Design and Certification of HEPA-filtered Containment Cabinets

SOP 26104 **Rev. 04**

Table of Contents

1.0 Purpose

This procedure outlines the design and certification of negative pressure, HEPA-filtered containment cabinets for use in protecting the operator from aerosol and spill containment.

2.0 Scope

Individuals who specify for procurement and certify HEPA-filtered containment cabinets shall follow this procedure. This SOP does not apply to Type II laminar flow Biological Safety Cabinets (BSC) or to equipment designed exclusively for providing a cleaner environment under positive pressure conditions. It applies only to Type I BSCs that are designed and or fabricated internally. Testing of any enclosure that meets Type I specifications will follow NSF/ANSI 49 Current Edition testing procedures.

3.0 Authority and Responsibility

3.1 The Associate Director, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 BDP Engineering is responsible for approval of design criteria and materials of construction.

3.3 Environmental, Health and Safety (EHS) is responsible for design, review, and approval of all scientific procedures employed in these cabinets.

3.4 Facilities, Maintenance and Engineering (FME), may design/review, construct and/or install and test these cabinets.

3.5 Testing/Certification is typically performed by the contracted BSC certifier or equipment vendor.

3.6 The BDP Facility Manager or Validation Manager is responsible for updating this SOP as necessary.

3.7 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Overview

4.1 Whenever possible, the preferred negative equipment enclosure will meet Class I BSC specifications as it greatly simplifies the testing process while potentially minimizing airflow testing.

4.2 Containment cabinets may be commercially procured or contracted for construction by Facilities, Maintenance and Engineering (FME) or an external contractor.

4.3 These cabinets are designed for research and production activities with low and moderate risk agents and are useful for containment of high-pressure chromatography equipment, disposable culture systems, or for analytical equipment. These cabinets are only designed to protect personnel and offer no additional protection to the product as there is inward flow of unfiltered air from the room. Devices that protect personnel and product are Class II.

5.0 Engineering Design

5.1 Materials of Construction (MOC) may vary but must be able to withstand the corrosion potential from routine disinfectants which may contain sodium hypochlorite and buffers used in production, support the HEPA filter box(es) and exhaust blower or connections as applicable, and withstand relocation if required by design. Stainless steel and plexiglass and approved and other materials may be used provided they are approved by EHS and BDP Engineering/Validation.

5.2 Cabinets will be constructed with blower motors and HEPA filter boxes to filter exhaust air from the enclosure. For new systems a minimal flow of 80 cfm is suggested. Consult with EHS if there are constraints in achieving this value.

5.3 containment Cabinet installations will be designed to be negative pressure. If the enclosure does not meet Type I criteria for flow, it will require airflow visualization testing to ensure that containment is maintained.

5.4 Cabinets are preferably equipped with differential pressure monitors for reference of air flow direction and verification of negative pressure or alarms for low air flow.

5.5 Cabinets should be designed to contain the volume of the largest possible spill of the equipment enclosed, plus the required volume of decontaminant to treat the spill.

6.0 Airflow Visualization Testing

6.1 Perform testing with the equipment to be contained in place. The equipment within should be specified on the testing documentation, preferably by MEF and description. Placement within the enclosure could impact performance and placement which allows desired flow should be recorded.

6.2 Testing should first evaluate static conditions and then dynamic conditions. If the contained equipment has fans or other components which could impact airflow these must be operating at the highest setting during dynamic testing as this represents the worst case for airflow disturbance. Dynamic testing should evaluate routine operation and any non-routine activity that may be needed during active containment prior to decontamination. Be sure to

consider operator access via the enclosure and opening of equipment panels during the evaluation.

6.3 Testing results from airflow visualization or certification may determine or restrict the maximum enclosure opening during operation or limit certain usage.

7.0 Containment Cabinet Certification

7.1 Following installation, certification is required.

7.2 Facilities, Maintenance, and Engineering (FME) or an outside contractor will provide certification of equipment in service at least annually for containment cabinets covered under this SOP according to the testing standards outlined in NSF-49, current edition. The integrity of the HEPA is tested and the airflow is measured.

7.3 Units not compatible with NSF-49 airflow specifications will rely on HEPA testing and airflow visualization to verify flow directionality at a minimum.

7.4 Units shall be stickered with a label showing the date of certification and recertification date at a minimum. It is understood that all NSF based tests may not be performed for all enclosures. Paperwork and unit labels as applicable shall clearly indicate testing performed.

8.0 References and Related Documents

NSF/ANSI 49 Current Edition.

9.0 Change Summary