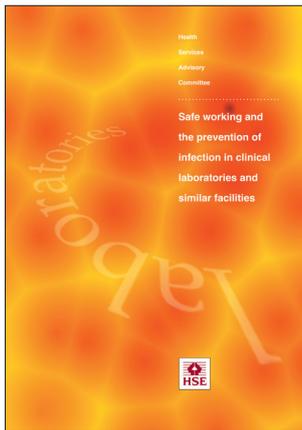


Safe working and the prevention of infection in clinical laboratories and similar facilities



This book provides health and safety guidance for managers, health and safety officers and employees in clinical pathology laboratories. The guidance is relevant to the collection and handling of diagnostic specimens in patient care areas as well as the laboratory.

The book will help you to identify and assess the risks of infection and take appropriate precautions to control such risks. It also focuses on preparing standard operating procedures and ensuring that everyone is aware of the risks and how to manage them.

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This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance as illustrating good practice.

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Introduction

1 This book provides guidance on health and safety for all those involved in work in clinical pathology laboratories. It updates and replaces the Health Services Advisory Committee (HSAC) publications *Safe working and the prevention of infection in clinical laboratories* and *The guidelines for staff and visitors*, both published in 1991. This document develops the content of the two earlier books by setting the guidance in the context of the requirements of the Management of Health and Safety at Work Regulations¹ and the Control of Substances Hazardous to Health Regulations.²

2 The guidance is relevant to work in hospitals and other facilities where people may be exposed to biological agents, for example in universities, research establishments, primary care facilities and veterinary laboratories. It applies to diagnostic work in patient care areas, such as outpatients departments, intensive therapy or neonatal units and to work by general practitioners at their surgeries.

3 Advice is given for all parties involved in the management and operation of clinical laboratories: employers and senior managers who have responsibility for setting policies and for ensuring that risks are assessed and eliminated or controlled; line managers, such as laboratory managers, who may be responsible for implementing policies and procedures; employees who work in clinical laboratories; and others who can influence policies and good practice, such as laboratory safety managers, risk managers, health and safety officers, and employee safety representatives.

4 This guidance is intended to help these parties:

- identify and assess the risks of infection;
- take appropriate precautions to eliminate or control such risks;
- prepare standard operating procedures, setting out the precautions and arrangements for carrying out the work;
- ensure that everyone is aware of the risks and what to do about them;
- meet their duties under health and safety law.

5 The guidance emphasises the need for employers and employees to work together to create an environment and culture in which safe practices and appropriate work procedures and policies are prepared, adopted, and reviewed.

6 A separate HSAC publication deals with safe working and the prevention of infection in the post-mortem room and mortuary.³

7 The Advisory Committee on Dangerous Pathogens (ACDP) has also published guidance, *The management, design and operation of microbiological containment laboratories*,⁴ which expands on the legal requirements set out in the Control of Substances Hazardous to Health Regulations 2002,² with a focus on the design, construction and operation of laboratories which are used for containment of microbiological work at containment levels 2 and 3.

8 The terms 'should' and 'must' are used throughout this document to convey obligation. They are of equivalent meaning, and are used where the guidance offers a way of complying with a legal duty, as distinct from recommendations on what constitutes good practice.

Health and safety law

Health and Safety at Work etc Act 1974

9 The Health and Safety at Work Act ⁵ places general duties on employers, employees and others.

Health and Safety at Work Act - key duties

Employers must:

- protect the health and safety of their employees;
- protect the health and safety of others who might be affected by the way they go about their work (for example, cleaners, visitors or contractors working in the laboratory);
- prepare a statement of safety policy and the organisation and arrangements for carrying it out (if 5 or more people are employed, this statement must be written down).

Employees must:

- take care of their own health and safety and that of others;
- co-operate with their employer.

Although only the courts can give an authoritative interpretation of the law, in considering the application of the Act and its regulations and guidance to people working under another's direction, the following should be considered:

'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 the Health and Safety at Work Act 1974 (HSW Act) ⁵ cannot be passed on by means of a contract and there will still be duties towards others under section 3 of HSW Act.⁵ 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.'

Management of Health and Safety at Work Regulations 1999

10 The general duties in the Health and Safety at Work Act are developed in the Management of Health and Safety at Work Regulations (the Management Regulations) and other more specific pieces of law. The Approved Code of Practice on the Management Regulations provides further guidance.¹

11 The duty under the Management Regulations to co-operate and co-ordinate with other employers and self-employed persons, is particularly pertinent in organisations with increasing use of contractors, including private finance initiative schemes and public/private partnerships.

The Management Regulations - key duties

Employers must:

- assess risks to staff and others, including visitors, young persons and new and expectant mothers; ^{6,7}
- make appropriate health and safety arrangements, which must be written down if five or more people are employed;
- appoint competent persons to help them comply with health and safety law;
- establish procedures to deal with imminent danger;
- co-operate and co-ordinate with other employers and self-employed persons who share the workplace.

Employees must:

- work in accordance with training and instruction given by their employer;
- report situations which they believe to be unsafe.

Control of Substances Hazardous to Health Regulations 2002

12 The Control of Substances Hazardous to Health Regulations (COSHH) ² deal specifically with risks from all hazardous substances including hazardous biological agents. Schedule 3 to the Regulations has special requirements for work with biological agents. Appendix 2 of the COSHH Approved Code of Practice ² gives practical guidance on the application of the Regulations.

COSHH - key duties

Employers must:

- assess risks created by work with substances hazardous to health;
- ensure the selection and use of appropriate control measures, including the use of the appropriate containment level(s) for the biological agents likely to be encountered;
- ensure the maintenance, examination and test of control measures, such as microbiological safety cabinets;
- keep lists of employees exposed to hazard group 3 and 4 biological agents for 40 years;
- notify HSE of the intention to use or store for the first time, biological agents in hazard groups 2, 3 and 4 - and each subsequent use of a new biological agent specified in Part V of Schedule 3;
- provide appropriate health surveillance of employees;
- provide information, instruction and training for employees about the risks and precautions to be taken.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995

13 The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) ⁸ require employers to report specified accidents, dangerous occurrences and cases of ill health to HSE.

Accidents and dangerous occurrences relevant to clinical laboratories which must be reported under RIDDOR include:

- any infection reliably attributable to work with micro-organisms;
- cases of specified infectious diseases such as hepatitis, tuberculosis;
- acute illness which requires medical treatment resulting from exposure to a biological agent or its toxins, or infected material;
- any incident which resulted in, or could have resulted in, the release or escape of a biological agent likely to cause severe human infection or illness;
- loss of consciousness caused by exposure to a biological agent.

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995: Guidance for employers in the healthcare sector provides further guidance on RIDDOR for the healthcare sector.⁹

Consulting employees

14 Two pieces of health and safety law cover consultation with employees: the Safety Representatives and Safety Committees Regulations 1977 deal with consulting recognised trade unions through their safety representatives and the Health and Safety (Consultation with Employees) Regulations 1996 cover employees who do not have trade union safety representatives. Detailed guidance is provided in *Safety representatives and safety committees and A guide to the Health and Safety (Consultation with Employees) Regulations 1996. Guidance on Regulations*.^{10,11}

Employers must consult employees and their representatives about aspects of their health and safety at work, including:

- any change which may substantially affect their health and safety;
- their employer's arrangements for getting competent health and safety advice;
- the information provided on reducing and dealing with risks;
- the planning of health and safety training;
- the health and safety consequences of introducing new technology.

Arrangements for dealing with infection risks in laboratories are only fully effective if employers closely involve employees and their representatives.

Duties to non-employees

15 Under the Health and Safety at Work Act ⁵, employers have general duties towards people who are not their employees, but who may be affected by their work activities. In a laboratory, these include cleaners, contract staff, patients and others who are not at work.

16 Contracts with any other employers who use the laboratory and with staff agencies need to take health and safety into account, so that everyone is clear about their responsibilities. In some cases, employers may owe the same duties towards agency staff under health and safety law as they do towards their own employees.

17 People employed by different organisations may share a workplace, or employees of one organisation may work in an area controlled by another. This is common, for example, in a teaching hospital. In such cases, the employers involved must co-operate and co-ordinate their activities, to enable everyone to comply with their legal duties. Employers need to ensure that everyone working in the laboratory has sufficient information, instruction and training to work safely.

Lone workers

18 There may be situations where staff work alone in the laboratory, particularly outside normal working hours. Although there is no general legal prohibition on working alone, the broad duties of the Health and Safety at Work Act and the Management Regulations apply.

19 Where lone working is foreseeable, a risk assessment should be made taking into account the risks from exposure to biological agents and other risks present in the laboratory. The risk assessment will need to determine whether the work can be done safely by a lone worker, and any necessary special control measures.

20 Procedures to ensure the continued safety of lone workers will need to be put into place. Systems should be set up to monitor lone workers to ensure they remain safe. These may include periodic visits to the laboratory by supervisors and providing means of raising the alarm in the event of an emergency. *Working alone in safety: Controlling the risks of solitary work* provides guidance on working alone safely.¹²

Health and safety management

Roles and responsibilities

21 Legal responsibility for health and safety in the laboratory cannot be delegated and rests primarily with the employer. This involves assessment of the risks, development of policies, putting arrangements in place to implement those policies and monitoring the way those arrangements work, ie employers must make arrangements to **manage** health and safety.

22 Effective management can only be achieved through involvement of the line management chain. Action to ensure that adequate precautions are in place is generally delegated down to line managers. The heads of department have a key role in managing health and safety in laboratories.

Supervision

23 All laboratories need arrangements for supervising work, checking that health and safety measures remain effective and standard operating procedures are observed. Effective management of health and safety is much more likely if senior managers give a clear lead and accept that it is an important part of their function. Some departments may designate a laboratory safety officer to oversee and implement the health and safety arrangements, help ensure standards are maintained and standard operating procedures observed.

Laboratory safety officers

24 Laboratory safety officers can play an important role in the day-to-day running of the laboratory, although responsibility for health and safety arrangements remains with line managers and heads of department. Safety officers need to be known by all members of staff and regular visitors to the laboratory.

25 Nominated safety officers need:

- appropriate training in health and safety matters;
- authority under the head of department to carry out their duties;
- sufficient time free from other commitments.

26 The duties of nominated laboratory safety officers may include:

- providing adequate, supervised health and safety training for all new members of staff in accordance with the standard operating procedures;
- regularly updating training programmes;
- preparing and introducing programmes for the training and familiarisation of staff with new work techniques;
- ensuring procedures for effective decontamination by disinfection or sterilisation are put into action;
- ensuring procedures for the safe collection and disposal of waste are followed;
- in consultation with others, preparing and regularly updating written instructions for safe working practices;
- ensuring that adequate supplies of protective clothing and safety equipment are available and kept in good working order;
- carrying out periodic inspections to detect and identify any unsafe work practices or items of equipment;
- ensuring that all hazardous materials are labelled, handled, stored and disposed of safely;
- liaising with the occupational health service, risk managers, the fire prevention officer, safety representatives and staff;
- ensuring that the work of staff and contractors, including those working outside normal hours, is properly supervised and arrangements are made for a responsible person to be available at all times, in case of accidents;
- checking that visitors are accompanied by a member of staff, to advise them on the appropriate safety measures to be observed;
- participating in safety committee or other health and safety meetings.

Health and safety arrangements

27 The Health Services Advisory Committee (HSAC) has published *Management of health and safety in the health services: Information for directors and managers* which details health and safety management in the health services.¹³ The elements of this framework are referred to throughout this guidance and are shown in Figure 1.

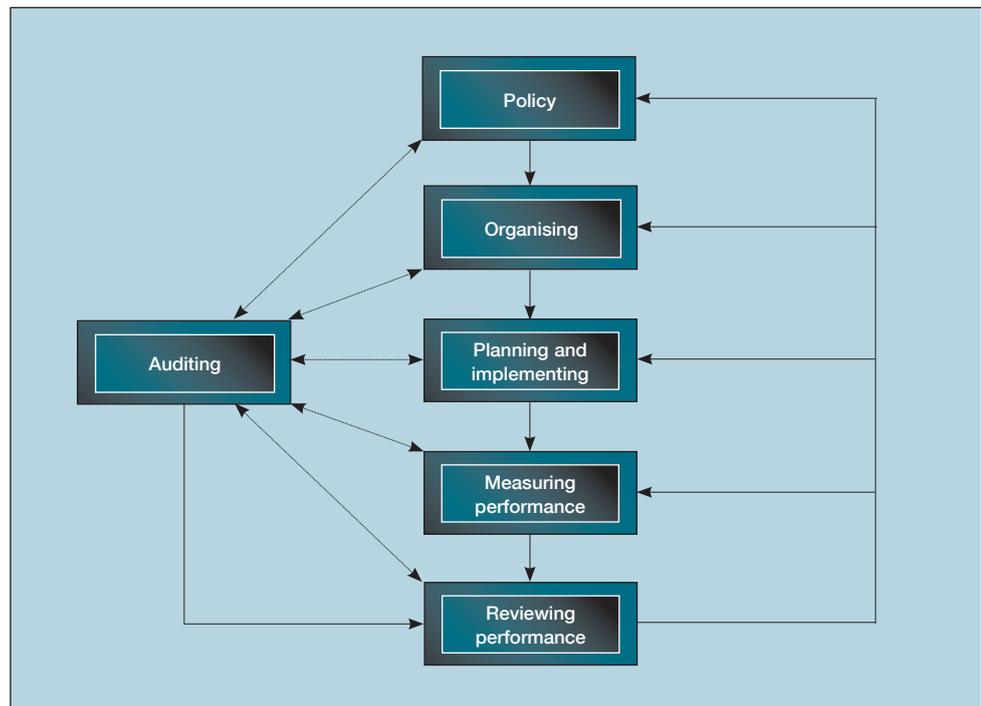


Figure 1 Key elements of successful health and safety management

28 Within this framework employers need to consider a number of key areas including:

- hazard group;
- risk assessment;
- containment levels;
- buildings and accommodation;
- standard operating procedures, including safe working practices;
- information, instruction and training;
- health surveillance;
- monitoring, audit, review.

Risk assessment

29 Risk assessment is not simply a paper exercise. Its purpose is to ensure that there are appropriate precautions in place. Risk assessment involves systematically looking at the work to see which biological agents may be present, identifying the significant risks and identifying the precautions needed to eliminate or control these risks. It can be simplified into a five-step process. Further guidance on the Management Regulations and risk assessment is contained in *Management of Health and Safety at Work Regulations 1999. Approved Code of Practice and guidance* and *Five steps to risk assessment*.^{1,14}

30 The risk assessment process should be integrated within the overall framework of Governance in the National Health Services.

Five steps to risk assessment:

- Step one: look for hazards;
- Step two: identify who might be harmed and how;
- Step three: evaluate the risks - consider the existing controls and assess the extent of the risks which remain;
- Step four: record the findings of the assessment - including the controls necessary and any further action needed to reduce risk sufficiently;
- Step five: review, revise and modify the assessment - particularly if the nature of the work changes or if developments suggest that it may no longer be valid.

31 In assessing infection risks, the key points to consider are:

- which hazardous biological agents may be present;
- the hazard groups to which they belong;
- their virulence, transmissibility, and route(s) of infection;
- the type of work being carried out;
- the likelihood of infection occurring (including during normal work and in the event of an accident);
- the prevalence of particular infections in the local community;
- risks to laboratory staff and others such as visitors, cleaners, maintenance staff, contractors.

32 Employers must assess the risks at all sites where diagnostic testing is carried out, including hospital wards, clinics, health centres and surgeries. If the assessments show that employers cannot adequately control the risk in some locations, they should either improve the arrangements or send the specimens elsewhere for processing. This may mean transferring some work to clinical laboratories.

33 Risks of infection are not the only ones which employers need to assess when looking at laboratory work. Other risks may include the use of liquid nitrogen, chemicals, manual handling of loads, ionising radiation and fire hazards. The hospital Radiation Protection Adviser should be consulted on how to work safely with specimens containing radioactive material.

Categorisation of biological agents

34 COSHH ² defines a biological agent as ‘any micro-organism, parasite, microscopic infectious form of larger parasite, cell culture, or human endoparasite, including any which have been genetically modified, which may cause any infection, allergy, toxicity or otherwise create a hazard to human health’.

35 The *Second supplement to: Categorisation of biological agents according to hazard and categories of containment 2000* ¹⁵ contains an Approved List (Categorisation 2000) which assigns biological agents into their hazard group as approved by the Health and Safety Commission (HSC). It contains the Exemption Certificate for those hazard group 3 agents which are subject to derogation from containment level 3 (see paragraph 39). The ACDP guidance, *The management, design and operation of microbiological containment laboratories*,⁴ details the containment levels appropriate for each hazard group. All employers whose work involves exposure of their employees to biological agents will need to refer to the ACDP guidance and the second supplement, to be able to comply with COSHH.

Categorisation of biological agents - definitions of hazard groups

- **hazard group 1:** A biological agent unlikely to cause human disease.
- **hazard group 2:** A biological agent that can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or effective treatment available.
- **hazard group 3:** A biological agent that can cause severe human disease and presents a serious hazard to employees; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available.
- **hazard group 4:** A biological agent that causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment.

36 Anyone working with blood-borne viruses, transmissible spongiform encephalopathies and viral haemorrhagic fevers, should follow the ACDP's specific guidance, *Protection against blood-borne infections in the workplace: HIV and hepatitis*, *Transmissible spongiform encephalopathy agents: safe working and the prevention of infection* and *Management and control of Viral Haemorrhagic fevers*.^{16,17,18}

37 Cases of hazard group 4 infection are rare in this country. However, when cases do occur, patients and clinical samples must be handled in appropriate facilities. Employers who intend to store or use for the first time, the agents responsible for Lassa and Ebola Fevers, must give the Health and Safety Executive advance written notification. This requirement applies to those intending to offer a diagnostic service, even if virus cultivation is not involved.

Containment levels

38 COSHH specifies minimum levels of containment for work with different groups of biological agents.

Containment levels

Containment level 2

Containment level 2 (CL 2) is designed to protect against biological agents of hazard group 2. As unidentified biological agents may be present in material sent for examination, CL 2 is the minimum standard for handling clinical specimens in a laboratory or decentralised testing station. Therefore, all work in clinical laboratories must be carried out at a minimum of CL2.

It is recognised that pathogens may be present in specimens which, had they been identified, would need to be handled at a higher level of containment. If such pathogens are identified during the course of work at CL 2, all further work on the specimen or associated specimens must be conducted at a higher containment level, usually CL 3 or exceptionally CL 4. If higher containment level facilities are not available, the isolate should be sent to an appropriate laboratory, or be destroyed. If it is suspected, for example from a clinical history, that a specimen may contain hazard group 3 biological agents, all work on that specimen or other specimens from that patient must be conducted at CL 3.

Containment level 3

Containment level 3 (CL 3) is designed for work with biological agents of hazard group 3. To reduce the risk and spread of infection (particularly by inhalation) requirements for CL 3 facilities are more stringent. *The management, design and operation of microbiological containment laboratories* provides full details of these requirements.⁴

The requirements for a CL 4 laboratory, both physical and procedural, are complex and are not dealt with in this document. The ACDP is preparing new guidance for work at CL 4.

39 COSHH requires a minimum of CL 2 for handling biological agents of hazard group 2, CL 3 for handling biological agents of hazard group 3 and CL 4 for handling biological agents of hazard group 4, unless specifically exempted from some of these requirements. Appendix 23 of the ACDP *Second supplement to: Categorisation of biological agents according to hazard and categories of containment 2000*¹⁵ contains Certificate of Exemption No. COSHH/HD/1999/1, which lists hazard group 3 pathogens subject to derogation from CL 3 requirements. In such cases, for example hepatitis viruses and HIV, employers must observe the conditions of containment and the recommended control measures in Appendix 24 of the ACDP *Second supplement*¹⁵ and other specified publications: *Protection against blood-borne infections in the workplace: HIV and hepatitis, Transmissible spongiform encephalopathy agents: safe working and the prevention of infection and Management and control of Viral Haemorrhagic fevers*^{16,17,18}

40 Some hazard group 2 biological agents, such as *Neisseria meningitidis*, are seen as higher risk to laboratory workers on the basis that they are transmitted by the airborne route. If an accident involving such agents was to occur in a CL2 laboratory, it would not be possible to seal the laboratory for fumigation, or maintain an inward airflow to prevent escape of the agent. It is important that such eventualities are considered as part of a risk assessment and the selection of appropriate control measures. Laboratory standard operating procedures then need to specify how the work may be conducted safely.

41 Advice on work with transmissible spongiform encephalopathy agents (TSEs) in experimental and clinical settings is contained in ACDP/SEAC guidance, *Transmissible spongiform encephalopathy agents: safe working and the prevention of infection*.¹⁷

42 Microbiology laboratories offering a diagnostic service to a hospital will from time to time isolate a hazard group 3 pathogen when working at CL2. Once identified, work on such isolates and on material known or suspected to contain hazard group 3 biological agents must be conducted in a CL 3 laboratory, unless the agent is specifically identified as an exemption in the ACDP *Second supplement 2000*.¹⁵

43 Requirements for CL 2 and 3 laboratories are laid out in Table 1.

Table 1 Requirements for containment levels 2 and 3 laboratories

Requirements of COSHH	Containment levels	
	2	3
Laboratory separated from other activities	No	Yes
Access restricted to the laboratory	Yes	Yes
Laboratory maintained at a negative pressure	Yes	Yes
	<i>(if mechanically ventilated)</i>	
Laboratory sealable for fumigation	No	Yes
Specified disinfection procedures	Yes	Yes
Benches impervious and easy to clean	Yes	Yes
	<i>(plus floors)</i>	
Safe storage of biological agents	Yes	Yes
Observation window	No	Yes
Laboratory to contain own equipment as far as possible	No	Yes
Procedures producing infectious aerosols should be conducted in a microbiological safety cabinet	Yes	Yes
Eating/drinking/application of cosmetics forbidden	Yes	Yes
Guidance		
Wash basin near exit	Yes	Yes
Autoclave in laboratory suite	Yes	Yes
	<i>(preferably in laboratory)</i>	
Contaminated waste to be collected, stored and disposed of safely	Yes	Yes
Laboratory coats to be:	a) side/back fastening	Yes
	b) autoclaved after use	No
	c) stored in safe and separate storage area	Yes
Mouth pipetting forbidden	Yes	Yes
Adequate space for each worker	Yes	Yes
Transport of materials to the autoclave in suitable, leak-proof, lidded containers	Yes	Yes
Hands to be washed when contamination suspected and on leaving the laboratory	Yes	Yes
Door closed when work in progress	Yes	Yes
	<i>(locked when not used)</i>	

Buildings and accommodation

44 Laboratory buildings and accommodation must meet the standards required by the relevant containment level and enable staff to work safely. A pleasant and comfortable working environment encourages safe working practices. Minimum requirements for the general workplace environment, such as lighting, temperature, heating and ventilation, are set out in the Workplace (Health, Safety and Welfare) Regulations 1992.¹⁹

45 Anyone involved in the design, construction or alteration of a workplace where biological agents are handled, must make sure the facilities comply with the relevant requirements. Further information is contained in *The management, design and operation of microbiological containment laboratories*⁴ and in Department of Health guidance, *Accommodation for pathology services*.²⁰

Security and access

46 COSHH requires that at CL2 and CL3, access to the laboratory must be limited to authorised persons only. See paragraphs 89-90 for further precautions for the safe storage of stock cultures.

47 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.

48 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.

49 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.

Heating, lighting and ventilation

50 All laboratories must have suitable and sufficient lighting. Emergency lighting must be provided if employees could be exposed to danger if artificial lights failed.

51 Effective general ventilation is usually achieved by mechanical systems which remove or dilute smells and dissipate noxious or flammable vapours. CL 2 laboratories which are mechanically ventilated and all CL 3 laboratories must be maintained at negative pressure to help reduce the risk of airborne infection. Mechanical ventilation systems must be maintained in efficient working order.

52 The temperature in a laboratory must be kept at a reasonable level during working hours. There should be arrangements to prevent excessive temperatures and which allow for heat generated by laboratory equipment.

Fittings and furniture

53 Benches should have impervious and easily cleaned surfaces. Other fittings and furniture also need to be constructed from hard-wearing, easily cleaned materials with impervious surfaces that are resistant to damage by stains or chemicals.

54 Employees working in the laboratory must have suitable seating, and workstations should be arranged so that each task can be carried out safely and comfortably. Materials and equipment in frequent use need to be within easy reach.

Floors

55 Laboratory floor surfaces need to be durable, easy to clean and prevent the absorption of spillage. They should be even, without holes, should not present a slip hazard and be well maintained. Carpeted flooring is not suitable for laboratories.

Staff welfare facilities

56 All laboratories should have dedicated hand washbasins. They are best sited near the exits and should have:

- taps which can be operated without touching by hand;
- soap dispensers containing suitable liquid soap;
- a sufficient supply of disposable paper towels;
- a container for used paper towels.

57 Staff toilets should be readily accessible to the laboratory.

58 Employers need to provide suitable accommodation for outdoor clothing. Separate storage should be provided for clean protective clothing. There should also be areas designated for disposal of used laboratory clothing or its storage before laundering.

59 It is good practice to provide a staff room, with facilities for storing and preparing food and drinks. This must be outside the normal laboratory work area, with no direct access to the laboratory. Where staff are required to be on call overnight, suitable accommodation, including a bedroom and shower facilities, should be available.

Standard operating procedures and safe working practices

Standard operating procedures

60 Laboratories should have standard operating procedures (SOPs) for the general work of the laboratory and for each diagnostic procedure carried out. By fully integrating health and safety arrangements into the SOPs, employers can also ensure they meet acceptable standards of health and safety in the day-to-day running of the laboratory. SOPs are an ideal place to record the significant findings of risk assessments.

61 Safe working practices are essential elements in controlling laboratory risk. SOPs need to reflect the safe working practices required to control risks. They are most likely to work well if they are prepared in consultation with staff, the local safety committee and safety representatives.

Effective standard operating procedures should set out clearly:

- the findings of risk assessments;
- safe working practices, ie what is to be done to ensure that work is done safely;
- who is authorised to perform particular tasks;
- rules of conduct and written guidance for ancillary and maintenance staff, contractors and visitors;
- procedures for disinfection and sterilisation;
- arrangements for disposal of clinical waste;
- requirements of COSHH (including chemicals and biological agents);
- procedures for the maintenance, examination and testing of engineering controls, eg exhaust ventilation systems and microbiological safety cabinets;
- arrangements for maintenance and inspection of other equipment;
- procedures for accident and incident reporting, showing clearly who should be contacted in the event of an accident.

62 Standard operating procedures need to be written down and kept up to date. All staff and visitors need to be aware of the local procedures which apply to them. To help employers prepare standard operating procedures, a set of staff guidelines for various categories of staff are provided in Appendix 4. These can be used as a checklist to review standard operating procedures.

63 The use of the term 'universal precautions' is not helpful with regard to the measures needed for handling biological agents, as it is not clearly defined. Adopting universal precautions may result in a standard of practice which is not high enough. The precautions needed must be based on an assessment of the risks involved, which may be influenced by several factors, such as the biological agents known or suspected to be present and the type of work being carried out.

Provision and use of personal protective equipment (PPE)

64 Employers must provide engineering controls such as local exhaust ventilation as the first line of defence against hazardous substances. Where exposure cannot be controlled by any other means, appropriate protective clothing should be supplied. It must afford the necessary level of protection and be appropriate for the job and the wearer. The laboratory standard operating procedures need to specify the type of PPE required at each containment level.

Laboratory coat or gown

65 Everyone in laboratory areas at CL 2 or above must wear a protective laboratory coat or gown. It should have long sleeves and afford protection when the wearer is standing or seated. Coats worn in CL 3 areas should have side or back closures, close-fitting cuffs and quick release studs or Velcro fastenings. They should be made of flame retardant material which resists shrinking when autoclaved, and is suitably absorbent to protect clothing worn underneath. A similar design is preferred in CL 2 areas. Disposable coats are available as an alternative.

66 Staff should remove coats and gowns before leaving the laboratory and leave them close to the exit. Staff moving between CL 2 and 3 areas should change their coats before leaving either area.

67 Laboratory coats in use should not be placed in personal lockers. There should be enough coats, in suitable sizes, to ensure that staff can change them regularly, and immediately if contaminated, and additional coats for visitors.

68 Coats used in CL 2 areas should be sent for disposal or laundering as 'soiled linen'. Those from CL 3 areas should be autoclaved before laundering or disposal. The autoclave should have been validated for this process.

Gloves

69 Laboratory staff should wear disposable gloves for all hazard group 3 work, and elsewhere whenever there is a risk of contamination. A supply of suitable disposable gloves in various sizes and materials should be readily available in the laboratory. The risk of latex sensitisation needs to be taken into account when selecting gloves. See *Latex and you* for further information.²¹ Gloves are available in a range of materials, and suitable options should be determined by risk assessment.

70 Staff should remove and safely dispose of any punctured glove, whether or not they have been injured. They should then wash their hands and put on fresh gloves.

Eye protection

71 Suitable eye protection to British Standard *BS EN 166: 1996*²² is needed where splashing is likely to occur and work cannot be carried out in a microbiological safety cabinet. If contaminated, eye protection should be thoroughly cleaned and disinfected before reuse.

Respiratory protective equipment

72 Respiratory protective equipment should only be required in very exceptional circumstances, such as following a fire. *The selection, use and maintenance of respiratory protective equipment: A practical guide*²³ provides respiratory protective equipment guidance.

Personal hygiene

73 Everyone working in laboratories should pay scrupulous attention to good personal hygiene. The main route for laboratory-acquired infection is via hand to mouth, therefore hand washing is of primary importance, and is essential before leaving the laboratory. Workers should avoid contact between their hands and eyes, nose or mouth. Eating, drinking, smoking, applying cosmetics etc should be forbidden in the laboratory. Appendix 4 gives more detailed advice.

74 The Infection Control Nurses Association has developed *Guidelines for Hand Hygiene*.²⁴

75 Before starting work, staff need to protect any cuts, abrasions, dermatitis or other open wounds with waterproof dressings and/or disposable gloves. Barrier creams are not suitable for this purpose.

76 Anyone who sustains a puncture wound should gently encourage it to bleed and wash with running water, but not scrub. They should then seek medical advice. See paragraphs 105-107 for information on actions to be taken in the event of a sharps injury or contamination with blood or other body fluids.

77 There should be a suitable means of eye irrigation near the washbasin and a mirror, so that people can see what they are doing in the event of eye contamination.

Risks and prevention of blood-borne infections

78 Potential sources of blood-borne viruses include blood, semen and vaginal fluids and other body fluids, particularly if they are bloodstained. In the laboratory, the most common means of transmission of these viruses is injection through the skin by either a needle or other sharp instrument. Infection may also be spread by spillage or splashing on to mucous membranes, eyes or damaged skin. There is no substantial evidence to support airborne transmission of these viruses in the laboratory. However, processes which generate large drops or aerosols of blood or similar infectious fluids must be carried out in a microbiological safety cabinet.

79 Diagnostic work and screening of materials that contain or may contain blood-borne viruses can be carried out at CL 2, if additional precautions are taken (see paragraph 39). These extra precautions are listed below. The aim is to prevent injection or contamination of skin, mucous membranes and working surfaces.

Procedures for working with diagnostic specimens that may contain blood-borne viruses

80 Procedures for the safe conduct of the work should be agreed and strictly adhered to.

81 Unauthorised access to the working area should be prevented to ensure that the person carrying out the work is free from the risk of disturbance or accidental physical contact with others. Each procedure should be conducted in a designated area of the laboratory with sufficient space for working safely.

82 Staff working with blood-borne viruses should:

- use a microbiological safety cabinet or other form of primary containment when infected material may be dispersed, for example by tissue homogenisation, or vigorous mixing;
- keep the designated working area clear of any unnecessary equipment;
- wear gloves and other personal protective equipment appropriate to the task, for example eye protection;
- cover cuts, grazes and broken skin on exposed skin with waterproof dressings;
- avoid using sharps and glassware;
- clean and disinfect bench surfaces and any equipment immediately on completing a work session;
- put into action a satisfactory disinfection policy.

83 Where blood-borne viruses are being concentrated or propagated, full CL 3 must be used.

Procedures for taking blood specimens

84 All blood should be considered potentially infectious. The following precautions are needed when taking specimens:

- a separate area should be provided for the taking of blood specimens from all patients who can walk. Blood should never be taken in any room normally used as a laboratory or office;
- protective clothing should be worn, as specified in the standard operating procedures. Such clothing normally includes a clean laboratory coat or gown and disposable gloves. Staff should never wear the same protection already worn in the laboratory when taking blood;
- when taking blood from people who are known or suspected to carry blood-borne viruses, staff also need to wear a disposable protective apron on top of their laboratory coat;

- care should be taken to avoid spillage or splashing onto the patient, staff, nearby surfaces, the outside of the sample tube, request form etc;
- if splashing is likely to occur, staff should wear suitable eye protection;
- capillary specimens and other samples in small vessels without a secure closure should be placed in a suitably sized container, with a secure closure, preferably a screw cap, for safe transport and delivery to the laboratory (see paragraphs 166-187);
- blood and other body fluids should not normally be sent to the laboratory in a syringe, and the needle should never be left attached. It is preferable to dispense the blood into appropriate containers, or to use an evacuated blood collection system. For special investigations, where the blood or pus is kept in the syringe, staff should carefully remove the needle, put it in a sharps container and replace it with a plug cap. They should not re-sheath needles;
- make sure that all specimens are appropriately labelled and accompanied by a properly completed request form (see paragraphs 163-165);
- at the end of blood taking, and after dealing with spillages or splashing, staff should discard disposable PPE into the designated receptacles. They should decontaminate non-disposable items, such as eye protection, before putting them away.

Handling specimens and biological agents

85 Staff should avoid contaminating bench surfaces and equipment. While gloves may adequately protect the wearer, care is needed to prevent contamination of equipment such as telephone handsets and computer keyboards. Plastic covers resistant to repeated treatment with disinfectant can protect equipment, such as keyboards, from contamination.

86 When work with specimens and biological agents may produce infectious aerosols, a microbiological safety cabinet must be used. **Mouth pipetting should be forbidden.** These precautions should be written into standard operating procedures.

87 Wherever possible, glass items should be replaced with plastic. Broken or chipped equipment should be replaced.

Stock cultures

88 Stock cultures of biological agents are kept in a variety of ways such as freeze-dried ampoules, in freezers, in liquid nitrogen storage units and on agar slopes.

89 Laboratories storing stock cultures should ensure:

- restricted of access to the storage unit, preferably by locating it within the laboratory;
- where the storage unit is outside the laboratory, it should be lockable;
- the routine safe disposal of unwanted stock;
- a comprehensive inventory of stock cultures is kept;
- cupboards, freezers, refrigerators and liquid nitrogen stores containing stocks of concentrated biological agents are clearly labelled using the biohazard warning sign.

90 Additional requirements for the safe storage of certain biological agents and toxins are contained in the provisions of the Anti-Terrorism, Crime and Security Act 2001.²⁵ Part 7 of the Act imposes obligations on the occupiers of premises where any of the 47 dangerous pathogens or toxins specified in the Act are held, to

prevent the possibility of such substances falling into the hands of terrorists. The list of pathogens is based on the so-called Australia Group list, but minute quantities of most toxins are exempted, as are pathogens and toxins occurring in clinical samples or test reagents. Where any of the specified dangerous substances are held, and none of the exemptions apply, the holder must:

- notify the Home Office of the premises where they are held;
- admit the police to the premises so that they can inspect the security arrangements;
- comply with any reasonable security directions which the police may make;
- furnish a list of people authorised to have access to the dangerous substances if the police require this information; and
- ensure that if the Secretary of State directs that any named person shall not have access to the substances, this direction will be complied with.

Ampoules

91 Ampoules are used in laboratories to contain a range of materials, some of which may be infectious, toxic or carcinogenic. When handling ampoules or serum vials staff need to:

- open them in a microbiological safety cabinet to prevent the contents from being dispersed into the laboratory atmosphere, either as dry particles or liquid droplets. A suitable method is described by the National Collection of Type Cultures, and is issued with all cultures;
- use a specially designed opener or hold glass ampoules in a wad of tissues to protect the gloved hands;
- take appropriate precautions for handling ampoules containing toxic/carcinogenic compounds.

Media preparation

92 Exposure to dehydrated culture media can cause sensitisation. Engineering controls should be provided, such as a weighing station fitted with local exhaust ventilation for the control of dust emissions.

Plating out

93 The following precautions reduce the risk of spread of infectious agents while using culture loops and petri dishes:

- use closed wire culture loops, shorter than 6 cm, with a diameter not greater than 3 mm, to help prevent dripping and splashing;
- place petri dishes in racks or baskets for transport and storage, rather than stacking them in unsupported piles.

94 Disposable loops are generally preferable to metal as they do not need flaming. If staff do use metal loops, to prevent spattering, they should use electric heaters, micro-burners or shielded Bunsen burners rather than flaming them in Bunsen burners.

Handling unfixed specimens for slide preparation

95 Before fixing, all blood and fresh tissue samples are potentially hazardous. Unfixed preparations on slides for microscopy should not normally present an infection risk if handled correctly. These sections should not be taken out of the laboratory into clean areas.

96 Some fixed tissue samples still present a risk (eg some large resection specimens where only the outer layer has been properly fixed, and neurological specimens which might contain TSE agents). These should be treated as unfixed. For guidance on the precautions for handling and disposal of prion-containing material see *Transmissible spongiform encephalopathy agents: safe working and the prevention of infection*.¹⁷

97 When processing unfixed tissue specimens:

- wear disposable gloves and, where appropriate (as specified in standard operating procedures), eye protection and an apron;
- minimise the risk of creating infectious airborne droplets and surface splashing by working on all unfixed specimens in a Class I microbiological safety cabinet, or at down-draught benches;
- clean and disinfect cutting boards and instruments after use and before storage.

98 Staff handling sputum or unfixed lung specimens for cytological or microbiological examination should use a microbiological safety cabinet either at CL 2 or 3.

99 Wet preparations, including those for urine deposits, faecal suspensions for protozoa, ova and cysts, slide agglutinations of enteric pathogens and immunofluorescence, may contaminate the operator's hands, the microscope stage and its controls if handled carelessly. Staff should always wear gloves if contamination with infectious material is likely, and prevent contamination of the microscope by:

- ensuring that wet preparations do not flood the slide;
- safely discarding coverslips and slides;
- regularly decontaminating the microscope stage with non-corrosive disinfectant.

Electron microscopy

100 Staff using electron microscopes need to take care to avoid injury from sharp-pointed grid forceps which may become contaminated during use. After using forceps on infectious material, they should be disinfected immediately and stored in a sealed container.

101 Standard operating procedures need to specify the precautions for preventing contamination of the grid carrier and for:

- disinfecting grids according to the manufacturer's instructions;
- disinfecting grid carriers before the microscope is serviced;
- storing grid carriers safely, for example in plastic petri dishes.

102 Staff using electron microscopes also need to be aware that negative staining materials, such as phosphotungstic acid solutions, cannot be relied on to inactivate hazardous biological agents.

103 Other hazards associated with electron microscopy, eg radiation and the use of hazardous substances such as some stains and buffer solutions, should also be assessed and included in the standard operating procedures.

Sharps

104 Sharp objects may cause cuts, puncture or stab wounds. Objects such as knives, scissors, scalpel blades, hypodermic needles, pointed forceps, and broken glass should be handled with great care. Sharps should never be left lying around. Immediately after use staff should either dispose of sharps safely, or make sure that they are cleaned, disinfected and/or sterilised as appropriate. HSAC guidance, *Safe disposal of clinical waste*, gives further detail on precautions which should be taken.²⁶

Precautions required for dealing with needles safely:

- avoid using needles as far as possible;
- make use of alternatives such as retractable or blunting needles where possible;
- use forceps or other appropriate devices for removing needles;
- do not re-sheath needles;
- dispose of needles safely in an appropriate sharps container;
- to prevent overfilling, replace sharps containers as they become $\frac{3}{4}$ full.

Action after sharps injury or contamination with blood or other body fluids

105 Employers should draw up procedures for dealing with sharps injuries, and contamination with blood or other body fluids. These should include the immediate steps to be taken following a needlestick/sharps injury:

- encourage wound to bleed. Do not suck. Wash with soap and water. Dry, and apply waterproof dressing;
- wash out splashes to the eyes using tap water or an eye wash bottle and to the nose and mouth with plenty of tap water. Do not swallow;
- record the source of the contamination/needlestick;
- report incident to line manager or senior staff in department. An accident form will need to be completed;
- if the source of the sharp is unknown, or is likely to be contaminated with hazardous material, eg blood from a patient known or suspected to be carrying a blood-borne virus, the advice of an occupational health physician or medical microbiologist should be sought **immediately**.

106 The Department of Health has produced guidance on post-exposure prophylaxis for workers occupationally exposed to HIV.²⁷

107 Some needlestick injuries are reportable under the Reporting of Injuries Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).^{8,9} These include:

- a reportable disease where, for example, a worker becomes sero-positive for Hepatitis B after contamination with blood from an infected patient;
- a dangerous occurrence, where a needlestick injury occurs from a needle and syringe known to contain Hepatitis B positive blood.

Equipment

Automated laboratory equipment

108 Laboratory risk assessments should consider how to deal with the risks of contamination from automated equipment, for example splashes on to surfaces of the equipment or adjacent areas. Splashing can be limited by providing shields around the appropriate parts. Any surfaces that are subject to contamination by splashing and to which the operator has access during work, including splash shields, should be regularly disinfected.

109 Machines causing excessive splashing that cannot be controlled should not be used.

110 Staff should treat any spillage that occurs inside the equipment in accordance with the supplier's instructions for decontamination. At the end of each working day they should disinfect the equipment.

111 Effluent from analytical equipment should either be trapped in bottles containing a suitable disinfectant or discharged directly into the waste water plumbing system. Where discharge is to the plumbing system, the following precautions are needed:

- the discharge tube should project at least 25 cm into the pipework;
- water should flow down the waste pipe while the machine is operating;
- at the end of each day, the waste pipe should be flushed with disinfectant so that the trap retains an effective concentration overnight.

112 If discharge is to disposable bottles, the standard operating procedures should specify the method for their safe removal and disposal.

113 People who maintain or repair automated equipment used to process pathological specimens need to take special precautions, which can be written into the standard operating procedures. The procedures should take account of the machine manufacturer's recommendations and be based on guidance published by the Department of Health,²⁸ Medical Devices Agency,^{28,29} NHS Estates³⁰ and NHS Executive.³¹ Appendix 4 provides an example of guidelines for maintenance staff and equipment service engineers.

Non-infection risks associated with equipment

114 Infection is not the only risk associated with equipment use. Hand, arm and shoulder problems have been associated with regular, repetitive use of equipment such as plunger-operated pipettes and display screen equipment. Awkward static postures, forceful movements and highly repetitive work with insufficient recovery time are all recognised risk factors for the development of pain, discomfort and restricted use of the hand and arm. Therefore, employers need to consider:

- appropriate selection of equipment;
- limiting the extent of daily use and providing breaks;
- using automated delivery systems;
- organising the design and layout of the workstation to prevent awkward body posture.

115 *Work related upper limb disorders and Upper limb disorders: Assessing the risks* provide further information.^{32,33}

Homogenisers and shakers

116 As a result of the nature of their operation, both shakers and homogenisers may give rise to droplet dispersion. Homogenisers and shakers used in the laboratory should provide effective containment; most importantly, adequate means for sealing primary containers. Staff should also follow appropriate systems of work, for example:

- always open containers in a safety cabinet, to contain any droplets;
- hold handheld homogenisers within a protective jacket to prevent possible breakage;
- deal with all breakages and spillages according to standard operating procedures.

Cryostats

117 Cryostats need to be decontaminated at suitable intervals depending on use and always before routine maintenance and repair. Tissue debris produced during frozen sectioning should not be allowed to accumulate in the freezing chamber but should be disposed of as clinical waste.

118 Cleaning routines for contamination with non-infective tissue involve:

- turn off the cryostat and allow it to reach room temperature;
- remove the knife carefully, wearing cut-resistant gloves;
- either place the disposable knife into a sharps container which complies with BS 7327:1990;³⁴ or
- if the knife is reusable, remove it from the machine before cleaning off any tissue fragments and treat with a suitable disinfectant;
- disinfect all surfaces in accordance with the manufacturer's instructions.

119 When contaminated with infective material, the cryostat should be decontaminated and then the cleaning routines for non-infective tissue should be followed.

120 The disinfectant used will need to be effective against a range of biological agents, compatible with the microtome equipment and kept in contact with the surfaces long enough to achieve adequate disinfection. If the cryostat is used on material with an inhalation hazard, eg *mycobacterium tuberculosis* (TB), disinfection using formalin vapour may be more appropriate. Similar volumes of formalin to those used for disinfecting microbiological safety cabinets are sufficient (see Appendix 1). The employer must control the exposure to formaldehyde vapour to a level as far below the maximum exposure limit (MEL) of 2 ppm, as possible. Employees must not be exposed to formaldehyde at levels at or above the MEL.

Centrifuges

121 Centrifuges processing pathological material can create considerable health risks by liquid spillage and droplet dispersion. It is important that they are properly designed, constructed, installed, operated and maintained. They should be sited so that operators can see into the bowl and easily load trunnion rings, buckets and containers. Centrifuges should not be placed within a Class I or Class II

microbiological safety cabinet, as their operation could affect the efficiency of the cabinet. Centrifuges may be used in Class III safety cabinets.

Staff using centrifuges should:

- use sealed buckets or rotors when processing blood, body fluids or microbial suspensions;
- check that bucket seals are intact so that they provide adequate protection against liquid dispersion in the event of an accident during use;
- only use containers strong enough to withstand the centrifugal forces to which they will be exposed;
- use good handling techniques when filling and emptying the buckets to prevent contamination;
- fill the containers according to the maker's instructions, normally leaving at least 2 cm space between the fluid level and the container rim;
- open sealed buckets containing known or suspected hazard group 3 biological agents in a microbiological safety cabinet;
- inspect sealing rings ('O' rings) regularly and change them if they are damaged.

Pressures inside overfilled containers can lead to failure of the seal. Overfilled containers also expel liquid droplets when opened.

122 Staff need to load centrifuges evenly and check their operation. This includes:

- pairing the centrifuge buckets, lids and trunnion rings by weight before starting the centrifuge;
- evenly distributing the pairing around the rotor so that the load is balanced;
- regularly inspecting centrifuge components and replacing them as necessary.

123 Staff should follow the manufacturer's instructions for decontamination and cleaning to prevent the risk of infection and to ensure that equipment is not damaged. Only non-corrosive disinfectants and cleaners may be used on metal parts.

Arrangements for cleaning and decontaminating centrifuges:

- remove any liquid spilt in or around the centrifuge;
- clean and disinfect the rotors and centrifuge buckets regularly;
- clean and disinfect the fixed parts at regular intervals.

Laboratory centrifuges require planned preventive maintenance, based on the manufacturer's instructions.

Breakages in the centrifuge

124 There is no need to transfer sealed buckets to safety cabinets for opening, if buckets have transparent lids which allow the operator to be sure there has not been a breakage. If leakage is suspected, or if there is no way of telling there is leakage before the lids are removed, the buckets should be opened in a microbiological safety cabinet by an operator wearing gloves and a disposable plastic apron, in addition to standard protective clothing.

125 If there is leakage, the operator should contact a senior member of staff for advice on whether to try to salvage or dispose of the specimen. In either case, the centrifuge bucket and its lid should be opened in a microbiological safety cabinet and disinfected or autoclaved, if possible.

126 Sealed buckets will usually contain a breakage and prevent leakage into the bowl of the centrifuge. However, if the integrity of the sealed bucket is breached then the following procedures for dealing with any breakage in a centrifuge bowl should be followed :

- switch off and isolate the motor, allow time for any aerosol to settle and assess if it is safe to open;
- wearing thick gloves and using metal forceps or swabs, remove any broken glass;
- safely dispose of all fragments, swabs and other waste;
- thoroughly clean and disinfect the whole of the inside of the bowl, the cover, containers and buckets etc.

127 Further information on safety requirements for centrifuges is contained in British Standard BS EN 61010-2-020:1995.³⁵

Microbiological safety cabinets

128 Microbiological safety cabinets are intended to protect the user and environment from the aerosol hazards of infected and other hazardous biological material. To be effective, all microbiological safety cabinets should conform to British Standard BS EN 12469:2000³⁶ in terms of type, specification and performance protection provided. Siting and air filtration requirements also need to be considered.

Types of cabinet

British Standard BS EN 12469:2000³⁶ covers three types of microbiological safety cabinet:

- Class I microbiological safety cabinets: open-fronted cabinets, which can be used for all except hazard group 4 pathogens. Most potentially infectious airborne particles will be contained within the cabinet. The cabinet must exhaust through a high efficiency particulate absorption (HEPA) filter to the outside air, or to the laboratory air extraction system if used for handling specimens that may contain hazard group 2 or 3 biological agents;
- Class II microbiological safety cabinets: designed to control airborne contamination of the work while at the same time controlling the exposure of the operator. In the simplified form of cabinet these two functions are achieved by a recirculating downward flow of HEPA-filtered air over the work area; part of this airflow is exhausted to the atmosphere through a HEPA filter and make-up air is drawn into the cabinet through the open work front. Modern Class II cabinets can provide protection of the same order as Class I cabinets, but are more susceptible to disruption of airflows. They should be used only where protection of the work is essential;
- Class III microbiological safety cabinets: a totally enclosed cabinet. The escape of airborne particles is prevented by a HEPA-filtered exhaust system. A HEPA inlet filter supplies sterile air to the interior, but because of the pattern of airflow there is a greater likelihood of contamination of the work after a spill than in a Class I cabinet.

129 Class III microbiological safety cabinets are not generally required for work in most clinical laboratories. They are primarily designed for total containment of work with hazard group 4 pathogens, although their use is advised for work with high titre cultures of some hazard group 3 pathogens or certain hazard group 3 pathogens which are assessed as being highly infective, eg *Brucella spp.*, particularly those infective by inhalation. The use of Class III cabinets demands high standards of maintenance and operator training.

130 Class I microbiological safety cabinets that are said to be modifiable to Class III (Class I/III hybrids) are not recommended. If such cabinets are used, they need to be tested to demonstrate satisfactory operator protection in the Class III mode, before being used to provide that level of containment.

Flexible film isolators

131 Flexible film isolators are a form of Class III microbiological safety cabinet constructed from plastic film. The operator is separated from the work by long gloves extending into the body of the unit. Flexible film isolators are not covered by BS EN 12469:2000. Advice on the construction, suitability for use and maintenance of flexible film isolators can be found in *The management, design and operation of microbiological containment laboratories*.⁴

Fume cupboards and laminar flow cabinets

132 Fume cupboards are not microbiological safety cabinets and should never be used as such. Horizontal and vertical laminar flow cabinets are primarily used to prepare material aseptically, by forcing sterile air towards the operator. They should not be confused with Class II cabinets, as they provide no protection whatsoever for the operator, and are therefore not suitable for handling specimens or other infectious materials.

External influences on microbiological safety cabinet performance

133 The flow of air into open-front cabinets (Class I and II) can be disturbed by:

- sudden movements of the arms of the operator;
- turbulence around equipment placed inside the cabinet, particularly if it is large;
- people moving directly behind the operator of the cabinet;
- air movements in the room such as those caused by opening doors and ventilation airflows from equipment.

134 Disturbances of this kind may significantly reduce the level of protection for the operator, particularly in a Class II cabinet. Pressure gauges on the cabinet should indicate acceptable limits and be fitted with audible alarms.

Use of cabinets

135 Certain operations, such as vigorous shaking, mixing or ultrasonic disruption of any material likely to contain pathogens, or work on any sputum specimen, must be conducted in a microbiological safety cabinet. In clinical laboratories the most commonly used type of cabinet is Class I. However, if protection of the work from airborne contaminants is essential, a Class II cabinet may be appropriate, provided an appropriate risk assessment is carried out. An in-use operator protection factor test should be carried out which takes into account the shaking movement.

136 Microbiological safety cabinets used to contain pathogens should comply with British Standard BS EN 12469:2000³⁶ or offer an equivalent level of operator protection. In laboratories other than microbiology laboratories, which handle material known to contain human pathogens, access to a microbiological safety cabinet will be needed from time to time for operations likely to disperse infectious airborne droplets.

Training

137 All staff who use a microbiological safety cabinet must be fully instructed by a competent person on:

- appropriate and inappropriate uses of the cabinet;
- the limitations of its performance;
- how it works and the function of all controls and indicators;
- how to work in the cabinet safely;
- how to disinfect the cabinet after use;
- the principles of air flow tests and operator protection.

Basic rules for effective use of microbiological safety cabinets

Staff using safety cabinets need to:

- check that the cabinet work surface is easy to clean and disinfect;
- check the fan is switched on and the air flow indicator is in the safe position before starting work;
- check the airflow regularly during use;
- keep any opening viewing panel closed while working;
- keep the minimum of apparatus and material in the cabinet during operation;
- position apparatus and material so as not to disrupt airflows. In Class I cabinets, larger items should be placed towards the rear, and in Class II cabinets all materials should remain on the work surface and not obscure air vents;
- never place large centrifuges in Class I or II cabinets;
- conduct work well into the inside of the cabinet, away from the opening and view through the screen;
- run the cabinet fan for at least five minutes after completion of work in the cabinet;
- after each work session, wipe the working surfaces with a disinfectant;
- test the airflow with an anemometer at least once every month.

Bunsen burners and other naked flames should never be used inside cabinets, as they distort the airflow and may damage filters.

Maintenance

138 Microbiological safety cabinets are covered by the requirements for maintaining local exhaust ventilation under COSHH.² Maintenance should therefore include thorough examination and test at least once every 14 months. Further information about the installation, testing, maintenance and fumigation of microbiological safety cabinets is provided in Appendix 1.

Laboratory autoclaves

139 The main hazards associated with autoclaves include:

- steam under pressure;
- incomplete sterilisation;
- burns or other injury during unloading.

140 The standard operating procedures should specify how to use autoclaves safely and effectively. It is helpful to display operating instructions beside each autoclave. Further information is given in Health Technical Memorandum 2010³⁷ and HSE Guidance Note PM73 *Safety at autoclaves*.³⁸

Autoclave installation

141 Autoclaves need to be correctly installed. It is important that the drainage system does not disperse splashes or steam into the working area. A simple open tin-dish is not suitable for the exhaust line of a laboratory autoclave. For activities which involve high titre concentrations of agents in hazard group 3, additional safeguards may be required. Further containment, filtration or heat treatment of discharge is necessary only for autoclaves used to process material infected with biological agents in hazard group 4.

Safe operation of autoclaves

142 The safe operation of autoclaves includes the following measures:

- conforming to the standard operating procedures;
- adequate supervision and training of operators in the hazards associated with autoclaves and in safe operating procedures;
- examination of the vessel and its fittings by laboratory staff each time it is used;
- regular systematic maintenance in line with manufacturers' recommendations;
- periodic examination by a competent person, in line with the written scheme of examination as required by the Pressure Systems Safety Regulations 2000;³⁹
- providing appropriate interlocking safety devices for the door.

143 Failure of the pressurised parts may result in a large release of energy.

Safe use of autoclaves

Staff need to be trained in the safe use of autoclaves and:

- wear a visor, heat-resistant gloves, a laboratory coat with sleeves and a heavy-duty apron while opening the door or during unloading;
- remove lids of discard containers before autoclaving, unless the autoclave cycle has been designed and tested to be effective for containers with lids in place;
- ensure autoclavable plastic bags are supported in solid containers with the mouth of the bag turned back over the rim of the container, to maintain an adequate opening for steam penetration;
- use a qualitative indicator, such as heat sensitive tape, on each discard container. This only indicates that the container has been through an autoclaving process;
- check cooling timers and door interlock controls for all cycles;
- treat all loads of unknown content as if they contain liquid.

Unloading hazards

144 Reaching into an autoclave which contains a hot load or handling the contents of the autoclave can be hazardous. During the cooling period the temperature indicated in the chamber exhaust line will be much lower than the load temperature. Sealed glass bottles containing liquid will be pressurised and may explode when the door is opened. Liquids spilled on unloading may cause scalding.

145 Devices such as temperature or timer-activated door interlocks are fitted to autoclaves to minimise the unloading hazard. Autoclaves intended for the sterilisation of liquids, whether for use in the laboratory (eg liquid culture) or in a 'make-safe' cycle, need an interlock to prevent the door mechanism being released until the temperature in all the containers has fallen to less than 80 °C. The sensing devices should be located in the parts of the vessel which are expected to remain at the highest temperature at the end of the cycle.

146 Staff should not lift heavy loads in or out of vertical autoclaves and need sufficient information, instruction and training on how to unload autoclaves safely. Mechanical lifting aids will help to reduce manual handling risks. For front-loading autoclaves, a load transfer system, either a sliding shelf or a carriage and trolley, may also be necessary.

The autoclave cycle

147 The essential stages of the autoclave cycle are:

- air removal;
- heat penetration;
- sterilisation (temperature and holding time);
- cooling.

148 Heat penetration times vary with the autoclave, the load and its contents. Indicator tape and indicators printed onto bags only distinguish items that have been processed from those that have not been processed. They do not indicate sterility of the load.

149 Sterilisation times and temperatures should be preset. Table 2 shows minimum values, deemed to be satisfactory for 'make-safe' cycles:

Temperature (°C)	Pressure (bar)	Holding time (minutes)
121	1.15	15
126	1.50	10
134	2.25	30

Table 2 Minimum values for 'make-safe' cycles

From: Medical Research Council Working Party 1959

NB: The temperatures listed are as sensed in the centre of the load. The recommended time/temperature relationships will destroy both vegetative and spore-bearing biological agents provided that penetration times are adequate to achieve the requisite temperature in all parts of the load.

Periodic checking and testing

150 Periodic testing consists of a programme of tests designed to demonstrate that the autoclave's performance is satisfactory. The tests are carried out at daily, weekly, quarterly and yearly intervals. These tests are preceded by safety checks which are intended to ensure the autoclave is both safe to use and to test. Sterilisation Health Technical Memorandum 2010 gives further information on safety checks and tests.³⁷

151 The user carries out the daily tests, although a suitably trained operator may also do the weekly tests in some circumstances. Some of the weekly tests require the services of a test person and use of specialised equipment, and therefore cannot be performed by the user. The quarterly and annual tests require specialised equipment and skills, and should be carried out only by a properly qualified, trained person. Records of these inspections should be kept.

152 If the autoclave fails any safety check, staff should not attempt to test it until the faults have been corrected and the autoclave passes all safety checks.

153 Door seals need to be maintained in good condition. Staff should report any escape of steam from the door seal immediately and take the autoclave out of use until any defect is rectified.

154 Performance testing of autoclaves to ensure that contaminated loads are 'made safe' should be carried out at least once a year. The test method described in section 3.3 of British Standard *BS 2646:Part 5*⁴⁰ 'make safe' performance tests, or a similar standard, is suitable. A registered authorised person should usually have the necessary experience, and will have access to the necessary calibrated thermometric measuring equipment.

155 Biological and chemical indicators of autoclaving efficiency are not appropriate for testing the effectiveness of laboratory autoclaves.

156 The Pressure Systems Safety Regulations 2000³⁹ apply to most autoclaves used in clinical laboratories. These regulations require a competent person to draw up a written scheme for the periodic examination of specified parts of the system. The written scheme must be suitable and specify the nature and frequency of the examination.

Benchtop autoclaves

157 Benchtop autoclaves achieve the conditions needed for sterilisation by electrically heating water within the chamber to produce steam at the required temperature and pressure. Guidance on their safe and effective use is given by the Medical Devices Agency.⁴¹

158 Staff should not leave these autoclaves unattended while in use. After use they should empty them of water to avoid corrosion and check the seals regularly.

159 Any autoclave forming an integral part of a culture media preparation system needs to be correctly installed and have appropriate interlocking devices. It should be tested in accordance with *HTM 2010*.³⁷

160 Benchtop autoclaves are not recommended for autoclaving laboratory waste because the process cannot be validated.

Review and revise practices and procedures

161 Employers should review practices and procedures regularly to check that they are still valid. It may include verifying that:

- standard operating procedures and containment level strategies are relevant to current work in the laboratory;
- staff have received appropriate information and training about their work;
- staff and visitors are following the standard operating procedures appropriately;
- the system for reporting and responding to accidents, incidents, near misses and ill health are in place and being followed.

162 If the review identifies deficiencies in any of the practices and procedures, employers should revise them and implement any necessary further changes and precautions.

Labelling, transport and reception of specimens

Information

163 Labelling specimens enables them to be easily identified, transported to the correct department and for immediate action to be taken in the event of an accident. Every specimen container and request form needs to contain sufficient information for laboratory staff to process the specimens effectively and safely. The person asking for a laboratory examination needs to complete the request form label correctly. The labels and request forms need to include the following details:

- the source of the specimen;
- the nature of the specimen;
- information about the patient, eg Case number, name, date of birth etc;
- location of the patient, eg ward number or details of doctor's surgery;
- time and date of collection.

164 The risk assessment for the laboratory should take account of the level of risk arising from the patient population and the type of work done, so that it can specify what additional information and labelling is required. For example, where there is a high risk of staff exposure to a hazard group 3 biological agent, laboratory staff may need additional information.

165 The most common method of providing information on specimens known or suspected of posing a risk of infection is to use a 'danger of infection' label. Use of a standard label for all such specimens coming into the laboratory reduces scope for confusion. Reception staff need to send specimens bearing a danger of infection label directly to the appropriate laboratory department, unopened.

Transport

Specimen containers

166 Anyone sending specimens to a laboratory should ensure that the container is appropriate for the purpose, is properly closed, and is not contaminated on the outside.

167 Specimen containers need to be sufficiently robust and not leak in normal use. Containers which comply with British Standards *BS ISO 6710:1995*,⁴² *BS 5213:1975*⁴³ or other recognised standards, normally comply with this requirement. Reusable containers need to withstand autoclaving or disinfection and remain leak-proof after each recycling process. Staff should discard damaged lids or containers.

168 Line managers and the laboratory safety officer should monitor reports of leakages and breakages to identify any unsatisfactory types of containers.

Specimen transport bags

169 After labelling, all specimens should be placed in an individual transparent plastic transport bag and sealed, either by an integral sealing strip, or by other suitable means to enable opening without using sharp-pointed instruments. Bags sealed with pins, staples, metal clips etc are not suitable for carrying specimens.

170 Containers for large specimens, such as some histopathology or 24-hour urine specimens, may be enclosed in individual clear plastic sacks, sealed to prevent leakage.

171 Some specimens may require being kept frozen during transport. Where dry ice is used, it should be placed around the secondary packaging, and the outer packaging should permit the release of carbon dioxide. The dry ice should not be placed inside the sealed primary container. This can lead to pressurisation of the primary container with the likelihood of it exploding.

172 The request form should not be placed in the bag with the specimen, nor stapled to the bag. A separate pocket for the request form in the transport bag is suitable for most specimens, but for larger containers the request form can be securely taped or tied to the neck of the sack.

173 Laboratory staff should discard specimen transport bags once they have been emptied.

On-site transport

174 When carrying specimens, staff must use secure specimen transport carriers, such as boxes or deep-sided trays. The carriers should preferably have a lid and be made of smooth impervious material, such as plastic or metal, which retains liquid and can be easily disinfected and cleaned.

Under no circumstances should anyone transport specimen containers in their hand or pockets.

175 Staff need to ensure that the carriers are:

- not used for any other purpose;
- never overfilled;
- cleaned and disinfected weekly, and whenever contaminated.

Pneumatic air tube systems

176 Pneumatic air tube transport systems can provide a safe, efficient and rapid means of sending certain types of pathology specimen around a hospital site. The use of these systems is increasing because they can improve the turnaround time patients and hospital staff have to wait for results.

177 As part of the local risk assessment in sending specimens in a pneumatic air tube system, safe operating procedures need to be set up to ensure its proper use at all despatch and reception points.

178 Safe use of a pneumatic air tube system is fundamentally reliant on:

- the suitability of the specimen for despatch by this method;
- on the design of the specimen carrier; and
- information and training for staff on the proper operating and control procedures.

179 There are many types of carrier available and their suitability needs to be assessed. Snap-top types may be more suitable than those with screw tops or fastenable straps. Containers should preferably be autoclavable. There is currently no leak-proof carrier available, but it is sound practice to use some form of absorbent packing material insert to contain any leakage that might occur. It is probably impractical to consider adequate disinfection, eg by formalin fumigation, of a pneumatic tube ducting system.

180 If a specimen container does break or leak within a carrier, and is of unknown origin, the carrier should be opened within the confines of a microbiological safety cabinet to contain any aerosols that may be generated. Gloves should also be worn and care exercised to avoid handling any sharp material.

181 Guidance on the management and use of pneumatic air tube systems is available in Pneumatic air tube transport systems. *Design considerations and Good practice guide* and *Safe use of pneumatic air tube transport systems for pathology specimens*.^{44,45}

Transport outside the hospital other than by post, eg by carrier and courier

182 Specimens sent to laboratories eg from GP surgeries should be packaged by the sender, in appropriate specimen containers and transport bags, and be properly labelled. Specimens should be transported in leak-proof, secure transport boxes with fastenable lids. Warning labels on the box should state that it should not be opened or tampered with, and give a contact telephone number in case it is found unattended. Further advice is given in Appendix 4 under guidelines for laboratory porters and messengers.

Carriage of specimens by road

183 Regulations controlling different aspects of the carriage of dangerous goods may apply when transporting specimens by road.^{46,47,48} HSE has issued a Certificate of Exemption⁴⁷. This allows consignors of diagnostic specimens that may contain biological agents in hazard groups 2 or 3 exemption from some of the Carriage of Dangerous Goods legislation until the end of 2003.

184 The exemption will allow such specimens to be sent in a more efficient way because of the less onerous packaging requirements, which are detailed in the Schedule to the Exemption and reproduced in Appendix 3.

185 For the purposes of this exemption, 'diagnostic specimens' are any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids being carried for purposes of diagnosis or research, but excluding live infected animals.

186 There are also requirements for providing information with each consignment of specimens.^{46,47}

Sending specimens by post

187 The current Royal Mail packaging specification for carriage of pathological specimen through the post is available from: Royal Mail Business and Consumer Markets. See Further Information for contact details.

188 Specimens containing hazard group 4 agents should not be sent by post.

Reception of specimens at the laboratory

189 A designated area is needed for receiving specimens, with entry restricted to authorised staff. This may be a room or part of a laboratory, but preferably not part of a clerical office or in a corridor. To be suitable for receiving specimens it needs:

- an impervious floor, which is not carpeted;
- a bench or table with a smooth impervious work surface that is resistant to disinfectants;
- a hand basin with taps that can be operated without touching by hand;
- a hatch or a fixed counter through which specimens can be delivered;
- facilities for disinfecting the area, including appropriate disinfectant at in-use dilution, disposable absorbent wiping material and disposable plastic gloves.

Dealing with damaged or leaking specimens

190 If a specimen container is found to be leaking or broken, reception staff should not touch it or any others in the same box or tray. They should contact a senior member of laboratory staff and report the leakage as required by the standard operating procedures. These need to specify:

- who should deal with damaged or leaking containers;
- the need to wear gloves;
- the use of forceps for broken glass;
- how to recover specimens where this is absolutely necessary;
- how to deal with contaminated request forms.

191 Specimen containers may contain hazardous materials in addition to the specimen itself, such as cytotoxic drugs, radioactive materials, or hazardous reagents (eg acid preservative). The standard operating procedures should specify any additional precautions needed for labelling and work with these specimens.

Cleaning, decontamination and waste disposal

192 Every laboratory should have a strictly administered policy for cleaning, decontamination and waste disposal. The employer should review and update this policy on a regular basis. All new members of staff should receive a copy of the current policy and all staff should receive information about any revision to it.

193 The disinfection policy should state which disinfectants are used and for what purposes. The COSHH assessments should identify any harmful effects of the disinfectants themselves and precautions to be taken. Details of appropriate disinfectants are given in Appendix 2.

194 Staff should segregate equipment for reuse from disposable items. Waste should, as far as possible, be discarded 'dry' rather than be placed in disinfectant. The quality assurance of dry discard followed by autoclaving is superior to liquid disinfectant discard alone, since the sterilisation process can be monitored with accuracy. Containers used for discarded material should have solid sides and bases, be made of metal or autoclavable plastic, and allow adequate steam penetration throughout the material within the container.

Cleaning and decontamination

195 Benches and other work surfaces, including those in the specimen reception area, should be cleaned with a suitable disinfectant as required and routinely at the end of each working day. Priority should be given to the use of low hazard materials. Suitable gloves should always be worn for decontamination. For information on dealing with spillages see paragraphs 237-244.

196 Reusable equipment and glassware arising from work in the laboratory should be made safe to handle by autoclaving or disinfection as defined in the standard operating procedures.

197 Equipment which has been in contact with pathological material and is to be serviced needs to be adequately disinfected. A certificate showing proof of decontamination should be available.

198 Maintenance staff should be made fully aware of all risks associated with work in the laboratory and with laboratory equipment. They should check if they need a permit to work or if equipment has a certificate of decontamination before starting work. Advice on the preparation for maintenance procedures is provided in *Decontamination of equipment prior to inspection, service and repair*²⁸ and *Sterilisation, Disinfection and Cleaning of Medical Equipment*.²⁹

Disposal of laboratory waste

199 Arrangements for handling and disposal of laboratory waste should be clearly defined in local standard operating procedures. These should be compatible with the overall policy for risk management which covers clinical waste. Staff should receive instruction on the correct methods for safe handling, segregation, storage and disposal of waste. If errors occur, they should be reported immediately to a designated member of staff and there should be an agreed policy to deal with such situations. Account also needs to be taken of whether the waste will leave the site for disposal and be transported by road. Reference should be made to HSE guidance on the transport of dangerous goods by road.^{46,47,48} HSAC guidance *Safe disposal of clinical waste*²⁶ gives detailed information on managing the safe handling and disposal of clinical waste from its point of origin to its point of final disposal.

200 Proposed changes to the legislation governing the transport of clinical waste by road are due to come in force on 1 January 2003. The changes will reflect the requirement to package clinical waste in sacks, inside a UN type-approved rigid container, and will permit the transport of clinical waste in bulk.

201 Microbiological cultures from CL 2 and 3 laboratories and all other potentially infected waste from CL 3 laboratories should be autoclaved before leaving the laboratory for final disposal. Such waste includes discarded bacterial cultures, tissue cultures and some specimens from immunology and other departments where viruses could have propagated because of the incubation conditions.

202 If material is known or thought to contain hazard group 3 prion/TSE material, eg variant Creutzfeldt Jakob Disease, then this should be handled for disposal in accordance with ACDP/SEAC guidance, *Transmissible spongiform encephalopathy agents: safe working and the prevention of infection*.¹⁷

203 Blood specimens, swabs, infected tissue etc (unless from patients infected with confirmed hazard group 3 agents) where significant microbial multiplication is unlikely to have occurred, are considered to be group A clinical waste and can be disposed of directly by incineration or other suitable method. Bulk fluid specimens (eg 24-hour urine specimens in plastic containers) which are difficult to autoclave should be disposed of according to local policy, for example in the sluice.

204 Waste for autoclaving should be suitably labelled before removal and be transported to the autoclave in robust containers which would contain any accidental spillage. The autoclave should be in the laboratory building and preferably in the laboratory itself.

205 Laboratories should have contingency plans for exceptional circumstances, such as autoclave malfunction, specifying how waste should be stored and handled. Waste which is normally autoclaved should be packaged in accordance with the Approved Requirements⁴⁸ and transferred to an incinerator as soon as possible. Such waste should not be allowed to accumulate for more than 24 hours during the working week.

Packaging sharps

206 All sharps should be discarded in an appropriate sharps box which either meets the requirements of BS 7320 and/or is UN type-approved.³⁴ The box should either be incinerated or undergo maceration and suitable heat or chemical treatment prior to disposal. Sharps which have been in contact with hazard group 2 or 3 microbiological cultures, eg broken petri dishes, should be autoclaved before disposal.

207 Staff should not put sharps boxes in other containers such as yellow bags.

Information, instruction and training

208 Employers must provide adequate information, instruction and training on all relevant aspects of health and safety at work for staff working in the laboratory, including what to do if things go wrong.

209 Occupational health staff or advisers, infection control staff and safety representatives have a key role in providing information and developing suitable training material.

Staff training

210 Employers need to identify any gaps in knowledge and/or experience, and then provide appropriate training. Practical training can be supplemented by placing the trainee with an experienced and competent member of staff.

211 Only competent staff should knowingly work with biological agents in hazard groups 3 and 4 or specimens likely to contain them. It is up to the employer to assess the competency of staff and keep training records.

All staff need adequate training before they start work in the laboratory. In particular they need:

- information about the risks likely to be encountered in their work;
- to understand the principles and practice of infection control in the laboratory;
- to know about the safe working practices and procedures for work in a particular laboratory;
- to know and understand the appropriate procedures in the event of an emergency.

212 Staff need to be aware of and have access to relevant health and safety information such as:

- their employer's health and safety policy statement;
- other relevant safety information and literature circulated or displayed in the department;
- laboratory standard operating procedures;
- incident/accident reporting procedures;
- emergency and evacuation procedures.

213 They also need to familiarise themselves with the procedures and to become competent in dealing with new methods or techniques.

214 To be of value, information needs to:

- be understood by all those to whom it is addressed, including those with a limited command of English or with disabilities;
- take into account the level of training, knowledge and experience of the worker;
- be up to date;
- be made available to all staff, including part-time, shift and temporary workers.

215 Contractors' employees working in laboratory areas need proper training and instruction in relevant health and safety procedures. Both their own and their 'host' employer have responsibilities towards them and must co-operate and co-ordinate in discharging these duties. Maintenance workers are often at higher risk than others, because they do non-routine work, and may enter areas where others do not have access. Cleaners should not work within a CL 3 laboratory. In CL 2 laboratories cleaners will need specific training in what they may or may not do in the laboratory.

Health surveillance and immunisation

216 Health surveillance and immunisation arrangements for laboratory staff and those who need to visit the laboratory on a regular basis should be based on advice from the Occupational Health Department or Adviser.

Before employment

217 Routine medical examination before employment may not be considered necessary. Instead, candidates can complete a health questionnaire. Only those whose replies suggest that a problem may exist need to see an occupational health nurse or physician. More detailed information on health surveillance is provided in *Health surveillance at work* and *Health assessment for employment in the NHS*.^{49,50}

218 In some cases, for example where staff are propagating HIV, the occupational physician may advise that a blood sample is taken and stored for checking in the event of an incident.

On employment: immunisation

219 Employers need to ensure that occupational health arrangements include agreed immunisation procedures for all laboratory staff. They should base these on guidance from the Joint Committee on Vaccination and Immunisation.⁵¹ Before staff begin working in the laboratory, the Occupational Health Department needs to obtain and record baseline information, including an assessment of immunisation status.

220 The need for immunisation (vaccination) will be determined as part of the risk assessment, but invariably should include protection against Hepatitis B, tetanus and tuberculosis. Staff should be immunised as soon as possible after they are appointed and ideally before they start work. Immunisation should only be seen as a useful supplement to reinforce procedural controls and the use of protective equipment.

221 COSHH ² requires employers to make effective vaccines available to employees exposed to biological agents. As this is a specific requirement under health and safety law, employers cannot charge their employees for such vaccines.

222 In addition, employers and employees have responsibilities to protect others who might be put at risk from their work activities, eg patients, visitors and members of the public. Vaccination of employees can help prevent the spread of infection to such individuals.

223 Employees should be informed of the benefits and drawbacks of both vaccination and non-vaccination. Protection against serious illness is the most obvious benefit; protection against spread of infection to patients and other members of the public is also important. Drawbacks include the possibility of reactions to the vaccine, and any potential effects on health should be explained to the individual. Having considered the risks and benefits, employers should recommend vaccination to their employees.

224 It is recommended that employers keep a vaccination record. In practice, this is often done by the occupational health provider.

225 The employer responsible for the laboratory should co-operate with employers of others who work there, such as contractors, to make sure that those at risk are immunised.

During employment

226 Occupational health records are needed for all staff, and more detailed records kept for those directly involved in work with specimens. It is important that where hazards exist, employers monitor the health of their staff and note and act on occurrences of work-related illness. Active health surveillance will be required for needlestick injuries and other incidents which may involve a risk of infection. Further advice is given in *Protection against blood-borne infections in the workplace: HIV and hepatitis*.¹⁶

227 Under COSHH,² employers must keep details about employees exposed to hazard group 3 or 4 biological agents, where there is a deliberate intention to work with or use the group 3 or 4 agent or, in the case of an incidental exposure, a risk assessment shows there is a significant risk. Employees should be considered as having been exposed unless exposure has been prevented, and not merely controlled. The details recorded should include:

- the type of work the employee does;
- the biological agents to which they have been exposed (where this is known);
- records of accidents and incidents involving exposure to the biological agents concerned.

228 These details should be kept for at least 10 years after the last known exposure, except in the case of certain exposures which may give rise to infections with longer-term implications, where they should be kept for 40 years. The COSHH ACoP gives further information.²

Medical contact cards

229 To facilitate reporting of occupational illness, employers may wish to supply medical contact cards to staff employed in clinical laboratories, including those employed for ancillary work. The information can be incorporated into security passes or provided separately.

230 Such information could include:

- employee's name, home address and telephone number;
- the work address, nature of employment and a brief description of the hazards involved;
- contact telephone number and/or addresses for:
 - (i) the employee's general practitioner;
 - (ii) an appropriate manager at work;
 - (iii) the occupational health service;
- immunisation data.

231 This may be useful to medical practitioners who might not otherwise be aware of possible links between ill health and occupational risks, particularly in the event of sudden unexplained illness.

Incidents and accidents

Dealing with incidents and accidents

232 The Management Regulations¹ require procedures for responding to serious and imminent danger. RIDDOR⁸ require employers to report specified accidents and incidents to HSE and keep records of them.

233 Both incidents and near misses need to be investigated to help everyone learn from experience. This depends on having an effective system of reporting and recording incidents and is only effective if everyone involved understands what is expected of them. Investigation should identify the underlying root causes of an incident, and the implications should be extrapolated to other work activities.

234 All laboratories need to clearly set out the appropriate procedures for dealing with incidents which may result in the release of biological agents, particularly those capable of causing severe human disease. These will include details of the arrangements for:

- dealing with spillages, and how to do this safely;
- immediate action in the event of an accident, fire, flood or other emergency, especially where there is a risk of infection;
- notifying employees and their representatives of the causes of the incident and the necessary remedial action;
- reporting, recording and investigating accidents, incidents and cases of ill health, including those with the potential to cause injury, ill health and loss;
- first aid.

235 For effective monitoring of health and safety arrangements, the internal reporting system needs to take account of all incidents and accidents which may occur in the laboratory, not just the more serious ones. Following up all such occurrences will help managers, safety representatives, safety managers and others:

- monitor the adequacy of precautions;
- check performance;
- learn from mistakes;
- identify jobs or activities which cause the greatest number of problems;
- identify gaps in staff training needs.

236 This information is also very useful when carrying out the risk assessment process.

Dealing with spillages

237 All laboratories need clear written procedures for dealing with spillages or other accidental microbial contamination. Appendix 3 of *The management, design and operation of microbiological containment laboratories* gives advice on spillages.⁴ Staff must be instructed and trained in the procedures and spillages should be attended to promptly.

238 The risks from a spillage depend on:

- the type of biological agents involved;
- the amount of material spilled;
- the nature of the material, eg blood or culture;
- whether the spilled material easily forms an aerosol.

239 A major spillage is one where there is significant splashing and/or aerosol generation, eg a spill of TB culture. A minor spillage is one which is confined to a small area with little splashing.

Minor spillages

240 Liquid spillage, for example viral cultures, blood serum or body fluids, should be disinfected with hypochlorite granules. This is not appropriate for urine (see Appendix 2). Staff should use a clear soluble phenolic liquid disinfectant at an appropriate concentration for bacterial cultures. The spillage and disinfectant should then be mopped up with disposable paper towels, discarded into a clinical waste bag and the area disinfected again. Concentrated disinfectant and disinfectant granules should be kept easily available in the laboratory.

Major spillages

241 After a major spillage in a CL 2 laboratory, the laboratory should be evacuated to allow any resulting aerosol to settle. CL 2 laboratories cannot normally be fumigated, and need to be thoroughly cleaned and disinfected following a major spillage.

242 Following a major spillage at CL 3, staff should leave the laboratory, preferably leaving behind protective clothing or any other contaminated clothing. The microbiological safety cabinet should be left on. Appendix 2 of *The management, design and operation of microbiological containment laboratories* provides information on fumigation of CL 3 laboratories.⁴

243 It is most important that following a major spillage no-one enters the laboratory until after it has been fumigated and the atmosphere checked for the absence of formaldehyde vapour.

244 In the event of a large-scale spillage of chemicals it may be appropriate to call the emergency services. In such circumstances a senior member of laboratory staff must be present to provide the emergency services with health and safety information.

Follow-up action

245 Spillages which result in the release of a biological agent likely to cause severe human infection or illness are reportable to HSE under the requirements of RIDDOR.⁸ An occupational health service should follow up the health of any member of staff put at risk from infection by an incident.

Fires

246 The NHS Estates series of publications Firecode provides detailed guidance on fire precautions for healthcare premises.^{52,53,54,55,56,57} Other NHS Estates guidance provides information about specific aspects of fire safety in laboratories on hospital premises.⁵⁸

247 Emergency services need to be made fully aware of risks associated with a fire in a laboratory. These will include those arising from work with biological agents and others such as the use of flammable substances or gas cylinders. A fire in a clinical laboratory may not kill all the pathogens in the area, creating a risk of infection during fire fighting, inspection, debris clearance, etc.

248 Following any fire, it is essential that a thorough inspection of the site is carried out by someone capable of providing competent advice.

249 A responsible person needs to be appointed to:

- oversee the clearing up operation;
- agree and advise on action necessary to render the site 'safe' before clean up and recovery;
- decide when it is safe for unprotected people to enter the area.

Measuring, auditing and reviewing performance

250 These are three essential elements of the management cycle. HSE guidance *Management of health and safety in the health services: Information for directors and managers*¹³ and *Successful health and safety management*,⁵⁹ gives further detail on the framework for managing health and safety.

Measuring performance

251 Organisations need to measure what they are doing to implement their health and safety policy, to assess how effectively they are controlling risks, and how well they are developing a positive health and safety culture. Monitoring health and safety performance against predetermined plans should be a line management responsibility and reinforces management's commitment to health and safety objectives. Much of this may be carried out by the laboratory safety officer. Monitoring systems should be both active and reactive.

252 **Active** systems monitor management arrangements, risk control systems and workplace precautions, and give an organisation feedback on its performance before an incident, accident or case of ill health arises. Active monitoring may include:

- routine procedures to monitor specific objectives, eg quarterly or monthly returns;
- systematic inspection of premises, plant and equipment;
- direct observation of work and behaviour by first line supervisors to assess compliance with SOPs and safe working practices;
- the operation of formal audit systems.

253 **Reactive** monitoring systems are triggered after an event such as injury or case of ill health, or after incidents which had the potential to cause harm or damage to property. The outcomes of investigations should:

- identify reasons for sub-standard performance;
- identify underlying failures in health and safety management systems;
- ensure everyone learns from events;
- prevent recurrences;
- satisfy legal and reporting requirements.

Auditing performance

254 Audit is the structured process of collecting independent information on the efficiency, effectiveness and reliability of the total health and safety management system, and drawing up plans for corrective action. The aims of the auditing process should be to establish that:

- appropriate management arrangements are in place;
- adequate risk control systems, eg SOPs, are implemented;
- appropriate precautions are in place and properly used.

255 The process involves:

- gathering information by interview, examining documents and visual observation;
- evaluating the data;
- making judgments on the adequacy of a health and safety management system by comparison against the relevant standard or benchmark.

Review of performance

256 Reviewing is the process of making judgments about the adequacy of performance and taking decisions about the nature and timing of the actions necessary to remedy deficiencies. It should be a continuous process undertaken at different levels within the laboratory, and includes responses:

- by first line supervisors, laboratory safety officers or managers to remedy failures to implement workplace precautions which they observe during routine activities;
- to remedy failures to comply with SOPs by active and reactive monitoring;
- to the results of audits.

257 The laboratory management should set the frequency of reviews. Relative priority of remedial action can be allocated according to the relative risk, as determined by the risk assessments.

Appendix 1: Microbiological safety cabinets

1 The following information is provided for use in conjunction with the standards concerning microbiological safety cabinets (MSCs) referred to in paragraphs 128-138.

2 This appendix provides information on the performance criteria for MSCs and offers practical recommendations for their safe use. For a full description of details relating to type, specification and performance of MSCs, reference should be made to British Standard *BS EN 12469:2000* (which supersedes *BS 5762: Parts 1 and 3*).³⁶

British Standard BS EN 12469:2000

3 The effectiveness of the microbiological safety cabinet depends on:

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

4 Performance criteria are given in *BS EN 12469:2000*.³⁶ This sets out minimum performance criteria for MSCs used with biological agents and specifies test procedures with respect to protection of the worker and the environment, product protection, and cross contamination. It does not, however, cover other precautions such as mechanical, electrical, chemical and radioactive safety.

5 *BS EN 12469:2000* specifies tests for the protection of operators, for example, volumetric air flow rate measurements, air flow 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 3 (see Page 48).

Table 3 Test methods for type testing, installations testing, and routine maintenance testing for Class I and II cabinets (adapted from Table 5 in *BS EN 12469:2000*)

Testing	Retention at front aperture	Filters ☞
Type testing	Microbiological or KI	Aerosol challenge
Installation testing	Check manufacturer's specification is met, volumetric airflow rate and airflow patterns Optional: operator protection factor (microbiological or KI or other suitable alternatives)	Aerosol challenge or when appropriate natural aerosol challenge
Routine maintenance testing	Check manufacturer's maintenance requirements, volumetric airflow rate and airflow patterns	As for installation testing

6 *BS EN 12469:2000* differs from the previous British Standard in that the need to carry out an operator protection factor test (referred to in the Standard as the Aperture Protection Factor, APF) at installations and 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 operator protection factor test is carried out in addition to the tests specified by *BS EN 12469:2000* (Table 3), at intervals not exceeding 14 months.

7 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 hazard group 3 and hazard group 4 biological agents. Cabinets used infrequently should be checked prior to operation. Table 4 contains details of recommended testing frequencies and Table 5 gives minimum expected results to achieve operator protection.

Table 4 Frequency of tests

Test	Class I	Class II
Alarms/indicators	daily	daily
Face velocity	monthly	
Inflow/down flow	Anually for CL2 6 monthly for CL3	
OPF Test	minimum 12 monthly	
In use OPF Test	As required by assessment 	

Table 5 Recommended performance of cabinets

Test	Class I	Class II
Alarms/indicators	Functioning as specified	
Face velocity	Measured velocity at all points should be between 0.7 m/s and 1.0 m/s	Not less than 0.4 m/s
Inflow/down flow	N/A	Inflow = not less than 0.4 m/s Down flow = 0.25 - 0.5 m/s
OPF Test	Greater than or equal to 1×10^5	
In use OPF Test	Greater than or equal to 1×10^5	

Operator protection factor test

8 The minimum inward air flow through the front aperture of a Class I or Class II cabinet is defined in *BS EN 12469:2000*. This is required to provide containment and is related to the operator protection factor (OPF) for which the minimum standard is 1×10^5 . This figure expresses the ratio of the number of airborne particles that would be generated in a procedure conducted on the open bench to the number resulting from the same procedure within a cabinet. This means that for every 100,000 particles used in a test as a challenge to the inward flow of air at the working aperture, not more than one should escape. The various methods involved and the conditions for conducting the test are defined in *BS EN 12469:2000*.

In use operator protection factor testing of open-fronted microbiological safety cabinets

9 To assess the efficiency of microbiological containment in actual conditions of use, it may be necessary to carry out an 'in use' OPF test. This may be required, for example, when working with hazard group 3 biological agents, particularly when there may be other sources of ventilation and movement of staff around the laboratory, and when commissioning a new MSC. This can result in alteration of air movements in the room which may reduce the containment ability of the MSC.

10 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 *BS EN 12469:2000* Appendix C. The following should also be considered:

- tests should be performed with the cabinet loaded with a typical arrangement of equipment and samples (NB, *BS EN 12469:2000* 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 OPF tests has been shown to be similar to that of an operator working with arms in the cabinet, even if arms are occasionally withdrawn);
- significant items of equipment normally used near the cabinet should be in place (and switched on if it normally produces discernible air flow 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 of 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 MSCs

11 Under normal circumstances, it is good practice to discharge exhaust air from MSCs to atmosphere through a dedicated extract system. If this presents difficulties, recirculation of discharged air back into the laboratory can be considered. When working with hazard group 3 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.

12 If recirculation is considered, then issues such as cabinet fumigation and subsequent clearing of fumigant need to be considered as part of an assessment for the overall work. The choice between total exhaust and recirculation for a particular installation will depend on local circumstances and should be reflected in the local risk assessment. For instance 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.

Location of MSCs

13 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.

14 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.

Fumigation of cabinets and filters

15 Before any service work, other than minor attention to controls and lamps fitted on the outside, a microbiological safety cabinet should be fumigated. Fumigation will be necessary when filters are to be changed, access to internal ducting or fittings is necessary or when the nature of the work or a spillage demands it. The procedure adopted should ensure that both sides of the filter are satisfactorily fumigated.

16 The generation of formaldehyde vapour from formalin is the simplest method of fumigation to carry out and is as follows:

- for a standard-sized safety cabinet, place 25 ml of formalin BP and 25 ml of water in a dish on an electric heater in the cabinet. Replace the front closure. Switch on and boil away the formalin mixture. The addition of a thermostatic control and a time switch are useful for this operation. For a larger cabinet, allow 60 ml of formalin and 60 ml of water for every cubic metre of cabinet volume. When half of the solution is evaporated switch on the cabinet briefly so that fumigant will penetrate the filter and ductwork;
- leave for a minimum of 6 hours;
- switch on the cabinet fan and open the front closure a few millimetres to allow air to enter and the remaining formaldehyde to be exhausted outside the building (cabinets with double filtered exhaust outlets which recirculate air within the room will require temporary ducting to carry away formaldehyde vapour).

Appendix 2: Disinfectants and disinfection in the clinical laboratory

Definitions

- 1 *Disinfectant*: A disinfectant is a chemical agent which under defined conditions is capable of disinfection.
- 2 *Disinfection*: Disinfection means the destruction of biological agents to levels such that any infection hazard is removed and the disinfected object is safe to handle.
- 3 *Sterilisation*: Sterilisation means the destruction of all viable biological agents

Introduction

- 4 Disinfection is commonly used where sterilisation is considered to be unnecessary, or impractical, eg due to the size of the object, or because it may be damaged by sterilisation. Disinfection is not an alternative to sterilisation. Sterilisation processes (eg steam sterilisation) are superior to chemical disinfection processes because their effectiveness can be checked.
- 5 Disinfectants do not necessarily kill all biological agents and do not usually destroy bacterial spores.
- 6 The main use of disinfectants in the clinical laboratory is to ensure that equipment and the environment are decontaminated and safe to handle. Microbial contaminants on hands are readily removed by washing with soap or detergent. Hand decontamination should be performed after all laboratory work, even when gloves have been worn.
- 7 COSHH ² has the following requirements that may involve the use of chemical disinfectants as control measures against the risk of infection:

“Where there is a risk of exposure to a biological agent it shall be adequately controlled by

- d) *drawing up plans to deal with accidents involving biological agents;*
- e) *specifying appropriate decontamination and disinfection procedures”.*

Considerations

- 8 In any disinfection procedure, regardless of the agent, a number of important factors need to be considered:

The need for a liquid disinfectant

- 9 When considering the types of disinfectant to be used in the laboratory, those responsible for selecting disinfectants need to take account of the efficacy of the products available and the hazard that the use of each presents. Autoclaving of dry discard should replace discard pots with disinfectant wherever possible.

Microbiocidal spectrum

10 Many different chemical disinfectants are available and each has a different range of biological agents against which it is effective. The concentration and susceptibility of the infectious agents present need to be considered. More than one infectious agent may be present.

Presence of inactivating agents or other factors

11 The activity of disinfectants can be affected by the presence of organic material, incompatible soaps or detergents, the presence of other chemicals, pH, and temperature.

Contact and duration of exposure

12 There must be adequate contact to enable the disinfection to be effective, eg objects should be fully immersed and air pockets should not be present. Deposits of organic matter should be removed, as far as possible, prior to disinfection. Adequate contact time should be allowed for the disinfectant to perform its function. This time will vary according to the type of disinfectant, the presence of inactivating or interfering factors and the microbial load.

Selection of disinfectants

13 The behaviour of a disinfectant can, to a large extent, be determined by knowledge of the active components of the particular product. It is therefore essential to select the right disinfectant, use it correctly and ensure that none of the factors which can affect it adversely are present. Disinfectants should be selected and used in accordance with the manufacturer's instructions. Full details of the effectiveness, use, storage, compatibility, safe handling and storage of a particular product should be obtained from the supplier.

Concentration of the disinfectant

14 Only freshly prepared 'in-use dilutions' should be used since stored dilutions may lose activity. Different concentrations may be recommended according to the amount of organic matter present, known as 'clean' or 'dirty' situations. Excessive dilution of the disinfectant agent during use will also reduce its activity.

Use of the disinfectant

15 Once a particular disinfectant has been selected, standards should be established for local use to enable periodic monitoring of its performance, especially when changes in work patterns or materials are proposed. General guidance on the use of chemical disinfection procedures is provided in Public Health Laboratory Service guidance, *Chemical Disinfection in Hospitals*.⁶⁰ Specific guidance on disinfection has been prepared for a number of situations.

16 The use of disinfectants should be specified in the local safety policy. This policy should state clearly the local rules and include the type of disinfectants, uses, working dilutions and renewal frequency. Suitable instruction and training on the applications, limitations and safe usage should be given to all staff using these agents.

Main types of disinfectant

17 The disinfectants in most common use in the clinical laboratory are hypochlorites, clear soluble phenolics and alcohols. This list is not exhaustive and alternative disinfectants, such as peroxygen disinfectants and quaternary ammonium compounds, are available. These may be used provided they have been assessed as fit for purpose.

Hypochlorites

18 These are highly effective against vegetative bacteria, viruses and fungi. They have limited activity against bacterial spores. They are not very effective against *Mycobacterium spp.*

19 They are compatible with anionic and non-ionic detergents, but are inactivated by organic matter and may corrode metals and damage rubber. Hypochlorites are commonly available as solutions of sodium hypochlorite and as powdered or tableted sodium dichloroisocyanurate (NaDCC). Sodium hypochlorite stock solutions will decay with time, light and temperature and should be stored in cool and dark conditions. NaDCC is very stable on dry storage but will decay as sodium hypochlorite once in solution. Also, working solutions of any hypochlorite need to be changed frequently because of the deterioration caused by the addition of organic matter.

20 The concentration of hypochlorite solutions is expressed in terms of parts per million available chlorine (ppm av Cl). Commonly used dilutions are:

- 1 000 ppm av Cl for general wiping of equipment and benches;
- 2 500 ppm av Cl for discard containers (if required);
- 10 000 ppm av Cl for spillages;
- 20 000 ppm av Cl for work surfaces, including microbiological safety cabinets where material containing prions/TSE agents has been handled (NaDCC is not effective in this context).

21 NaDCC granules are available and are recommended for spillages.

22 Hypochlorites should not be mixed with acids as gaseous chlorine is released at low pH. Hypochlorites are oxidising agents and this activity can be checked with starch-iodide indicator paper periodically before disposal to ensure that the hypochlorite is not being overloaded. The paper will turn from white to blue-black in the presence of oxidising agents.

NB: High available chlorine concentrations will bleach the blue-black colour as soon as it appears. Dilute "failed" hypochlorite solutions about 1 in 100, and test again. If there is still no colour development, failure is confirmed.

Clear soluble phenolics

23 These are effective against vegetative bacteria, fungi and have some activity against a limited range of viruses but are poor against non-enveloped viruses. They have no activity against bacterial spores. They are normally the agent of choice for *Mycobacterium spp.*

24 Phenolics are compatible with anionic and non-ionic detergents and metals and are phenol-based compounds kept in aqueous solution by detergents. They are slightly inactivated by organic materials and may be inactivated by rubber and some plastics. They need to be diluted for use but should not be stored diluted.

Peroxygen-based disinfectants

25 Peroxygen-based disinfectants are effective against bacteria, fungi and viruses. Activity against bacterial spores and *Mycobacterium spp.* is variable, but peracetic acid preparations are generally effective. They do cause some corrosion, varying with individual products, but less than hypochlorite. Most have to be activated or dissolved before use and will have a limited shelf-life thereafter.

Alcohols

26 These are effective against many bacteria including *Mycobacterium spp.* and fungi, have variable activity against viruses (less effective against non-enveloped viruses) and have no activity against bacterial spores. They have poor penetration of organic matter, particularly proteinaceous material, and are flammable. They should not be used near flames or equipment likely to generate sparks.

27 Alcohols should not be used undiluted. The most effective strength for alcohol disinfection is a 70-80% (v/v) solution of isopropanol or methanol in water. A surface wipe is a convenient method of disinfection, but due to evaporation has a limited effect and therefore should be confined to surfaces with no visible contamination.

28 While hand washing is the preferred method of hand cleansing, alcohol hand rubs may be used in situations where this is not readily available. Applications of approximately 1 ml 70% (v/v) alcohol to keep hands wet for 10-15 seconds whilst being rubbed to dryness is recommended.

Glutaraldehyde

29 Glutaraldehyde has long been recognised as a cause of ill health, with dermatitis and respiratory problems being the most significant effects. It is now also classified as an asthmagen and respiratory sensitiser and has been assigned a Maximum Exposure Limit (MEL) of 0.05 ppm (0.2 mg m⁻³) 8-hour Time Weighted Average reference period and 15-minute reference period under COSHH.^{2,61}

30 While glutaraldehyde is an effective disinfectant, its use in the laboratory is not generally recommended. Small amounts may be used for disinfecting equipment in safety cabinets, but it should not be used elsewhere. Lower hazard alternatives are available and should always be considered during risk assessment.

General precautions

31 Employers should carry out a COSHH assessment on the use of all chemical disinfectants to determine the particular precautions for each. In general the following precautions will be needed:

- concentrates should be dispensed using closed systems, eg pump or syphon;
- staff should always wear suitable gloves when handling disinfectants;
- all persons handling concentrated stock solutions of disinfectants should wear suitable safety spectacles, goggles or a full-face visor and a disposable plastic apron if splashing may occur;
- adequate ventilation and/or wearing of suitable respiratory protective equipment when handling concentrated disinfectants.

Appendix 3: Packaging requirements for some diagnostic specimens

EXTRACT FROM MULTILATERAL SPECIAL AGREEMENT M96

The packaging shall meet the following conditions:

1 General provisions

- (a) diagnostic specimens shall be packed in good quality packaging, which shall be strong enough to withstand the shocks and loadings normally encountered during carriage, including transshipment between vehicles and/or warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packaging shall be constructed and closed so as to prevent any loss of contents when prepared for carriage which might be caused under normal conditions of carriage, by vibration or by changes in temperature, humidity or pressure;
- (b) primary receptacles shall be packed in secondary packaging in such a way that under normal conditions of carriage they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packaging shall be secured in outer packaging with suitable cushioning material. Any leakage of the contents shall not substantially impair the protective properties of the cushioning material or of the outer packaging;
- (c) each package shall be clearly and durably marked with the words **'DIAGNOSTIC SPECIMENS'**;
- (d) outer packaging may consist of paper, fibreboard, plastics or metal.

2 Liquids

- (a) the primary receptacle(s) shall be leak-proof and not contain more than 100 ml;
- (b) there shall be absorbent material placed between the primary receptacle and the secondary packaging; if several fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them. The absorbent material, such as cotton wool, shall be in sufficient quantity to absorb the entire contents of the primary receptacles, and there must be a secondary packaging, which must be leak-proof;
- (c) the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar);
- (d) the outer packaging shall not contain more than 500 ml.

3 Solids

- (a) the primary receptacle(s) shall be waterproof and not contain more than 100 g;
- (b) if several fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them and there must be a secondary packaging which must be waterproof;
- (c) the outer packaging shall not contain more than 500 g.

Appendix 4: Staff safety guidelines

Introduction

1 The following guidelines cover the main work activities undertaken in clinical laboratories and associated workplaces. They are prepared for use as a 'check list' during the preparation of standard operating procedures which take into account local needs and requirements.

2 Anyone entering a laboratory where pathological specimens are handled, examined or stored will be subject to the health risks associated with such materials. Staff need to observe certain precautions to protect both themselves and others whom their work might affect. The degree of risk will depend upon the sort of work they do and how well they observe the safety guidelines.

General precautions

3 The following general precautions should be observed by everyone entering a laboratory or similar workplace. Other guidelines specific to a particular work activity should also be observed.

4 Any cuts or grazes, dermatitis or other forms of open wound, especially on the hands, should be covered by a waterproof dressing before you start work. The cover should be adequate to prevent contamination.

5 To prevent your own clothing from becoming soiled during work and acting as a vehicle for infection, always wear the protective gown or coat provided for your use in the laboratory. Do not enter a clinical laboratory unless you are wearing a properly fastened protective gown or coat. Coats or gowns should be changed regularly. The frequency will be determined by a risk assessment.

6 To help protect both yourself and others with whom you come into contact:

- never take personal items such as pens, pencils, combs, brushes, cosmetics and handbags, etc into the laboratory. Leave them in the locker provided for your use in the changing room. Essential items such as pens and pencils will be provided;
- never take food, drink, cigarettes, etc into the laboratory. Either leave such items in your locker or in the staff rest room;

- eating, drinking, smoking and applying cosmetics in the laboratory is forbidden. All actions that may bring your hands into contact with your face and your eyes, nose and mouth should be avoided (eg cleaning or adjusting contact lenses);
- if you want to do any of these things, first remove your coat or gown, thoroughly wash your hands, leave the laboratory and use the facilities in the rest room;
- if your protective coat or gown is contaminated with material that is known or thought to be infectious, change it immediately. Place the dirty coat in the container for infected linen, wash your hands and put on a clean coat or gown.

7 The standard operating procedures for the laboratory will say when you should wear gloves and what type to wear. If you think that your hands or gloves may have been in direct contact with blood, body fluids or other biological material, stop work at once, discard the gloves, if wearing them, and wash your hands. If a glove becomes perforated during work, even if you are not injured, stop work immediately, remove it and dispose of it into the appropriate bag. Wash your hands and put on new gloves.

8 If you have, or are involved in, an accidental breakage of equipment and/or a spillage of material that could be infectious, report the incident to a senior member of the laboratory staff at once.

9 Any broken equipment, especially if the pieces could cause puncture wounds, should be placed in a container that provides protection for those who handle it. All used cleaning materials should be placed in an appropriately marked container and disposed of in the manner described in the standard operating procedures.

10 Special work activities in the laboratory such as disinfection, autoclaving and cleaning should only be performed according to the written instructions. Always follow these instructions – never change a procedure unless instructed to do so by your line manager or other responsible person on the laboratory staff to meet special circumstances.

11 Avoid all practices and procedures that may cause splashing or the release of airborne liquid droplets or dusts, eg powder culture medium, into the atmosphere of the laboratory. Operations that disperse airborne droplets from work with pathological materials should be carried out in a microbiological safety cabinet. Some other form of appropriately designed containment or protection should be used to guard against splashing (eg a transparent screen).

12 If there is a possibility that you will be splashed by pathological materials you should put on a full-face visor, gloves and a disposable plastic apron over your gown or coat.

13 If you have an accident and puncture your skin while at work, the wound should be gently encouraged to bleed while washing with running water. Do not scrub a wound, as this may encourage biological agents to enter the bloodstream. The wound should be properly treated and dressed - seek medical advice if necessary. Report the accident at once to your line manager or to one of the senior laboratory staff- no matter how small the wound is. Independent medical advice may be considered necessary.

14 When you leave the laboratory, for any reason, you should first remove the coat or gown and hang it on one of the hooks provided by the exit. Gloves should be discarded into the appropriate waste container and any other protective equipment, such as visors or aprons, placed in the container for decontamination or disposal according to laboratory instructions. Then thoroughly wash your hands and leave the laboratory. Never take your coat or gown outside the laboratory.

15 If you are called on to see a patient during the course of your work, put on a clean coat. Never see them in the coat or gown you have been wearing in the laboratory.

16 If you become ill, remember to tell your doctor where you work. Show your Medical Contact Card, if one has been issued, and ask the doctor to talk to one of the medical staff or appropriate line manager in the laboratory if further information is required.

17 Do not take unnecessary risks - always follow the guidelines.

Guidelines for clinical, scientific, technical and medical laboratory staff working in the laboratory

18 Most of the work carried out by clinical, scientific, technical and medical laboratory staff will inevitably be concerned with handling specimens from patients. They should therefore always observe all of the requirements of the general precautions above. In addition, when handling or dealing with specimens they should observe the following points:

- Use protective clothing and equipment (ie gloves, aprons, eye protection, etc) as appropriate for the risk to which you are exposed. The dispersion of airborne droplets should be contained within a microbiological safety cabinet;
- Mouth pipetting is forbidden. Always use the pipetting devices provided;
- Wash your hands at the end of each job or when they become contaminated during bench work, and always before leaving the laboratory, even when going to an office within the laboratory;
- Sustaining a puncture wound or cut at work is particularly dangerous. Ensure you follow the procedure at paragraph 13 above. Minimise your use of sharp objects. When such use is unavoidable handle tools, equipment and especially any glass objects with extreme caution. Wherever possible use plastic instead of glass. Do not leave 'sharps' lying around - put them in a safe container;
- Keep your workbench as clear as possible. Use racks or trays to contain specimens;
- Clear up spillages immediately using the agreed laboratory procedure;
- Dispose of used consumables safely. Items such as Pasteur pipettes should be placed into a freshly prepared disinfectant or dry discard container and autoclaved or disinfected before reuse. Disposable items, such as pipette tips, may be discarded directly into a suitable container, autoclaved and incinerated;
- Dispose of waste safely. Never leave it lying around and make sure that the approved methods for dealing with spillage or breakage are always used;
- When you are fully trained, be prepared to assist other members of staff to deal with spillages or breakages;
- Wear disposable gloves when there is a possibility that your hands may become contaminated with blood, body fluids or other biological materials;
- Place Petri dishes in racks or baskets for storage, rather than stacking them in unsupported piles which may become unstable.

Guidelines for phlebotomists/venepuncturists

19 The work of phlebotomists/venepuncturists involves the collection of blood using aseptic techniques from patients whose history of infectivity may be unknown. Blood is collected by venepuncture or with a sterile disposable lancet. Staff will therefore be exposed to the risks associated with the constant handling of blood specimens in the presence of 'sharps'. As well as following the general precautions outlined above, phlebotomists and venepuncturists should in addition observe the following points:

- Wear the gown or coverall provided for your protection. Wear gloves and other protective equipment, such as eye protection, as required by the standard operating procedures and always when attending patients where a high risk of infection is suspected or known to exist. Blood samples should not be taken in offices or general workrooms in the laboratory. A special room should be set aside for taking blood specimens;
- Discard the gown/coverall worn during sampling immediately if it becomes contaminated with blood, and/or at the end of each day;
- Wash your hands between attending patients and at the end of each work period or if they become contaminated. Cover cuts, grazes and broken skin with an impervious waterproof dressing;
- Needles should be removed from the syringe or other sampling device using forceps or another appropriate device. Needles should never be re-sheathed;
- After removing the needle from the syringe, the blood should be transferred carefully to avoid external contamination of the specimen container;
- Where the laboratory has a policy of using 'danger of infection' labels, containers should be clearly labelled to indicate any known or suspected risk and details provided on the accompanying paperwork;
- Specimen containers should be placed in a specimen transport bag before being taken from the phlebotomy room to laboratory reception. Labels and request forms should be checked for accuracy and the forms placed in the separate pocket of the transport bag;
- Syringes, needles and disposable lancets should be disposed of safely - directly into a sharps container, never into plastic waste sacks;
- The armrest used for taking specimens should be regularly cleaned using fresh disinfectant, preferably after each patient. Any spillage should be dealt with immediately.

Guidelines for laboratory office staff

20 Much of the work in the laboratory is concerned with the handling of specimens that may be infectious. Office staff are not required to come into direct contact with these materials but may accidentally do so when handling bags and packages containing specimens. Such workers, in addition to following the general precautions outlined above, should also take the following safety measures:

- If you work in an office that has direct access into the laboratory, wear a coat or gown, like the other laboratory staff;
- Wash your hands after you have been into the laboratory and may have come into contact with laboratory items or materials that could be infectious;
- Never lick stamps or labels. Use a roller pad, damp sponge or self-adhesive labels.

If you are required to package specimens, only do so if the containers are in a sealed transport bag. If there is any sign of breakage or leakage do not touch the bag. Report it to senior laboratory staff immediately.

Guidelines for laboratory reception staff

21 The work of reception staff will involve handling bags and packages containing specimens sent to the laboratory for clinical examination. In some laboratories they will be required to unpack specimens. They should always follow the general precautions given above as well as the guidelines prepared specifically for people in this work category:

- **Never** lick labels. Use either a roller pad or damp sponge or self-adhesive labels;
- Make sure that you clearly understand the hazard warning labels used on specimens. Wear gloves when instructed to do so by standard operating procedures;
- If a leaking or broken specimen arrives, do not touch it or any others on which it has leaked. Ask a senior member of staff to deal with it;
- Do not unpack or remove from its plastic bag any specimen with a label indicating a 'danger of infection'. It should be delivered directly and unopened to the relevant department in the laboratory;
- Keep all specimens together on the reception bench. Never put them on a desk or elsewhere where leakage could cause a direct risk to yourself or those with whom you work;
- Wash your hands frequently during the course of your daily work – always before a break and at the end of the day. You should wash them at once if they become contaminated.

Guidelines for laboratory porters and messengers

22 Some of the work carried out by laboratory porters and messengers in the hospital may involve accidental contact with material that could be infectious. You should always follow the general precautions outlined above and observe the following guidelines:

- Cover any cuts, grazes or broken skin on your hands with a waterproof dressing;
- Carry all specimens in the trays or boxes provided, never in your hands or pockets;
- Always wash your hands before meal breaks and at the end of a work period;
- If a specimen leaks into a tray or box, tell one of the reception staff. They will ask one of the senior laboratory staff to make it safe;
- If you drop and break a specimen, do not touch it or try to clear it up. Stay with the specimen to prevent other people touching it and send someone to the laboratory for help. If you spill the specimen onto your work clothes, you should remove the contaminated clothing at once and then wash your hands and put on clean work clothes. Dispose of the contaminated clothing with the used coats from the laboratory. Do not take it home for laundering. Report the accident to one of the senior laboratory staff and your supervisor as soon as possible;
- If you drive a van, make sure that you have gloves and a spillage kit with you on the vehicle. If a specimen leaks and runs out of the tray or box, put on gloves, pour hypochlorite granules over the spillage and cover it with absorbent material or granules. Do not mop it up. Drive to the laboratory for help;
- If your vehicle breaks down or you have an accident, do not let anyone touch the specimen box, unless they come from a hospital and know the appropriate procedure;
- Handle specimen containers gently at all times;

- Take care when carrying any waste or rubbish from the laboratory. Do not touch broken glass or needles, but tell your supervisor. Special 'sharps' containers are provided for glass, syringes and needles - these should be handled carefully;
- Only fully trained personnel may enter the mortuary body store. If you have to go there and are not fully trained, do not enter without the permission of the senior technician. They will explain about any special precautions that should be taken, eg wearing special protective clothing. Follow the instructions carefully;
- Wear your work clothes, eg overall, properly fastened, especially when carrying specimens, even when you are not in the laboratory. Keep your work clothes separate from your outdoor clothing, not in your locker. Pegs are provided. Never wear your overall in the staff room or canteen. If you do you could spread infection.

Guidelines for cleaning staff in the laboratory (domestic and ancillary)

23 The work of cleaning and other ancillary staff, including contractors, may involve accidental contact with materials that could be infectious. As well as the general precautions outlined above, cleaning staff should also observe the following safe working practices:

- Always wear the overall provided for your protection when working in the laboratory and fasten it properly;
- Never take your overall out of the laboratory or take it home to wash. Like everyone else in the laboratory you should take off your laboratory overall before you leave and hang it on one of the hooks by the door;
- Wash your hands often while at work, especially after you have handled laboratory equipment or materials that you have been instructed to move or clean, and always before leaving the laboratory or going to the toilet or the staff room. Cover cuts and grazes with impervious waterproof dressings. You may sometimes be instructed to wear gloves;
- Do not touch any bottles, tubes, dishes or equipment on the laboratory benches. Do not dust or clean any work benches unless you have been specifically directed to do so by a member of the laboratory staff. Laboratory staff should make arrangements to let you know what they want you to clean;
- If you have an accident of any kind, or knock over or break any bottle, jar or tube, or piece of equipment, tell your supervisor and one of the laboratory staff at once. You should make sure that the matter is reported because the accident may have caused infectious material to be spilled. Do not attempt to clear up after any accident with laboratory items or materials;
- Do not enter any room which is labelled containment level 3 on the door unless you are told that it is safe and are required to do so by a senior member of the laboratory staff;
- Never empty any laboratory waste containers unless you have been told to by a member of laboratory staff.

24 Employees working in the wash-up room should observe the following instructions as well as the general precautions above:

- Do not handle or wash any material that comes from the laboratory until it has been sterilised (autoclaved) or one of the laboratory staff or your supervisor has told you that it is safe;
- Do not place broken glass in plastic waste bags; use the labelled 'sharps' containers provided for this purpose;

- When handling dirty glassware you should wear heavy-duty gloves. Be very careful when putting your hands into bowls or other receptacles which contain glassware items, as some could be broken and could cause cuts.

Autoclaving duties

- Do not attempt to use the autoclave until you have been taught how to do so by a senior member of laboratory staff and they are satisfied that you are competent to operate it on your own. Follow the operating instructions displayed near the autoclave at all times;
- Items requiring autoclaving should not be allowed to build up. They will be infectious and the risks are likely to get worse if not dealt with straightaway;
- If you have to stack waste containers or other materials awaiting autoclaving, do so carefully. If stacks collapse or fall over, the spilt material could spread infection. If waste or other materials are spilt, report it to a senior member of the laboratory staff and your own supervisor at once and get instructions on how to deal with it. Do not try to do it yourself if you have not been trained to decontaminate a spillage;
- If pressure or temperature indications are incorrect, report it to a senior member of the laboratory staff. Do not use the autoclave if you suspect that it is not working properly. If there are any doubts, all of the material already in the chamber should be autoclaved again.

Handling waste

- When collecting waste from disposal points, make sure that it is labelled showing where it has come from and properly bagged or otherwise safely contained according to standard operating procedures. If it is not, refuse to handle it;
- Be very careful when handling sharps containers because both the sharp points and the liquids can cause infection. Always wear heavy-duty gloves and check them for damage before you put them on. If any of the liquid spills on your overall you should change it. If any gets on your gloves, wash them at once.

Guidelines for maintenance staff and equipment service engineers in clinical laboratories

25 Much of the work in a clinical laboratory is concerned with handling specimens and materials that are infectious, and repair and maintenance staff will be required to handle equipment that has been used to process these materials. Although laboratory staff should ensure that the equipment is decontaminated and cleaned, maintenance staff and equipment service engineers may accidentally come into contact with infectious material. They should, therefore, always follow the general precautions as well as the additional instructions outlined below:

For work in laboratories

- Maintenance work on building fabric, services, drainage, fixtures, fittings, plant or equipment, should usually be covered by a permit to work system. This should specify that appropriate cleaning and decontamination procedures have been carried out. Alternatively, where decontamination is not possible, you should be informed of this and receive special instructions concerning protective measures that you should take while working;
- Report to the laboratory safety officer to receive any such special instructions before commencing any work in the laboratory;
- You should wear the protective clothing deemed necessary by the laboratory or safety officer;
- Any tools or test equipment used in the laboratory should be inspected afterwards and, when considered necessary, they should be decontaminated before being returned to the workshop. You may need technical advice from laboratory staff about how to decontaminate equipment.

Equipment to be sent to the workshop or elsewhere

- All equipment should be labelled to record whether any cleaning or decontamination has been carried out, and to inform those concerned of any special precautions that still need to be taken;
- These special precautions, which may include the use of protective clothing or equipment, should be closely followed by all maintenance and/or repair staff;
- Joints, seals and connections should not be opened or broken unless advice about the possible contents of pipes, tubes or containers has first been obtained from the laboratory staff. They should have been drained and decontaminated. If materials are found inside pipes or tubes, they should not be touched. Immediately reseal the joint and obtain advice from the safety officer.

Guidelines for visitors to laboratories

26 Most visitors to a clinical laboratory will not be conversant with the general precautions or standard operating procedures associated with the workplace. Visitors should not be allowed to enter the laboratory area unless accompanied by a senior member of staff who will be responsible for their welfare. Visitors should:

- wear an approved coat or gown, properly fastened;
- be instructed not to touch anything while in the laboratory, unless their visit demands such action, in which case they should comply with the standard operating procedures. In some cases frequent hand washing may be necessary but visitors should, in any case, wash their hands thoroughly after removing their protective coat, before leaving the laboratory;
- not use personal items such as pens or pencils while in the laboratory if they have handled any laboratory equipment and should be instructed not to smoke etc before entering;
- not be taken into areas of the laboratory where they could become exposed to a risk of infection;
- not be left unsupervised while they are in the laboratory. It is the responsibility of the employer to decide where visitors may and may not go unless additional precautions are taken.

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