University Occupational Health and Safety Guidance Notes

SAFE USE OF MICROBIOLOGICAL SAFETY CABINETS

1. PURPOSE

This document details the technical and management requirements for the safe use of microbiological safety cabinets used for handling biological material. It includes the selection, installation, commissioning, use, maintenance and testing of the microbiological safety cabinet. It should be used in conjunction with the Occupational Health and Safety Biological Safety Standard.

2. SCOPE

This document applies to those who are responsible for the management and maintenance requirements of the microbiological safety cabinets and to all users.

3. ABBREVIATIONS

COSHH	Control of Substances Hazardous to Health
DBSC	Departmental Biological Safety Co-ordinator
DSC	Departmental Safety Convenor
HEPA	High Efficiency Particulate Air filter
HG	Hazard Group
HoD	Head of Department
LEV	Local Exhaust Ventilation
MSC	Microbiological safety cabinet
SHaW	Safety, Health and Wellbeing
OPFT	Operator Protection Factor Test
PI	Principle Investigator

4. DEFINITIONS

4.1 HEPA filter

A filter that is commonly used for work with biological agents and is an integral component of the MSC. It is capable of filtering very small particles.

4.2 LEV system

A ventilation system that takes hazardous gases, vapour, fume, mist, dust and other aerosolised particles out of the air to prevent inhalation.

4.3 Microbiological Safety Cabinet

As defined in the European Standard (BS EN 12469:2000), a "Ventilated enclosure intended to offer protection to the user and the environment from the aerosols arising from the handling of potentially hazardous and hazardous micro-organisms, with air discharged to the atmosphere being filtered".

5. SPECIFIC RESPONSIBILITIES

5.1 Head of Department

Have ultimate responsibility for the management of MSCs within their department although duties may be delegated to designated individual(s) within the department such as the DBSC or DSC. The HoD must:

- Appoint a member of their departmental staff to manage MSCs within their area of control;
- Incorporate areas of improvements into the objectives for the Annual Safety Report.

5.2 Biological Safety Co-ordinate/Departmental Safety Convenor or other person nominated by the Head of Department

The person responsible for the management of MSCs within the department, as nominated by the HoD, must ensure that:

- Estates Services are liaised with regarding the installation of, commissioning of, and the maintenance of MSCs;
- Where existing MSCs are repaired, serviced or moved that they pass relevant tests before being permitted to be used with hazardous biological agents;

- MSCs are subject to regular examination and testing by a competent person;
- MSCs are subject to additional airflow monitoring where determined by the risk assessment;
- A system is in place to record the location of and the results of the examination and testing;
- There is a process for identifying, recording and reviewing COSHH and general risk assessments involving the use of MSCs;
- All users of MSCs are suitably trained and competent in their safe use;
- All users of MSCs are aware of the procedure to follow where a fault occurs;
- MSCs are effectively decontaminated prior to an engineer carrying out servicing, examination and testing, and also where an MSC is decommissioned.

5.3 Users of MSCs

All users of MSCs must:

- Have, as a minimum, undertaken the Biological Safety online modules 1-3 before working with any biological agents;
- Use the MSC in accordance with any training received;
- Under fault conditions, render safe any work and discontinue use of the MSC. Report any faults promptly to the lab manager/line manager/technician or other responsible person as detailed during training. Discontinue use of the MSC until the fault has been investigated and rectified.

6. CLASSIFICATION AND SELECTION OF MSCs

A risk assessment must be undertaken to determine the class of MSC that is appropriate for the nature of the work. The class of MSC is not directly associated with the containment level or hazard group of the biological agent being used, and they must not be confused with laminar flow cabinets or fume cupboards.

There are 3 types of MSC that are in common use:

6.1 Class I

An open fronted MSC designed to **protect the operator** by continuously drawing air into the front of the MSC. Air is filtered through a HEPA filter before being discharged to the outside atmosphere. See Figure 1A for further details. This type of MSC is used for working with microorganisms up to HG3 where there is the likelihood of the production of infectious aerosols. It does not provide protection to the work.

6.2 Class II

An open fronted MSC designed to protect the operator from exposure and protect the work from external contamination. Inward air is directed downwards below the work surface and is filtered before being redirected into the work area as a laminar down flow of clean air. See Figure 1B for further details. The balance of this down flow air with the incoming air provides an air curtain at the front and therefore provides operator protection, which with good technique and proper user positioning and MSC siting, should be equivalent to that of Class 1 MSC. Their performance is, however, more affected by other factors such as operator movement and air movements inside the MSC.

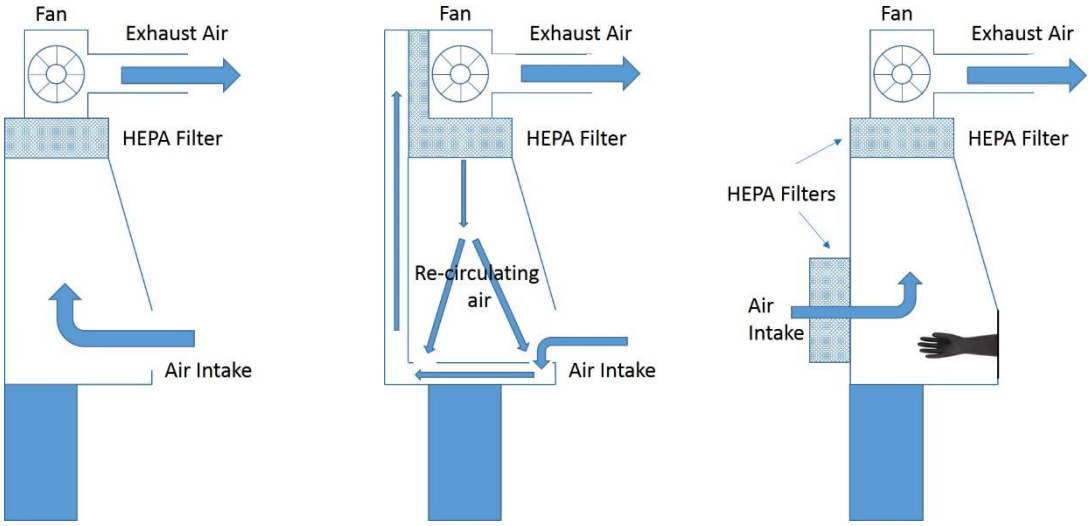
Class II MSCs are must be used for all work involving the use of human blood, blood products and bodily fluids (see Guidance for 'Working with Blood, Blood Products and Bodily Fluids') where aerosols may be generated. MSCs are not normally designed to contain radioactive, toxic or corrosive substances though a special type of Class II MSC where only 30% of the air is re-circulated is available for work with large volumes of carcinogenic and toxic compounds. Ideally this type of MSC should exhaust to outside atmosphere.

6.3 Class III

A closed MSC designed to provide total operator protection and protection for the work. It is completely sealed and air is drawn in through a HEPA filter and exhausted to the outside

atmosphere through another HEPA filter. See Figure 1C for further details. The operator works in the MSC using integrated rubber gauntlets.

Class III MSCs are used mainly for work with HG3 or 4 organisms. They offer the greatest protection to the worker and work, but movements are more restricted and this may affect dexterity. The University of Strathclyde must not handle HG3 or 4 organisms other than authorised HG3 derogated material.



A. Class I **B. Class II** **C. Class III**

Figure 1. Classification of MSCs

6.4 Ultra Violet (UV) light

The use of UV light for the purpose of disinfection is not recommended. If UV installation is insisted upon by the user/purchaser, the following conditions should be met:

- UV lighting must be installed in a manner that cannot affect the performance or durability of the MSC, thus only materials that are unaffected by UV rays should be used for the construction and coating of the MSC;
- Electrical interlocking must be fitted and operational to prevent direct operator exposure to UV light;
- The efficacy of the microbiocidal activity of the light must be monitored regularly but should not replace effective sterilisation; and
- The lamp must be changed whenever its efficacy is reduced (or regularly at a pre-determined frequency that ensures the light is still effective).

UV now falls within the Control of Artificial Optical Radiation at Work Regulations (AOR), 2010. These regulations aim to protect staff and others from experiencing adverse health effects to the skin and eyes and require that equipment sources with UV are risk assessed and that suitable control measures are implemented and used where necessary including information and training, and the use of appropriate warning signs.

Further information: OHS Standard Artificial Optical Radiation

7. MSC INSTALLATION PROJECT MANAGEMENT

7.1 Design

It is the responsibility of the Estates Services Project Manager to work with the Department to consider both the siting and the final exit point of the extract from the University building. **The discharge point should not be near an air intake.**

There are four major components that contribute to ensuring safe working with MSCs:

- The design, construction and function of the MSC itself;

- Good laboratory design (specifically with respect to MSC location and room ventilation);
- Safe systems of work that incorporate good operational technique; and
- Regular appropriate testing and maintenance.

7.2 Siting of MSCs

MSCs should be sited to minimise disturbance of the airflow at the front of the cabinet, as shown in Figure 2. The British Standard, BS 5726:2005, gives further recommendations on siting. For new MSCs the supplier should visit the site, undertake a site survey and advise on installation. Particular care must be taken in locating re-circulating MSCs where the exhausted air may cause air disturbance at the front of the cabinet, adversely affecting containment performance. The key issues are that:

- the MSC is located with sufficient clearance from walls, corners and doorways;
- no obstacles are placed where they may interfere with the airflow; and
- sufficient room is provided for the operator to avoid interference with other workers.

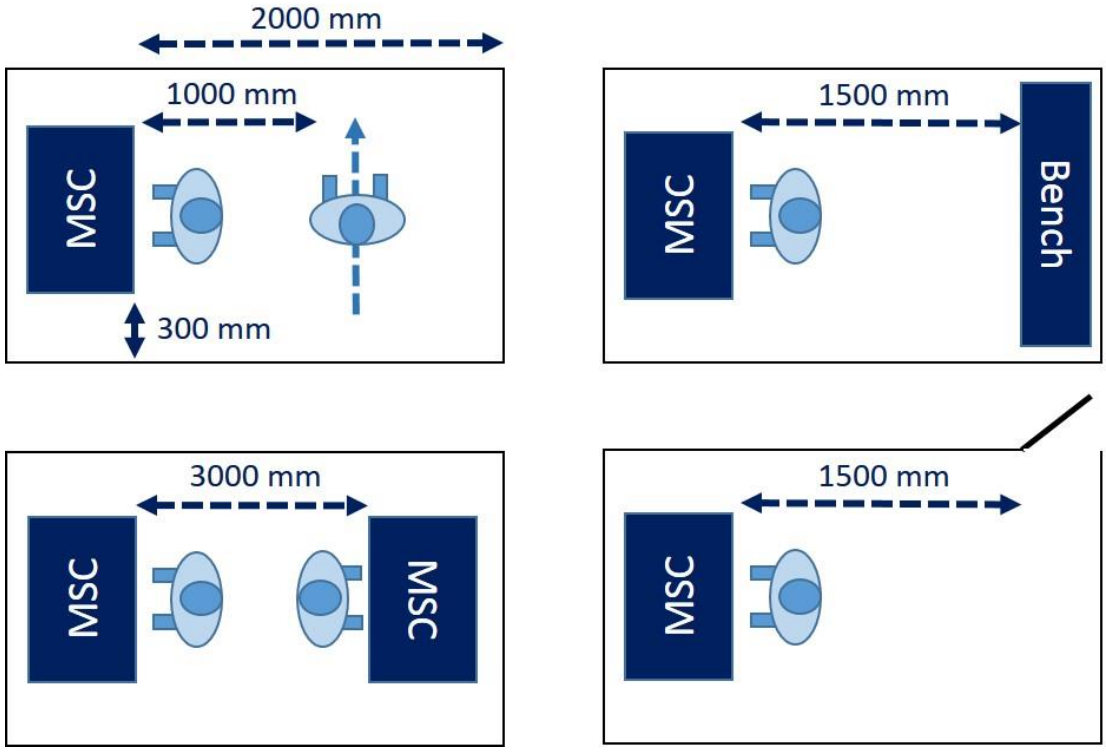


Figure 2. Correct siting of MSCs.

7.3 Installation and Commissioning

BS 5726:2005 gives recommendations and guidance on information to be supplied by the purchaser to the vendor and to the installer, on siting, and on use, of MSCs. Installation is normally carried out by the supplier or an experienced agent. However, they should discuss the siting of the MSC with the Project Manager and the department to ensure that the position chosen is consistent with maintaining the required level of safe performance. Factors to be considered include the proximity of the MSC to doors, windows, ventilation ducts and to movement routes (See Figure 2 and BS 5726:2005).

Preliminary tests with smoke tubes may help select the optimum position of the MSC. Once installed, commissioning tests should be conducted to verify the performance of the MSC in situ. The importance of installation testing cannot be over emphasised; it demonstrates the MSC's performance and level of protection achieved in practice.

It may also be necessary to carry out additional thorough inspection and testing when changes have been made to the laboratory that may affect the containment performance of the MSC.

Following installation, all required information must be supplied, recorded and held with both the department concerned and Estates Services. Prior to use, commissioning must be carried out, a record made and a copy provided to the department.

No LEV system, including MSC's, should be utilised in any way until commissioning has taken place. If a repair to a major part of equipment or re-siting of the MSC is deemed necessary then following its installation, the MSC should be re-commissioned prior to commencement of usage.

7.4 Venting of Exhaust Air from MSCs

The **preferred** option for venting MSCs is to duct the exhaust air to the exterior of the building. This option confers some significant advantages:

- the MSC exhaust can provide a cheap and simple method of keeping a containment laboratory under negative pressure;
- the discharge of fumigant gas after decontamination of the room or the MSC is made significantly easier; and,
- there may be occasions when a worker needs to treat cultures with small amounts of volatile toxic chemicals in which circumstances discharging the exhaust air back into the laboratory would not be acceptable.

In CL2 facilities, where it is clear that the only risk in the work is microbiological and no toxic chemicals are involved in the work, it is acceptable for MSCs to discharge the exhaust air into the workroom. However, in these circumstances the exhaust **must** be filtered through 2 HEPA filters in series. If re-circulated MSCs are in use, then fumigation and subsequent clearing of fumigant **must** be considered as part of the risk assessment for the work.

7.5 Performance standards

The British Standard, BS EN 12469: 2000, sets out the minimum performance criteria for MSCs used with biological agents and specifies test procedures with respect to protection of the worker and the environment, product protection and cross contamination. It gives detailed information on volumetric airflow rate measurements, airflow patterns, HEPA filter testing and also tests for determination of product protection and leak tightness.

8. MAINTENANCE AND TESTING

There are various testing and maintenance requirements for MSCs as stated under both the British Standards and as a legislative requirement under COSHH. Before any maintenance activities are carried out, the engineer must be given a written assurance that the cabinet has been decontaminated if it has been used for work with any infectious material (see also Section 9 Fumigation).

8.1 Statutory requirements

Under COSHH, MSC's come under the term "local exhaust ventilation" (LEV) and as such must be subject to thorough examination and testing at intervals of not more than 14 months. For ease of organising this maintenance within the required timeframe, it is recommended this is undertaken on an annual basis. A list of approved technical service providers who can carry out this examination for the University can be supplied by Estates Services.

All records of examination and testing must be kept for a minimum of 5 years and be available for inspection if required.

It may also be necessary to carry out additional testing when changes have been made to the laboratory that may affect the containment performance of the MSC.

8.2 Testing and Servicing of MSCs

For Class II MSCs used for work with biological agents, additional appropriate 'in use' tests which reflect normal operating procedures in the laboratory may be required where work is proposed with HG2 agents. Two examples of additional 'in use' tests are:

- The four-headed test as specified in the British Standard (but without the artificial arm) with an operator in position with both hands and lower arms within the MSC throughout the test. The operator should perform repetitive and continuous procedures (e.g., pipetting to and from a multi-well plate and a bottle with a suitable automatic pipette); and
- The same test but with a second person wearing a properly fastened laboratory coat or gown walking backwards and forwards behind the operator at approximately 100 paces per minute at the rate of 3 to 5 passes per minute.

Should MSCs be moved to a new position then full commissioning tests **must** be carried out as mentioned above.

A record should be kept of all testing and maintenance work done on MSCs and it is useful to indicate on each cabinet, the type of cabinet (e.g. Class I) and when servicing is due to be done.

If any of these additional tests are required, then the servicing company must be given advanced warning to enable the correct testing equipment to be sourced.

8.3 Operator Protection Factor Test – The KI Discus Test

This is referred to in the standard as the Aperture Protection Factor (APF). BS EN 12469:2000 differs from the previous British Standard in that the need to carry out an OPFT at installation and during subsequent routine maintenance testing is now only optional. However, to satisfy COSHH requirements and to ensure that control measures are performing as intended, it is recommended as best practice that an OPFT is carried out in addition to the tests specified by BS EN 12469:2000 at intervals not exceeding 14 months.

8.4 Airflow monitoring

In addition to the airflow measurements that are made by the engineer during the annual thorough examination and testing, MSC inflow airflow must also be tested by a nominated person(s) at least monthly, and downflow measurements 6-monthly. Records of these measurements must be kept by the department. The 'Class II Microbiological Safety Cabinets Monthly Airflow Check Form' is available to keep a record of the check.

Vane and hot rod anemometers are available for loan free of charge from the SHaW office. Anemometers, as with all other equipment taken into laboratory areas where infectious material is handled, must be effectively decontaminated prior to removal from the laboratory and return to the SHaW office. See Section 11.1 for training requirements.

Further information on monitoring inflow velocity can be found in the 'Management and operation of microbiological containment laboratories'.

9. MSC FUMIGATION

The risk assessment process should identify conditions that determine the need for MSC fumigation, for example HEPA filter disposal (See Section 10) or in the event of a spillage within the cabinet. The type of cabinet, whether ducted or re-circulated, should be considered as part of the risk assessment. The use of formaldehyde is generally discouraged unless identified by the risk assessment. The method of decontamination used must be validated for the biological agents that may be contaminating the MSC.

Further information: Contact the DBSC or the UBSA.

10. DISPOSAL OF FILTERS

HEPA filters must be replaced as and when users identify via their own airflow monitoring checks or when an engineer identifies that the filters are blocked as part of the routine testing of

the MSC. A permit to work must be issued to the engineer before entry to the lab and before work on the MSC is allowed to commence.

HEPA filters should be decontaminated in situ prior to disposal where they have been used for work with HG2/Class 2 or higher biological agents, unscreened human tissues or human primary cell cultures. The requirement for, and the method of, decontamination of HEPA filters must be by risk assessment.

HEPA filter disposal should be by double bagging and final disposal via either the clinical waste route or hazardous waste route dependent on the outcome of the risk assessment and will largely depend on the decontamination method used.

Further information: Contact the DBSC or the UBSA.

Further information: Contact Estates Services for clinical waste and hazardous waste disposal routes.

11. TRAINING, COMPETENCE AND SAFE USE OF MSCs

11.1 Management of LEV systems

Participation in the 'Practical Management of Local Exhaust Ventilation' is mandatory for all persons (including technical or academic staff) who may be required to advise on the design and installation of LEV systems to control airborne contaminants or those who are responsible for the management and effective operation of LEV systems.

11.2 All users of MSCs

All users of MSCs must be trained in the safe use of any MSCs that they work with. Training should be achieved locally within departments and will usually be practical in nature. Competence should be demonstrated prior to undertaking any independent work with biological agents within the MSC. Training and competence may be recorded by using the 'Training and Competence Record'. Basic training should include:

- Classification of MSCs.
- Principles of how MSCs work, including airflow and limitations.
- Appropriate and inappropriate use of MSCs.
- How to operate and work safely within MSCs.
- Recognition of faults and appropriate action to take.
- Decontamination of the MSC.

Guidance for the safe use of MSCs is provided in the following sections.

11.2.1 Prior to Use

Pre-use preparation of both the MSC and the work should be carried out, including:

- Put on the appropriate protective clothing according to the level of containment and the risk assessment for the work.
- Remove the night door or open the sash.
- Ensure that the MSC is switched on and running for sufficient time to allow air-flow stability before starting the work.
- Do not use unless the airflow indicator is registering in the 'safe' zone and no alarms are sounding.
- Prepare thoroughly for the work, e.g. number or tubes, flasks, dishes etc., organise media, solutions, etc. (a check list may be useful, and/or referral to protocols, codes).
- Ensure active solutions of appropriate disinfectants (and granules or powders as required) are available according to arrangements and in the proper container.
- Ensure the inside of the MSC is clean and free of clutter. It is commonly good practice, prior to commencing work, to clean the outer window with 70% Ethanol, then clean the interior of the window and the surface of the MSC.
- Ensure the laboratory door is closed.
- Ensure any equipment required for the work is available and ready for use;
- Care must be taken in the selection of equipment in order to minimise the disruption to the air flow.

- Place work items in the MSC, ensuring clean and dirty materials are kept separate.

11.2.2 During Use

Whilst working at the MSC safety precautions should be taken, including:

- Never use a MSC if its operational safety is in doubt. If the alarm sounds, make the work secure, for open-fronted MSCs place the front on the cabinet/close the sash, and inform the appropriate responsible person according to local arrangements.
- Do not overcrowd the MSC.
- For open-fronted MSCs, always work as near to the centre of the work area as possible, but at least 15 cm from its front.
- For Class II MSCs, never obstruct the air in-flow grill or any exhaust grills.
- Obstructions will adversely affect performance, in particular operator protection. Large equipment (e.g. centrifuges, especially air-cooled models) should not be used within an open fronted MSC unless appropriate testing has been done to establish that containment performance is maintained.
- All other authorised users of the facility should be discouraged from making movements that may affect the performance of the MSC.
- Avoid passing potentially infected material over clean material.
- Clean any spills up immediately and according to training.
- Dispose of equipment and contaminated material appropriately after use. Wherever practicable at CL2, this means disposal into appropriate and approved containers or into a discard jar within the MSC.

11.2.3 After use

Actions are required after completing work in the MSC include:

- Wipe down flasks and containers etc. with an appropriate disinfectant before removing from the MSC.
- Ensure that all containers for autoclaving and incineration are labelled correctly and secured. Only remove contaminated materials from the MSC as directed by local arrangements.
- Wipe all surfaces with disinfectant and discard tissues into an autoclave waste bag - do not place into the normal waste stream.
- Let fan(s) run for at least 5 minutes before next user.

12. FACTORS AFFECTING MICROBIOLOGICAL SAFETY CABINET PERFORMANCE

Inward airflow to Class I and II MSCs can be disturbed by a number of factors including:

- Sudden movement of the arms of the operator and turbulence in and around the equipment placed inside the MSC;
- Movement of personnel walking behind the operator;
- Centrifuges should not be placed in or near MSCs unless they are totally enclosed or an OPFT shows that the centrifuge does not affect the containment level;
- Bunsen Burners - these are not recommended for use in MSCs because of concerns regarding the effect of a localised heat source on airflow patterns and the obvious fire risk to the filters; and
- Other factors - open windows and doors and other changes in air pressure may significantly affect the level of protection for the operator.

Inflow should be recorded monthly, see Section 8.4.

13. DECOMISSIONING OR RELOCATION OF MICROBIOLGICAL SAFETY CABINETS

MSCs must be decontaminated prior to decommissioning. Decontamination is subject to risk assessment and may involve the decontamination of the HEPA filters (see Section 10). It is the responsibility of the PI to ensure that any cabinet that has been used during the course of their research is made safe prior to its decommissioning or where the cabinet is to be relocated. Written assurance must be provided to the engineer, prior to maintenance being carried out, that the cabinet has been decontaminated if it has been used for work with infectious biological

agents. Once decontaminated the MSC must be labelled as such by displaying a certificate of decontamination in a clearly visible location on the MSC.

Access to containment laboratories is restricted and access should be controlled by a formal permit to work system. For further information on restricted access to containment laboratories see Section 6.12.3 of the OHS Biological Safety Standard.

Further information: 'Procedure for vacating or decommissioning rooms'.

14. FURTHER INFORMATION AND GUIDANCE

- The Control of Substances Hazardous to Health Regulations 2002
- BS EN 12469:2000 – Biotechnology-Performance criteria for microbiological safety cabinets
- BS 5726:2005 Parts 1-4 – The selection, installation and maintenance of microbiological safety cabinets
- The Control of Artificial Optical Radiation Regulations 2010