



# Microbiological Safety Cabinets

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# Discussion

- ▶ COSHH
- ▶ Cabinet Classifications
- ▶ Siting & Installation
- ▶ Commissioning
- ▶ Testing Requirements
- ▶ Handover - Contractors and Cabinet usage



# Risk Assessment - COSHH Reg 6 - Identify the hazards

## The Approved List of biological agents

**Must** be used during Risk Assessment!

Advisory Committee on Dangerous Pathogens



# Risk Assessment - COSHH Reg 6 - Identify the hazards

► E.g. to what **Hazard Group** does the pathogen belong?

Information box: Hazard group definitions When classifying a biological agent, it should be assigned to one of the following groups according to its level of risk of infection to humans.		Examples?
Group 1	Unlikely to cause human disease.	<i>Adeno-associated viruses (AAV)</i>
Group 2	Can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available.	<i>Legionella pneumophila, Noroviruses, Influenza A, B, C</i>
Group 3	Can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available	<i>Bacillus anthracis, Yellow fever virus, SARS-CoV-2</i>
Group 4	Causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.	<i>Ebolavirus, encephalitis virus</i>

# Control Measures - COSHH Reg 7 - Appropriate Choice of MSC Classification

- ▶ How do we achieve optimum control?
- ▶ User Requirement Specification (URS) - commonly adopted process in the Pharma sector, particularly when GMP applies
- ▶ Selection of appropriate Lab containment level (CL1, CL2, CL3, or CL4)?
- ▶ (COSHH Reg 6 & 7) How is the hazard being handled? Accessibility, usability, manoeuvrability etc...
- ▶ (COSHH Reg 6 & 7) What equipment, apparatus (centrifuges, balances, automation etc) are being used, and how might this impact control/containment?
- ▶ (COSHH Reg 6 & 7) Is the intention to handle chemicals as well as biologicals?

# Control Measures - COSHH Reg 7

## Regulation 7 ... Schedule 3

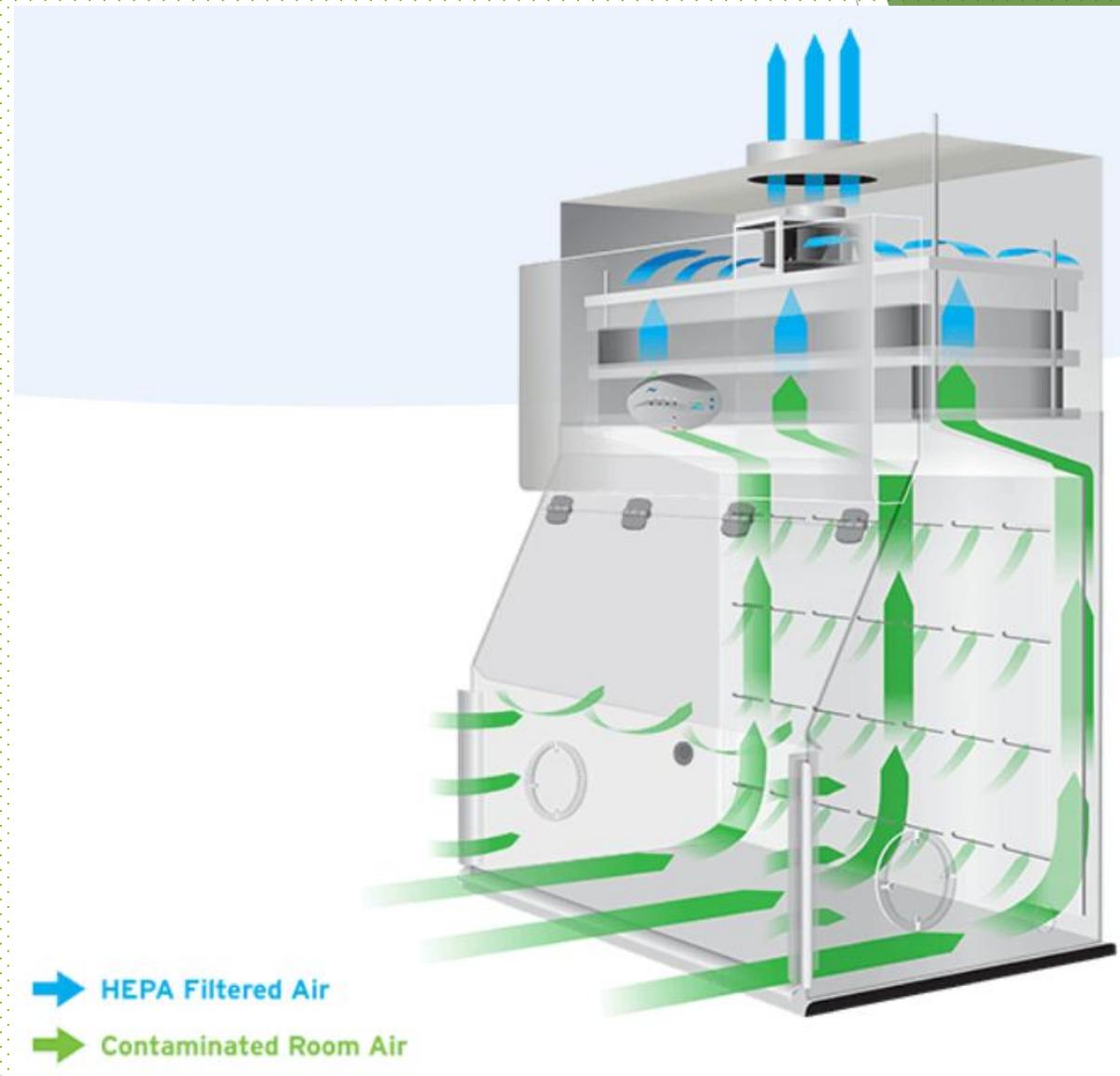
Sets out **containment measures** for health and veterinary care facilities, laboratories and animal rooms

*‘Every employer who is engaged in any of the activities specified in sub-paragraph (3) shall ensure that measures are taken to adequately control the exposure of his employees to biological agents’*

*‘the containment level must match the Hazard Group identified as a minimum e.g., **Level 2** for activities which involve working with a **Group 2 biological agent**’*

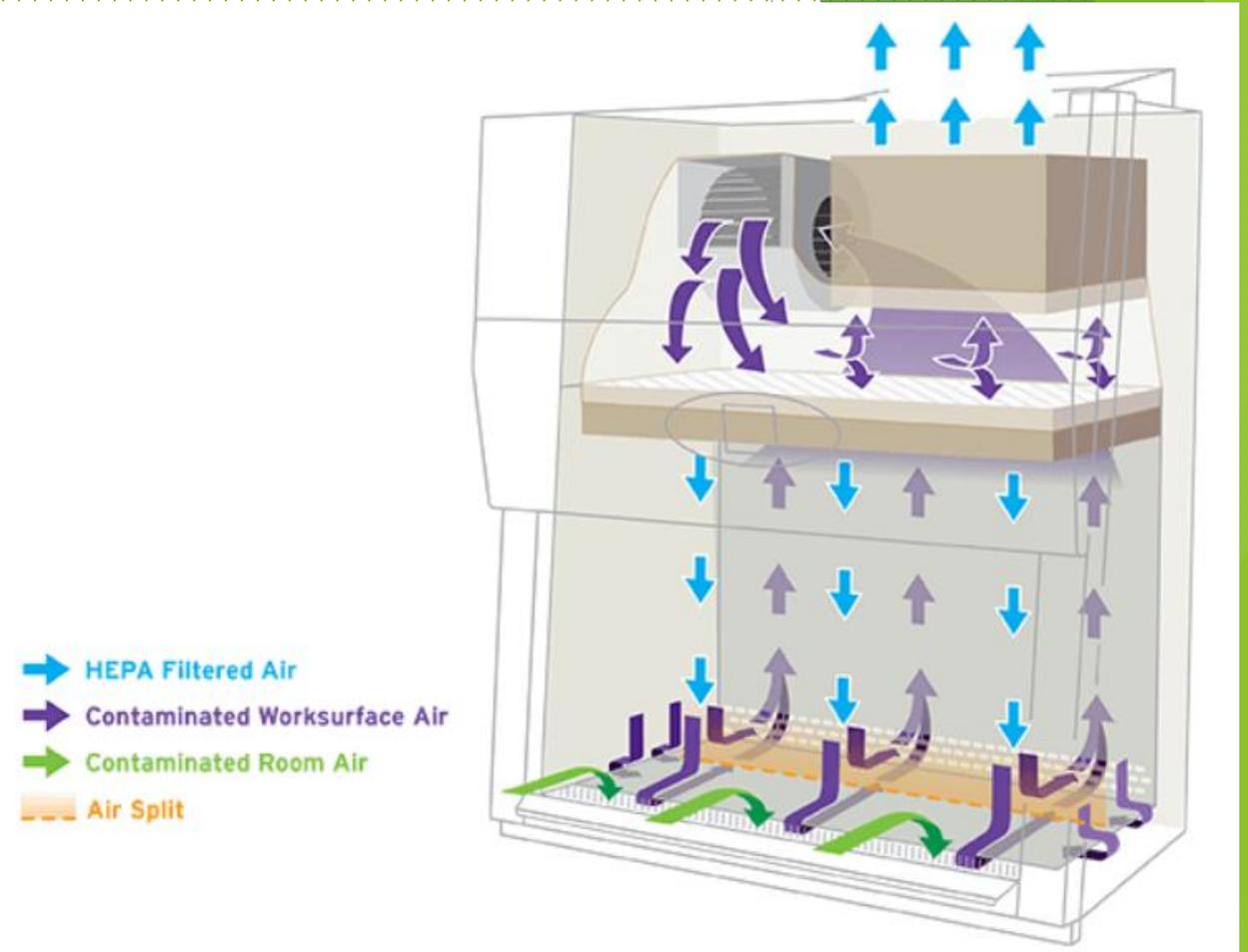
# Safety Cabinet Classifications

- ▶ **Class I** - Provides Operator Protection only, partially enclosed
- ▶ Minimum inflow (BSEN12469) = 0.7m/s
- ▶ Maximum inflow (BSEN12469) = 1.0m/s
- ▶ Class I & Class III hybrids?



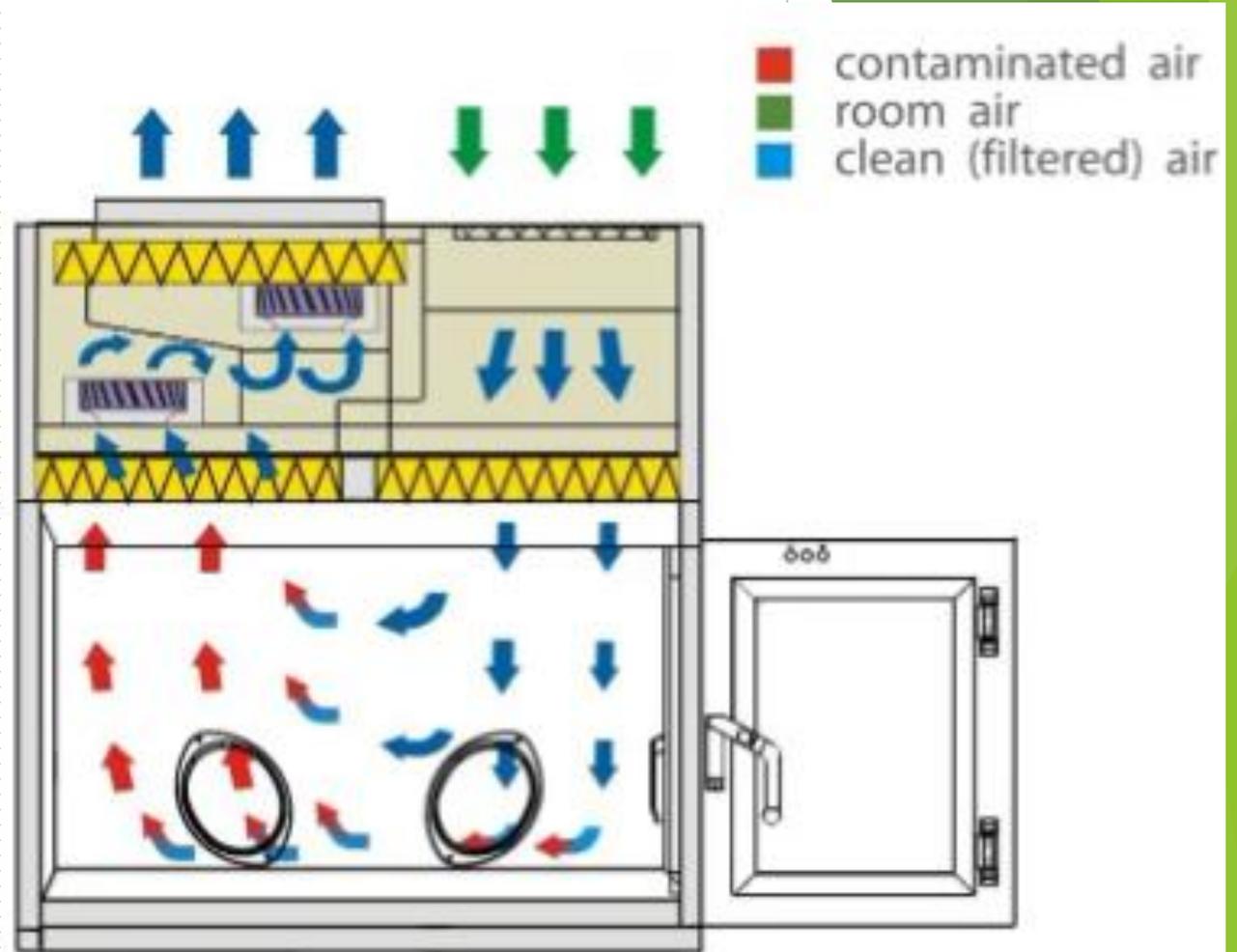
# Safety Cabinet Classifications

- ▶ **Class II** - Provides operator AND product protection, partially enclosed
- ▶ Minimum inflow (BSEN12469) = 0.4m/s
- ▶ Permissible downflow range (BSEN12469) = 0.25m/s - 0.5m/s
- ▶ Cytotoxic Class II Cabinets - For use with Chemical solids & powders - Primary HEPA filter is below the cabinet work surface



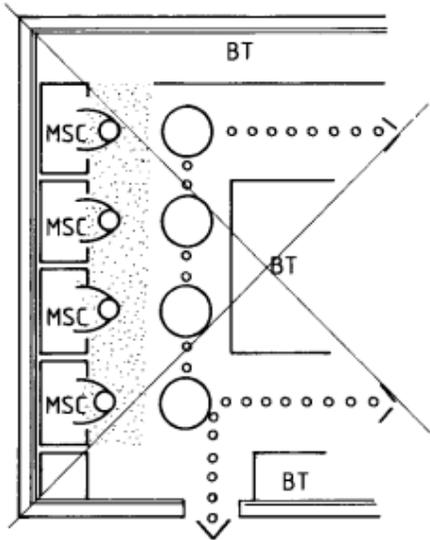
# Safety Cabinet Classifications

- ▶ **Class III** - Provides operator AND product protection, FULLY enclosed
- ▶ Minimum breach velocity (BSEN12469) = 0.7m/s
- ▶ Working pressure should not be any less that -200 Pa relative to the Laboratory (BSEN12469)
- ▶ Similarities with Negative Pressure Isolators



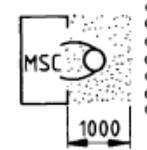
# Installation, positioning & siting

- ▶ **BS 5726:2005** Microbiological safety cabinets – Information to be supplied by the purchaser to the vendor and to the installer, and siting and use of cabinets – Recommendations and guidance

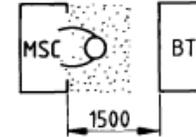


g) Danger of too much movement in front of safety cabinet: should be avoided by allowing more space between the apertures of the safety cabinets and the bench tops

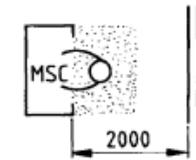
a) Separation of an undisturbed zone around a safety cabinet from traffic routes



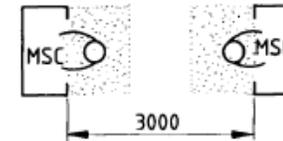
b) Spacing when the same operator uses a safety cabinet and a bench top opposite, or where occasional traffic only is anticipated



c) Spacing determined by airflow requirements with an opposing wall



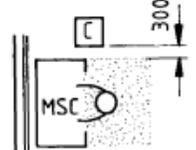
d) Spacing determined by airflow requirements when safety cabinets are opposite each other



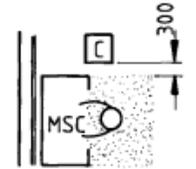
e) Spacing determined by airflow requirements with adjacent walls



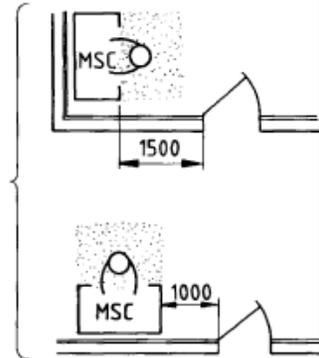
f) Spacings that avoid undue disturbance to airflow. Face of column not in front of plane of cabinet aperture



g) Spacing to avoid undue disturbance to airflow when face of column is in front of plane of cabinet aperture

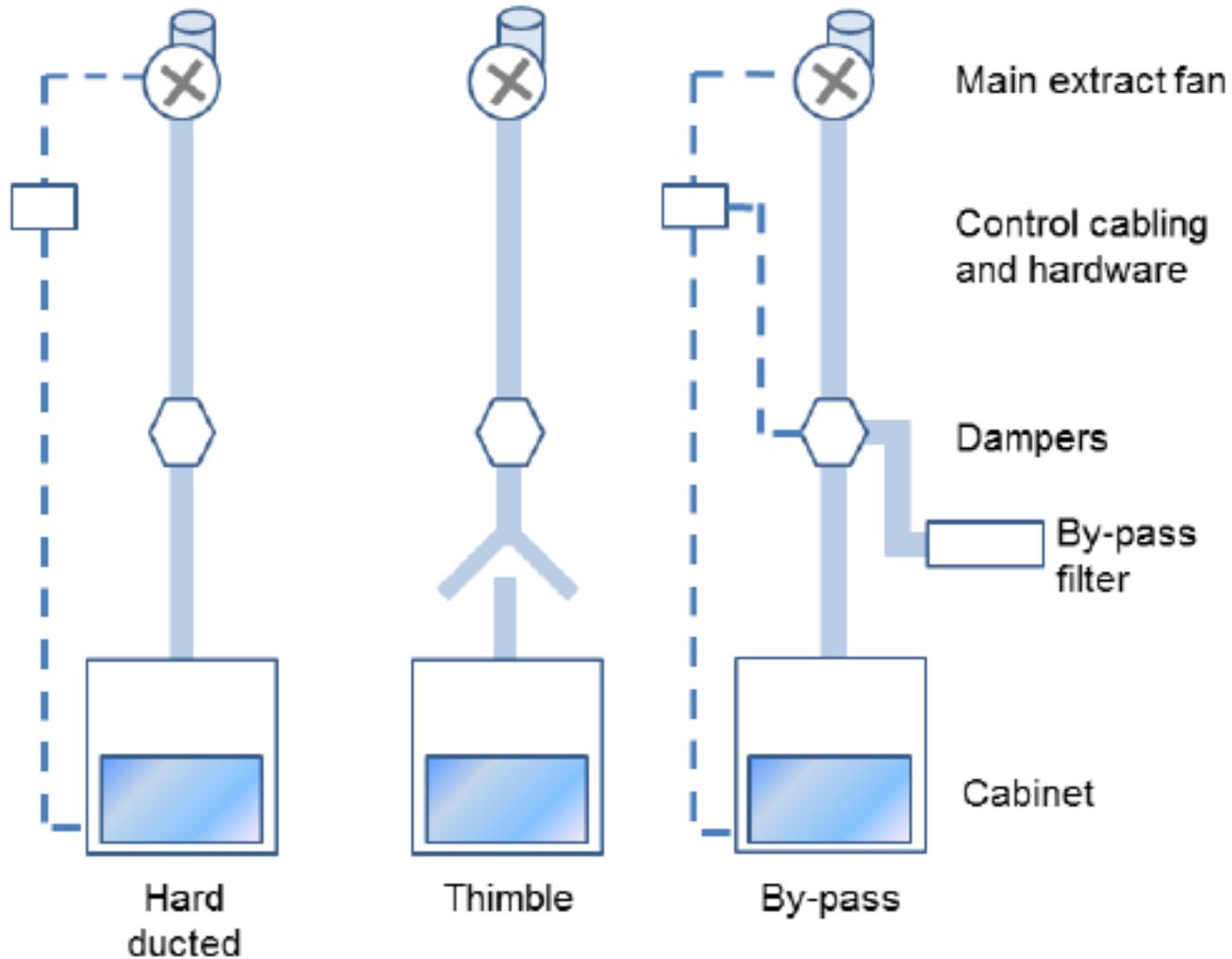


h) Spacings that avoid undue disturbances to airflow in relation to door openings



# Installation, positioning & siting

## ► Exhaust arrangements

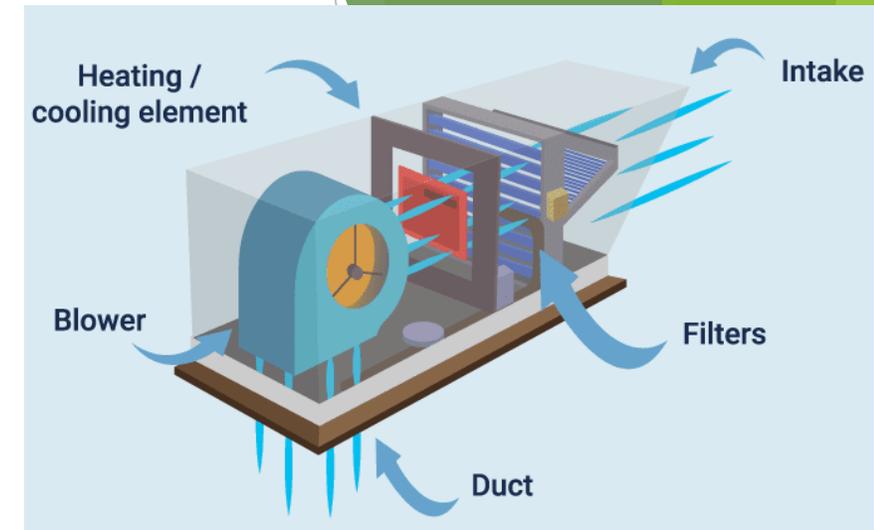


# Installation, positioning & siting

- ▶ Make-up air

## What goes out, must come back in!

- ▶ Ensure suitable diversity
- ▶ Keep diffusers away from the vicinity of the Cabinets.
- ▶ Air should be adequately filtered, conditioned, heated etc to comply with Lab URS (AHUs etc).
- ▶ Pressure cascades should not hinder performance of the Safety Cabinet
- ▶ Care should be taken not to compromise integrity of the Building fabric i.e., 30/60-minute fire walls without consultation of a suitable fire professional.



# Commissioning

*'ACDP Management and operation of microbiological containment laboratories'*

## Commissioning of the MSC

- 15 MSCs will be manufactured to specifications in standard BS EN 12469 to ensure leak tightness, operation protection and product protection as appropriate.
- 16 Once installed, commissioning tests, eg volumetric airflow rate measurements, airflow patterns and HEPA filter testing should be carried out to verify the performance and level of protection of the MSC *in situ*. It may also be necessary to carry out additional testing when changes have been made to the laboratory that may affect the performance of the MSC.

# Commissioning

- ▶ **DQ IQ OQ PQ** - Required under GMP, GLP, GDP, GCP and ISO 15189
- ▶ **Factory Acceptances Tests (FAT)**, Site acceptance tests etc (SAT)
- ▶ **IQ** – provides documented evidence and verification that the MSC has been delivered and installed according to both manufacturers and user specification
- ▶ **OQ** – provides documented verification that the MSC is operating as designed. Verifies that the functionality of a MSC meets the manufacturer's operational specifications.

# Commissioning

- ▶ **PQ** - provides documented verification that the MSC can perform effectively and reproducibly within performance specifications.

Helps ensure confidence in results by verifying that the accuracy and precision of its components are maintained.

Hand over User manuals & maintenance schedules

- ▶ **Decontamination Cycle Generation (VHP?)** - will vary depending on cabinet temperature, humidity, size, volume etc

# Testing and Testing Intervals

MBSCs are Local Exhaust Ventilation (LEV) controls.

Therefore subject to a **Thorough Examination & Test (TExT)** at least once in every 14-month period under CoSHH Regulation 9.

\*\*\* Pay close attention to requirements under **Reg 9**, & do not fall into the trap of only 'testing to standard' **(BS EN 12469)**...



# Testing and Testing Intervals



**Health and Safety  
Executive**

## **HSE ebulletin**

Issued: 23 January 2025

Visit HSE's website for more guidance about [local exhaust ventilation \(LEV\)](#).

## **Thorough Examination and Testing (TExT) duties**

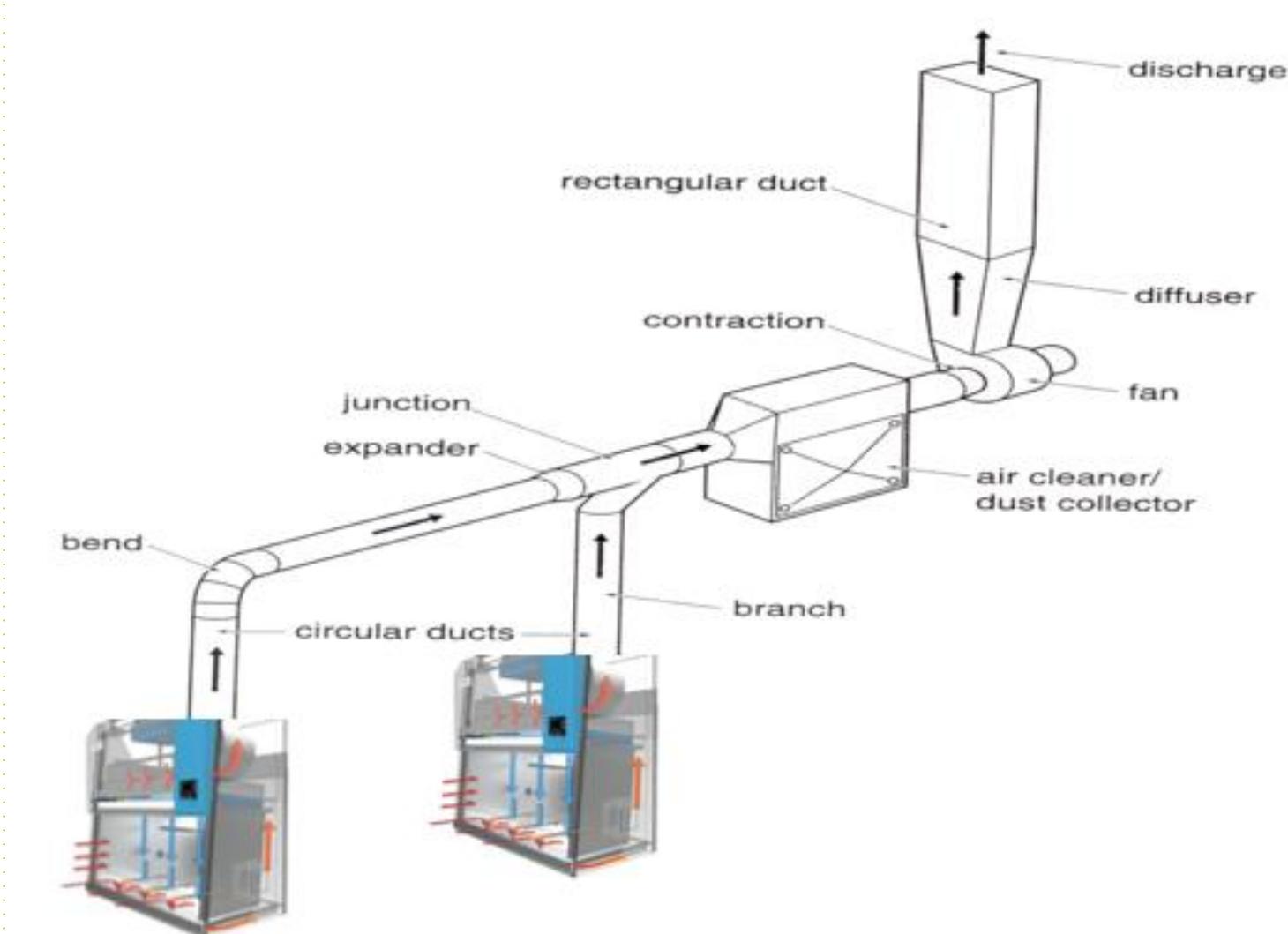
### **Ensure you understand your duties when conducting TExT of microbiological safety cabinets (MBSCs) and other laboratory-based LEV systems**

There is increasing evidence to suggest that some sectors using MBSCs and other laboratory-based LEV systems do not fully understand their TExT duties under [Regulation 9\(2\) of the Control of Substances Hazardous to Health Regulations \(COSHH\) \(as amended\)](#).

While testing to the relevant standard (for example, BS EN 12469: 2000) is encouraged, this does not fulfil all the requirements of Regulation 9(2) of COSHH, which has additional information and testing requirements.

# TExT - COSHH Reg 9/HSG 258

Remember!! Under **Reg 9**, test the whole system!



# Testing and Testing Intervals

- ▶ How and how often are we testing MSCs - testing methods can differ depending on cabinet type
- ▶ Decontamination e.g. VHP
- ▶ Face Velocity/Inflow
- ▶ Downflow (where applicable)
- ▶ OPFT (commonly KI DISCUS™)
- ▶ HEPA Filter Integrity (DOP using Photometry) - 12 monthly in accordance with BSEN12469
- ▶ Lux & decibel levels

Table 1 Test frequency and recommended performance of cabinets

	Test	Class I MSC	Class II MSC	Class III MSC
Frequency of tests	Alarms/indicators	Daily		
	Face velocity/inflow	Monthly		N/A
	Inflow/downflow	N/A	Annually for work with HG2, 6-monthly for HG3	6-monthly for work with HG3
	OPFT	12-monthly		N/A
	In-use OPFT	As required by assessment		N/A
	Recommended performance of cabinets	Alarms/indicators	Functioning as specified	
Face velocity/inflow		Measured velocity at all points should be between 0.7 m/s and 1.0 m/s	Not less than 0.4 m/s	At least 0.7 m/s with one glove removed
Downflow		N/A	Between 0.25-0.5 m/s	N/A
OPFT		Greater than or equal to $1 \times 10^5$		N/A
In-use OPFT		Greater than or equal to $1 \times 10^5$		N/A

# Contractors - Suppliers, Designers, Installers...

## Compliance & Certification

- ▶ Correct classification (Class I, II, or III) to match Containment level as per URS

## Satisfactory Installation & Commissioning

- ▶ Confirmation the location meets airflow, clearance, and power requirements.

## Training

- ▶ Safe operating procedures, maintenance tasks, and troubleshooting.

## Documentation

- ▶ **User Manual & Logbook**

## After-Sales Support

- ▶ Warranty, Maintenance, Service call-outs, Spare parts availability etc

# Contractors - Testing

As with any LEV - HSG 258 chapter 2!

## What examiners should know

- The parts of an LEV system and their function.
- The legal requirements for the thorough examination and testing of LEV systems.
- How to recognise a damaged part from a visual inspection.
- The purpose of, and how to use, the measuring and assessment instruments and techniques.
- The most suitable instrument to test the performance of each part of the LEV system.
- The standard to which each part of the LEV system should perform.
- How to recognise when a part of the LEV is performing unsatisfactorily, based on the measurements taken and assessment methods used.
- How to check whether the LEV is effective in reducing airborne contaminant emission and operator exposure.
- How to collate and record information in a clear, concise and usable way.
- How to work safely with the LEV plant and the hazards associated with it.

# Usage

**BS 5726 - 2005**

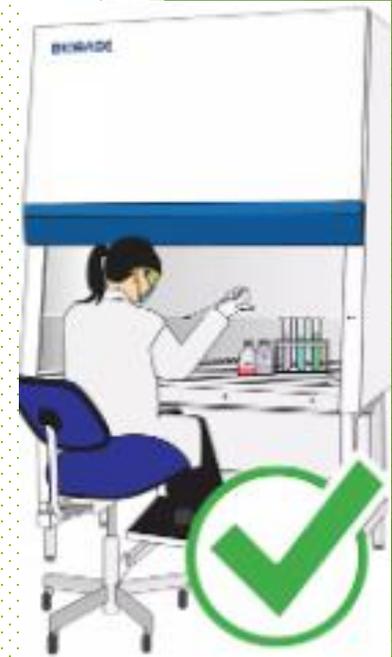
## **8 Training of users**

All users of cabinets should be fully instructed on the following:

- a) classification of cabinets;
- b) appropriate and inappropriate use of cabinets;
- c) mode of operation and function of all controls and indicators;
- d) limitations of performance;
- e) how to work at cabinets safely;
- f) how to decontaminate cabinets after use;
- g) principles of airflow and operator protection tests.

# Usage

- ▶ Sudden and extensive changes in air pressure in the laboratory can seriously compromise cabinet performance such as opening doors or autoclaves
- ▶ If cabinet is used 'loaded' - in a **Class I**, items should be moved as far back into the cabinet as possible. In **Class II**, equipment should never obstruct downflow vents.
- ▶ Centrifuges should not be used inside **Class I** and **Class II** cabinets
- ▶ On completion of work, an MBSC should be allowed to run or 'purge' for a period of **at least 5 minutes**.



# Usage



Spot the problems here!?

## In summary...

- ▶ Identify the hazard
- ▶ Select appropriate cabinet
- ▶ Ensure it is installed, sited, and positioned correctly
- ▶ IQ, OQ, PQ, FAT, SAT - Suitably commission the cabinet, consider VHP cycle generation
- ▶ Test at routine intervals - BSEN12469, COSHH Reg 9
- ▶ Ensure compliant handover and maintain correct usage, record & log any checks highlighted within User manuals

For  
more  
info...



## Controlling airborne contaminants at work

A guide to local exhaust ventilation (LEV)



This is a free-to-download, web-friendly version of HSG258 (published 2006). This version has been adapted for online use from HSE's current printed version.

You can buy the book at [www.hsebooks.co.uk](http://www.hsebooks.co.uk) and most good bookshops.

ISBN 978 0 7176 6236 2  
Price £12.95

This book provides guidance on the supply of new local exhaust ventilation (LEV) equipment. It describes the principles and good practice of deciding on, designing, commissioning and testing cost-effective LEV.

The guidance is written for the suppliers of LEV goods and services, but will also be helpful for employers and managers in medium-sized businesses, and trade union and employee safety representatives. All of these groups need to work together to provide, maintain and use effective LEV and to reduce exposure from inhalation of hazardous substances.

The book contains information about the roles and legal responsibilities of suppliers, and of their clients as employers; competence; principles of good design; practice for effective LEV hoods and their classification; ducts, air movers, air cleaners; and system documentation – with checking and maintenance schedules, and the marking of protective equipment.

It also includes guidance on the specification of LEV, the supplier's quotation; commissioning; zone marking; the user manual and logbook; testing and hood seals.



## Control of substances hazardous to health

The Control of Substances Hazardous to Health Regulations 2002 (as amended)



Approved Code of Practice and guidance



## The Approved List of biological agents

Advisory Committee on Dangerous Pathogens



BS 5726:2005



BSI Standards Publication

Microbiological safety cabinets. Information to be supplied by the purchaser to the vendor and to the installer, and siting and use of cabinets. Recommendations and guidance

bsi.

...making excellence a habit™

BS EN 12469:2000



BSI Standards Publication

Biotechnology. Performance criteria for microbiological safety cabinets

bsi.

...making excellence a habit™



## Management and operation of microbiological containment laboratories

Advisory Committee on Dangerous Pathogens

