Biological Risk Management and Containment

Biological Safety Cabinets

Equipment Types and Certification

Containment Laboratory Guidelines

Version 3- February 2021

Approved by: Vice-Chancellor
Document Owner: Associate Director, Health, Safety and Wellbeing
Content Manager: Manager, Hazard and Containment

Version: 3
Issue Date: 16 Feb 2021

This document was originally Version 2 which was extensively reviewed and approved in February 2021.

Record of Amendments to Version 3

Date	Page number	Nature of amendment

Contents

1. Who are these guidelines for?

These guidelines are intended for **principal investigators (PIs), designated persons in charge, designated laboratory person (DLPs)**, technical staff and students trained in the safe use of **risk biologicals** in appropriate containment facilities.

2. What are biological safety cabinets used for?

Biological safety cabinets (BSCs) are the primary means of containment in process support laboratories and during the early stages of culture development.

Based on design and the protection afforded, BSCs are designated as Class I, II, and III.

The capabilities of the various classes of BSCs and the distinctions between subtypes is summarised in Tables 1 and 2 below.

Table 1: Capabilities of BSC classes

Cabinet class	Product protection	Personnel protection	Environment	PC level
I	No	Yes	Yes	1-3
II (A and B)	Yes	Yes	Yes	1-3
III	Yes	Yes	Yes	4

Note that laminar flow "clean benches" are not biological safety cabinets. They do not offer any operator protection and must not be used to handle pathogenic or potentially pathogenic micro-organisms.

Table 2: Distinctions between BSC classes

Class		Inflow velocity (m/s)	Recycled air (%)	Exhaust air (%)	Control plenum surrounded by	Exhaust
I		0.38	0	100	Outside air	Hard duct

II	(Type A1)	0.38	70	30	Outside air	To room
II	(Type A2)	0.5	70	30	Negative plenum	To room
II	(Type B1)	0.5	30	70	Negative plenum	Hard duct
II	(Type B2)	0.5	0	100	Negative plenum	Hard duct
III		Closed (>125Pa differential Pressure)	0	100	Negative plenum	Hard duct

3. BSC classes

3.1. Class I BSCs

Class I cabinets (Fig.1) do not protect the work area against microbial or particulate contamination (i.e. they do not offer any product protection). The operator is protected so long as a minimum linear air velocity of 0.4 m s^{-1} is maintained through the front opening. The cabinet is hard-ducted to the building exhaust system (Fig.1).

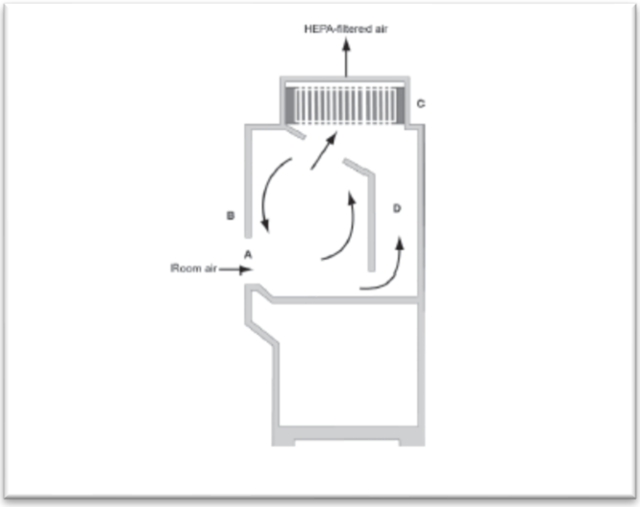

Figure 1 – Class 1 Biological Safety Cabinets

Note that only the exhaust air is HEPA filtered, and the air within the work area is not HEPA filtered

3.2. Class II Type A BSCs

The Class II Type A biological safety cabinet is the most common Class II cabinet. It is also the most common of all the different types available. It has a common plenum from which 30% of air is exhausted, and 70% re-circulated to the work area as the down flow.

Type A cabinets exhaust air directly back to the laboratory, and they may contain positive pressure-contaminated plenums. When toxic chemicals must be employed as an adjunct to microbiological processes, these cabinets should not be used. Exhaust HEPA filtration only removes airborne aerosols (including biohazards), and not chemical fumes.

The Class II Type A1 has the positively-pressurised contaminated plenum bordering the ambient environment, and therefore is less safe than the Class II Type A2 that has a negative pressure surrounding the positively pressurised contaminated plenum. In case there is a leakage on the positive plenum, the leaking aerosol will be pulled by the negative pressure back to the positive plenum, so that it does not leak out. Because of this safety issue, the Type A1 design is now considered obsolete.

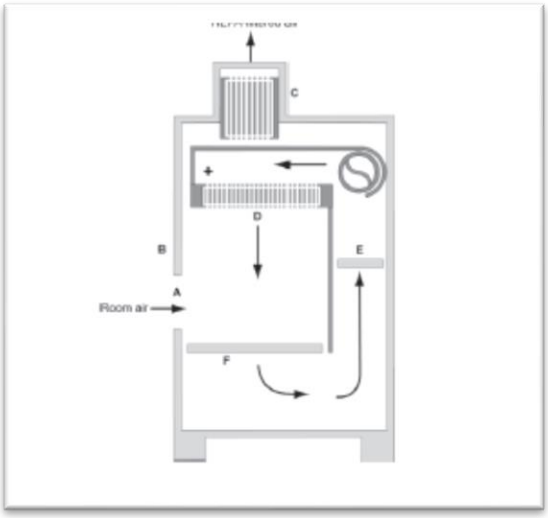

Figure 2: Class II A2 BSC

Note: The positive plenum (the area next to the fan and above the work area) is surrounded by negatively pressured areas and the exhaust for Class 2A BSCs is not hard-ducted.

The work area is bathed in downward laminar flow of particle-free, recirculated air. In addition, air from the room is drawn in through the front opening to prevent leakage of aerosols and contaminated air. The linear air flow rate at the opening should be 0.4 m s-1 or greater. HEPA filtered air may be exhausted into the laboratory as in Class II Type A cabinets (Fig. 2).

3.3. Class II Type B BSCs

Class II Types B1-3 are hard-ducted to the building exhaust (Fig 3). Type B1 cabinets recirculate part of the air over the work area, hence they may be used to process only minute amounts of volatiles. Type B2 cabinets are total exhaust devices that may also be used for some chemical containment, so long as the fumes are not susceptible to electrical ignition. As a general rule, no class of BSC is suited to handling volatile toxic substances, but non-volatile toxic chemicals can be handled in all classes of BSCs.

Class II Type B3 cabinets are ducted Type A cabinets that, like Type B cabinets, provide a minimum linear air velocity of 0.5 m s^{-1} at the opening. All positive-pressure-contaminated plenums within a Type B3 cabinet are surrounded by negative-pressure chambers to prevent leakage into the environment.

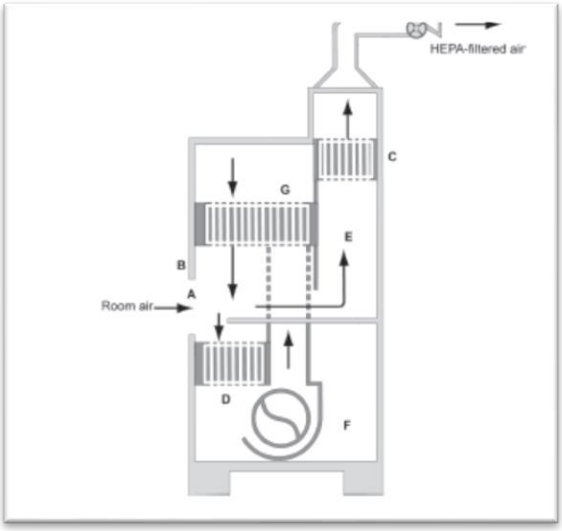

Figure 3: Class II B1 BSC

Note: The exhaust for Class 2B BSCs is hard-ducted.

3.4. Class III BSCs

Class III biosafety cabinets (Fig. 4) are designed for handling Risk Group 4 biohazard agents. The cabinet is a fully sealed chamber with HEPA-filtered air inlet and exhaust. The front end is provided with a sealed window and ports with heavy-duty, arm-length rubber gloves. Access to the chamber is through a side-mounted, disinfectant-filled dunk tank or through a sterilisable double-door pass-through such as an autoclave. The operator, the environment and the work area are protected. Air from Class III cabinets is to be exhausted through two HEPA filters in series, or one HEPA filter and an incinerator. A dedicated, independent exhaust system exterior to the cabinet is used to maintain air flow. The enclosed work chamber is kept at a lower pressure than the laboratory (i.e. a 125 Pascal pressure differential is maintained at all times). Class III cabinets are usually installed only in maximum containment (PC4) laboratories that have other suitable safeguards.

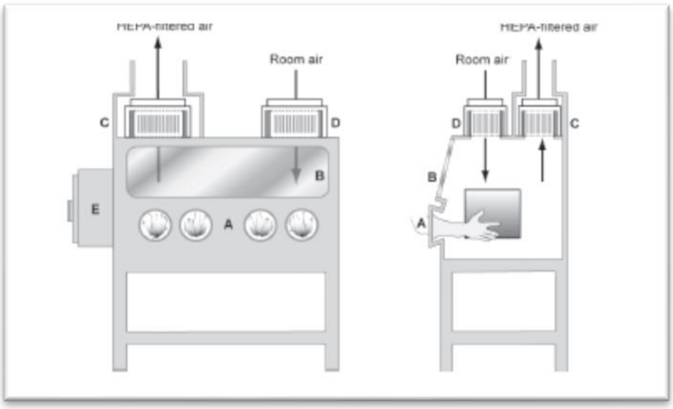

Figure 4: Class III BSC

4. HEPA filters in BSCs

Biological safety cabinets rely on HEPA filters at air exhaust and/or intake to provide the required protection to personnel, product and the environment. Generally, HEPA filters are rated to remove particles down to 0.3 mm with an efficiency of 99.97 %, but more expensive higher efficiency filters are available (99.99 % or higher). The 0.3 mm particles are least easily filtered compared with larger or smaller particles; hence that size is used for HEPA filter performance specifications. Filters are susceptible to shock-induced mechanical damage, therefore, performance and integrity of a BSC is to be certified after initial installation, after relocation, after repair, and at yearly intervals.

Figure 5: HEPA filter construction

Note: the pack is glued into a frame which is gasketed to form the final assembly.

HEPA filters should be decontaminated prior to replacement. Decontamination is usually done with formaldehyde or hydrogen peroxide vapour, and decontamination provisions should be provided during installation. Class II cabinets usually have sensors for monitoring the pressure drop across the HEPA filter, and a low exhaust flow alarm is provided.

5. Installation of BScs

Refer to Expert User Guide on Location and Use of Biological Safety Cabinets

6. Testing and certification of BSCs

All biological safety cabinets are to be tested on installation and thereafter annually against a number of standards (depending on the standard under which they were designed):

1. Biological safety cabinets designed and installed against AS/NZS 2252.2 are to be certified against test methods specified in AS 1807, i.e. Test Methods AS 1807.1, 5, 6, 15, 20, 22 and 23.

2. Biological safety cabinets designed against European standards (e.g. Heraus) are to be certified against test methods specified in EN1249.
3. Biological safety cabinets designed against United States standards (e.g. NuAire) are to be certified against test methods specified in NSF ANSI 49.

Testing is also to be undertaken whenever the BSC is moved.

The specific certification tests depend on the type of cabinet. Some essential tests include the down flow velocity and volume testing (Class I and II); the inflow velocity test (Class I and II); the negative-pressure testing (Class II and III); air flow smoke patterns tests (Class I and II); the HEPA filters leak tests (Class I-III); the cabinet leak test (Class II and III); and testing of alarms and interlocks (Class III).

7. Definitions

Designated laboratory person (DLP) means the trained person in each research group who has been given the authority to receive purchase requests made in SQERM and to make a formal request for a purchase order via PeopleSoft. In containment and transitional facilities DLPs will have additional training to enable them to scrutinise documentation for restricted items and provide support to researchers.

Designated person in charge means a staff member in any of the following roles: sector manager, facility manager, floor manager, technical manager or an appointed delegate.

Principal Investigator (PI): In the context of hazard containment and transitional facilities, a principal investigator is the holder of an independent grant administered by the University and the lead researcher for the grant project, usually in the sciences, such as a laboratory study or a clinical trial. The phrase is also often used as a synonym for "head of the laboratory" or "research group leader." The PI is responsible for assuring compliance with applicable University standards and procedures, and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks, they retain responsibility for the conduct of the study.