Frederick National Laboratory for Cancer Research, Frederick, MD

BIDP

Biopharmaceutical Development Program

Standard Operating Procedure

Title: Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, and Centrifuges

SOP Number: 19102

Revision Number: 10

Supersedes: Revision 09

Effective Date: JUN 26 2019

Originator/Date: [redacted]

Approval/Date: [redacted]

Approval/Date: [redacted]

Table of Contents

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 (BOP) 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***

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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 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)
- Sporicidin, BDP PN 30135 or equivalent
- 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.

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

4.1.4 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 19102-01A** or **Form 19102-01B**) each time the parameters of the incubator are changed.

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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. Otherwise, monitor the temperature if attached to a chart recorder per ***SOP 21507 - Monitoring Temperatures with Chart Recorders***. 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_2 percentage as directed by the area supervisor or BPR.

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

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.

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

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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 ATRF – Advanced Technology Research Facility

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**, 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.

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

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.

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

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

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

7.3 **SOP 21526** *Engineering Event Management*

7.4 **SOP 21531** *Equipment Logs*

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

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

8.0 Attachments

8.1 **Attachment 1** Form 19102-01-A, Incubator Use, Disinfection, Maintenance, and Calibration (For C_2 Incubators)

8.2 **Attachment 2** Form 19102-01-B, Incubator Use, Disinfection, Maintenance, and Calibration (For Non- C_2 Incubators)

8.3 **Attachment 3** Form 19102-02, Biological Safety Cabinet Use, Maintenance, Disinfection, and Certification

8.4 **Attachment 4** Form 19102-03, Centrifuge Use, Maintenance, Cleaning, Calibration and Disinfection Log Sheet

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

Attachment 1

Form 19102-01-A, Incubator Use, Disinfection, Maintenance, and Calibration (For CO_2 Incubators)

FNLCR, BDP
Form No.: 19102-01-A
SOP No.: 19102
Revision 09: JUN 26 2019

Biopharmaceutical Development Program
Equipment Logbook EL-XXXX-XXXX

Page 1 of 1

Incubator Use, Disinfection, Maintenance, and Calibration *(For CO_2 Incubators)*

Building/Room Number: _____ Incubator Name/Model: _____ MEF #_____

CO_2 Setpoint: _____ Min: _____ Max: _____

Temperature Setpoint: _____°C Min: _____°C Max: _____°C

Approved Disinfectants: **1**. Decon-Ahol (70% IPA); **2.** Sporicidin; **3.** Clorox Bleach Germicidal Cleaner, **4.** Cavicide. **5**. Steri-Perox
Rotate the use of at least two approved disinfectants using one per day of use of equipment, or one per campaign. After the incubator has been cleaned with Cavicide or Clorox Bleach Germicidal Cleaner, clean with Decon-Ahol to remove residue.

Date	Time	Temperature	CO_2	% RH	Disinfectant Used	Disinfectant Release No.	Product Lot Number or QC Test No.	Performed By	Activity/Comments

Reviewed By/Date: _____

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

Attachment 2

Form 19102-01-B, Incubator Use, Disinfection, Maintenance, and Calibration (For Non- CO_2 Incubators)

FNLCR, BDP
Form No.: 19102-01-B
SOP No.: 19102
Revision 09: JUN 26 2019

Biopharmaceutical Development Program
Equipment Logbook EL-XXXX-XXXX

Page 1 of 1

Incubator Use, Disinfection, Maintenance, and Calibration *(For Non-CO_2 Incubators)*

Building/Room Number_____Incubator Name/Model:_____MEF #_____

Temperature Setpoint: _____°C Min: _____°C Max: _____°C

Approved Disinfectants: **1.** Decon-Ahol (70% IPA); **2.** Sporicidin; **3.** Clorox Bleach Germicidal Cleaner, **4.** Cavicide. **5.** Steri-Perox

Rotate the use of at least two approved disinfectants using one per day of use of equipment, or one per campaign. After the incubator has been cleaned with Cavicide or Clorox Bleach Germicidal Cleaner, clean with Decon-Ahol to remove residue.

Date	Time	Temperature	Disinfectant Used	Disinfectant Release Number	Product Lot Number or QC Test No.	Performed By	Activity/Comments

Reviewed By/Date: _____

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

Attachment 3

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

FNLCR, BDP
Form No.: 19102-02
SOP No.: 19102
Revision 09: JUN 26 2019

Biopharmaceutical Development Program
Equipment Logbook EL-XXXX-XXXX

PAGE 1 OF 1

Biological Safety Cabinet Use, Maintenance, Disinfection and Certification

Building/Room Number: _____ BSC Make/Model: _____ MEF #_____

Approved Disinfectants: **1**. Decon-Ahol (70% IPA); **2.** Sporicidin; **3**. Clorox Bleach Germicidal Cleaner; **4**. Cavicide. **5**. Steri-Perox

NOTES:

- Cleaning by Clorox Bleach Germicidal Cleaner needs to be followed by a Decon-Ahol cleaning after the kill time has been met to remove residue.
- Rotate the use of at least two approved disinfectants using one per day of use of equipment, or one per campaign.

Date	Time In	Time Out	Disinfectant Used/Release No.	Product, Lot Number, or QC Test Number	Performed By	Activity/Comments

Reviewed By/Date: _____

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Attachment 4

Form 19102-03, Centrifuge Use and Disinfection Log Sheet

FNLCR, BDP
Form No.: 19102-03
SOP No.: 19102
Revision 09: JUN 26 2019

Biopharmaceutical Development Program
Equipment Logbook EL-XXXX-XXXX

Page 1 of 1

Centrifuge Use, Maintenance, Cleaning, Calibration, and Disinfection

Centrifuge Name/Model: _____ Building/Room No. _____ MEF Number _____

Approved Disinfectants: **1**. Decon-Ahol (70% IPA); **2**. Sporicidin **3**. Clorox Bleach Germicidal Cleaner; **4.** Cavicide. 5. Steri-Perox
If Clorox Bleach Germicidal Cleaner is used follow with Decon-Ahol to remove residue.

Date	Time In	Time Out	Rotor	RPM	Temp. °C	Disinfectant Used	Disinfectant Release No.	Product & Lot Number*	Activity/ Comments	Performed/ By

*Or Sample Number

Reviewed By_____Date_____

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