 19102-03** Centrifuge Use, Maintenance, Cleaning, Calibration and Disinfection Log Sheet