LEV LOCAL EXHAUST VENTILATION 2024

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Hosted by

BOHS British Occupational Hygiene Society

Microbiological safety cabinets

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Microbiological Safety Cabinets

Presented by

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Where, what, how, why?

- Commonly found in the Healthcare and Pharmaceutical sectors. In some cases, in educational facilities, research Facilities, MOD etc).

- Visual and functional Similarities with let's say…. Fume Cupboards?? Laminar flows (HLAF, VLAF)?? However, palpable differences.

- Used mostly for biocontainment, In some cases Chemical containment as well

- And me? 3 years as LEV/Containment Subject Matter Expert (SME – don't like the term!) at GSK R&D Stevenage, Ware, Cambridge, and Harlow. Prior to that - Several HVAC commissioning/decommissioning projects at various Healthcare, Pharmaceutical, Medical research & MOD sites across the UK & EU.

GSK THE FRANCIS CRICK INSTITUTE NHS sanofi AstraZeneca

Risk Assessment – COSHH Reg 6 – Identify the hazards

- E.g. to what hazard group does the pathogen belong?

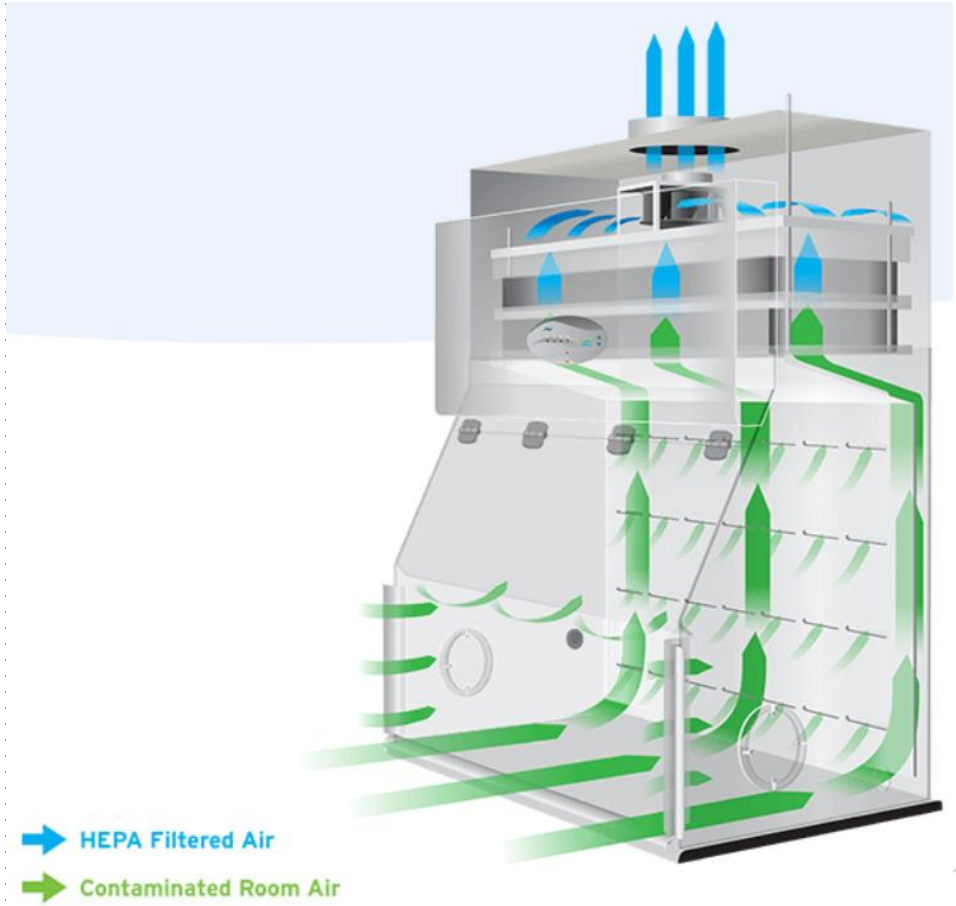
Information box: Hazard group definitions When classifying a biological agent, it should be assigned to one of the following groups according to its level of risk of infection to humans.		Examples?
Group 1	Unlikely to cause human disease.	*Adeno-associated viruses (AAV)*
Group 2	Can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available.	*Legionella pneumophila, Noroviruses, Influenza A, B, C*
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	*Bacillus anthracis, Yellow fever virus, SARS-CoV-2*
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.	*Ebolavirus, encephalitis virus*

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?

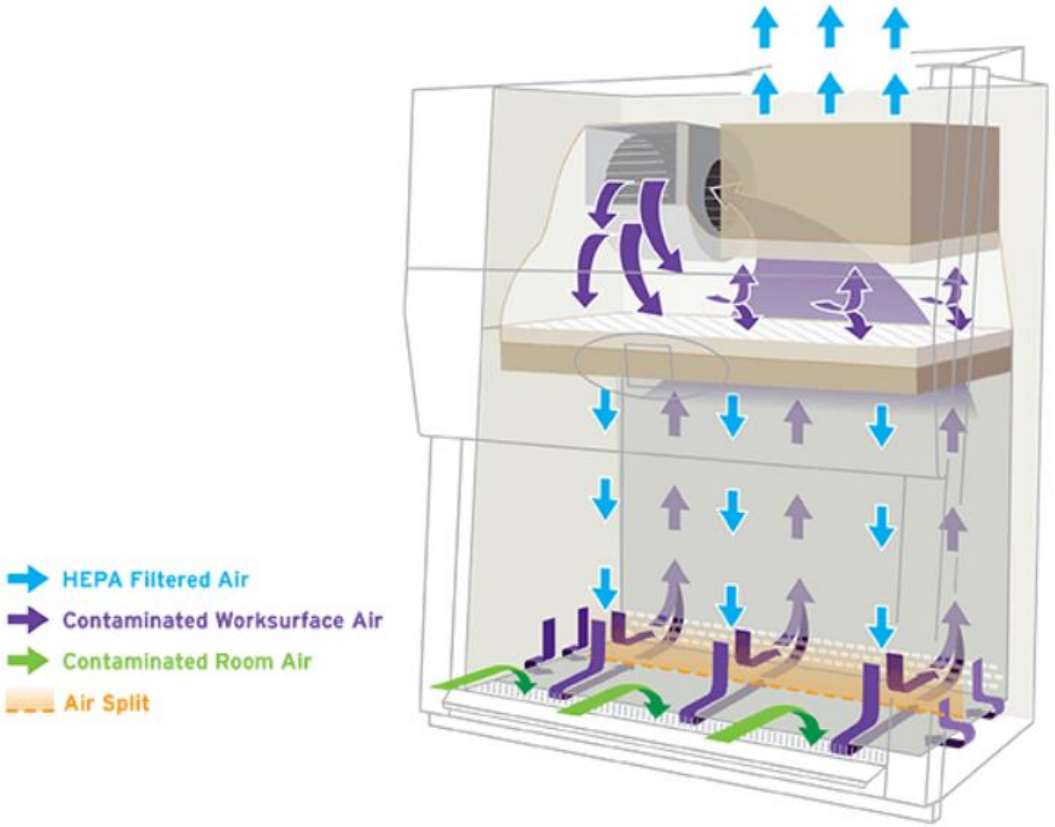
Safety Cabinet Classifications

- 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?



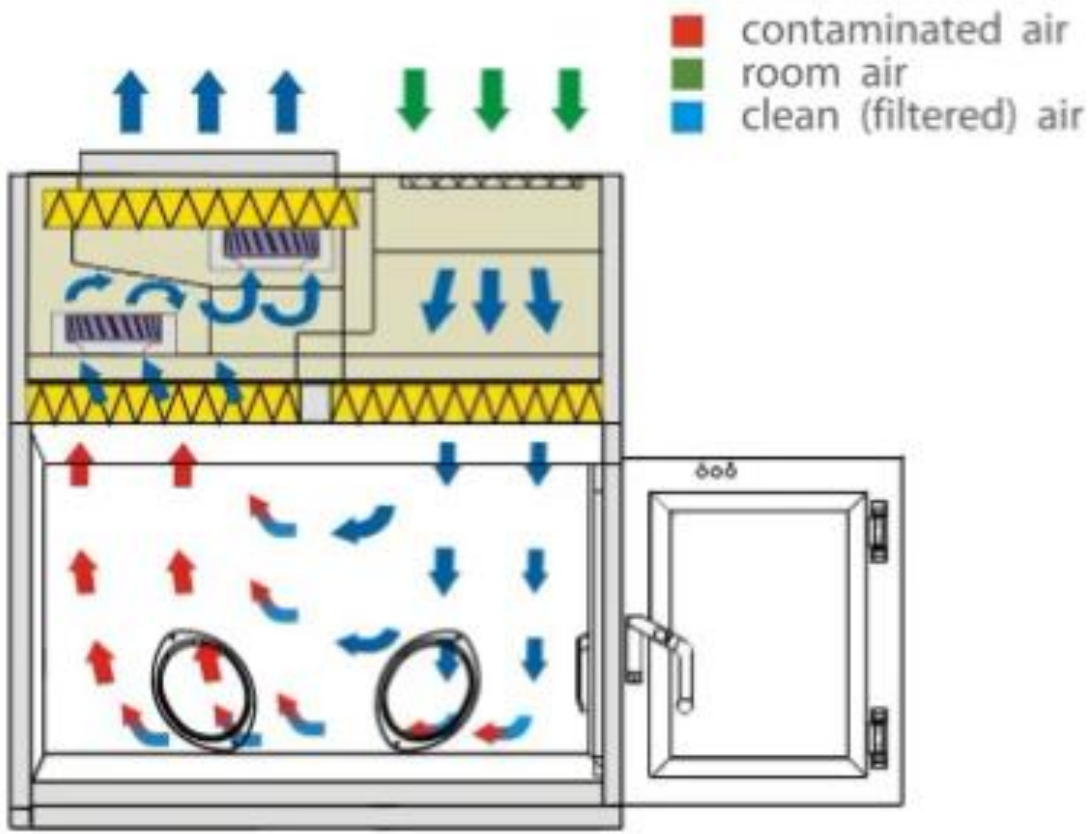
Safety Cabinet Classifications

- 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



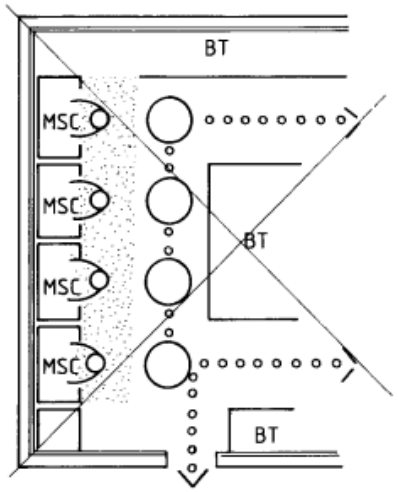
Safety Cabinet Classifications

- 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



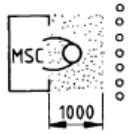
Installation, positioning & siting

- 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

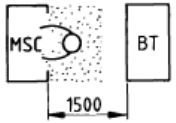


g) Danger of too much movement in front of safety cabinets should be avoided by allowing more space between the apertures of the safety cabinets and the bench tops

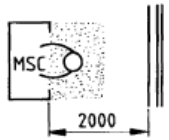
a) Separation of an undisturbed zone around a safety cabinet from traffic routes



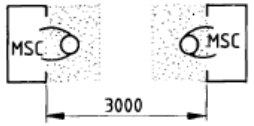
b) Spacing when the same operator uses a safety cabinet and a bench top opposite, or where occasional traffic only is anticipated



c) Spacing determined by airflow requirements with an opposing wall

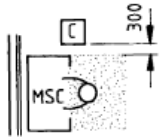


d) Spacing determined by airflow requirements when safety cabinets are opposite each other

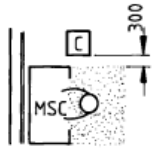


e) Spacing determined by airflow requirements with adjacent walls

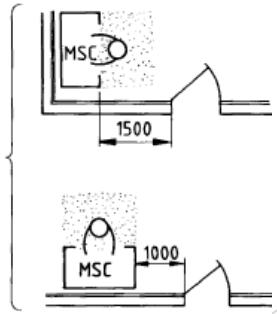
f) Spacings that avoid undue disturbance to airflow. Face of column not in front of plane of cabinet aperture



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



IQ, OQ, PQ – (a proper good commissioning!)

- Required under GMP, GLP, GDP, GCP and ISO 15189
- **IQ** – provides documented evidence and verification that the MSC has been delivered and installed according to both manufacturer's 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.
- **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

- 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 1×10^5		N/A
	In-use OPFT	Greater than or equal to 1×10^5		N/A

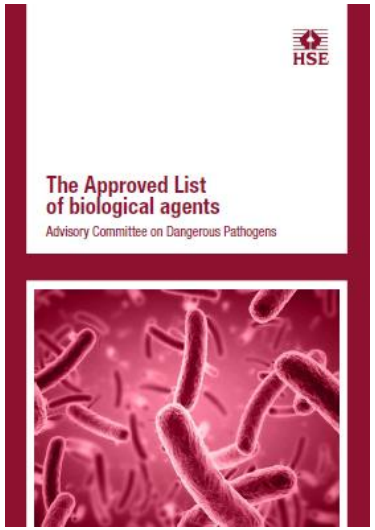
Cabinet usage & bad Loading

Spot the problems here!?

In summary…

- Identify the hazard, and determine process design through URS
- Select appropriate cabinet based on URS
- Ensure it is installed, sited, and positioned correctly
- IQ, OQ, PQ – Suitably commission the cabinet, consider VHP cycle generation
- Test at routine intervals – BSEN12469, COSHH Reg 9
- Maintain correct usage, record & log checks highlighted within User manuals

For more info…

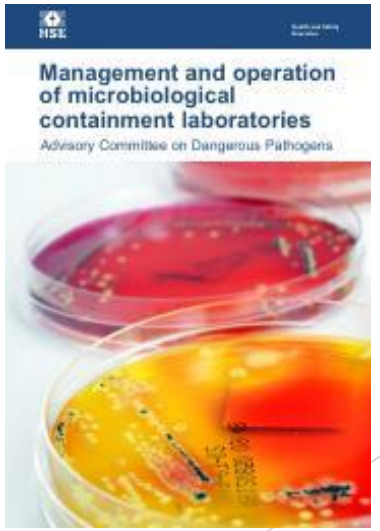


Biotechnology. Performance criteria for microbiological safety cabinets

bsi. ...making excellence a habit"

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"



Thank you for your time, happy to take any questions