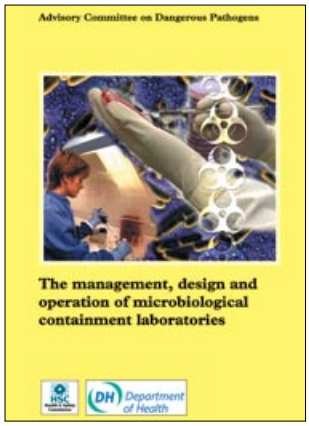
# The management, design and operation of microbiological containment laboratories

## Advisory Committee on Dangerous Pathogens




**This is a free-to-download, web-friendly version of *The management, design and operation of microbiological containment laboratories* (First edition, published 2001). This version has been adapted for online use from HSE's current printed version.**

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**This guidance from the Advisory Committee on Dangerous Pathogens gives detailed technical information on the design, management and operation of containment laboratories, especially Containment Levels 2 and 3. The guidance expands and explains the legal requirements set out in the biological agents provisions of COSHH, with particular attention to how these requirements influence design, construction and operation of laboratories.**

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This guidance is prepared in consultation with the Health and Safety Executive, by the Advisory Committee on Dangerous Pathogens, which was appointed by the Health and Safety Commission as part of its formal advisory structure and by Health Ministers.

The guidance represents what is considered to be good practice by members of the Committee. It has been agreed by the Commission and Health Ministers. Following the guidance is not compulsory and you are free to take other action but if you do follow it 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 as illustrating good practice.

# Contents

# Introduction

## Purpose of guidance

1 The implementation in 1995 of the EC Biological Agents Directive via the Control of Substances Hazardous to Health Regulations 1994 (COSHH) introduced, for the first time, legal requirements for all types of laboratories. The Advisory Committee on Dangerous Pathogens (ACDP) issued guidance on work at all containment levels in the *Categorisation of biological agents according to hazard and categories of containment*[1] in support of the legal requirements of COSHH. However, ACDP has since identified a need for detailed technical guidance on the management, design and operation of such laboratories to ensure that they are designed to operate safely and so meet the requirements of the legislation.

2 Although this guidance concentrates on the requirements under COSHH, Figure 1 (see page 5) gives an overview of the relevant health and safety legislation and guidance that should be consulted when working with biological agents in microbiological containment laboratories (see also paragraph 6).

3 This guidance is aimed at those responsible for the management and operation of Containment Levels 2 and 3 (CL2 and CL3) microbiological laboratories. It should also be useful to those involved in the building of new facilities as well as when existing facilities are being refitted or upgraded. The purpose of this guidance is to expand and explain the legal requirements set out in the biological agents provisions of COSHH, with a particular focus on the way in which these requirements influence the design, construction and operation of laboratories used for the containment of microbiological work; especially work carried out at CL2 and CL3. The guidance comprises three sections: general guidance on health and safety management in laboratories; general principles of the design and operation of laboratories; and the principal requirements for CL2 and CL3 laboratories.

4 This guidance complements that given in the Health and Safety Commission's Health Service Advisory Committee's (HSAC) guidance on *Safe working and the prevention of infection in clinical laboratories*[2] but replaces that given in ACDP's previous Categorisation guidance[1] which has now been withdrawn. This latter publication will be replaced by new ACDP guidance which will link all the more specific ACDP guidance, eg on safe working in animal containment facilities[3] and large-scale work with biological agents.[4] New guidance is being prepared for work at Containment Level 4.

5 Table 1 (see page 3) sets out the **minimum** containment requirements of COSHH for work in CL2 and CL3 laboratories. In addition to guidance on the means of meeting these requirements, there is also advice on **good practice** with respect to related aspects of the design, operation and management of such facilities.

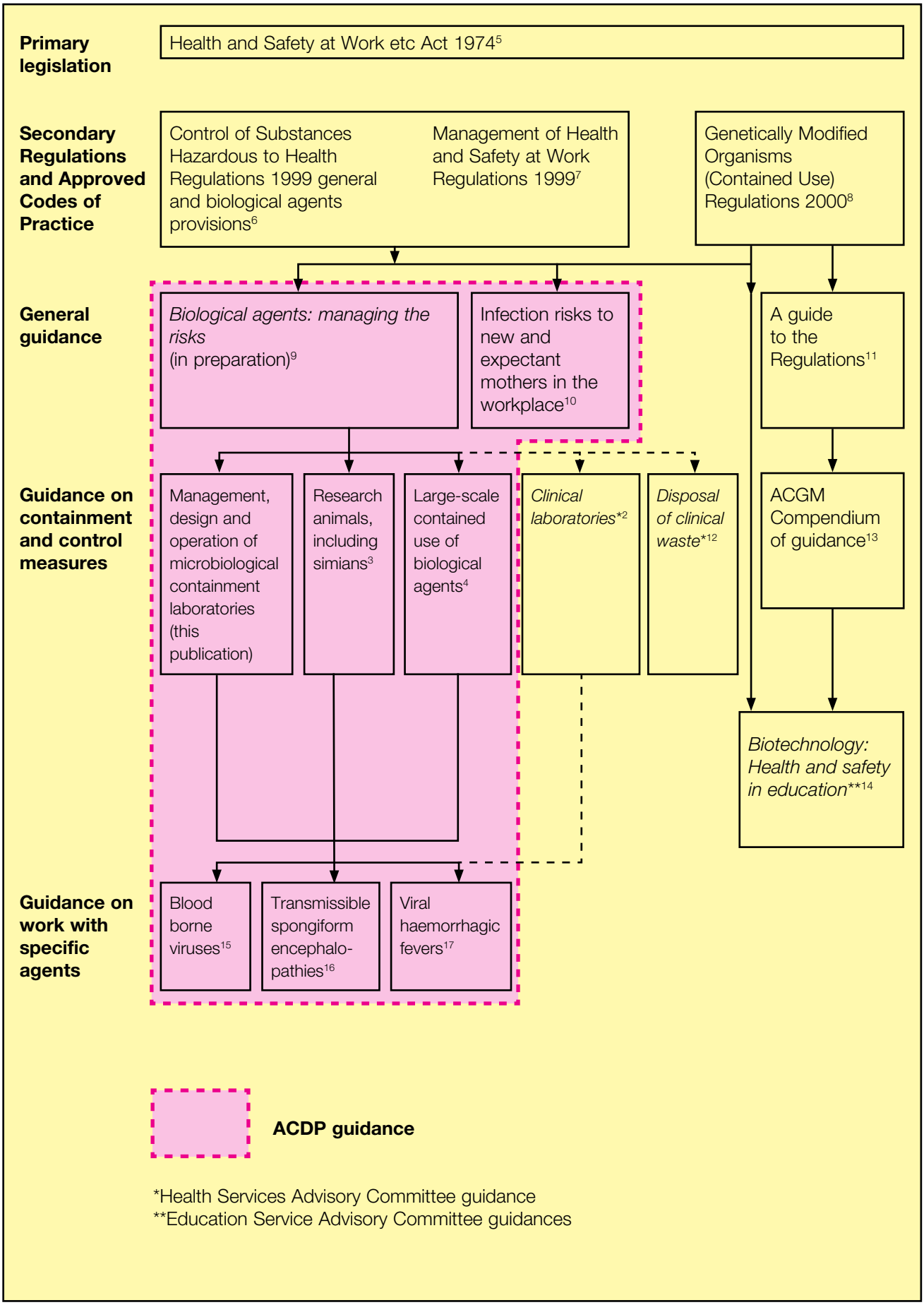



**Figure 1** Health and safety legislation and guidance relevant to work with biological agents in microbiological containment laboratories

**Table 1** Containment measures for CL2 and CL3 laboratories

| **Containment measures** | **Containment Level** | | **See guidance in paragraphs** |
|---|---|---|---|
| | **2** | **3** | |
| **Air handling** | | | |
| The workplace is maintained at air pressure negative to atmosphere | No, unless mechanically ventilated | Yes | 86-95 |
| Input air and extract air to the workplace are to be filtered using high efficiency particulate absorption (HEPA) or equivalent | No | Yes, on extract air | 96-100 |
| **Security and access** | | | |
| Access is to be restricted to authorised people only | Yes | Yes | 101-105 |
| The workplace is to be separated from any other activities in the same building | No | Yes | 106-108 |
| Efficient vector control, eg rodents and insects | Yes, for animal containment | Yes, for animal containment | See *Working safely with research animals: Management of infection risks*[3] |
| An observation window, or alternative, is to be present so that occupants can be seen | No | Yes | 109-113 |
| Safe storage of a biological agent | Yes | Yes | 114-116 |
| A laboratory is to contain its own equipment | No | Yes, so far as is reasonably practicable | 117-121 |
| **Disinfection and disposal procedures** | | | |
| The workplace is to be sealable to permit disinfection | No | Yes | 122-128 |
| Specified disinfection procedures | Yes | Yes | 129-133 |
| Surfaces impervious to water and easy to clean | Yes, for bench | Yes, for bench and floor (and walls for animal containment) | 134-144 and 149 |
| Surfaces resistant to acids, alkalis, solvents disinfectants | Yes, for bench | Yes, for bench and floor (and walls for animal containment) | 134-144 and 149 |
| Incinerator for the disposal of animal carcasses | Accessible | Accessible | See *Working safely with research animals: Management of infection risks*[3] |

**Table 1** Containment measures for CL2 and CL3 laboratories (continued)

| **Protective equipment and procedures** | | | |
|---|---|---|---|
| Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable equipment | Yes, where aerosol produced | Yes, where aerosol produced | 160-166 |

6 Some of the work carried out in microbiological containment may also be subject to control under the Genetically Modified Organisms (Contained Use) Regulations 2000 (GM Regulations). There are some similarities between the laboratory containment measures required under COSHH and those required by the GM Regulations. Where there is a mismatch, the more stringent requirements should be followed. There are also some additional containment measures required under the GM Regulations as follows (Certain measures are 'required where and to the extent that the risk assessment shows it is required'. This means that if the risk assessment indicates that the measure is necessary to control the risk then it must be applied):

- Autoclaves are required in the building at CL2 and within the laboratory suite at CL3.
- There needs to be specific measures in place to control aerosol dissemination. Aerosol production must be minimised at CL2 and prevented at CL3.
- The need for a shower at CL3 must be determined by risk assessment.
- Suitable protective clothing is required at CL2 and CL3. The need for protective footwear at CL3 must be determined by risk assessment.
- Gloves are required at CL3 and their need determined by risk assessment at CL2.
- Written training records are required for staff working at CL3 and their need at CL2 must be determined by risk assessment.
- There are also specific requirements concerning the inactivation of waste containing genetically modified micro-organisms.

7 In some cases, users can apply for derogation from the containment measures required under the GM Regulations. This must be fully justified by a comprehensive risk assessment and the reduced containment measures must be agreed in writing by HSE.

## Purpose of containment

8 The term 'containment' describes the way in which biological agents are managed in the laboratory environment so as to prevent, or control, the exposure of laboratory workers, other people and the outside environment to the agent(s) in question. This can be achieved in a number ways.

9 **Primary containment**, ie the protection of the worker and the immediate environment can be achieved through a combination of good microbiological practices or techniques and the use of appropriate containment devices or safety equipment, eg microbiological safety cabinets. Further protection may be achieved through the use of appropriate immunisations, although immunisation should be seen only as a useful supplement to reinforce procedural controls and the use of safety equipment, not the only protective measure (see second bullet point in pragraph 58).

10 **Secondary containment**, ie the protection of the people and the environment outside the laboratory can be achieved by a combination of laboratory design and operating procedures, eg restriction of access, air handling and safe disposal of waste.

11 In addition to the more general means of preventing or controlling exposure to biological agents set out in COSHH,[6] there is also a requirement for the use of certain minimum containment measures for laboratories handling particular groups of biological agents:

- working with Hazard Group (HG) 2 biological agents requires a minimum of CL2; HG3 agents being handled at a minimum of CL3;
- CL2 must also 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 if it is clear that the activity might involve a serious risk for employees.

## Aims of guidance

12 This guidance focuses on work with biological agents at CL2 and CL3. Although there are no legal minimum containment requirements under COSHH for CL1 laboratories, the practices, safety equipment and facilities are essentially similar to those that are required at CL2. These should be used in addition to the more general COSHH control measures that must be considered (for example, prohibiting eating and drinking in the laboratory).

13 CL1 is appropriate for secondary education and undergraduate teaching laboratories for work with well defined and characterised strains of HG1 biological agents, which are by definition, 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.[11] Toxic and allergenic risks should also be assessed (and prevented or controlled as appropriate).

14 CL2 is probably 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 (see paragraph 11 for other situations where CL2 should be used). Examples of agents that must be handled at CL2 include common clinical isolates such as *Staphylococcus aureus*, respiratory syncitial virus and *Toxoplasma* spp.

15 CL3 laboratories are the highest containment laboratories in common use in the UK. As at CL2, 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 are capable of causing severe disease and pose a serious hazard to employees (because of their infectivity and/or route of transmission). Such agents may also spread within the community but effective treatment or prophylaxis is usually available.

Examples of such agents include *Mycobacterium tuberculosis*, hepatitis B (when being cultured) and *Naegleria fowleri*.

16 CL4 laboratories are highly specialised and those considering the design and construction of such facilities should consult other experienced users and HSE's Specialist Microbiology Inspectorate Tel: 0151 951 4718; Fax: 0151 951 3474.

17 Although COSHH sets out the minimum requirements for each level of containment, certain HG3 agents can be worked with under reduced containment in particular circumstances. In order to be able to do this the employer must follow the relevant ACDP guidance agreed or approved by the Health and Safety Commission. The HG3 agents eligible for reduced containment are listed in the latest edition of the HSC *Approved list of biological agents*.[18] Derogation from CL3 does not imply that the work can be carried out at CL2, it simply allows certain physical containment requirements, normally expected at CL3, to be dispensed with. All other aspects of the work, in particular supervision and training, should reflect the high standards expected at CL3. Any decision to reduce containment measures should be made on the basis of a local risk assessment which takes into account the specific nature of the work.

18 Although in many respects the requirements of CL3 are outwardly similar to CL2 laboratories, because of the more hazardous nature of the agents being handled, the standards that must be achieved are higher. The key differences between CL3 and CL2 laboratories relate to the way in which they are managed and the degree of supervision required, as well as certain specific physical containment requirements. It should be remembered that, at any containment level, the risk from work with biological agents is dependant on the severity of infection, the means of infection, quantity of agents being handled and the nature and location of the work. This needs to be addressed in the local risk assessment and, if necessary, specific control measures, in addition to the minimum required under COSHH, should be put in place to ensure that the work is carried out safely.

# Health and safety management in microbiological containment

## Management responsibilities

19 Employers have general duties under health and safety legislation to protect both employees and non employees from risks to their health and safety arising from work activities; non employees include students and visitors. Students who are involved in genetic modification activities are treated as if they were employees of the university or college, etc, where they are studying.[11]

20 The legal responsibility for health and safety rests primarily with the employer and in view of the potential risks associated with work with biological agents, especially at CL3, it is essential that there is a clear and effective health and safety policy in place for the organisation to follow. Acceptance of, and commitment to, the management of health and safety by senior managers is key in achieving effective management of health and safety.

21 Under the Health and Safety at Work etc Act 1974 (HSW Act), employers must prepare a statement of their health and safety policy. There is a similar provision in the Management of Health and Safety at Work Regulations 1999 (MHSWR) and where there are five or more employees, these health and safety arrangements must be recorded and the health and safety policy brought to the notice of all employees. Details of the management structure, individual responsibilities and employee involvement and responsibilities should be included.

22 In practice, to ensure that adequate precautions are in place, the responsibility is delegated down the line management chain. In some occupational settings a formal line management structure may not be obvious. However, if an individual is responsible for directing, controlling or supervising the work of others, eg researchers, biomedical scientists (BMS) and ancillary staff, etc, then they should be regarded as 'managers' for the purposes of identifying who is responsible for health and safety management. For instance, while a head of department in a hospital or university laboratory will have a key role in health and safety management, they may designate a laboratory supervisor to assist them to oversee and implement health and safety arrangements.

23 Employees have a duty to report defects and deficiencies in management arrangements and to co-operate with their employer, eg by applying agreed local rules and procedures.

24 If people working under the control and direction of others are treated as self-employed for tax and national insurance purposes they are nevertheless treated as their 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 could be clarified and included in the terms of a contract. However, a legal duty under section 3 of HSW Act cannot be passed on by means of a contract and there will still be duties towards others under section 3 of HSW Act. If such workers are employed on the basis that they are responsible for their own health and safety, legal advice should be sought before doing so.

### *Working in a shared facility*

25 Some laboratories may be shared facilities, for example, a laboratory owned by a university may be used by researchers employed by a research council and students or employees of the university itself. Alternatively, the employer, ie the person who 'owns' the laboratory, may co-locate two different research groups within the same laboratory. In such cases, the employers involved have duties under MHSWR to co-operate and co-ordinate their activities so as to ensure that their respective obligations under the law are met. They need to ensure that everyone working in the laboratory is sufficiently informed about **all** the risks that may be present, eg by exchanging information about the nature of the work being carried out. In order for such shared facilities to be properly managed in terms of assessing and controlling risks, there needs to be someone in overall charge. This can be achieved by authorising a named, competent individual to take management responsibility for health and safety within the laboratory - this should be someone directly involved in the work of the facility and not the safety officer or biological safety officer.

26 Where one employer is in overall control of the premises, the other employer(s) should assist the controlling employer in assessing the shared risks and co-ordinating any necessary control measures, primarily by providing information. Where there is no controlling employer, joint arrangements need to be agreed such as the appointment of a health and safety co-ordinator. A single code of practice agreed by all parties should be used by all those working in the shared facility.

## Risk assessment

27 MHSWR require that all employers and self-employed people assess the risks to their employees and others who may be affected by their work activity. More specifically, COSHH requires assessment of the risks of work with substances hazardous to health. Although the main focus of this guidance is to help employers comply with the requirements of COSHH, they will also need to consider other risks likely to be encountered in the laboratory, eg radiation, noise and ergonomic factors such as the design of laboratory furniture (see Appendix 1). Identification of all the likely risks before the design of the laboratory is finalised should allow elimination of certain risks through the design process itself.

28 Where an assessment is carried out for the purpose of COSHH, or other more specific legislation, it does not have to be repeated for the purpose of MHSWR. The general rule is that where the duties laid down in MHSWR go beyond those in the more specific legislation such as COSHH, the more stringent requirements must be met.

29 The COSHH risk assessment for biological agents should consider:

- the biological agents that may be present and their hazard groups;
- the forms in which agents may be present - eg as spores;
- the diseases caused and how they can be transmitted;
- likelihood of exposure and consequent disease (those who may be more susceptible to disease, eg the immunocompromised, or pregnant workers should be identified);
- the activities being carried out;
- control measures to be applied and how exposure will be controlled (both in terms of numbers of people exposed and the quantity of the agent that will be used);

- whether monitoring for the presence of agents outside primary containment is necessary; and
- the need for health surveillance/pre-employment screening.

30 COSHH also requires that exposure to a biological agent be avoided if possible or that a safer biological agent is used. Therefore, for certain types of work, the possibility of using less pathogenic or non-toxigenic strains must be considered and such alternatives used where practicable, for example where work is being carried out for quality control/quality assurance or teaching purposes.

31 The local risk assessment of a particular project, task or activity, may be carried out by the individual responsible for that work (either alone or under supervision, depending on competency and experience). However, there should be procedures in place to ensure that the assessment is checked and authorised by others - who are independent of the specific project and competent to do so (see paragraphs 39-40). This may be the local safety officer or biological safety officer, or else it could be considered by the local safety committee or genetic modification safety committee. It is recommended that local risk assessments for work that involves the propagation and concentration of HG3 agents should be reviewed by the biological safety officer or committee and that the work is authorised by senior management.

## Staff selection, training and supervision

32 All employees must have a clear understanding of any identifiable risks to their health arising from work and the actions to be taken in dealing with situations in which exposure may occur. The level of training provided should be appropriate to the level of risk and the complexity of work being undertaken.

33 Employers have defined responsibilities under HSW Act and MHSWR to provide suitable and sufficient information, instruction and training for their employees. COSHH also contains specific requirements to provide information, instruction and training for those who may be exposed to substances hazardous to health, including biological agents.

34 Under MHSWR, employees must receive comprehensive and relevant information on the risks and preventative and protective measures together with adequate health and safety training which should be at an appropriate level to ensure competence in their work.

35 The employer should first identify any gaps in knowledge or experience and then identify and provide appropriate training. This may not necessarily be a formal training course, eg the person being trained could shadow a more competent and experienced member of staff. Training may, however, be part of a formal qualification process, eg as a BMS, or else be designed for the specific needs of individual/project/laboratory/task.

36 Although appropriate training must be given before an employee is allowed to start work in the laboratory, it should also be an ongoing process since a person's competence will decline if skills are not used regularly. 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 process also needs to be evaluated, ie there should be some means of demonstrating that the training has achieved the desired outcome.

37 Training should take into account the breadth of work that is likely to be undertaken within a laboratory and the different levels of risk associated with the work, eg from working with samples suspected of containing biological agents to large-scale propagation and concentration of biological agents. It may be necessary to gain experience of and become proficient in techniques and procedures using agents that are in a lower hazard group. Since laboratory workers may work in a number of laboratories throughout their career, the keeping of personal training records/portfolios (suitably endorsed by the relevant employer) provides a useful means of demonstrating professional development and competence to future employers.

38 Training should not be limited to those working at the bench. Laboratory managers, supervisors and safety advisors should be appropriately trained to ensure that they are competent and they should maintain their professional competence by refresher training or other means. It is also necessary for auxiliary staff (eg cleaners and porters) and others (eg maintenance staff, external contractors and administrative staff) to receive sufficient and appropriate information, instruction and training about the hazards they may encounter when working in a laboratory. They should also be appropriately supervised while carrying out their work.

### *Competence*

39 Previous experience should not automatically be taken as a demonstration of a person's competence to work in the laboratory in question. Competence should be viewed as a product of sufficient training, experience, knowledge and other personal qualities to undertake a job safely. Neither should seniority or grade necessarily be associated with competence - not all qualified people are competent. Similarly, a lack of qualification does not automatically mean a person is not competent. It should be remembered that visiting researchers from other countries may be used to working to different standards from those used in the UK.

40 It is also important that all individuals in a multidisciplinary team are able to do their jobs safely, although there may be degrees of ability/experience (so that people can be ranked) associated with degrees of responsibility within the team. In addition, it should be remembered that competence gained in one situation need not necessarily mean that an individual can carry out **all** work at any containment level.

## Local safety policies and codes of practice

### *Local codes of practice*

41 Local codes of practice form part of the process of giving information on safe working, eg by serving as a checklist for identifying areas which staff should understand before being judged as competent, but thorough training and instruction on their day-to-day application is needed in order to make them work effectively. Specific information on the arrangements for working safely day-to-day can best be set out in local codes of practice. Employers have a responsibility to make the policy and codes freely accessible either by putting them on display or by individual issue. All staff, including all newcomers and temporary workers, must be made aware of them. A guide to the main areas that should be covered in a microbiological containment laboratory is given in Infobox 1.

### *Local health and safety policy*

42 The local health and safety policy sets out in general terms how the management intends to develop and maintain a safe working environment. It should also make reference to ways in which the safe day-to-day working of the laboratory will be achieved and managed. Much of this information should also be contained in the local codes of practice.

### *Standard operating procedures*

43 Another route for conveying health and safety information to employees is through the use of standard operating procedures as many procedures within the laboratory will be carried out using them. They are often used to meet external (and internal) quality standards but by integrating the health and safety arrangements into the standard operating procedures, employers can ensure that they also meet acceptable standards of health and safety. The standard operating procedure should be developed in consultation with staff to ensure commitment to the safe working procedures.

**INFOBOX 1: SUGGESTED TOPICS TO BE COVERED IN A LOCAL CODE (NOTE: SOME OF THESE ITEMS COULD ALSO BE USED AS A COMPETENCY CHECKLIST.)**

- *Introduction* - this should state the reasons for having such a code and refer to other relevant health and safety documents. Staff should be made aware of the nature and range of agents to which they 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, staff should be made aware of all the risks to which they might be exposed.
- *General procedures* - these should specify which staff (or grade of staff) are authorised to carry out particular procedures, there should also be appropriate guidance for ancillary and maintenance staff, contractors and visitors (see also Infobox 4).
- *Operation of unit* - this should detail start-up procedures, etc, how the ventilation system works and its controls, operation of safety cabinet(s), procedures for operating equipment, eg centrifuges and use of personal respiratory protective equipment, cleaning procedures.
- *Local rules* - these should cover such issues as arrangements for lone working, maximum numbers allowed in laboratory, entry/exit procedures, etc.
- *Waste* - this should detail the waste disposal and disinfection policy (both routine, emergency, eg spills and fumigation).
- *Staff health* - this should include the immunisation policy and arrangements for reporting injuries/infections (see paragraphs 52 -55), including the name of the person to whom incidents should be reported.
- *Testing and maintenance* - this should cover the maintenance and test procedures for engineering controls such as microbiological safety cabinets.
- *Emergency procedures* - this should cover procedures for dealing with accidents involving biological agents including the name of the person to whom incidents should be reported (see paragraphs 48-55 for more detail).

44 Employers need to make arrangements for supervising work and checking that health and safety measures remain effective. Supervision is necessary because even after safe working practices are put in place, people can still deviate from established practices and ill health or injuries may then result. The level of supervision will depend on the risk associated with the job or task and the competence of the person being supervised. Even fully competent individuals will require some level of periodic monitoring to ensure that standards are being met consistently.

45 Employers also have a duty to consult employees on health and safety matters. The Safety Representatives and Safety Committees Regulations 1977 and the Health and Safety (Consultation with Employees) Regulations 1996 require employers to consult trade union safety representatives, other employee representatives, or employees where there are no representatives, about health and safety matters. This includes changes to the work that may affect their health and safety at work, arrangements for getting competent help, information on the risks and controls, and the planning of health and safety training. Further information and details of additional guidance can be found in a free HSE leaflet.[19]

46 Once the arrangements for safe working are in place, management need to monitor to ensure that the systems and controls are effective and that they remain so. Monitoring should be both active and reactive. Active monitoring, ie before things go wrong, involves regular inspection and checks to ensure that the safe working practices are being implemented by all staff, where appropriate, and that management controls are working. The safe working practices should themselves be reviewed to ensure that they are effective and still relevant to the work being carried out.

47 Reactive monitoring takes place after things have gone wrong and involves investigating injuries, cases of ill health, equipment damage and near misses. In each case, both the immediate and underlying causes of the incident need to be identified and communicated to ensure that all learn from the incident. Most importantly, if monitoring (either active or reactive) reveals risks, then there needs to be a system in place to prioritise and deal with them.

## Emergency procedures/contingency plans

48 COSHH requires the employer to draw up plans for dealing with accidents involving HG3 or HG4 biological agents. There should be instructions (written, or if necessary displayed as notices) about the procedures to be followed if there is a significant accident or incident when working with biological agents, for example, in the event of a significant spill involving HG3 agents. It is considered good practice to have similar arrangements in place for handling **major** incidents at CL2, for example large volume spills.

49 Emergency procedures for the laboratory should be documented (either in the local code or as a stand-alone document). The MHSWR require procedures to be in place for responding to serious and imminent danger, eg fire or flooding, however the risk assessment should identify all the readily foreseeable incidents to be covered by the procedures. The procedures should also cover:

- roles and responsibilities of individuals 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 regular 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 individuals other than employees (eg visitors).

50 The emergency procedures should also contain arrangements to ensure that the emergency services have sufficient knowledge of the risks within the laboratory in the event of, say, a fire.

51 Employees (or their representatives) must be informed of such accidents/ incidents, their cause and the action taken to rectify the situation. The accidental release of a HG3 or HG4 biological agent must be reported to HSE under the Reporting of Injuries, Diseases and Dangerous Occurrence Regulations 1995 (RIDDOR) (see paragraph 55).

## Incident reporting

52 An official local record should be made of all incidents and occurrences with infectious or potentially infectious material involving the exposure of individuals (including near misses). This will include a wider range of incidents than would be covered by statutory schemes such as RIDDOR to help those responsible for laboratory safety to check the effectiveness of safety precautions within the laboratory and if necessary make changes (see paragraph 47).

53 COSHH requires that a list of employees exposed to HG3 agents is kept for 10 years (40 years in the case of certain agents where delayed effects may occur) following the last known exposure - this means that anyone working with HG3 agents in a CL3 laboratory should be on a list. It is often sensible to duplicate the relevant information with the individual's health record (see paragraphs 59-60 and Infobox 2).

54 Such a list is only required where there is a deliberate intention to work with such agents or where the risk assessment shows that there is a significant risk. The risk is deemed to be significant if more than basic hygiene measures are necessary to protect staff or if the control measures in COSHH are specifically applied. The decision to keep a list will depend on a local risk assessment. It is important to emphasise that the list is required where there is a likelihood of exposure, not simply when there has been a known incident or accident (although it should also include details of these). It is not the same as the requirement to report certain diseases and accidents to HSE under RIDDOR.

55 In addition to local reporting of accidents and exposures, in some cases the HSE must be notified under RIDDOR. There is a requirement in RIDDOR for employers to report any infection reliably attributable to work with live or dead humans or animals, exposure to blood or body fluids or any potentially infected material derived from any of the above. Accidents or incidents which result in or could result in the release or escape of a biological agent likely to cause severe human disease, ie a HG3 or HG4 agent (defined as a dangerous occurrence) also have to be reported under RIDDOR. Further information can be found in HSE guidance.[20]

## Health surveillance

56 Health surveillance is required under COSHH where:

- there is an identifiable disease which may be related to workplace exposure;
- there is a reasonable likelihood that the disease may occur; and
- there are valid techniques for detecting indications of the disease or its effects.

57 There are no hard and fast rules about the features of a health surveillance programme and the precise details should be discussed with a qualified occupational health practitioner.

58 A suitable health surveillance programme for laboratory work may range from self-checks by employees through to medical surveillance and clinical examination, depending on the nature of the work and the biological agents involved. It is important to include visiting researchers in these checks as well as more permanent staff. As a practical guide, some of the following features may be relevant; further details can be found in HSE guidance:[21]

- **pre-employment screening** - which may be by questionnaire, rather than medical examination. One purpose is to check the immune status of employees and offer the appropriate immunisation or to identify those who may be more susceptible to infection because of a pre-existing medical condition such as eczema or impaired immune function. In rare cases it may be necessary to take baseline serum samples for checking in the event of an incident, or else samples may be taken after incidents. However, the storage of serum may only be relevant in some specific circumstances. Before a decision is taken, the ultimate purpose of such a procedure should be considered. Long term, effective serum storage requires good organisation and record keeping.
- **immunisation** - if the risk assessment shows that there is a risk of exposure to biological agents for which effective vaccines exist, such vaccines should be offered unless the employee is already immune. Immunisation should only be seen as a useful supplement to reinforce procedural controls and the use of protective equipment, not the sole protective measure. Staff should be made aware of the benefits and drawbacks of both vaccination and non-vaccination. The HSW Act requires that workers are not charged for protective measures, including vaccinations.
- **monitoring** - checking employees' health to detect workplace illness by, for example, following up sickness absence or explaining symptoms of infection to employees so that they can monitor their own health. In some cases it may be useful to provide medical contact cards to alert medical practitioners about the nature of the work in the event of sudden unexplained illness.

## Record keeping

59 Any health surveillance programme should include keeping a health record for each individual. The elements of a health record are given in the Appendix to COSHH[6] and include:

- personal details of the individual;
- an historical exposure record (it may be sensible to combine this with any list of workers' exposure to a HG3 or HG4 biological agents - see paragraphs 53-54);
- dates and a record of any immunisations and the conclusions of any checks on immunity. The conclusions should be about the individual's fitness for work or any specific precautions that should be taken.
  It should **not** include any confidential clinical data.

60 The health record is different from a clinical record and may be kept with other confidential personnel records. The health record and any list of exposed workers needs to be accessible by the employer in order to monitor control measures that are in place and to ensure that employees are not at risk. Records which include medical information arising from clinical examination are held in confidence by the doctor or nurse and can only be released with the written consent of the individual.

**INFOBOX 2: THE DATA PROTECTION ACT 1998**

If records (computerised or manual) are kept about individuals (such as employees) in connection with health and safety legislation, eg health or medical surveillance records, the requirements of the Data Protection Act 1998 may apply. These requirements may include informing people that certain information is held on them and granting them access to that information, should they request it. Guidance on the Act can be requested from the Office of the Data Protection Commissioner, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF (Tel: 01625 545745).

# General principles of the design and operation of microbiological containment laboratories

## Introduction

61 The following section sets out the main principles that should be followed in the initial phases of the construction, upgrading or conversion of a laboratory. While the scale and the purpose of a containment laboratory can vary considerably, eg from simple processing of specimens to large-scale fermentation, the guidance details the key principles that need to be addressed.

62 One of the essential things that should be remembered when embarking on a building project is that there will be many external constraints which will influence the design of the laboratory. It is important to try to establish a consensus of opinion and balance the various needs and wishes of all the parties involved.

63 The design and construction of a containment laboratory will have to meet the specific requirements laid out in Schedule 3 of COSHH (see also Table 1) but there are more general regulatory requirements, including other health and safety legislation which need to be considered. Appendix 1 lists some of the hazards, other than microbiological, that need to be taken into account.

64 The Construction, Design and Management (CDM) Regulations 1994[22] (as amended) require that health and safety is taken into account and managed throughout all stages of a project, from conception, design and planning through to site work and subsequent maintenance and repair of the structure. These regulations apply to most common building, civil engineering and engineering construction work (including demolition, dismantling and refurbishment).

65 In addition to all the mandatory requirements that have to be addressed, the laboratory should also be designed to take account of the recommendations in guidance or standards produced by such bodies as the Advisory Committee on Dangerous Pathogens, Advisory Committee on Genetic Modification, Health Services Advisory Committee, British Standards Institution and relevant professional organisations.

66 There are also a number of publications which provide more detailed information on the design and construction of laboratories (both general and microbiological). Details of these are given in Further reading.

## The design process: liason with designers and builders

67 Laboratory design should be a collaborative project between the client, ie the person for whom the work is being carried out, and the designer, although these are likely to be teams rather than individuals. The first stage in the process is likely to consist of an initial briefing which will establish the broad requirements of the client. It is useful, at this point, for the client to appoint a responsible person to act as project manager to co-ordinate and oversee the project, including liaison with the design team and later the 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 ensure that the end result meets the required needs and expectations.

68 Clients have specific duties under the CDM Regulations: they have to pass relevant information reasonably available to them about health and safety matters which relate to the project, to those who are responsible for planning the project. Designers also have duties under the CDM Regulations. They should ensure that when they design for construction they assess the foreseeable health and safety risks during construction as well as the eventual maintenance and cleaning of the structure in the balance with other design considerations such as aesthetics and cost. This can be achieved by applying the normal hierarchy of risk control. They should identify all the hazards inherent in carrying out the construction work and, where possible, alter the design to avoid them. If the hazards cannot be removed by changing the design, then the risks will need to be controlled and the designer should provide information about the remaining risks.

### *Liaison with other agencies*

69 In addition to the health and safety requirements covered in this guidance, a number of other agencies have mandatory requirements which will influence the design process. These include:

- Home Office - Fire Regulations, animal welfare (standards for the design and construction of animal facilities);[23]
- 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*

70 There are a number of factors which will need to be considered, as appropriate, by the project/design team when setting the specifications of the new laboratory:

- **adaptability and flexibility** - while the need for the laboratory may have arisen because of the requirements of a particular project, the design should allow for as many different programmes of work as possible to occupy the laboratory space with minimal changes. A flexible design will enable the needs of new projects and organisational changes to be addressed by moving staff and their equipment, rather than physically changing the layout of the laboratory. An adaptable design allows the accommodation to be tailored for specific needs by altering the physical layout of the facility.
- **building services** - the need to provide both general and local exhaust ventilation will have to be considered. It may also be necessary to provide temperature and humidity controls which provide both operator comfort and meet any special requirements of the facility or equipment. Controls and service areas, etc, should ideally be located away from the main laboratory areas and should be accessible without having to enter the laboratory.

- **relationship between space and function** - in a new laboratory complex, the various aspects of the work can be considered and located accordingly, for example centralised support facilities could be provided for a number of individual laboratories within a complex. However, if a new laboratory is to be constructed within an existing facility, then careful consideration will need to be given to its location to maximise 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 section on siting of laboratories, paragraph 75).
- **user population** - knowing the number of staff likely to be working in a particular laboratory will give an indication of the space requirements and room sizes. Figures are given in various publications (see paragraphs 71-73) but these should be used as a guide only with an individual assessment made of the laboratory in question.
- **ergonomics** - the laboratory design should take into account 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 user friendliness of the environment which in turn has a positive influence on health and safety.

71 The laboratory should be of sufficient size to allow each worker adequate 'free air' space. The Workplace (Health, Safety and Welfare) Regulations 1992 (as amended) 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) specifies that the volume of the room, when empty, divided by the number of people normally working in it should be at least 11 $m^3$. However, this is a minimum and may be insufficient depending on the layout, contents and the nature of the work. In making the calculation, the 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 will need to be assessed when determining ceiling height.

72 In determining the space required, consideration should be given to factors such as the intended nature of the work and the space required for equipment, both free standing and bench mounted as well as numbers of staff. 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.[24] This sets out the critical dimensions which affect the efficient functioning of an activity:

- **component dimensions** - these relate to the size and position of components, eg equipment, furniture and fittings; and
- **activity dimensions** - these define the user space, which is the minimum space required to perform an activity.

73 The European Standard (BS EN 12128:1998)[25] 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.

74 The laboratory should be designed for ease of cleaning and maintenance. For example, control systems for heating and ventilation should be accessible from outside the laboratory containment area so as 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 their resistance to commonly used disinfectants and other substances which will be used within the laboratory. Proper housekeeping will limit physical clutter, control contamination and help to use chemical disinfectants efficiently.

## Siting of the laboratory

75 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 a number of points to consider which will influence the positioning (the list is not exhaustive and there may be other physical constraints on the final position of the laboratory). Similar points should also be considered when designing a new building:

- **headroom** - this should be adequate for the installation of ductwork and utilities and should be sufficient to allow the movement of large equipment into 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** - these 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; and
- **other facilities** - office areas should be sited outside the laboratory containment zone.

## Commissioning and validation

76 Validation can be defined as a documented procedure for obtaining, recording and interpreting the data required to show that a process/equipment/activity will consistently comply with predetermined specifications.

77 Before the laboratory can be brought into service, 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 in order to ensure that it meets the standard specified in the design and construction brief.

78 There will be a number of key items that should be tested and performance verified before work commences in the laboratory. For example, in the CL3 laboratory:

- the laboratory itself must be sealable for fumigation (the process of fumigation should be validated - see Appendix 2) and should able to withstand the loading characteristics imposed by negative air pressure when the laboratory is in operation;
- all seals, eg around pipework, etc, should be checked visually and smoke tested under static pressure;
- it is recommended that all air supply and exhaust ductwork is checked *in situ* for leak-tightness, eg using bubble testing. The air supply and exhaust should be checked to ensure that there is a means of preventing reverse airflows;
- all high efficiency particulate absorption (HEPA) filters should be tested to ensure that they meet the required specification after installation and all HEPA filter housings should be leak-tight.

79 At both CL2 and CL3, microbiological safety cabinets, autoclaves and other equipment should be tested against the appropriate standards where these exist, or else against recommendations/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 ensure proper functioning.

80 Validation of all the key 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 when there is obvious wear and tear noted (this may be localised, eg around pipework). The process of validation should be documented; the initial validation records will serve as a baseline performance measure for subsequent tests.

# Principal requirements for containment level 2 and 3 laboratories

81 The following sections offer guidance on how to meet the legal minimum requirements in COSHH, with good practice guidance given on both design principles and operating policies for each containment level (those requirements specific for animal work are covered elsewhere).[3]

82 Where the word 'must' or other imperative wording has been used in the following text, this indicates an essential requirement as defined in legislation - these are also shown in ***bold italic underlined*** text.

83 Where guidance is given on how to comply with these requirements, this is based on what is considered to be best practice for CL2 or CL3 (or both); **however, the guidance is not mandatory and use of the measures should be determined by local risk assessment**.

84 As well as the specific containment requirements, the more general control measures in the biological agents provisions of COSHH such as displaying the biohazard sign, putting in place procedures for the safe collection, storage and disposal of contaminated waste and the provision of adequate and appropriate washing and toilet facilities also need to be addressed.

85 For the purposes of this guidance, the following definitions apply:

- a **laboratory** is the room in which biological agents are handled;
- the **laboratory suite** is one or more laboratories, not necessarily of the same discipline or containment level, and ancillary rooms within a section or department with shared use of equipment and facilities such as media preparation, autoclaves and centrifuges, etc; and
- a **laboratory unit** is a separate building or self-contained suite within a building containing one or more laboratories and with ancillary rooms such as airlocks, changing rooms, showers or autoclave rooms.

## Air handling

86 ***COSHH requires that at CL3, the workplace must be maintained at an air pressure negative to atmosphere.***

### Design

87 At CL3, the air handling system is one of the most critical systems in the laboratory in terms of ensuring both operator safety and operator comfort. Early planning for such systems is essential in order to allow sufficient space for ducting, etc. This is particularly important if the CL3 laboratory is a conversion or renovation of an existing room where location of ducting will be influenced by existing building structures. At CL3, the ventilation should be dedicated to the laboratory. Where this is not possible and the exhaust system is integral with the building exhaust ventilation system, the laboratory should also incorporate some means of preventing reverse airflows. The exhaust air should not be able to be recirculated back into the general building ventilation system.

88 The requirements for positive pressure because, for example, some processes may require a positive air pressure to maintain product integrity versus the requirement for negative pressure at CL3 need to be addressed. The use of localised airflow units or isolators which would allow both product and operator protection should be considered.

89 At CL3, the mechanical ventilation system should be capable of isolation, eg by the use of mechanical or electrical dampers, to ensure that the room can be closed and sealed for fumigation, however if this is not practicable, extract/input points may need to be blanked off manually during fumigation, provided this can be done from outside the laboratory.

90 Atmosphere in the context of *'maintaining a pressure negative to atmosphere'* should be interpreted as meaning the external air and/or other surrounding parts of the laboratory suite or unit. In effect, this means arranging engineering controls such that there is a continuous inward airflow into the laboratory but this is generally only necessary when work with biological agents is actually in progress. Whether work could be considered to be in progress should be determined by assessing the need for containment in the event of an incident, for example leaving a centrifuge running would require maintenance of an inward airflow because of the consequences of a breach of centrifuge containment. Activities such as the incubation of plates should not need an inward airflow.

91 At CL3, negative pressure can be achieved by any one of the following:

- extracting the laboratory air through independent ducting to the outside air through a HEPA filter (or equivalent);
- extracting the laboratory air to the outside air with a fan and HEPA filter (or equivalent) sited in a wall or window of the laboratory;
- ducting the exhaust air from the microbiological safety cabinet to the outside air through a HEPA filter (or equivalent); or
- a safe variation of these methods.

92 At CL2, ventilation may be supplied to provide a comfortable working environment. If, however, the laboratory is purpose-designed to be fully mechanically ventilated (ie forced inflow and extract of air and not simply extraction through a safety cabinet), the system should be capable of maintaining a net inward flow of air. It should be remembered, however, that it is unlikely that a **constant** pressure could be maintained at all times because of the amount of traffic in and out CL2 labs. In such circumstances, it is important to ensure that the laboratory cannot become positively pressurised with respect to the surrounding environment.

93 At both CL3 or CL2 (see paragraph 92), the design of systems to achieve negative pressure should aim for simplicity to avoid the chances of failure due to overcomplicated control mechanisms. Instrumentation should be relevant and sensitive to the factors that contribute to safety. Engineers should be asked to consider as a priority the safety features of the room when arranging heating and ventilation and the dispersal of heat generated by equipment. In particular, the inflow of air and the siting of ventilation outlets and extracts can have a significant effect on the performance of safety cabinets.

94 Both CL3 or CL2 laboratories should have provision made for comfort factors, ie supply of fresh air, temperature control. Where extraction of air is via a cabinet, the need for make up air will need to be considered.

**INFOBOX 3: LABORATORY CONTAINMENT AND INWARD AIRFLOW**

Laboratory containment is usually measured on the basis of the pressure differentials between the laboratory and the external air (either the outside or other parts of the laboratory suite or building). Typical values range from -30 to -50 Pa (for a CL3 laboratory). The traditional approach to increasing the containment afforded by the laboratory has been to increase the pressure differential between the laboratory and the outside environment. This can be achieved by either increasing the amount of air being drawn into the room or, more usually, by keeping the exhaust static and sealing the laboratory door.

Recent research has shown that while the latter method works as long as the door is kept closed, when the door is opened the pressure differential is reduced and containment compromised. The research has also shown that a better means of ensuring containment is to specify the amount of air inflow through the doorway. This has been shown to be directly related to the Laboratory Protection Factor (LPF - a measure of the total microbial aerosol in the laboratory expressed as a fraction of the total microbial aerosol outside the laboratory) with an increase in airflow through the door increasing the LPF.

**Operation**

95 COSHH requires that maintenance, examination and test of control measures including local exhaust ventilation' (this include microbiological safety cabinets) 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. At CL3 it is common practice to carry out testing at 6-monthly intervals. It should be remembered that the simpler the system in place, the fewer the demands for maintenance, although it will still be required on a regular basis.

96 ***COSHH requires that at CL3, extracted air must be HEPA filtered (or equivalent).*** HEPA filters should meet the performance criteria of a class H14 filter as defined in BS EN 1822-1: 1998.[26]

## Design


**Figure 2** Alarm to indicate fan failure

97 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 it is switched off if the extract fan fails. This will prevent reverse airflows and so positive pressurisation of the room.

98 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 (see Figure 2). If work is considered critical, arrangements should be made to ensure continued inward airflow, for example, through the installation of a small, adequately sized battery-operated fan which could be used in the event of a mains power failure.

99 The positioning of filters will depend on the design of the laboratory. Where filters are located outside the laboratory, eg for ease of changing, it is better to position the fan at or near the discharge end of the system to maintain the ducting under negative pressure and so ensure minimum leakage from the ducting (while ensuring that duct length is kept to a minimum). Arrangements will need to be put in place to decontaminate ducting prior to maintenance or repair. Where filters are not located outside of the laboratory, they should be sited as early on in the system as possible so that the remainder of the duct work is uncontaminated and safe to work on when required. If the laboratory is mechanically ventilated (either at CL2 or CL3), 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.

100 For both CL3 and CL2, 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 to use a sealed type of unit that recirculates cooled air into the room. If the unit extracts air direct to the exterior, this has to be HEPA filtered.

## Security and access

101 ***COSHH requires that at CL2 and CL3, access to the laboratory must be limited to authorised persons only.***

### Design

102 At CL3 or CL2, restriction of access can be achieved by installing, for example a lock and key, a swipe card, card key (see Figure 3) or digital lock entry system (see Figure 4).

**Figure 3** Card key entry


**Figure 4** Digital lock entry

### Operation

103 Restriction of access may be imposed at the entrance to the laboratory itself or else 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, indicating the level of work undertaken.

104 At CL3, to ensure 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 means of signalling occupancy of the room and that work is in progress. The CL3 laboratory should be locked when unoccupied.

105 At CL2, the number of authorised staff is likely to be greater than at CL3, so a list of authorised staff (either by name or description, etc) could be kept as part of the local code of practice. The list should be kept up to date.

**INFOBOX 4: PERMITS TO WORK**

A formal permit-to-work 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 key features of such a procedure are as follows:

- A written permit-to-work, 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 permit-to-work systems should have adequate knowledge, experience and training before they are given the authority to issue or receive permits.
- The permit-to-work should be signed off by both parties on completion of the work.

106 ***COSHH requires that at CL3, the workplace must be separated from other activities in the same building.***

**Design**

107 Separation of activities can be achieved for CL3 laboratories by locating them away from main public thoroughfares of the building. Additional protection against unauthorised entry can be achieved by means of a lobby. The lobby also provides an additional protection factor in the event of a laboratory accident involving the release of biological agents (see Infobox 5).

108 Although not a requirement at CL2, it is sensible to locate such laboratories away from, say, patient or other public areas within a hospital.

**INFOBOX 5: LOBBIES**

Lobbies can provide additional protection against unauthorised entrance into laboratories and serve to remind users working in a CL3 laboratory that they are entering a different and potentially more hazardous work environment.

Recent research has shown that the presence of a lobby also provides an additional protection factor in the event of a laboratory accident involving the release of biological agents. Using the concept of LPF, it has been has shown that a lobby/ante-room offers approximately a 100-fold increase in laboratory containment (albeit in an experimental setting).

It is recommended that designs for new CL3 laboratories should incorporate a lobby where practicable. The lobby should be viewed as being within the curtilage of the containment area but not be used to store equipment such as fridges, etc, that might contain biological agents. The lobby can, however, 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 feasible arrangements should be put in place to ensure that both doors cannot be opened at the same time. The lobby does not require a separate air supply - the key issue is to ensure 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.

109 ***COSHH requires that at CL3, the laboratory must have some means of viewing the occupants.***

**Design**

110 This can be achieved by means of an observation window (either in the door or in an internal wall, eg allowing a view from a CL2 into the CL3 laboratory) or cctv (see Figure 5). It is recommended that where windows are installed, this should be done in such a way that all occupants can be seen wherever they are working in the room; this may require one or more windows. Alternatively, strategically placed convex security mirrors may provide a total room view.

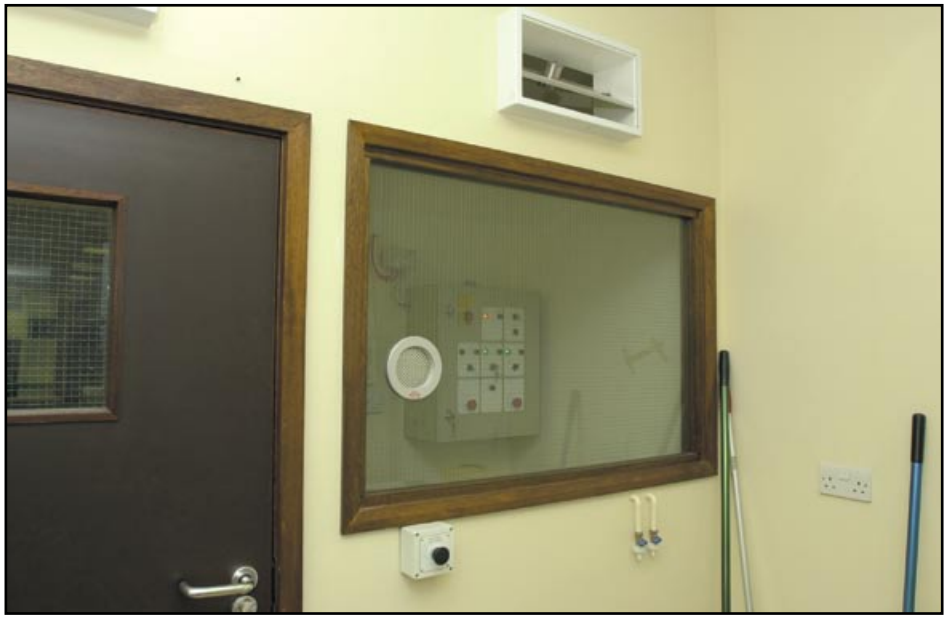


**Figure 5** Observation window into CL3 laboratory

111 The need for observation windows in CL2 laboratories should be considered as part of the local risk assessment, for example as a means of checking on those working alone and/or out of hours.

## Operation

112 The local risk assessment will identify any specific hazards for lone working (see Infobox 6) 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.


**Figure 6** Button to summon assistance

113 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.

## INFOBOX 6 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 HSW Act and MHSWR still apply.

The lone worker should be capable of responding correctly 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 assistance if in difficulties (see Figure 6). Further general information can be found in a free HSE leaflet.[27]

114 ***COSHH requires that HG2 and HG3 biological agents must be stored safely.***

**Design**

115 HG2 or HG3 biological agents (or material that contains the agents) should be located within a secure area, eg the laboratory/laboratory suite in order to prevent unauthorised access. Fridges or freezers (or other storage) used to store HG2 or HG3 agents outside the main laboratory area should be lockable. Storage should be constructed of material which is easy to clean, impervious to water and resistant to acids and alkalis.

**Operation**

116 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.

117 ***COSHH requires that at CL3, the laboratory must contain its own equipment, so far as is reasonably practicable.***

**Design**

118 At both CL3 and CL2, consideration will need to be given to the positioning of equipment within the laboratory, for example convection currents from centrifuges located in close proximity to microbiological safety cabinets may disrupt airflows, leading to loss of containment. Equipment may also be a source of noise, vibration or heat gain which may interfere with other operations in the laboratory.

119 Whether at CL3 or CL2, if equipment is located outside the main containment area, it should be located as close as possible to minimise movement of hazardous agents.

**Operation**

120 At CL3, where it is not reasonably practicable for the laboratory to contain its own equipment, for example, deep-freezers, material should be transported and stored, without opening, in robust, properly labelled secured containers. The material should only be removed from its container for processing in CL3 accommodation.

121 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. Examples of equipment to consider are given in Infobox 7.

**INFOBOX 7: EQUIPMENT TO CONSIDER**

- Filtration devices.
- Magnetic bead separation systems.
- Cryostats - Cryostat microtomes can produce aerosols of particles dislodged from tissue as it is sprayed with the fluorocarbon coolant.
- Cell disruptors (sonicators, homogenisers).
- Microscopes.
- Fluorescence activated cell sorting (FACS) machine.
- Robotics eg ELISA plate washers and reading systems, and other autoanalysers - These have the potential to generate aerosols.
- Automatic pipettes.
- Water baths - Constant temperature water baths can become contaminated and provide a suitable environment for growth of biological agents. Appropriate disinfectant should be added to the water and the water/ disinfectant changed regularly. Solid heated block incubators can provide a safe alternative.
- Computer equipment which may have been touched by potentially contaminated gloves/hands.
- Centrifuges (rotors and buckets).
- Liquid nitrogen containers and the liquid nitrogen - The use of vapour phase storage and the use of appropriate vials can significantly reduce the likelihood of contaminating liquid nitrogen and liquid nitrogen containers. Plastic rather than glass ampoules should be used. They should be securely sealed to prevent entry of liquid nitrogen which vaporises and expands when the ampoule is removed resulting in explosions.
- Ultrasonic cleaning baths - These can produce aerosols and heavily contaminated glassware should be decontaminated, eg by disinfection before being cleaned in the bath.
- Incubators and shakers - Glassware should not be used in incubators or shakers used in CL3 laboratories. Glassware used in CL2 laboratories should be checked (and discarded if damaged) before being used in such equipment.

## Disinfection and disposal procedures

122 ***COSHH requires that at CL3, the laboratory must be sealable to permit disinfection.***

### Design

123 The ability to seal the laboratory depends on the physical construction of the walls, ceilings, etc. Ceilings should be solid or continuous and preferably coved to the walls. It should be clear where the boundary of the room is, to determine the sealability of the room. If it is necessary to fit a false ceiling to hide pipework, etc, there should be a solid ceiling above the false ceiling and the space between the two should not run on into adjacent rooms. It should be remembered that fumigant will need to be able to penetrate this space during fumigation. The sealability of a room can be checked using a smoke test.

124 The walls and ceilings should be seamless/jointless and not permit leakage, eg of fumigant. Any piped services which enter the room should be sealed around the entry/exit points so that the room can be sealed for fumigation. Sealants used should be resistant to disinfectants, eg the fumigant used for disinfection, and should be non-hardening. All sealed joints should be subject to routine monitoring, and also checked before any planned fumigation, in case any small gaps have appeared, eg due to shrinkage or building movement.

125 Ideally, controls for carrying out fumigation should be located outside the laboratory so that re-entry into the room in the event of a spillage, etc, is not required (see paragraph 128).

**Operation**

126 COSHH requires that CL3 laboratories are sealable in order to permit **disinfection**. In practice, the most likely method of disinfection of the laboratory will be by gaseous formaldehyde fumigation. The room therefore needs to be sealed in order to contain the gas for at least 12 hours (or preferably overnight) (see Appendix 2).

127 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 (to prevent cross contamination). The process of fumigation should be planned and validated (whether it is required in an emergency or as part of scheduled/routine maintenance) and appropriate staff should be trained in the correct procedures. If the process is carried out by contractors, they should also be trained and should have visited the premises where fumigation may be required.

128 If the process cannot be controlled from outside the laboratory, the equipment and chemicals required should be located as close as possible to the door to minimise time spent in the laboratory in the event of an incident involving biological agents. It may, for example, be possible to have the generating equipment permanently wired to the socket closest to the door (with fumigant located close by).

129 ***COSHH requires that at CL2 and CL3, there must be specified disinfection procedures in place.***

**Design**

130 The laboratory structure, furniture and fittings should be resistant to the most commonly used disinfectants (see paragraph 95).

**Operation**

131 Disinfection protocols are required to be in place for both routine use and for use in spills. As well as documenting how disinfection should be carried out, the protocol should record that the disinfectant has been assessed for its efficacy under in-use conditions. Efficacy may be determined by:

- examining the manufacturers' literature;
- by examining the relevant peer-reviewed literature; or
- in-house testing.

The local protocol should indicate the type of disinfectants, in-use concentrations and contact times that are suitable for the biological agents that may be present in the laboratory.

132 The laboratory should have a clear written procedure, displayed as notices if necessary, 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.

All spillages should be dealt with without delay. A minor spillage involving little splashing and which is limited to a small area should be handled by applying disinfectant to the spillage and leaving for an appropriate period (see Figure 7). The spillage and disinfectant should then be mopped up with disposable paper towels which should be discarded as clinical waste. For larger liquid spills, it may be appropriate to contain the spill before applying disinfectant.

**Figure 7** Clearing up a small liquid spill

133 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 and it is recommended that planning for major incidents should also be addressed at CL2. See Appendix 3 for further information on procedures to be followed in the event of a major spillage.

## Laboratory structures and fittings

134 ***COSHH requires that at CL2, bench surfaces must be resistant to acids, alkalis, solvents, disinfectants, impervious to water and easy to clean. Both benches and floor surfaces have to meet these criteria at CL3.***

### Design

135 Although varnished wood would meet the above specification for benches, it requires regular maintenance to ensure its integrity. Bench tops should preferably be constructed of solid plastic laminate. MDF covered with plastic laminate can chip and split and so 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. Benching should also be of a smooth finish and stable (see Figure 8).

**Figure 8** Bench surface sealed to wall

136 Laboratory sinks provided for general washing up may be inset in benches or provided as separate sink units. The former should include a bowl and draining board as a complete unit (see Figure 9). This should be integral with the bench top without joints or else sealed (as in paragraph 135). 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 rather than discharge into a dilution recovery trap or catch pot.

**Figure 9** Integral sink/drainer unit

**Design**

137 Furniture should be kept to a minimum and under bench storage should be on castors for ease of cleaning under benches.

138 Floors should be smooth, slip resistant and seamless at CL2 and CL3.

139 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, and be impervious to water in order to allow proper cleaning and prevent absorption of infectious material onto floor surfaces. (See Infobox 8 for examples of suitable materials). For ease of cleaning, floor coverings should be coved to the wall.

140 If floor drains are present at CL3, they should not be open to the room and covers should be flush with the floor for ease of cleaning.

**INFOBOX 8: MATERIALS COMMONLY USED IN CONSTRUCTION AND FOR SURFACE COVERINGS**

- Coved vinyl - there is a coving on the interface between the walls and the floor.
- Epoxy - coatings of epoxy are used on solid floors such as concrete.
- Linoleum - this is used where vinyls are unacceptable for environmental reasons.
- Terrazzo - these floors comprise chips of marble in epoxy resins. The floor is polished once laid.
- Ceramic - use of this material may be dictated by chemicals in use in the laboratory. The joints are filled with grout so that the floor is easy to clean. This type of flooring requires good maintenance and the grout should be impervious.

**Operation**

141 Benches and other work surfaces should be kept clear of infrequently used equipment and other materials, eg disposables. It is recommended that work surfaces should be wiped down with an appropriate disinfectant (ie one which has been tested for efficacy under in-use conditions) at regular intervals, eg before restarting work after a break and routinely at the end of each working day. Suitable gloves should always be worn during such decontamination procedures.

142 Laboratory sinks should be cleaned regularly, eg at the end of each working day as part of the normal cleaning regime.

143 Floors should be cleaned periodically by wet mopping with a cleaning agent solution. Dry sweeping and dusting should be avoided.

144 As already indicated, CL3 laboratories should not normally have floor drains so residual cleaning solution should be removed by wiping over with a disposable dry mop or squeegee mop.

### *Doors and windows*

145 Doors and frames should be of a solid finish construction, chip resistant and should be of sufficient size to allow passage of equipment likely to be located in the laboratory. Location and type of windows may be influenced by the need to ensure that the occupants cannot be viewed from outside the building, for example where animal work is being undertaken, the use of one- way glass may be required.

**Design**

146 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. Windows at CL2 should also be designed for ease of cleaning, although they may be capable of being opened.

**Operation**

147 At CL3, if entry to the laboratory is via a lobby, there should be some means of safeguarding the pressure differential between the laboratory and the lobby, eg by providing interlocking doors which are alarmed in the event of a pressure drop. At CL3, doors should be locked when the laboratory is empty.

148 At CL3 and CL2, in the event of having to leave the laboratory via fire exits, these should be arranged so that travel through high-hazard areas is minimised.

### *Walls*

149 Walls should be smooth, easily cleanable and resistant to liquids and disinfectants in common use (including fumigants) in the laboratory. They should be regularly maintained to ensure integrity.

**Figure 10** Floors covered to walls for easy decontamination

**Design**

150 Materials which meet these criteria include epoxy or polyester coated plaster, rubberised paint, or equivalent surfaces. Two coats of a good quality vinyl or oil-based emulsion or silk finish paint is also adequate. Such materials should also be resistant to the normally 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 (see Figure 10).

### *Other services or utilities*

151 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.

**Design**

152 At CL3, electrical and other conduit services should be capable of being sealed to prevent escape of fumigant.

153 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 for cleaning and maintenance or else should be accessible from above for cleaning and maintenance.

154 If gas is not supplied as a mains service into the laboratory, cylinders used as a local supply of compressed gas should be located outside the laboratory. An alarm may be required to indicate when the cylinder needs to be changed. Controls for all piped services are ideally located in utility cupboards outside laboratory. This enables maintenance and calibration of instruments to be carried out outside the laboratory.

**Operation**

155 Consideration should be given to the way in which information is recorded and removed from the CL3 laboratory. For example, phones, e-mail, voice-activated dictating machines or faxes could be used to send information out without the need for decontaminating paper, etc.

### *Waste handling*

156 All waste from CL2 and CL3 laboratories which contains biological agents should be treated to render it non-infectious before it is removed from the laboratory or laboratory suite or unit. Policies and methods for the treatment and disposal of waste should be identified and in place before work with HG2 or HG3 agents begins. As part of the commissioning of the laboratory, the suitability of waste treatment equipment and methods should be assessed and documented.

**Design**

157 Steam sterilisation is the preferred method of treatment for infectious waste for both health and safety and quality control reasons. An autoclave conforming to BS 2646 1990-1993[28] and BS EN 12347,[29] should be available in the laboratory or suite at CL3. At CL2, the autoclave should be accessible, eg in the same building.

**Operation**

158 There should be documented procedures or protocols incorporating risk assessment of the biological agents likely to be present in the wastes and their concentration, the types and quantities of waste, and the treatment and disposal options. Such procedures should identify each treatment option and operating parameters or conditions known to kill the agents that may be present under the laboratory conditions (see Appendix 5 for further details).

**Operation**

159 Materials for autoclaving should be transported to the autoclave in containers with secure lids and without spillage. At CL3, only under exceptional circumstances should untreated waste be removed from the laboratory for treatment elsewhere in the same building. Infectious waste that is removed from the laboratory for treatment must be first put into an autoclave bag or container and then in an outer robust, leak-proof container with removable lid or cover which is secured in position. The double-contained waste load is taken directly to a secure area where the outer container can be opened and the waste removed or treated *in situ*. The waste should be treated immediately and should not be left unattended. If the waste cannot be treated on arrival at the autoclave, it should be stored safely in the CL3 laboratory until the autoclave is available for use.

## Personal protective equipment and procedures

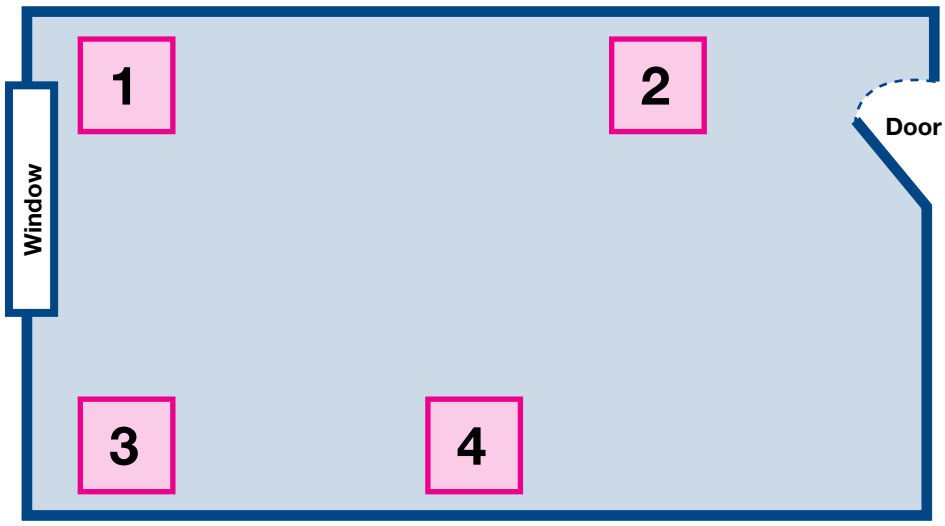
160 ***COSHH requires that, at CL2 and CL3, procedures that may give rise to infectious aerosols must be carried out in a microbiological safety cabinet or other suitable containment.***

**Design**

161 When siting cabinets within the containment laboratory, it is important to ensure that the cabinets' performance are not affected by:

- air currents from doors (or, at CL2, windows which can open);
- draughts caused by ventilation and air conditioning units;
- air currents caused by passers-by; and
- airflows from other microbiological safety cabinets, fume cupboards, laminar flow cabinets, etc, or other equipment which could disrupt airflows, eg centrifuges.

Figure 11 gives examples of good and poor sites for cabinets within a laboratory.




1 = At CL2, this would be poorly sited if window open - affected by air currents between door and window. If window not open then should be a safe distance from cabinet opposite. Sitting OK if used at CL3, since windows should be sealed.
2 = Poorly sited, affected by air currents from opening door and pedestrian traffic.
3 = Well sited.
4 = Well sited (better than 3 as not so near corner).

**Figure 11** Siting of cabinets

162 In other respects such as cleanability, sterilisability and leaktightness, they should comply with the performance specifications detailed in BS EN 12469: 2000[30] (but see also Appendix 6).

**Operation**

163 Safety cabinets 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. If cabinets are exhausted via the laboratory extract, dampers are required to prevent removal of fumigant from cabinets by the external extract system. The HEPA filter should ideally be part of the cabinet, but if not they should be located as close to the cabinet exhaust as possible, to avoid inadvertent contamination of the building exhaust system with biological agents.

164 At CL3, if it is difficult to arrange for the cabinet to exhaust to open air (either directly or indirectly via the laboratory exhaust), recirculation of exhaust air through two HEPA filters in series may be considered as an alternative. In such circumstances, there will be difficulties in dispersing fumigant when the cabinet has been fumigated so the local fumigation protocol should include information on safe methods for conducting away fumigant when the cabinet is to be decontaminated. Suitable methods include the use of neutralisation techniques or temporary ducting connected to the air outlet and leading to a fume cupboard.

165 Recirculation would be inappropriate if a gas or vapour phase chemical contaminant were released in the work process unless, for example, some form of monitored charcoal absorption system was used on the exhaust line. Further details on the operation, testing and disinfection of microbiological safety cabinets can be found in Appendix 6.

166 Negative pressure flexible film isolators (FFIs) have been used for a wide range of activities including isolation of patients with highly infectious diseases, handling of infectious animals and to provide secondary containment of laboratory equipment. They can also be used under positive pressure, eg in the pharmaceutical industry for product protection purposes. COSHH requires that any procedure involving infectious material which is likely to give rise to an aerosol should be carried out in a microbiological safety cabinet, isolator or equivalent. Although there are no UK or European standards for the design, construction and testing of FFIs, if they are to be used for containment, then they should achieve at least the same protection afforded by microbiological safety cabinets (MSCs) as defined in BS EN 12469: 2000.[30]

167 ***COSHH requires that all personal protective equipment, including protective clothing, must be:***

- ***stored in a well-defined place;***
- ***checked and cleaned at suitable intervals;***
- ***when discovered to be defective, repaired or replaced before further use.***

***Personal protective equipment 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.***

**Design**

168 There should be facilities for changing into laboratory wear 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 take the form of pegs immediately inside the entrance. At CL3, space should be provided for a container to store used laboratory clothing prior to autoclaving.

**Operation**

169 Suitable protective clothing should be worn in the laboratory. At CL3, dedicated side or back-fastening laboratory gowns or coats should be worn. They should have close fitting cuffs (see Figure 12) and be fastened using quick release studs or Velcro (see Figure 13). They should be made of a material which is flame retardant and resists shrinking even when autoclaved. The material should be sufficiently impermeable to protect clothing worn underneath. A similar specification is preferable for work at CL2 also.

**Figure 12** Close fitting cuffs on laboratory coat

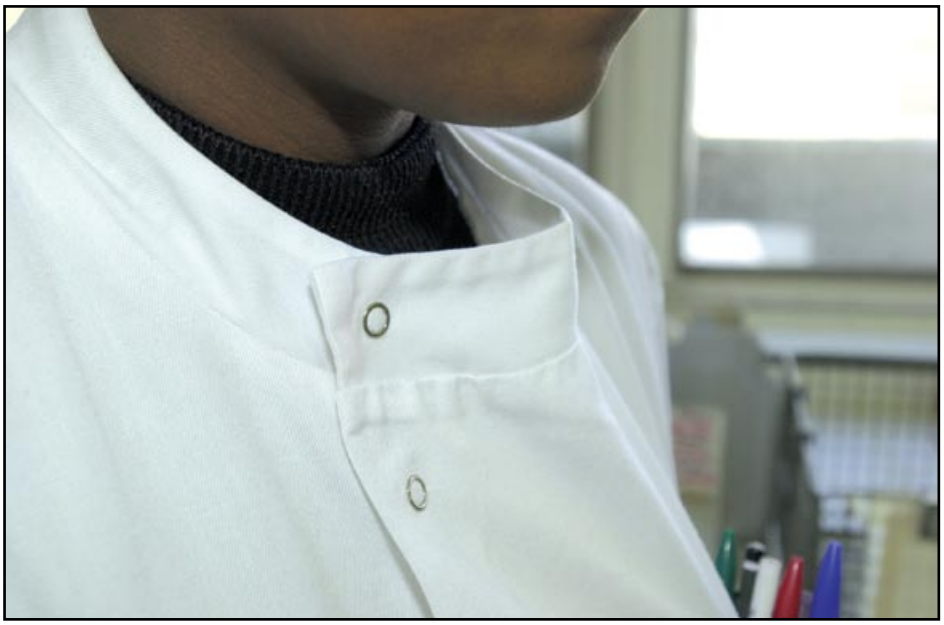


**Figure 13** Neck fastening on laboratory coat

170 Additional protection, eg disposable coats/gowns, aprons, footwear, oversleeves for work in microbiological safety cabinets should also be available, if the risk assessment indicates its need.

171 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 for ease of recognition. Procedures for frequency of changing of lab coats, eg weekly or when obviously contaminated, should be covered in the local code of practice. At CL3, all non-disposable coats should be autoclaved before being sent for laundering. Disposable protective equipment should be also autoclaved prior to disposal.

172 CL2 coats should be sent to the 'hot' laundry for washing. They should be packed such that they can be loaded into a washing machine without the need for pre-sorting by laundry staff. At CL2, disposable protective equipment can be either be autoclaved and disposed of in the general waste stream or else bagged and sent for incineration.

173 Gloves should 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 similarly protected, eg telephone handsets.

174 Facilities should be provided for hand washing (ie separate from other laboratory sinks).

**Design**

175 A wash-hand basin(s) should be located near to the exit of the laboratory. Local codes/policies on changing out of protective clothing when leaving the laboratory will determine the exact location and number of basins required. Basins should be of the type that can be operated without using the hands (eg the elbow, foot or the knee) or else supplied with automatic controls (eg infrared 'magic eye'). Drainage from such sinks can be discharged directly to the main sewerage system.

**Figure 14** Laboratory sink in CL3 room (with gowns ready for autoclaving)

176 Hands should be washed immediately contamination is suspected and before leaving the laboratory (see Figure 14). Alcohol handrubs are a useful substitute for handwashing in the event of needing to answer the telephone, etc.

# Appendix 1
# Other laboratory hazards

1 In addition to the microbiological hazards which are the subject of this guidance, there are other hazards that need to be assessed when working in a laboratory. The specific controlling legislation is listed below together with examples of relevant HSE guidance as sources of further information.

| HAZARD | LEGISLATION | HSE GUIDANCE |
|---|---|---|
| **Chemical** | | |
| Flammables | The Chemicals (Hazard Information and Packaging for Supply) Regulations 1994 (CHIP)<br><br>The Fire Precautions Act 1971 | *The safe use and handling of flammable liquids*[31]<br><br>*The storage of flammable liquids in containers*[32] |
| Carcinogens | COSHH | *Occuptional exposure limits*[33] |
| Toxins | | |
| Compressed gases | The Chemicals (Hazard Information and Packaging for Supply) Regulations 1994 (CHIP)<br><br>The Fire Precautions Act 1971 | *The safe use of gas cyclinders*[34] |
| **Radiological** | | |
| Radionuclides<br><br>Equipment that produces ionising radiation | The Ionising Radiations Regulations 1999 (IRR99) | *Working with ionising radiation*[35]<br><br>Ionising radiation protection series of Information Sheets[36] |
| **Physical** | | |
| Pressure systems, eg autoclaves | Pressure Systems and Transportable Gas Containers Regulations 1989 | *Safety at autoclaves*[37] |
| Lasers<br><br>UV radiation | None specific - general controls under HSW Act and MHSWR | |
| Noise | The Noise at Work Regulations 1989 | *Reducing noise at work. Guidance on the Noise at Work Regulation 1989*[38]<br><br>*Noise at work - A guide for employees*[39] |

| | | |
|---|---|---|
| Vibration | No specific legal provisions, general provisions of HSW Act, MHSWR and the Provision and Use of Work Equipment Regulations 1992 apply. In particular, under the Supply of Machinery (Safety) Regulations 1992, manuacturers and suppliers of machinery are obliged to reduce risks to a minmum and identify vibration leves in their literature. | *Hand arm vibration*[40]<br><br>*Vibration solutions*[41]<br><br>*Health risks from hand-arm vibration. Advice for employees & self employed*[42]<br><br>*Health risks from hand-arm vibration. - Advice for employers*[43] |
| High voltage | Electricity at Work Regulations 1989 | *Electricty at work - safe working practices*[44] |
| **Ergonomic** | None specific - general controls under HSW Act and MHSWR | *If the task fits - Ergonomics at work*[45] |
| Manual handling | The Manual Handling Operations | *Manual handling. The Manual Handling Operations* Regulations 1992 *Regulations 1992 Guidance on Regulations*[46]<br><br>*Manual handling: Solutions you can handle*[47] |

# Appendix 2
# Fumigation

1 Formaldehyde vapour is the fumigant most commonly used in laboratories. The usual source is formalin which is readily available as a 40% solution of formaldehyde vapour in water. When heat is applied, the vapour is generated in quantity. Formaldehyde has a maximum exposure limit (MEL) of 2 ppm (both 8-hour TWA and short term). Formaldehyde vapour is explosive at 7.75% in dry air. Its auto-ignition point is 430 °C. An ACOP has been issued as a supplement to the COSHH Regulations which provides practical guidance on the law relating to fumigation: see *Control of Substances Hazardous to Health in Fumigation Operations, Approved Code of Practice.*[48]

2 A number of factors affect the efficiency of fumigation:

- the ratio of formalin to water used and thereby the relative humidity created;
- the volume of the space to be fumigated;
- the surface area exposed in that space and the presence of absorbent materials such as cardboard boxes; and
- temperature - formaldehyde fumigation is less effective below 18 °C. Below 9 °C, formaldehyde sublimes and is less easy to vaporise.

3 To have maximum effect, the formaldehyde must be able to:

- penetrate (so pre-cleaning should be carried out if this can be done without compromising safety, eg if fumigation is a planned exercise); and
- dissolve at adequate concentrations in the film of moisture in the immediate vicinity of the organisms to be inactivated. Water vapour generated in the process of dispersing formaldehyde (see paragraph 4) provides the essential optimum level of relative humidity (ie greater than 35% but less than 80%). Too much formaldehyde results in the deposition of sticky deposits of paraformaldehyde.

4 There are a number of methods of generating formaldehyde vapour:

- heating a mixture of formalin and water in a thermostatically controlled heating unit (such as an electric frying pan or electric kettle);
- depolymerisation of paraformaldehyde;
- using commercially available formaldehyde-generating kits; and
- heating formalin in a purpose-made vaporising unit (safety cabinets) (see Figure 15, page 47).


**Figure 15** Device for fumigating cabinet

## Validation

5 Plans for fumigation should be documented in the local code and should include details of the initial validation of the process. This can be achieved by placing spore strips/discs carrying Bacillus subtilis var niger (filter paper inoculated with a suspension of the organism) at various points in the room or cabinet to test penetration of the fumigant. Similarly, a standardised spore suspension can be painted onto small marked areas on surfaces which are later swabbed to recover any surviving organisms. Contact plates can also be used.

## Fumigation of microbiological safety cabinets

6 Microbiological safety cabinets should always be fumigated if:

- a large spillage of infectious material occurs within them; and
- before filters are changed or any maintenance work is carried out which involves gaining access to the interior of the cabinet (eg air ducts).

7 The fumigant should be generated with the night door securely sealed and the non-return valve left closed. Passive migration of the fumigant through the filter can occur but the valve could be left open and the fan running for 10-15 seconds to ensure penetration of the filter medium. The valve should then be closed and the fan switched off while the remainder of the fumigant is left to disperse within the cabinet. After at least six hours, or preferably overnight, the fumigant should be exhausted to atmosphere by switching on the fan and allowing air from the room to enter the cabinet. Before venting the formaldehyde in this way, it is essential to ensure that no-one is in the vicinity of the exhaust outlet and that the exhaust air cannot enter nearby windows or ventilation air intakes.

8 If the cabinet exhaust is connected to the building extract system, the safety cabinet exhaust damper should be closed to prevent fumigant being dragged from the cabinet by the extract. In this case the building extract should not be connected to the building's air circulation system, if this is the case then, the fumigant will need to be exhausted as detailed in the main guidance (see paragraphs 164-165).

9 If filters are to be changed after fumigation, the discarded filter unit should be bagged and incinerated. There are special difficulties if the cabinet is used with the agents causing transmissible spongiform encephalopathies as they are resistant to inactivation by formalin. More detailed guidance is given elsewhere.[29]

## Fumigation of rooms

10 Before fumigating with formaldehyde, hydrochloric acid and chlorinated disinfectants should, if possible, be removed from the room. This is to prevent the possibility of forming bis (chloromethyl) ether which may be carcinogenic.

11 After at least 12 hours and preferably overnight, fumigant may be extracted from the area by the air handling system. This method should only be used where there is a total loss ventilation system present so that there is no possibility of formaldehyde vapour contaminating other areas. However, if available, a microbiological safety cabinet or a fume cupboard can be used to extract the fumigant, provided it exhausts to atmosphere. In all cases, the plant or equipment extracting the air should be operated preferably by an external switch so as to avoid the need for people to enter the room.

12 After the fumigant has been removed, a thorough check of the level of residual vapour should be carried out before anyone re-enters the laboratory. This can be achieved by, for example, sampling the air through a small port fitted in the door for this purpose. Meters and other assay devices are available to indicate the concentration of formaldehyde vapour remaining in the air. Staff should not re-enter an area when the fumigant has been generated except in an emergency. Full breathing apparatus which provides air from an independent source must be worn and only by those trained in its the use (see Appendix 4). Respirators are not appropriate for use in the concentrations of formaldehyde vapour achieved when carrying out these procedures.

# Appendix 3
# Action to take in the event of a spillage

## Introduction

1 The types of accident that might be encountered in the laboratory will vary from low hazard, small-scale releases of biological agents, eg the discharge of aerosol droplets from a pipette to more serious (but less frequent) incidents such as dropping a culture flask or a centrifuge accident. Some accidents have the potential for generating significant aerosols, for example dropping of material from a height. The risk of accidental release may be increased when using particular combinations of equipment, for example the use of glassware in orbital incubators is not recommended at CL3. While also addressing some general points about contingency plans, this appendix primarily gives specific guidance on dealing with spills at CL2 and CL3.

## Assessing the risks

2 When drawing up contingency plans (see paragraphs 48-51), a number of different factors/scenarios will need to be considered to determine the most appropriate course of action:

- Type of agent - the Hazard Group, route of transmission, infectious dose (if known), stability in the environment.
- Type of accident - instantaneous or delayed - for example, a dropped flask as compared to a broken centrifuge tube which may be undiscovered until centrifuge is opened.
- Severity of accident - amount and concentration of material that could potentially be released and form, for example, is aerosol formation likely?
- Numbers of staff potentially exposed - this may depend on location of accident (see below).
- 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 - this needs to be known to enable an assessment to be made of the time needed before staff can safely re-enter the laboratory after a spillage.

## Post-exposure prophylaxis

3 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).

4 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 (for example, see Department of Health guidance on post-exposure prophylaxis for those exposed to HIV or hepatitis B[49,50]), 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.

## Immediate action

5 At both CL2 and CL3, in the event of a significant spillage (either in terms of quantity or hazard presented by the agent or both) inside the laboratory, staff should immediately leave the laboratory, removing any contaminated clothing. This should be left in the laboratory (or lobby if present). At CL2, if present, the safety cabinet should left running or switched on before leaving the laboratory. Evacuation allows time to determine the most appropriate course of action without leaving staff exposed.

6 If necessary (and available), an emergency shower should be used if there is significant skin contamination. 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 assistance/ treatment may be required immediately (see paragraph 4).

7 The door to the laboratory should be locked or made secure and warnings posted (eg notices/alarms).

## Spillage in the CL3 laboratory

8 It is recommended that, **regardless of whether the agent being handled presents a risk of aerosol transmission,** following a significant spillage the room should first be cleared of infectious aerosol and then fumigated (see Appendix 2). Fumigation is recommended even if the agent is not transmitted by the aerosol route as this will facilitate safe cleaning of the laboratory, as contamination may be extensive, depending on the nature of the spillage.

## Clearing the room of infectious aerosol

9 Assessing the time to clear the laboratory requires the following information:

- concentration of micro-organisms in solution spilled;
- quantity of solution spilled; and
- the room ventilation air change rate

10 Table 3.1 indicates the airborne concentration of micro-organisms/$m^3$ for different volumes and concentrations of solution spilled. 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 3:1:** Airborne concentration of micro-organisms/$m^3$ vs 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 |
| $10^{8}$ | 50 000 | 500 000 | 5 000 000 |
| $10^{7}$ | 5 000 | 50 000 | 500 000 |
| $10^{6}$ | 500 | 5 000 | 50 000 |

11 Table 3.2 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 Infobox 9.

**Table 3.2:** Percentage removal vs 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 |

## Re-entring the laboratory

12 Before staff re-enter the laboratory, sufficient time should be allowed for any aerosol to be removed from the room and fumigation to have been carried out. Staff can then re-enter the laboratory wearing appropriate personal protective clothing.

13 The spillage should be contained if necessary (to avoid spreading) and an appropriate disinfectant applied; this should be left for a suitable period of time. The spillage and disinfectant should then be mopped up with disposable paper towels. The nature of the spillage will influence the extent of further cleaning required, for example, a flask dropped from a height has the potential to contaminate areas away from the point of impact and the laboratory may require extensive cleaning.

## Spillage inside a microbiological safety cabinet

14 Spillages inside a safety cabinet are usually contained and can be mopped up immediately with disinfectant followed by fumigation of the cabinet if this is considered necessary. If for any reason, it is suspected that an infectious aerosol may have escaped the cabinet then room fumigation may be required.

## Spillage at CL2

15 **At CL2, COSHH requires that work with any biological agent that could create an infectious aerosol must be undertaken inside a safety cabinet. To prevent spillages within the laboratory, the agent or material containing the agent should be adequately contained during transfer procedures from safety cabinets to other areas of the laboratory, eg incubators.**

16 However, in the event of an accident resulting in significant spillage inside the laboratory the safety cabinet should be left to run until the room is cleared of infectious aerosol (see Tables 3.1 and 3.2). Staff, who have been properly trained, can then re-enter the laboratory wearing appropriate personal/respiratory protective equipment. The spillage can then be dealt with as previously described, again assessing the nature of the spillage in determining the extent of cleaning required.

17 Spillages of CL2 agents which do not present an aerosol risk can be mopped up using appropriate disinfectants.

**INFOBOX 9: 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 3.1, the airborne concentration is 50 000 spores/$m^3$ on leaving the laboratory. From Table 3.2, after 58 minutes, 99.99% of the airborne spores will have been removed, leaving a concentration of 50 spores/$m^3$. After a further 35 minutes, a further 99.9% of the remaining spores will have been removed, and the concentration will have dropped to 0.05 spores/$m^3$, ie the laboratory will be almost free of any airborne spores.

# Appendix 4
# Respiratory Protective Equipment

1 The COSHH hierarchy of controls require the use of the procedural and engineering control measures described in this guidance; containment at source should be the primary aim. However, as a last resort respiratory protective equipment (RPE) may be used, eg in emergency situations.

2 **There are unlikely to be many situations where RPE is required to control exposure to biological agents in a laboratory setting, in fact RPE is more likely to be used to prevent exposure to chemical agents, eg formaldehyde.**

3 The employer must ensure that the equipment used is suitable for the work undertaken. If the equipment is available, albeit for emergency use only, it is important to ensure that staff are properly trained in its use and that refresher training is undertaken to maintain competence in the use of RPE. Training should also cover the cleaning, maintenance, storage and disposal of such equipment.

4 RPE is not specifically approved by HSE for work involving exposure to biological agents. However, RPE approved for use in other work situations may be suitable. There is a large variety of RPE available, including positive pressure equipment (full face mask and half suits/blouses). This type does not place the same reliance on face-seal integrity as the negative pressure type and is therefore preferred. However, for incidental type exposure, where filter type RPE may be used, the equipment should be chosen on the basis of the highest filter efficiency available.

5 In order to determine whether equipment is capable of providing adequate protection, an assessment should be made of its performance in relation to conditions in the workplace. The following points should be considered when selecting appropriate protection - these relate only to the agent, not any additional hazards that may be present in the workplace:

- the identity of the agents(s) likely to be present, their hazard group(s) and their routes of transmission;
- the quantity of material to be handled and an estimation of the length of time the work will take - for example, if work time is limited, a high efficiency particle mask (which could be disposable) may be suitable, however, for longer periods powered breathing apparatus may be more appropriate; and
- the quantity of airborne material likely to be generated.

6 Other considerations will include performance data, including filter efficiency and face-seal leakage which is obtainable from the manufacturer. Such data must include the results of biological tests (eg using spores of *Bacillus subtilis var niger*) or conventional physico-chemical tests (eg using a sodium chloride aerosol). For low performance equipment such as disposable and some half-mask respirators, sodium chloride aerosol has been shown to be an effective indicator of performance in relation to biological aerosols.

7 In deciding which types of RPE are suitable for the task, the following general factors need to be considered (see HSE guidance for more detailed information[51]):

- the wearer;
- medical fitness;
- thermal strain;
- face to facepiece seal (this is affected by facial hair/glasses);
- compatibility with other PPE; and
- work-related factors including: length of time RPE is worn, physical work rate, mobility, visibility, other PPE, communication, work environment, use of tools and other equipment and nature of contamination.

8 When selecting suitable RPE, other hazards should also be considered. These include contamination or infection by skin contact or splash, gas/vapour and/or oxygen deficiency, physical hazards, humid and hot environments and confined spaces. This will help to identify what other PPE should be compatible or integral with the chosen RPE and help to control secondary risks.

# Appendix 5
# Guidance on preparing standard operating procedures for waste treatment

## General

1 There should be documented standard operating procedures or protocols incorporating risk assessment of the biological agents likely to be present in the wastes together with:

- their concentration;
- the types and quantities of waste; and
- the treatment and disposal options.

2 Standard operating procedures should identify each treatment option and operating parameters or conditions known to kill the agents that may be present under the laboratory conditions.

## Autoclaving

3 Standard operating procedures for autoclaving should specify:

- the solid and liquid wastes that are to be autoclaved, eg cultures and media, sharps (if sharps bins are autoclaved prior to incineration, they should be able to withstand the process), pipettes, other disposable and reusable articles, gloves and laboratory coats, paper towels and tissues;
- the containers (which allow steam penetration) that are to be used;
- the required sterilising cycle, eg temperature and time settings and cycles;
- whether biological or chemical indicators are to be used and their location in the load;

- the unloading procedure;
- the checks to be made and recorded by users and others, eg maintenance staff; and
- the emergency procedure in the event of a malfunction or failure.

4 Effective sterilisation by autoclaving depends on:

- installation and commissioning using test loads to validate load temperatures 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;
- achieving and maintaining suitable load temperatures and holding times and the ability to validate these under operating conditions by independent thermocouple tests rather than by the use of biological and chemical indicators; and
- regular examination and testing by a competent person under a written scheme of examination including the checking of safety valves, steam pressure indicating valves and in the case of bench top autoclaves water level indicators.

5 There should be appropriate monitoring or indicating devices to warn the user to shut down the autoclave safely if critical operating conditions are not achieved. Emergency procedures should be established to deal with an unsterilised or partly sterilised load so that the waste can be repackaged for transfer to another autoclave or to an 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 standard operating procedure should specify the conditions, eg the use of robust, leak-proof and sealed inner and outer container, 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 then standard operating procedures should specify the disinfectants and disinfection methods that are to be used.

## Disinfection

6 Standard operating procedures for disinfection should specify:

- the 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;
- the disinfectant that is to be used, its use-dilution and how often it should be changed;
- the contact times to ensure inactivation;
- the methods for routine or occasional validation of the disinfection process;
- the safe disposal of used disinfectants and the need for decontamination of containers: and
- the means for the safe removal and disposal of treated waste.

7 Disinfection is widely used for treating liquid wastes and for removing contamination from equipment and other reusable items that may be damaged by steam or heat.

8 Disinfection is not as effective as steam sterilisation in destroying biological agents nor as easily monitored. It should not be used for treating wastes which could contain spores of HG3 agents. 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 standard operating procedures or laboratory codes of practice.

9 Disinfectant choice should be determined by:

- the general type or identity of agents for which the disinfectant has demonstrated efficacy;
- the presence of protein or other substances likely to reduce efficacy or be chemically incompatible with the disinfecting agent; and
- the pH and temperature of the waste that are compatible with safe disinfection.

10 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. Intimate contact must be achieved between the disinfectant, whether gaseous or liquid, 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.

## Incineration

11 Standard operating procedures for the destruction and disposal by incineration of treated and untreated wastes should specify:

- the wastes that are to be incinerated without prior treatment by autoclaving or sterilisation and those that are to be incinerated after treatment;
- the specification for the containers that are to be available in the laboratory for depositing infectious waste for incineration, eg polyethylene material, robustness, size, sealability and labelling. Containers will need to meet specifications set out in the Carriage of Dangerous Goods (Classification, Packaging and Labelling) Regulations [52] (if they are to be removed off-site for incineration);
- the frequency and method of removal of containers from the laboratory to a place of secure storage;
- the packaging and labelling requirements for transportation to the incinerator; and
- the responsibility for keeping records of all waste transfers and disposals including transfer or consignment notes.

**Note:** Producers of treated waste who do not want it treated as clinical waste under environmental legislation need to be able to show the Environment Agency or the Scottish Environmental Protection Agency that it is safe and non-infectious and cannot be distinguished from other similar non-clinical wastes (see: *Safe disposal of clinical waste*[12]).

# Appendix 6
# Microbiological safety cabinets

1 A microbiological safety cabinet (MSC) is a ventilated enclosure intended to offer protection to the user and the environment from aerosols generated when handling biological agents or material that may contain such agents. Air discharged from an MSC to the atmosphere must always be filtered. MSCs are not normally designed to contain radioactive, toxic or corrosive substances.

2 This appendix provides information about the performance criteria for MSC's and offers practical recommendations for their safe use. For a full description of details relating to type, specification and performance of MSC's, reference should be made to British Standard BS EN 12469:2000.[30]

## Types of microbiological safety cabinet

3 CLASS I - a cabinet with a front aperture through which the operator can carry out manipulations inside the cabinet. It is constructed so that the operator is protected and the escape of airborne particles generated within the cabinet is controlled by means of an inward airflow through the working front aperture, with HEPA filtration of the exhaust air. This type of MSC is not designed to provide product protection and is suitable for work with all categories of biological agent, except HG4.

4 CLASS II - a cabinet with a front aperture through which the operator can carry out manipulations inside the cabinet. It is constructed so that both the worker and product are protected. The escape of airborne particles generated within the cabinet is controlled by means of an inward airflow at the front of the cabinet, which is filtered before circulation within it, while the down flow of HEPA filtered air over the working surface protects the work. This type of MSC is also suitable for work with all categories of biological agent, except HG4.

5 CLASS III - a cabinet in which the working area is totally enclosed providing maximum protection for the operator, the work and the environment. Incoming and outgoing air is HEPA filtered. Access to the interior of a Class III cabinet is provided by use of arm-length gloves attached to ports in the front panel of the unit. The use of Class III cabinets is usually confined to work with biological agents in HG4.

## British Standard BS EN 12469:2000

6 The effectiveness of the microbiological safety cabinet depends on:

- good design;
- suitable installation;
- ongoing maintenance; and
- correct use.

7 Performance criteria are given in BS EN 12469 2000[30] (which supersedes BS 5726:1992). This sets out minimum performance criteria for MSC's used with biological agents and specifies test procedures with respect to protection of the worker and the environment, product protection, and cross contamination. It does not however, cover other precautions such as mechanical, chemical, and radioactive safety.

8 BS EN 12469:2000 specifies tests for the protection of operators, for example, volumetric airflow rate measurements, airflow patterns, HEPA filter testing and also tests for determination of product protection and leak tightness. A summary of the test methods to be used for type testing, installation testing and maintenance testing of Class I and II cabinets is given in Table 6.1.

**Table 6.1:** Test methods for type testing, installations testing and routine maintenance testing for Class I and II cabinets (adapted from BS EN 12469:2000[30])

| Testing | Retention at front aperture | Leaktightness | Filters |
|---|---|---|---|
| Type testing | Microbiological or potassium iodide (KI) | Soap solution | Aerosol challenge |
| Installation testing | **Check:** manufacturer's specification is met, volumetric airflow rate and airflow patterns<br><br>**Optional:** OPFT (microbiological or KI or other suitable alternatives | N/A | Aerosol challenge or when appropriate natural aerosol challenge |
| Routine maintenance testing | **Check:** manufacturer's maintenance requirements, volumetric airflow rate and airflow patterns | N/A | As for installation testing |

9 BS EN 12469:2000[30] differs from the previous BS standard in that the need to carry out an operator protection factor test - OPFT (referred to in the standard as the Aperture Protection Factor, Apf) at installation and during subsequent routine maintenance testing is now only optional. However, COSHH, in referring to 'local exhaust ventilation', requires a thorough examination and testing of equipment including safety cabinets on installation and as part of routine ongoing maintenance, at intervals not exceeding 14 months. To ensure that control measures are continuing to perform as intended, it is recommended, as a best practice measure, that an OPFT is carried out in addition to the tests specified by BS EN 12469:2000[30] (Table 6.1), at intervals not exceeding 14 months.

10 In some cases however, it may be appropriate to test more frequently. For example, it is common practice to test at six-monthly intervals when working with HG3 and HG4 biological agents. Table 6.2 contains details of recommended testing frequencies and Table 6.3 gives minimum expected results to achieved operator protection (where applicable).

**Table 6.2:** Frequency of tests

| Test | I | II | III |
|---|---|---|---|
| Alarms/indicators | daily (see Figure 16) | | |
| Face velocity/inflow | monthly (see Figure 17) | | N/A |
| Inflow/downflow | N/A | Annually for CL2, 6-monthly for CL3 | 6-monthly for CL3 and CL4 |
| OPFT | 12-monthly | | N/A |
| In-use OPFT | As required by assessment (see paragraph 12) | | N/A |

**Figure 16** Alarms/indicators on safety cabinet

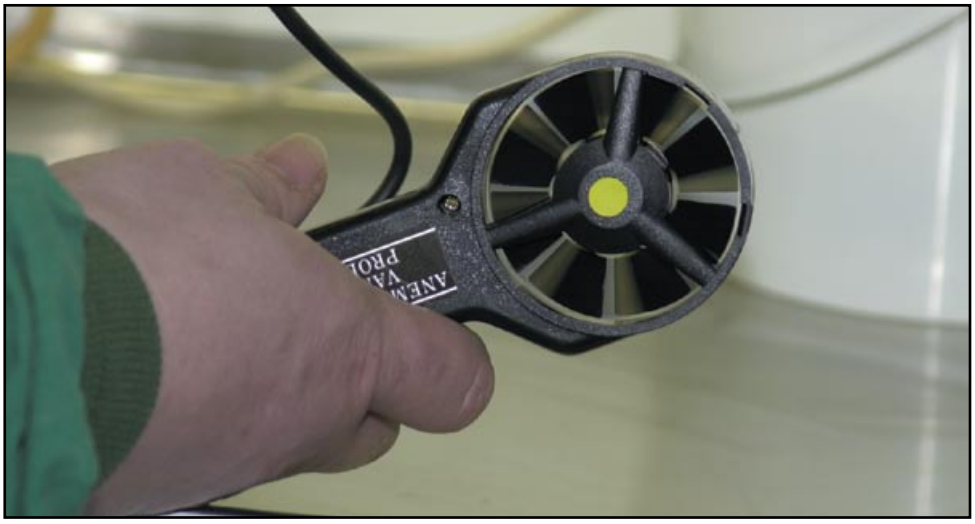


**Figure 17** Using a vane anemometer

**Table 6.3:** Recommended performance of cabinets

| Test | I | II | III |
|---|---|---|---|
| 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 x $10^5$ | | N/A |
| In-use OPFT | Greater than or equal to 1 x $10^5$ | | N/A |

## Operator protection factor test

11 The minimum inward airflow through the front aperture of a Class I or Class II cabinet is defined in BS EN 12469:2000.[30] This is required to provide containment and is related to the operator protection factor (OPF) for which the minimum standard is 1 x $10^5$. 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. The various methods involved and the conditions for conducting the test are defined in BS EN 12469: 2000.[30]

## In-use Operator Protection Factor testing of open-fronted microbiological safety cabinets

12 To assess the containment under actual conditions of use, it may be necessary to carry out an 'in-use' operator protection factor test. This may be required, for example, 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 laboratory set up changes significantly from the initial OPFT, for example, if the layout of the laboratory has been changed, or if new equipment has been installed.

13 The key requirement for in-use testing is to ensure that the MSC and laboratory conditions are as representative as possible of normal working conditions. The basic technique however, should be the same as set out in Appendix C of BS EN 12469:2000.[30] The following should also be considered:

- tests should be performed with the cabinet loaded with a typical arrangement equipment and samples (NB: BS EN 12469:2000[30] states that a 'false arm' should be used to simulate the effect of a worker using the cabinet. The effect of an artificial arm on cabinet operator protection factor tests has been shown to be similar to that of an operator working with arms in the cabinet, even if arms are occasionally removed);
- significant items of equipment normally used near the cabinet should be in place (and switched on if they normally produce discernible airflow currents). If there are normally other microbiological safety cabinets, fume cupboards or appliances, such as fans, functioning while the cabinet is used then these should also be working during the tests;
- traffic which would occur normally in the laboratory should be reproduced in the tests, for example this may involve people entering and leaving the room (ie opening and closing the door), walking around in the laboratory and past the cabinet;
- there should be no modifications to the laboratory or working practices and the room ventilation system should be working as normal. The laboratory should not be modified in any way for the tests;
- it may sometimes be useful to define more than one scenario for in use testing. For example, where different groups share the use of a laboratory.

## Recirculation of exhaust from MSC's

14 Under normal operational circumstances, it is good occupational hygiene practice to discharge exhaust air from MSC's to atmosphere through a dedicated extract system. If this is not reasonably practicable, recirculation of discharged air back into the laboratory can be considered. When working with HG3 biological agents under these circumstances, it will be necessary to discharge the air through two HEPA filters in such a way that each of the filters and their seals can be tested independently.

15 If recirculation is considered, then issues such as cabinet fumigation and subsequent clearing of fumigant must be considered as part of an assessment for the overall work. The choice between total exhaust or recirculation for a particular installation will depend on local circumstances and should be reflected in the local risk assessment. For example, recirculation would be inappropriate if a gas or vapour phase of contamination was released into the work process unless, for example, some form of monitored charcoal absorption system was used on the exhaust line. It is also important to consider, as part of any assessment, safe methods for conducting away fumigant when the cabinet is to be decontaminated. A number of suitable methods are available including the use of temporary ducting to an air outlet or the use of neutralisation chemicals.

## Siting of MSC's

16 The installation and commissioning of the cabinet is normally carried out by the supplier or an experienced agent. However, they should discuss siting of the MSC with the customer/user(s) to ensure that the position chosen is consistent with maintaining the required level of safe performance. Factors to be considered include the proximity of the cabinet to doors, windows, ventilation ducts and to movement routes.

17 Preliminary tests with small smoke tubes may help select the optimum position of the cabinet. Once installed, commissioning tests should be conducted to verify the performance of the cabinet *in situ*. The importance of installation testing cannot be over emphasised. It demonstrates the cabinet's performance and level of protection achieved in practice. It may also be necessary to carry out additional thorough inspection and testing when changes have been made to the laboratory that may affect the containment performance of the MSC. If, for example, a cabinet is moved to a new position in the laboratory, full commissioning tests should be carried out.

## Factors affecting MSC containment performance

18 The inward airflow to an MSC which is drawn through the working aperture of open front cabinets (Class I and Class II), can be disturbed by a number of factors including:

- Sudden movement of the arms of the operator and turbulence in and around the equipment placed inside the cabinet.
- Centrifuges - these should not be placed inside a safety cabinet unless it is totally enclosed or else an 'in-use' operator protection factor test shows that the overall containment of the cabinet is not affected by the operation of the centrifuge.
- Bunsen burners - these are not generally recommended for use in safety cabinets because of concerns about the affect of a localised heat source on the cabinet airflow patterns. If however, they are used, they should be placed towards the back of the cabinet away from any activity and the gas flow should be set at its lowest feasible level. 'In-use' operator protection factor testing should also be carried out to establish that protection is not compromised in any way.
- People moving in the vicinity of the cabinet, air movements in the room or changes in air pressure (for example if a door is opened) - Disturbances of this nature may significantly affect the level of protection for the operator. Tests have shown that Class I cabinets are less affected by external factors and variable internal flow rates than Class II cabinets, because this type of cabinet generally has a lower inward air velocity through the upper part of the working aperture. Users should be fully aware of these potential limitations and of the way in which safety cabinets operate.

## Training

19 All users of cabinets should be instructed on the mode of operation and function of all controls and indicators, how to work at cabinets safely, how to decontaminate cabinets after use, the principles of airflow, operator protection factor tests and the appropriate and inappropriate use of the cabinet.

## Maintenance of safety cabinets

20 Fumigation (see Appendix 2) and decontamination of cabinets should be carried out before maintenance engineers are allowed to work on the equipment. BS EN 12469:2000[30] also provides guidance for decontamination procedures. Recommendations about the type of cabinet testing and frequency can be found in Table 6.2.

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## Video

*Working safely at Containment Level 3* Video cassette HSE Books 2001 ISBN 0 7176 1877 3 Price £40.00 + VAT

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