

Management and operation of microbiological containment laboratories

Advisory Committee on Dangerous Pathogens



Advisory Committee on Dangerous Pathogens (ACDP)

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This guidance is issued by the Advisory Committee on Dangerous Pathogens (ACDP). Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

Contents

Section 1: Introduction	4
Section 2: Management arrangements for biosafety	8
Section 3: Principles of design and operation	19
Section 4: Assessing and controlling the risks	28
Section 5: Selection and application of containment and control measures	37
Appendix 1: Containment tables	45
Appendix 2: Microbiological Safety Cabinets	57
Appendix 3: Decontamination, fumigation and sealability	72
Appendix 4: Microbiological waste in laboratory facilities	80
Appendix 5: Transport of infectious substances	86
Appendix 6: Dealing with accidents including spillage of biological agents	94
Appendix 7: Provision and use of personal protective equipment, including respiratory protective equipment, in the laboratory	99
Appendix 8: Work with hazard group 3 parasites	101
Further reading	103

Section 1: Introduction

Scope

- 1 This publication provides guidance on the general duties under the Health and Safety at Work etc Act 1974 (the HSW Act) and the requirements under the Control of Substances Hazardous to Health Regulations 2002 (COSHH) as they relate to those who deliberately work with biological agents that pose a risk to human health, other than genetically modified organisms (GMOs). It also describes the minimum containment requirements that implement the minimum standards required by the European Directive (Directive 2000/54/EC) on the protection of workers from risks related to exposure to biological agents at work.
- 2 There is separate guidance covering work with GMOs www.hse.gov.uk/pubns/books/l29.htm and pathogens covered by the Specified Animal Pathogens Order (SAPO) www.hse.gov.uk/pubns/books/hsg280.htm which should also be considered in the context of other work related to biological agents.
- 3 In addition to COSHH, this guidance provides practical advice on applying the relevant parts of the Management of Health and Safety at Work Regulations 1999 (MHSWR) for deliberate work with biological agents and how to assess and control the risks associated with working with biological agents.
- 4 This guidance applies to contained use work in all types of laboratories where biological agents are handled including research, teaching, clinical, forensic, veterinary and environmental laboratories. It covers both deliberate work with biological agents and work with material that contains or may contain biological agents and describes in detail the minimum containment measures required at containment level 2 (CL2) and 3 (CL3); and should be used in conjunction with the control measures specified in Schedule 3, COSHH. Further details on biosafety management in containment level 4 (CL4) laboratories can be found in the Principles, Design and Operation of Containment Level 4 Facilities www.hse.gov.uk/pubns/web09.pdf.
- 5 There are no legal minimum containment requirements under COSHH for containment level 1 laboratories. However, the practices, safety equipment and facilities are similar to those for containment level 2, as required by an assessment of the risks, and these should be used in addition to the more general COSHH control measures.

Purpose of guidance

- 6 This guidance is aimed at those responsible for managing, supervising, assessing and coordinating work in microbiological containment laboratories. Safety Advisers, Biological Safety Officers and other safety professionals who provide competent advice to their employer may also find this useful. It should also be considered before any changes in function, upgrading or building of facilities to be used for the type of work previously described.
- 7 One of the important aims of this guidance is to emphasise that it remains the dutyholders' responsibility to manage the risks created from the work undertaken at their premises and should be used to make sure that any containment and control measures are suitable and sufficient to meet the minimum requirements.

Section 2: Covers the general management for biosafety and health and safety issues, such as health and safety management that are applicable to all relevant workplaces.

Section 3: Covers the principles of design and operation of microbiological containment laboratories.

Section 4: Gives specific guidance on assessing and controlling the risk arising from deliberate work with biological agents.

Section 5: Explains the rationale for the selection of appropriate containment and control measures.

- 8 Managing the risks that arise from deliberate work with biological agents requires that sufficient management controls are in place. To prevent or control the potential release of a biological agent a combination of safe working practices, suitably trained staff with physical and procedural measures are required.

Biological agents

- 9 A biological agent is defined in COSHH as:

'a microorganism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health.'

- 10 Most biological agents are microorganisms, ie bacteria, viruses, fungi, microscopic endoparasites such as the malarial parasite, amoebae and trypanosomes and the microscopic forms of the larger endoparasites such as the ova and larval forms of helminths. A microorganism is defined in COSHH as:

'a microbiological entity, cellular or non-cellular, which is capable of replication or of transferring genetic material.'

- 11 COSHH classifies biological agents into one of four hazard groups (HG) based on their ability to infect healthy humans using the following criteria:
- the likelihood that it will cause disease by infection or toxicity in humans;
 - how likely it is that the infection would spread to the community; and
 - the availability of any prophylaxis or treatment.
- 12 The four HGs are defined as follows:
- **HG1:** unlikely to cause human disease;
 - **HG2:** 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;
 - **HG3:** 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; and
 - **HG4:** 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.
- 13 The Approved List of Biological Agents www.hse.gov.uk/pubns/misc208.htm (The Approved List) is a list of biological agents and their classification (HG), approved by HSE through ACDP. COSHH implements the EU Directive 2000/54/EC on the protection of workers from the risks related to exposure to biological agents at work. The Directive requires that Member States classify biological agents that are, or may be, a hazard to human health. Annex III (community classification) to the Directive contains a list of biological agents and the Approved List is based on that.
- 14 The Approved List is relevant to risk assessment for work with biological agents and the application of appropriate control measures. A risk assessment under COSHH regulation 6(2)(k), of work likely to expose any employees to biological agents, should consider the approved classification of any biological agent. The Approved List only includes agents in HG2-HG4. The list is not exhaustive, and unlisted agents should not automatically be categorised into HG1. The categorisation of unlisted agents should be determined by the assessment. Further guidance on this is given in Section 4.
- 15 Categorisation gives an indication of the inherent hazard of the agents listed, but it does not consider the route of transmission, the work undertaken using the agent (eg volume), the titre used, or procedures undertaken. It does not cover additional risks to those who have reduced or compromised immunity or are pregnant, which must be addressed in the risk assessment.

Hazards other than infection

- 16 As indicated by the definition in COSHH, the risks of allergenicity and toxicity should be considered. Certain biological agents are recognised as respiratory sensitisers (Allergenic) or known to be toxigenic and are appropriately marked on the Approved List. The risk assessment should identify whether other agents pose these hazards (or any other hazards that may harm human health), apart from infection.

Section 2: Management arrangements for biosafety

Health and safety legislation

- 17 The HSW Act places duties on employers and others, where the risks from exposure to biological agents may arise from work activities.
- 18 Here is a summary of general duties under the HSW Act.
 - To ensure the health, safety and welfare at work of employees so far as is reasonably practicable (SFAIRP). Further guidance on the principles of SFAIRP can be found at www.hse.gov.uk/risk/theory/alarp1.htm.
 - To conduct their undertakings in such a way as to make sure, SFAIRP that non-employees who may be affected by the work are not exposed to risks to their health and safety. This includes students working with biological agents in educational establishments, and visitors.
 - Employees have a general duty to take reasonable care for the health and safety of themselves and others who may be affected by their work, and to cooperate with their employer or any other person to enable them to comply with any health and safety duties.
 - Self-employed people have general duties to conduct their undertakings in such a way as to make sure, SFAIRP, that other people may not be exposed to their work activity where it poses a risk to the health and safety of others.
- 19 If people working under the control and direction of others are treated as self-employed for tax and national insurance purposes, they may be treated as employees for health and safety purposes. It may therefore be necessary to take appropriate action to protect them. If any doubt exists about who is responsible for the health and safety of a worker this must be clarified and should be included in the terms of a contract or other documentation. However, the legal duty under the HSW Act cannot be passed on by means of a contract and there will still be duties towards others. If workers are employed on the basis that they are responsible for their own health and safety, legal advice should be sought first.
- 20 MHSWR provides a broad framework for controlling health and safety at work. As well as requiring risk assessments, they also require employers to have access to competent help in applying the provisions of health and safety law; to establish procedures for workers if there are situations presenting serious, imminent danger; and for cooperation and co-ordination where two or more employers or self-employed people share a workplace.
- 21 COSHH provides a framework of actions designed to control the risk from a range of hazardous substances, including biological agents. Together the two frameworks, MHSWR and COSHH, will align to make sure employees are protected from health and safety risks created in the workplace.

Health and safety management

- 22 There is a legal duty for employers to put in place suitable arrangements to manage for health and safety, and MHSWR requires that arrangements are put in place to control health and safety risks. The responsibility for health and safety rests primarily with the employer and they must ensure the organisation has the necessary management framework to comply with health and safety at work legislation. As a minimum, the processes and procedures required to meet the legal requirements include:
- a written health and safety policy (if you employ five or more people);
 - arrangements for effective planning, organisation, control, monitoring and review of the preventative and protective measures that come from risk assessment;
 - access to competent health and safety advice;
 - providing employees with information about the risks and how they are protected;
 - instruction and training for employees in how to deal with the risks and ensure adequate and appropriate supervision; and
 - consulting with employees about the risks at work.
- 23 Acceptance and commitment by senior managers is crucial in achieving effective management of health and safety. The policy must be brought to the notice of all employees, particularly in view of the potential risks associated with work with biological agents, especially at higher hazard levels.
- 24 The policy should include details of the management structure and a statement of the general policy on health and safety at work, with a commitment to managing health and safety effectively, and set out individual responsibilities. It should detail what will be done in practice to achieve the aims set out in the policy and how employees will be involved.
- 25 The complexity and hazards associated with the biological agent(s) will determine the extent of the management arrangements and the level of oversight required. The management arrangements should be clear, practical, robust and effective, people at all management levels should understand, accept and commit to delivering the arrangements.
- 26 Although not a requirement, other safety management systems apply the 'Plan, Do, Check, Act' cycle to implement their arrangements effectively. This approach emphasises the importance of devising and implementing appropriate containment management systems, and their monitoring and adaptation to remain effective.
- 27 Core elements underpin each stage of the Plan, Do, Check, Act model including leadership, management, competence, risk profiling, worker involvement and legal compliance. Additional information and detail on the Plan, Do, Check, Act model and its core elements are available in

Information box 2.1 (more from the HSE website www.hse.gov.uk/pubns/indg275.htm).

Information box 2.1 Approach for managing health and safety - Plan, Do, Check, Act

PLAN	Determine and prepare a suitable policy which should include a plan of how this will be implemented (ie roles and responsibilities, scope of the activities encompassed); how the system will be monitored (ie the desired performance benchmarks) and the resources required to implement the plan and achieve those performance benchmarks.
DO	Assess the risks and identify what could cause harm in the workplace, who it could harm and how, and what you will do to manage the risks including applying appropriate containment and control measures.
CHECK	Measure and review performance, through proactive monitoring to assess how well the risks are being controlled; and investigate the causes of accidents, incidents or near misses.
ACT	Review performance and act on lessons learnt by implementing the findings from the monitoring, investigations, performance measurements and reviews undertaken.

- 28 Employees have responsibilities under health and safety law to take care of their own health and safety and that of others; and to cooperate with their employer, eg by applying agreed local rules and procedures. Employees must also follow any instructions or health and safety training provided and report any work situations that present a serious and imminent risk, or any other failings they identify in the health and safety arrangements.

Competent people

MHSWR Regulation 7

- 29 To help them comply with their statutory duties, the employer should appoint one or more competent people. This requirement can be met by the appointment of a Biological Safety Adviser (BSA). A competent person should have sufficient training, experience and knowledge of the type of work undertaken in the facility, and must be given adequate time and resource to carry out their duties. It is important to remember that appointing a competent person does not absolve the employer from their responsibilities under health and safety legislation, rather it gives further assurance that responsibilities will be met.
- 30 In some occupational settings a formal line management structure may not be obvious. Where an individual is responsible for directing, controlling or supervising the work of others (eg researchers, scientists, ancillary staff), they should be regarded as 'managers' for the purposes of identifying who

is responsible for health and safety management. A head of department for a laboratory will have an important role in health and safety management, but may designate a laboratory supervisor to help oversee and implement health and safety arrangements.

- 31 Safety committees can play a valuable role in the organisation of safety procedures, including:
- providing advice on the adequacy of risk assessment;
 - formation of local rules;
 - consideration of accidents and incidents; and
 - influencing good practice.
- 32 Depending on the nature of the work, the safety committee may have representatives from various technical disciplines, management, employees (including trade union representatives) and health and safety advisers, such as a BSA. Establishing a Biological Safety Committee will offer more specialist advice for work with biological agents. Where work with GMOs is also undertaken in the facility, a Genetic Modification Safety Committee (GMSC) may already be established as required under the Genetically Modified Organisms (Contained Use) Regulations 2014 (GMO(CU)). In such cases, the GMSC function may be extended to cover work with biological agents.

Cooperation and coordination

MHSWR Regulation 11

- 33 Some workplaces may be shared by more than one employer and this could include the self-employed, such as:
- a laboratory in a teaching hospital may be shared by university researchers and biomedical scientists;
 - research council employees may work in a university laboratory; or
 - research hotels or science parks may be owned and used by one organisation, but also have space let out to universities or small businesses.
- 34 Those sharing a workplace are required to cooperate with each other to comply with their respective duties under health and safety law. Everyone in the workplace must be fully informed about all the risks that may be present, by sharing information about the nature of the work being undertaken.
- 35 Where there is no controlling employer in charge of a shared workplace, those sharing should agree joint arrangements to meet the requirements of the law, eg the appointment of a health and safety coordinator. These arrangements should be documented and signed by all those concerned.

Safety policies and codes of practice

HSW Act
Section 2(3)

MHSWR
Regulation 5

- 36 Health and safety policies provide important general information about how managers intend to develop and maintain a safe working environment. They should refer to general safe working practices in the laboratory and how they will be supervised and managed.
- 37 Most of this information will usually be found in local codes of practice which provide important information to employees. Managers should arrange for codes to be drawn up and made accessible to help as a checklist for identifying areas which staff, including contractors and temporary workers, should understand before being assessed as competent. See Information box 2.2 for the main areas to be covered in local codes of practice.

Information box 2.2 Main areas to be covered in local codes of practice

Introduction - should state the reasons for having a code and reference relevant health and safety documents. Staff should be made aware of the nature and range of biological agents to which they or the environment might be exposed, the possible source of infection and the containment (physical and procedural) measures to be used. Staff should be made aware of the training and supervision arrangements for working in the laboratory. If the laboratory is a shared facility, all staff should be made aware of all the other risks to which they might be exposed.

General procedures - should specify which staff (or grade of staff) are authorised to carry out certain procedures. There should also be appropriate guidance for maintenance staff, contractors and visitors etc.

Out of hours/lone working - consider if the work is appropriately managed both in and out of normal working hours.

Operation of unit - should detail start-up procedures, etc how the ventilation system works and its controls, operation of equipment, eg Microbiological Safety Cabinet(s) (MSC), centrifuges, and use of personal/respiratory protective equipment and cleaning procedures.

Local rules - should cover such issues as entry/exit procedures for the facility, maximum numbers allowed in the laboratory or other local rules as required depending on the nature of the work. It may be a suitable place to include details on sending and receiving infectious material, quarantine periods for staff working with animal pathogens to minimise the risk posed to susceptible species if applicable.

Waste - this should detail the waste disposal and disinfection procedures.

Whole room disinfection - should cover the circumstances when fumigation of the facility may be necessary, the procedures to be followed and those

authorised to carry it out. It is also important to include details of the initial validation of the process, and information on the actions to take in the event of an emergency (eg escape of fumigant from the laboratory).

Staff health - should include the immunisation policy and arrangements for reporting injuries/infections and post exposure prophylaxis and details of the health records required to be maintained under COSHH.

Testing and maintenance - should cover the day-to-day maintenance and testing procedures for engineering controls such as MSCs, autoclaves etc.

Emergency procedures - should cover procedures for dealing with accidents involving biological agents, the name of the person to whom incidents should be reported and arrangements for notifying enforcing authorities.

- 38 Health and safety information can also be included in standard operating procedures (SOPs), which are often used to meet external (and internal) quality standards. They can help provide employers with assurance that they are meeting acceptable standards of health and safety. SOPs should be developed in consultation with employees to demonstrate their commitment to the safe working procedures.
- 39 Employers should plan for supervising work to make sure that health and safety measures remain effective. Supervision will help to prevent people from deviating from established procedures that may result in ill health, injuries or damage to the wider environment. The level of supervision will depend on the risk associated with the task and the competence of the worker and should include fully competent people to make sure that standards continue to be met.
- 40 Employers are required, under the Safety Representatives and Safety Committees Regulations 1977 and the Health and Safety (Consultation with Employees) Regulations 1996, to consult employees and/or their safety representatives about health and safety matters. This includes: changes to work that may affect their health and safety; arrangements for getting competent help; information on the risks and controls; and planning of health and safety training.

Training

- 41 Employees must have a clear understanding of any identifiable risks to their health arising from work and the actions to be taken in the event of exposure to a biological agent. Information box 2.3 provides examples of different types of training to consider when developing a training programme. The level of training provided, as required under COSHH, should be appropriate to the level of risk or the complexity of the procedures being undertaken. At CL3 written records of training should be kept.

**MHSWR
Regulations
11 and 13**

**COSHH
Regulation 12**

- 42 Previous experience or seniority does not mean a person is competent to work in the laboratory. Competence should be viewed as the combination of training, skills, experience and knowledge that a person has and their ability to apply them to perform a task safely. Other factors, such as attitude and physical ability can also affect someone's competence. Although competence gained in one situation does not mean that an individual can carry out **all** work at any containment level, eg the step up from CL2 to CL3.
- 43 Investigations of incidents involving the contained use of biological agents often identify contributory factors. Failures in training and supervision are a recurring factor and their importance should not be underestimated.

Information box 2.3 Considerations when developing a training programme

- Induction training following recruitment, eg training in good microbiological practice and familiarisation with the local rules before beginning practical work.
- Ongoing training is appropriate to the tasks required; ensuring staff remain competent to perform their duties.
- Enhancement of fundamental microbiological knowledge with specific information about the biological agent being handled, eg mode of transmission and epidemiology.
- Training when a significant change to work, equipment, work environment, work activity or responsibilities takes place, especially where increased or new risks may be involved.
- Dealing with emergencies and procedures for moving infectious material in/out of the laboratory (and off-site).
- Refresher or background training (where appropriate) to maintain standards and to make sure there is an understanding of the risk of the biological agent being worked on.
- Training to make sure of ongoing competence and continued professional development.
- Training in risk assessment procedures will often be useful (although not specifically required by the legislation).
- Training may be part of a formal qualification process, eg as a biomedical scientist, or in some cases may be tailored for the specific needs of individual/project/laboratory/task.
- Training should be documented, eg in the personal training records of the individual, and be signed off by both the trainer and the trainee. The training process should also be evaluated, ie there should be some means of demonstrating that the training has achieved the desired outcome.
- Training should not be limited to those working at the bench. Laboratory managers, supervisors and safety advisors should be appropriately trained to make sure that they are competent. It is also necessary for auxiliary staff (eg cleaners and porters) and others (eg maintenance staff, external contractors and administrative staff) to receive appropriate information, instruction and training about the hazards they may encounter when working in a laboratory.

Emergency procedures

**MHSWR
Regulation 9**

**COSHH
Regulation 13**

- 44 Employers are required to draw up plans for dealing with accidents involving biological agents. It is important that nominated competent people are always available to make sure any accident or incident is managed. Clear, up-to-date instructions should be available to all relevant staff to make sure they are familiar with the procedures. It may also be useful to carry out incident simulations for training purposes. Guidance on the action to take following a spillage is in Appendix 6.
- 45 Emergency procedures for the laboratory should be documented, either in the local code of practice or as a stand-alone document. MHSWR requires emergency procedures are in place for responding to serious and imminent danger, eg fire or flooding.
- 46 The emergency procedures should contain arrangements to make sure that the emergency services have sufficient knowledge of the risks within the laboratory, eg in the event of a fire. They should also cover:
- roles and responsibilities of employees during an emergency - this should include a first point of contact;
 - training requirements - all new staff should be trained in emergency procedures. Such arrangements can be tested by periodic drills;
 - arrangements for the investigation of accidents/incidents;
 - first-aid arrangements - including the availability of post-exposure prophylaxis if appropriate; and
 - procedures for reporting of incidents/accidents involving people other than employees, eg visitors.

Accident and incident reporting

**MHSWR
Regulation 9**

**COSHH
Regulation 13**

- 47 Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR 2013) requires employers to report all diseases and any acute illness caused by an occupational exposure to a biological agent www.hse.gov.uk/riddor/carcinogens.htm.
- 48 There are additional reporting requirements if an accident occurs while deliberately working with a SAPO agent or a GMO.

Monitoring and checking control

**MHSWR
Regulation 5**

**COSHH
Regulations
8 and 9**

- 49 MHSWR covers the supervision of workers and the monitoring of standards. Arrangements must be made for the effective planning, organisation, control and monitoring of preventive and protective measures.
- 50 Monitoring of health and safety standards by locally organised inspections is recommended. It is important that monitoring should be recorded so trends can be evaluated, actions assigned and followed up. The level of monitoring will depend on the risks associated with the work and the competence of the workers. The safe working practices should be reviewed

to make sure that they are effective and relevant to the work being carried out.

Health surveillance

MHSWR Regulation 6

COSHH Regulation 11

- 51 Health surveillance is about putting in place procedures to detect early signs of work-related ill health among employees that are exposed to certain health risks because of their work, and acting on the results to prevent further harm. Health surveillance is critical where the biological agent causes serious disease, and where there is an effective treatment available.
- 52 Health surveillance is required where:
- the work could result in harm to health;
 - there are safe and practical ways of detecting diseases or conditions associated with exposure;
 - damage to health may occur under certain conditions at work; and
 - surveillance will benefit the employee or workforce.
- 53 The benefits of health surveillance are that it can:
- provide information so you can detect harmful health effects at an early stage, so protecting employees and confirming whether they are still fit to do their jobs;
 - provide data, by means of health records, to detect and evaluate health risks;
 - provide an opportunity to train and instruct employees in safe working practices, eg how to use personal protective equipment (PPE) properly;
 - give employees the chance to raise any concerns about the effect of their work on their health; and
 - alert employers of any changes to the health status of their employees that may affect work with biological agents.
- 54 Employees should be familiar with the clinical symptoms resulting from infection with the biological agent being worked with, eg vaccinia virus lesions, and the correct procedures for reporting instances of disease/ill health to their employer. Occupational health providers should be alert to unusual patterns of disease or ill health within the workforce, irrespective of the control measures being used. It may be possible to check the immune status of workers to see if they have protection against a potential infectious biological agent they could be exposed to during their work. This could be carried out as part of pre-employment screening, or by making checks on immunity following a course of vaccination.
- 55 Any health surveillance programme undertaken should include keeping a health record for all employees. The health record is different from a medical record as it should be about the employee's fitness for work or any specific precautions that should be taken. It should not include any

confidential clinical data and should be kept for 40 years after the employee's work with the biological agent ceases.

- 56 The key elements of a health record include:
- personal details of the individual;
 - a historical exposure record to HG 3 or 4 biological agents; and
 - a record of any immunisations and the conclusions of any checks on immunity.

Immunisation

COSHH Regulation 7(6)(f)

- 57 If the risk assessment shows a risk of exposure to biological agents for which effective vaccines are readily available, these should be offered if the employee is not already immune. The advantages and disadvantages of immunisation versus non-immunisation should be fully explained when making the offer.
- 58 The HSW Act requires that employers provide protective measures such as immunisation to workers free of charge. Where employees may not wish to take up the offer of immunisation, or may not respond to a vaccine, employers should carry out a local assessment to determine the likelihood of that employee being exposed and acquiring an infection. If employees are not immunised, it is important to consider the existing controls and whether any additional ones should be implemented to allow them to work safely, eg the provision of extra PPE.
- 59 Immunisation should only be a useful supplement to control measures required for preventing or adequately controlling exposure and should never be relied upon for worker protection.

Suitable exposure record keeping

COSHH Regulation 10

- 60 An exposure record is not the same as a health record required for the purposes of health surveillance under MHSWR or COSHH. Exposure in this context means deliberately working with the biological agent. However, exposure records must be available to any individual appointed for health surveillance, eg the local occupational health physician. It must also be available to any employee specifically responsible for health and safety.
- 61 Each employee must have access to the information that relates to them. If records are kept, written or electronic, about employees relating to health and safety legislation, the requirements of the Data Protection Act 2018 may apply. These requirements include informing people that certain information is held about them and providing access to that information, should they request it.
- 62 In practice, the exposure record might best be kept with other transferable confidential information, eg information accessible only by authorised individuals, in the employee's health record (see paras 55 - 56).

- 63 Any such records should be stored securely. Upon termination of a contract, a copy of the records should be given to the worker so that they may be given to the next employer. This may be particularly important for researchers undertaking several short-term contracts.

Section 3: Principles of design and operation

- 64 While the scale and purpose of a containment laboratory can vary considerably, eg from simple processing of specimens to larger scale work, this guidance details the important principles that should be followed in the initial phases of the upgrading or conversion of a laboratory. Further information relating to design and building of new laboratories is at www.hse.gov.uk/foi/internalops/hid_circs/administration/spc-admin-83.htm
- 65 The design and construction of a containment laboratory must meet the specific requirements laid out in COSHH Schedule 3 parts II and III (see also Appendix 1 General COSHH measures to control exposure to biological agents). There are however, more general regulatory requirements, including other health and safety legislation which should be considered. Table 3.1 lists some of the hazards, other than microbiological, that should be considered.

Table 3.1 Other laboratory hazards

Hazard	Legislation	HSE guidance
Chemical		
Flammables	<p>The Classification Labelling and Packaging Regulations 2015 (CLP)</p> <p>The Regulatory Reform (Fire Safety) Order 2005 covers general fire safety in England and Wales</p> <p>In Scotland, requirements on general fire safety are covered in Part 3 of the Fire (Scotland) Act 2005, supported by the Fire Safety (Scotland) Regulations 2006</p> <p>Dangerous Substances and Explosive Atmospheres Regulations 2002</p>	<p><i>The safe use and handling of flammable liquids</i> (HSG140)</p> <p>Storage of flammable liquids in process areas, workrooms, laboratories and similar working areas</p> <p><i>The storage of flammable liquids in containers</i> (HSG51)</p>
Carcinogens	COSHH	<i>EH40/2005 Workplace exposure limits</i> (EH40/2005)
Toxins	<p>COSHH</p> <p>Anti-terrorism, Crime and Security Act 2001 (ATCSA)</p>	
Compressed gases	<p>Gas Safety (Installation and Use) Regulations 1998</p> <p>The Regulatory Reform (Fire Safety) Order 2005 covers general fire safety in England and Wales</p> <p>In Scotland, requirements on general fire safety are covered in</p>	<i>Gas Safety (Installation and Use) Regulations 1998. Approved Code of Practice and guidance</i> (L56)

Hazard	Legislation	HSE guidance
	Part 3 of the Fire (Scotland) Act 2005, supported by the Fire Safety (Scotland) Regulations 2006	
Radiological		
Radionuclides	Ionising Radiation Regulations 2017 (IRR17)	<i>Work with ionising radiation: Approved Code of Practice and guidance (L121)</i> <i>Ionising radiation protection series (information sheets)</i>
Equipment that produces ionising radiation		
Physical		
Pressure systems, eg autoclaves	Pressure Systems Safety Regulations 2000 (PSSR) & Provision and Use of Work Equipment Regulations 1998 (PUWER)	<i>Safety requirements for autoclaves (Guidance Note PM73)</i>
Lasers	Non-specific – general controls under the HSW Act and MHSWR	<i>The Control of Electromagnetic Fields at Work: A guide to the Control of Electromagnetic Fields at Work Regulations 2016 (HSG281)</i>
Electromagnetic Fields (magnets)	The Control of Electromagnetic Fields at Work Regulations 2016 and The Control of Artificial Optical Radiation at Work Regulations 2010 (UV/visible and IR including lasers)	
UV radiation		
Noise	The Control of Noise at Work Regulations 2005	<i>Noise at work: A brief guide to controlling the risks (INDG362)</i> <i>Controlling noise at work (L108)</i>
Vibration	The Control of Vibration at Work Regulations 2005 (the Vibration Regulations),	<i>Hand-arm vibration at work: A brief guide (INDG175)</i> <i>Vibration solutions: Practical ways to reduce the risk of hand-arm vibration injury (HSG170)</i>
High voltage	Electricity at Work Regulations 1989	<i>Electricity at work: Safe working practices (HSG85)</i>
Ergonomic	Non-specific – general controls under the HSW Act and MHSWR	<i>Ergonomics and human factors at work: A brief guide (INDG90)</i>
Manual handling	The Manual Handling Operations Regulations 1992	<i>Manual handling at work: A brief guide (INDG143)</i> <i>Manual handling: Solutions you can handle (HSG115)</i>

Note: All guidance is available to view on www.hse.gov.uk

- 66 The Construction (Design and Management) Regulations (CDM 2015) www.citb.co.uk/health-safety-and-other-topics/health-safety/construction-design-and-management-regulations/cdm-guidance-documents/ are the main set of regulations for managing the health, safety and welfare of construction projects. CDM applies to all building and construction work and includes new build, demolition, refurbishment, extensions, conversions, repair and maintenance.
- 67 In addition to the mandatory requirements, the laboratory design should also consider recommendations in guidance or standards produced by ACDP and other bodies such as the Scientific Advisory Committee on Genetic Modification, British Standards Institution and relevant professional organisations.

The design process: liaison with designers and builders

- 68 Laboratory design should be a collaborative project between the client and the designer. The first stage in the process is to establish the broad requirements of the client. The client may appoint a responsible person to act as project manager to coordinate and oversee the project, including liaison with the design team and building contractors. A project team consisting of representatives of the client, designer, health and safety professionals and the end users of the laboratory, (including those in support services such as maintenance engineers) should also be set up to make sure that all requirements are met.
- 69 Clients have specific duties under CDM, this includes making sure that:
- other duty holders are appointed;
 - sufficient time and resources are allocated;
 - relevant information is prepared and provided to other duty holders;
 - the principal designer and principal contractor carry out their duties; and
 - welfare facilities are provided.
- 70 The designer's role when preparing or modifying designs is to remove, reduce or control foreseeable risks that may happen during construction, maintenance and use of a building after construction. The designer also provides information to other members of the project team to help them fulfil their duties.

Liaison with other agencies

- 71 In addition to the health and safety requirements covered in this guidance, there are other mandatory requirements which will influence the design process. These include:
- Home Office - animal welfare (standards for the design and construction of animal facilities) and security standards (pathogens and toxins);
 - appropriate agriculture departments - work with animal or plant pathogens;

- environment agencies or local authorities - waste disposal, effluent discharge (the local water company may also need to be contacted); and
- local authorities - building control/planning permission.

General design considerations

- 72 The project/design team should consider the following factors when setting the specifications of a new and refurbished laboratories.
- *Adaptability and flexibility.* A flexible design will future-proof the laboratory for different programmes of work with minimal change to the physical layout.
 - *Building services.* Consider the need to provide both general and local exhaust ventilation. It may also be necessary to include temperature and humidity controls which will provide operator comfort and meet any special requirements of the facility or equipment. Where possible, controls and service areas should be located away from the main laboratory areas.
 - *Relationship between space and function.* In a new laboratory complex, the various aspects of the work can be considered and located accordingly, eg centralised support facilities for individual laboratories within a complex. However, if a new laboratory is to be constructed within an existing facility, careful consideration should be given to its location to maximise the use of existing facilities while ensuring that any risks created by the new laboratory, such as the use of HG3 biological agents, do not adversely impact on adjoining areas (see Siting of the laboratory, para 77).
 - *User population.* Knowing the number of staff likely to be working in a laboratory will give some indication of the space requirements and room sizes. Figures are given in various publications (see paras 73 and 75) but these should only be used as a guide with an individual assessment made of the laboratory in question.
 - *Ergonomics.* The laboratory design should consider the principles of ergonomics, ie by adapting the work to the employee and not the employee to the work. In addition to the provision of sufficient natural and artificial lighting, comfortable working temperature/humidity will also contribute to the comfort of the environment and a positive influence on health and safety.
- 73 The laboratory should be of sufficient size to allow each worker adequate 'free air' space. The Workplace (Health, Safety and Welfare) Regulations 1992 www.hse.gov.uk/pubns/books/l24.htm specify that every room where people work must have sufficient floor area, height and unoccupied space for purposes of health, safety and welfare. The accompanying Approved Code of Practice (ACOP) (L24) specifies that the volume of the room, when empty, divided by the number of people normally working in it should be at least 11 m³. However, this is a minimum and may be insufficient depending on the layout, contents and the nature of the work. In making the calculation, this ACOP states that where the ceiling or part of the ceiling is more than 3 m high, it should be counted as 3 m high. In a laboratory

setting, the need to install and remove large items of equipment should be assessed when determining ceiling height.

- 74 In determining the space required, consideration should be given to the nature of the work, the space required for equipment (free standing and bench mounted), staff numbers and work flow. Overcrowding of work space can make it difficult to work safely and may lead to accidents. More detailed advice on deciding space allocation as determined by the critical dimensions of an activity can be found in guidance from NHS Estates: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/149167/HBN_15.pdf. This sets out the critical dimensions which affect the efficient functioning of an activity.
- *Component dimensions* - relate to the size and position of components, eg equipment, furniture and fittings.
 - *Activity dimensions* - define the user space, which is the minimum space required to perform an activity.
- 75 The European Standard (BS EN 12128) on containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements also includes guidance on spaces necessary between work surfaces or equipment.
- 76 The laboratory should be designed for ease of cleaning and maintenance. Control systems for heating and ventilation should be accessible from outside the laboratory containment area to minimise the need for maintenance staff to enter the laboratory. Finishes, fittings and equipment should also be designed or selected for ease of cleaning and for resistance to commonly used disinfectants and other substances used in the laboratory. Good housekeeping will limit physical clutter, control contamination and help to use chemical disinfectants efficiently.

Siting of the laboratory

- 77 Unless the laboratory is being constructed as a stand-alone building, it is likely that it will have to be built within the confines of an existing structure, either as part of new building or conversion of an existing room. When deciding on the location of the laboratory there are many points to consider which will influence the positioning (the list is not exhaustive and there may be other physical constraints).
- *Headroom* - this should be adequate for the installation of ductwork and utilities and sufficient to allow the movement of large equipment in and out of the laboratory.
 - *Access* - good access to a staircase and/or service lift may be required for transport of materials, including waste. Consideration should be given to the need to move materials through communal areas. Laboratory traffic should be separated from 'public' areas wherever possible.
 - *Daylight and visibility* - ideally, access to natural light should be provided.

- *Utilities* - should be of sufficient capacity to support the laboratory but space may be required to install additional capacity should the requirements of the laboratory change.
- *Air handling and ventilation* - the location of the air inlet and air extract for the building should be considered to avoid cross-contamination. The location of existing inlets/extracts (including windows as other rooms in the building may be naturally ventilated) should also be considered.
- *Other facilities* - office areas should be sited outside the laboratory containment zone.

Commissioning and validation

- 78 Validation can be defined as a documented procedure for obtaining, recording and interpreting the data required to show that a process, equipment and/or activity will consistently comply with predetermined specifications.
- 79 Before the laboratory can be brought into service, as part of the commissioning process it is the responsibility of the organisation/establishment in which the laboratory is being built to ensure that the facility, and the work that is to be carried out in that laboratory, meet acceptable standards. The laboratory (together with its equipment and procedures) should be tested to make sure that it meets the standard specified in the design and construction brief.
- 80 There will be many important items that should be tested and performance verified before work commences in the laboratory. In a CL3 laboratory the following should be considered.
- The laboratory must be sealable for fumigation and the process should be validated (see Appendix 3) and should be able to withstand the loading characteristics imposed by negative air pressure when the laboratory is in operation.
 - The ability to seal the laboratory depends on the physical construction of the room. Ceilings should be solid or continuous and preferably covered to the walls. It should be clear where the boundary of the room is to determine its sealability, as fumigant must not be able to penetrate the boundary of the room.
 - Sealability can be checked using a smoke test or similar effective means. All seals, eg around pipework, should be checked visually and smoke tested under static pressure.
 - The walls and ceilings should be seamless and any piped services should be sealed around the entry/exit points. Sealants used should be resistant to disinfectants, eg the fumigant, and should be non-hardening. All sealed joints should be routinely checked, and before any planned fumigation for gaps due to shrinkage or building movement.
 - It is recommended that all air supply and exhaust ductwork is checked *in situ* for leak-tightness (see Appendix 3). The air supply, exhaust and associated controls should also be checked to make sure that there is a means of preventing reverse airflows.

- All high efficiency particulate air (HEPA) filters should be tested to make sure that they meet the required specification after installation and all HEPA filter housings should be leak-tight.
- COSHH requires that maintenance, examination and testing of control measures including local exhaust ventilation (including MSCs) must take place at regular intervals. This means that HEPA filters and their fittings and seals must be thoroughly examined and tested at intervals not exceeding 14 months; depending on the frequency of use these tests are commonly carried out at shorter intervals. The simpler the system in place, the fewer the demands for maintenance, although it will still be required on a regular basis.
- HEPA filters should be easily accessible and positioned as early in the system as possible so that the remainder of the duct work is uncontaminated and safe to work on. Where filters are located outside the laboratory, the ducting must be under negative pressure to prevent leakage and arrangements must be put in place to decontaminate ducting before maintenance or repair. If the laboratory is mechanically ventilated, it is preferable to locate the inlet and extract supply to produce maximum mixing with, and consequent dilution of room air. This is normally done by supplying the air via terminal air diffusers that push air along the ceiling, after which it will flow down the walls, eddying and losing velocity as it goes.
- Consideration should be given to the installation of a separate air conditioning system to control the heat gain from equipment with high heat outputs, eg fridges and incubators. It is preferable at CL3 to use a sealed type of unit that recirculates cooled air into the room but if the unit extracts air direct to the exterior, this must be HEPA filtered.

- 81 At both CL2 and CL3, MSCs, autoclaves and other equipment should be tested against the appropriate standards where these exist, or against guidance produced by such bodies as ACDP or relevant professional organisations. All alarm systems, eg for air systems failure, electrical failure or fire should be checked to make sure they are functioning properly.
- 82 Validation of all the important items should be repeated on a regular basis, eg during annual maintenance and whenever there is a significant modification to the laboratory. Validation may also be required where there is obvious wear and tear (this may be localised, eg around pipework). The validation process should be documented and used as a baseline performance measure for subsequent tests.

Laboratory structures and fittings

Bench tops and sinks

- 83 Bench tops should preferably be constructed of solid composite material, solid plastic laminate or epoxy resin. Fibreboard covered with plastic laminate can chip and split and would not be acceptable for use in the laboratory. Bench tops should have coved splash backs where possible. These should be seamless but if sealing is required, non-shrinking sealant should be used, eg two-part epoxy grout.
- 84 Laboratory sinks provided for general use may be inset in benches or as separate units. The former should include a bowl and draining board as a complete unit. This should be integral with the bench top without joints or else sealed. Polypropylene or epoxy resin bowls and drainers are preferable to acid resisting stainless steel because of their greater resistance to disinfectants. Sinks should drain directly to waste via a simple S-bend trap, or deep bottle trap, rather than discharge into a dilution recovery trap or catch pot.
- 85 Hand-wash sinks should be separate from other laboratory sinks and located near to the exit of the laboratory. Local codes/policies on changing out of protective clothing when leaving the laboratory will determine the location and number of sinks required. Sinks should be of the type that can be operated without using the hands (eg the elbows, foot or the knee) or supplied with automatic controls (eg infrared 'magic eye'). Drainage from these sinks can be discharged directly to the main sewerage system.
- 86 Hands should be washed immediately when contamination is suspected and before leaving the laboratory.
- 87 At CL3, furniture should be kept to a minimum and under bench storage units should be on wheels to allow cleaning.

Floors

- 88 Floors should be smooth, slip resistant and seamless at CL2 and CL3. Although CL2 floors do not have to meet the same requirements as specified for CL3, in practice they should still be able to resist the most commonly used disinfectants etc. They should be impervious to water to allow effective cleaning and prevent absorption of infectious material into floor surfaces. Floor drains should not be open to the room and their covers should be flush with the floor.

Doors and windows

- 89 Doors and frames should be of a solid construction, chip resistant and of sufficient size to allow passage of equipment likely to be in the laboratory. The location and type of windows will depend on the nature of the work, eg where animal work is being undertaken, the use of one-way glass may be required.

- 90 Fire-resistant windows should be sealed in place at CL3 and double-glazed windows are recommended, which are flush on the inside for ease of cleaning.
- 91 Windows at CL2 should also be designed for ease of cleaning, but may be capable of being opened.

Walls

- 92 Walls should be smooth, easily cleanable and resistant to liquids and disinfectants in common use (including fumigants) in the laboratory. Materials which meet these criteria include epoxy or polyester coated plaster, rubberised paint, or equivalent surfaces. Such materials should also be resistant to commonly used disinfectants, detergents, acids, alkalis, solvents or other chemical preparations. Junctions of the walls with the ceiling and floor should be coved for easy decontamination.
- 93 In some instances, the design requirements specified in this guidance may be exceeded by the security standards specified by the Home Office for laboratories working with Schedule 5 agents.¹ Further details on physical security requirements can be found in the Home Office publications *Security standards for laboratories* and *Personnel security measures for laboratories* which are available on request from National Counter Terrorism Security Office (NaCTSO).

Other services or utilities

- 94 It is important to ensure that utilities are of sufficient capacity to support the laboratory (consideration should be given to the need for space to install additional capacity should the requirements of the laboratory change). Such services should be easy to maintain and, where appropriate, clean.
- 95 At CL3, electrical and other conduit services should be capable of being sealed to prevent escape of fumigant. Standard light fittings and electrical socket outlets are appropriate for use at CL2 and CL3 but they should be waterproof/resistant or protected by barriers or covers from entry by liquids and particulates. Light fittings should be capable of being removed or accessible from above for cleaning and maintenance.
- 96 If gas is not supplied as a mains service into the laboratory, compressed gas cylinders should be located outside the laboratory with an easily accessible shut-off valve. An alarm may be required to indicate when the cylinder should be changed. Controls for all piped services are ideally located in utility cupboards outside the laboratory to allow easy access.

¹ Part 7 of the Anti-terrorism, Crime and Security Act 2001 contains further legal requirements to make sure that the storage and use of dangerous pathogens and toxins listed in Schedule 5 of the Act is as secure as practicable. This is achieved by effective levels of physical security and by limiting access to those authorised to work with Schedule 5 agents.

Section 4: Assessing and controlling the risks

Risk assessment

**MHSWR
Regulation 3**

**COSHH
Regulation 6**

- 97 The purpose of risk assessment is about understanding the relevant hazards and identifying and taking sensible and proportionate measures to control the risks. The management arrangements in place must ensure that risk assessments are performed before work begins; they are suitable and sufficient and regularly reviewed. This section focuses on the risks associated with working with hazardous biological agents. Further information on the risk assessment process is available on the HSE website at: www.hse.gov.uk/toolbox/managing/managingtherisks.htm.
- Hazard - anything that may cause harm.
 - Risk - the chance, high or low, of somebody being harmed by the hazard and how serious the harm could be.
- 98 The risk assessment must be suitable and sufficient, should set out the principal hazardous characteristics of the substance being used and reflect the nature of the work activity being assessed. It may be necessary to draw on specialist advice as required, eg from health and safety professionals, the infection control department, or other infectious disease specialists. The assessment should be viewed as a living document that must be reviewed regularly to make sure it remains up-to-date and specifically, whenever there is reason to suspect it is no longer valid.
- 99 The Approved List classifies biological agents into one of four HGs based on a range of characteristics including: pathogenicity to humans; ability to spread in the community; and the availability of effective prophylaxis or treatment (see paras 11 and 12). The HG assigned to the biological agent is fundamental to the risk assessment but does not take account of the nature of the work being carried out (eg scale of the work, titre used, or procedures undertaken such as work with infected animals). It does not consider whether there may be any additional risks to those who have reduced or compromised immunity or are pregnant. The risk assessment must address these factors.
- 100 Where the biological agent does not have an approved classification, it should not be assumed to be harmless. The hazardous properties of the agent (if any) should be considered in respect of its level of risk of infection and should be assigned a HG in accordance with the criteria in para 12. The classification should be based on available scientific information and, in certain circumstances; advice may be sought from HSE. Further information is available in The Approved List.
- 101 Where a biological agent has an approved classification, but presents a different risk of infection from the agent listed, because it is attenuated or has lost known virulence genes, then that agent should be reclassified in consultation with HSE. If as a result, the biological agent is handled at a different containment level, the risk assessment must consider the nature of

the intended work as the containment measures required will depend on this, including the consideration of the agent's hazardous properties.

102 There are two main types of laboratory activity that could result in exposure to biological agents:

- deliberately working with biological agents (eg research), which may increase the risk of exposure (eg by propagation or concentration); and
- working with materials that may contain biological agents (eg clinical diagnostics), in which the risk may not always be known. However, the risk of harm extends beyond infection to include allergenicity and toxicity of biological agents, which must also be considered when appropriate in the risk assessment.

103 Further guidance on assessing and controlling the risks from these types of work is provided in Sections 4A and 4B respectively.

104 Risk assessment should consider the following stages:

Stage 1 *Identify the hazards;*

Stage 2 *Decide who might be harmed;*

Stage 3 *Evaluate the risks;*

Stage 4 *Record and implement your findings; and*

Stage 5 *Regularly review your assessment.*

105 Where existing risk assessments are in place in relation to GMOs or SAPO agents, a similar approach can be applied. This can be in the form of a single risk assessment that satisfies the requirements of the different legislative regimes.

Controlling the risks

**MHSWR
Regulation 4**

106 COSHH requires that the methods to prevent or control the risks identified by the risk assessment follow this hierarchical approach:

**COSHH
Regulation 7**

- **prevent or eliminate risks** - eg by substituting a hazardous biological agent with something less/non-hazardous, eg using a non-toxigenic strain of a biological agent;
- design and use of appropriate work **processes, systems** and **engineering controls** and the provision and use of suitable work equipment and materials;
- **control risks at source:** by using engineering controls and giving collective protective measures priority, eg using an MSC where work could create an infectious aerosol; and
- **provide suitable PPE:** where adequate control of exposure cannot be achieved by other means, in addition to the measures above. For more information on PPE in the laboratory see Appendix 7.

107 COSHH requires that exposure to a biological agent be prevented, where possible, or a safer biological agent used. For certain types of work, where

practicable, less pathogenic or non-toxigenic strains must be considered, and alternatives used (see Information box 4.1 Substitution).

Information box 4.1 Substitution

For many types of laboratory work, such as diagnostic work, this may not be possible, but it can be achieved in other types of work.

Example: Quality control/quality assurance work associated with a screening programme for a toxin-producing food-borne agent such as *E. coli* O157 can easily be carried out using non-toxin-producing strains. Such strains are readily available from culture collections or else as part of commercially available testing kits.

108 Where prevention or substitution is not possible, the risk assessment should consider:

- the biological agents that may be present and their HGs (see Approved List);
- the forms in which biological agents may be present;
- the diseases caused by the agent and how it can be transmitted;
- the activities being carried out;
- the likelihood of exposure and consequent disease;
- control measures to be applied (see Section 5) and how exposure will be controlled (both in terms of numbers of people exposed and the quantity of the biological agent that will be used);
- whether monitoring for the presence of biological agents outside primary containment is necessary; and
- the need for health surveillance/pre-employment screening.

Notification

109 COSHH requires notification to HSE where you are working with HG2, 3 or 4 biological agents at a premises for the first time, and notification of the subsequent use of any other biological agent listed in Part V of Schedule 3, COSHH at those premises. For some types of work, eg handling clinical samples in diagnostic facilities, some materials are likely to contain these biological agents. If the work does not involve activities that concentrate or propagate those agents, there is no need to notify either first use or subsequent use. Further guidance and the notification form can be found on the HSE website at:

<https://www.hse.gov.uk/forms/notification/cba1notes.htm>

<https://www.hse.gov.uk/forms/notification/cba1.pdf>

110 Where the biological agent is genetically modified or is a specified animal pathogen, additional licensing or notification requirements will apply.

- 111 Additionally, Part 7 of the [Anti-terrorism, Crime and Security Act 2001](#) (ATCSA) requires the safe storage and use of pathogens and toxins listed within Schedule 5 and requires laboratories to:
- register with the Home Office their holdings of Schedule 5 substances;
 - inform the Home Office of the security measures in place and that the premises in which the Schedule 5 substances are kept, stored, worked on and disposed of, are secure; and
 - ensure that access to these substances is authorised and controlled.

Section 4A Deliberate work with biological agents

- 112 This section covers those laboratories deliberately working with biological agents, eg propagating and concentrating, which could include teaching, research, development or diagnostic work (where the latter requires the deliberate propagation of biological agents as part of the procedure).
- 113 There is further specific guidance on deliberate work available on the HSE web site (biosafety topic pages www.hse.gov.uk/biosafety/).

Stage 1 Identify the hazards

- 114 Identify the hazardous properties of the biological agent and consider how it can harm health. The first stage is to check if the biological agent has an approved classification and, if so, the HG. The HG is based on some of the agents' hazardous properties (including severity of harm, infectivity, spread in the community) but this alone is not sufficient for risk assessment purposes. Both the Approved List (para 99) and the factors shown in Table 4.1 should be addressed when considering the hazards associated with a biological agent.

Table 4.1 Consideration of the hazards

Pathogenicity	How severe is the disease caused - morbidity v mortality; acute v chronic. Are any groups of people more susceptible to infection? Can the agent cause harm by other means, ie cause an allergy, produce a toxin?
Epidemiology	The natural hosts of the agent and what is known about the incidence of infection.
Infectious dose	Data on infectious doses may be useful if available.
Routes of transmission	To become infected, the biological agent usually has a natural route of entry, although in some cases infection can occur by more than one route: <ul style="list-style-type: none"> ▪ a biological agent that is transmitted naturally via an insect vector could be transmitted in the laboratory via a penetrating sharps injury; ▪ breathing in infectious aerosols;

	<ul style="list-style-type: none"> ▪ hand to mouth contact from contaminated surfaces; ▪ splashes of blood and other body fluids into the eye and other mucous membranes, such as the nose and the mouth; and ▪ broken skin if it comes into direct contact with, or something contaminated by, the biological agent.
Medical data	Consider whether there are prophylactic treatments available; whether there is any known resistance to such treatment; if there are vaccines readily available; the symptoms of the infection. Such information can be used for health surveillance purposes.
Environmental stability	Consider what is known about the survival of the biological agent outside the host, eg can it form spores; is it sensitive or resistant to desiccation?

Stage 2: *Consider the nature of the work and decide who might be harmed*

115 The assessment may be linked to a particular piece of research, but it is easier to assess if the work is broken down into individual activities. There should be sufficient detail to identify situations that could foreseeably result in exposure. The assessment should consider:

- where the work will be carried out;
- whether the work:
 - could create aerosols;
 - could create splashes;
 - will require the use of sharps; or
 - will involve high titres/concentrations or large volumes of the biological agent and the media to be used, eg solid, liquid;
- what equipment will be used, whether equipment is shared and how it will be decontaminated (if not disposable);
- how waste material will be handled and disposed;
- who will carry out the work and whether they are part of any vulnerable group;
- location of the work (eg hospital, research department);
- whether others could be affected by the work, eg cleaners, engineers; and
- whether the work is:
 - routine;
 - one-off;
 - undertaken out of hours and/or by lone workers.

Stage 3: *Evaluate the risks and select the control measures*

116 In considering the hazards associated with the biological agent and the nature of the work that is to be carried out, the risk assessment should identify where employees (and others) could be exposed to a source of infection during the work.

- 117 Selection of appropriate control measures for work with the biological agents is largely dictated by the requirements of COSHH, where the minimum requirement is for the containment level to match the HG of the agent, ie minimum of CL2 for working with HG2 agents.
- 118 The containment tables in Appendix 1 detail the appropriate containment measures for each level. Once the minimum containment level required for the work is determined, the assessment should reflect whether these precautions are adequate and/or appropriate. Examples of this are:
- Where there is potential for an aerosol of infectious material to be produced the assessment should reflect this risk and the work be carried out in suitable containment, eg an MSC may be required. An example is work with *Neisseria meningitidis*.
 - Where supplementary controls are needed in addition to those required by the containment level.
 - Where additional PPE is required when working with certain biological agents because of their route of transmission, eg wearing disposable gloves when working with enteric pathogens.
- 119 If the work involves certain biological agents that do not require all the control measures of a containment level, eg those biological agents that are not transmitted by the airborne route (see Section 5, Table 5.1) the appropriate control measures should be determined by the risk assessment before requesting HSE approval.

Stage 4: *Record and implement your findings*

- 120 Make a record of findings, including the control measures selected and any action identified as necessary to reduce the risk of exposure further. Employers must record and write down the findings if there are five or more employees and communicate this to all staff involved in the work.

Stage 5: *Regularly review your assessment*

- 121 Review and revise the assessment as necessary, especially if the nature of the work changes or if something else suggests that it may no longer be valid, eg because of an incident.

Section 4B Work with materials likely to contain biological agents

- 122 This section covers work with material that could contain biological agents but where there is no intention to deliberately propagate biological agents. This could include teaching, biomedical or academic research, development or diagnostic work (eg cytology, haematology or serology, see Information box 4.2 – Inadvertent culture).
- 123 Some work with material that could contain biological agents may involve a culture stage (eg preliminary isolation of bacteria as might occur in a clinical microbiology, diagnostic laboratory or environmental testing laboratory) but

this does not constitute deliberate propagation of a **known** agent (paras 125 - 130).

Information box 4.2 Inadvertent culture

Where there is no intention to deliberately propagate biological agents, there may be certain types of work where there is a risk of inadvertent culture. The risk assessment should consider whether this can take place and under what conditions. If culture can take place, additional containment measures may be required to control exposure. There is specific guidance on this issue in relation to work in cytogenetics laboratories via the Department of Health website.

Stage 1: Identify the hazards

- 124 The assessment should consider the types of material being handled and the potential for it to contain biological agents including:
- urine;
 - faeces;
 - genital tract samples;
 - skin and soft tissue samples;
 - respiratory tract samples including nose, throat, eye and ear swabs and sputum;
 - cerebrospinal fluid;
 - pus;
 - other fluids such as pleural, pericardial and joint aspirates;
 - blood;
 - bone marrow;
 - biopsy samples;
 - autopsy samples;
 - forensic samples;
 - environmental samples, eg food, water, soil, air, sewage; and
 - archaeological samples.
- 125 Certain biological agent or agents will usually be associated with material of human or animal origin.
- 126 Diagnostic specimens should be supplied with as much information as possible from the requesting clinician, including the types of biological agents that might be present (eg whether the specimen comes from a returning traveller or is associated with an outbreak scenario). Other specimen types may include information to help inform the assessment, eg environmental samples taken from an open farm associated with an outbreak of *Escherichia coli* O157 (see Information box 4.3 Confirmatory testing).

- 127 There should be procedures for diagnostic specimens to ensure that:
- clear guidelines for the completion of specimen request forms are in place, along with measures to provide assurance that guidelines are followed;
 - procedures are reviewed to make sure they adequately cover the completion of specimen request documentation, eg recent history of relevant foreign travel that may increase the likelihood of unusual or high-risk pathogens being present;
 - clinical details supplied on specimen request forms contain clear information regarding the nature of test being requested and sufficient detail to inform laboratory staff on the safety precautions they should take to process the specimen without risk of infection;
 - guidelines include a system to link different specimens from a patient so that all contain the same information in relation to safety;
 - information that becomes available due to patient intervention, that has implications for the safety of laboratory staff, is communicated immediately to the laboratory so that appropriate steps regarding containment can be taken;
 - important personnel involved in the collection of relevant clinical details and the completion of specimen request documentation receive appropriate training, including refresher training; and
 - a system is in place for monitoring and auditing the correct completion of specimen request documentation and for taking appropriate action.
- 128 Where clinical material is used for research purposes, particularly blood and blood products, a risk assessment should consider the possibility of blood borne viruses being present. Where they cannot be excluded, appropriate controls should be put in place. This does not imply that such specimens cannot be used if required for the research (see paras 158 - 159).

Information box 4.3 Confirmatory testing

If sending a specimen to another laboratory for confirmatory testing and it is known or strongly suspected to contain a HG3 biological agent, there is a legal duty to pass this and other relevant information onto the receiving laboratory (see Appendix 5 - Transport). This will enable the laboratory to undertake their own risk assessment and select the most appropriate containment measures.

Stage 2: *Consider the nature of the work*

- 129 The assessment may be linked to a piece of research or diagnostic technique, but it will be easier to assess if broken down into individual activities. There should be sufficient detail to identify situations that could foreseeably result in exposure. The risk assessment should consider the same factors detailed in Section 4A, Stage 2.

Stage 3: *Evaluate the risks and select control measures*

Note: To be read in conjunction with paras 116 and 117.

130 While CL2 is sufficient for most routine diagnostic work, additional controls may be necessary dependent on the nature of the work. Additionally, where there is reason to believe that HG3 pathogens may be present or where the intention is to isolate a HG3 pathogen, then CL3 may be required.

Stage 4: *Record and implement your findings*

131 See para 120 for further information.

Stage 5: *Regularly review your assessment*

132 See para 121 for further information.

Section 5: Selection and application of containment and control measures

- 133 For any work with a biological agent, containment measures are required to ensure that biological agents are not transmitted to workers or released outside the containment facility. This section sets out the containment and control measures that are suitable and sufficient to meet the minimum requirements of the regulations, as specified in COSHH, Schedule 3.
- 134 It also covers the principles for applying containment measures for work with biological agents in all types of facilities, including research, teaching, clinical, forensic, veterinary and environmental laboratories, and explains the rationale for the various containment and control measures. This can be achieved by using a combination of primary and secondary containment measures.
- Primary containment provides protection of the worker and the immediate environment and can be achieved through a combination of good microbiological practices or techniques and the use of appropriate containment devices or safety equipment, eg MSCs. Further protection may include procedural controls and use of other safety equipment, and may be supplemented by immunisation.
 - Secondary containment provides measures to protect those outside the immediate facility and can be achieved by a combination of laboratory design and operating procedures, eg restriction of access, air handling and safe disposal of waste.

Containment levels

- 135 There are no legal minimum containment requirements under COSHH for CL1 laboratories. However, it may be appropriate to follow the practices, safety equipment and facilities like those used at CL2. CL1 is appropriate in secondary education and undergraduate teaching laboratories for work with well-defined and characterised strains of HG1 biological agents, which are unlikely to cause disease in healthy humans. If work at this level (or at any containment level) involves genetic modification, then other legislative controls, in addition to COSHH, will also apply. Toxic and allergenic risks should also be assessed and prevented or controlled as appropriate.
- 136 CL2 is the most commonly used containment level and is suitable for a broad range of clinical, diagnostic and research work with biological agents which, although capable of causing disease, only present a low-to-moderate risk to employees and are unlikely to spread to the community, with effective treatment or prophylaxis being available. Examples of agents that must be handled at CL2 include common clinical isolates such as *Staphylococcus aureus*, human *respiratory syncytial virus* and *Toxoplasma gondii*.
- 137 CL3 laboratories are the highest containment laboratories in common use in the UK. The type of work carried out at this level varies but containment

measures must provide adequate protection to employees and others from laboratory work with biological agents which can cause severe disease and pose a serious hazard to employees (because of their infectivity and/or route of transmission). These agents may also spread within the community, but effective treatment or prophylaxis is usually available. An example of such an agent is *Mycobacterium tuberculosis*.

Control measures

- 138 Appendix 1, para 2(a-g) sets out the application of control measures of a more general nature to control exposure to biological agents, as set out in COSHH regulation 7(6). The table in Appendix 1 details the application of control measures more specifically in relation to work with biological agents in 'Containment measures for health and veterinary care facilities, laboratories and animal rooms', as set out in COSHH Schedule 3, Part II.
- 139 When working with a biological agent in a particular HG, COSHH requires that the containment level selected matches the HG of the agent as a minimum:
- minimum CL2 for activities which involve working with a HG2 agent;
 - minimum CL3 for activities which involve working with a HG3 agent;
 - CL2 must be used where there are any uncertainties about the presence of HG2, HG3 or HG4 agents if the intention is not to deliberately propagate and concentrate such agents;
 - CL3 or CL4 must be used, where appropriate, if the employer knows or suspects that such a containment level is necessary even if there is no intention to deliberately propagate and concentrate biological agents; and
 - CL3 must be used when it has not been possible to carry out a conclusive risk assessment but where there is concern that the activity might involve a serious risk for employees.
- 140 At any containment level, the risk from work with biological agents is dependent on the HG which considers the severity and means of infection, the quantity of agents being handled and the nature and location of the work. This must be addressed in the local risk assessment. If necessary, specific control measures, in addition to the minimum required under COSHH, should be put in place to make sure that the work is carried out safely.
- 141 The requirements of CL3 are broadly similar to CL2 laboratories; there are however some important physical differences, due to the more hazardous nature of the agents being handled and the protection of people outside the facility. This includes laboratory access, the standard of management, the need for special training and the degree of supervision.
- 142 Although COSHH sets out the minimum requirements for each level of containment, the Approved List classifies certain biological agents (denoted by asterisk) that are not normally infectious to humans via the airborne route (eg blood borne viruses) and provides guidelines on circumstances

where certain measures may not be required, subject to the outcome of a local risk assessment. This does not imply that the work can be carried out at CL2 but simply allows certain physical containment requirements to be changed or dispensed with.

- 143 When carrying out a suitable and sufficient assessment, employers must inform employees how the work will be carried out safely. A local code of practice can set out how and where the work should be carried out and should consider the following.
- *Location of the work* – where the assessment indicates that the physical measures normally required at CL3 are not necessary to control the risk, it may be possible to conduct some work (eg diagnostic testing of specimens containing non-airborne HG3 biological agents) in a segregated area of a CL2 laboratory, provided it can be managed as a CL3 facility with all the relevant additional controls. Work should be undertaken at a different time from other CL2 work in a shared laboratory.
 - *Information, instruction and training* – this must be of the standard required for CL3 work. Where the work is undertaken in a segregated CL2 laboratory, consider if there are any training implications for those not directly involved in the work, eg if they have been informed about the nature of the work and if they know what to do in the event of an emergency, eg a spillage.
 - *Supervision* – consider if the work is appropriately supervised both in and out of normal working hours.
 - *Use of dedicated equipment* – this is required, so far as is reasonably practicable at CL3 but the use of dedicated equipment in a CL2 laboratory will reduce the potential for exposure for those not working with the HG3 agents.
 - *List of exposed workers* – exposure records of those deliberately working with HG3 agents must be kept. If the work takes place in a CL2 laboratory used by others, the risk assessment should identify how and if others could be exposed to the HG3 agents, and if so, their exposure records must also be kept.

Appropriate containment measures for non-airborne transmissible biological agents

- 144 Further guidance on containment measures appropriate for work with these HG3 biological agents is listed in Table 5.1 and in paras 145 to 161. For each of the agents, the additional precautions shown in Information box 5.1 should also be used.

Table 5.1 Selecting appropriate containment measures for non-airborne transmissible biological agents (COSHH, Schedule 3 para 3(5))

Biological agent	Guidance on appropriate containment	
	Diagnostic work	Deliberate work
Enteric bacteria: <i>Escherichia coli</i> , verocytotoxigenic strains (eg O157:H7 or O103) <i>Salmonella typhi</i> , <i>Salmonella paratyphi</i> , <i>Shigella dysenteriae</i> (Type 1)	Paras 145 - 148	All deliberate work must be carried out at CL3 – however the requirement for inward airflow and HEPA filtration (for extract air) should be determined by the risk assessment.
Mycobacteria: <i>Mycobacterium microti</i> , <i>Mycobacterium ulcerans</i>	Paras 149 – 150	
Parasites: <i>Echinococcus granulosus</i> , <i>E. multilocularis</i> , <i>E. vogeli</i> , <i>Leishmania braziliensis</i> , <i>Leishmania donovani</i> , <i>Plasmodium falciparum</i> , <i>Taenia solium</i> , <i>Trypanosoma brucei rhodesiense</i>	Paras 151 - 152, and Information box 5.1	All deliberate work must be carried out at CL3 – however the requirement for inward airflow and HEPA filtration (for extract air) should be determined by the risk assessment. (see Appendix 8)
Blood borne viruses: hepatitis B, hepatitis C, hepatitis D, hepatitis E, Human pegivirus, human immunodeficiency viruses, Primate T-cell lymphotropic viruses, hepatitis viruses not yet identified, simian immunodeficiency virus	Paras 155 - 158 and Information box 5.1	All deliberate work must be carried out at CL3 – however the requirement for inward airflow and HEPA filtration (for extract air) should be determined by the risk assessment.
Agents responsible for transmissible spongiform encephalopathies	Paras 159 – 161 See also <i>Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection</i>	
Other non-airborne biological agents listed in Approved list: <i>Rickettsia akari</i> , <i>R. Canada</i> , <i>R. Montana</i> , Louping ill virus, Wesselsbron virus, Chikungunya virus, Everglades virus, Mucambo virus, Tonate virus		All deliberate work must be carried out at CL3 - however the requirement for inward airflow and HEPA filtration (for extract air) should be determined by the risk assessment.

HG3 enteric biological agents

- 145 Work may be carried out at CL2 if it is unlikely that HG3 enteric agents are present, eg the routine examination of diagnostic stool specimens or screening of food samples for enteric agents.
- 146 Work should take place at a higher containment level if there is a strong likelihood or indication that HG3 enteric agents are present, eg samples associated with patients with symptoms of disease (eg haemolytic uremic syndrome (HUS) or typhoid fever); samples associated with an ongoing outbreak or investigation; or samples from animals where agents such as *E. coli* O157 are part of the normal flora. However, the following measures normally required at CL3 may not be required if the laboratory does not need to:
- be maintained at an air pressure negative to atmosphere;
 - be sealable to permit fumigation; and
 - have exhaust air extracted using HEPA filtration, although in practice this may be the case if an MSC is in use. However, any work that could give rise to an aerosol of infectious material must be carried out in an MSC (or equivalent containment).
- 147 Where certain physical containment measures are not considered necessary and the work can take place in a CL2 laboratory, such measures will need to be documented. Other procedural/management measures normally required at CL3 (above those required at CL2) must still be in place. If the assessment indicates the need to separate the work from other activities, it does not necessarily require a separate laboratory, but the work could be undertaken at the beginning or end of a work period or on a separate bench. However, it is important to separate the work from the routine diagnostic work carried out in the laboratory. Similarly, if an observation window is not available, an alternative measure should be put in place to allow for adequate supervision particularly for individuals working alone, eg CCTV or regular phone calls.
- 148 Work that can be carried out under such conditions includes preliminary microbiological isolation from specimens and serological tests to identify presumptive isolates. However, sub-culturing (but not incubating) a primary isolate for sending on to a reference laboratory may be done under the conditions outlined above if there are no CL3 facilities available. Ideally, the original clinical specimen should be sent to avoid the need for further handling.

Mycobacterium microti* and *M. ulcerans

- 149 In general, work with *M. microti* should be carried out at full CL3, as it can cause severe pulmonary disease and is classified as part of the M. tuberculosis complex. Subject to a risk assessment of the likelihood of shedding of the agent, infected animals could be housed at CL2, with

procedures such as taking blood and post-mortem examination taking place in an MSC or other suitable containment.

- 150 Diagnostic work with clinical material that is known or suspected of containing *M. ulcerans* can be carried out at CL2, as can intentional work with the agent (subject to local assessment) although the additional precautions listed in Information box 5.1 should be used.

HG 3 parasites

- 151 For diagnostic work where there is no intention to propagate or concentrate the agents, eg examination of a blood film for *Plasmodium falciparum* or a faecal sample for *Echinococcus spp*, the work may be conducted at CL2.
- 152 However, additional measures will be required to protect against sharps injury, other forms of skin penetrating injury and ingestion – see Information box 5.1.
- 153 When working with certain HG3 parasites there may be circumstances where not all the requirements of CL3 are necessary for the work to be carried out safely. However, this must be based on an assessment of the risks associated with the work.
- 154 Guidance on work involving the intentional propagation and/or concentration of certain HG3 parasites is given in Appendix 8.

HG3 blood-borne viruses (BBVs)

- 155 Routine diagnostic work with specimens that contain or may contain BBVs can be carried out at CL2. This includes work carried out in such areas as academic research, clinical chemistry, haematology, histopathology, cytology, serology, transfusion microbiology, immunology, drug testing and forensic work. However, additional measures will be required to control the risk of sharps injuries and contamination of the skin and mucous membranes (see Information box 5.1).

Information box 5.1 Additional precautions

- Cover cuts/lesions with waterproof dressings.
- Wear gloves and discard before handling items likely to be used by others, eg telephones.
- Avoid the use of sharps including glassware as far as is reasonably practicable.
- Work should be carried out in a designated area of the laboratory with sufficient space to work safely. The workspace should be kept clear of any unnecessary equipment.
- Wear eye protection if there is a risk of splashing.

Note: Controls such as the restriction of access to the working area and the use of an MSC (if infectious aerosols are produced) should already be in place for routine CL2 work.

- 156 The risk assessment should consider and record whether the procedures being carried out could increase the likelihood of exposure. For example, if it is not the intention to deliberately work with HIV but there are high titres of the virus in the samples being used, eg in early acute HIV infection or end-stage AIDS patients; and the work involves increasing the risk of exposure, eg the use of sharps, then additional control measures should be considered. For deliberate work with these viruses see Information box 5.1.
- 157 For deliberate work with BBVs a risk-based approach can be applied as it may not be necessary to use all the containment measures required at CL3, for example inward airflow and HEPA filtration (for extract air). Whilst these control measures are intended to prevent the dispersal of airborne biological agents beyond the confines of the laboratory, where the risk assessment for the activity concludes that there is no evidence of airborne transmission, these specific measures may not be required. This is consistent with COSHH and the Approved List classification which identifies certain biological agents (denoted by an asterisk) that are not normally transmitted to humans via the airborne route.
- 158 Dispensing with any containment measures must take into consideration the basic characteristics of the biological agent(s) being handled and the nature of the work to be carried out and should be determined by a local risk assessment. The procedural and management measures normally required at CL3 must still be in place.

HG3 TSE agents

- 159 For deliberate work with TSE agents, all the containment measures normally required at CL3 may not be necessary, eg a sealable laboratory and inward airflow. Brain and spinal cord samples present the greatest risk of exposure to the TSE agent, as compared to other diagnostic specimens.

Although certain containment measures may be dispensed with, the following additional protective measures should be taken.

- Care should be taken to avoid accidental inoculation or injury, eg when preparing samples for microscopy or culture.
- Disposable equipment should be used wherever practicable, eg cell counting chambers etc.
- Any items contaminated by the specimens should be either destroyed by incineration, autoclaved or disinfected to the required standard.
- Any residual contamination of automated equipment should be minimised and dealt with before servicing.
- Delicate equipment such as microscopes should be cleaned and maintained regularly to avoid accumulation of potentially contaminated debris.

160 'Low' risk specimens such as cerebrospinal fluid, blood, urine and faeces can be handled in accordance with the guidance in para 147.

161 Further specific guidance on appropriate containment for experimental and diagnostic work with human and animal TSEs is given in *Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection*: <https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>.

Appendix 1: Containment tables

- 1 This appendix sets out the general COSHH measures which must be used to control exposure when working with biological agents, and the containment measures and controls taken from COSHH, Schedule 3, which represents the minimum containment measures to be implemented at different containment levels. Whilst the containment measures for CL4 are included here the focus of this guidance is for work at CL2 and CL3.
- 2 COSHH requires that where it is not reasonably practicable to prevent exposure to a biological agent, the following general measures must be applied in all circumstances.

COSHH Regulation 7(6)

- a. **Displaying suitable and sufficient warning signs, including the biohazard sign.**



- b. **Putting in place appropriate decontamination and disinfection procedures** – To consider the spectrum of activities, the active ingredient or mechanism of action and contact and duration of exposure of the disinfectant to the biological agent.
- c. **Putting in place the means for the safe collection, storage and disposal of contaminated waste – this includes the use of secure and identifiable containers for use both before and after treatment if appropriate** – Waste should be segregated at source, eg infectious or non-infectious, and arrangements should be put in place to make sure that exposure to contaminated waste is controlled both when being stored and when being transported within and from premises.
- d. **Testing, where it is necessary and technically possible, for the presence of biological agents outside primary physical containment** – Examples of testing include the Operator Protection Factor Test (OPFT) for MSCs, testing of integrity of seals, filters etc in a bioprocessing plant environment, or environmental sampling in food testing laboratories.
- e. **Setting out the procedures for working with (and on-site transport of) biological agents or material that could contain them** – Work with biological agents could be covered in local codes of practice or SOPs, or else form verbal instructions to employees if appropriate. When considering transport, remember to consider all forms including pneumatic tubes. Where transport of material such as clinical specimens

need to go via the public highway, they must be carried in accordance with the relevant standards in Carriage of Dangerous Goods Regulations (see Appendix 5).

- f. **Where appropriate, making effective vaccines available to employees who are not already immune** – For further information see para 57.
- g. **Putting in place good occupational hygiene measures including the provision of appropriate and adequate washing and toilet facilities. Where appropriate, eating and drinking is prohibited in any workplace where there is a risk of contamination with biological agents** – These are the basic measures to control infection in any work setting. General guidance on the provision of welfare facilities can be found in the ACOP that accompanies the Workplace (Health, Safety and Welfare) Regulations 1992 www.hse.gov.uk/pubns/books/l24.htm. The principles of good occupational hygiene should be applied in healthcare and laboratory settings.

COSHH Schedule 3 - Part II

Containment measures for Health and Veterinary Care Facilities, Laboratories and Animal Rooms

Containment measures		Containment levels		
		2	3	4
1	The workplace is to be separated from any other activities in the same building.	No	Yes	Yes
2	Input air and extract air to the workplace are to be filtered using HEPA or equivalent.	No	Yes, on extract air ¹	Yes, on input and double on extract air
3	Access is to be restricted to authorised people only.	Yes	Yes	Yes, via airlock key procedure
4	The workplace is to be sealable to permit disinfection.	No	Yes	Yes
5	Specified disinfection procedure.	Yes	Yes	Yes
6	The workplace is to be maintained at an air pressure negative to atmosphere.	No	Yes ¹	Yes
7	Efficient vector control, eg rodents and insects.	Yes, for animal containment	Yes, for animal containment	Yes
8	Surfaces impervious to water and easy to clean.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes, for bench, floor, walls and ceiling
9	Surfaces resistant to acids, alkalis, solvents, disinfectants.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes, for bench, floor, walls and ceiling
10	Safe storage of biological agents.	Yes	Yes	Yes, secure storage
11	An observation window, or alternative, is to be present, so that occupants can be seen.	No	Yes	Yes
12	A laboratory is to contain its own equipment.	No	Yes, so far as is reasonably practicable	Yes
13	Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable containment.	Yes, where aerosol produced	Yes, where aerosol produced	Yes
14	Incinerator for disposal of animal carcasses.	Accessible	Accessible	Yes, on site

¹ In the table, COSHH Schedule 3 - Part II, the requirement for several containment measures at CL3 is risk based, eg the need for HEPA filtration of extract air and the provision of an inward airflow is

dependent on the ability of the biological agent to be transmitted via the airborne route. The *Approved list of biological agents* helpfully identifies, with an asterisk, which biological agents are not normally transmitted via an airborne route. This information should be used in the first instance to inform the risk assessment. The actual specifics of the contained use then need to be considered to make a final decision on the extent to which it is necessary to protect workers from exposure to airborne biological agents, eg propagation of blood-borne viruses such as Hepatitis B virus is unlikely to require room air to be extracted through a HEPA filter or an inward airflow into the room, but would require the use of a microbiological safety cabinet. However, other containment requirements will still necessitate the laboratory being designated as CL3.

Guidance on the containment measures for health and veterinary care facilities, laboratories and animal rooms

Containment measures		2	3	4
1	The workplace is to be separated from any other activities in the same building.	No	Yes	Yes

- 3 For CL3 laboratories lobbies can provide additional protection against unauthorised entrance into laboratories and remind users working in a CL3 laboratory, that they are entering a different and potentially more hazardous work environment. The lobby also provides an additional protection factor (LPF) in the event of a laboratory accident involving the release of biological agents. Using the concept of LPF it has been shown that a lobby/ante-room offers about a 100-fold increase in laboratory containment.
- 4 It is recommended that designs for new CL3 laboratories should incorporate a lobby where practicable. The lobby should be viewed as being within the boundary of the containment area but should not be used to store equipment such as fridges that might contain biological agents. The lobby can be used to change clothing and store emergency equipment, eg respiratory protective equipment (RPE). It is recommended that the doors are interlocked but if this is not practical, arrangements should be in place to make sure that both doors cannot be opened at the same time. The lobby does not require a separate air supply - the important issue is to make sure that there is a gradation of negative pressure with air flowing from the outside, through the lobby and into the laboratory. If, in an existing lobby, there is a separate air supply or extract, care should be taken that this does not compromise the net inward flow of air.
- 5 Separation helps to reinforce the separation between the different working practices and management arrangements required at CL3 compared with CL2.

Containment measures		2	3	4
2	Input air and extract air to the workplace are to be filtered using HEPA or equivalent.	No	Yes, on extract air ¹ ¹ See full table for note	Yes, on input and double on extract air

- 6 HEPA filters on the extract air system are required at CL3 when transmission of the agent occurs by the airborne route. HEPA filters on the extract system are required at CL3 to maintain containment of the facility in the event of an uncontrolled release of biological agents.
- 7 HEPA filters should meet the appropriate performance criteria as defined in BS EN 1822-1.

Containment measures		2	3	4
3	Access is to be restricted to authorised people only.	Yes	Yes	Yes, via airlock key procedure

- 8 Restriction of access to CL2 and CL3 laboratories is required to prevent accidental or deliberate access to the facility by people who are unaware of the risks posed in such facilities, or have not been appropriately trained. Restriction of access may be imposed at the entrance to the laboratory, or at the entrance to the laboratory suite or unit, depending on the design of the facility and the proximity to non-laboratory areas of the building. The boundary should be established and made clear. A biohazard sign should be posted at the access point to CL2 and CL3 laboratories, eg the main entrance to the laboratory suite.
- 9 How access is restricted will vary between facilities and will depend on the containment level. At CL2, it would be acceptable to restrict access using management controls, ie monitoring who is entering the laboratory during periods when the doors are unlocked.
- 10 At CL3 or CL2, restriction of access can be achieved by installing a lock and key, a swipe card, card key or digital lock entry system.
- 11 At CL3 it is more important to restrict who enters the laboratory or animal facility, so it may be necessary to install mechanical restriction. One possible solution could be to install a lock and key or swipe/proximity card system. Digital locks that operate by pressing a sequence of buttons on the lock may be acceptable, but it is important that the sequence code is changed if staff members change or the code becomes known by unauthorised individuals. Prolonged use of the same code can also provide clues to the code sequence due to wear and tear on the buttons.

Information box 1 Permit-to-work (PTW)

A formal PTW procedure is an established means of ensuring that a safe system of work is in place to carry out engineering maintenance and other activities related to containment laboratories, eg non-routine cleaning. They should only be issued by authorised individuals. The important features of such a procedure are as follows:

- A written PTW, signed by a designated responsible person, who has carried out a risk assessment of the work area and the work proposed. This constitutes a formal authorisation for the work, which it describes, to be carried out. The work should be completed in the manner described, using the safety precautions detailed, by the recipient or by people under their control.
- People appointed to positions which involve them in PTW systems should have adequate knowledge, experience and training before they are given the authority to issue or receive permits.
- The PTW should be signed off by both parties on completion of the work.

- 12 At CL3, to make sure that access is restricted and controlled, a list of members of staff with authorised access to the room should be posted on the entrance door to the laboratory. This list could also be held in personnel files. There should be some way of showing the laboratory is occupied and that work is in progress. An additional means ensure access is restricted and controlled is using a permit-to-work system usually issued to engineers before undertaking maintenance work at CL3 (see Information box 1 Permit-to-work).

Containment measures		2	3	4
4	The workplace is to be sealable to permit disinfection.	No	Yes	Yes

- 13 At CL3 the laboratory must be capable of being sealed to allow it to be effectively disinfected. In practice, the most likely and effective method of disinfection of the laboratory will be by gaseous fumigation. Fumigation should take place in the event of a significant spillage or aerosol release. According to local risk assessment, it may also be required before routine maintenance or at the end of major work programmes as part of re-commissioning.
- 14 At CL3 the laboratory should be sealable to make sure that fumigant is retained within the laboratory at sufficient concentration for a period long enough to effectively decontaminate surfaces. Escape of fumigant from the room during the fumigation process (which could potentially occur if there are breaches in the room integrity) should be prevented, due to the harmful effects on human health that could result from exposure to the fumigant.

Containment measures		2	3	4
5	Specified disinfection procedure	Yes	Yes	Yes

- 15 A specified disinfection procedure must be in place and its efficacy assessed at all containment levels for both routine use and following an accidental release of biological agents. Efficacy can be assessed using manufacturers' literature, peer-reviewed literature and in-house testing.
- 16 Disinfection procedures should detail the type of disinfection to be used, its working concentration and contact times required for effective disinfection of the biological agents in use. Disinfection procedures will be influenced by the hazards posed by the biological agents used, eg it is likely that an accidental release of HG3 agents outside an MSC will result in fumigation of the room unless the risk assessment indicates otherwise. COSHH requires that there are plans in place to deal with such incidents at CL3 and it is recommended that planning for major incidents should also be addressed at CL2. See Appendix 6 for further information on procedures to be followed in the event of a major spillage.
- 17 Further advice on disinfection procedures at CL2 and CL3 can be found in Appendix 4.

Containment measures		2	3	4
6	The workplace is to be maintained at an air pressure negative to atmosphere.	No	Yes ¹ See full table for note	Yes

- 18 At CL3 maintaining negative air pressure ensures that there is a net inward airflow and a means of providing secondary containment of the facility, ie to protect people and the environment outside of the facility in the event of an uncontrolled release of HG3 or HG4 biological agents within the laboratory.
- 19 There are no legally specified pressure differentials but typically CL3 laboratories should operate at negative pressure of at least -30 Pa or lower. The important factor is that there should be sufficient rate of inflow of air.
- 20 For CL3 facilities negative pressure can be achieved by a variety of means. Depending on the size of the room, some facilities can generate sufficient inward airflow by means of an MSC ducting exhaust air to atmosphere using passive make-up air through vents in walls or doors. For other CL3 facilities, independent mechanical ventilation may be used to provide the necessary negative pressure, or there may be a combination of both.
- 21 At CL3, if the laboratory uses mechanical ventilation, ie forced inflow and extract of air, then the supply fan should be interlocked with the extract so that the supply is switched off should the extract fan fail. This will prevent reverse airflows and positive pressurisation of the room. In the event of fan

failure, the system should fail to safe, ie positive pressurisation does not result and this failure should be indicated by an alarm. If work is considered critical, arrangements should be in place to make sure there is continuous inward airflow. This can be achieved through the installation of a back-up generator or uninterrupted power supply system in the event of a mains power failure.

- 22 At CL3, where independent mechanical ventilation provides inward airflow, it must be capable of safe isolation, eg by means of gas tight/air tight dampers to make sure that the room can be sealed to allow fumigation.

Containment measures		2	3	4
7	Efficient vector control, eg rodents and insects.	Yes, for animal containment	Yes, for animal containment	Yes

- 23 The control method will depend on the nature of the vector, eg rodents or insects. At CL2 and CL3 there is a requirement to control vectors when working with biological agents where the risk assessment indicates that it is required.

- 24 This measure will be especially important when working with biological agents that can also infect rodents or be transmitted by insects including mechanical transmission.

Containment measures		2	3	4
8	Surfaces impervious to water and easy to clean.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes, for bench, floor, walls and ceiling
9	Surfaces resistant to acids, alkalis, solvents, disinfectants.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes, for bench, floor, walls and ceiling

- 25 COSHH requires that laboratory fabric and equipment is easily cleaned, impervious to water, and maintained in a condition that allows effective cleaning and disinfection. This is fundamental to ensuring that the risk of exposure to infectious agents is kept to a minimum, especially at CL3. Benches and other work surfaces should be cleaned with a suitable disinfectant as required and routinely at the end of each day. Floors should be cleaned periodically by wet mopping with a cleaning agent solution. Dry sweeping and dusting should be avoided.
- 26 Surface materials used for benching, flooring, etc that have been damaged due to the use of acids, disinfectants and wear and tear, should be repaired or replaced, as they could be penetrated by biological agents following spillages, making them difficult to decontaminate.

- 27 For all types of biological agents, impervious surfaces are required for benches at CL2, and benches and floors at CL3. This is particularly important where *in vivo* work is conducted which could result in widespread contamination of all surfaces depending on the biological agent being studied.

Containment measures		2	3	4
10	Safe storage of biological agents.	Yes	Yes	Yes, secure storage

- 28 At CL2, cultures should be stored in appropriate vessels, be clearly labelled and be, SFAIRP, stored within the laboratory or laboratory suite.
- 29 Ideally, viable materials requiring level 3 containment should only be stored and handled within the CL3 laboratory. Fridges and freezers used for storage outside of the laboratory should be kept locked and in areas where access can be controlled. Fridges, freezers and storage containers should be kept locked when not in use. Fridges and freezers used to store viable agents should be connected to a maintained or back-up power supply. Alternatively, they should have an audible or other alarm to indicate loss of power.
- 30 For work with biological agents (and toxins) listed in Schedule 5, Part 7, [Anti-Terrorism, Crime and Security Act 2001](#), it is likely there will be a requirement for secure storage for biosecurity purposes. The increase in stringency with increasing containment levels is a simple reflection of the potential damage that could be caused to humans if unauthorised access was gained to viable material either accidentally or intentionally.

Containment measures		2	3	4
11	An observation window, or alternative, is to be present, so that occupants can be seen.	No	Yes	Yes

- 31 The ability to view the laboratory occupants allows people outside to see when work is being undertaken and whether it is appropriate to enter the laboratory.
- 32 At CL3, an observation window or alternative method of observing the laboratory occupants is required, eg to offer additional protection for lone workers (see Information box 2 Lone working). A glass panel in the laboratory door/wall is usually sufficient unless the view into a laboratory is restricted, where it may be suitable to install a convex mirror in the laboratory.
- 33 Alternatives are sometimes used where laboratory suites are often stand-alone buildings where, for security reasons, there may not be windows or glass panels in doors. In such cases, it may be necessary to install a closed-

circuit television system, or equivalent, to be able to observe occupants of the laboratory.

Information box 2 Lone working

The nature of experimental, research and diagnostic work means that it may be necessary to work out of hours and/or alone. However, establishing safe working procedures for the lone worker in the containment laboratory is no different from ensuring the health and safety of other employees in other work premises. There is no general legal prohibition to lone working and the broad duties of the HSW Act and MHSWR still apply.

The local risk assessments will identify any specific hazards for lone working in the containment laboratory. In addition to ensuring that the individual is competent to work at the containment level in question, the type of work that will be carried out should also be taken into consideration. For some tasks, eg routine diagnostic work, there may be minimal risk. However, for more complex tasks, eg fumigating a safety cabinet or dispensing large volumes of chemicals, it is recommended that accompanied work be undertaken.

Procedures should be in place for monitoring the safety of the lone worker. This can include logging in of lone workers and regular visual checks by security; regular contact between the lone worker and security, eg via telephone; automatic warning devices which operate if specific signals are not received periodically from the lone worker; or other devices which are designed to raise the alarm in the event of an emergency and which can be operated manually or automatically in the absence of activity.

The lone worker should be able to respond in the event of an emergency, eg in case of fire, and they should have access to and be trained in the use of materials to deal with spillages. The worker should be able to summon help if in difficulties. Further general information can be found in an HSE guidance document *Working alone: Health and safety guidance on the risks of lone working* (www.hse.gov.uk/pubns/indg73.htm).

Containment measures		2	3	4
12	A laboratory is to contain its own equipment.	No	Yes, so far as is reasonably practicable	Yes

- 34 There is no requirement to have dedicated equipment in CL2 laboratories. However, equipment should be cleaned and decontaminated before removing from the laboratory for repair or servicing.
- 35 As part of any risk assessment, at both CL2 and CL3, equipment should be considered for its potential to act as a source of contamination for those using or maintaining it. Such equipment should be identified and procedures put in place to decontaminate it regularly, when it leaves the containment facilities or when it is serviced or maintained. A local decontamination certificate is often used to demonstrate that equipment has been suitably decontaminated before undergoing maintenance.
- 36 At CL3 there is a requirement for the laboratory to contain its own dedicated equipment, where the risk assessment indicates that it is necessary. However, there may be instances where you may occasionally wish to use specialised equipment located at CL2 which is used almost exclusively for lower hazard work, such as specialist imaging equipment.
- 37 Where it is not reasonably practicable to have a duplicate piece of equipment, the entry of staff into CL3 to use equipment for lower hazard work may create additional risks and should not be allowed, particularly if they are not trained to work at CL3. If it is necessary to remove material from CL3, procedures should be covered in a risk assessment and designed to prevent loss of containment, eg material should be transported and stored without spillage in properly labelled robust containers and should only be outside the CL3 facility for a short period of time.

Containment measures		2	3	4
13	Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable containment.	Yes, where aerosol produced	Yes, where aerosol produced	Yes

- 38 At CL2, if the biological agents can be spread by aerosol and can cause human disease, procedures that are likely to create aerosols, eg vigorous shaking or sonication of liquids, must take place within an MSC or similar containment. Class I or II MSC's may be used depending on which is deemed the most appropriate. Extract air from MSCs must always be HEPA filtered. (For further information on the use of MSCs refer to Appendix 2.)
- 39 At CL3 all work with infectious materials that can be spread by aerosol and can cause human disease must take place in an MSC or similar

containment. Normally a Class I or Class II MSC will be used, but a risk assessment may indicate a Class III cabinet is required for work with biological agents with an airborne route of transmission that can cause serious human disease, eg multi-drug resistant TB. Where re-circulating MSCs are used, exhaust air should be passed through two HEPA filters in series and consideration given to heat and humidity build-up and fumigation procedures.

Containment measures		2	3	4
14	Incinerator for disposal of animal carcasses.	Accessible	Accessible	Yes, on site

- 40 At CL2 and CL3 an incinerator must be accessible for the disposal of animal carcasses, but this can be off-site provided that the final disposal method, eg incineration, is validated and that waste is stored and transported in a way that does not increase risk.

Appendix 2: Microbiological Safety Cabinets

Definitions and requirements

- 1 An MSC is a ventilated enclosure which offers protection to the user and the environment from infected and hazardous biological material. MSCs use a combination of airflow and filtration to contain airborne droplets and particles generated during handling of biological agents or infectious material, preventing their escape and exposure of workers and the local environment. All exhaust air discharged to atmosphere from an MSC must be high-efficiency particulate absorption (HEPA) filtered.
- 2 Under COSHH (regulation 7 (10) and schedule 3 part II) there is a requirement that, at CL2 and 3, procedures that may produce infectious aerosols must be carried out in an MSC or other suitable containment. There are additional requirements within COSHH for the thorough examination and testing of MSCs and isolators.

**COSHH
Regulation
7(10) and
Schedule 3
part II**

Principles of operations of MSCs

- 3 MSCs vary in design but operate under the same basic principle of providing user protection by enclosure and discharge of exhaust air through HEPA filtration. They fall into three different classifications,² Class I, Class II and Class III, each offering different levels of protection to workers and materials.

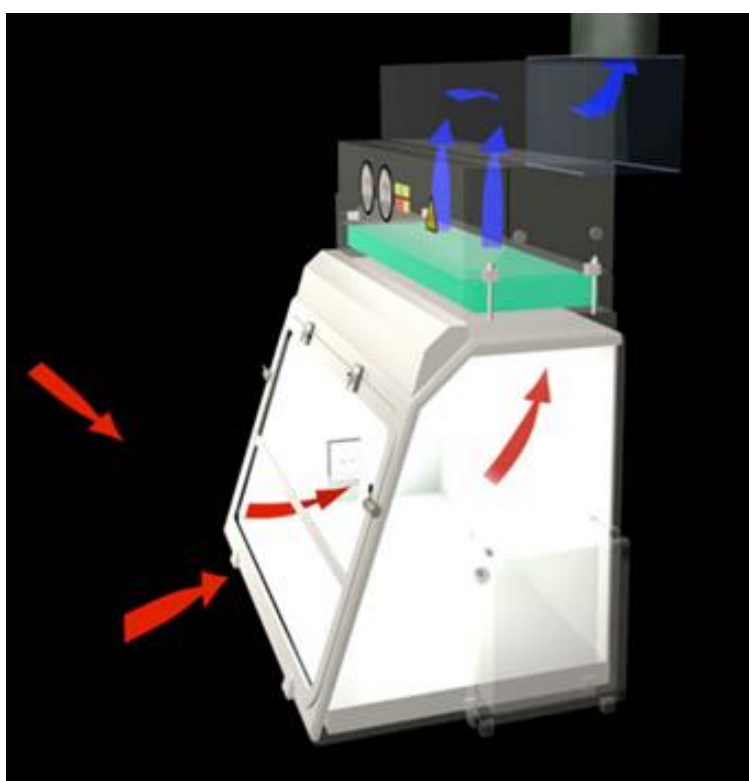


Figure 1 Class I MSC. Coloured arrows indicate airflow – red arrow denotes ‘dirty’ unfiltered air, blue arrow denotes ‘clean’ filtered air’

² MSC classifications do not correspond to Containment Levels.

Class I MSCs

- 4 Class I MSCs have an open aperture at the front through which the operator can carry out manipulations on potentially hazardous materials. They provide operator protection by maintaining a single inward flow of air past the operator and over the work surface (Figure 1).
- 5 Exhaust air is HEPA filtered, but incoming air is unfiltered, therefore this type of cabinet is not designed to offer protection to material being handled. Class I MSCs are suitable for work with all biological agents up to HG3 but not with HG4 agents.

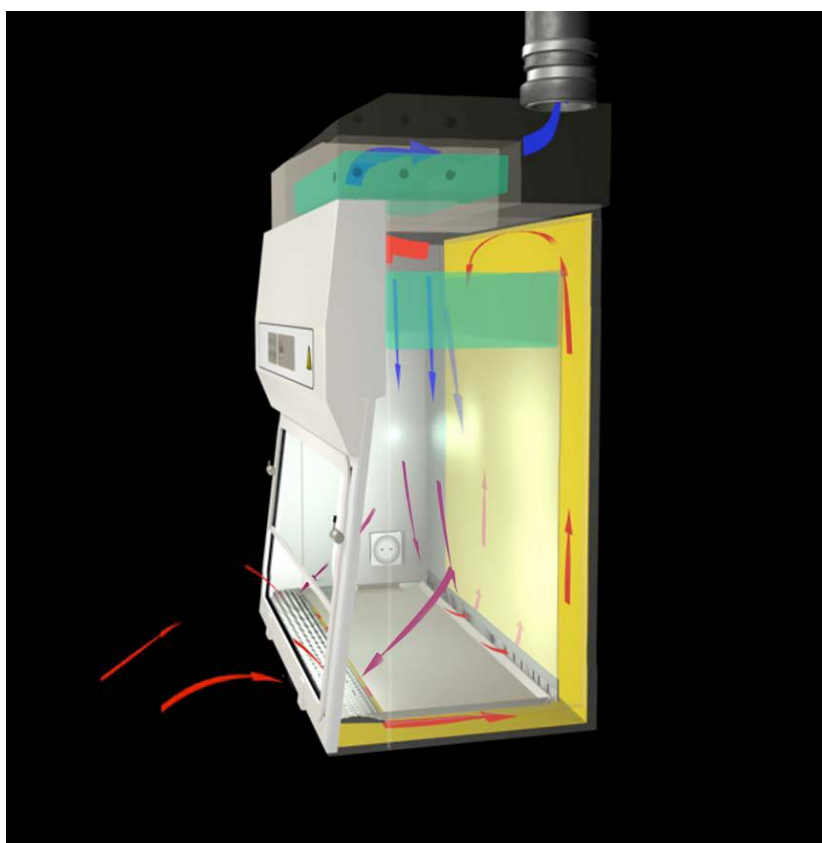


Figure 2 Class II MSC. Coloured arrows indicate airflow – red arrow denotes 'dirty' unfiltered air, blue arrows denote 'clean' filtered air

Class II MSCs

- 6 Class II cabinets have an open aperture at the front through which the operator can carry out manipulations on potentially hazardous materials. They provide protection to both the operator and the materials being handled as the inward airflow is diverted beneath the work surface and is HEPA filtered before recirculation within the work area. The downward airflow onto the work surface also minimises the possibility of cross-contamination within the cabinet (Figure 2).

- 7 Modern Class II MSCs will offer similar operator protection to a Class I MSC. However, Class I MSCs are less affected by external factors and internal flow rates than Class II. Users should consider the needs of the work and be aware of the limitations of the equipment before selection. Class II MSCs are suitable for work with all categories of biological agent except HG4.

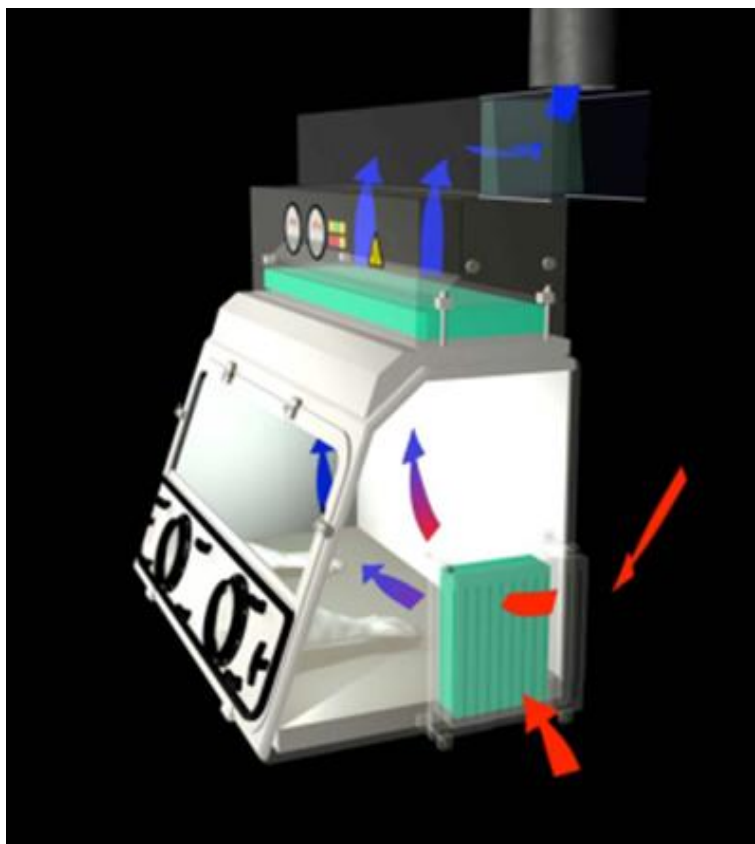


Figure 3 Class III MSC. Coloured arrows indicate airflow – red arrows denote 'dirty', unfiltered air; blue arrows denote 'clean', filtered air

Class III MSCs

- 8 Class III MSCs are totally enclosed and provide maximum protection for the operator, the work and the environment. All inward and exhaust air is HEPA filtered and access to the work area is using full arm-length gloves (gauntlets) that are sealed to ports in the front of the cabinet (Figure 3). Use of Class III MSCs is usually restricted to work with HG4 biological agents.

Class I/III hybrid MSCs

- 9 Some manufacturers also produce Class I/III hybrids, which can be used as either Class I, or Class III by means of a removable port that attaches to the front aperture. For either mode, they must be tested to demonstrate satisfactory operator protection before being used to provide that level of containment.

Performance criteria and installation requirements for safe operation of MSCs.

HEPA filtration

- 10 MSCs must exhaust through a HEPA filter or equivalent, preferably direct to the outside air or, if this is not practicable, via the laboratory air extract system. The HEPA filter works by removing particulates (generally called aerosols) such as microorganisms, from the air. There is a requirement within BS EN 12469 that the minimum grading of filtration in MSCs is equivalent to H14 as defined within BS EN 1822, ie with a collection efficiency of 99.995% of 0.3 µm to 0.5 µm sized particles. The HEPA filter should ideally be part of the MSC, but if not, they should be located as close to the cabinet exhaust as possible, to avoid accidental contamination of the building exhaust system with biological agents.

Note: Laminar flow cabinets or 'clean air' systems are **not** MSCs and should not be used when handling potentially infectious materials. They are designed to deliver a stream of HEPA filtered 'clean' air over a working surface to prevent sterile materials, eg culture media or drug preparations, becoming contaminated, or as clean work stations for molecular work with non-infectious samples. Any airborne droplets are actively directed at the operator so any material that is potentially infectious is hazardous.

Re-circulation of exhaust air to the laboratory

- 11 If it is not practical for the MSC to exhaust to open air, either directly or indirectly via the laboratory exhaust, re-circulation of exhaust air through two HEPA filters in series may be considered as an alternative. While this method will remove biological agents from the air it may be difficult to remove chemicals, eg fumigant, when the cabinet has been fumigated. Therefore, the local fumigation protocol should include information on safe methods to remove the fumigant when the MSC is to be decontaminated (see Appendix 3).

Positioning of MSCs within the laboratory

- 12 MSCs should be installed and commissioned by trained personnel. When positioning an MSC within the laboratory, it is important to make sure that the cabinet's performance is not affected by air flows (examples given in Figure 4). For further information on siting and use of cabinets refer to BS 5726:2005.



Figure 4 Siting of Microbiological Safety Cabinets

- Position 1** At Cl2, this would be poorly sited if window was open – as affected by air currents between door and window. If the window is sealed then it should be at a safe distance from the MSC opposite.
- Position 1** At CL3 would be suitable since windows should be sealed.
- Position 2** MSC is poorly sited, affected by air currents from opening door and pedestrian traffic.
- Position 3** Well sited.
- Position 4** Well sited (better than 3 as not so near corner).

- 13 There are many factors that may affect containment performance of MSCs (see Information box 3). 'In-use' operator protection factor testing should be carried out to establish that protection is not compromised by these in any way. Other considerations include competing airflows from air conditioning units and other equipment within the laboratory, such as other MSCs, fume cupboards, laminar flow cabinets, centrifuges etc.

Information box 3 Factors affecting MSC containment performance when in use

The inward airflow through the working aperture of open front MSCs (Class I and Class II) can be disturbed by factors including:

- the presence and location within the cabinet of large pieces of equipment;
- heat sources such as a hotplate;
- centrifuges that can disturb air movement;
- sudden movement of the arms of the operator and turbulence in and around equipment placed inside the cabinet; and
- people moving near the cabinet, air movements in the room or changes in air pressure. Disturbances of this nature may also significantly affect the level of protection for the operator.

MSC air extraction systems

14 Choice of the air extraction system is normally considered at the initial design stage of the laboratory. When designing and installing the extract ductwork and fans, there are many different concepts available, which include the following:

- **Hard-ducted extract** systems direct to a fan either on the roof or out of a window. The duct is continuous from cabinet to fan and requires volume control dampers in the ductwork that control the air taken from the cabinet. The mechanical dampers allow for a constant air volume.
- **Thimble extract** systems differ from the hard-ducted systems in that the air from the cabinet is blown into an open capture thimble from which a volume of air is extracted by the main extract fan. This system must be balanced to make sure that more air is extracted via the thimble than from the cabinet exhaust. This makes sure that the net flow of air is from the laboratory into the thimble, and not the reverse. They are often used where it is necessary to have more than one cabinet ducted via the same extract system.
- **By-pass extract** systems draw additional air from the laboratory via a by-pass which can be fitted with a HEPA filter when required. These systems will require controls to determine whether the air is drawn from the cabinet or from the by-pass.

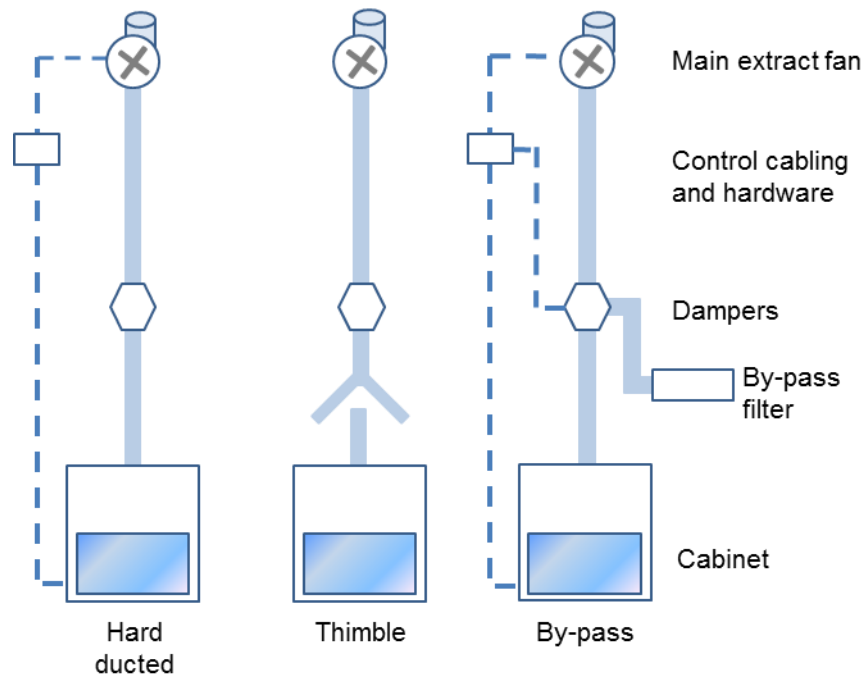


Figure 5 Options for air extract systems for MSCs

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.

Instruction and training

- 17 Staff should be adequately trained in the use of MSC (see Information box 4 for factors to consider when working in an MSC). Training should cover:
 - the operational characteristics of the type of MSC in use;
 - the principles of airflow and limitations of performance;
 - safe use, including the function of all controls and indicators, eg the action to take following a MSC failure, eg alarm sounding;
 - testing and monitoring of performance, eg airflows, operating protection factor tests; and
 - decontamination protocols.

Information box 4 Factors to consider when working in an MSC

Commonly reported faults have revealed instances of unsafe practice while using MSCs, eg where the MSCs audible air flow alarm had been deliberately muted, or instances where MSCs were used without the air extract fan in operation while handling HG3 agents.

- Before using the MSC - Check that it is functioning, ie the pressure gauge readings are within the acceptable range.
- Test the airflow alarm and make sure it is switched to the 'on' position and has not been muted.
- Where the MSC has no warning alarms or an interlinked light/extraction fan electrical supply, managers must:
 - carry out appropriate checks to make sure the extraction fan is operating before working in it; and
 - suitable systems should be in place to monitor these checks to ensure they are being followed.
- Only load the MSC with the equipment you need - care should be taken not to overcrowd or block the MSC so as not to compromise the cabinet airflow.
- Place aerosol generating equipment (eg mixers, vortex) towards the back of the MSC to avoid compromising the airflow within the MSC.
- While working within the MSC, perform operations as far towards the rear of the work area as possible and make sure that elbows and arms do not rest on the grille or work surface.
- Avoid excessive movement of hands and arms through the front opening, which may disrupt the air curtain at the front of the MSC.
- Keep a bottle of an appropriate disinfectant in the MSC while work is performed, to avoid having to move hands outside of the MSC.
- At the end of each day, disinfect the internal surfaces with an appropriate disinfectant.
- Material should be discarded in a waste container located towards the rear of the MSC workspace. Do not discard materials in containers outside of the MSC, avoiding moving hands out of and back into the MSC.

Ergonomics

- 18 It is important that users understand the benefits associated with good posture when working at an MSC.

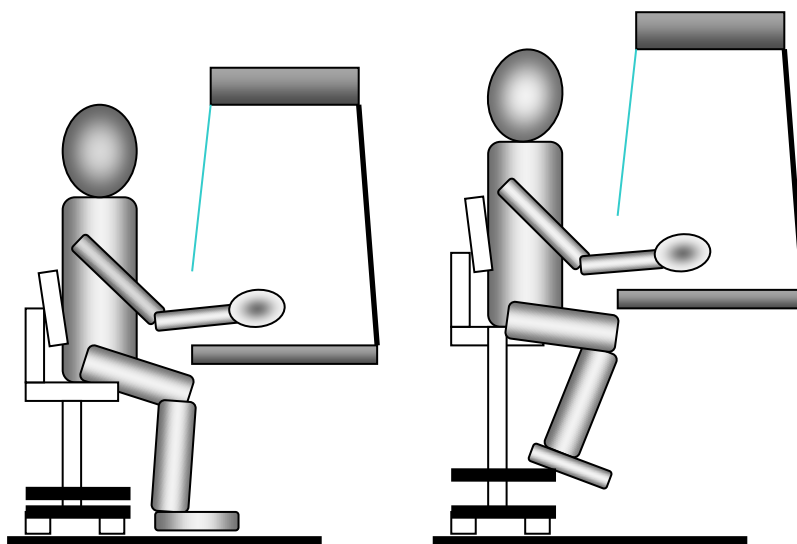


Figure 6 Diagrams illustrating examples of good posture when using MSCs

- Good vision of the working area; maximum protection for the face, eyes, respiratory area against possible spillage or release of biological material inside the MSC.
- User's feet well supported.
- Chair supports the user's back.
- The back and shoulders are not under unnecessary strain.
- Area underneath the MSC kept free from obstruction to allow user to sit comfortably.

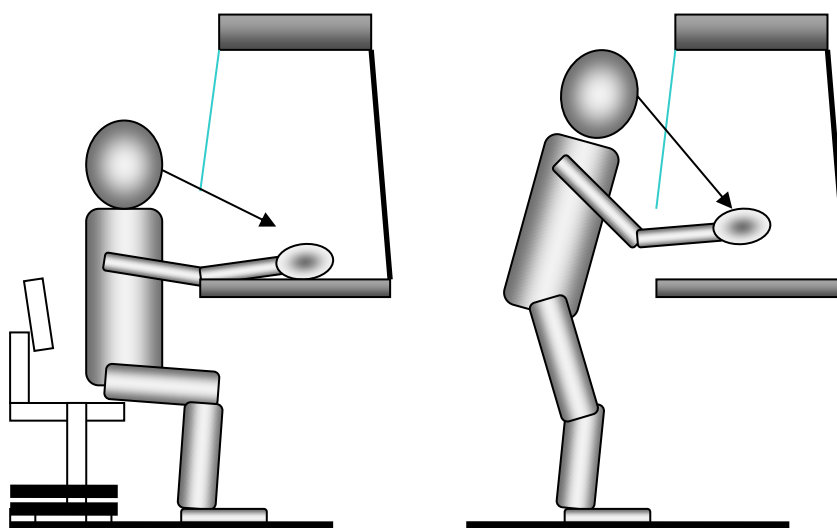


Figure 7 Diagrams illustrating examples of poor posture when using MSCs

- The user on the left is sitting too low. The user on the right is standing slightly stooped. Neither is positioned comfortably, nor are they using the cabinet in the safest manner.
- Both positions are uncomfortable and will quickly fatigue the user over a longer working period. Prolonged and frequent work in these positions

could cause musculo-skeletal strain or aggravate existing muscular conditions.

- View of the work being done may be obscured for the user on the right, or there may be unnecessary glare from external light sources reflecting off the cabinet face.

Fumigation of MSC and filters

- 19 Before any service work, other than minor attention to controls and lamps fitted on the outside, an MSC should be fumigated. Fumigation will be necessary when filters are to be changed; access is required to internal ducting or fittings, or where an assessment deems it necessary, eg following a spillage.
- 20 In most laboratories, formaldehyde vapour is the method used to fumigate MSCs, and Information box 5 summarises the procedure to follow as validated and recommended by MSC manufacturers. Other fumigants and methods of fumigation are also commercially available, and the suppliers of such equipment will be able to advise on validation for use in MSCs.

Information box 5 Formaldehyde fumigation

The generation of formaldehyde vapour from formalin is the simplest method of fumigation. The following quantities of formaldehyde solution are based on MSC manufacturers' recommendations and are as follows.

- For a 1200 mm MSC, place 20 ml of formalin BP and 20 ml of water in a dish on an electric heater in the cabinet (for a standard-sized (1500 mm) MSC, use 25 ml of formalin BP and 25 ml of water). Replace the front closure. Alternatively, some MSCs have an integral vaporiser unit that is filled from outside the cabinet and delivers the vapour through an aperture into the cabinet. Switch on and boil away the formalin mixture. The addition of a thermostatic control and a time switch are useful for this operation.
- For larger MSCs (1800 ml) allow 30 ml of formalin and 30 ml of water for every cubic metre of cabinet volume. When half of the solution is evaporated switch on the cabinet briefly so that fumigant will penetrate the filter and ductwork.
- Leave for a minimum of 6 hours – for practical purposes often it is useful to leave overnight.
- Switch on the cabinet fan and open the front closure a few millimetres to allow air to enter and the remaining formaldehyde to be exhausted outside the building.
- MSCs with double filtered exhaust outlets which recirculate air within the room will require temporary ducting to carry away formaldehyde vapour, or alternatively vaporiser units are available in which the formaldehyde is then neutralised by ammonia vapour.
- Wipe down internal surfaces of the MSC with water or detergent solution to remove any surface deposits of chemical residues before returning it to use.

Routine maintenance

- 21 The routine maintenance of an MSC is vital to ensure that it continues to operate effectively and offers the optimum protection to the user.
- 22 Performance criteria are given in BS EN 12469 which outlines the minimum performance criteria for MSCs when using biological agents and specifies test procedures with respect to protection of the worker and the environment, product protection, and cross contamination.
- 23 Operator protection factor is a measure of the degree of protection provided to an operator of an open-fronted MSC when particles are released inside.
- 24 BS EN 12469 suggests that the need to carry out an Operator Protection Factor Test (OPFT) at installation and during subsequent routine maintenance testing is only optional. However, COSHH, in referring to 'local exhaust ventilation', requires a thorough examination and testing of equipment including MSCs on installation and as part of routine ongoing maintenance, at intervals not exceeding 14 months.

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

- 25 To make sure that the MSC is continuing to perform as intended, it is recommended, as good practice, that an OPFT is carried out in addition to the tests specified by BS EN 12469, at intervals not exceeding 14 months.
- 26 In some cases, it may be appropriate to test more frequently than 14 months, eg at six-monthly intervals when working with HG3 biological agents. Table 1 gives details of recommended testing frequencies and minimum expected results to achieved operator protection (where applicable).

Testing alarms/indicators

- 27 Alarms and indicators (Figure 8) should be calibrated and checked at installation and during the 6-monthly and 12-monthly engineer visits. Before beginning any hazardous work in the MSC, the individual working at the MSC should confirm that all alarms and indicators are operating within their normal parameters.



Figure 8 Alarms/indicators on safety cabinet

Monitoring airflows

- 28 In addition to the airflow measurements undertaken by the engineer during the 6-monthly and 12-monthly visits, inward airflow tests on MSCs should be done at least monthly by suitably trained people. This can be done using a vane anemometer (Figure 9). Hot wire anemometers can also be used, but are more flow-directional and less simple to use. Due to the varying complexities associated with the airflows in a Class I and Class II MSC, different methods are required to undertake the airflow tests effectively.



Figure 9 Vane anemometer

Measuring the inflow velocity for a Class I MSC

- 29 To undertake the inflow velocity measurement the cabinet should be left running and a calibrated vane anemometer held vertically at the opening of the MSC. Airflow measurements are recorded at a minimum of five positions, ie the geometric centre of the aperture, and each of the four corners of the opening (with the centre of the anemometer 50-55 mm from the side and top or bottom edge of the aperture). See Figure 10.

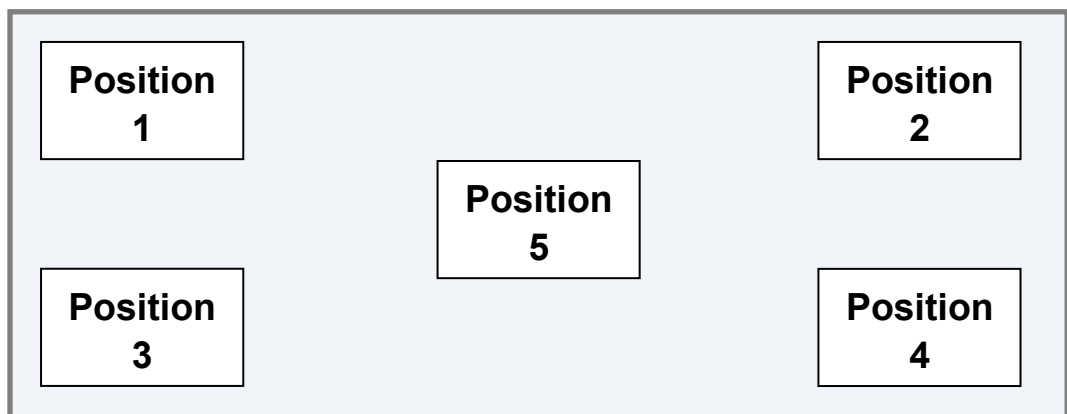


Figure 10 Five positions at the face of the Class I MSC. The measured airflows at all points within the Class I MSC should be between **0.7** and **1.0 m/sec** with no individual measurement differing from the mean by more than 20%

Measuring the inflow/downflow velocity for a Class II MSC

- 30 To do the inflow and downflow velocity measurements the cabinet should be left running. To measure the inflow air velocity, a calibrated vane anemometer is held vertically at the opening of the MSC and measurements taken at three positions in the centre horizontal plane. See Figure 11.

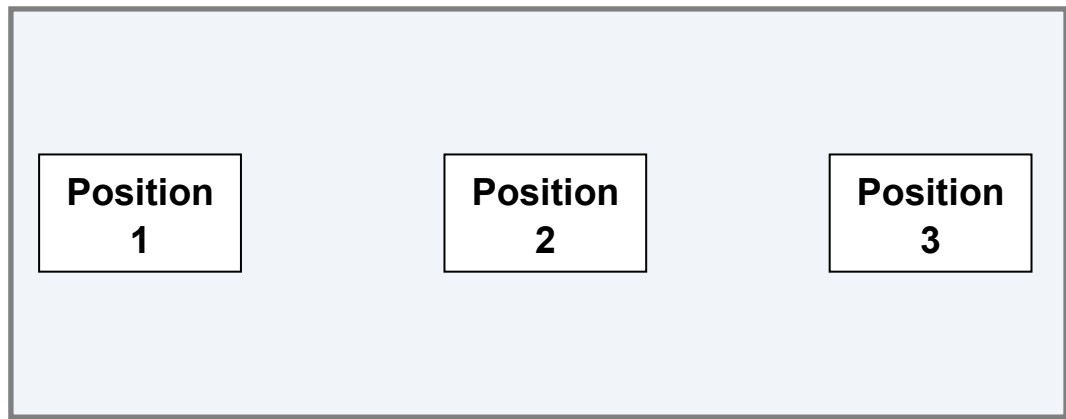


Figure 11 Three positions at the face of the Class II MSC. The measured inflows of the Class II MSC at all positions should be over **0.4 m/sec**

31 To measure the downflow of the Class II MSC the vane anemometer is placed in the horizontal plane within the Class II MSC 100 mm above the top edge of the working aperture. As shown in Figure 12, air velocity measurements are taken at a minimum of eight positions within the MSC at:

- four positions along a line a quarter of the depth of the working space forward from the rear wall of the MSC; and
- four positions along a line the same distance behind the front window of the MSC.

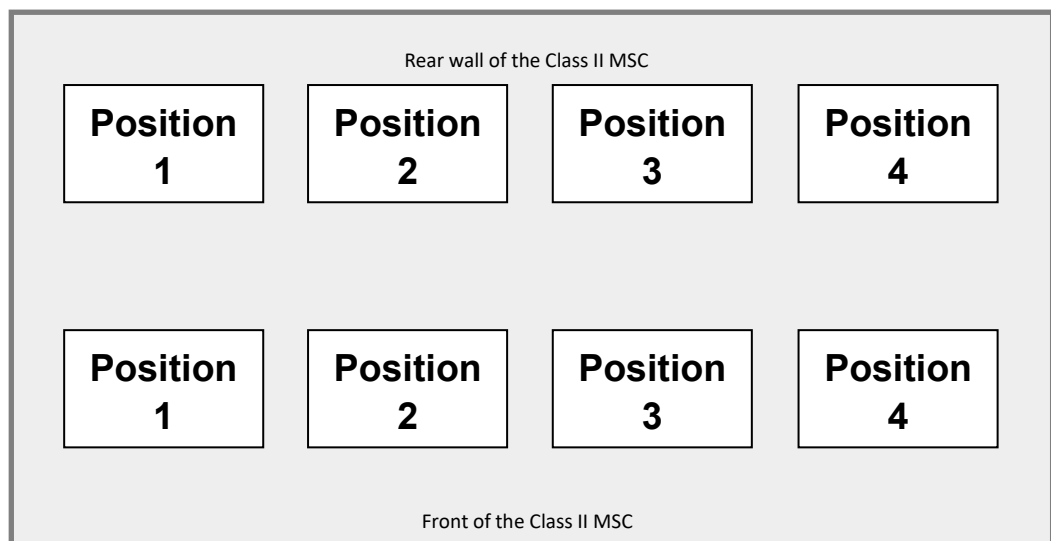


Figure 12 Aerial view of the working surface within the Class II MSC. Downflow measurements at all positions should be between **0.25** and **0.5 m/sec** with no individual measurement differing from the mean by 20%

OPFT performance criteria

- 32 The minimum inward airflow through the front aperture of a Class I or Class II MSC is defined in BS EN 12469 the minimum standard is 1×10^5 . This figure expresses the ratio of the number of airborne particles that would be generated in a procedure conducted on the open bench to the number resulting from the same procedure within a cabinet. This means that for every 100 000 particles used in a test as a challenge to the inward flow of air at the working aperture, not more than one should escape.

In-use OPFT of open-fronted MSC

- 33 To assess the containment under actual conditions of use, it may be necessary to carry out an 'in-use' OPFT, eg when working with HG3 biological agents, particularly when there may be other sources of ventilation and movement of staff around the laboratory. This can result in alteration of air movements in the room which may reduce the containment ability of the MSC. In-use tests may also be required if the set-up of the laboratory changes significantly since the initial OPFT, eg changes to laboratory layout, installation of new equipment.

Information box 6 Important requirements specific to in-use testing of an MSC

- Conditions represent normal working conditions.
- Tests should be performed with the MSC loaded with a typical arrangement of equipment.
- Any other items of equipment normally used nearby, eg other MSCs, fume cupboards that produce airflow currents should also be on during the tests.
- Traffic which would occur normally in the laboratory should be reproduced in the tests, eg people entering and leaving the room (ie opening and closing the door), walking around in the laboratory and past the MSC.
- There should be no modifications to the laboratory or working practices and the room ventilation system should be working as normal.

Appendix 3: Decontamination, fumigation and sealability

Introduction

- 1 This Appendix provides information on managing the risks associated with whole-room gaseous disinfection³ and is aimed at those responsible for managing and operating facilities where deliberate work with biological agents is undertaken at CL3. It will also be useful to those involved in providing CL3 maintenance, fumigation or sealability assessment services. It includes advice on ensuring that disinfection is effective and carried out safely, minimising the potential for escape of hazardous fumigant beyond the facility boundary.
- 2 Safe and effective decontamination of work surfaces and equipment is important when managing the risks associated with work involving infectious agents. It is particularly important at CL3 if agents being handled are aerosol transmitted and the consequences of infection may be serious.
- 3 Methods of disinfection include manual spray-and-wipe using liquid disinfectants; fogging techniques (which also use liquid disinfectants); and gaseous fumigation systems. The latter may comprise of true gases, eg chlorine dioxide (ClO₂) and ozone, or vapour generated by heating source liquids, eg formaldehyde and hydrogen peroxide (H₂O₂).
- 4 Fumigation offers comprehensive spatial and surface coverage. It allows effective disinfection of difficult to reach areas such as the underside of benches and shelving, corners and crevices, and inaccessible ductwork and ventilation systems. It can be used to decontaminate HEPA filters *in situ* and, with appropriate design, planning and preparation, allows entire rooms to be disinfected without operators needing to enter a contaminated area.
- 5 The efficacy of all fumigants depends on factors which include concentration, contact time, the biological agent, temperature, humidity and the presence of organic matter in the material to be decontaminated, which can have a neutralising effect. Some fumigants can absorb to cardboard, so you should limit cardboard boxes in areas likely to need fumigation.
- 6 While each fumigant has been shown to have biocidal activity, they may vary significantly in their efficacy, spectrum of activity, and safety profile.
- 7 In practice, fumigation is only required in certain circumstances and its principal use within the laboratory context, mainly at CL3, are to make sure equipment (eg MSCs, isolators, and air handling systems) are free of infectious contaminants in preparation for routine maintenance and

³For the purposes of this guidance: the term '*Whole-room gaseous disinfection*' means fumigation of any area or areas within a facility where the fumigant is not restricted to within primary containment, eg not fully enclosed within equipment or a specialised chamber. This may include a single room, a collection of rooms, and/or the adjoining space.

performance testing, or for whole-room disinfection following a spillage (see Appendix 6). Information box 7 summarises the requirements and considerations before undertaking fumigation.

Information box 7 Important requirements and considerations for room fumigation

- Only fumigate when justified by risk assessment, eg emergency room fumigation following a significant spillage, in advance of routine maintenance of equipment that may be contaminated with infectious material, testing or replacing room HEPA filters which may contain trapped infectious agents that could be released during the process.
- Those carrying out fumigation, including external contractors or those overseeing the process, must be trained and competent.
- Turn off the air handling system, make sure dampers are closed and seal any other escape routes for the fumigant, eg grilles and gaps around doors.
- Make sure others know when fumigation is being done, eg site maintenance team who could otherwise be exposed to fumigants being vented to atmosphere.
- Post-fumigation and before anyone re-enters the room, fumigant must either be fully removed using the ventilation system, or neutralised.
- If venting to atmosphere, make sure fumigant cannot be drawn back into the building through windows or other ventilation systems.
- Only re-enter room when fumigant levels are confirmed as below the relevant workplace exposure limits (WEL).
- If, in an emergency, it is necessary to enter the area before fumigant is removed, suitable breathing apparatus or RPE must be worn.

- 8 Fumigation carries significant risk because most gaseous disinfectants are respiratory irritants even at low levels, and at higher levels they can be highly toxic or carcinogenic. To be effective, fumigants are used at concentrations at more than safe WELs. Risk of exposure to fumigant is *not* limited to those directly involved in the fumigation process, as it can also affect people outside the facility if not contained.
- 9 For most fumigants hand-held real-time air quality monitors are available and should be used to ensure fumigant concentrations are below the WEL before re-entering any treated area. Most commonly, fumigant levels are assessed and monitored by sampling the air through a small port fitted in the door for this purpose.
- 10 The main laboratory fumigants are described below, with safety factors associated with their use summarised in Table 2.

Formaldehyde

Properties and uses

- 11 Formaldehyde gas is a highly effective broad-spectrum disinfectant with a long history of use. It is simple and inexpensive to generate, and remains the fumigant most commonly employed in biocontainment laboratories and animal rooms.
- 12 It kills a wide range of microorganisms, including bacterial spores that are generally considered to be the biological agents most resistant to chemical inactivation.

Note: Formaldehyde will not inactivate the agents that cause TSEs and should not be used for this purpose.

Efficacy

- 13 As well as factors common to all fumigants (see Table 2) room humidity and temperature are particularly important. To be effective, formaldehyde gas must dissolve at adequate concentrations in a film of moisture in the immediate vicinity of the organisms to be inactivated.
- 14 Formaldehyde fumigation is less effective at lower temperatures (<18 °C) because it condenses on cold surfaces which could limit coverage of a room being treated. For this reason, outside walls and windows may develop condensate in cold weather and this should be taken into consideration when planning room treatments.
- 15 In addition, temperature and relative humidity should be maintained within an appropriate range for maximum effect and, as formaldehyde penetrates slowly into air spaces and porous surfaces, a prolonged contact time of at least 12 hours is required (see Information box 8).

Generation and delivery

- 16 Although there are various ways to generate formaldehyde gas, heating a mixture of stabilised formalin solution and water is the most common. Formalin is commercially available as a stock 35-40% solution and adding more water maintains a relative humidity at which the gas has maximum antimicrobial effect. Information box 8 summarises the parameters to maximise effectiveness. This concentration range typically makes sure a 6-log reduction (survival rate of less than one bacteria in a million) even for bacterial spores known to be most resistant to formaldehyde gas.

Information box 8 Important points to remember when fumigating with formaldehyde

To achieve an efficacious concentration range, typically 600 – 1400 ppm:

- adjust the ratio of formalin to water used to achieve a relative humidity between 70% and 90%;
- calculate the quantities of formalin/water required from the volume of the space to be fumigated - typically a 1:9 ratio of formalin to water; 100 ml formalin and 900 ml of water for every 28.3 m³ of space;
- consider the surface area exposed in that space and the presence of absorbent materials such as cardboard boxes, increasing the volume used to allow for this; and
- aim to achieve a room temperature between 15 and 32 °C but bear in mind that below 18 °C formaldehyde fumigation is less effective. Below 9 °C formaldehyde sublimates and is less easy to vaporise.

Hydrogen peroxide vapour (HPV)

Efficacy

- 17 HPV is effective against a range of pathogens, including bacterial spores. It has also been used successfully to decontaminate HVAC systems and associated filters. Advances in HPV technology permit the decontamination of increasingly larger spaces, from small pass-through boxes to areas more than 300 m³. However, multiple fumigant delivery systems may be required for effective fumigation of larger facilities, with active mixing of the air to achieve consistent efficacy throughout the treated areas.

Generation and delivery

- 18 HPV is produced from a solution of liquid H₂O₂ and water (30%-35% typical) in generators specifically designed for the purpose. These produce typical concentrations of 0.5-10 mg/l H₂O₂ with 400-500 ppm peak levels typical in air during room treatment. However, some 'dry mist' fumigation systems are available that use a source H₂O₂ solution in the 5%-8% range, and which deliver the fumigant as a fine particle spray, often with associated silver ions. These typically achieve room fumigant concentrations in the 50 ppm to 100 ppm range and may not be suitable for all laboratory use. They do offer the advantage of reduced residues of fumigant post-treatment which may make them better for some applications. Full validation is required for any system before use.
- 19 HPV can be generated in a 'wet' or a 'dry' process, which is controlled by the commercial systems used to deliver these treatments. In the wet process, the vapour produced undergoes micro-condensation, which gives a high concentration of liquid H₂O₂ on surfaces. In the dry process, the H₂O₂ is maintained as vapour below the 'dew' point, so minimising surface condensation, although raised levels of relative humidity are still required to deliver the desired biocidal effect.

Chlorine dioxide gas (ClO₂)

Efficacy

- 20 ClO₂ is available as an active biocidal product in wet disinfectants, but for the purposes of this Appendix only true gas (fumigant) delivery of the chemical is considered. In addition, solutions of ClO₂ do not fog well and are prone to foaming, so gas generation is more effective and practical
- 21 ClO₂ fumigation can kill a range of challenge microorganisms, with multi-log reductions possible against known pathogens, including spore forming bacteria.

Generation and delivery

- 22 Gaseous ClO₂ systems are available for fumigating laboratory rooms or suites of rooms up to 800 m³. These usually require a source gas supplied from compressed gas cylinders, containing 2% chlorine gas mixed with 98% nitrogen as an inert carrier. The ClO₂ decontamination cycle is controlled by the delivery system and consists of several phases, finishing with aeration.
- 23 Humidifiers and fans are used within the treated area to maintain relative humidity, typically in the 65% to 75% RH range, and to encourage uniform mixing of gas and moisture in the treated area.

Table 2 Safety and operational requirements for use of the three fumigants most frequently used in laboratories

Safety and operational considerations	Fumigant		
	Formaldehyde	Hydrogen peroxide vapour	Chlorine dioxide
Inhalation effects and Workplace Exposure Limit (WEL)	WEL 2 ppm both long and short-term; severe respiratory effects above 20 ppm and potentially fatal above 50 ppm.	WEL 1 ppm long term or 2 ppm short term.	ClO ₂ WEL 0.1 ppm long term or 0.3 ppm short-term. Source gas contains chlorine with WEL 0.5 ppm short-term.
Potential health problems from other routes of exposure	Eye irritation and cough at up to 5 ppm; skin irritation. Category 1B carcinogen and Category 2 mutagen.	Harmful through contact with skin, eyes, other mucous membranes.	Associated with high toxicity.

Safety and operational considerations	Fumigant		
	Formaldehyde	Hydrogen peroxide vapour	Chlorine dioxide
Other operational factors	<p>Can react with hydrochloric acid and chlorinated disinfectants (eg Chlorox) to form potential carcinogen bis (chlormethyl) ether, these products should be kept sealed to prevent contact or removed from laboratory before fumigation. Must consider where disinfectant dunk tanks used. If dealing with spill, any absorption granules must be free from chlorine-based chemicals.</p> <p>Formaldehyde removal units are available as alternative to ventilation to atmosphere. They operate by drawing air over carbon filter to bind residue for safe removal. Can also neutralise with ammonia gas from ammonium carbonate or bicarbonate. Systems should be fully validated before use.</p>	<p>No toxic by-product residues as broken down into oxygen and water.</p> <p>Compatible with most materials and finishes, but not with some materials, eg natural rubbers, some plastics and paints. Can be absorbed into porous materials and then off-gas producing local emission levels that may exceed WEL.</p> <p>Potentially explosive so commercial delivery systems carefully controlled to make sure of safe use at high airborne concentrations.</p>	<p>All lights must be turned off in the room during decontamination as ClO₂ broken down by UV light.</p> <p>With some commercial systems, to avoid corrosion damage, the decontamination device is placed outside the treated room and the gas piped in via a one-way valve.</p>

Validating fumigation

- 24 The efficacy of fumigation should be validated in normal working conditions and the results documented. This should be repeated if changes are made which significantly affect efficacy.

- 25 Biological indicators are commonly used to assess efficacy, eg 'spore strips' which use a range of agents such as *Bacillus atrophaeus* or *Geobacillus stearothermophilus*. In some circumstances it may be more appropriate to use an alternative indicator organism representative of the agents being handled.
- 26 Chemical indicators can be used to check fumigant levels in combination with spore strips during validation.
- 27 Biological and chemical indicators should be positioned to provide adequate coverage of the laboratory including areas where fumigant levels might be lower.

Room sealability

- 28 At CL3, the laboratory must be capable of being sealed to allow it to be effectively disinfected. An ongoing programme of formal assessment, eg an annual test is recommended to make sure sealability is maintained. However, more frequent visual inspections should be undertaken, eg for cracks, or dust trails which may provide early indication of breaches in sealability of the facility. In this event, remedial work should be carried out and verified as effective.
- 29 The frequency of the sealability assessment may depend on many factors including:
 - the materials used to construct the facility;
 - the stresses imposed on the fabric of the facility by the negative air pressure; and
 - the age of the facility.
- 30 Methods to test for sealability include smoke plume-generating devices such as smoke pencils, hand-held battery-powered devices, smouldering fabric wicks and wick pencils.
- 31 Sealability is usually carried out with the laboratory operating at normal working pressure and leaks are detected by observing any deviation of the smoke plume (see Figure 13) and should be performed by a competent person. Common leakage sites include:
 - around doors (including door furniture);
 - around windows;
 - pipework, conduit and cable entry points from outside areas;
 - lighting units;
 - in the ductwork of the ventilation system;
 - at access areas of dry riser points; and
 - in the sealing of the fabric of the building.

- 32 An alternative to smoke pencils is to fill the room with smoke with the facility operating under neutral pressure and to observe any leakage to the outside surrounding areas. Smoke can be generated either by igniting smoke pellets inside the room or from a purpose-built smoke machine. This method is limited by the inability to view every potential leakage point from outside.



Figure 13 Visible smoke plume emission from a smoke pencil

- 33 Other methods can also be effective. These include:
- Room pressure decay testing - the room is held at a specified negative pressure relative to atmosphere and loss of the pressure differential measured at regular intervals over a set time. Specialist advice and equipment may be required for this method and guidance is available in the Canadian Biosafety Standard www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/second-edition.html. If leakage is detected, further follow-up tests will be required, eg using smoke tests to locate and remedy the leakage points.
 - Use of non-harmful tracer agents such as sulphur hexafluoride – this requires release of the gas into the room and examination of the exterior for leaks using a portable detector. This method is limited by the inability to view every potential leakage point from outside.
 - Use of soap bubbles - a concentrated solution of soapy water is applied to an area of concern while the room operates at a negative pressure. If leakage points are present air will be drawn in through them, generating soap bubbles.

Appendix 4: Microbiological waste in laboratory facilities

- 1 Many factors need to be considered in the safe management of waste generated from microbiological laboratories. Such facilities cover a range of microbiological activities and this Appendix relates principally to infectious waste from:
 - research laboratories;
 - teaching laboratories;
 - clinical laboratories;
 - forensic laboratories;
 - veterinary laboratories; and
 - environmental laboratories.
- 2 Waste may be generated by the intentional propagation or concentration of pathogens, such as work with infected cell cultures, infected animals, or large-scale propagation of pathogens. Alternatively, it could come from materials such as clinical specimens that may contain pathogens (eg diagnostic work in pathology, microbiology, haematology or serology departments).
- 3 The Department of Health publication, *Health Technical Memorandum* (HTM) 07-01 <https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste> provides detailed information in relation to waste generated in healthcare premises and healthcare waste from other occupational settings.

General requirements

- 4 To ensure that infectious waste is managed safely it is important to:
 - undertake a risk assessment of the biological agents likely to be present in waste; and
 - prepare and follow documented SOPs for dealing with such waste.
- 5 This should cover classification of the waste, its segregation and packaging to make sure risks are managed, and transport, treatment and disposal arrangements appropriate to the type of waste and the risk it poses.

Waste classification and segregation

- 6 The HG categorisation for biological agents in COSHH will help determine the waste classification group (see Appendix 5). This then determines its transport classification, into:
 - Category A (which includes HG4, many HG3, and some HG2 pathogens); or
 - Category B and the associated UN number.

- 7 The classification determines the requirements for colour-coded segregation, packaging, transport, treatment and disposal.

Storage, transport and inactivation of infectious waste

Storage

- 8 Infectious (Category A) waste should be stored in the laboratory before inactivation, while temporary storage of Category B waste is acceptable in a dedicated collection area, eg at the autoclave facility.

On-site transport

- 9 Category A waste generated from CL3 laboratories should be inactivated in the laboratory suite. However, in some circumstances, waste may need to leave the containment area, passing through communal areas, before inactivation. In such cases it must be transported as safely as possible, eg within at least two layers of containment where the secondary containment is robust, leak-proof and has a secure lid (see more detail in Appendix 5).

Inactivation

- 10 COSHH does not require explicitly that cultures of biological agents are inactivated on-site, but the regulations place a duty on employers to assess risk and apply control measures to reduce the risk of exposure to harmful substances to a minimum. It is recommended that both Category A and B wastes are inactivated on-site before final disposal because they may contain high concentrations of biological agents and pose an increased risk of exposure.
- 11 Clinical specimens (eg excreta, secreta, blood, tissue and tissue fluid, swabs), when discarded, could form part of a laboratory waste stream and must be managed appropriately. The infectivity associated with this waste type is highly variable; diagnostic specimens resulting from investigations in clinical laboratories (eg haematology) will have a low probability of containing pathogens, but clinical specimens used for microbiological testing are more likely to contain pathogens. Whether it is appropriate to segregate such waste into the two categories should be considered as part of the risk assessment, and for transportation it may be simpler to treat all the same.
- 12 Where infectious waste must be transported off-site before inactivation, a licensed contractor should be used and the packaging and transport specifications described in Appendix 5 must be met. The laboratory should make sure that the contractor is provided with information to deal with any spillages safely.

Treatment and disposal options

Autoclaving

- 13 Autoclaving is a means of sterilising material by applying high-pressure saturated steam at a temperature and time known to be effective. Effective sterilisation by autoclaving depends on:
- correct installation and commissioning of the autoclave equipment, using surrogate test loads to validate temperatures achieved within the load and other operating conditions;
 - effective removal of air from the vessel and all parts of the load, including the use of containers that allow steam penetration; and
 - achieving and maintaining suitable load temperatures and holding times and the ability to validate these under operating conditions by independent thermocouple tests as well as biological and chemical indicators.
- 14 It is important that procedures are established to deal with a failure in the autoclave run resulting in an unsterilised or partly sterilised load. The waste can then be re-autoclaved or repackaged for transfer to another autoclave or incinerator. Direct access to a dedicated waste treatment autoclave in the laboratory or laboratory suite is normally required at CL3. If this is impracticable, the SOP should reflect the findings of the risk assessment and specify the conditions, eg the use of robust, leak-proof and sealed inner and outer containers, under which the removal of waste to an autoclave outside the laboratory or to a suitable clinical or animal incinerator is permitted. Where materials cannot be autoclaved, SOPs should specify the disinfectants and disinfection methods that should be used. Information box 9 provides a check list for what should be considered in an autoclave SOP.

Information box 9 SOPs for autoclaving

SOPs for autoclaving should specify:

- the type of waste to be autoclaved, eg cultures and media, sharps, pipettes, other disposable and reusable articles, gloves and laboratory coats, paper towels and tissues;
- the containers that are to be used, eg for sharps;
- the required sterilising cycle, eg temperature and time settings, validated for the load type;
- whether biological or chemical indicators are to be used and their location in the load;
- the checks to be made and recorded by users, eg cycle print outs;
- the unloading procedure;
- subsequent handling and disposal of the autoclaved waste;
- the procedure in the event of a malfunction or failure; and
- maintenance regime (routine servicing, repair, examination and testing).

- 15 Regular examination and testing of autoclaves by a competent person is required under a written scheme of examination (Pressure Systems Safety Regulations 2000 8(1)).

Disinfection

- 16 Disinfection is widely used to treat liquid wastes and remove contamination from equipment and other reusable items, especially those that may be damaged by steam or direct heat.
- 17 Disinfection is not as effective or as easily monitored for efficacy as steam sterilisation in destroying biological agents and should not be used to treat wastes which could contain spores of HG3 agents.
- 18 Many disinfectants are hazardous to health and may produce toxic or corrosive effects or induce an allergic sensitisation. Details of disinfectants and conditions for their use in the laboratory should be specified in SOPs or laboratory codes of practice. Information box 10 provides a check list for what should be considered in a SOP for disinfection.
- 19 The choice of disinfectant should be determined by:
- evidence of efficacy against the agent;
 - the presence of protein or other interfering substances (eg blood) likely to reduce efficacy or be chemically incompatible with the disinfectant; and
 - the pH and temperature of the waste, ensuring that they are compatible with safe disinfection.
- 20 Contaminated items should be completely immersed in liquid disinfectants, taking care to prevent air bubbles forming. Gaseous disinfectants (fumigants) should be used in sealed enclosures or rooms to maintain an effective airborne concentration throughout the whole treatment process (see Appendix 3 on sealability and fumigation). Contact must be achieved and maintained between the disinfectant and the waste or contaminated surface for a sufficient length of time. Oil and grease residues on surfaces may prevent effective contact with the disinfectant.

Information box 10 SOPs for disinfection

SOPs for disinfection should specify:

- target agents for which the disinfectant is known to be effective (and ones for which it is **not** effective if appropriate);
- wastes and contaminated articles that are to be disinfected, eg disposable or reusable articles that are heat sensitive, liquid wastes and effluents other than cultures;
- disinfectant that is to be used and how it should be prepared, including its in-use dilution and any safety considerations during preparation and use, referring to manufacturer's safety information;

- how often it should be changed and how to make sure users know it is within its specified use period;
- how it should be used, including contact time for effective inactivation;
- methods for routine validation of the disinfection process;
- safe disposal of used disinfectants; and
- means for the safe removal and disposal of treated waste.

Incineration

- 21 Incineration is a waste treatment process that involves the combustion of organic substances contained in waste materials. Incineration requires specialist facilities often used for clinical waste. HTM 07-01 provides more details of the specifications.
- 22 While a limited number of laboratories may have access to incineration facilities on site, it is likely that some secure means of transportation of material to the facility will be needed, or for transportation to a remote incineration facility.
- 23 In some instances, incineration on or off site is used secondary to autoclaving or disinfection to provide additional assurance of sterilisation or to destroy materials that may not be appropriate for disposal via landfill.

Other treatment and disposal options

- 24 There are other methods available for sterilisation and disposal of clinical and laboratory waste. These are summarised in Table 3, and described in more detail in HTM 07-01.

Table 3 Summary of alternative waste treatment methods

Type of treatment	Method	How it works
High temperature	Pyrolysis	Waste heated at 545 – 1000 °C in absence of oxygen in primary chamber. Synthesis gas produced then mixed with air in secondary chamber and combusted. Initial high temperatures destroy pathogens and reduce waste volume.
	Gasification	Like pyrolysis but with air in primary chamber which is insufficient for full combustion but releases energy to raise temperature to 900 – 1100 °C.
	Plasma technology	Electric current passed through inert gas such as argon produces plasma temperatures up to 6000 °C. Waste fed into plasma chamber achieves 1300 – 1700 °C.
Non-burn/ low temperature	Steam auger	Waste is shredded then turned by auger with steam injection at atmospheric pressure to achieve temperature and residence time needed to inactivate pathogens.
	Dry heat	Inactivation temperature achieved using electrically – generated heated air, oil or molten plastic.

Type of treatment	Method	How it works
	'Wet' microwaves	Thermal inactivation using microwaves – waste needs to be wet to achieve necessary temperature either through natural moisture in waste or steam injection. Other systems use microwaves to generate steam for thermal treatment.
	'Dry' microwaves	As above but using microwaves in a nitrogen atmosphere – achieves higher temperatures.
	Macrowaves	Low frequency radio waves which generate heat within the waste.
Chemical - based	Alkaline hydrolysis	Mostly applicable to animal waste as an alternative to incineration. Animal tissue dissolved at high temperature, pressure and pH. Sterile hydrolysate produced consists of sugars, amino acids and soaps with some residual bone calcium and cellulose which can be compacted and sent to landfill.

Appendix 5: Transport of infectious substances

'On-site' transport

- 1 The transport of infectious substances (and materials containing them) is important for most routine laboratory-based activities in both research and diagnostic settings. The process, however, presents risk of exposure and infection in the event of mis-identification, inappropriate access, spillage or accidental release during transit.
- 2 Transfer of infectious material in a laboratory, eg from an MSC to an incubator, should be carried out using good laboratory practices so as to minimise the potential for spillage. The precautions applied should be proportionate to the inherent hazard associated with the infectious material, eg screw capped tubes are recommended in preference to snap-cap lids. Deep-sided and leak-proof trays or boxes can be used to transport higher risk materials and where appropriate these may be securely-lidded to minimise potential for spill and/or leakage. They should be made of smooth impervious material, eg plastic or metal, which can be effectively cleaned and disinfected.
- 3 If trolleys are used for transfer of materials they should be loaded so that samples cannot fall off. Spill kits should be readily available in the event of a spillage during transport, and appropriate people trained in their use.
- 4 In addition to the above control measures, transfer of infectious materials from one laboratory to another within the same building should be planned, organised and carried out to minimise transit through communal areas and public spaces.
- 5 Transport containers should be suitably labelled to identify their contents, and surface-decontaminated before leaving the containment area.
- 6 It is recommended that large or unwieldy containers are transported by trolley which should contain some form of guard rail or raised sides to secure the load during transit.

Transport between buildings on the same site

- 7 Transfer of infectious materials between buildings on the same site will require sufficient control measures to minimise the risk of leakage in transit and make sure that those in the transport chain are aware of the hazard presented by the contents. Consideration should be given to suitable packaging (eg triple packaging, use of absorbent material) and labelling, determined by the risk assessment to make sure of the safe transfer of the content.
- 8 Spill kits should be readily available for use in the event of a spillage during transport, and appropriate people trained in their use.

- 9 Before transfer, the recipient should be notified in advance.

Use of pneumatic air tube transport systems

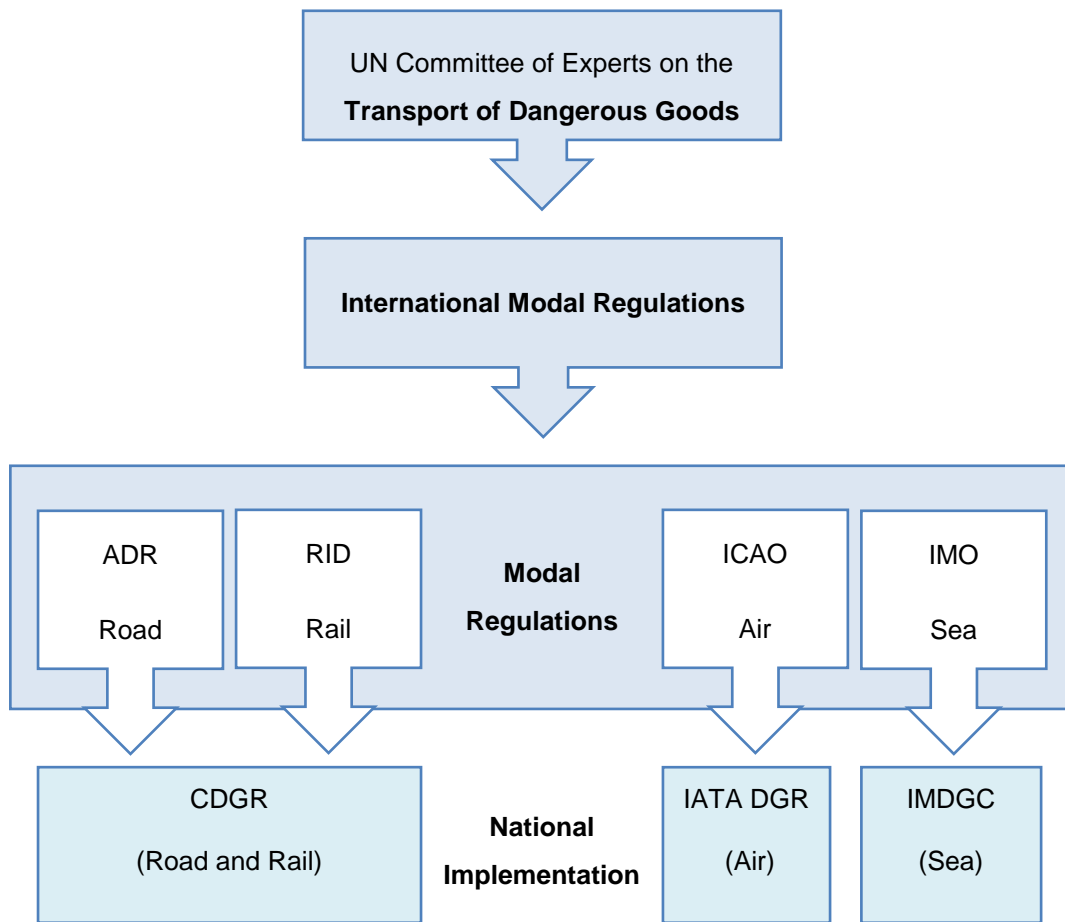
- 10 Pneumatic air tube transport systems can provide a safe and efficient way to transport specimens around a hospital site. As part of the local risk assessment, safe operating procedures should be used for sending specimens by pneumatic air tube systems to make sure its proper use at all despatch and reception points. This assessment should be based on establishing that:
- the specimen is suitable for despatch by this method;
 - the design of the specimen carrier is suitable; and
 - staff are suitably informed and trained, using proper operating and control procedures.
- 11 Many types of carrier are available and their suitability must be assessed. Containers should be made of materials that can be effectively decontaminated.
- 12 Leak-proof carriers should be employed along with absorbent packing material to contain the material should leakage occur.
- 13 Damaged or leaking specimen containers should be opened in an MSC or other suitable means of primary containment to contain any aerosol that may be generated. Gloves should also be worn and care taken to avoid handling any sharp material.

'Off-site' transport of infectious substances

Domestic and international transport legislation and scope of application

- 14 Where infectious materials are transported beyond the facility boundary (eg between sites of the same organisation, or from one organisation to another in the same country or internationally), those at risk include not only the those directly involved in the transport chain but also the general public. The law requires that infectious substances are packaged, labelled, and transported safely.
- 15 The international regulations governing the transport of dangerous goods (including infectious substances) are based upon United Nations (UN) Modal Regulations produced by the UN Committee of Experts on the Transport of Dangerous Goods. These are reflected in law through more specific internationally agreed 'Modal' regulations applying to transport by road, rail, air and sea; some of which are implemented in the UK through national legislation (Figure 14).

- 16 The main UK legislation for the international and domestic transport of infectious substances by road, rail and air are listed here.
- **Road and rail:** The *Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009* (CDGR; as amended) apply both to international and domestic transport in the UK.
 - **Air:** The *International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air* apply to air transport both within the UK and internationally.
- 17 The legislation is not limited to the transport of infectious substances. It applies to all dangerous goods, categorised within the UN Modal Regulations into nine separate classes and reflecting their hazardous properties. Infectious substances are allocated to UN Class 6.2 and include pathogenic bacteria, viruses, parasites, fungi and any other biological agents that may cause disease in humans or animals. It also extends to biological waste and (with certain limited exceptions) clinical materials where viable pathogens are known (or reasonably expected) to be present.
- 18 The Department for Transport (DfT) is the Competent Authority for the carriage of infectious substances by road, rail, air and sea. DfT is supported by HSE and by the Civil Aviation Authority. Within DfT, responsibility falls to the Dangerous Goods Division and the Maritime and Coastguard Agency. HSE have primary responsibility to enforce CDGR. These regulations also allow suitably appointed police or Vehicle and Operator Services Agency officers to enforce the regulations applying to transport by road and rail.



- Road and Rail: *CDGR* apply to both international and domestic transport in the UK. The regulations are derived from and implement the internationally agreed modal provisions for the transport of dangerous goods by road and rail (commonly referred to as *ADR* and *RID*, respectively). The *CDGR* make direct reference to *ADR* and *RID*, both of which are revised biannually with amendments incorporated into the UK legislation by revision of *CDGR*.
- Air: The requirements for the transport of dangerous goods by air are contained in ICAO *Technical Instructions for the Safe Transport of Dangerous Goods by Air*. These provisions, which apply to air-transport both within the UK and internationally, are incorporated into *Dangerous Goods Regulations* produced by the International Air Transport Association.
- Sea - The requirements for the transport of dangerous goods by sea are contained in The *International Maritime Dangerous Goods Code* published by the International Maritime Organization (IMO). These are not considered further in this document. Those consigning infectious substances for transport by sea should therefore contact the IMO directly for guidance.

ADR - *Accord européen relatif au transport international des marchandises dangereuses par route* (European agreement concerning the international carriage of dangerous goods by road).

RID - *Règlement concernant le transport international ferroviaire de marchandises dangereuses* (Regulations concerning the international carriage of dangerous goods by rail).

Figure 14 Legal frameworks for the international transport of dangerous goods

Classification of infectious substances for transport

- 19 Classification of infectious substances for transport is risk-based, reflecting the potential for harm from exposure should the substance be released from its packaging in transit or on receipt. Its primary purposes are:
- to determine whether the material to be transported is subject to the provisions of the regulations, and
 - if so, to identify the appropriate UN number from which the packing, marking, labelling and documentation requirements follow.
- 20 A summary overview of the important elements of the classification process is provided in Figure 15.
- 21 Human or animal specimens for which there is minimal likelihood of infectious substances being present are exempt, provided that the specimen is transported in packaging which will prevent any leakage and which is marked with the words 'Exempt human specimen' or 'Exempt animal specimen', as appropriate.

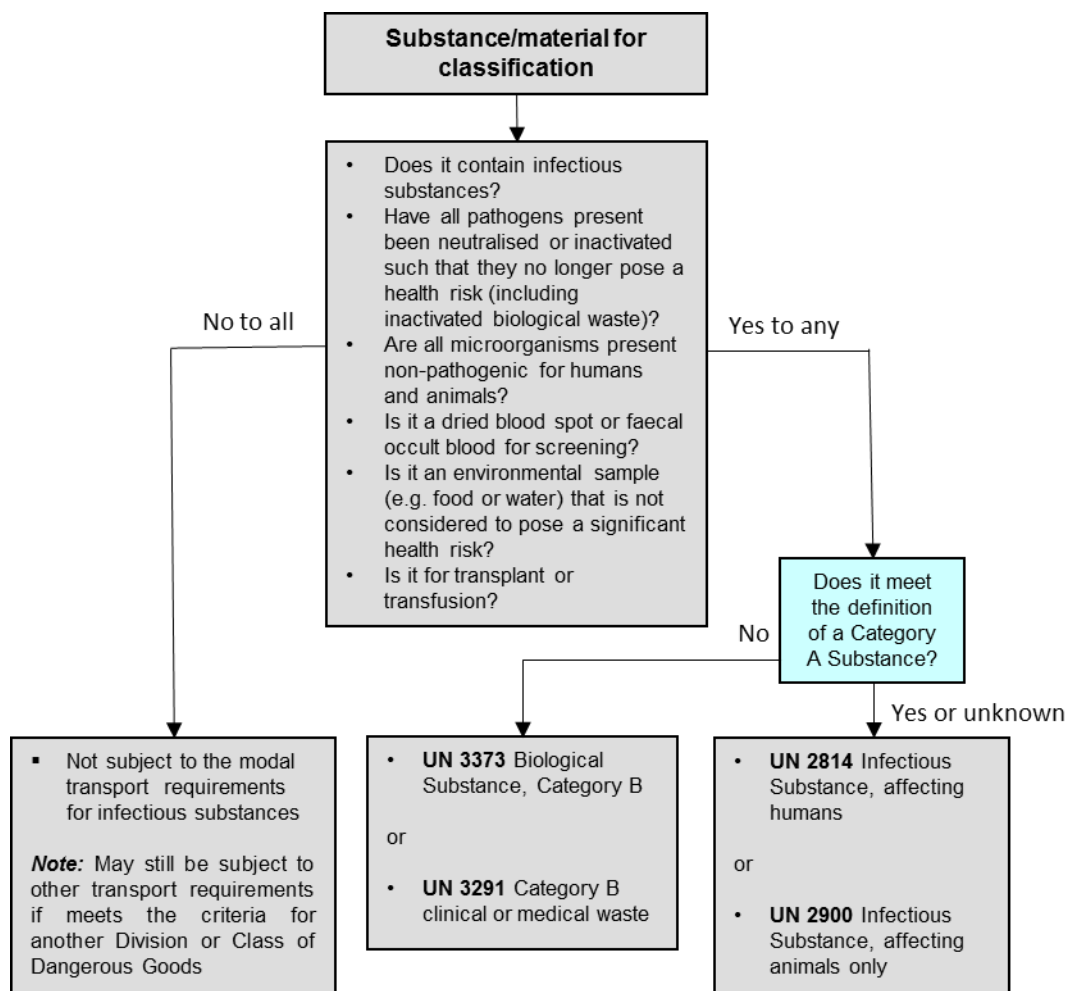


Figure 15 Flow chart for the classification of infectious substances for transport

Assignment of infectious substances to Category A or Category B

- 22 As shown in Figure 15, for the purposes of transport, infectious substances that are not exempt from the regulations are required to be classified as either *Category A* or *Category B*.
- **Category A:** Infectious substances are those transported in a form that, when exposure occurs, can cause permanent disability, life-threatening or fatal disease to healthy humans or animals; indicative examples of which are specified in the list below. This includes all agents classified as HG4 in the Approved List of biological agents, many HG3 agents, and the HG2 agent *Clostridium botulinum*.
 - **Category B:** Infectious substances are those that do not meet the criteria for inclusion in Category A.
- 23 Specimens from patients (human or animal) known, or suspected to be infected with an agent meeting the Category A criteria, should be classified as Category A. This includes clinical wastes.
- 24 It is recommended that all patient specimens such as blood, tissue, excreta and secreta should be classified as a minimum Category B unless the material has been treated to neutralise pathogens or verified as pathogen-free. This includes specimens from apparently healthy individuals.
- 25 It is the responsibility of the consigner to make sure of the correct classification. New or emerging pathogens, which do not appear in the indicative list of Category A substances but which meet the same criteria, must be classified as Category A. If there is uncertainty as to whether or not a pathogen falls within this category as a precaution it must be assigned to, and transported as, Category A.

UN classification, packaging and documentation requirements

- 26 The principal relevant UN numbers applying specifically to the transport of infectious substances (or materials containing them) for transport are listed here.
- **UN 2814:** Category A Infectious substances (affecting humans **or** both humans and animals).
 - **UN 2900:** Category A Infectious Substance, affecting animals only.
 - **UN 3373:** Category B Infectious substances (ie not on the indicative list or otherwise meeting the criteria for inclusion as Category A).
 - **UN 3291:** Category B clinical or medical waste.
- 27 Clinical wastes containing Category A substances should be assigned to UN 2814. UN 3373 includes patient specimens of human or animal material. This includes, but is not limited to, excreta, secreta, blood and its components, tissue and tissue fluid, swabs, and body parts being transported for purposes such as research diagnosis, investigational activities, disease treatment or prevention.

- 28 Category A waste must be transported in accordance with Packing Instruction 620 (PI620) and Category B waste in accordance with Packing Instruction 650 (PI650).
- 29 DfT Guidance Note Number 17/2012[REV.7] provides information of the transport of infectious substances under Category A (UN2814 and UN2900) or Category B (UN3373). Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/527069/dangerous-goods-guidance-note-17.pdf. This includes a description of the packaging requirements and marking and labelling requirements necessary to meet the legislation. More information, including more detail on packaging requirements, is available in the World Health Organisation's *Guidance on regulations for the transport of infectious substances* available at: www.who.int/ihr/publications/biosafety/en/. Further information is also available in the *Carriage of dangerous goods manual* on the HSE website at www.hse.gov.uk/cdg/manual/index.htm.
- 30 For UN 2814 (Category A), packages containing infectious substances should be marked with the proper shipping name "Infectious substance, affecting humans", the appropriate UN number (UN 2814) and the appropriate warning label. The name address and telephone number of a person responsible must be provided on the outer package. An itemised list of contents should be enclosed between the secondary and outer packaging along with names and addresses of the consigner and the consignee.
- 31 For Category B (UN 3373) infectious substances, other than the proper shipping name "Biological substance, Category B" the appropriate UN number (UN 3373) and the appropriate warning label, there is no requirement for an itemised list of contents. However, the name and address of the shipper and of the consignee must be provided on each package, and the name, address and telephone number of a person responsible must be provided on a written document or on the package.

Quantity limits for infectious substances

- 32 For transport by road or rail, there are no quantity limits on package contents for either Category A or Category B packages.
- 33 For air transport, limits on maximum quantities for PI620 are 50 ml (liquid) or 50 g (solid) for passenger aircraft and 4 L or 4 Kg for cargo aircraft, and for PI650 are 4 L or 4 Kg, with a limit of 1 L per primary receptacle. This limitation does not apply to body parts or organs. These limits exclude refrigerant.

Transport or importation of animal pathogens

- 34 Transport of some animal pathogens is regulated under SAPO. Further information can be found in the guidance *Guidance for licence holders on containment and control of specified animal pathogens* www.hse.gov.uk/pubns/books/hsg280.htm.

Appendix 6: Dealing with accidents including spillage of biological agents

- 1 The types of accident that can occur in the laboratory range from small-scale releases of a biological agent eg aerosolised droplets discharged from a pipette, to more serious incidents, eg spilling the contents of a culture flask, or a centrifuge accident. Some accidents have the potential to generate significant aerosols, eg a spillage caused by dropping material from a height. This appendix gives specific guidance on emergency procedures for dealing with spills at CL2 and CL3 and covers general points about contingency plans for dealing with accidents involving larger releases of biological agents.

Emergency room fumigation

- 2 Entry into contaminated areas should, where reasonably practicable, be avoided to help minimise the potential for the re-aerosolisation of infectious material when dealing with spillages that have occurred outside of primary containment. Where this is not practicable, or it is justified by the risk assessment, equipment and controls for carrying out room-fumigation should be located outside of the laboratory. This includes personal protective equipment, and spill kits, and fumigant monitoring devices.
- 3 If the process cannot be entirely controlled from outside the laboratory, the equipment and chemicals required should be suitably located to minimise the time spent in the contaminated room, eg having a wok/kettle permanently wired to a socket close to the door when fumigating with formaldehyde.
- 4 In the event of a spillage outside of primary containment it may be necessary to carry out emergency room fumigation and the risk assessment should consider many factors including:
 - the nature of the spillage;
 - the spill volume; and
 - the location and area affected and the titre of the agent.
- 5 Re-entry into the facility before fumigation should be avoided; unless the assessment concludes re-entry is required (eg to set up fumigation or fumigant dispersal equipment). The laboratory air handling system should be allowed to clear airborne particles before re-entering. Upon re-entry, the use of RPE may be necessary for the process of disinfecting large spillages (see Appendix 7).
- 6 Although fumigation is an important part of dealing with emergency spillages, fumigant is unlikely to completely penetrate a large liquid spillage and it may be necessary to treat a large spill with an appropriate disinfectant. Where this is required, the safest procedure would be to:
 - evacuate the laboratory;
 - perform a local risk assessment while the ventilation system removes airborne particles;

- fumigate the laboratory; and
- apply disinfectant to the main volume of spillage and remove any debris.

Assessing the risks

**MHSW
Regulation 8**

**COSHH
Regulation 12
and 13**

- 7 The laboratory should have a clear written procedure, displayed as notices for dealing with spillages and other forms of contamination, eg aerosol release. Training on how to deal with spillages should be part of the overall training required for working at CL2 and CL3.
- 8 A major spillage may involve considerable splashing and/or aerosol production. COSHH requires that there are plans in place to deal with such incidents at CL3. When drawing up contingency plans for larger releases (see also Emergency procedures paras 44 – 46), the factors/scenarios to be considered should include the following to determine the most appropriate course of action.
 - Type of agent - the HG, route of transmission, infectious dose (if known), stability in the environment.
 - Type of accident - instantaneous or delayed, eg a dropped flask as compared to a broken centrifuge tube which may not be discovered until the centrifuge is opened.
 - Severity of accident - amount and concentration of material that could potentially be released and form, eg is aerosol formation likely?
 - Numbers of staff potentially exposed - this may depend on location of accident.
 - Location within the laboratory - an accident in the open laboratory may require evacuation, as compared to a more 'contained' accident in a microbiological safety cabinet.
 - Room air change rate - required to calculate and assess the time needed before staff can safely re-enter the laboratory after a spillage.

Post-exposure prophylaxis

- 9 As part of the risk assessment, the need for post-exposure prophylaxis should be considered. The need for immediate medical treatment following exposure will depend on the:
 - nature of the agent;
 - likely risk of developing disease; and
 - availability of treatment (including a consideration of maximum time after exposure that treatment can be administered with effect).
- 10 This should be discussed with an occupational health practitioner. If there is a significant risk of disease or the consequences of the disease are serious and there is safe prophylaxis available, then it should be offered to the exposed worker. The need to have relevant drugs available, either locally or by arrangement with the local A&E department should also be considered.

Spillage inside an MSC

- 11 Spillages inside an MSC are usually contained and can be mopped up immediately with disinfectant. This can be followed by fumigation if considered necessary, eg for a highly infectious or airborne transmissible agent. If infectious aerosol is suspected to have escaped the MSC then room fumigation may be required.

Spillage at CL2

- 12 A minor spillage should be handled by applying disinfectant to the spillage and leaving for an appropriate period (see Figure 16). The spillage and disinfectant should then be mopped up with disposable paper towels or spillage absorption granules which should be discarded as clinical waste. For larger liquid spills, it may be appropriate to contain the spill before applying disinfectant.
- 13 If there has been significant skin contamination this should be washed off with water or an emergency shower used if available. If high titre material has contaminated skin, the affected area should be bathed with a suitable disinfectant. Depending on the nature and duration of exposure and the agent release, medical help/treatment may be required immediately.



Figure 16 Clearing up a small liquid spill

Information box 11 Example spillage

A flask containing 20 ml of a 10^8 spores/ml suspension of *Bacillus anthracis* is accidentally dropped on the laboratory floor. The laboratory ventilation rate is 12 air changes per hour.

From Table 5, the airborne concentration is 50 000 spores/m³ on leaving the laboratory. From Table 6, after 58 minutes, 99.99% of the airborne spores will have been removed, leaving a concentration of 5 spores/m³. After a further 35 minutes, a further 99.9% of the remaining spores will have been removed, and the concentration will have dropped to 0.005 spores/m³, ie the laboratory will be almost free of any airborne spores.

Spillage in a CL3 laboratory

- 14 In the event of a significant spillage outside of an MSC, staff should immediately leave the laboratory, removing any contaminated clothing. This should be left in the laboratory, or lobby. Evacuation allows time to determine the most appropriate course of action without leaving staff exposed. Following a spillage, the room should be cleared of infectious aerosol and then fumigated (see Appendix 3).
- 15 To assess the time needed to clear a laboratory of an aerosol, the following information is required:
 - likely concentration of microorganisms in solution spilled;
 - estimated quantity of solution spilled; and
 - the room ventilation air change rate (usually obtained from service engine).
- 16 Research has established the potential airborne concentration of microorganisms/m³ air for different volumes and concentrations of solution spilled, and these are summarised in Table 5. This assumes a worst-case scenario where the aerosol potential is high but has assumed exposure time is short because of the recommendation for immediate evacuation. The aerosol potential is a measure of how much of the suspension spilled becomes aerosolised.

Table 5 Airborne concentration of microorganisms/m³ v volume and initial solution concentration

Solution concentration (per ml)	Quantity of solution		
	Small (<50 ml)	Medium (50-500 ml)	Large (>500 ml)
10^{10}	5 000 000	50 000 000	500 000 000
10^9	500 000	5 000 000	50 000 000
10^5	50 000	500 000	5 000 000
10^7	5 000	50 000	500 000
10^5	500	5 000	50 000

- 17 Table 6 indicates the number of minutes, for a given number of room air changes, required to remove 90%, 99% or 99.9% of airborne contaminants. A worked example is shown in Info box 11.

Table 6 Percentage removal v number of air changes

Air changes per hour	% Removal			
	90	99	99.9	99.99
6	23	46	69	115
7	20	39	59	98
8	17	35	52	87
9	15	31	46	77
10	14	28	41	69
12	12	23	35	58
14	10	20	30	50
16	9	17	26	43
18	8	15	23	38
20	7	14	21	35
25	6	11	17	28
30	5	9	14	23
40	3	7	10	17

- 18 Staff must not re-enter the laboratory until sufficient time has been allowed for any aerosol to be removed from the room and fumigation completed.

Appendix 7: Provision and use of personal protective equipment, including respiratory protective equipment, in the laboratory

Personal protective equipment

COSHH Regulation 9

- 1 Where exposure to biological agents cannot be controlled by any other means, appropriate protective clothing should be available. It must provide the necessary level of protection and be suitable for the task and the wearer. The laboratory SOPs should specify the type of PPE required at each containment level.
- 2 COSHH requires that all PPE, including protective clothing, must be:
 - stored in a well-defined place;
 - checked and cleaned at suitable intervals; and
 - repaired or replaced when found to be defective.
- 3 PPE which may be contaminated by biological agents must be removed on leaving the working area, kept apart from uncontaminated clothing and equipment, and decontaminated and cleaned or, if necessary, destroyed.
- 4 There should be facilities for changing into laboratory clothing adjacent to or in the containment area. At CL3, if space allows this could form part of the entrance lobby area. Storage facilities should be provided for both laboratory clothing and outer clothing removed before entering the laboratory. At CL2, this could be pegs immediately inside the entrance. At CL3, space should be provided for a container to store used laboratory clothing before autoclaving.
- 5 At CL3, dedicated side or back-fastening laboratory gowns or coats should be worn. They should have close fitting cuffs and be fastened using quick release studs or Velcro. They should be made of a material which resists shrinking or damage if autoclaved. The material should be sufficiently impermeable to protect clothing worn underneath. A similar specification is preferable for work at CL2.
- 6 Additional protection, eg disposable coats/gowns, aprons, footwear, over sleeves for work in MSCs, should also be available if indicated by the risk assessment.
- 7 If entry into the CL3 area is via a CL2 laboratory then there should be separate laboratory coats or gowns available. These may be of a different colour from those used in CL2 to tell them apart. Procedures for the frequency of changing laboratory coats, eg weekly or when contaminated, should be covered in the local code of practice. At CL3, all non-disposable coats should be autoclaved before laundering. Disposable protective equipment should be also autoclaved before disposal.

- 8 When sent for laundering, CL2 coats should be packed so that they can be loaded into a washing machine with minimal handling by laundry staff. At CL2, disposable protective equipment can be autoclaved, disposed of in the general waste stream or bagged and sent for incineration.
- 9 Gloves must be worn for all work with material known or suspected of containing HG3 biological agents. A supply of suitable disposable gloves in various sizes and materials should be available in the laboratory. Gloves should be removed and hands washed before touching items that will be touched by others not equally protected, eg telephone handsets.

Respiratory protective equipment (RPE)

- 10 RPE is only likely to be used in a laboratory setting in an emergency, such as providing extra protection against biological aerosols when re-entering a laboratory after spillage of a pathogen. In these circumstances RPE should also protect against exposure to chemical agents such as formaldehyde or other fumigants.
- 11 The employer must make sure that RPE used in these circumstances is suitable for the work to be undertaken and that staff are properly trained in its use. This will include refresher training to maintain competence. Training should also cover the cleaning, maintenance, storage and disposal of RPE.
- 12 HSE provides separate guidance on the selection and use of RPE, which includes use for work involving exposure to biological agents in *Respiratory protective equipment at work* www.hse.gov.uk/pubns/books/hsg53.htm.

Appendix 8: Work with hazard group 3 parasites

- 1 When working with certain HG3 parasites (see table 5.1), there may be circumstances where not all the requirements of CL3 are necessary for the work to be carried out safely. However, this must be determined by an assessment of the risks associated with the work.
- 2 The main physical control measures that may not be required are:
 - the laboratory does not need to be maintained at negative air pressure because the agents are not transmissible by the airborne route;
 - the laboratory does not need to have exhaust air extracted using HEPA filtration, although in practice this may be the case if a MSC is in use. Any work that could give rise to an aerosol of infectious material must be carried out in a MSC (or equivalent containment); and
 - the laboratory does not need to be sealable to permit fumigation because these agents are easily broken down and cannot survive in the environment.
- 3 Dispensing with these physical containment measures means that work can take place in a CL2 laboratory, but the other procedural/management measures normally required at CL3 must still be in place:
- 4 It is important to separate work with parasites from the routine work that may also be carried out in the laboratory to control potential exposure.
- 5 The need for a MSC (at CL2 and CL3) will depend on whether the work could produce aerosols or droplets that have the potential to contaminate skin or mucous membranes and should include a consideration of:
 - whether the work involves the infectious and/or transmissive stage of the parasite;
 - whether the work involves tissue culture;
 - whether the work involves passaging the parasite in an intermediate host (vertebrate and/or invertebrate);
 - potential means of transmission of the parasite from host to host (including humans).
- 6 Where work involves tissue culture of the parasite, the use of glassware and sharps should be avoided where possible to avoid injury.
- 7 Where work requires an intermediate animal host to maintain the parasite, infected and non-infected hosts should be stored separately, ideally in separate rooms. Consideration should be given to when and how the animal is likely to shed infectious particles, eg in faeces, blood, saliva or other secretions/excretions, and precautions taken to control the risk of transmission.
- 8 The type of PPE will depend on the likely route of transmission of the individual parasite and stage in its life cycle. Lesions on exposed skin should

be covered with waterproof dressings and a high standard of personal hygiene should be in place for all work with parasites. For some work, disposable waterproof gloves should be worn as many laboratory-acquired parasite infections have occurred where no percutaneous injury had been noted and where there were no obvious visible signs of pre-existing skin lesion or abrasion. For all work there must be a safe means of effective disinfection of surfaces, and treatment and disposal of clinical waste.

- 9 For invertebrate animal hosts, additional consideration should be given to whether they fly, jump, crawl, live in water or are amphibious, and should be reflected in the containment measures used (see Appendix 5 of Working safely with research animals: Management of infection risks).
<http://www.hse.gov.uk/pubns/books/animal-research.htm>

Further reading

- 1 *Health and Safety at Work etc Act 1974 (c37)* The Stationery Office 1974
www.legislation.gov.uk
- 2 *Anti-Terrorism, Crime and Security Act 2001 (c24)* The Stationery Office 2001
www.legislation.gov.uk
- 3 *Part 7 of the Anti-terrorism, Crime and Security Act 2001 (Extension to Animal Pathogens) Order 2007* www.legislation.gov.uk
- 4 *Schedule 5 to the Anti-terrorism, Crime and Security Act 2001*
www.legislation.gov.uk
- 5 *The Management of Health and Safety at Work Regulations 1999* SI 1999/3242 The Stationery Office www.legislation.gov.uk
- 6 *The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009* SI 2009/1348 The Stationery Office
www.legislation.gov.uk
- 7 *Control of substances hazardous to health (COSHH). The Control of Substances Hazardous to Health Regulations 2002 (as amended). Approved Code of Practice and guidance L5 (Sixth edition)* HSE 2013
www.hse.gov.uk/pubns/books/l5.htm
- 8 *The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013* SI 2013/1471 The Stationery Office www.legislation.gov.uk
- 9 *The Approved List of biological agents* MISC208(rev3) HSE 2013
www.hse.gov.uk/pubns/misc208.htm
- 10 *Managing for health and safety* HSG65 (Third edition) HSE 2013
www.hse.gov.uk/pubns/books/hsg65.htm
- 11 *Guidance on the use, testing and maintenance of laboratory and animal isolators for the containment of biological agents*
www.hse.gov.uk/biosafety/isolators.pdf
- 12 *Respiratory protective equipment at work: A practical guide* HSG53 (Fourth edition) HSE 2013 www.hse.gov.uk/pubns/books/hsg53.htm
- 13 *HID Regulatory Model: Safety Management in Major Hazard Industries* HSE 2013 www.hse.gov.uk/hid/hid-regulatory-model.pdf
- 14 *Guidance on regulations for the transport of infectious substances* 2015 World Health Organisation
http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015.2_eng.pdf?ua=1&ua=1

- 15 *Transport of Infectious Substances UN2814, UN2900 and UN3373* Guidance Note Number 17/2012 [Rev.7] Department for Transport
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/527069/dangerous-goods-guidance-note-17.pdf
- 16 *Canadian Biosafety Standard (CBS) for Facilities Handling or Storing Human and Terrestrial Animal Pathogens and Toxins* (Second edition) 2015
<http://canadianbiosafetystandards.collaboration.gc.ca/cbs-ncb/assets/pdf/cbsg-nldcb-eng.pdf>
- 17 CEN Workshop Agreement (CWA 15793:2011) Laboratory biorisk management <https://shop.bsigroup.com>
- 18 BS EN 12128:1998 Biotechnology. Laboratories for research, development and analysis. Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements
- 19 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* <https://shop.bsigroup.com>