

# Biological agents: Managing the risks in laboratories and healthcare premises

Advisory Committee on Dangerous Pathogens

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# Introduction

## Scope

1 This publication provides guidance on your duties under the Control of Substances Hazardous to Health Regulations 2002 (COSHH)<sup>1,2</sup> (as amended) as they relate to biological agents (micro-organisms/infection risks). In the past, the Advisory Committee on Dangerous Pathogens (ACDP) has issued COSHH-based guidance primarily for the laboratory sector. However, some of their publications, eg on blood-borne viruses and transmissible spongiform encephalopathies, have included guidance for healthcare professionals.

2 This guidance covers:

- work in all types of laboratories where biological agents are handled. This includes research, teaching, clinical, forensic, veterinary and environmental laboratories. It covers both deliberate use of biological agents and work with material that contains or could contain biological agents; and
- work with infected patients in human and animal healthcare settings.

3 **Part 1** contains guidance on some general health and safety issues, such as health and safety management, that are applicable to all the relevant workplaces. An overview of the assessment and management of risks from biological agents is also given.

4 **Part 2** contains more specific guidance on assessment and management of work involving infected patients in human and animal healthcare settings.

5 **Part 3A** covers work in laboratories where biological agents are intentionally handled eg propagation and concentration.

6 **Part 3B** covers work in laboratories where potentially infectious material is handled.

## Purpose of guidance

7 This guidance is aimed at all those who have responsibility for assessing and managing the risks from exposure to biological agents at work in either a laboratory or a healthcare setting. For example, you may be a Biomedical Scientist Grade 3 (BMS3) in a National Health Service (NHS) laboratory, or principal investigator in a university laboratory, a clinical director, a nurse manager, or the veterinary manager of a veterinary hospital. Safety advisors, biological safety officers and other safety professionals may also find the guidance useful when providing competent advice to their employer.

8 In addition to COSHH<sup>1</sup> this guidance also provides advice on duties in other health and safety legislation as it relates to work with biological agents. (See Part 1 *Managing health and safety*). Figure 1 illustrates the main legislation covered by

**Figure 1** Legislation and guidance for work with biological agents

<b>Primary legislation</b>	Health and Safety at Work etc Act <sup>3</sup>		
<b>General health and safety regulations</b>	Control of Substances Hazardous to Health Regulations <sup>1</sup>	Management of Health and Safety at Work Regulations <sup>4</sup>	
<b>Specific health and safety legislation</b>	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations <sup>5</sup>	Carriage of Dangerous Goods (Classification, Packaging and Labelling) Regulations <sup>6</sup>	Genetically Modified Organisms (Contained Use) Regulations <sup>7</sup>
<b>Guidance</b>	<b>Laboratories</b>	<b>Healthcare</b>	
<b>ACDP guidance</b>	Biological agents: Managing the risks in laboratories and healthcare premises		
	Protection Against Blood-borne Infection in the Workplace: HIV and Hepatitis <sup>8</sup>		
	Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection <sup>9</sup>		
	Management and Control of Viral Haemorrhagic Fevers <sup>10</sup>		
	The management, design and operation of microbiological containment laboratories <sup>11</sup>		
	Working safely with research animals: Management of infection risks <sup>12</sup>		
<b>Other HSC/E guidance</b>	Safe disposal of clinical waste <sup>13</sup>		
	Safe working and the prevention of infection in clinical laboratories and similar facilities <sup>14</sup>	Safe working and the prevention of infection in the post mortem room <sup>15</sup>	
	Advisory Committee on Genetic Modification: Compendium of guidance <sup>16</sup>		
<b>DH/NHS guidance</b>	Accommodation for Pathology Services <sup>17</sup>	Guidance for Clinical Health Care Workers: Protection Against Infection with Blood-borne Viruses <sup>18</sup>	
		Hospital Infection Control <sup>19</sup>	
		The prevention and control of tuberculosis in the United Kingdom <sup>20</sup>	
		Infection control in the built environment <sup>21</sup>	

this guidance. It also shows the key guidance issued by the Health and Safety Executive (HSE) and other government departments that covers work with biological agents in the laboratory or healthcare setting. Guidance on other areas, eg agriculture or controlling the risks from legionella bacteria, is not included.

9 Not all of the guidance is issued by HSE, but the listed publications all contain information that should assist you in complying with your duties under health and safety legislation.

10 The guidance for laboratories has previously been aimed at those who deliberately work with biological agents. The containment and control measures given in COSHH<sup>1</sup> and ACDP guidance have also, quite rightly, been applied in areas where there is work with potentially infectious material. This includes routine pathology disciplines (haematology/blood transfusion, chemical pathology, immunology, cellular pathology, genetics and cytology), university research and teaching laboratories, forensic laboratories or food testing laboratories.

11 This guidance now covers these latter areas more explicitly in line with COSHH.<sup>1</sup> Also covered for the first time is incidental exposure in the healthcare setting (both human and animal). ACDP considers this to be the highest risk of exposure outside the laboratory. ACDP has also issued guidance on risk assessment for other occupations where there may be incidental exposure, *Infection at work: controlling the risks.*<sup>22</sup>

12 The intention is that this publication links the specific pieces of ACDP guidance, and provides advice on the central themes of managing the risks from biological agents at work, such as risk assessment. It does not duplicate the more specific guidance, eg on containment requirements, but signposts the reader to other appropriate publications, both ACDP and the Department of Health (DH)/NHS publications.

## COSHH<sup>1</sup>

13 The biological agents provisions in COSHH were changed in 2002. The main changes were to move all of the general provisions, including those on risk assessment and control of biological agents, to the main body of the COSHH Regulations. Only those additional measures relating to work with biological agents remain in Schedule 3 to the Regulations. An Appendix to the main COSHH ACO<sup>2</sup> supplements the Schedule.

14 A number of other minor changes have been made including:

- clarification of definitions used, eg 'use' and 'handling';
- better explanation of the application of derogation - exemption certificates are no longer used (see also Parts 3A and 3B of this document);
- clarification and extension of the notification duties required for biological agents (see paragraph 153); and
- minor amendments to the containment measures in Part II of Schedule 3.

## Biological agents

15 A biological agent is defined in COSHH<sup>1</sup> as:

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

16 Most biological agents are micro-organisms, ie bacteria, viruses, fungi, microscopic endoparasites such as the malarial parasite, amoebae and trypanosomes and the microscopic forms of the larger endoparasites such as the ova and larval forms of helminths. A micro-organism is defined in COSHH<sup>1</sup> as:

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

17 COSHH<sup>1</sup> classifies biological agents into one of four Hazard Groups (HGs) based on their ability to **infect** healthy humans. The classification is based on the following criteria:

- whether the agent is pathogenic for humans;
- whether the agent is a hazard to employees;
- whether the agent is transmissible to the community; and
- whether there is effective treatment or prophylaxis available.

The four Hazard Groups are defined as follows:

- **Hazard Group 1:** unlikely to cause human disease;
- **Hazard Group 2:** can cause human disease and may be hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available;
- **Hazard Group 3:** can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available;
- **Hazard Group 4:** causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

18 ACDP have been responsible for issuing a categorisation of biological agents since the first edition of their containment guidance was published in 1984. The classification has been reviewed and updated from time to time, with the last major revision published in 1994 as a result of the implementation of a European Directive.<sup>23</sup> This marked a change in status of the categorisation as it now had the status of law, being an Approved List made under the Health and Safety at Work etc Act 1974 (HSW Act).<sup>3</sup> Amendments may be made to the list from time to time, and you should consult the Approved List<sup>24</sup> on HSE's website to ensure that you are using the most up-to-date version (see also Information box 1).

19 Only agents in Hazard Groups 2-4 appear on the Approved List.<sup>24</sup> The list is not exhaustive, and you should not automatically categorise unlisted agents into Hazard Group 1. The categorisation of unlisted agents needs to be determined by your assessment, using the criteria listed above. Further guidance on this is given in Part 3A.

20 The categorisation gives an indication of the inherent hazard of the agents listed, but it does not take into account the work that you carry out using the agent, eg amount, titre used or procedures undertaken. Nor does it indicate whether there may be any additional risks to those who, for example, have reduced or compromised immunity or are pregnant. This must be addressed in your risk assessment.

#### **Hazards other than infection**

21 As indicated by the definition in COSHH,<sup>1</sup> the risks of allergenicity and toxicity also have to be considered. Certain agents on the Approved List that are well recognised as respiratory sensitisers or that are known to be toxigenic are marked

with an 'A' and 'T' respectively. However, your risk assessment should identify whether other agents pose these hazards (or any other hazards that may harm human health), apart from infection.

#### Information box 1 The Approved List and other classifications

The HSC Approved List classifies biological agents on the basis of their ability to cause harm to **human** health. There are other statutory lists, eg the Anti-terrorism, Crime and Security Act<sup>25</sup> contains a list of agents subject to legislative control (see Appendix 1.3 for further details).

Appendix 1.4 specifically lists the micro-organisms covered by **animal** health legislation, which classifies them on the basis of harm to animal health; there are also specific containment requirements for work with such agents. Some micro-organisms may be on both lists and you will need to take account of any differences in classification and/or containment requirements when working with such agents. The differences in containment are because of the need to protect the environment, but the health and safety of employees must also be addressed.

22 The definition of biological agents in COSHH<sup>1</sup> also includes **genetically modified micro-organisms** (GMMs), but not all GMMs can be classified as biological agents (as defined in COSHH); only those which present a hazard to human health can be included. Unlike the Genetically Modified Organisms (Contained Use) Regulations 2000,<sup>7</sup> COSHH does not consider environmental risks.

### Biological agents at work - scope of guidance

23 There are three ways in which you might be exposed to biological agents at work:

- exposure as a result of working with biological agents, eg in a microbiology laboratory;
- exposure which does not result from the work itself but is incidental to it, mainly because biological agents are present as contaminants, eg farming, refuse collection, sewage treatment (see also: *Infection at work: Controlling the risks*<sup>22</sup>); and
- exposure which is not a result of the work that you do, eg catching flu from a work colleague.

24 Only the first two categories are covered by COSHH.<sup>1</sup> This guidance deals specifically with deliberate work with, and incidental exposure to, biological agents in laboratories. It also covers the healthcare setting as this is likely to be of higher risk than other types of incidental exposure, given the nature of the work.

25 As well as considering risks to employees, this guidance also considers risks to those without specialist training who may be affected by the work that you do, eg visitors, maintenance workers, engineers, patients and cleaners.

26 Although students are not employees, there is still a duty in COSHH<sup>1</sup> to assess and control risks to others on your premises, so far as is reasonably practicable. However, those students carrying out activities involving genetic modification are treated as employees of the educational establishment where they are studying (by virtue of amendment of the relevant section of the HSW Act<sup>3</sup>). This is for the purposes of the Genetically Modified Organisms (Contained Use) Regulations<sup>7</sup> only.

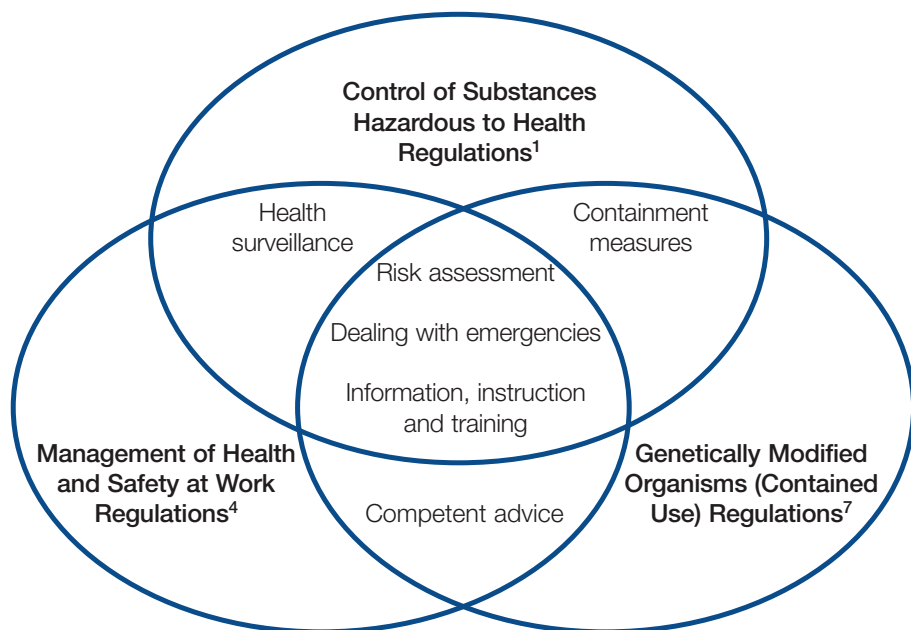
27 Although only the courts can give an authoritative interpretation of the law, in considering the application of regulations and guidance to people working under your direction, you should consider the following. If you have people working under your control and direction who are treated as self-employed for tax and national insurance purposes, they may nevertheless be treated as your employees for health and safety purposes. You may therefore need to take appropriate action to protect them. If you are in any doubt about who is responsible for the health and safety of a person working for you this could be clarified and included in the terms of the contract. However, remember that you cannot pass on a legal duty that falls to you under the HSW Act<sup>3</sup> by means of a contract and you will still have duties towards others under Section 3 of HSW Act.<sup>3</sup> If you intend to employ such workers on the basis that you are not responsible for their health and safety, you should seek legal advice before doing so.



# Part 1 Managing health and safety

## Health and safety legislation and biological agents

28 The main legislation of relevance to controlling the risks of exposure to biological agents at work is COSHH.<sup>1</sup> However, there are other health and safety regulations that overlap with COSHH, as shown in Figure 2.



**Figure 2** Overlap of duties

29 Where there is an overlap between pieces of legislation, the general rule is that the more specific requirements must be met. You only need to comply with the duty in the more specific legislation, eg work with biological agents should be covered in the COSHH risk assessment, and does not have to be repeated for the purposes of the corresponding duty in the other regulations. However, hazards and issues not covered by the specific legislation will need to be considered in the context of the more generic legislation.

30 For further guidance on work with genetically modified micro-organisms (GMMs) and genetically modified organisms (GMOs), see *A guide to the Genetically Modified Organisms (Contained Use) Regulations*<sup>26</sup> and the Advisory Committee on Genetic Modification's (ACGM's) *Compendium of Guidance*.<sup>16</sup>

31 Other health and safety legislation may also be applicable to work involving biological agents, and Appendices 1.1 and 1.2 of this guidance contain advice on the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995

(RIDDOR)<sup>5, 27</sup> and the transport of infectious substances respectively. Appendix 1.3 lists some of the other legislation and standards applicable to work involving biological agents.

**Management of Health  
and Safety at Work  
Regulations (MHSWR)<sup>4, 28</sup>  
regulation 5**

**Health and safety management**

32 The legal responsibility for health and safety rests primarily with the employer. It is their responsibility to make sure the organisation has the necessary management framework to ensure compliance with health and safety at work legislation. This means taking an active role in carrying out risk assessments, setting health and safety standards and developing policies, together with the monitoring of standards and enforcement of compliance, where necessary. Specific functions, such as carrying out risk assessments, may be delegated down the line management chain, but ultimate responsibility for health and safety cannot be delegated.

33 One aspect of this management system will be the control of exposure to hazardous substances, including biological agents. Other more general duties are outlined in Reference box 1, together with references to more specific guidance where available.

**Reference box 1**

Further and/or sector-specific guidance on key elements of effective health and safety management systems can be found in:

- *Successful health and safety management;*<sup>29</sup>
- *Management of health and safety in the health service,*<sup>30</sup> *NHS health and safety issues;*<sup>31</sup>
- *University Health and Safety Management: Code of Best Practice.*<sup>32</sup>

**HSW Act<sup>3</sup> Section 2(3)  
MHSWR<sup>4</sup> regulation 5**

**Health and safety policies**

34 All organisations must have arrangements in place to manage all aspects of health and safety. This includes preparing a written statement of their health and safety policy. This should be a declaration of their intent to provide and maintain a safe and healthy working environment, and to enlist the support of employees towards achieving these ends. It should detail health and safety responsibilities within the organisation and the arrangements for ensuring health and safety in the workplace. This should cover the systems and procedures in place for ensuring employees' health and safety. It may refer to other documentation such as risk assessments and standard operating procedures. The policy needs to be brought to the attention of all employees (see Reference box 2).

35 A local health and safety policy should set out, in general terms, how local managers intend to develop and maintain a safe working environment. Local codes of practice can give further detail on how safe working will be achieved on a day-to-day basis. Local safety policies and codes should be made freely accessible, and all employees, including newcomers and temporary workers, must be made aware of them.

36 Standard operating procedures are often required to meet internal (and external) quality standards, but health and safety information can be integrated into such systems as a means of providing relevant information to employees.

37 Whatever method is used to convey information, it should be developed in consultation with employees to ensure commitment to safe working procedures.

#### Reference box 2

Further and/or sector-specific advice on the formulation of health and safety policies can be found in:

- HSE guidance, eg *An introduction to health and safety*,<sup>33</sup> *Stating your business*,<sup>34</sup> *Management of health and safety in the health services: Information for directors and managers*,<sup>30</sup>
- CPA's *Standards for the Medical Laboratory*,<sup>35</sup>
- Healthcare standard on safety,<sup>36</sup>
- The British Small Animal Veterinary Association's *Guide to practice*.<sup>37</sup>

### MHSWR<sup>4</sup> regulation 7 **Access to competent help**

38 Employers may need help and advice to carry out their duties under health and safety law. There is a requirement to appoint one or more competent people to fulfil this role, eg the health and safety advisor/assistant, safety officer, occupational health advisor, biological safety officer and infection control team. They need to have the status and competence to advise management and employees or their representatives with authority and independence. A competent person is someone who has sufficient training and experience or knowledge to do the required job. This will include an understanding of relevant statutory requirements and an appreciation of the hazards involved.

39 Those providing the advice/help must be given enough time and resources to fulfil their responsibilities. It is important to remember that appointing a competent person does not absolve the employer from their responsibilities under health and safety, it just gives further assurance that responsibilities will be fulfilled adequately.

### MHSWR<sup>4</sup> regulation 11 **Co-operation and co-ordination**

40 Some workplaces may be shared by more than one employer. This could include the self-employed. For example:

- a laboratory in a teaching hospital may be shared by university researchers and trust biomedical scientists;
- research council employees may work in a university laboratory; or
- research hotels or science parks may be owned and used by one organisation but also have space let out to universities or small businesses.

41 There is a requirement for those sharing a workplace to make sure that there is co-operation and co-ordination to ensure that respective duties under the law are met. Everyone in the workplace needs to be sufficiently informed about **all** the risks that may be present, eg by exchanging information about the nature of the work being undertaken.

42 If there is no controlling employer in charge of the workplace, then those using the workplace will need to agree joint arrangements to meet the requirements of the law, eg the appointment of a health and safety co-ordinator.

43 Once arrangements are agreed, it is recommended that they are documented and signed by all those concerned.

MHSWR<sup>4</sup> regulation 3  
COSHH<sup>1</sup> regulation 6

### Risk assessment

44 Central to most health and safety legislation is the requirement for an assessment of the risks arising from work. A risk assessment is simply a means of determining the risk associated with work with a particular hazard. In the workplace, this is most often broken down into five steps:

- hazard identification;
- deciding who is at risk from the hazard and how harm could arise (see Information box 2);
- assessing how likely it is that harm will arise and whether existing precautions are adequate;
- making a record of findings, including the control measures you have selected and any action you have identified as necessary to reduce the risk of exposure further; and
- reviewing and revising the assessment as necessary especially if the nature of the work changes or if something else suggests that it may no longer be valid, eg as a result of an incident.

#### Reference box 3 HSE risk assessment guidance

Specific guidance on risk assessment for the healthcare and laboratory sector is given in Parts 2 and 3, but general HSE guidance on risk assessment can be found in:

- *Five steps to risk assessment*;<sup>38</sup>
- *A guide to risk assessment requirements*;<sup>39</sup>
- *Infection at work: controlling the risks*.<sup>22</sup>

45 Your assessment needs to be 'suitable and sufficient'. It should:

- reflect the nature of the work activity being assessed - the more hazardous a scenario, the more in-depth the assessment required;
- draw on specialist advice as required, eg from the infection control department, health and safety advisors;
- consider all those who may be affected by the work (see Information box 2);
- anticipate foreseeable risks (see also paragraphs 62-68); and
- be appropriate to the nature of the work and identify how long the assessment is likely to remain valid.

#### Information box 2 Those affected by the work

In addition to those directly involved in the work, your assessment should consider all those who may be affected by the work. You should also consider:

- those who may be at greater risk, eg new and expectant mothers,<sup>40, 41</sup> those whose immune system is not fully functioning (eg because they are undergoing medical treatment, they have had their spleen removed);
- those who may not be in the workplace all of the time, eg cleaners, engineers, maintenance/service workers, students; and
- members of the public, eg visitors.

MHSWR<sup>4</sup> regulation 4  
COSHH<sup>1</sup> regulation 7

## Controlling the risks

46 The methods chosen to control the risks identified by the risk assessment should follow the hierarchical approach which is common to both MHSWR and COSHH. The hierarchy reflects the fact that eliminating and controlling risk by using physical engineering controls and safeguards is more dependable than relying solely on systems of work:

- **eliminating risks:** eg by substituting a hazardous biological agent with something less/non-hazardous, eg using a non-toxigenic strain of a biological agent when carrying out laboratory quality control (QC) tests;
- **controlling risks at source:** by using engineering controls and giving collective protective measures priority, eg using a microbiological safety cabinet when work could create an infectious aerosol, or using needle safety devices to prevent and control needlestick injuries (but see Information box 3); and
- **minimising risks by designing suitable systems of working:** eg having an effective hand hygiene policy in place in laboratory or healthcare settings. This option also includes the use of personal protective clothing and equipment (PPE), but PPE should only be used as a last resort after considering elimination or tackling at source.

### Information box 3 The COSHH hierarchy and work with biological agents

Although the principles of the hierarchical approach to control should be applied whenever practicable, there is a slightly different emphasis when working with biological agents. For example, all laboratory workers wear protective clothing in the form of a laboratory coat, but may not always need to use a microbiological safety cabinet. In addition, the physical control measures in place are underpinned by the principles of good microbiological practice, eg the use of good aseptic techniques. Such techniques need to be taught and practiced as part of the training for the work to ensure competence, both in terms of scientific technique and safe working practices.

In the healthcare setting, reducing and controlling the risk of incidental exposure may be more reliant on safe systems of work and the use of PPE rather than the use of containment.

47 In addition to the general controls outlined in paragraph 46, COSHH also sets out a number of specific measures which must be used to control exposure to biological agents, as indicated by the risk assessment (Table 1).

48 COSHH also specifies the **minimum** containment measures to be applied when working with biological agents in laboratories, animal rooms and in industrial processes (Table 2). Some of the measures listed in Table 2 may need to be used when nursing patients (humans or animals) that are infected, or are suspected of being infected, with HG3 or HG4 biological agents (see Part 2, paragraph 138).

49 Further guidance on containment and control in laboratories can be found in Part 3 (see also *The management, design and operation of microbiological containment laboratories*).<sup>11</sup>

**Table 1** General COSHH measures to control exposure to biological agents

Measure	Notes
Displaying suitable and sufficient warning signs, including the biohazard sign.	For example, displaying the containment level (CL) on a laboratory door, displaying signs on patient isolation rooms to indicate the types of controls required when in the room, eg barrier nursing.
Putting in place appropriate decontamination and disinfection procedures.	You need to consider spectrum of activity, presence of inactivating agents and contact and duration of exposure of the disinfectant to the biological agent.
Putting in place the means for the safe collection, storage and disposal of contaminated waste. This includes the use of secure and identifiable containers after treatment if appropriate.	Waste needs to be segregated at source, eg clinical and non-clinical, and arrangements need to be put in place to ensure that exposure to clinical waste is controlled both when being stored and when being transported within and from premises.
Testing, where it is necessary and technically possible, for the presence of biological agents outside primary physical containment.	Examples of testing include the Aperture Protection Factor Test for microbiological safety cabinets, testing of integrity of seals, filters etc in a bioprocessing plant environment, or environmental sampling in food testing laboratories.
Setting out the procedures for working with (and on-site transport of) biological agents or material that could contain them.	Work with biological agents could be covered in local codes of practice or standard operating procedures, or else form verbal instructions to employees if appropriate. When considering transport, remember to consider all forms including pneumatic tubes. Where transport of material such as clinical specimens needs to go via the public highway, these will need to be carried in accordance with the relevant standards in carriage of dangerous goods regulations (See Appendix 1.2).
Where appropriate, making effective vaccines available to employees who not already immune.	See Information box 6.
Putting in place good occupational hygiene measures including the provision of appropriate and adequate washing and toilet facilities. Where appropriate, eating, drinking or smoking is prohibited in any workplace where there is a risk of contamination with biological	These are the central, basic measures to control infection in any work setting. General guidance on the provision of welfare facilities can be found in the Approved Code of Practice <sup>42</sup> that accompanies the Workplace (Health, Safety and Welfare) Regulations 1992. <sup>43</sup> Very high standards of good occupational hygiene will be required in healthcare and laboratory settings.

**Table 2** COSHH containment measures for the laboratory, animal room or industrial processes

	Containment Level		
	2	3	4
<b>Air handling</b>			
The workplace is to be maintained at air pressure negative to atmosphere	No	Yes	Yes
Input air and extract air to the workplace are to be filtered using high efficiency particulate absorption (HEPA) filters or equivalent	No	Yes, on extract air	Yes, on input and double on extract air
<b>Security and access</b>			
The workplace is to be separated from any other activities in the same building	No	Yes	Yes
Access is to be restricted to authorised persons only	Yes	Yes	Yes, via air-lock key procedure
Efficient vector control, eg rodents and insects	Yes, for animal containment	Yes, for animal containment	Yes
Safe storage of a biological agent	Yes	Yes	Yes, secure storage
An observation window, or alternative, is to be present, so that occupants can be seen	No	Yes	Yes
A laboratory is to contain its own equipment	No	Yes, so far as is reasonably practicable	Yes
<b>Disinfection and disposal procedures</b>			
The workplace is to be sealable to permit disinfection	No	Yes	Yes
Specified disinfection procedure	Yes	Yes	Yes
Surfaces impervious to water and easy to clean	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes, for bench, floor, walls and ceiling
Surfaces resistant to acids, alkalis, solvents, disinfectants	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes, for bench, floor, walls and ceiling
Incinerator for the disposal of animal carcasses	Accessible	Accessible	Yes, on site
<b>Protective equipment and procedures</b>			
Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable equipment	Yes, where aerosol produced	Yes, where aerosol produced	Yes

**Note:** Where there are human patients or animals that are, or are suspected of being, infected with a HG3 or HG4 biological agent, the most appropriate control and containment measures from this table should be selected with a view to adequately controlling the risk.

## COSHH<sup>1</sup> regulations 8 and 9

### Use and maintenance of controls

50 COSHH requires that your employees use the control measures you provide, including PPE, properly and report any problems with them to you. You need to take all reasonable steps to make sure that the control measures are used, which is why you need to provide information and training as well as appropriate supervision of employees.

51 Any equipment (not just that used to control exposure) provided for use at work has to meet the requirements of the Provision and Use of Work Equipment Regulations 1998.<sup>44, 45</sup> These regulations require that the equipment you provide for use at work is:

- suitable for the intended use;
- safe for use, maintained in a safe condition and (in certain circumstances) inspected to ensure this remains the case (see paragraph 52);
- used only by people who have received adequate information, instruction and training; and
- accompanied by suitable safety measures, eg protective devices, markings, warnings.

52 If you use any engineering controls, including respiratory protective equipment (RPE) to control exposure, then you need to make sure that they are kept in efficient working order and good repair. You will need to carry out regular examination and testing of the controls. In the case of local exhaust ventilation, eg microbiological safety cabinets (MSC), or room air HEPA filtration systems, this needs to take place at least every 14 months. However, there are certain circumstances when more frequent checks should be carried out, eg when using a MSC with HG3 or HG4 biological agents. Further information on recommended testing frequencies for MSCs is given in Appendix 6 of *The management, design and operation of microbiological containment laboratories*.<sup>11</sup>

53 Those working in a laboratory setting are unlikely to need RPE to control exposure for routine work as all work that gives rise to aerosols of infectious material must be carried out in microbiological safety cabinet. However, there may be circumstances when its use is required. For example, following a spillage of infectious material in a laboratory, you may need to use RPE to re-enter the laboratory to set up fumigation equipment (but see Appendix 3 of the *Management, design and operation of microbiological containment laboratories*).<sup>11</sup>

54 If RPE is used to control exposure to biological agents (or other hazardous substances), then you need to ensure that selected RPE has the potential to provide adequate protection for individual wearers. You can do this by carrying out a face-fit test.<sup>46</sup> If RPE is used to control exposure to biological agents, you should use filter-type RPE that controls exposure down to the lowest levels, ie the highest efficiency P3.<sup>47</sup>

55 The type of RPE will also depend on the nature of the work that is being carried out. You need to think about the work rate, the length of time that your workers will need to wear the RPE, and the environment where the work will be carried out. You should also think about possible contamination by skin contact or splash (hoods, blouses and suits may be preferable if this is a significant problem). At the same time, consider the need for protection against chemicals, gases/vapours, oxygen deficiency, physical hazards and humid and hot environments. This will help to identify what other PPE should be compatible or integral with the chosen RPE and help to control secondary risks.<sup>48</sup>



56 Any non-disposable PPE, eg laboratory coats, overalls or aprons, must be stored in appropriate facilities (separately from usual outdoor clothing), checked and kept clean and, if faulty, repaired or replaced (see Information box 4). If PPE may be or has been contaminated by biological agents, it must be removed safely before leaving the workplace and kept apart from uncontaminated PPE and normal 'street' clothes. It should be cleaned and decontaminated or, if necessary, destroyed.

#### Information box 4 Uniforms and PPE

Uniforms are not PPE as defined in the regulations<sup>48</sup> but PPE includes protective clothing such as aprons, which may be worn over uniforms or normal clothing to control the risk of contamination. If uniform/personal clothing is contaminated, there should be spare clothing available for staff to use, eg theatre scrubs, disposable boiler suits.

Your risk assessment should identify how uniforms/protective clothing could become contaminated and how decontamination will be carried out (if items are not disposable).

MHSWR<sup>4</sup> regulations 11  
and 13  
COSHH<sup>1</sup> regulation 12

#### Information, instruction and training

57 Employers have responsibilities under health and safety legislation to provide suitable and sufficient information, instruction and training for their employees.

58 Employees need to know:

- what biological agents they could be exposed to and the risks created by any exposure;
- the main findings of your risk assessment;
- the precautions they should take to protect themselves and other employees;
- how to use any PPE and clothing that is provided; and
- what procedures to follow in the event of an emergency.

59 You will need to ensure that employees are kept up to date with any changes that may take place that could affect the risk and, if necessary, carry out further training. The training provided needs to be appropriate to the level of risk involved, and in a format that will be understood. You also need to make sure that the training achieves its desired outcome by having some form of evaluation process in place.

60 You also have a specific duty to consult with your employees on health and safety matters. The Safety Representatives and Safety Committees Regulations 1977<sup>49</sup> and the Health and Safety (Consultation with Employees) Regulations 1996,<sup>50, 51</sup> require you to consult trade union safety representatives, other employee representatives or employees (if there are no formal representatives) about health and safety matters. This includes:

- information about the risks and the control measures that are in place;
- changes to the work that may affect employee health and safety;
- arrangements for getting competent help; and
- plans for health and safety training.

61 You should also make sure that other people who may be affected by the work, eg maintenance staff or external contractors, receive sufficient and

appropriate information, instruction and training about the hazards they may encounter. They should also be appropriately supervised while carrying out their work. One means of ensuring that work is carried out safely is to use a permit-to-work system.<sup>52</sup>

**MHSWR<sup>4</sup> regulation 9**  
**COSHH<sup>1</sup> regulation 13**

### **Handling incidents/emergency planning**

62 There is a statutory requirement to report infections at work and dangerous occurrences which result in, or could have resulted in, the release of a biological agent that could cause a severe infection under RIDDOR<sup>5</sup> (Appendix 1.1). In addition, a local record should be kept of all incidents (including near misses) involving infectious material. This identifies problem areas and allows checks to be made on the effectiveness of control measures already in place. This information might be kept by the safety department or infection control team, or it might be part of a larger risk management scheme, eg as is required in the NHS.

63 MHSWR and COSHH both require arrangements to be made to deal with emergencies, eg to deal with fire or flooding. COSHH specifically deals with events that expose employees to hazardous substances, such as biological agents, well beyond that associated with day-to-day work activities.

64 Emergency plans need to include:

- the foreseeable types of incidents, accidents or emergencies that might occur;
- the role, responsibilities and authority of individuals during an emergency;
- procedures for employees to follow – including regular safety drills and identifying the special needs of any disabled employees;
- the safety equipment and PPE to be used;
- arrangements for liaison with emergency services;
- first-aid facilities (see also Information box 5); and
- procedures for cleaning up and disposal of waste.

65 In addition to the general requirements of COSHH with regards to plans, there are specific requirements for dealing with incidents involving the release of a HG3 or HG4 biological agent. For example, this could include dealing with spillages outside the confines of a microbiological safety cabinet in a laboratory, failure of sterilizing equipment in a central sterile services department (CSSD), or positive pressurisation of a TB isolation room.

66 You should display the procedures for dealing with such a release if it would help employees to have instant access to the emergency procedures, or if by having such information displayed in a prominent position, the likelihood of incidents occurring is reduced. Employees have to report such releases to you straight away (this includes anyone with responsibility for health and safety). Given this need for reporting it is important that your employees are trained to deal with such incidents and know who to report to.

67 As part of the increased surveillance of healthcare-associated infections, NHS trusts also have to report serious untoward incidents associated with infection. This is done via their normal reporting system for all 'Serious Untoward Incidents'. Such untoward incidents associated with infection are those that produce, or have the potential to produce, unwanted effects involving the safety of patients, employees or others (see Information box A1 in Appendix 1.1).

68 Regulation 21 of the Genetically Modified Organisms (Contained Use) Regulations 2000,<sup>7</sup> requires the notification of accidents involving GMOs to HSE.

This may be in addition to reporting to HSE under RIDDOR,<sup>5</sup> eg if a person were to require hospital treatment. Further guidance is available from HSE's Biological Agent Unit.<sup>53</sup>

#### **Information box 5** Exposure to biological agents and post-exposure prophylaxis (PEP)

When preparing your emergency plans, you should consider (in consultation with your occupational health provider) what PEP is available and how it will be accessed. For example, does the treatment need to be given by a qualified medical practitioner? You should make sure that such treatments can be accessed out of hours if required.

Guidance on *HIV post-exposure prophylaxis*<sup>54</sup> has been issued by the Department of Health.

MHSWR<sup>4</sup> regulation 6  
COSHH<sup>1</sup> regulation 11

### **Health surveillance and occupational health**

69 Health surveillance is about putting in place procedures to detect early signs of work-related ill health among employees exposed to certain health risks, and acting on the results.

70 Health surveillance is required by COSHH (and MHSWR) if you can answer 'yes' to all of the following.

- Is the work known to harm health in some way?
- Are there valid ways of detecting the disease or condition? Health surveillance is only worthwhile where it can be reliably shown that damage to health is starting to happen or becoming likely. The techniques used for detection are only useful if they provide accurate results and are safe and practical.
- Is it reasonably likely that damage to health may occur under particular conditions at work?
- Is surveillance likely to benefit the employee?

71 The benefits of health surveillance are that it can:

- provide information so you can detect harmful health effects at an early stage, so protecting employees and confirming whether they are still fit to do their jobs;
- check that control measures are working well by giving feedback on risk assessments, suggesting where further action might be needed and what it might be;
- provide data, by means of health records, to detect and evaluate health risks;
- provide an opportunity to train and instruct employees further in safe and healthy working practices, eg how to use PPE properly; and
- give employees the chance to raise any concerns about the effect of their work on their health.

72 In practice, health surveillance for biological risks (as strictly defined) may not be appropriate. The circumstances where it may be useful could be where the agent causes serious disease which might have an insidious onset, and for which there is effective treatment available. However, it is important that you do not think of it in isolation from other health monitoring or occupational health procedures. For example, for many infections, a high level of personal vigilance by workers is required so that prompt medical attention is sought if they develop early signs of infection, eg for leptospirosis. Some people may call this health surveillance.

73 Another example is checking to see if workers are immune to a potential occupational infectious agent that they could be exposed to in the course of their work, either incidentally or else if they are working with the agent. This could be carried out as part of pre-employment screening, or else by making checks on immunity following a course of vaccination, eg hepatitis B. You might also carry out immunity checks following an incident. You should make sure that your procedures, including pre-employment screening, ensure that those who may be at additional risk are identified, and any additional controls put in place to protect them (see Information box 2).

#### Reference box 4

Further and/or sector-specific advice on occupational health and health surveillance can be found in:

- *Health surveillance at work*;<sup>55</sup>
- *Management of occupational health in the health services*.<sup>56</sup>

74 The exact term used is not as important as understanding the principle that information, training and health checks amounting to health surveillance (as defined) often go closely in hand. Further advice can be obtained from HSE's local offices via specialist medical and occupational health inspectors.

75 If you are carrying out checks on employees' health, you must keep an up-to-date record for each individual. The key features of a health record are given in COSHH (regulation 11) and should include:

- personal details of the individual;
- an historical exposure record - this could include a record of exposure to HG3 or HG4 biological agents, as required by COSHH (see paragraph 77-80); and
- dates and records of any immunisations and the results of any checks on levels of immunity. This should address the individual's fitness for work or any specific precautions that should be taken.

76 A health record should not include any confidential clinical information. This is because it is not the same as a clinical record, as it needs to be accessible by the employer to help inform local risk assessments to enable appropriate controls to be put in place. For example, a manager needs to know whether someone is immune or not, but not necessarily the level of immunity or any reasons for lack of immunity. This latter, more detailed information could be kept with the clinical record.

#### Information box 6 Immunisation

COSHH requires that if the risk assessment shows there to be a risk of exposure to biological agents for which effective vaccines exist, then these should be offered if the employee is not already immune. The pros and cons of immunisation/non-immunisation should be explained when making the offer.

You should also be aware that the HSW Act<sup>3</sup> requires that your employees are not charged for protective measures such as immunisation. Employees may not wish to take up the offer of immunisation, or else do not respond to a vaccine. If so, you should carry out a local assessment to determine the likelihood of infection for that particular individual carrying out the work that could result in exposure. If existing controls are not thought to be adequate then adjustments to work should be made to allow them to work safely. This might include the provision of extra

**Information box 6** Immunisation (continued)

PPE. Immunisation should only be seen as a useful supplement to reinforce physical and procedural control measures, not the sole protective measure.

Specific guidance on hepatitis B immunisation in the healthcare sector, including advice on non-responders, can be found in a number of Department of Health publications including: *Guidance for Clinical Health Care Workers: Protection Against Infection with Blood-borne Viruses*,<sup>18</sup> *Protecting healthcare workers and patients from hepatitis B*,<sup>57</sup> *Health Clearance for Serious Communicable Diseases: New Health Care Workers*.<sup>58</sup>

Information about vaccines available in the UK can be found in a Joint Committee on Vaccination and Immunisation publication *Immunisation against infectious disease*.<sup>59</sup> Some vaccines may not be licensed for use in the UK but may be available on a named patient basis. The use of a vaccine should be considered in the light of an assessment of the risk of exposure and in consultation with your occupational health provider and those who are to be immunised.

**Exposure records**

77 COSHH<sup>1</sup> requires that you keep a record of employees exposed to HG3 or HG4 agents at work for 40 years following their last exposure. The record is required for all those who deliberately work with such agents, so anyone working with such agents in a laboratory should be recorded.

78 The rationale for keeping such records is to allow occupational health monitoring of exposed workers if new data becomes available about the agents. Such records may also have value in compensation procedures. Although many of the infections caused by HG3 and HG4 infections will be acute and occur shortly after exposure, others can cause illnesses such as cancer many years after exposure, eg hepatitis C. Some infections may be associated with an acute illness, but may have longer-term chronic ill-health effects too, eg there is evidence linking *Salmonella typhi* with hepatobiliary cancer.

79 A record is required where there is a likelihood of exposure, not just when there has been a known incident or accident. It should indicate the type of work done and (where known) any specific exposures, incidents or accidents (some of which may be reportable under RIDDOR).<sup>5</sup>

80 For those not working with such agents but who may be incidentally exposed, eg healthcare workers, if the risk assessment indicates that there is a significant risk of exposure, then these employees should also be recorded. The risk is deemed significant if more than basic hygiene measures are needed to protect employees. For example, employees providing routine clinical care for patients infected with HG3 agents (see Part 2 for examples) on an open ward would not need to be recorded. However, if infected patients are handled in isolation facilities, then those employees exposed should be recorded.

**Other relevant legislation and guidance**

81 Clearly there will be other mandatory requirements that you also need to comply with when working with biological agents. For example, you will need to consider whether there are risks to the public or the wider environment arising from the work that you do.

82 Appendix 1.3 lists the main legislation and guidance (not an exhaustive list) that should be considered, together with relevant British Standards.

# Part 2 Working in healthcare

## Introduction

83 The extent to which healthcare employees will be exposed to biological agents during the course of their work will vary. Some will be directly exposed to infection, eg clinical and nursing employees caring for a patient with TB or a veterinary surgeon examining animals infected with a zoonotic disease. Others may be exposed to potential sources of infection, eg the porter who transports specimens from ward to laboratory and other ancillary employees who remove clinical waste or clean wards or surgeries.

84 This section of the guidance focuses on the risks to those more directly involved in patient care where the risk of exposure is likely to be greater than for those who are more likely to be incidentally exposed to biological agents as part of their work.

**Note:** The term 'patient' is used in this guidance to cover both humans and animals receiving medical treatment.

85 The guidance for those involved in animal care is most likely to be of more use to those working in larger facilities such as veterinary hospitals, although it may be of some use to those in small practices. However, there is also general ACDP guidance on risk assessment, *Infection at work: controlling the risks*,<sup>22</sup> that may be more practical for smaller premises.

86 The aim of this guidance is not to further increase the burden on the healthcare sector, but to show how the process of risk assessment is an integral part of managing the control of infection, and that the control measures required by health and safety legislation should already largely be in place as part of the infection control policy. Appendix 2.1 maps the various control measures given in COSHH<sup>1</sup> against those indicated in some of the existing (human) healthcare guidance on infection control.

## Human healthcare

### Population

87 Healthcare is a major employer in Britain, and spans both public and private sectors. The NHS is Britain's largest employer, with around one million employees. Healthcare services are provided by over 500 NHS trusts and by primary care services (GPs and dentists).

### Risk of infection

88 The estimated prevalence of healthcare-associated infection (ie infections in patients) is about 9% in England. However, the extent to which hospital employees themselves are affected by infections acquired at work is not known. Although apparently low, it is likely to be subject to under-reporting. Reports to a specialist

surveillance scheme<sup>60</sup> indicate that healthcare workers, particularly care assistants and attendants, have the highest estimated number of cases of work-related infections.

## Animal healthcare

### Population

89 There are around 14 000 registered veterinary surgeons working in the UK, an estimated 9000 of whom work in around 2300 private practices. Of the remainder, the main employers are government (eg DEFRA, the Veterinary Laboratories Agency and the Meat Hygiene Service), followed by universities, industry and various charities. Many vets work both in private practice and for the government. Around 3% of vets work in specialist practices offering only a referral service for other practices. The organisation of private veterinary practice has changed enormously over the past 20 years. There has been a move away from small, 'one-man' practices to much larger organisations employing several vets and many support employees. The proportion of veterinary time spent on companion animals rather than food-producing animals has increased year-on-year, although the veterinary profession has also taken on an increasing role in being responsible for the safety of human foods.

### Risk of infection

90 As in human healthcare, there is little information available on work-acquired infections amongst animal healthcare workers. A recent study<sup>61</sup> in Austria showed vets (and farmers and slaughterhouse workers) to be at higher risk of infection from a number of zoonoses than the population at large. Such infections are, however, probably very much under-reported. This is because, in part, many cases will be sub-clinical or go undiagnosed, but also because some infections will be regarded as 'part of the job'. Many veterinarians working with sheep would view orf (a parapoxvirus infection) as something not worth consulting their GP about, while infections from bites and scratches are not uncommon in small animal practice, and only severe cases would lead to medical advice being sought.

## Infection control

91 The traditional approach in the healthcare setting has been to control exposure to biological agents by following the infection control policy, which may include the use of universal or standard precautions (see Information box 7). Although the primary aim of such a policy is to protect the patient and prevent the spread of infection within a healthcare setting, the measures taken also have the effect of protecting employees.

92 Control of infection is important at all levels throughout the healthcare environment. Policies should cover all areas where there is potential exposure to a range of biological agents. This will include patient care areas such as wards, surgeries and operating theatres. They should also cover service departments such as sterile services, and domestic services such as cleaning, laundry and portering.

93 Infection control policies usually include protocols on, for example, hand washing, patient isolation, aseptic procedures, disinfection and decontamination, including domestic cleaning and waste disposal procedures.

94 Infection control policies are important in complying with relevant duties in health and safety legislation, but the policies tend to focus on how to control risks, and may not necessarily address the assessment of risk *per se*. That is not to say that the policies have not at some point been informed by a generic assessment of



the risks. However, those actually carrying out the work need to have an understanding of the risks they face. This should then help employees to work safely if faced with a situation that is not fully described in the infection control policy.

#### **Information box 7** Universal precautions (also known as standard precautions)

Universal precautions, as originally defined by the Centers for Disease Control in the US, were the precautions taken to control exposure to blood and body fluids that had been implicated in the transmission of blood-borne infections. The precautions did not apply to other body fluids and excreta unless they contained visible blood. However, the concept has been applied to other potential sources of infection in the healthcare setting. The precautions allow a basic level of infection control in the absence of information about the infection status of an individual, but where the infection status of a patient is known, additional precautions may be required.

### **Approach to assessment**

95 An organisation's health and safety policy must set out (in general terms) how risks such as occupationally-acquired infection will be managed. For the management of infection risks to be successful, an understanding of how such risks are assessed and managed must be present at all levels – from managers to clinical and nursing and support staff.

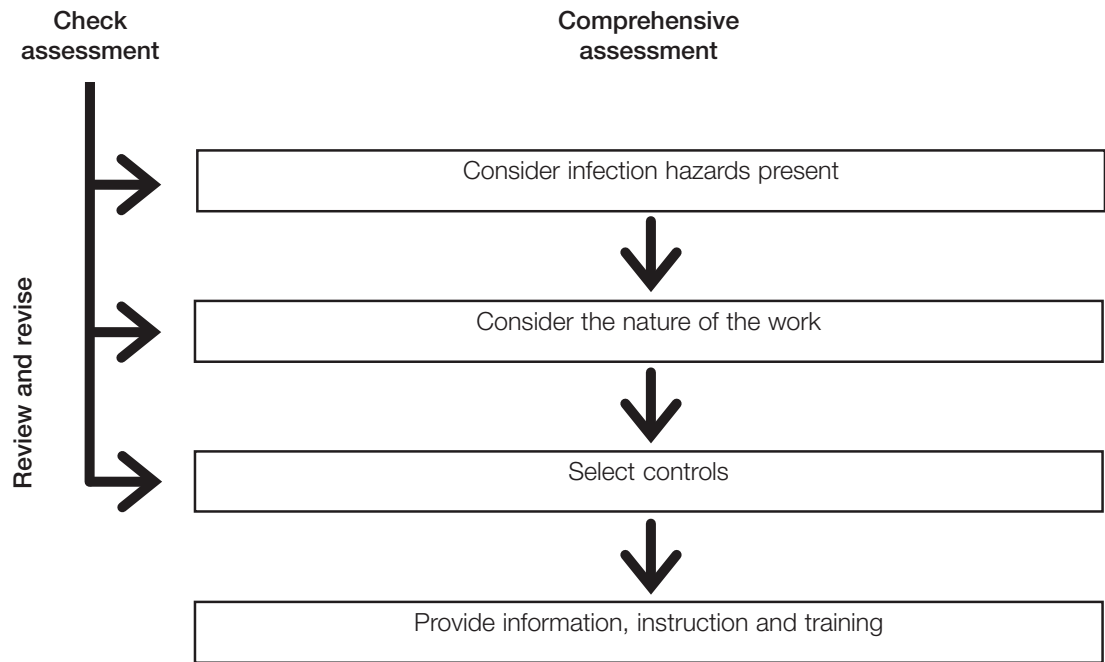
96 A local assessment of the work should be carried out by those in charge of a particular work area, eg a ward, an operating theatre, or a veterinary practice. The definition of 'local' will depend on the complexity of the organisation in question. For example, a small veterinary practice may have assessments that cover the whole premises whereas a large hospital may have ward or room-specific assessments.

97 The main infection hazards that are likely to be encountered when carrying out particular work activities should be identified in the assessment. The results of your assessment should be recorded and so inform the local working practices, eg the control of infection policy. Employees must then receive appropriate information, instruction and training about the risks and how those risks will be controlled.

98 Employees can then use this information on a day-to-day basis to check the assessment of specific tasks and activities. This is not a formal paper-based assessment process but an opportunity to mentally review the various steps of the comprehensive assessment and revise as necessary. The process is shown in Figure 3.

99 Any significant changes, eg to reflect new information about a particular infectious disease, should be fed back into the comprehensive assessment which can be updated.

Figure 3 Assessing the risks



### Assessing the risks

#### Stage 1: Identify the hazards

100 The nature of work in healthcare means that your employees will come into contact with a number of sources of infection, either through direct contact with patients or with contaminated materials, including waste. These may include:

- blood, body fluids and body parts;
- excreta - faeces, urine and vomit;
- direct skin contact; and
- respiratory secretions and excretions.

101 Each source of infection is likely to be associated with a particular type of micro-organism (or group of organisms). These can be characterised in terms of:

- how the micro-organism is transmitted, eg by contact (see Table 3). Some micro-organisms can be transmitted by more than one route, and this will need to be reflected in the controls used;
- the severity of the disease caused by the micro-organism and the symptoms associated with the disease;
- how easily the disease is spread (communicability);
- whether there is a vaccine available (or post-exposure prophylaxis); and
- how well the micro-organisms survive in the environment – this should include a consideration of susceptibility to disinfectants, and can be used to inform ward/room cleaning regimes (both routine and emergency) and physical inactivation methods, eg autoclaving, for decontamination of objects.

102 COSHH<sup>1</sup> also refers to classifying biological agents into Hazard Groups; agents are classified into one of four Hazard Groups based on their ability to **infect** healthy adult humans. The ability to infect such people is based on some of the

criteria listed in paragraph 101 (see paragraph 17 for details). You do not need to classify all the agents that could be present for the purposes of your assessment but knowing the Hazard Group will assist in the selection of control measures to some extent. It should also help guide you as to when you need to consider using additional measures (see paragraph 109). The Hazard Group of some of the more common disease-causing agents in the healthcare setting are given in Table 3.

103 Although the identity of any infectious agent in a patient may not be known, identifying the most likely micro-organisms that could be present in each source of infection will allow appropriate selection of control measures. Where the status is known, additional measures may be required to control exposure (see Stage 3).

### **Stage 2: Consider the nature of the work**

104 For the purpose of assessment, you may find it easier to break the work down into discrete activities, eg changing a dressing, administering injections or gene therapy, and disposal of waste. Consider in particular:

- where the work will be carried out, eg in an isolation room or in the general ward environment – this will give you an indication of who could be exposed;
- whether the work:
  - could create airborne particles, eg splashes or aerosols; or
  - will require the use of sharps;
- who will be carrying out the work – this will help you identify whether they are part of any 'vulnerable' group (see Information box 2);
- whether others (those not actually doing the work) could be affected by the work, eg visitors, cleaners, maintenance workers;
- whether the work is routine or only carried out on an infrequent basis – this will have implications for the information, instruction and training given to those carrying out the work.

**Table 3** Examples of infections and routes of transmission

Route of infection	Examples:		
	Type of disease	Organisms	Hazard Group
<b>Contact:</b> either direct via hands of employees, or indirect via equipment and other contaminated articles	Gastrointestinal disease	<i>E. coli</i> O157	3
		<i>Salmonella typhi</i>	3
		<i>Clostridium difficile</i>	2
		<i>Campylobacter jejuni</i>	2
		Hepatitis A	2
	Skin and soft tissue infections	<i>Staphylococcus aureus</i> (including MRSA)	2
		Ringworm	2
		Orf	2
	Viral respiratory tract infections	Respiratory syncytial virus	2
<b>Droplet:</b> large particles that do not remain airborne for very long and do not travel far from source	Respiratory tract infections	<i>Bordetella pertussis</i>	2
		Mumps	2
	Infectious rashes	Varicella zoster	2
	Meningitis	<i>Neisseria meningitidis</i>	2
<b>Airborne:</b> small particles that can remain airborne and travel considerable distances	Respiratory tract infections	<i>Mycobacterium tuberculosis</i>	3
		<i>Mycobacterium bovis</i>	3
		Avian flu	3
		<i>Chlamydia psittaci</i>	3
	Infectious rashes	Rubella	2
<b>Blood-borne:</b> either direct contact with blood or body fluids (or via skin-penetrating injury) or indirect via contaminated articles, eg dressings	Hepatitis	Hepatitis B	3
		Hepatitis C	3
	Immune system disease	HIV	3
		HTLV	3

### Stage 3: Evaluate the risks and select controls

105 The next stage is to consider how likely it is that each hazard can cause harm (ie the risk) which will determine whether measures need to be taken to reduce the risk. The primary duty in COSHH<sup>1</sup> is to prevent exposure to biological agents, but if this cannot be achieved then exposure needs to be controlled. There is a general hierarchy of controls that needs to be considered first as follows:

- controlling exposure at source, eg having a clinical waste policy which ensures safe collection, storage, transport and final disposal of such waste;
- designing and using appropriate work processes, systems and engineering controls and providing and using suitable work equipment and materials, eg preparing a hand washing policy that is monitored and providing appropriate facilities for employees to use; and
- providing suitable PPE in addition to the above, eg using gloves where there is potential for exposure to blood, as well as following general hygiene measures.

106 Reducing and controlling the risk for incidental exposure in the healthcare setting may be more reliant on safe systems of work and the use of PPE rather than the use of containment, although preventing or controlling exposure by this means should be considered in the first instance (as set out in paragraph 105).

107 COSHH also sets out a number of general measures that are to be applied to control exposure to biological agents (see Table 1). In the healthcare setting, you should use these (as required by the risk assessment) where there are patients infected with HG2 agents (see Table 3). However, certain HG2 infections may require extra measures to control the risk of infection. For example, a decision might be made to isolate patients infected with *Neisseria meningitidis*, a HG2 agent. In this situation, employees should wear appropriate RPE when carrying out certain procedures; visitors might also be advised to wear masks.

108 Most of the measures in Table 1 should be familiar from the infection control policy, and control of exposure to most infections should be achievable using these general measures. Appendix 2.1 maps these measures against those in existing (human) healthcare guidance on the control of infection.

109 Where patients are infected with HG3 or HG4 agents, the need for additional control measures should be considered. These control measures are shown in the first column of Table 4 (see Information box 9 for specific information on patients infected with HG4 agents). You will not need to use all the measures in any given situation, but you need to consider and use a particular measure if it could reduce the risk of exposure to infection. Some of the measures are particularly relevant when isolation is being considered; the degree of isolation (and consequent containment) will depend on the degree of suspicion about the nature of infection. For example, a patient may be physically isolated on first admission pending initial tests, but moved to more appropriate isolation, eg a negative pressure room, once the exact nature of the infection has been determined. Although this guidance focuses on the concept of isolation, some of the measures may also need to be considered in other areas where infectious patients may be treated, eg during surgical procedures (see Information box 8).

110 A summary of the measures that should be considered to control exposure to certain infections (depending on the route of transmission) is given in Table 4. If used, these are of course **in addition** to routine control measures such as hand washing, cleaning and disinfection. The guidance in paragraphs 112-138 explains how these measures control exposure in a healthcare setting and the issues that need to be considered to ensure that the measures are effective.

111 Some measures can be implemented easily by means of incorporation into current work practices and procedures. Others may require more fundamental changes to building structures, eg the provision of lobbies for negative pressure rooms, and so may only be considered when new facilities are constructed or existing facilities are to be refurbished. If the risk assessment indicates that such measures are required to control the risk, then they should be put in place as soon as is practicable.

**Table 4** Additional COSHH control measures to be considered for certain infections (by route of transmission), ie plus standard COSHH precautions

COSHH control measures	Route of infection			
	Airborne	Droplet	Contact	Blood-borne
<b>Air handling</b>				
Maintaining the workplace at air pressure negative to atmosphere	Yes	Consider	No	No
Filtering extract air using high efficiency particulate air (HEPA) filters (or equivalent)	Consider (see paragraph 120)	No	No	No
<b>Security and access</b>				
Separating the workplace from other activities	Yes	Yes	Yes	No
Limiting access to authorised persons	Yes	Yes	Yes	No
Safely storing biological agents (or material that may contain them)	Yes	Yes	Yes	Yes
Having a means of viewing patients in rooms	Yes	Yes	Yes	Yes (if in separate room)
Using dedicated equipment	Yes	Yes	Yes	Yes
<b>Disinfection and disposal procedures</b>				
Having a room that is sealable for fumigation	Consider (see paragraph 133)	No	No	No
Having disinfection policies in place	Yes	Yes	Yes	Yes
Having surfaces, eg floors and walls, that are impervious to water, easy to clean and resistant to commonly used disinfectants	Yes	Yes	Yes	Yes
<b>Protective equipment and procedures</b>				
Isolating infected patients in suitable secondary containment	May need to be considered for certain procedures	No	No	No

## Air handling

### *Maintaining the workplace at air pressure negative to atmosphere*

112 You should use negative pressure rooms when caring for patients infected with respiratory diseases such as tuberculosis, SARS or avian flu. Although not essential for those infected with droplet-transmitted disease, using this measure could provide additional control.

113 'Negative to atmosphere' is generally interpreted as meaning negative relative to the surrounding areas, but not necessarily the external environment. Negative pressure can be achieved by having a ventilation system that ensures a continuous inward airflow into a room. Having an inward airflow means that contaminated air is removed from the room and replaced with clean air, so reducing the risk of exposure for employees both inside and outside the room.

114 Additional controls may be required when employees carry out certain exposure-prone procedures with infectious patients, eg sputum induction in infectious TB cases. Although the hierarchy of controls in COSHH<sup>1</sup> indicates that RPE should only be considered as a last resort, the practicalities of carrying out patient care mean that a combination of approaches should be taken. For example, filtering respirators (not surgical masks) should be used when carrying out procedures that give rise to infectious aerosols (see HPA guidance on SARS<sup>62</sup> for descriptions of types of protection). However, there may be certain procedures, eg laser therapy, where local exhaust ventilation can be used in conjunction with a mask.

#### **Information box 8** Controlling ventilation in healthcare premises

Recent research looking at room design and ventilation effects in the healthcare setting has shown how effective negative pressure can be in controlling the risk of infection. Without an inward airflow, and especially if the rooms can become positively pressurised:

- contaminated air can escape from rooms;
- air can be lost to surrounding areas via gaps in the fabric of the rooms. Inert gas tracer testing has shown that the escaping air can travel some distance with implications for those who may be exposed;
- even in well-designed rooms, performance will be adversely affected if staff continually open and shut doors.

115 Air should move from cleaner areas into the room. This could be achieved on a room-by-room basis or on a wider basis, eg a suite or building. However, it is important to ensure that there is a clear graduation of pressures from the least to the most negative to the area where control is required, ie that housing the infected patient.

116 Air should be discharged to the outside either directly or via the general building exhaust ventilation system. The air should be discharged away from openable windows and other air inlet systems, ie it should not be able to enter other patient areas. Discharge into areas where the general public could be exposed should also be avoided. Air from such rooms should not be recirculated into the general building ventilation systems.

117 If the room is fully mechanically ventilated, ie there is forced inflow and extract of air, these should be interlocked so that if the extract fails, the supply is stopped to prevent positive pressurisation of the room.

118 Ideally windows in such rooms should not be capable of being opened (eg sealed in place or only openable using special tools) to prevent contaminated air leaving the room in an uncontrolled manner. Doors should be kept closed when the room is occupied by an infectious patient.

119 The use of lobbies in a laboratory setting has been shown to increase the containment provided by the room. This is achieved by reducing the escape of potentially contaminated air into the general environment when the room door is opened. Such an approach could provide similar protection if used in combination with a negative pressure isolation room. Lobbies can also serve to remind employees and others they are entering an area of increased risk and that additional precautions may be required to control infection. NHS Estates guidance<sup>21</sup> indicates that lobbies must be used when housing patients infected with MDR-TB.

#### ***Filtering extract air using high efficiency particulate air (HEPA) filters (or equivalent)***

120 HEPA filters should be used to filter air in negative pressure isolation rooms where it is not possible to safely discharge the extracted air (see paragraph 116).

121 If HEPA filtration is used, there is a requirement in COSHH<sup>1</sup> for regular maintenance, examination and testing of such controls. The filters and their fittings and seals need to be thoroughly examined and tested at intervals not exceeding 14 months.

## **Security and access**

### ***Separating the workplace from other activities***

122 This is one of the main principles of isolation, ie controlling the spread of infection by separating the infected patient from others (eg other patients, employees and visitors who could come into contact with them). To reduce such contact, it is better to locate isolation areas/rooms away from main thoroughfares, eg at the end of a ward area.

123 Lobbies can also be used as a means of providing physical separation of the isolation room from the main thoroughfare of a ward area.

124 If there is insufficient space to house patients in isolation rooms on an individual basis, eg during an outbreak, you could locate patients with the same infection as a cohort in small bays. The location and type of bay used will depend on the means of transmission of the infecting organism. For example, for certain infections it would be better to use bays with en-suite toilet and washing facilities that can be separated from the rest of the ward area by means of physical barriers such as doors. Enteric infections and diseases spread by large droplets (as opposed to aerosols) should be managed in this way.

### ***Limiting access to authorised persons***

125 One of the primary control measures required by COSHH<sup>1</sup> is to reduce the number of employees exposed to a substance hazardous to health to a minimum for the work required; in this case the infectious patient. Again, this is one of the key principles of isolation, and one way you can achieve this is to restrict access to the patient room to certain authorised individuals only, eg having dedicated nursing and medical staff per shift.

126 You can impose restriction of access on a room-by-room basis, or else on a bay/ward basis depending on the number of infected patients. This could be achieved by means of signage or else by physical methods such as swipe cards.



127 You need to make sure that others who access the patient room/area, eg visitors and cleaning staff, know about the hazards posed by the infection and the control measures in place, eg the need to wash hands. They should also be provided with appropriate protective equipment. Some degree of supervision may also be necessary to ensure that control measures are used.

128 You should restrict movement of infectious patients outside of isolation. If movement is required, eg for specialist treatment, a risk assessment should be carried out on the process and appropriate controls put in place.

#### ***Safely storing biological agents (or material that may contain them)***

129 On the rare occasions that you handle live biological agents in a clinical setting, eg if you use a live vaccine or are involved in clinical trials involving live micro-organisms (including those that have been genetically modified), you need to store the material in such a way as to control access; this could be within a secure area or else in a lockable cupboard, fridge or freezer.

130 Although biological agents themselves are not generally handled in a clinical setting, contaminated waste from infectious disease patients is likely to contain biological agents. Although this waste will enter the general clinical waste stream for final disposal, it should remain in the room/area in an appropriate container until it can be removed safely.

#### ***Having a means of viewing patients in rooms***

131 Having a means of viewing occupants allows you to make simple visual checks on patients without the need to enter the room. It also allows patients to see out, reducing the sense of isolation that may be an issue for patient well-being. This can be achieved by having windows fitted in internal walls or else by installing viewing panels in doors.

#### ***Using dedicated equipment***

132 Items that come into contact with infected patients have the potential to transmit infection unless appropriately handled. Many items used for patient care will be single-use and should be disposed of in accordance with local policies. Other equipment, eg medical devices, may be reusable but should not be re-used until it has been appropriately cleaned and disinfected.

### **Disinfection and disposal procedures**

#### ***Having a room that is sealable for fumigation***

133 Such a measure is unlikely to be needed on a routine basis as most cleaning, including the 'deep clean' between patients, is likely to be achieved by means of extensive surface decontamination only. However, if you are considering gaseous disinfection (ie fumigation or fogging) in new builds or refurbishments, the room needs to be sealable to contain the toxic gas while the disinfection is in progress (see also *The management, design and operation of microbiological containment laboratories*).<sup>11</sup>

#### ***Having disinfection policies in place***

134 Your policy should address both routine and emergency disinfection and also the cleaning/disinfection that will be required before re-use by another patient.

135 Local policies should indicate the types of disinfectant that are to be used and in what circumstances, eg some disinfectants may not be effective against certain micro-organisms. The policy should also cover the in-use concentration (if not supplied ready for use) and contact time. See *Safe working and the prevention*

of infection in clinical laboratories and similar facilities<sup>14</sup> and NHS Estates guidance on cleanliness in hospitals<sup>63</sup> for further information.

***Having surfaces, eg floors and walls, that are impervious to water, easy to clean and resistant to commonly used disinfectants***

136 Floor surfaces should be selected on this basis, ie carpet is not appropriate in isolation rooms because of the difficulties of both cleaning and ensuring adequate disinfection. The flooring should be smooth, slip-resistant and seamless. However, if joints are necessary, these should be welded or sealed. Ideally the flooring should be coved to the walls to allow easy cleaning.

137 Walls should also be smooth and impervious. Furniture should be kept to a minimum and should be easy to move to aid cleaning, eg on castors.

## **Protective equipment and procedures**

***Isolating infected patients in suitable secondary containment***

138 Although total secondary containment (eg patient isolators) is unlikely to be required (except for those infected with HG4 agents such as Lassa fever (see Information box 9)) certain procedures involving infectious patients, particularly those with respiratory disease such as tuberculosis, may require the use of local containment measures. This could be within the room used by the patient or else in specialised treatment areas such as bronchoscopy suites or rooms used for chest physiotherapy (expectoration).

### **Information box 9** Infection with a Hazard Group 4 biological agent

Patients suspected of being infected with a HG4 agent (see list below) should be admitted (or transferred, if already in hospital) either to an intermediate isolation facility/medium security infectious disease unit or to a High Security Infectious Disease Unit (HSIDU), after consultation with the clinician in charge. The control measures for some of the diseases are set out in specific guidance (see below).

Diseases caused by HG4 agents:

- Lassa fever
- Kyasanur forest disease
- Guanarito haemorrhagic fever
- Omsk haemorrhagic fever
- Argentinean haemorrhagic fever (Junin)
- Russian spring summer encephalitis
- Bolivian haemorrhagic fever (Machupo)
- Nipah
- Brazilian haemorrhagic fever (Sabia)
- Hendra

**Information box 9** Infection with a Hazard Group 4 biological agent (continued)

- Crimean/Congo haemorrhagic fever
- Smallpox
- Ebola
- *Herpesvirus simiae* infection (B virus)
- Marburg

Specific guidance: *The Management and Control of Viral Haemorrhagic Fevers*;<sup>10</sup> *Hendra virus and Nipah virus: management and control*.<sup>64</sup>

# Part 3 Working in the laboratory

## Introduction

### *Population*

139 At the time of writing there are around 230 000 people who work in biomedical sciences in the UK - with an estimated 12 500 scientists working in NHS laboratories. However, assessing the real risk of acquiring infection in this occupation is a problem. There is a statutory duty to report occupational infection in the UK (RIDDOR),<sup>5</sup> but estimating the number of laboratory workers who report infections is difficult. In part, this is because laboratory work can be carried out in a number of occupational settings such as medical schools and higher education establishments. There is therefore no single, standard occupational descriptor for laboratory work.

### *Risk of infection*

140 There have been a number of surveys of infection in various types of laboratory. In the UK, there was a series of surveys carried out between 1970 and 1989 looking at the rates of infection among workers in UK clinical laboratories. Data from the 1988/89 survey<sup>65</sup> suggested an infection rate of 82.7 infections per 100 000 person-years. A more recent study<sup>66</sup> of clinical laboratories (1994/95) gave an estimate of infection rates as 16.2 per 100 000 person-years, with the majority of these being associated with HG2 agents in diagnostic laboratories.

141 It might be argued that the apparent reduction in infection rates has come about in part because of ACDP guidance, and more recently the application of COSHH<sup>1</sup> to control exposure. Safety technology has also undergone a period of development and improvement. However, analysis of reports of laboratory-acquired infections is just one means of monitoring the effectiveness of control measures. Other methods would include looking at incidents and accidents involving biological agents. RIDDOR<sup>5</sup> also requires that any incident which results in or could have resulted in the release of a biological agent likely to cause severe human disease is reported (see Appendix 1.1).

## What kind of work?

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

- **intentionally working with the agents and increasing the risk of exposure**, eg by propagation or concentration - guidance on assessing and controlling the risks from this type of work is given in Part 3A (paragraphs 148-165);
- **working with materials that may contain biological agents**, eg diagnostic work - guidance on assessing and controlling the risks from this type of work is given in Part 3B (paragraphs 166-192).

143 Guidance is given on the assessment, but you need to remember that the assessment needs to be recorded, reviewed and revised as necessary – it is a living document. Your assessment also needs to reflect the actual work being carried out, and not simply be a statement of the containment level (or measures) being used.

### What containment measures are required?

144 Although COSHH<sup>1</sup> sets out the minimum containment requirements that must be applied in particular circumstances (Schedule 3, 4(a-f)), there are certain circumstances when not all the measures normally required at a particular containment level need to be applied, because of either the nature of the work and/or the nature of the biological agent.

145 You can take this approach only when working with the **specified HG3 agents in Table 5**. COSHH<sup>1</sup> enables you to do this provided that you follow the guidance on selecting the most appropriate containment measures given in this and other ACDP guidance (see Table 5). Taking this approach is not an automatic right. Any decision to change the containment conditions should be justified in a local risk assessment.

146 It should be noted that changing some of the physical containment measures does not imply that the work can be carried out at containment level 2 (CL2), but, subject to following the guidance set out below, a laboratory that meets the physical containment requirements of CL2 may be appropriate for certain types of work. However, despite the requirements of a CL3 laboratory being outwardly similar to CL2 laboratories, if work with HG3 agents is carried out in a CL2 laboratory, then the standards that must be achieved are higher because of the more hazardous nature of the agents. This is particularly the case for the way in which they are managed, the need for special training, and the degree of supervision.

147 Your assessment should inform employees how the work will be carried out safely, eg in a local code of practice. You will need to consider issues such as:

- **Location of the work:** if your assessment indicates that the physical measures that are normally required at CL3 are not needed to control the risk, does the work still need to take place in a separate CL2 laboratory to control the risks? Or can it be undertaken at a different time from other 'standard' CL2 work in a shared laboratory?
- **Information, instruction and training:** if the work is carried out in a shared CL2 laboratory, are there any implications for training of those not directly involved in the work? For example, have they been informed about the nature of the work (see paragraph 40), and do they know what to do in the event of an emergency, eg a spillage?
- **Access control:** if the work is to take place in a CL2 laboratory, access control is still required. However, you may need to consider the most appropriate CL2 laboratory to use to ensure that you can control access easily.
- **Supervision:** can the work be appropriately supervised both in and out of normal working hours?
- **Use of dedicated equipment:** this is required (so far as is reasonably practicable) at CL3 but the use of dedicated equipment in a CL2 laboratory will reduce the potential for exposure for those not working with the HG3 agents.
- **List of exposed workers:** those intentionally working with HG3 agents will need to have a record kept of their exposure. If the work takes place in a CL2 laboratory used by others, your risk assessment should identify how and if

others could be exposed to the HG3 agents, and so whether they need to have a record of exposure kept.

**Table 5** Selecting appropriate containment measures (COSHH, Schedule 3, paragraph 3(5))

Agent	Guidance on appropriate containment	
	Diagnostic work	Intentional work
<b>Enteric bacteria:</b> <i>Escherchia coli</i> , verocytotoxigenic strains (eg O157:H7 or O103) <i>Salmonella typhi</i> , <i>Salmonella paratyphi</i> , <i>Shigella dysenteriae</i> (Type 1)	Paragraphs 179-183	All intentional work must be carried out at full CL3
<b>Mycobacteria:</b> <i>Mycobacterium microti</i> , <i>Mycobacterium ulcerans</i>	Paragraphs 164-165	
<b>Parasites:</b> <i>Echinococcus granulosus</i> , <i>E. multilocularis</i> , <i>E. vogeli</i> , <i>Leishmania braziliensis</i> , <i>L. donovani</i> , <i>Plasmodium falciparum</i> , <i>Taenia solium</i> , <i>Trypanosoma brucei rhodesiense</i>	Paragraph 188 and checklist	Appendix 3.2
<b>Blood borne viruses:</b> hepatitis B, hepatitis C, hepatitis D, hepatitis E, hepatitis G, human immunodeficiency viruses, human T-cell lymphotropic viruses, hepatitis viruses not yet identified, simian immunodeficiency virus	Paragraphs 184-186 and checklist	All intentional work must be carried out at full CL3
	See also <i>Protection Against Blood-borne Infections in the Workplace: HIV and hepatitis</i> <sup>10</sup>	
<b>Transmissible spongiform encephalopathies:</b> the agents of Creutzfeldt-Jacob disease, variant Creutzfeldt-Jacob disease, fatal familial insomnia, kuru, Gerstmann-Sträussler-Scheinker syndrome, bovine spongiform encephalopathy (BSE) and other related animal TSEs	Paragraphs 190-192	Paragraphs 162-163
	See also <i>Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection</i> <sup>11</sup>	

### Part 3A Working with biological agents

148 This section covers those laboratories intentionally working with biological agents, eg growing and concentrating the agents. This could include teaching, research, development or diagnostic work (if the latter requires the deliberate propagation of agents for the purpose of the test).

149 Specific guidance on:

- work with cell cultures (that have been infected with biological agents or else may contain biological agents) is given Appendix 3.1;
- work with animals that have been deliberately infected with biological agents is given in *Working safely with research animals: Management of infection risks*<sup>12</sup>;
- the large-scale use of biological agents is given in *Large-scale contained use of biological agents*.<sup>67</sup>

#### Assessing the risks Stage 1: Identify the hazards

150 As with any other risk assessment, you need to consider the way in which the hazard, ie the biological agent, can harm health (see also Information box 10).

151 The first stage is to check whether the agent that is to be used has an approved classification, and if it does, the Hazard Group of the agent. Biological agents are classified in the Approved List of biological agents.<sup>24</sup> However, knowing the Hazard Group alone is not sufficient for risk assessment purposes. Although the Hazard Group of the agent is based on some of its hazardous properties, it is not a complete picture, for example, it does not address the route(s) of transmission that may influence the risk assessment in terms of deciding whether additional control measures are required.

152 Table 6 lists the factors that need to be addressed when describing the hazards associated with a particular agent.

**Table 6** Consideration of the hazards

Issue	Notes
<b>Pathogenicity</b>	How severe is the disease caused - morbidity vs mortality; acute vs chronic. Are any groups of people more susceptible to infection? Can the agent cause harm by other means, ie cause an allergy, produce a toxin?
<b>Epidemiology</b>	Consider the natural hosts of the agent and what is known about the incidence of infection.
<b>Infectious dose</b>	Remember that data on infectious doses may be useful but they are limited and can be a function of the immune status of the exposed individual.
<b>Routes of transmission</b>	Remember to consider both natural and potential routes of laboratory transmission - eg an agent that is transmitted naturally via an insect vector could be transmitted in the laboratory via a penetrating sharps injury.
<b>Medical data</b>	Consider whether there are prophylactic treatments available and also whether there is there any known resistance to such treatment. Consider also if there are vaccines readily available (see Information box 4). Consider the symptoms of the infection and if such information can be used for health surveillance purposes (see Part 1, paragraphs 69-76).
<b>Environmental stability of agent</b>	Consider what is known about the agent's survival outside the host, eg can it form spores; how susceptible is the agent to disinfectants (what kinds); and what are the physical inactivation methods?

#### Information box 10 Substitution

Your first duty under COSHH<sup>1</sup> is to prevent exposure to biological agents either by avoiding their use or substituting with a safer alternative. For many types of laboratory work, such as diagnostic work, this may not be possible but it can be achieved in other types of work:

- **Example:** quality control/quality assurance work associated with a screening programme for a toxin-producing food-borne agent such as *E. coli* O157 can easily be carried out using non-toxin-producing strains. Such strains are readily available from culture collections or else as part of commercially available testing kits.
- **Example:** research work looking at the surface transfer of a HG3 agent between food animals could be carried out using appropriate HG1 marker agents.

***What happens if?******You are starting work with an agent for the first time or are starting a new piece of work with an agent that you have not used before***

153 COSHH<sup>1</sup> requires that you notify HSE of the first use of biological agents in Hazard Groups 2, 3 or 4 at a particular premises and also that you notify the subsequent use of any of agent listed in Part V of Schedule 3 at a particular premises. You also have to notify HSE if you plan to move a Hazard Group 4 agent from one premises to another (this includes importing or exporting such an agent into/from the UK to cover transport from the airport to your premises or vice versa). Further guidance on notification can be found in on the HSE website, together with the notification form.

***You are working with an unlisted agent***

154 If the agent does not appear on the Approved List,<sup>24</sup> this does not necessarily mean you should classify it as a HG1 agent. You still need to consider the agent's hazardous properties (if any) to provisionally classify the agent in accordance with COSHH<sup>1</sup> (see paragraph 17) and inform the risk assessment. Although the agent itself may not be listed, the Approved List does indicate whether *some* species in a certain genus may be hazardous by use of the term 'spp'. However, this does not mean that *all* species and strains of that genus are hazardous. You should base your classification and consideration on the best available information. It is recognised that sometimes information may be limited because the agent is newly discovered/emerging. In such situations you may have to classify the agent on a precautionary basis and review this as and when further information becomes available. It may be appropriate to seek advice from HSE/ACDP in such instances.

***You are working with an agent that is 'different' from the agent appearing on the list***

155 You may consider that the agent you are using does not have the same properties as the parent agent that is listed - it may be more or less hazardous. If you wish to reclassify the agent in a lower hazard group, this classification assessment must take into account the nature of the intended work. The containment measures required will depend on this as much as on your consideration of the hazardous properties of the agent. You must also consult HSE's Biological Agents Unit inspectors about the reclassification.

**Example**

**Higher:** a laboratory is proposing to carry out some research on different subtypes of the influenza A virus. Although the Approved List indicates that influenza A is classified as a HG2 agent, one of the strains to be used is an avian strain (H<sub>5</sub>N<sub>1</sub>) that was associated with human disease in Hong Kong, so the virus is locally reclassified as a HG3 agent.

**Lower:** a laboratory is proposing to work with live attenuated vaccine strain of yellow fever virus, a HG3 agent. Given that the probability of reversion to the disease-causing form is remote, the virus is locally reclassified as a HG2 agent.

***You are carrying out a number of activities/projects which use the same agent***

156 Clearly you do not need to repeat this stage of the assessment for each activity/project, as the information will remain largely the same. If you do create a portfolio of agent-based data, it is important that this is kept under review so that your assessment is based on the most up-to-date information about the hazards.

***Assessing the risks Stage 2: Consider the nature of the work***

157 Although the assessment may be linked to a particular piece of research, it may be easier to assess if you break the work down into the individual activities



that make it up. You need to ensure that there is sufficient detail to enable identification of all situations that could foreseeably result in exposure.

158 Consider in particular:

- where the work will be carried out;
- whether the work:
  - could create aerosols;
  - could create splashes;
  - will require the use of sharps; or
  - will involve high titres/concentrations or large volumes of the agent, and the media to be used, eg solid, liquid;
- what equipment will be used and how it will be decontaminated (if not disposable);
- who will be carrying out the work (and whether they are part of any 'vulnerable' group - see Part 1 Information box 2);
- whether others could be affected by the work, eg cleaners, engineers;
- whether the work is:
  - routine;
  - one-off;
  - undertaken out of hours or by lone workers.

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

159 By looking at the hazards associated with the agent in conjunction with the work that is to be carried out, you should be able to identify in what circumstances employees (and others) could be exposed to a source of infection during the work, ie the risk(s); namely the likelihood of exposure and the risk of developing disease.

160 Selection of control measures for work with biological agents is largely dictated by the requirements of COSHH.<sup>1</sup> The minimum requirement is that the containment level matches the hazard group of the agent used, ie HG2 agents must be worked with at CL2. The containment measures for each level are shown in Table 2 in Part 1 of this guidance and are expanded on in other ACDP guidance.<sup>11</sup> However, having determined the baseline containment level required for the work, your assessment should reflect whether these precautions are adequate and/or appropriate. For example, whether:

- a microbiological safety cabinet is required, eg because there is potential for an aerosol of infectious material to be produced as a result of the work being undertaken. Although many laboratory activities (eg centrifugation) are known to generate aerosols, other routine tasks (eg slide agglutination and even opening ampoules) may also have the potential for aerosol production. When carrying out such activities with biological agents that are infectious by the respiratory route, eg *Neisseria meningitidis*, the assessment should reflect this risk and therefore be carried out in suitable containment, eg a microbiological safety cabinet;
- any supplementary measures are needed in addition to the basic measures required by a particular containment level;
- additional PPE may be required when working with certain agents because of their route of transmission. For example, gloves should be worn when working with agents that can infect by skin contact (even when skin is apparently intact) such as *Leptospira interrogans*, *Treponema pallidum* or herpes simplex virus.

161 If the work involves certain agents that do not necessarily need all of the control measures of a particular containment level (see Table 5), control measures should be selected on the basis of controlling the risk (see below and Appendix 3.2; diagnostic work is addressed in Part 3B, paragraphs 178-192).

**Transmissible Spongiform Encephalopathies (TSEs)**

162 TSE agents such as BSE and CJD are classified as HG3 biological agents. However, because of the unique properties of the infectious agents, not all the containment measures normally required at CL3 may be needed. Any decision to change the containment measures must be on the basis of a risk assessment.

163 The main physical CL3 measure that might not be required is the need to use a laboratory that is sealable to allow fumigation since the TSE agents are not affected by normal fumigants. Further specific guidance on appropriate containment for experimental and diagnostic work with human and animal TSEs is given in *Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection*.<sup>9</sup>

***Mycobacterium microti* and *M. ulcerans***

164 All work (intentional and diagnostic) with *M. microti* should be carried out at full CL3, as it can cause severe pulmonary disease in immunocompetent humans and is classified as part of the *M. tuberculosis* complex. Subject to a risk assessment of the likelihood of shedding of the agent, infected animals could be housed at CL2, with procedures such as taking blood and post-mortem examination taking place in a microbiological safety cabinet or other suitable containment.

165 Diagnostic work with clinical material that is known or suspected of containing *M. ulcerans* can be carried out at CL2, as can intentional work with the agent (subject to local assessment) although the additional precautions shown in the checklist at the end of paragraph 192 should be used.

**Part 3B Working with materials that may contain biological agents**

166 This section covers work with material that could contain biological agents but where there is no intention to deliberately propagate agents (see Information box 11). This could include teaching, biomedical research, development or diagnostic work (eg cytology, haematology or serology).

167 Although some work with material that could contain biological agents may involve a culture stage, eg preliminary isolation of bacteria as might occur in a clinical microbiology diagnostic laboratory or environmental testing laboratory, this does not constitute deliberate propagation of a **known** agent (see also paragraphs 171 and 177).

168 Further general guidance on work in clinical laboratories and similar facilities where there may be incidental exposure to biological agents is given in *Safe working and the prevention of infection in clinical laboratories and similar facilities*.<sup>14</sup>

**Information box 11** Inadvertent culture

Even if there is no intention to propagate biological agents, there may be particular types of work where there is a risk of inadvertent culture. Your risk assessment should consider whether this can take place and under what conditions. If culture can take place, additional containment measures may be required to control exposure.

There is specific guidance on this issue for work in cytogenetics laboratories.<sup>68</sup>

**Assessing the risks Stage 1: Identify the hazards**

169 You need to consider the types of material being handled and the potential for it to contain biological agents, this includes:

- urine;
- faeces;
- genital tract samples;
- skin and soft tissue samples;
- respiratory tract samples including nose, throat, eye and ear swabs and sputum;
- cerebrospinal fluid;
- pus;
- other fluids such as pleural, pericardial and joint aspirates;
- blood;
- bone marrow;
- biopsy samples;
- autopsy samples;
- forensic samples;
- environmental samples, eg food, water, soil, air, sewage; and
- archaeological samples.

170 Material that is of human or animal origin will usually be associated with a particular type of micro-organism (or group of organisms) which can be characterised in terms of:

- routes of transmission;
- severity of disease caused;
- communicability, ie how easily they are spread;
- availability of vaccine (or post-exposure prophylaxis);
- environmental survival;
- susceptibility to disinfectants; and
- physical inactivation.

171 Diagnostic specimens should be supplied with information from the requesting clinician. This may offer some (albeit limited) further information about the types of micro-organisms that might be present, eg whether the specimen comes from a returning traveller or is associated with an outbreak scenario. Other types of specimens may also come with information that can be used to inform the assessment, eg environmental samples taken from an open farm associated with an outbreak of *E. coli* O157 (see also Information box 12).

172 If you are using clinical material, particularly blood and blood products, for research purposes, you should ensure that (where possible) samples from individuals thought to be at high risk of blood-borne viruses are excluded. This does not imply that such specimens cannot be used if required for the purpose of the research. Any additional hazards posed by such specimens will need to be addressed in the risk assessment and appropriate controls selected (see paragraphs 184-186).

**Information box 12** Confirmatory testing

If you are sending a specimen to another laboratory for confirmatory testing and you know or strongly suspect that it contains a HG3 biological agent, you have a duty under health and safety law to pass this and other relevant information onto the receiving laboratory so that they can carry out their own risk assessment and use the most appropriate containment measures.

**Assessing the risks Stage 2: Consider the nature of the work**

173 Although your assessment may be linked to a particular piece of work, eg investigation of a sputum specimen, the work should be broken down into the activities that go to make up the work. You need to ensure that there is sufficient detail to enable identification of all foreseeable situations that could result in exposure.

174 Consider in particular:

- where the work will be carried out;
- whether the work:
  - could create aerosols;
  - could create splashes;
  - will require the use of sharps; or
- might involve material containing high titres/concentrations of the agent, and the media to be used, eg solid, liquid;
- volume of work, ie routine throughput or high throughput, eg in an outbreak;
- previous results, eg samples come from an area with a high positivity rate for a particular disease;
- what equipment will be used and how it will be decontaminated (if not disposable);
- who will be carrying out the work (and whether they are part of any ‘vulnerable’ group - see Part 1, Information box 2);
- whether others could be affected by the work;
- whether the work is:
  - routine (see Information box 13);
  - infrequent or one-off (see Information box 13); or
  - undertaken out of hours or by lone workers.

175 The resulting assessment is likely to be generic in that it covers a series of activities undertaken with a particular type of specimen, but it should contain sufficient detail to identify any special risks (see paragraph 174).

**Information box 13 Routine versus non-routine**

Although most of the work in a diagnostic laboratory will be routine in nature, there may be some that falls outside the normal scope of the work, eg evaluation of new media or new test kits. It is important to ensure that there are arrangements in place to assess such work, as it may require different or additional control measures to those usually in place. For example, if the work requires the growth and manipulation of a HG3 enteric biological agent, this has to be carried out under full CL3 conditions, whereas diagnostic work with clinical material that could possibly contain such agents does not normally require all these measures (see paragraph 179).

**Assessing the risks Stage 3: Evaluate the risks and consider control measures**

176 By looking at the identified hazards associated with the agent in conjunction with the work that is to be carried out, you should be able to identify in what circumstances employees (and others) could be exposed to a source of infection during the work, ie the risk(s) - namely the likelihood of exposure and the risk of developing disease.

177 Selection of control measures for work with biological agents is largely dictated by the requirements of COSHH.<sup>1</sup> The majority of routine diagnostic work can be carried out at CL2. However, your risk assessment needs to reflect the likelihood of HG3 (and HG4) agents being present, and whether the work will lead to a risk of exposure. Additional containment measures may be required if indicated by the risk assessment, otherwise work should be carried out at CL3.

***What happens if I am carrying out work with material that is likely to contain agents listed in Table 5?***

178 When carrying out work with material that is likely to contain agents listed in Table 5, because of the way in which these agents are transmitted, not all of the measures normally required at CL3 may be required. Paragraphs 179-192 give guidance on containment measures appropriate for diagnostic work with the HG3 enteric biological agents, parasites, blood-borne viruses and TSE agents listed in Table 5.

***Hazard Group 3 enteric biological agents***

179 If it is unlikely that HG3 enteric agents are present then work may be carried out at CL2, eg:

- examination of diagnostic stool specimens from patients not suspected of disease associated with such agents, eg haemolytic ureamic syndrome (HUS) or typhoid fever; or
- screening of food samples for enteric agents.

180 If however, there is a strong likelihood or indication that HG3 enteric agents are present, eg:

- samples associated with patients with symptoms of disease;
- samples associated with an ongoing outbreak investigation; or
- samples from animals where agents such as *E. coli* O157 are part of the normal flora;

then work should take place at a higher containment level, but the following measures normally required at CL3 may not be required:

- the laboratory does not need to be maintained at an air pressure negative to atmosphere. In practice, negative pressure may be achieved if a microbiological safety cabinet is in use;
- the laboratory does not need to be sealable to permit fumigation; and
- the laboratory does not need to have exhaust air extracted using HEPA filtration, although in practice this may be the case if a microbiological safety cabinet is in use. Any work that could give rise to an aerosol of infectious material must, in any case, be carried out in a microbiological safety cabinet (or equivalent containment).

181 Having dispensed with these physical containment measures means that work can take place in a CL2 laboratory, but the other procedural/management measures normally required at CL3 (above those required at CL2) must still be in place:

- Separation of the work from other activities does not necessarily mean having a separate laboratory; the work could be carried out at the beginning or end of a work period or else on a separate bench. What is important is to separate the work from the routine diagnostic work that may also be carried out in the laboratory.
- If an observation window (or alternative) to allow occupants to be seen is not available, then there will need to be some means of checking on employees, eg using CCTV or regular phone calls/agreed check-ins. Such measures will ensure that adequate supervision is in place when individuals are working alone.

182 The need for a microbiological safety cabinet (at CL2 and CL3) will depend on whether the work could produce aerosols or droplets that have the potential to contaminate. Examples of such activities include immunomagnetic separation and inoculation of biochemical test kits.

183 Work that can be carried out under such conditions includes preliminary microbiological isolation from specimens and serological tests to identify presumptive isolates. Any further work involving the intentional culture or manipulation of these isolates or any other intentional work with HG3 enteric agents must be carried out under full CL3 conditions. However, sub-culturing (but not incubating) a primary isolate for the purposes of sending on to a reference laboratory may be done under the conditions outlined above if there are no CL3 facilities available. Ideally, the original clinical specimen should be sent to avoid the need for further handling at CL2.

#### *Hazard Group 3 blood-borne viruses*

184 Routine diagnostic work with specimens that contain or may contain blood-borne viruses can be carried out at CL2. This includes work carried out in such areas as clinical chemistry, haematology, histopathology, cytology, serology, transfusion microbiology, immunology, drug testing and forensic work.

185 However, additional measures will be required to control the risk of sharps injuries and contamination of the skin and mucous membranes (see checklist at end of paragraph 192).

186 Your risk assessment should reflect whether the work procedures could otherwise increase the risk of exposure by virtue of the nature of the work. For example, even if the work does not involve a deliberate intention to work with HIV, if you know that there are high titres of the virus in the samples being used (eg in early acute HIV infection or end-stage AIDS patients) and the work involves increasing the risk of exposure, eg the use of sharps, then additional control measures should be considered.

187 Intentional work with these viruses must be carried out at full CL3.

#### *Hazard Group 3 parasites*

188 For diagnostic work where there is no intention to propagate or concentrate the agents, eg examination of a blood film for *Plasmodium falciparum* or a faecal sample for *Echinococcus* spp, the work may be conducted at CL2. However, additional measures will be required to protect against sharps injury, other forms of skin penetrating injury and ingestion (see checklist at end of paragraph 192).

189 Guidance on work involving the intentional propagation and/or concentration of certain HG3 parasites is given in Appendix 3.2.

#### *Hazard Group 3 TSE agents*

190 As with intentional work with this agent, not all the containment measures normally required by CL3 may be necessary. As before, the main containment measures that might not be required are the need for a sealable laboratory and the requirement for an inward airflow. Brain and spinal cord samples present the greatest risk of exposure to the TSE agent as compared to other diagnostic specimens and although certain containment measures may be dispensed with, additional protective measures will need to be taken as follows:

- care should be taken to avoid accidental inoculation or injury, eg when preparing samples for microscopy or culture;
- disposable equipment should be used wherever practicable, eg cell counting chambers etc;
- any items contaminated by the specimens should be either destroyed by incineration, autoclaved or disinfected to the required standard;
- any residual contamination of automated equipment should be minimised and dealt with before servicing;

- delicate equipment such as microscopes should be cleaned and maintained regularly to avoid accumulation of potentially contaminated debris.

191 'Low' risk specimens such as cerebrospinal fluid, blood, urine and faeces can be handled in accordance with the guidance in paragraph 181.

192 Further specific guidance on appropriate containment for experimental and diagnostic work with human and animal TSEs is given in *Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection*.<sup>9</sup>

**Checklist:** Additional precautions

Additional precautions include:

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

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

# Appendix 1.1 The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations

## Main duties

1 Under RIDDOR<sup>5</sup> you must report all work-related accidents, disease and dangerous occurrences. The following are reportable if they arise 'out of or in connection with work':

- accidents which result in an employee or self-employed person dying, suffering a major injury, or being absent from work or being unable to do their normal work for more than three days;
- accidents which result in a person not at work suffering an injury and being taken to hospital (if the accident happens at hospital, it must still be reported);
- an employee or self-employed person suffering one of the specified work-related diseases; and
- one of the specified 'dangerous occurrences' – these do not necessarily result in injury but have the potential to do significant harm.

2 The duty to notify and report rests with the 'responsible person'. This may be the employer of an injured person, a self-employed person or someone who is in control of the premises where the work is carried out.

## Infections

3 In terms of reportable incidents that might arise as a result of work with biological agents, you must report certain **infections** (see Table A1) as well as any other infection that is reliably attributable to work with biological agents or materials that may contain them, eg blood and other body fluids or animals.

4 Infections must be reported only when you have been notified by a doctor, in writing, that one of your employees is suffering from one of the infections listed in RIDDOR<sup>6</sup> which is linked to the corresponding activity (see Table A1).

5 Infections that could have been acquired equally easily in the community as at work are not reportable. Many infections such as those causing diarrhoea and colds are common in the community and everyone is exposed to them. These minor illnesses cannot generally be attributed to infection contracted at work and they are not generally reportable. However, where there is reasonable circumstantial evidence, eg known contact with the infectious agent in laboratory work, then a report should be made.

6 For the purpose of RIDDOR,<sup>5</sup> an infection is the entry and multiplication of an infectious biological agent in the body, causing a damaging reaction in the tissue. The infection and the damage caused may give clinical signs and symptoms of disease or may not be evident (asymptomatic/sub-clinical).

7 Colonisation, ie the presence and multiplication of infectious biological agents, such as *Staphylococcus aureus*, on or in the body without a damaging reaction in the tissue, is not the same as infection and is not reportable as a disease.



**Table A1** RIDDOR-reportable infections

Infection	Activity
Anthrax	(a) Work involving the handling of infected animals, their products or packaging containing infected material; or (b) work on infected sites.
Brucellosis	Work involving contact with: (a) animals and their carcasses (including parts of) infected by brucella, or untreated products (eg milk) of the same; or (b) laboratory specimens or vaccines of or containing brucella.
Avian chlamydiosis	Work involving contact with birds infected with <i>Chlamydia psittaci</i> or the remains or untreated products of such birds.
Ovine chlamydiosis	Work involving contact with sheep infected with <i>Chlamydia psittaci</i> or the remains or untreated products of such sheep.
Hepatitis	Work involving contact with: (a) human blood or human blood products; or (b) any source of viral hepatitis.
Legionellosis	(a) Work on or near cooling systems which are located in the workplace and use water; or (b) work on hot water service systems located in the workplace which are likely to be a source of contamination.
Leptospirosis	(a) Work in places which are or liable to be infested by rats, fieldmice, voles or other small mammals; (b) work at dog kennels or involving the care or handling of dogs; or (c) work involving contact with bovine animals or their meat products or pigs or their meat products.
Lyme disease	Work involving exposure to ticks including, in particular, work by forestry workers, rangers, dairy farmers, gamekeepers and other people engaged in countryside management.
Q fever	Work involving contact with animals, their remains or their untreated products.
Rabies	Work involving handling or contact with infected animals.
<i>Streptococcus suis</i>	Work involving contact with pigs infected with <i>Streptococcus suis</i> , or with carcasses, products or residues of pigs so affected.
Tetanus	Work involving contact with soil likely to be contaminated by animals.
Tuberculosis	Work with people, animals, human or animal remains or any other material which might be a source of infection.
Any infection reliably attributable to work	Work with: (a) micro-organisms; (b) alive or dead human beings in the course of providing any treatment or service or in conducting any investigation involving exposure to blood or any body fluid; (c) animals or any potentially infected material derived from any of the above.

### Examples of reportable infections

8 Reportable:

- a nurse catches TB after nursing a patient with TB;
- a laboratory worker catches typhoid after processing specimens containing *Salmonella typhi*;
- a veterinary nurse catches psittacosis after cleaning out the cages of infected birds;
- a paramedic becomes hepatitis B positive after contamination by blood from an infected patient.

9 Not reportable:

- a nurse is found to be MRSA positive (but free from disease) during routine screening after having nursed patients infected with MRSA;
- a hospital porter catches chicken pox. Patients in the area where they work have chicken pox but so does their child.

### Dangerous occurrences

10 You must also report any accident or incident which results in, or could have resulted in, the release of a biological agent that could cause severe human disease. This is known as a dangerous occurrence. This would include diseases caused by HG3 and HG4 agents as well as certain HG2 agents, eg *Neisseria meningitidis* or *Corynebacterium diphtheriae*.

### Examples of reportable dangerous occurrences

11 Reportable:

- a nurse suffers a needle stick injury from a needle and syringe known to contain hepatitis B-positive blood;
- a university research worker drops and breaks a flask containing a culture of *Mycobacterium tuberculosis*.

12 Not reportable:

- a hospital cleaner suffers a needle stick injury but the source of the sharp is unknown;
- a doctor suffers a needle stick injury and is exposed to a patient's blood. The patient is not known to be suffering from any infection.

**Note:** Although these examples are not reportable under RIDDOR,<sup>5</sup> they may be reportable under local adverse incident schemes.

## How to report

13 You should report all qualifying incidents to the Incident Contact Centre (ICC), in Caerphilly.<sup>69</sup> You can report incidents in a variety of ways, by telephone, fax, via the internet, or by post. If you use the internet or telephone service you may not have your own copy of the official reporting forms (2508 and 2508A) - and you are required to keep a record of reported incidents for inspection by visiting officers. For arrangements in Northern Ireland, see the HSENI website.<sup>70</sup>

### Information box A1 Reporting of serious untoward incidents (by trusts)

Reportable infection incidents are those that:

- result in significant morbidity or mortality; and/or
- involve highly virulent organisms; and/or
- are readily transmissible; and/or
- require control measures that have an impact on the care of other patients, including limitation of access to healthcare services.

These incidents can be broadly divided into:

- outbreaks: two or more linked cases in healthcare settings;
- infected healthcare worker or patient incidents necessitating consideration of look-back investigations (eg TB, vCJD, blood-borne infections);
- significant breakdown of infection control procedures with actual or potential for cross-infection (eg release of products from a failed sterilisation cycle, contaminated blood transfusion).

# Appendix 1.2 Transport of infectious substances

**Note:** This guidance anticipates the changes that will be implemented in ADR 2005. All consignors who transport infectious substances by road can make use of this by virtue of an authorisation<sup>71</sup> issued by HSE.

1 The GB regulations covering the carriage of dangerous goods by road and rail are derived from European Directives (ADR (road) and RID (rail)), which in turn implement international modal agreements governing the transport of dangerous goods. The GB regulations directly reference ADR in relation to the classification, packaging and labelling of all classes of dangerous goods, including infectious substances, and are updated every two years.

2 The requirements for air transport of dangerous goods, both within Great Britain and overseas, are contained in the International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air. They are essentially similar to those for road and rail as they mirror the same international modal agreements, but there are some minor differences (highlighted in the following text).

3 Biological agents, or materials that contain or may contain them, are allocated to UN Division 6.2 - infectious substances. Division 6.2 includes biological products, cultures, genetically modified micro-organisms (GMMs) and genetically modified organisms (GMOs) and medical/clinical waste.

## Definitions (from ADR)

### *Infectious substances*

4 Infectious substances are substances that are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) and other agents such as prions which can cause disease in humans or animals.

### *Biological products*

5 Biological products are those products derived from living organisms which are manufactured in accordance with the requirements of appropriate national authorities (in the UK: the Department of Health and the Medicines and Healthcare Regulatory Authority), which may have special licensing requirements, and are used either prevention, treatment or diagnosis of disease in humans or animals or for related development, experimental or investigational purposes. They include (but are not limited to) finished or unfinished products such as vaccines.

### *Cultures*

6 Cultures (laboratory stocks) are the result of processes by which pathogens are amplified or propagated in order to generate in high concentrations, thereby increasing the risk of infection should exposure occur. This definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic and clinical purposes.

### *Genetically modified micro-organisms and organisms*

7 Genetically modified micro-organisms and organisms are those micro-organisms and organisms in which genetic material has been purposely altered

through genetic engineering in a way that does not occur naturally.

### **Medical or clinical wastes**

8 Medical or clinical wastes are wastes that are derived from medical treatment of humans or animals or biological research.

### **Transport of infectious material**

9 There are 4 steps involved in the safe transport of infectious material. These are:

- classification;
- packaging;
- labelling; and
- transporting.

### **Classification**

10 Infectious substances are divided into the following categories:

- **Category A:** an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. See Table A2 for indicative list. This includes all agents classified as HG4 in the Approved List of biological agents,<sup>24</sup> many HG3 agents and two HG2 agents (*Clostridium botulinum* and poliovirus). Those that can cause disease in humans or animals are assigned to UN 2814. Those that affect animals only are assigned to UN 2900 (additional requirements are in place for animal pathogens in the UK – see the DEFRA website<sup>72</sup> for further details). Exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.
- **Category B:** any infectious substance that does not meet the criteria for inclusion in Category A. These are assigned to UN 3373, with the exception of cultures, which are assigned UN 2814 or 2900 as appropriate.

11 Samples of materials such as blood, tissue, excreta, secreted etc collected from humans or animals are considered, as a minimum, Category B infectious substances. For example, samples from otherwise healthy individuals or where there is no reason to suspect that they are suffering from a severe infectious disease. However, if there is evidence to suggest otherwise, eg on the basis of known medical history, local endemic conditions or professional judgement concerning the circumstances of the source material, then such material should be assigned to Category A.

12 GMMs or GMOs that do not meet the definition of an infectious substance but are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction are assigned to Class 9 (UN 3245).

13 Clinical or medical waste that contains Category B infectious substances (with the exception of cultures) or that only has a low probability of containing infectious substances is assigned to UN 3291.

14 The following substances are not subject to the provisions of the regulations:

- non-pathogenic micro-organisms (for either humans or animals);
- blood and blood components for transfusion or transplant and tissues or organs for use in transplants;
- samples (non-human/animal derived) where there is only a low probability of

infectious substances being present, eg food screening samples, environmental samples (water, soil etc) or else material (including material derived from human or animal sources) that has been treated to inactivate any infectious substances;

- biological products that have been manufactured and packaged in accordance with MHRA/DH requirements, and are carried for the purposes of final packaging and distribution;
- decontaminated clinical or medical waste;
- live animals that have been intentionally infected or are known to be infectious (see Information box A2); and
- GMMOs or GMOs when authorised for use by the competent authorities of the governments of the countries of origin, transit and destination.

#### Information box A2 Transport of live animals

The regulations covering the transport of live animals, whether they are infectious or not, are the responsibility of the Home Office and DEFRA. These are:

- the Animals Scientific Procedures Act 1986;<sup>73</sup>
- the Animal By-Products Order;<sup>74</sup> and
- the Welfare in Animals Transport Order 1997.<sup>75</sup>

COSHH<sup>1</sup> also applies, and a risk assessment that includes emergency procedures, eg dealing with the escape of an infectious animal, will be required.

#### Packaging

15 Category A infectious substances (either UN 2814 or 2900) should be packed using Packaging Instruction 620 (PI620) (see Table A3). This packaging must meet UN performance requirements as shown by design type testing. These are known as UN-type approved packaging for Class 6.2 substances and they are certified and marked accordingly. Packaging for Category B infectious substances, packed using PI650, are not required to meet UN performance requirements provided they are capable of passing a 1.2 m drop test.

16 If air transport is to be used, the ICAO PI602 should be followed. The two instructions are essentially the same, but there are quantity limits imposed on material sent by air (see Information box A3).

17 Substances assigned to UN 3373 should be packaged in accordance with PI650 (see Table A3). The same PI number is used for air transport, but again there are limits on quantities that can be sent per package (see Information box A3).

18 If you send infectious substances packaged and labelled in accordance with PI650, no other requirements of the legislation apply.

**Information box A3** Limits for air transport

**PI602:** For passenger aircraft, there is a 50 ml/50 g limit; for cargo craft, there is a 4 litre/4 kg limit, with a limit of 500 ml/500 g per primary receptacle.

**PI650:** 4 litre/4 kg limit, with a limit of 1 litre in primary receptacle for liquids. Primary receptacles containing solids must not exceed the outer packaging mass limit.

**Labelling**

19 Packages containing infectious substances should be marked with:

- the proper shipping name, eg 'Infectious substance, affecting humans'. (It is no longer necessary to show the technical name, ie the name of the micro-organism, on the package but the proper shipping name should be supplemented with the technical name in the accompanying transport documentation);
- with the appropriate UN number (eg for 'Infectious substances, affecting humans' this would be UN 2814); and
- the appropriate warning label. The danger sign for infectious substances is shown in Figure 4.

**Figure 4** Danger sign for infectious substances



20 For frozen specimens being transported in an overpack, any certificated markings must be visible through the overpack or repeated on the overpack itself. The packaging should also be marked to indicate any subsidiary hazards.

**Transport**

21 Although the regulatory requirements only apply to transport of infectious material off site, on-site transport still needs to be carried out in a safe manner. Further detail on this can be found in *Safe working and the prevention of infection in clinical laboratories and similar facilities*.<sup>14</sup>

22 Transport between one part of private premises and another part of those premises situated in the immediate vicinity of that first part, where both parts are occupied by the same person even if those parts may be separated by a road, does not fall within the scope of the regulations.

23 You should always discuss your transport requirements with your chosen carrier, in particular, you may need to provide some of the information that will be used on the accompanying documentation. You will need to establish whether any of the intended transport will be by air, even within the UK, to ensure that the correct packaging is used and that quantity limits are not exceeded. The detail of the documentation that may be required is not given here. You should consult your

carrier about this information, as it may vary depending on the carrier and/or the final destination.

24 In general, samples that are sent using UN 3373 can normally be sent via the postal service. Packaging will need to comply with the ICAO standards, as a proportion of the post in the UK will travel by air at some point in its journey.

### Importation of biological agents

25 There is no requirement under health and safety law to obtain a licence to import biological agents into the UK, other than the requirement under COSHH<sup>1</sup> to notify the movement of HG4 agents (this would cover movement from, for example, the airport to the receiving laboratory). There is a requirement to notify first use of HG2-HG4 agents at a particular premises (see paragraph 153), but this relates to use of the agents in the laboratory, not the consignment of those agents. This only applies to human pathogens, importation of animal pathogens (some of which may be zoonotic agents) is covered in separate legislation (see Appendix 1.3).

26 You will also need to notify the Home Office in advance if the agent you are importing is covered under the Anti-terrorism, Crime and Security Act 2001<sup>25</sup> (see Appendix 1.3).

**Table A2** Indicative list of Category A infectious substances

UN Number and Name	Micro-organism
UN 2814 Infectious substances affecting humans	<i>Bacillus anthracis</i> (cultures only) <i>Brucella abortus</i> (cultures only) <i>Brucella melitensis</i> (cultures only) <i>Brucella suis</i> (cultures only) <i>Burkholderia mallei</i> – <i>Pseudomonas mallei</i> – Glanders (cultures only) <i>Burkholderia pseudomallei</i> – <i>Pseudomonas pseudomallei</i> (cultures only) <i>Chlamydia psittaci</i> – avian strains (cultures only) <i>Clostridium botulinum</i> (cultures only) <i>Coccidioides immitis</i> (cultures only) <i>Coxiella burnetii</i> (cultures only) Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) <i>Escherichia coli</i> , verotoxigenic (cultures only)



**Table A2** Indicative list of Category A infectious substances (continued)

UN Number and Name	Micro-organism
UN 2814 Infectious substances affecting humans	Ebola virus
	Flexal virus
	<i>Francisella tularensis</i> (cultures only)
	Guanarito virus
	Hantaan virus
	Hantaviruses causing hantavirus pulmonary syndrome
	Hendra virus
	Hepatitis B virus (cultures only)
	Herpes B virus (cultures only)
	Human immunodeficiency virus (cultures only)
	Highly pathogenic avian influenza virus (cultures only)
	Japanese Encephalitis virus (cultures only)
	Junin virus
	Kyasanur Forest disease virus
	Lassa virus
	Machupo virus
	Marburg virus
	Monkeypox virus
	<i>Mycobacterium tuberculosis</i> (cultures only)
	Nipah virus
	Omsk hemorrhagic fever virus
	Poliovirus (cultures only)
	Rabies virus
<i>Rickettsia prowazekii</i> (cultures only)	
<i>Rickettsia rickettsii</i> (cultures only)	
Rift Valley fever virus	
Russian spring-summer encephalitis virus (cultures only)	

**Table A2** Indicative list of Category A infectious substances (continued)

UN Number and Name	Micro-organism
	<p>Sabia virus</p> <p><i>Shigella dysenteriae</i> type 1 (cultures only)</p> <p>Tick-borne encephalitis virus (cultures only)</p> <p>Variola virus</p> <p>Venezuelan equine encephalitis virus</p> <p>West Nile virus (cultures only)</p> <p>Yellow fever virus (cultures only)</p> <p><i>Yersinia pestis</i> (cultures only)</p>
<p>UN 2900 Infectious substances affecting animals only</p>	<p>African horse sickness virus</p> <p>African swine fever virus</p> <p>Avian paramyxovirus Type 1 – Newcastle disease virus</p> <p>Bluetongue virus</p> <p>Classical swine fever virus</p> <p>Foot and mouth disease virus</p> <p>Lumpy skin disease virus</p> <p><i>Mycoplasma mycoides</i> – Contagious bovine pleuropneumonia</p> <p>Peste des petits ruminants virus</p> <p>Rinderpest virus</p> <p>Sheep-pox virus</p> <p>Goatpox virus</p> <p>Swine vesicular disease virus</p> <p>Vesicular stomatitis virus</p>

**Table A3:** Packaging Instruction 620

<b>PACKING INSTRUCTION PI620</b>
This instruction applies to UN 2814 and UN 2900.
<p>The following packagings are authorised provided the special packing provisions are met (see below).</p> <p>Packaging should be UN-type approved and consist of:</p> <p>(a) Inner packagings comprising:</p> <ul style="list-style-type: none"> <li>(i) leakproof primary receptacle(s);</li> <li>(ii) a leakproof secondary packaging;</li> <li>(iii) other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple 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.</li> </ul> <p>(b) A rigid outer packaging of adequate strength for its capacity, mass and intended use. The smallest external dimension shall be not less than 100 mm.</p>
<p><b>Additional requirements:</b></p> <p>1 Inner packagings containing infectious substances shall not be consolidated with inner packagings containing unrelated types of goods. Complete packages may be overpacked, such an overpack may contain dry ice.</p> <p>2 Other than for exceptional consignments, eg whole organs which require special packaging, the following additional requirements shall apply:</p> <ul style="list-style-type: none"> <li>(a) <b>Substances consigned at ambient temperatures or at a higher temperature.</b> Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided, eg a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, eg tape, paraffin sealing tape or manufactured locking closure.</li> <li>(b) <b>Substances consigned refrigerated or frozen.</b> Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with regulatory requirements. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used.</li> <li>(c) <b>Substances consigned in liquid nitrogen.</b> Plastic primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually. Provisions for the consignment of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen.</li> <li>(d) <b>Lyophilized substances</b> may also be transported in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.</li> </ul> <p>3 Whatever the intended temperature of the consignment, 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 and temperatures in the range -40 °C to +55 °C.</p>

**Note:** The information given in Table A3 is based on the United Nations' Model Regulations on the Transport of Dangerous Goods.<sup>76</sup>

**Table A3:** Packaging Instruction 620

<b>Special packing provisions for infectious substances (Division 6.2)</b>
<p>Consignors of infectious substances shall ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport. Liquids shall be filled into packagings, including IBCs, which have an appropriate resistance to the internal pressure that may develop under normal conditions of transport.</p> <p>For UN 2814 and 2900, an itemised list of contents shall be enclosed between the secondary packaging and the outer packaging. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in Category A and assignment to UN 2814 or UN 2900, the words "suspected Category A infectious substance" shall be shown, in parentheses, following the proper shipping name on the document inside the outer packaging.</p> <p>Before an empty packaging is returned to the consignor, or sent elsewhere, it shall be thoroughly disinfected or sterilized and any label or marking indicating that it had contained an infectious substance shall be removed or obliterated.</p>

**Note:** The information given in Table A3 is based on the United Nations' Model Regulations on the Transport of Dangerous Goods.<sup>76</sup>

**Table A4** Packaging Instruction 650

<b>PACKAGING INSTRUCTION PI650</b>
<p>This packing instruction applies to UN 3373.</p>
<ol style="list-style-type: none"> <li>1 The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during carriage, including trans-shipment between vehicles and containers and between vehicles or containers and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of carriage by vibration or by changes in temperature, humidity or pressure.</li> <li>2 The packaging shall consist of three components: <ol style="list-style-type: none"> <li>(a) a primary receptacle;</li> <li>(b) a secondary packaging; and</li> <li>(c) an outer packaging.</li> </ol> </li> <li>3 Primary receptacles shall be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings shall be secured in outer packagings with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.</li> <li>4 For transport, the mark illustrated in Figure 5 shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The width of the line shall be at least 2 mm; the letters and numbers shall be at least 6 mm high.</li> <li>5 The completed package shall be capable of successfully passing the drop test set out in the regulations except that the height of the drop test shall not be less than 1.2 m. The smallest external dimension of the outer packagings shall not be less than 100 mm.</li> </ol>

**Note:** The information given in Table A3 is based on the United Nations' Model Regulations on the Transport of Dangerous Goods.<sup>76</sup>

**Table A4** Packaging Instruction 650 (continued)**Figure 5** Packaging marking

## 6 For liquid substances:

- (a) The primary receptacle(s) shall be leakproof.
- (b) The secondary packaging shall be leakproof.
- (c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.
- (d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substances will not compromise the integrity of the cushioning material or of the outer packaging.
- (e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).

## 7 For solid substances:

- (a) The primary receptacle(s) shall be siftproof.
- (b) The secondary packaging shall be siftproof.
- (c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.

## 8 Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen:

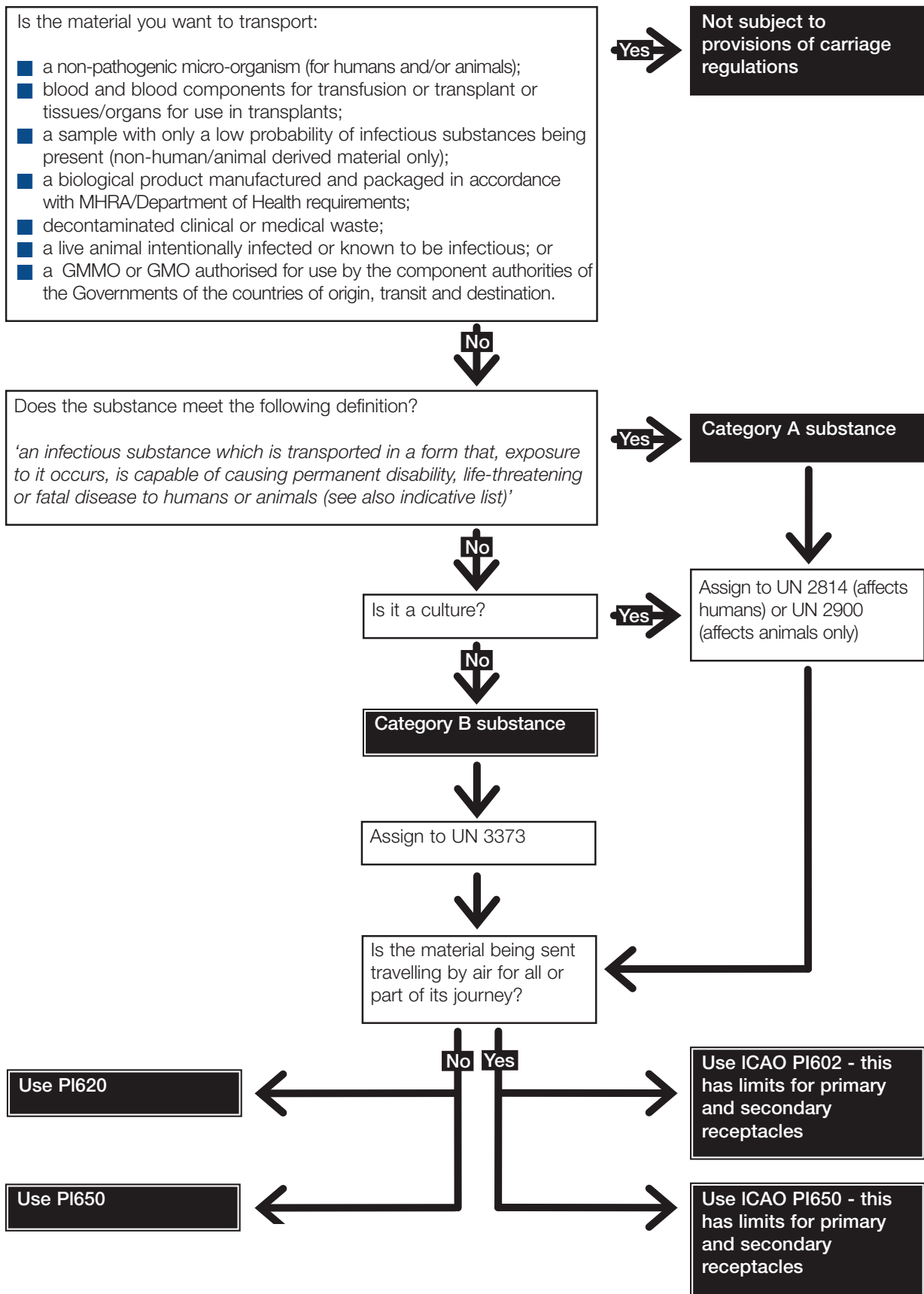
- (a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outside packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up pressure that could rupture the packagings and shall be marked "Carbon dioxide, solid" or "Dry ice".
- (b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures that could result if refrigeration were lost.

9 Infectious substances assigned to UN 3373 and are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Regulations.

10 Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (eg patient) to enable the package to be correctly prepared for transport.

11 If any substances has leaked or has been spilt in a vehicle or container, it may not be reused until after it has been thoroughly cleaned, and, if necessary disinfected or decontaminated. Any other goods or articles carried in the same vehicle or container shall be examined for possible contamination.

Figure 6 Transport of infectious substances: an overview



## Appendix 1.3 Other relevant legislation and standards

1 This list is not exhaustive and other relevant legislation and standards may apply.

<b>Public Health (Control of Disease) Act 1984<sup>77</sup></b>	There is a requirement for doctors in England and Wales to notify a ‘proper officer’ of the local authority of suspected cases of certain infectious diseases (see the HPA website <sup>78</sup> ). Similar duties exist in Scotland.
<b>Importation of Animal Pathogens Order<sup>79</sup></b>	The IAPO prohibits the importation of an animal pathogen or carrier into England <sup>80</sup> except under the authority of a licence issued in writing by the appropriate minister. The conditions attached to that licence stipulate how an imported pathogen or carrier must be transported, handled and kept and how it may be used. The purpose of this Order is to prevent the introduction and spread of disease (see Appendix 1.4 for pathogens covered).
<b>Specified Animal Pathogens Order 1998<sup>81</sup></b>	This Order prohibits any person from having in their possession, or introducing into animals, any of the organisms listed in the Schedule to the Order except under the authority of a licence issued by the appropriate minister. The purpose of this Order is to prevent the introduction and spread of disease into Great Britain (see Appendix 1.4 for pathogens covered).
<b>Controlled Waste Regulations 1992<sup>82</sup></b>	Any <b>waste</b> which consists wholly or partly of human or animal tissue, blood or other body fluids, excretions, drugs or other pharmaceutical products, swabs or dressings, or syringes, needles or other sharp instruments, and any other <b>waste</b> arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, care, teaching or research, or the collection of blood for transfusion, which may cause infection to any person coming into contact with it is defined as ‘clinical waste’ under these Regulations. Such waste has to be treated as industrial waste for the purposes of Part 11 of the Environmental Protection Act, <sup>83</sup> and so is controlled waste subject to the Environmental Protection (Duty of Care) Regulations. <sup>84</sup> Waste producers are under a duty to keep the waste safely and to transfer it only to an authorised person, ie someone who is registered or licensed as a waste carrier who transports waste or as a waste manager who processes or disposes of the waste. Waste producers have a duty to provide a proper description of the waste to enable it be safely transported, packaged, labelled and disposed of and they should know how and where their waste is disposed of or treated if it is consigned to others. Guidance on the disposal of clinical waste is given in the HSAC publication <i>Safe disposal of clinical waste</i> . <sup>13</sup>
<b>Water Industry Act 1991<sup>85</sup></b>	Discharges of liquid waste effluent (other than domestic sewage) to the public sewers from any land or premises used for scientific research or experiment are subject to the Act. The discharge of such waste requires the consent of the sewerage undertaker who will generally impose conditions regulating the nature or composition of the discharge, the maximum quantity and rate of discharge, the temperature, pH and the exclusion or control of any specified constituents

<p><b>Anti-terrorism, Crime and Security Act 2001<sup>25</sup></b></p>	<p>Part 7 of the Anti-terrorism, Crime and Security Act 2001<sup>25</sup> deals with the security of pathogens and toxins. These regulations are overseen by the Home Office and enforced by the police. The purpose of the regulations is to enable checks to be made on the physical security and access by individuals to specified dangerous pathogens, toxins and related genetic material. The list of agents covered by the Act can be found in Schedule 5 to the Act.</p> <p>Premises holding stocks of any of the prescribed materials are required to be notified to the Home Office. The Home Office passes details of notifications to the local police force, which may then exercise the following powers:</p> <ul style="list-style-type: none"> <li>● The police, at their request, may require submission to them of information relating to the substances held and/or the names of people with regular access to areas of the premises where the controlled substances are held.</li> <li>● The police may visit to carry out security checks, following due notification by them of their intention to do so, and must be admitted to the premises.</li> <li>● Any reasonable recommendation made by the police as to security measures must be complied with (there will be an appeal process in case police recommendations are not considered reasonable).</li> <li>● If the secretary of state directs that a named person should not be allowed access to areas of the premises where the controlled substances are held, the person responsible for the premises must ensure compliance. It will be an offence to fail to comply with any of these obligations.</li> </ul>
<p>BS EN 12469: 2000 <i>Performance criteria for microbiological safety cabinets</i><sup>86</sup></p>	
<p>BS EN 12128: 1998 <i>Biotechnology. Laboratories for research, development and analysis. Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements</i><sup>87</sup></p>	
<p>BS EN 12347: 1998 <i>Biotechnology. Performance criteria for steam sterilizers and autoclaves</i><sup>88</sup></p>	
<p>BS EN 12738: 1999 <i>Biotechnology. Laboratories for research, development and analysis. Guidance for containment of animals inoculated with microorganisms in experiments</i><sup>89</sup></p>	
<p>BS EN 12740:1999 <i>Biotechnology. Laboratories for research, development and analysis. Guidance for handling, inactivating and testing of waste</i><sup>90</sup></p>	
<p>BS EN 12741:1999 <i>Biotechnology. Laboratories for research, development and analysis. Guidance for biotechnology laboratory operations</i><sup>91</sup></p>	



# Appendix 1.4 Classification of animal pathogens

1 The importation of all of the following groups of organisms needs to be licensed under the Importation of Animal Pathogens Order 1980<sup>79</sup> (as amended) if imported from outside the European Communities. Licences under the Specified Animal Pathogens Order 1998<sup>81</sup> are necessary for specified animal pathogens, whether or not they are to be imported and irrespective of the country of origin. You should check the DEFRA website<sup>80</sup> to ensure that the list you are using is up to date.

<b>Defra Group 1: Specified animal pathogens</b>	There are no specified animal pathogens in Defra Group 1.
<b>Defra Group 1: Animal pathogens that are <i>not</i> specified animal pathogens</b>	Enzootic animal pathogens not listed in Defra Groups 2, 3 and 4.
<b>Defra Group 2: Specified animal pathogens</b>	<p>Aujeszky's disease virus</p> <p><i>Babesia bigemina</i></p> <p><i>Babesia bovis</i></p> <p><i>Babesia caballi</i></p> <p><i>Babesia equi</i></p> <p>Bovine leukosis virus</p> <p><i>Cowdria ruminatum</i></p> <p><i>Echinococcus multilocularis</i></p> <p><i>Echinococcus granulosus</i></p> <p><i>Mycoplasma agalactiae</i></p> <p><i>Mycoplasma capricolum</i> subspecies <i>capripneumoniae</i></p> <p><i>Mycoplasma mycoides</i> var <i>capri</i></p> <p><i>Theileria annulata</i></p> <p><i>Theileria parva</i></p> <p><i>Trichinella spiralis</i></p> <p><i>Trypanosoma brucei</i> †</p>

<p><b>Defra Group 2: Specified animal pathogens (continued)</b></p>	<p><i>Trypanosoma congolense</i> †</p> <p><i>Trypanosoma equiperdum</i> †</p> <p><i>Trypanosoma evansi</i> †</p> <p><i>Trypanosoma simiae</i> †</p> <p><i>Trypanosoma vivax</i> †</p> <p>Viral haemorrhagic disease of rabbits</p>
<p><b>Defra Group 2: Animal pathogens that are <i>not</i> specified animal pathogens</b></p> <p>* Special arthropod containment conditions required.</p> <p>** <i>Trypanosoma</i> species that are specified animal pathogens are included in the Group 2 list of specified animal pathogens above – marked †).</p>	<p><i>Anaplasma</i> spp.</p> <p>Avian paramyxoviruses other than paramyxovirus 1 (PMV1) group</p> <p>Borna disease virus</p> <p>Bovine malignant catarrh virus (African type)</p> <p>Chlamydia psittaci</p> <p>Derzsky's disease virus (goose parvovirus)</p> <p>Equine viral arteritis virus</p> <p>Getah virus</p> <p><i>Hypoderma bovis</i> *</p> <p><i>Hypoderma lineatum</i> *</p> <p>Maedi-visna virus</p> <p><i>Mycobacterium bovis</i></p> <p><i>Mycobacterium tuberculosis</i></p> <p><i>Mycobacterium africanus</i></p> <p><i>Mycobacterium kansasii</i></p> <p><i>Mycobacterium leprae</i></p> <p>Newcastle disease virus – Hitchener B1 and F strains only (other strains are specified animal pathogens)</p> <p>Porcine influenza viruses</p> <p>Pox viruses – camel</p> <p><i>Psoroptes communis var ovis</i> *</p> <p><i>Theileria</i> (other than annulata and parva) **</p> <p><i>Trypanosoma</i> spp. excluding the species that are specified animal pathogens</p> <p><b>Any other non-enzootic animal pathogen not listed in Defra Groups 3 and 4</b></p>

<p><b>Defra Group 3: Specified animal pathogens</b></p> <p>*** Where small quantities of vesicular stomatitis virus are being handled as part of a plaque assay system for human immunodeficiency viruses, Defra Category 2 containment is sufficient. Any procedures likely to cause aerosols must be performed in a microbiological safety cabinet, and any persons having contact with the virus must not have contact with equidae for 48 hours thereafter. In all other circumstances, Defra Category 3 containment is required.</p>	<p>African horse sickness virus</p> <p><i>Bacillus anthracis</i></p> <p>Bluetongue virus</p> <p><i>Brucella abortus</i></p> <p><i>Brucella melitensis</i></p> <p><i>Brucella ovis</i></p> <p><i>Brucella suis</i></p> <p><i>Burkholderia (Pseudomonas) mallei</i></p> <p>Classical swine fever virus</p> <p><i>Cochliomya hominivorax</i></p> <p>Eastern and Western equine encephalomyelitis viruses</p> <p>Equine infectious anaemia virus</p> <p><i>Histoplasma farciminosum</i></p> <p>Japanese encephalitis virus</p> <p>Lumpy skin disease virus</p> <p><i>Mycoplasma mycoides</i> sub-species <i>mycoides SC</i> and <i>mycoides LC</i> variants</p> <p>Rift Valley fever virus</p> <p>Sheep and goat pox virus</p> <p>Venezuelan equine encephalomyelitis virus</p> <p>Vesicular stomatitis virus ***</p>
<p><b>Defra Group 3: Animal pathogens that are not specified animal pathogens</b></p>	<p>Akabane virus</p> <p>Bovine ephemeral fever virus</p> <p>Epizootic haemorrhagic disease of deer virus</p> <p><i>Francisella tularensis</i></p> <p>Ibaraki virus</p> <p>Nairobi sheep disease and Ganjam viruses</p> <p>St Louis encephalitis virus</p> <p>Vesicular exanthema virus</p> <p>Wesselsbron disease virus</p>



## Appendix 2.1 COSHH controls and healthcare guidance

Measure	Healthcare guidance
Displaying suitable and sufficient warning signs, including the biohazard sign.	<i>Wayfinding: Effective Wayfinding and Signing Systems: Guidance for Healthcare Facilities</i> <sup>92</sup>
Putting in place appropriate decontamination and disinfection procedures.	<p><i>Sterilization, Disinfection and Cleaning of Medical Equipment</i><sup>93</sup></p> <p><i>Guidance for Clinical Health Care Workers: Protection Against Infection with Blood-borne Viruses</i><sup>18</sup></p> <p><i>Hospital laundry arrangements for used and infected linen</i><sup>94</sup></p> <p><i>National standards of cleanliness for the NHS</i><sup>63</sup></p> <p><i>Sterilization</i><sup>95</sup></p>
Putting in place the means for the safe collection, storage and disposal of contaminated waste. This includes the use of secure and identifiable containers after treatment if appropriate.	<p><i>Healthcare Waste Management</i><sup>96</sup></p> <p><i>Guidance for Clinical Health Care Workers: Protection Against Infection with Blood-borne Viruses</i><sup>18</sup></p> <p><i>Infection control in the built environment</i><sup>21</sup></p> <p><i>Safe disposal of clinical waste</i><sup>13</sup></p>
Testing, where it is necessary and technically possible, for the presence of biological agents outside primary physical containment.	<i>Winning ways: Working together to reduce Healthcare Associated Infection in England</i> <sup>97</sup>
Setting out the procedures for working with, and on-site transport of biological agents or material that could contain them.	<p><i>Pneumatic Air Tube Transport Systems</i><sup>98</sup></p> <p><i>Guidance for Clinical Health Care Workers: Protection Against Infection with Blood-borne Viruses</i><sup>18</sup></p>
Making effective vaccines available to employees.	<i>Guidance for Clinical Health Care Workers: Protection Against Infection with Blood-borne Viruses</i> <sup>18</sup>
Putting in place good occupational hygiene measures including the provision of washing and toilet facilities and not allowing eating, drinking or smoking in the workplace where there is a risk of contamination with biological agents.	<i>Infection control in the built environment</i> <sup>21</sup>

## Appendix 3.1 Cell cultures

1 Cell culture is defined in COSHH<sup>1</sup> as ‘the in-vitro growth of cells derived from multicellular organisms’ and is included in the definition of a biological agent in COSHH as they may be infected (deliberately or adventitiously) with biological agents so they could present a risk of infection and could, in exceptional circumstances, proliferate if inoculated *in vivo*. They may also present other risks such as allergy or toxicity if they are producing biologically active substances.

2 Uncontaminated cell cultures do not appear to present a significant hazard as even direct dermal inoculation may result in only local inflammation, however, the long term consequences of direct inoculation are uncertain. The main risk presented by cell cultures is as a result of their ability to sustain the survival and/or replication of a number of adventitious agents. The major agents of concern are viruses, but other agents, eg mycoplasmas such as *Mycoplasma pneumoniae*, should also be considered. In addition to these infection risks, other hazards that should also be assessed include:

- components of the cell culture media – products of animal origin can act as a source of microbial contamination; and
- cell products that could be biologically active.

### Assessing the risks

#### Stage 1: Identify the hazards

3 There are a number of factors that should be addressed in a risk assessment, including:

- **Origin of cell line and source population from which cell line was derived:** the risk from any cell line should be considered in terms of the likelihood of contamination **and** the ability of the cell line to support growth. Agents infectious for humans are most likely to arise from cells of human or primate origin but other mammalian, avian and invertebrate cell lines may also present risks.
- **Source of tissue:** this will give an indication of potential contaminants and potential for expression/reactivation of latent viruses. Cells derived from peripheral blood and lymphoid cells present the greatest likelihood of contamination with serious human pathogens.
- **Type of cell line:** primary cell cultures present the greatest risk of carriage and followed by continuous cell lines unless known to be persistently infected (eg B95-8 with EBV, MT4 with HTLV), and well authenticated/characterised cell lines such as those used for the manufacture of vaccines or recombinant proteins.

This information should be available from the supplier (or the originator of the cell line, if not the same as the supplier), and/or peer-reviewed literature. Some cell lines may have undergone multiple passages in different laboratories and this may

not have been recorded. The risk of infection associated with such cell lines would be difficult to assess, and it is better to obtain material from the originator of the cell line or a culture collection where the cell strains/lines will have been well characterised/authenticated, have a documented provenance and should have been screened for human pathogens.

4 You should ensure that your employees do not use their own cells (or cells of anyone else who is working in the laboratory) for experimental purposes. This presents a particular hazard as any self-inoculation injury could have potentially serious consequences, as cells would essentially circumvent the normal protection of the immune system.

### ***Stage 2: Consider the nature of the work***

5 Consider in particular:

- where the work will be carried out;
- whether the work:
  - could create aerosols – eg pipetting, pouring or scraping;
  - could create splashes; or
  - will require the use of sharps;
- the level of production of any virus – this will depend on the culture conditions so any changes in conditions would require a reassessment of the risks;
- volume of culture; and
- number of samples.

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

6 Table A5 should be used as a guide to select appropriate containment measures. A baseline containment level is given for different cell types. Where a cell line is deliberately infected with a biological agent, or where it is likely that the cell line is contaminated with a particular agent, the containment level used must be appropriate for work with that agent.

7 COSHH<sup>1</sup> requires the use of a microbiological safety cabinet if the procedures carried out are likely to give rise to infectious aerosols. However, many users will automatically use a cabinet (Class II) to protect the cells from contamination. It is important that employees understand this difference and ensure that the work is carried out safely, eg by regularly checking the performance of the cabinet by measuring airflows.

**Table A5** Containment measures for work with cell cultures

Hazard	Cell type	Baseline containment level
Low	Well characterised or authenticated finite or continuous cell lines of human or primate origin with a low risk of endogenous infection with a biological agent presenting no apparent harm to laboratory workers and which have been tested for the most serious pathogens.	CL1
Medium	Finite or continuous cell lines/strains of human or primate origin not fully characterised or authenticated, except where there is a high risk of endogenous biological agents, eg blood-borne viruses.	CL2
High	Cell lines with endogenous biological agents or cells that have been deliberately infected.	Containment appropriate to the agent
	Primary cells from blood or lymphoid cells of human or simian origin.	Containment appropriate to the potential risk

**Note:** Any work that could give rise to infectious aerosols, such as with medium or high risk cells lines, must be carried out in suitable containment, eg a microbiological safety cabinet.



## Appendix 3.2 Work with Hazard Group 3 parasites

1 When working with certain HG3 parasites (*Echinococcus granulosus*, *E. multilocularis*, *E. vogeli*, *Leishmania braziliensis*, *L. donovani*, *Plasmodium falciparum*, *Taenia solium*, *Trypanosoma brucei rhodesiense*), there may be circumstances where not all of the requirements of CL3 are necessary for the work to be carried out safely. However, this must be determined on the basis of an assessment of the risks associated with the work in question.

2 The main physical control measures that may not be required are:

- the laboratory does not need to be maintained at an air pressure negative to atmosphere because the agents are not transmissible by the airborne route;
- the laboratory does not need to have exhaust air extracted using HEPA filtration, although in practice this may be the case if a microbiological safety cabinet is in use. Any work that could give rise to an aerosol of infectious material must be carried out in a microbiological safety cabinet (or equivalent containment); and
- the laboratory does not need to be sealable to permit fumigation because these agents are extremely easily broken down and cannot survive and/or multiply in the environment.

3 Dispensing with these physical containment measures means that work can take place in a CL2 laboratory but the other procedural/management measures normally required at CL3 (above those required at CL2) must still be in place:

- It is important to separate work with parasites from the routine work that may also be carried out in the laboratory so as to control potential exposure. Ideally, a separate room should be used. If this is not possible, the work can be carried out in a designated area of a larger laboratory but could be separated temporally, eg the work could be carried out at the beginning or end of a work period. If work with HG3 parasites is required to take place at the same time as other work in the laboratory, you need to ensure that the designated area is away from the main thoroughfare, ie not in the middle of a busy diagnostic bench. The use of a spillage tray will help denote the specified work area as well as contain any spills.
- If an observation window (or alternative) to allow occupants to be seen is not available, then there will need to be some means of checking on employees, eg using CCTV or regular phone calls/agreed check-ins. Such measures will ensure that adequate supervision is in place when individuals are working alone.

4 The need for a microbiological safety cabinet (at CL2 and CL3) will depend on whether the work could produce aerosols or droplets that have the potential to contaminate skin or mucous membranes. The need for additional containment should be informed by the risk assessment, and should include a consideration of:

- whether the work involves the infectious and/or transmissible stage of the parasite;
- whether the work involves tissue culture;

- whether the work involves passaging the parasite in an intermediate host (vertebrate and/or invertebrate);
- potential means of transmission of the parasite from host to host (including humans).

5 Where work involves tissue culture of the parasite, the most likely means of accidental transmission to laboratory workers is via percutaneous injury. Therefore, glassware and sharps should be excluded as far as is practicable.

6 Where work requires an intermediate animal host to maintain the parasite, infected and non-infected hosts should be stored separately, ideally in separate rooms. Consideration should be given to when and how the animal is likely to shed infectious particles, eg in faeces, blood, saliva or other secretions/excretions, and precautions taken to control the risk of transmission by these routes.

7 The need and type of PPE will depend on the likely route of transmission of the individual parasite and stage in its life cycle. Lesions on exposed skin should be covered with waterproof dressings and a high standard of personal hygiene should be in place for all work with parasites. For some work, disposable waterproof gloves should be worn as many laboratory-acquired parasite infections have occurred where no percutaneous injury had been noted and where there were no obvious visible signs of pre-existing skin lesion or abrasion. For all work there must be a safe means of effective disinfection of surfaces, and treatment and disposal of clinical waste.

8 For invertebrate animal hosts, additional consideration should be given to whether they fly, jump, crawl, live in water or are amphibious, and should be reflected in the containment measures used (Appendix 5 from *Working safely with research animals*<sup>12</sup> is reproduced below).

### The containment of invertebrates

9 Many invertebrates are the natural or experimental hosts or vectors for a range of infectious agents. Work with invertebrates may vary from simple species identification to detection of any infectious agents they may be carrying, through to their deliberate infection for research purposes.

10 The important invertebrates are:

- protozoans;
- platyhelminths;
- aschelminths;
- molluscs;
- annelids;
- arthropods; and
- echinoderms.

11 Where invertebrates are known to be infected or may be infected with biological agents, the principles of containment described for animal rooms must be applied. For example, a wild-caught invertebrate is to be examined for the presence of a human pathogen that it may normally be expected to transmit (eg *Trypanosoma cruzi* in a triatomine bug), then work should be done at the level of containment appropriate to the hazard grouping of the agent concerned. A risk assessment is necessary, based on the intended nature of the work. In adopting the principles used in the containment of animals, the following additional points should be borne in mind, as given in paragraphs 12-14 of this appendix.

12 Separate rooms should be used for infected and non-infected invertebrates and they should be contained appropriately according to whether they:

- live in water (aquatic);
- are amphibious;
- crawl or jump;
- fly.

13 Aquatic or amphibious invertebrates should be kept in tanks with lids to prevent escape.

14 For invertebrates that crawl, jump or fly, the following additional precautions should be taken:

- rooms should be insect-proof;
- ventilation inlets and outlets should be screened;
- entry to the rooms should be through an airlock - consideration should be given to placing 'insectocutors' in the airlock;
- measures should be taken to enable escaped invertebrates to be easily detected and recaptured or destroyed;
- a laboratory sink should be provided with an adequate trap for waste - if there is a possibility that escaped invertebrates could escape through the trap, liquid waste should be treated before disposal (preferably by heat);
- solid waste is most effectively treated by heat because it may harbour invertebrates that may not be killed by chemical disinfectants or fumigants;
- insecticidal sprays may be necessary in an emergency but it should be remembered that their use in a small room may render the room unfit for accommodating invertebrates for a long period, if not permanently. Non-residual type insecticides should be chosen;
- arthropods may be chilled to reduce their activity and minimise the risk of escape;
- at CL1 and CL2, flying or crawling arthropods should be handled on white trays to detect escapees;
- for ticks and mites, containers should be kept over trays of oil;
- flying insects infected with agents in Hazard Groups 2, 3 or 4 should be kept in double cages (eg a sleeved netting cage inside a clear substantial plastic bag) and both enclosures should be labelled;
- experimental cages/containers should be numbered and labelled or otherwise documented to indicate the hazard;
- at CL3 and CL4, flying or crawling arthropods should be kept in identified lots and each lot accounted for. They should also be handled in an appropriate containment device;
- laboratories receiving potentially infected invertebrates for identification or examination where the specimens are not known to be dead should ensure that containers are opened in an appropriate safety cabinet or other safe form of enclosure;
- a record should be made of the number of individual invertebrates at the earliest practicable time, and each invertebrate should be accounted for as the work proceeds through to final fixation or disposal;
- where identification of flying or crawling invertebrates alone is required, the container may be frozen at -20 °C (or lower as necessary as some arthropods can withstand prolonged freezing) for two hours to kill them.

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