Health and Safety Services

University of Reading

Safety Code of Practice 14
Part 1

Biological Safety

In University Laboratories

Contents

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1. Scope

This Safety Code of Practice sets out what managers, staff, students and tenants have to do to ensure legal compliance when working in laboratories with biological materials that are hazardous to human health or to the environment. This CoP applies to all staff, however, it is of particular importance to Principal Investigators, those with laboratory management responsibilities and those who are responsible for undertaking risk assessments.

A separate Code of Practice is available for farm and maintenance work where workers may be exposed to biological hazards (Code of Practice 14 part 2), and for exposure to laboratory animal allergens (Code of Practice 14 part X).

This Code covers:

- Management responsibilities within the University
- Approval of work with biological agents
- Relevant legislation
- Biological hazards
- Risk assessment
- Control measures and safe working practices
- Facilities and equipment

Details on laboratory requirements and working practices are limited to Containment Level 1 & 2 laboratories. Further details on requirements for work at higher levels e.g. CL3 can be provided by H&S Services as required.

2. Introduction and definitions

Work which involves coming into contact with biological material which is hazardous to human health falls under the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended). These regulations apply to work where biological agents are deliberately used or where material or living organisms may be contaminated with biological agents.

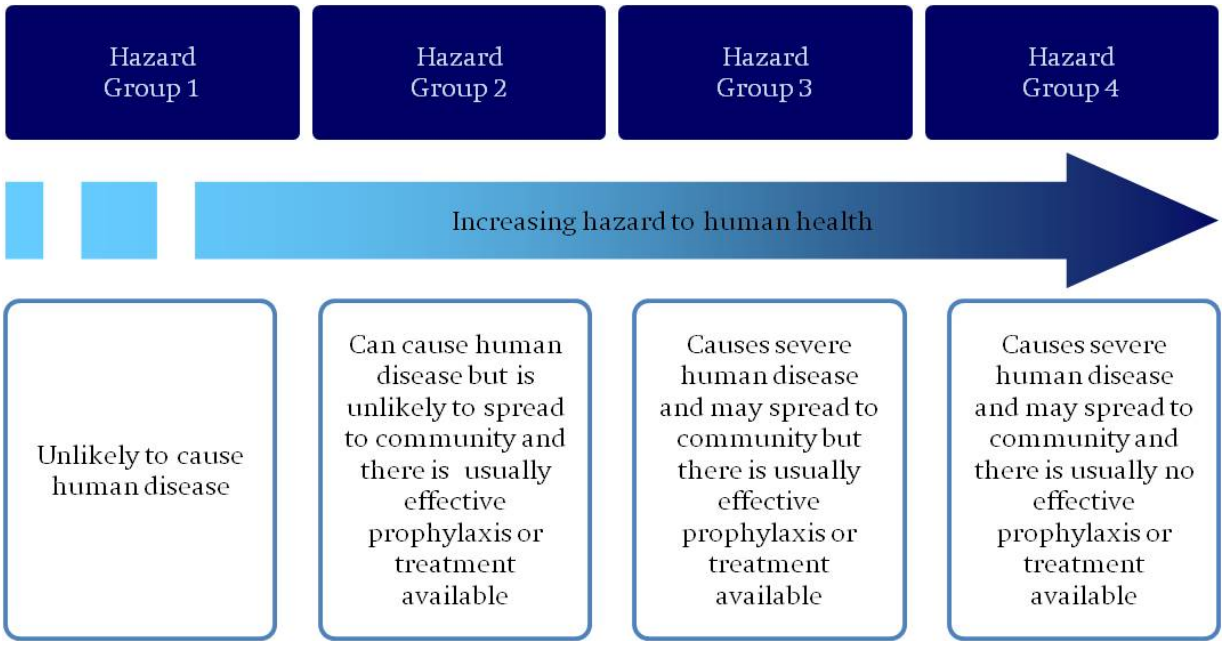
2.1. Biological agents

The term "**Biological Agent**" relates to a micro-organism, cell culture, or human endoparasite, **which may cause infection, allergy, toxicity or otherwise create a hazard to human health**. This includes:

- micro-organisms such as bacteria, viruses, fungi, and the agents that cause transmissible spongiform encephalopathies;
- parasites, e.g. malarial parasites, amoebae and trypanosomes;
- the microscopic infectious forms of larger parasites, e.g. the microscopic ova and infectious larval forms of helminths; and
- cell cultures i.e. in-vitro growth of cells derived from multicellular organisms.

Biological agents (excluding cell cultures) are classified into four hazard groups. Figure 1 gives an outline of the classification criteria.

Figure 1 – Classification of hazard groups



Biological agents which fall into Hazard Groups 2 to 4 are listed in the Advisory Committee on Dangerous Pathogens (ACDP) "*Approved list of biological agents*". The list is not exhaustive and a biological agent that does not appear on it does not automatically fall into Group 1. Even where a non-infectious biological agent does fall into Group 1, substantial control measures may still be needed for it, depending on its other harmful properties.

Determining the hazard group of the organism is the first stage of the risk assessment process. University (Sub-Committee for Biological Safety) approval is required for work with Hazard Group 2 agents or above. The hazard group will determine the required containment level of the laboratory where work can be carried out and help identify the control measures required to prevent or control exposure.

There is no definitive classification for **cell cultures**, however a low, medium and high classification system can be applied, depending on their potential to cause harm to humans (see page 11 for further details). The COSHH regulations also apply to the use of human and animal tissues - such as blood and other body fluids (which themselves fall outside the definition of "biological agent"), because of the possibility of their contamination by biological agents which may present a risk to human health.

2.2. Environmental hazards

In addition to substances hazardous to human health, other microorganisms or material containing microorganisms which represent a risk to the environment are also covered by this Code of Practice.

This includes the **Specified Animal Pathogens Order 1998** (as amended) and the **Importation of Animal Pathogens Order 1980** (as amended) which aim to prevent the introduction and spread of specified animal pathogens which are not endemic to Great Britain, and which if introduced, would cause serious disease and economic loss to the livestock industry. The Orders prohibit any person from importing or having in their possession any specified animal pathogen or any carrier in which they know such a pathogen is present without the necessary licence.

There are also regulations covering the importation of animal products or by products into the UK, including animal tissue or cell cultures, bodily fluids, feathers, hides, manure etc. Importation of any such material is likely to require an Animal Health Importation Licence.

Work involving Plant pathogens is covered by the Plant Health Order 2005 and the Environment Act 1995. This Code of Practice covers microorganisms pathogenic to plants, however a similar approach to control of other plant pests should be applied.

Any work with Genetically Modified Material must also comply with the requirements of the Genetically Modified Organisms Regulations and requires approval by the Sub-Committee for Biological Safety – see Safety Code of Practice 15 for further details.

2.3. Security issues

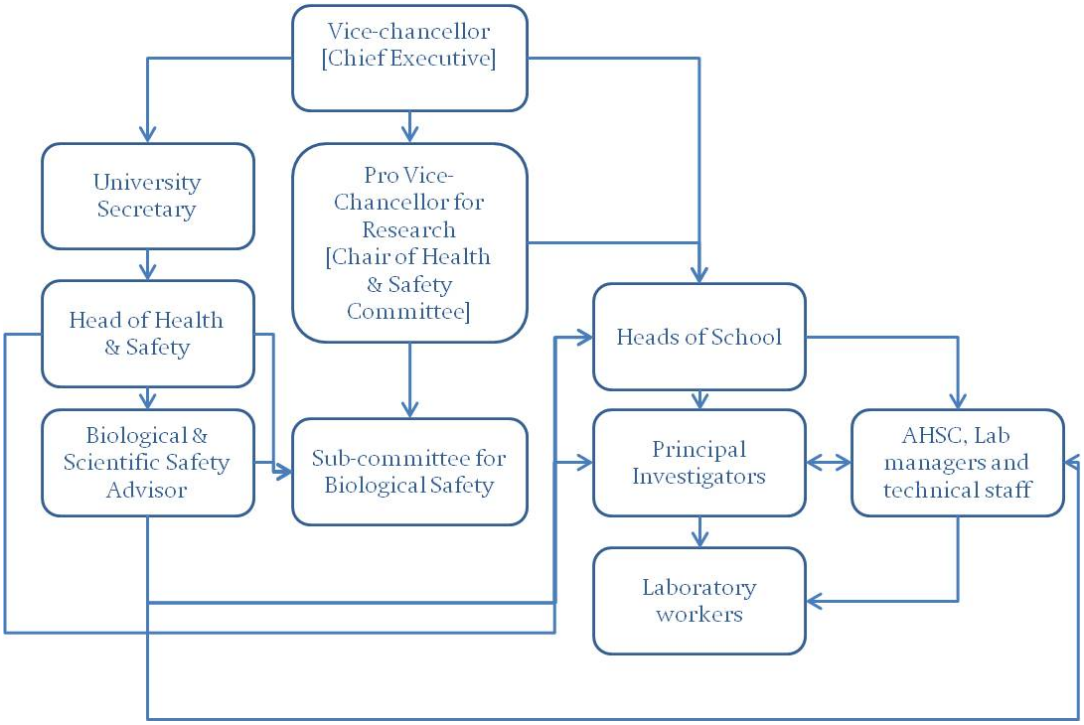
In addition to the health and environmental protection aspects, some work will also be covered by **Schedule 5 "Pathogens and Toxins" of the Anti-Terrorism, Crime and Security Act 2001**. This Act requires that adequate security of dangerous substances that may be targeted or used by terrorists is put in place.

3. Organisational structure and responsibilities

3.1. University management structure

The management structure for the control of biological hazards is given in Figure 2 below.

Figure 2 University of Reading Biological Safety Management Structure



3.2. Sub-Committee for Biological Safety

This is a sub-committee of the University Health and Safety Committee. Its overall responsibility is to monitor and advise on all aspects of biological safety including biological agents, environmental pathogens (e.g. plant or animal pathogens) and human and animal tissues and biofluids. Terms of reference are set out in Appendix 1.

3.3. Responsibilities of appointed persons

The responsibilities outlines below are supplementary to the responsibilities detailed in the University Safety Management system (Safety Code of Practice 2).

The Biological and Scientific Safety Advisor
The Biological and Scientific Safety Advisor overseas the use of biological agents and materials at the University. Their duties include:

- Developing policies, standards, systems of work and providing advice on local rules for intentional work with biological agents
- Advise on and approve risk assessments

- Maintain a register of all hazardous biological agent projects (hazard group 2-3 microorganisms, animal pathogens – see section 4 – approval of work for full details)
- Assist in the acquisition of any required licences or authorisations for work with hazardous biological agents
- Advise on the referral of staff and students to the University's Occupational Health provider for health surveillance when necessary
- Monitoring and auditing health and safety performance
- Investigating accidents and incidents involving biological agents or incidental exposure and the provision of advice on remedial actions
- Advising Schools and Estates & Facilities on the suitability of containment level facilities
- Assist in the provision of suitable training for those involved in activities using biological agents
- Liaison with the relevant regulatory authorities
- Operation of the Sub-Committee for Biological Safety.

The BSSA has the authority to stop biological activities where the containment measures are considered insufficient to control the risks. The project should then be referred to the Sub-Committee for Biological Safety.

Occupational Health

The Occupational Health Advisor/Physician shall:

- Advise on the need for vaccination prior to work commencing
- Maintain a record of immunisation
- Advise where additional measures may be requirement to protect the health of individuals working with biological material
- Carry out health surveillance and clearance in line with the occupational health policy and procedures

Estates and Facilities

Estates and Facilities are responsible for the general maintenance of all biological containment level laboratories.

Estates and Facilities Security Services are responsible for providing assistance with security arrangements to comply with Schedule 5 of the Anti-terrorism Crime and Security Order.

Heads of School

Heads of School are responsible for managing health and safety within their School. This includes ensuring adequate resources and appropriate measures are in place for the protection of all persons working with hazardous biological agents or materials. Heads of School must have arrangements in place to ensure:

- requirements of this University Code of Practice are implemented
- risk assessments are carried out
- laboratory facilities are fit for purpose
- a good standard of housekeeping maintained
- local rules are drawn up and followed
- appropriate waste disposal procedures are in place and are followed
- emergency plans are drawn up and practiced if required

- microbiological safety cabinets and autoclaves are tested at least annually (see Safety Code of Practice 14 parts 6 and 7) and that all equipment is in good repair
- staff and students receive adequate training and supervision
- accidents and spillages are investigated and reported to H&S Services
- laboratories are inspected on a regular basis and remedial action taken where working practices, housekeeping and maintenance are found not to meet an acceptable standard
- recommendations of School and University inspections are implemented.

Principal Investigators/Research supervisors

PIs and research supervisors are responsible for managing health and safety of their research projects and must ensure that:

- a suitable and sufficient assessment of risks is performed for all activities involving biological hazards
- this assessment is approved, where necessary (see section 4), by the Sub-Committee for Biological Safety before work starts
- risk assessments are reviewed whenever there are significant changes to the work and at least every 1 to 2 years to ensure that they remain relevant and up-to-date
- that only appropriate containment level laboratory facilities are used for the work and that a good standard of housekeeping maintained
- all persons working under their supervision have received appropriate training and information, including awareness of risks, appropriate control measures to apply, waste and emergency procedures
- all workers with hazard group 3 microorganisms are registered with Health & Safety Services
- all workers with biological hazards are enrolled on the occupational health surveillance programme
- all workers with unscreened human blood, tissues or biofluids receive the appropriate vaccination (see section 8)
- they provide or organise appropriate supervision to assess and monitor competence of persons under their control to work safely
- all accidents and spillages are reported to H&S Services

Staff and other individuals must:

- be familiar with and understand the risk assessments that apply to their work
- adopt safe practices in activities involving biological hazards material,
- wear appropriate protective equipment and clothing
- dispose of waste in the specified manner
- report any incident, accident or defect in equipment relating to the handling of biological materials
- co-operate with their supervisors, School and Health & Safety Services to monitor safety in the School
- attend the relevant training courses (see section 14)

Tenants

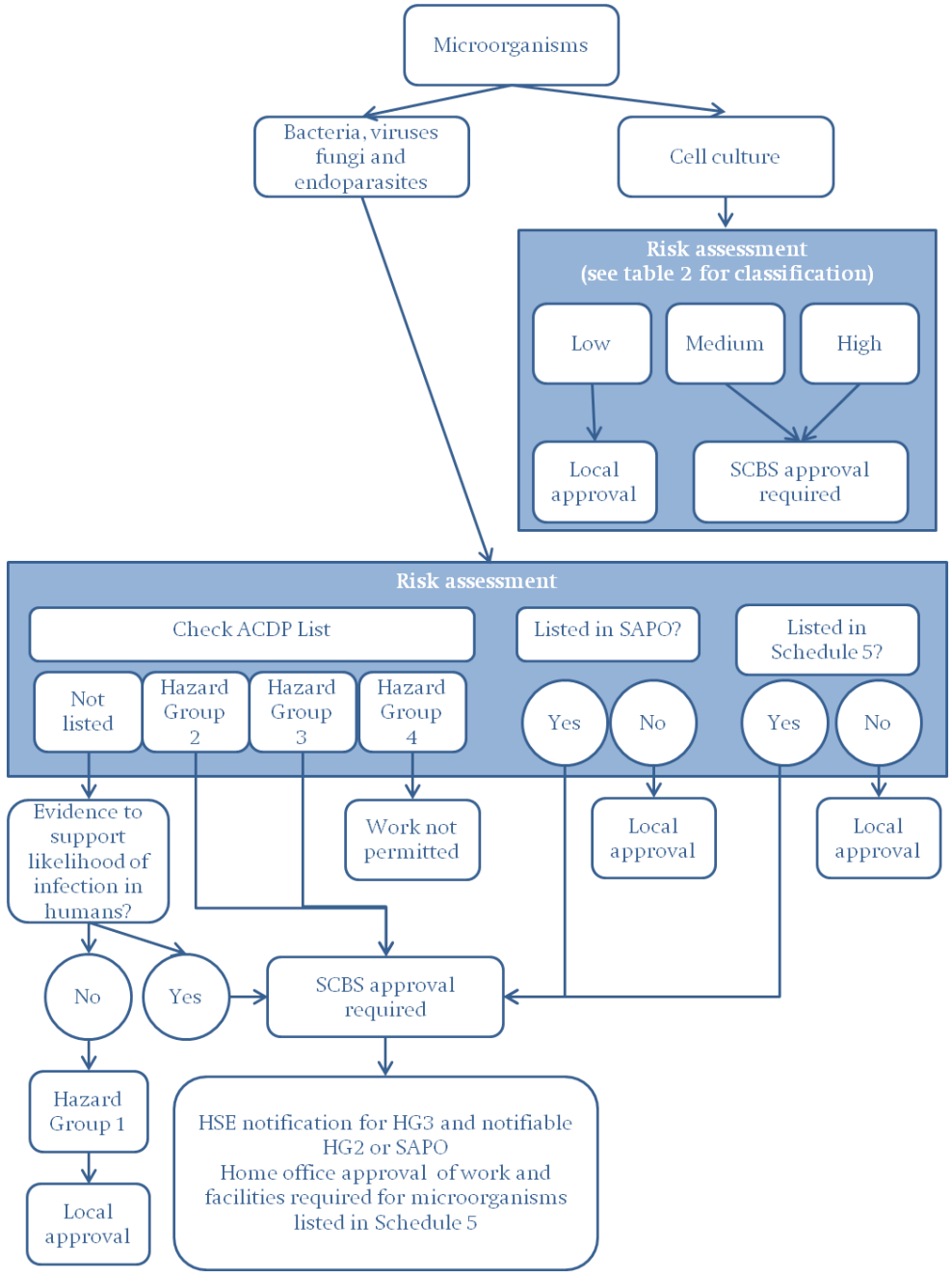
Companies working with biological hazards within University premises (excluding the Science & Technology Centre) must:

- provide a copy of their risk assessment to H&S Services, documenting the material, facilities to be used and procedures
- comply with **all** local rules and procedures issued by the University

4. Approval of work

Work with hazard group 2 organisms or above must be approved **in advance** by the Sub-Committee for Biological Safety (SCBS), as must all work involving specified animal pathogens (SAPO), or Anti-Terrorism Schedule 5 agents. Detailed planning must be undertaken at a preliminary stage to ensure that the work can be carried out in accordance with the various regulations. A full risk assessment must be conducted and submitted to the Sub-Committee for Biological Safety for approval.

Figure 3 Approval requirements for work with biological agents and animal pathogens



In addition, all work involving :

- genetically modified organisms
- work involving animal or human samples from individuals with known infectious disease or with a high likelihood of infectious diseases
- microorganisms are propagated from human or environmental samples and which are likely to contain human or animal pathogens

requires approval of the Sub-Committee for Biological Safety prior to work beginning.

Approval Process

Risk assessments requiring Sub-Committee for Biological Safety approval should be submitted to H&S Services by email to safety@reading.ac.uk.

Risk assessments for work with, or samples likely to contain hazard group 3 biological agents or SAPO level 3 pathogens will be reviewed by a peer review panel, consisting of members of the Sub-Committee for Biological Safety and experienced members of academic staff and a recommendation made to Sub-Committee for Biological Safety for approval or modifications to the risk assessments by email.

All other risk assessments will be reviewed by an independent reviewer or the Biological & Scientific Safety Advisor who may ask for revisions to the risk assessment or provide temporary approval for work, subject to ratification by Sub-Committee for Biological Safety at the next committee meeting.

Where HSE notification is required, they must be notified in writing at least 20 days in advance of proposed work commencing and the biological agent cannot be used until the notification has been acknowledged by the HSE.

Note: Existing Projects

In order to ensure that existing research and teaching activities are captured and the requirements of this Code of Practice are met, a review of biological activities will be undertaken by H&SS and the Schools in the academic year 2013/14 and risk assessments of activities requiring Sub-Committee for Biological Safety approval will be reviewed.

4.1. Use of biological hazards during teaching practicals

It is permissible to use hazard group 2 biological agents as part of undergraduate or taught postgraduate practical class so long as:

- their use is justified (i.e. the same teaching objective cannot be met using less hazardous materials)
- the activities are risk assessed and approved by the Sub-Committee for Biological Safety
- activities are adequate supervised and appropriate containment facilities (CL2) are used.

4.2. Young persons

Under 18 year olds are only permitted to work with hazardous microorganisms (HG2), human, farm or wild animal samples as registered students as part of an undergraduate taught practical

session. Under 18 year olds are not permitted to work with hazardous microorganisms in research facilities as part of any work-experience or summer studentship programme.

5. Microorganisms & Parasites

For any work entailing possible exposure to biological agents, correct identification of the hazard category of an agent is an essential element of the risk assessment.

5.1. Biological agents classification

Biological agents (excluding cell cultures) may be categorised into one of four Hazard Groups based on their hazards to human health:

- Is the organism pathogenic for humans?
- Is it transmissible to the community at large? and
- Is effective prophylaxis or treatment available?

Table 1 Definition of Hazard Groups

Hazard Group	Definition	Containment level lab	Level of approval for work required
1	A biological agent considered unlikely to cause human disease" (by infection)	1	Local (School) approval
2	A biological agent that can cause human disease and may be a hazard to employees; it is unlikely to spread to the community, and there is usually effective prophylaxis or effective treatment available	2	Sub-committee for Biological Safety approval
3	A biological agent that can cause severe human disease and presents a serious hazard to employees; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available	3	Approval of Head of School and H&S Services required prior to applying for funding. SCBS protect approval and HSE notification
4	A biological agent that causes severe human disease and presents a serious hazard to employees, it is likely to spread to the community, and there is usually no effective prophylaxis or treatment available	4	This level of work is not permitted at the University

The Advisory Committee on Dangerous Pathogens (ACDP) publish an "*Approved List of biological agents*" which lists recognised hazard group 2-4 agents. The categorisation scheme is based on the risks to the health of a "normal" healthy population. It does not take into account the fact that certain individuals may be more at risk, for example, due to a pre-existing medical condition (disease; compromised immunity; the effects of medication, pregnancy, etc.). For this reason, people who may be more at risk are advised to consult their medical practitioner or the

University Occupational Health provider on the advisability of starting or continuing with work involving possible exposure to biological agents.

In general, the hazard the organism presents is related to the ability of the organism to infect and colonise the human body, and cause deleterious effects during the process. However, some microorganisms and parasites may cause severe deleterious effects without infecting the body, due to the intrinsic properties of one or more components of the organism. For example, fungal spores may be highly allergenic, and may induce asthma and/or other allergenic responses in sensitised individuals. When the risk assessment is undertaken, such properties must be taken into account.

5.2. Scheduled Agents

Additional requirements apply to named biological agents that are listed in Part V of Schedule 3 to the COSHH Regulations. These agents include all Hazard Group 3 and Hazard Group 4 agents, plus named organisms in Hazard Group 2 (*Bordetella pertussis*; *Corynebacterium diphtheriae* and *Neisseria meningitidis*). "First use" of any agent on the list must be notified in advance to the Health and Safety Executive (HSE), **by H&S Services**, together with specified details of the notifying organisation and a copy of the risk assessment. Work may not begin until the HSE has acknowledged receipt of the notification; any subsequent changes which render a previous notification invalid must also be notified.

5.3. Unclassified agents

No published list of biological agents can ever be complete or exhaustive. All employers are required to assign any unlisted agents to a provisional hazard grouping, according to criteria set out in Table 1 above (see also Figure 3).

If any information is obtained which suggests that an “unlisted agent” currently in use could be allocated to either Hazard Group 3 or 4, work must be stopped immediately, and this information discussed with the BSSA without delay.

If a provisional categorisation is confirmed, details must be notified as soon as possible to the HSE via H&S Services. Any agent allocated to Hazard Group 4 must be safely destroyed as soon as possible. Agents allocated to Hazard Group 3 must be stored safely in appropriate containment facilities pending a comprehensive review of the proposed work, having regard to the allocated classification. Work may not restart until the Sub-Committee for Biological Safety has examined the information and given their express permission.

6. Cell culture

Cell cultures are included under the definition of biological agents under COSHH as they may:

- be infected with adventitious biological agents;
- cells may also present other hazards to human health, such as the ability to produce toxins or allergens; or
- be able to persist and proliferate *in vivo*.

An assessment of the risk must therefore be undertaken before work involving any cell culture commences.

If it is intended to genetically modify the cell culture in anyway, then the requirements of the GM Regulations [Genetically Modified Organisms (Contained Use) Regulations 2000 as amended] will also have to be considered and Sub-Committee for Biological Safety approval will be required (see Safety Code of Practice 15). A detailed risk assessment made under GM Regulations will also satisfy the risk assessment requirements of COSHH.

The risk to health will vary depending on the nature of the cells being handled. Plant cells or cell lines from the European Collection of Cell Cultures (ECACC) or the American Type Cell Culture collection (ATCC) are characterised and generally can be considered of low infection risk unless accompanying information states otherwise. Unscreened cells, cells with a less well defined history and primary cultures from normal human donors must be handled at CL2.

Table 2 Determining an appropriate containment level for cell culture work

Cell type	Risk level	Containment level required	Approval required
Established culture collections presenting a low-infection risk or for primary animal cell culture with a low risk of infection with biological agents	Low	CL 1	Local
Cell lines where there is a risk of endogenous biological agents e.g. human or wild/farm animal primary cell culture	Medium	CL 2	SCBS if culture > 72 hrs.
Cell lines with a high likelihood or known endogenous biological agents or cells that have been deliberately infected	High	CL2 or CL 3	SCBS approval required

Modified from SACGM Compendium of Guidance (HSE 2007)

Primary cultures

As well as the possibility of contamination of human primary cultures with infectious agents, a major concern is that they may undergo spontaneous transformation, if these cells are re-introduced back into the circulatory system of the individual it will not be recognised as foreign. Because of this researchers must not use their own cells, or cells of anyone else who is working in the laboratory for experimental purposes as self-inoculation injury could have potentially serious consequences, as cells would essentially circumvent the normal protection of the immune system.

Wherever practicable, any primary cells should only be cultured for a short term period (<72 hrs), which will reduce the possibility of spontaneous transformation. Where possible, tissues from screened sources should be used.

7. Environmental Pathogens

7.1. Animal Pathogens

The Department for Environment, Food and Rural Affairs (DEFRA) has published a list of specified animal pathogens (a list of these pathogens can be found on the H&S Services website), for which a licence to hold the pathogen, or material likely to contain the pathogens is required. There are 4 SAPO hazard group ratings of animal pathogens:

SAPO group	Classification criteria	SAPO CL lab	Approval required
1	Disease-producing organisms which are enzootic (native in animal in this country) and do not produce notifiable disease.	1	Local School approval
2	Disease producing organisms which are either exotic (outside the EU) or produce notifiable disease, but have a low risk of spread from the laboratory.	2	SCBS approval and DEFRA licence required
3	Disease producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.	3	SCBS approval and DEFRA licence required*
4	Disease producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.	4	This group of organisms are not permitted at the University

**Please note that there are no SAPO level 3 facilities currently in the University.*

Any microorganisms classified in SAPO Group 2, 3 or 4 by the Department for Environment, Food and Rural Affairs (DEFRA) are required to be registered and appropriate SAPO containment facilities used. Risk assessments should be submitted to H&S Services and Sub-Committee for Biological Safety for approval. H&S Services are responsible for applying for the requisite licence.

Additionally under the Importation of Animal Pathogens Order a DEFRA import license may be required prior to bring animal pathogens, carriers (e.g. mites, ticks, fleas, animal samples etc.) into the UK . Further information can be found on the DEFRA website. Risk assessments should be submitted to H&S Services and Sub-Committee for Biological Safety for approval. The School or Principal Investigators are responsible for applying for the requisite licence (copied to H&S Services).

See also section 8.2 for guidance on working with animal samples.

7.2. Plant pathogens

Plant health legislation (Plant Health Order 1980) controls the import and movement of certain plants, seeds and organic matter - such as soil - and certain plant products, including fruit, potatoes, vegetables, cut flowers, foliage and grain from outside the European Union. The aim of the Order is to reduce the risk to commercial crop production and the environment from the introduction of plant pests and diseases. Controls differ according to the species - and whether or not they are classified as quarantine organisms - but could include the need for classification, a phytosanitary certificate, a plant passport and/or inspection requirements.

The Food and Environment Research Agency's (FERA's) Plant Health Division is responsible for plant health policy. There is no university template for environmental risks from plant pathogens; risk assessments should identify routes of transmission, severity of disease and control measures which would prevent dissemination into the environment.

8. Incidental exposure to biological agents

There are many areas of research where exposure to biological agents may occur although there is no deliberate intention to work with them, for example:

- work with human blood, biofluid or tissue samples;
- work with animal samples that may be carrying or infected by biological agents, or parasites that can themselves be infected by and/ or transmit biological agents.
- work with materials liable to be contaminated with biological agents - e.g., soil, (especially if recently manured, or of exotic origin),

In all cases, the requirements of COSHH apply, i.e., the risks created by the work must be properly assessed, and, where necessary, appropriate control measures put in place before the work is commenced.

8.1. Human tissue and biofluids

Human blood, tissue and other biofluids may potentially carry infections. Although occupational transmission of such infections is rare, all blood tissue and secretions should be treated as potentially infectious particularly if they are from an unscreened source and all operations should be performed within **containment level 2 laboratory facilities.**

Work involving samples from individuals with known infectious disease is prohibited without direct approval from the Sub-Committee for Biological Safety. Where infections are with hazard group 3 agents then work at containment level 3 is likely to be required.

Type of work	**Level of approval required (note additional ethical approval required)**
Work with human tissues, blood, faecal, saliva samples etc from "healthy" individuals	Local approval
Work with samples from people with known infectious diseases	SCBS approval required
Primary culture of human cells for > 72 hrs	SCBS approval required
Culture or enrichment of microorganisms from human material	SCBS approval required

The main blood-borne infections in the UK are Hepatitis B, Hepatitis C and Human Immuno-deficiency Virus (HIV). All individuals with a significant risk of exposure to unscreened human blood should be immunised against Hepatitis B before starting work. Similarly individuals working with human faecal samples should be immunised against Hepatitis A.

Info box – Bloodborne viruses

Hepatitis B is a bloodborne virus which causes inflammation of the liver. Many infected people have no symptoms, but others have a flu-like illness with nausea and jaundice. Hepatitis B becomes a chronic infection when the infection persists longer than six months. Hepatitis B infection is endemic in the UK, with an carriage rate of approximately 0.5% (1 in 2,000 people).

Hepatitis C is another bloodborne virus which causes inflammation of the liver. Many people who are infected have no symptoms and are unaware that they are carrying the virus. Chronic infection (infection lasting longer than six months) occurs in up to 80% of infected people. People with chronic hepatitis C infection are at long term risk of developing cirrhosis and liver cancer. It is estimated that 0.5-1 % (1 in 1-2,000) of the UK population has chronic HCV infection.

HIV (Human Immuno-deficiency Virus) is the infection which through progressive destruction of specific immune cells (CD4 cells) leads to AIDS. Opportunistic infections, specific malignancies, HIV wasting or HIV encephalopathy are part of a complex case definition which comprise the Acquired Immuno Deficiency Syndrome. Approximately 0.2% (1 in 5,000) of UK population is thought to have HIV.

It is important to understand rates of infection with bloodborne viruses vary, depending on socio-economic factors, such as intravenous drug use and medical practices and these viruses, particularly Hepatitis B and HIV are much more common in developing countries.

Any work with human samples, including saliva, blood and tissues is also subject to the requirements of the University's Research Ethics policy and of the Human Tissue Act 2004. Further information can be found on the Research ethics website.

8.2. Animal samples

Animals may harbour biological agents that can be transmitted to humans and cause disease. Samples taken from unscreened wild or farm animals (blood, faecal material, tissues etc) should be treated as potentially infectious and operations should be performed ***within containment level 2 laboratory facilities***.

Where samples from animals where there is a known or high-likelihood of infection (either with an animal or human pathogen) then additional precautions may be required, including work in an appropriate level containment laboratory. For example materials taken from badgers or cattle herds where there is a high incidence of tuberculosis (caused by a hazard group 3 pathogen) may require containment level 3 laboratory facilities. Work with such material will require Sub-Committee for Biological Safety approval.

Farm animal tissues which have been certified by a vet and have a low risk of contamination with infectious agents (e.g. fresh meat or internal organs sourced from an abattoir) may be handled at containment level 1, with the principles of good hygiene applied.

9. Other sources of hazardous biological agents

9.1. Work involving exposure to contaminated soils

Many soils, especially those exposed to or treated with animal manures, have a high probability of containing spores of the Hazard Group 2 agent *Clostridium tetani*. Any case of serious injury involving contamination of the wound by dirt or soil may require additional anti-tetanus treatment, especially if it has been several years since the last anti-tetanus inoculation.

In addition to spores of *Cl. tetani,* soils may also contain other viable biological agents or their spores, including bacteria; fungi or parasites. The likelihood will depend upon the past history of the sample. Note that soils brought back from overseas may contain "exotic" biological agents (viable organisms, and/or their spores or cysts), including Hazard Category 2 and/or 3 species of bacteria, parasites and fungi. Such soils must only be imported under licence (from DEFRA), and any conditions attached to the licence must always be observed.

Where microorganisms are propagated from soil and which are likely to contain human or animal pathogens, then Sub-Committee for Biological Safety approval is required.

10. Pathogens and toxins covered by the Anti-Terrorism regulations

Part 7 of the Anti-Terrorism, Crime and Security Act (2001) requires that any occupier of premises must notify the Home Office before specified "dangerous substances" may be kept or used on those premises and that the prescribed security measures for the category of material are applied.

The specified substances include:

- specified pathogenic microorganisms (as listed in Schedule 5 to the Act.) The term microorganism here includes nucleic acid sequences associated with pathogenicity of the listed microorganisms, and genetically modified organism containing such a sequence.
- toxins, including subunits or any sources of nucleic acid sequences coding for the toxin.

All such notifications must be carried out through H&S Services. The notification will alert the local Counter Terrorism Security Advisor who will review details of:

- the material proposed
- the security systems in place
- the names of people with regular access to the areas of the facility where such material is held.

The Act also authorises the access of the Police to the facility (usually following due notification of an intention to visit). Visits would be undertaken to conduct security check. Following such a

visit, the University must comply with any reasonable recommendation in respect of security measures.

A list of the current pathogens and toxins on the Schedule 5 list can be found on the H&S Services website.

Due to the security requirements for holding such materials Principal Investigators must discuss any proposals to work with these materials with the Head of School and H&S Services prior to making any applications for funding.

11. Allergenic biological material

Many biological materials are known to be respiratory sensitisers, in that exposure by inhalation can lead to the development of an immune response and may lead to the development of asthma. Some materials may also affect the skin - for example, they are classified as irritants or skin sensitisers. Other materials may induce a severe response in the form of anaphylactic shock. Examples of allergenic biological materials include:

- Hardwood and softwood dust
- Enzyme preparations (e.g. subtilisins) as used in enzyme washing powders;
- Insect cuticle protein and faecal material (frasse);
- Animal dander (N.B. - this includes urinary proteins, as well as skin particles and animal fur) – please see Safety Code of Practice 14 part X for further information.

For respiratory sensitisers, further exposure to the agent (at work) can lead to an allergic response that is expressed by elicitation of bronchial spasm and narrowing of the airways - i.e. the development of (occupational) asthma. Skin sensitisation may be accompanied by the development of (occupational) dermatitis (including eczema), where further exposure leads to cracking and irritation of the skin, etc.

In some cases, sensitisation may be so severe that an anaphylactic, life-threatening response may occur on subsequent exposure to even minute quantities of the agent involved. In such cases, an individual would have to be removed from all possibility of further contact with the agent and may even be permanently disabled by the disease.

The essential feature of the control regime to be adopted is that of controlling exposure, where exposure cannot be prevented. The normal hierarchy of control measures applies, with the priority being given to “engineering controls” which aim to control exposure at source by either enclosing the hazardous substance/ process, or applying a measure such as local exhaust ventilation to remove the hazardous substance from the vicinity of the worker. Where exposure cannot be controlled by other means, personal protective equipment such as Respiratory Protective Equipment (RPE - for example a filtering face mask) may be required.

The initial COSHH assessment should identify the possibility of sensitisation and appropriate control measures for the materials. See safety code of practice 28 for further information on COSHH assessments, including work exposure limits for dusts).

12. Risk assessments

The COSHH regulations require all activities involving substances hazardous to health to be risk assessed and the results recorded. In this code, this is extended to biological materials which are hazardous to the environment.

The BioRA risk assessment form should be used. An example of a completed risk assessment form for intentional work with a hazard group 2 bacteria, and for work with human blood can be found on the Biological Safety website..

For each activity the assessment should identify:

1. The microorganisms involved or hazardous material including hazard group level
2. The normal route of infection and any risk factors, for example enhanced virulence, low multiplicity of infection, clinical samples or antibiotic resistance
    - The main modes of transmission of infectious diseases are:

Percutaneous	Inoculation wounds e.g. from • contaminated needles, scalpel blades, • breaches in the skin e.g. cuts or wounds • a bite or sting from an infected animal or insect
Mucocutaneous	Infection via the eye or the mucous surfaces of the respiratory, gastrointestinal or urogenital tracts
Respiratory	Inhalation of airborne particles
Ingestion	Into the gastrointestinal tract

3. Procedures to be carried out including any "risk procedures" such as centrifugation, vortexing, homogenisation etc and identify potential routes of exposure (see info box on page 19 for more details).
4. Control and containment measures, including:
    - Containment level of laboratory required – *normally equivalent to the hazard group level, see section 15 for further details*
    - Use of microbiological safety cabinets to control aerosols containing infectious agents – *see info box on page 19 for more details on aerosols. Safety Code of Practice 14 part 6 outlines the requirements for the selection, use, maintenance and testing of Microbiological Safety cabinets.*
    - Prohibition of restriction of use of sharps - *see info box on page 19 for more information*
    - Personal protective equipment *such as laboratory coats, gloves, safety glasses and respiratory protective equipment (see section 14)*
    - Good occupational hygiene *(see section 13)*

Info Box - Sharps

The use of sharps in laboratories should be restricted, particularly when working with microorganisms infectious via the percutaneous route or when working with human samples which may contain blood borne viruses.

Glass pasteur pipettes have caused a number of injuries in laboratories both during use and disposal, where practicable other systems should be used, for example use of disposable plastic aspirators. Where this is not possible, procedures should be put in place to ensure correct use and safe disposal.

Needles and syringes should not be used unless absolutely necessary. Where possible blunt-end needles should be used, for example during cell separation in cell culture. If sharp needles are required, luer-lock needles should be used, users should be given appropriate training including instructions never to re-sheath needles and ensure correct disposal (sharp bin located at point of sharp use).

Info Box - Aerosols

Aerosols (small droplets of liquid containing infectious material) can be generated during a number of laboratory procedures, for example during plating, pipetting, opening tubes, centrifugation, vortexing, homogenisation etc. Aerosols may be inhaled into the lungs via the mouth or nose or may be deposited on laboratory surfaces. Because of this care must be taken to minimise aerosol production, examples of measures to control aerosol generation include:

- Plating – ensure plates are dry, use plastic disposable loops or spreaders rather than metal loops or glass spreaders and Bunsen burners.
- Vortexing – mix by another means if possible, use screw cap tubes rather than eppindorfs to prevent accidental opening/leakage. Allow tubes to settle before opening.
- FACS cell sorting – fix cells (e.g. with paraformaldehyde) which should deactivate any contaminating microorganisms, if un-fixed cells are used and there is a likelihood of infectious material being present additional precautions such as HEPA filtered local exhaust ventilation may be required.

At containment level 2 where aerosol production is unavoidable, a suitable microbiological safety cabinet should be used, particularly if working with an organism transmissible by inhalation.

5. Vaccination requirements – *where an effective vaccination is available against the organisms in use, or likely contaminant – see the HepB policy for vaccinations recommended for human samples. The Approved List of Biological agents identifies microorganisms where there is an effective vaccination available.*
6. Emergency procedures – *for example actions to take in the event or a spillage or needlestick injury – these may be detailed in the local rules for the facility (section 21).*
7. Health surveillance *(see section 17)*
8. Waste – *local rules should detail arrangements for the disposal of waste. See Safety Code of Practice 14 part 7 for further information.*
9. Supervision, instruction and training requirements *(see section 15)*

13. Working practices and control measures

The *Principles of good occupational safety and hygiene* aim to protect laboratory workers from contamination by hazardous agents, to prevent the dispersal of organisms from the laboratory into the community at large, and to minimise the risk to others who may be affected by the work.

The following rules should be applied to ensure good occupational hygiene:

Personal hygiene

- A suitable laboratory coat must be worn at all times when working in a microbiology laboratory
    - At containment level 2 this must be side-fastening (Howie style), or back-fastening, with elasticated cuffs and should protect the arms, neck and lap.

Lab coats should be removed before leaving the laboratory suite, and stored properly, out of contact with outdoor clothing. Lab coats should be changed regularly or if they have been grossly contaminated.

- Any wounds or skin abrasions should be covered with a waterproof dressing.
- Disposable gloves should be worn when handling infectious material.
- Disposable gloves should be changed regularly or if they have become contaminated. Once removed they should be disposed as biological waste and should never be re-worn.
- Hands should be washed with a suitable disinfectant soap before leaving the laboratory or whenever there is a suspicion that they may have been contaminated with viable microorganisms.
- Glove(s) should be removed when using telephones, opening door handles etc. When transporting samples a gloved hand may be used to hold the samples and an un-gloved one to open doors.
- Workers must NEVER:

Pipette by mouth, pipetting aids must be used.

Store food or drink intended for human consumption in the laboratory. All such materials used for experimental purposes must be clearly marked "Not for human consumption".

Eat, chew gum, drink, apply cosmetics, take snuff or smoke within the laboratory.

Laboratory and procedures

- The laboratory door should be kept closed at all times and never propped open (doors between adjoining labs may be propped open during work to allow ease of movement).
- Windows to CL2 laboratories should be kept closed, to prevent positive-pressurisation with respect to the corridor and disruption of fume cupboards, microbiological safety cabinets and general ventilation airflows.
- Workbenches should be kept clean and free of clutter, there should be sufficient space to carry out work in an ergonomic and safe manner. Paperwork stored in the lab should

be kept to a minimum (e.g. protocols, risk assessments, equipment manuals, lab books which are required for lab activities)

- Samples should be placed in appropriate racks to minimise the likelihood of spillages. All samples should be labelled with the identity of the organism/material, name of the worker generating the material and date.
- In general, work may be conducted on the open bench but care must be taken to minimise aerosol production. At containment level 2 where aerosol production is unavoidable, a suitable microbiological safety cabinet must be used, see info box on page 19 for more details.

When centrifuging viable cultures of such organisms, use sealed tubes or a sealable rotor. These must then be opened in a Microbiological Safety Cabinet. Do not operate a centrifuge in an open-fronted Safety Cabinet, as the air currents created will disrupt the air flow in the cabinet.

- To prevent spillages outside the laboratory samples/materials should be placed in secondary containment during transfer between laboratories or buildings.
- Benches and safety cabinets must be cleaned with an approved disinfectant after work is completed.
- Housekeeping must be of a high standard. In containment level 2 laboratories storing items in cardboard or wooden boxes on or underneath benches must be avoided as these may become contaminated in the event of spillage.

All contaminated material that is awaiting collection for sterilisation/disposal must be stored safely, in suitable leak-proof containers. These should not be overfilled - this includes pipette discard containers.

14. Information, supervision and training

14.1. Information

Staff, students, and visitors must be provided with relevant information relating to the risks associated with their work and any relevant control measures. The safety information for laboratory workers should generally be written and would include:

- local rules
- standard operating procedures and
- risk assessments

Typical content of local rules

- Organisms in use in the area
- Lab rules, such as prohibitions, mandatory PPE requirements
- Disinfectant policy (types of disinfectant in use vs efficacy on organisms), concentration and shelf-life
- Waste arrangements for disposal of biologically contaminated solid and liquid waste
- Emergency procedures such as spillage or first aid

14.2. Training

Before commencing work, all staff and students must have read the relevant local rules and risk assessments, have received appropriate training in safe handling of the materials they are working with, and have demonstrated that they are competent. It is expected that at containment level 2, records are keep of training against Standard Operating Procedures (SOPs) and risk assessments.

Where equipment is used as a control measure, e.g. a microbiological safety cabinet, its proper use must be demonstrated and the worker advised of any routine checks to be undertaken that indicate normal function.

Training courses relating to biological safety are available from H&S Services and include:

- Introduction to Laboratory Safety (mandatory for all new PhD students and research assistants)
- Managing Biological Safety - designed for Area H&S Coordinators, Lab Managers and Principal Investigators, covering biological risk assessment, facilities and university procedures (3hrs)
- Laboratory Safety Management - developed for laboratory managers covering H&S legislation, safety management, selection, installation, use and maintenance of microbiological safety cabinets, laboratory design, pressure systems, hazardous waste and laboratory inspections (12hrs)

14.3. Supervision

The degree of ongoing supervision required will depend on the individual(s) being supervised and the tasks being carried out.

Undergraduates are not permitted to work unsupervised in research laboratories. A competent person who understands the risks in the area must be available at all times to intervene if safe working practices are not followed, or in an unexpected event happens, such a fire, spillage of hazardous material, or equipment malfunction.

15. Facilities and equipment

15.1. Laboratory facilities for work with biological agents

COSHH Regulations require that the level of containment to be used is numerically equal to the hazard category of the agent(s): thus Containment level 1 (the lowest level) is required for Hazard Group 1; Containment level 2 for Hazard Group 2 etc. The "normal" level may be modified by detailed consideration of the risks associated with the work and the particular properties of the agent concerned – for example, if working with a biological sample where there is a strong indication of infection with a hazard category 3 agent which does not pose a risk by inhalation of infected aerosols, then full containment category 3 conditions may not be required (subject to application to the HSE).

The containment measures are designed to limit the exposure of workers to the agent, and to prevent or minimise the dispersal of the agent from the laboratory.

Where the hazard is not primarily that of infection (i.e., where there are toxic or allergenic hazards), Containment level 1 is normally sufficient to control risks to humans unless the agent produces a potent toxin that is readily dispersed into the environment.

Environmental considerations may require a higher level of containment than is necessary to protect human health – for example, Foot and Mouth Disease Virus (FMDV) is not a hazard to human health and under COSHH containment level 1 would be sufficient HOWEVER work with the virus requires SAPO level 4 containment because of the pathogenicity towards animals such as cattle, sheep, pigs, etc. and it is listed as being subject to controls under DEFRA legislation.

For the purpose of this guidance the following definitions apply:

- A laboratory is a room in which biological agents/materials are handled
- An ancillary room is a room where biological agents/materials may be stored, or where equipment is used with biological agents/materials which are in primary containment (e.g. centrifuges, incubators) and are not directly handled.

15.2. Existing facilities

Whilst the COSHH approved code of practice and guidance describe in some detail what a containment level 2 laboratory should look like, there is no definitive guidance as to a containment level 1 laboratory (unless Genetically modified materials are in use). In practice, an existing containment level 1 laboratory should meet general "wet" lab standards; impervious (cleanable) benches, floors and seating, and handwash facilities would be expected. Unless the laboratory is used for Class 1 GM activities, containment level 1 laboratories do not require the Biohazard symbol to be displayed on the door by law but should be labelled as a CL1 lab.

15.3. New or refurbished laboratories

The aim should be to achieve (as a minimum) the Containment Level 2 (CL2) standard for any biological lab refurbishment, as detailed in the following table.

Note – in order to ensure compliance of laboratories with biological safety regulations, all works in containment level 2 laboratories involving changes to fixtures or fittings must be carried out by, or in agreement with Estates & Facilities and H&SS Services.

15.4. Ancillary rooms

In practice, ancillary rooms should meet the same general standards of cleanability as the equivalent level laboratory (impervious benches, floors and seating). There should be sufficient space to carry out the required activity, including space to put down samples, racks or trays etc and space to be able to deal with any spillages or incidents.

15.5. (COSHH) Containment Level 2

The standards are based on ACDP recommendations, plus those of the British Standard relating to Biotechnology laboratories used for research.

Bench surfaces	Must be easy to clean, impervious to water and resistant to the effects of alkalis, acids, solvents, disinfectants and other materials expected to be in use. The edges of benches, cupboards, drawers, etc, (where these are made of wood or veneer over chipboard) must also be impervious to penetration by liquid spills. Bench to bench/upstands or wall joints should be sealed to prevent ingress of contamination or sufficient space allowed between benches to allow cleaning. The aim is to be able to effectively disinfect any spill of infectious materials, and to design out cavities, cracks, porous surfaces, etc, where infectious biological agents can lodge and remain viable for long periods. If existing benches are to be re-used, all wooden surfaces must be stripped back to bare wood and re-varnished with a durable varnish that meets the above criteria. Such benches must be regularly inspected (e.g., monthly) for damage, and any damage found made good without delay. Ideally, all wooden bench surfaces should be replaced by a suitable laminate or solid impervious surface such as Corian® or Trespa®.
Laboratory sinks	Must be easy to clean and resistant to disinfectants. If chlorine-based disinfectants are to be used, the use of polypropylene or epoxy resin bowls is preferable to the use of stainless steel, because of the greater resistance to corrosion. Catch pots or large raps should not be fitted on the waste, a simple "S-bend" is preferable, followed by a direct discharge to a foul sewer.

Flooring	An impervious floor surface is not a regulatory requirement at CL2 – but in practice, the aim should be to adopt "one-piece" impervious flooring sealed at floor/wall junctions as standard for all containment laboratories. Floors should be kept in a good condition, with any damage to the integrity of the flooring repaired. Wooden floors should be sealed with appropriate sealant.
Hand-wash basin	There should be a dedicated hand-wash basin, located near the laboratory exit. Taps should be operable without touching by hand (elbow, knee or foot-operated or proximity-sensor operation) and provide both hot and cold water. A soap dispenser and hand drying facilities should be located at convenient point near the basin, together with a bin for waste paper towel (unless hand-dryers are provided)
Air-handling	When work is in progress, there is a need to maintain laboratory at a negative pressure with respect to surrounding areas. This applies "where [the room is] mechanically ventilated". There should be no recirculation of extracted air i.e. air from one room being re-supplied to another via the general ventilation system. Air must be expelled from the building in such a way that it cannot re-enter via air intakes. Doors should be kept shut whilst work is in progress. In practice, windows should remain shut whilst work is in progress to prevent a positive pressurisation of the lab in comparison with the corridor. An appropriate planned maintenance programme should be in place to ensure air-handling equipment is functioning correctly and maintaining negative pressure.
Security	Access to the laboratory must be restricted to laboratory personnel and other authorised persons. The laboratory must be secured in a way to prevent unauthorised access, for example: **access control systems for entry into containment level 2 suites** **small laboratories may be locked with a key or pin-code lock when un-occupied, however in large multi-occupancy laboratories, unauthorised access should be prevented even when occupied**
Space	The ACDP guideline is $24m^3$ per worker.
Lab coat storage	There must be separate storage space for lab-coats which should be kept within the laboratory (preferably near the hand-wash basin and lab exit) or an annex room of the laboratory.
Storage	Use of cardboard or (un-sealed) wooden boxes to store materials on, or under benches (on the floor) should be avoided. If under-bench storage cannot be avoided, consumables should be transferred to cleanable plastic boxes. Use of cardboard boxes for storage in other locations in the laboratory

	should be minimised as far as possible.
Signage	With respect to COSHH, Containment level 2 laboratories and above must be labelled with the Biohazard symbol, and identify the containment level.
Laboratory seating	Should be cleanable e.g. polyurethane or vinyl seating.
Separation of activities	In order to minimise exposure and contamination, office space should be provided separate to the laboratory. Some space may be provided to write-up laboratory books but should not be used for general office activities or for the storage of non lab-essential paperwork.

15.6. Equipment

Incubators, orbital shakers and fermenters **Fridges and Freezers**	Must be located inside designated laboratories or annexes (annexes should meet the same general requirements as laboratories in terms of cleanability and resistance to disinfectants) and security.
Microbiological safety cabinets	Must be selected, installed, used and maintained in line with the requirements of Safety Codes of Practice 14 part 6.
Autoclaves	At containment level 2, autoclaves must be available within the building. See Safety Codes of Practice 14 part 7.
Centrifuges	Centrifuges and their rotors/buckets must be subject to routine cleaning and inspection of seals. Regular service by a competent engineer is recommended for all centrifuges.

15.7. Permit to work, decontamination and clearance

In the event of the failure of a piece of plant or equipment requiring attendance by service maintenance personnel, all adjacent surfaces and the equipment **must** be decontaminated and a signed permit to work must be issued by the member of staff responsible for the area (or other nominated personnel). Details of the University's procedure for entry into lab areas by maintenance staff and contractors can be found in Safety Note 56 and 58.

Where a significant amount of maintenance work is required, for example during a refurbishment of a lab, the whole laboratory should be decontaminated and an area clearance and decommissioning form should be completed and handed over to the project manager (see Safety Note 65).

16. Occupational health surveillance and list of exposed employees

16.1. Health clearance and surveillance

Within the University, work with hazard group 2 biological agents requires pre-assessment of each individual worker for their suitability for the proposed work, based on the response to a health questionnaire with an annual review. All those who work with hazard category 3 organisms are required to be under annual health surveillance.

Workers should register for health clearance and annual surveillance using the form on the Universities occupational health web site.

Where health surveillance is undertaken, the records of that surveillance must also be maintained for 40 years, these are retained centrally by the Occupational Health Service.

16.2. Lists of exposed employees

Where the intention is to work with biological agents in Hazard Category 3 or 4, the COSHH Regulations require that all those potentially exposed be identified, and details of the work (plus details of any exposures, accidents and incidents) be kept. This list should be kept for a minimum of 40 years following the date of the last (potential) exposure (regarded as the last occasion of work with the agent), its is assumed that any intentional work with a particular type of biological agent also carries the risk that an individual may be exposed to that agent. These records are held centrally by H&S Services.

At containment level 2 the School should keep lists of "authorised personnel" (i.e. laboratory workers) for the laboratories, these names may be displayed on the laboratory door, if practicable, or kept by the laboratory or building manager.

17. Pregnancy

Certain biological agents within groups 2,3 and 4 can affect the unborn child if the mother is infected during pregnancy. These may be transmitted across the placenta while the child is in the womb or during or after birth e.g. if the child is breast-fed. Examples of agents that might affect the child in this way are hepatitis B & C, HIV, Herpes, syphilis, chickenpox, brucella and typhoid.

Risk assessments must take account of the nature of the biological agent, how the infection may be spread, how likely contact is and the control measures in place.
These include notification of the hazard, the level of containment for working, protective equipment in use, hygiene measures in place and surveillance measures. The use of available vaccines is recommended, with due regard for contra-indications especially in the early stages of pregnancy.

If there is a known or suspected risk of exposure to a highly infectious agent, then it is appropriate for the pregnant worker to avoid exposure altogether.

Rubella (German Measles) and toxoplasmosis can harm the unborn child, as can some other biological agents e.g. cytomegalovirus. Exposure to these biological agents should be avoided except where the pregnant woman is protected by her state of immunity.

If a worker expects to conceive or believes herself to be pregnant, she may wish to discuss this with the Occupational Health Advisor. If confidentiality is required the worker may complete the relevant sections of the OH line management referral form and send to the Occupational Health service with an explanatory email.

18. Storage and inventory

Each Principal Investigator or manager storing or using hazardous biological agents (hazard group 2 or above) should keep a detailed inventory of all such agents within the laboratory. This also applies to material likely to be contaminated by hazardous biological agents - thus, for example, human tissues samples and body fluids (such as blood) should be included in the inventory.

The inventory should record details of the:

- identity of each organism or potentially contaminated sample
- name of the person in charge
- amount stored (in long-term storage, such as freeze-dried culture); and
- location and type of storage.

The detailed inventory should be kept in a secure location, but be accessible to all persons authorised to enter the particular laboratory and a copy of each laboratory inventory should be stored centrally, i.e. each School should have secure central records showing the type and location of all hazardous biological agents used/ stored within the building in case of an emergency affecting one or more laboratories in the building, or in situations when the laboratory supervisor cannot be contacted. Records must be updated if there are any significant changes - for example, addition of new biological agents, or removal of existing agents from the inventory.

19. Transportation on and off site

19.1. On site

Transportation off biological material between university labs or buildings (not requiring use of off-campus/public roads) must be carried out in a way to ensure containment of the samples if dropped. Material should be in sealed vessels (tubes or plates) placed in (at least) a secondary sealed container with sufficient absorbent material (e.g. paper towel) to absorb a spill. Boxes should be labelled with name of the person responsible and their contact details and should never be left unattended.

19.2. Off site

Transport of dangerous goods, which includes biological samples and specimens is regulated to prevent, as far as practicable, harm to persons or the environment and damage to property during all stages of the transport chain. The two main regulations are:

- **Road and rail:** The *Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2007*.
- **Air:** The *Air Navigation (Dangerous Goods) Regulations 2002 (as amended)* implements the *International Air Transport Association (IATA) Regulations* and additional measures in the UK.

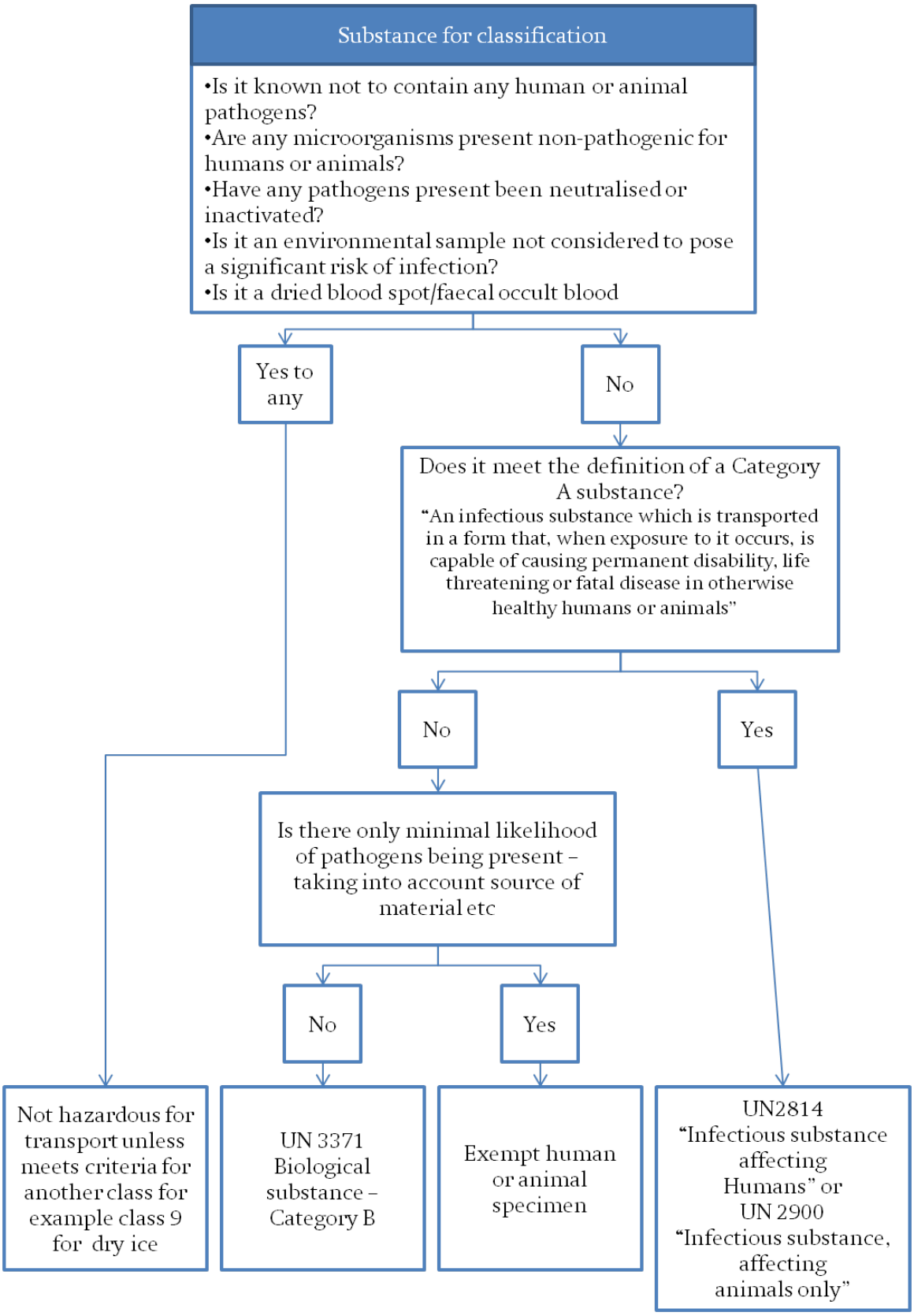
The UN harmonisation system describes nine hazard classes each relating to a different type of hazard and further subdivides some of the more wide-ranging classes into hazard divisions. Biological materials are covered by Class 6.2 category A or B or Class 9 where relevant. Some biological materials may be transported in chemicals that are themselves classified as dangerous goods (e.g. formaldehyde). In these circumstances the requirements of other relevant classes will also need to be addressed.

Transportation of hazardous biological material by public transport e.g. tube, bus or passenger rail is prohibited. Transportation via private vehicle in the UK may be permissible as long as the requirements of the *Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2007* are met.

In order to comply with the complex requirements each person who ships biological material must:

- **Complete the relevant on-line training module (Note - national and international Regulations dictate that any individuals involved in the transport of hazardous goods must be trained, tested, certified every two years and retain a record of their training)**
- **Classify the material to be transported into the appropriate category**
- **Identify the UN number and proper shipping names**
- **Check for carrier or state variations and limitations**
- **Select the proper packaging material and package items accordingly.**

Please see figure below for a summary of the transport classification system, further details are available from H&S Services.



20. Emergency procedures

20.1. Emergency planning

Plans to deal with foreseeable incidents should be in place. When drawing up emergency plans a number of different factors will need to be considered to determine the most appropriate course of action, these include:

- **Type of agent - the Hazard Group, route of transmission, infectious dose (if known) and the stability in the environment.**
- **Severity of accident - amount and concentration of material that could potentially be released and its form, for example, is aerosol formation likely?**
- **Location within the laboratory - an accident in the open laboratory may require evacuation, as compared to a more 'contained' accident in a microbiological safety cabinet.**

20.2. Spillages

In the event of significant spillage inside the laboratory immediate evacuation may be required. This will depend upon the nature of the biological agent and should be identified in the risk assessment. Where feasible the microbiological safety cabinet in the laboratory should be left running to clear the lab of infectious aerosol, or the laboratory evacuated for approximately 60 mins to allow infectious aerosol to settle. Doors should be secured and signs posted to prevent others entering.

Hazard group 2 organisms which do not present a risk of aerosol transmission can be mopped up using the appropriate disinfectant (at the correct final concentration). For organisms which do present a risk of infection via inhalation, appropriate face masks should be worn (recommended minimum of a half face ffp3 mask – note that this does not provide any protection in the event of a hazardous chemical spillage).

In the event of ***personal contamination***, any contaminated clothing should be removed and left in the laboratories, the clothing will need to be bagged up and sent for autoclaving.

In most cases, ***spillages inside a microbiological safety cabinet*** can be cleaned up immediately with an appropriate disinfectant. Fumigation of the cabinet will be required for CL3 organisms and for gross contamination with certain CL2 organisms (subject to risk assessment).

If there is reason to believe a breakage may have occurred in a ***centrifuge*** the lid should remain shut to contain the aerosol and left for 30 minutes to allow aerosols to settle. A notice should be left on the lid to alert other users to the problem. The lid should be opened carefully and the interior sprayed with an appropriate disinfectant (active against the agent spilled), followed by a neutral pH detergent and wiped down with 70% alcohol. The rotor /buckets should be inspected, and if intact transferred to a microbiological safety cabinet for opening and disinfection. For Hazard group 2 organisms with risk of airborne transmission, respiratory protective equipment should be worn (as above).

Users of ***orbital shakers*** should always check through the observation panel for signs of leaks or spills. If in doubt do not open the lid, turn off and leave at least 30 minutes before opening, following the procedures outlined for centrifuges above.

20.3. Needlestick injuries and first aid

For any accident involving broken skin, bleeding should be encouraged and the area washed with soap and water. A First Aider should be called. Where the wound may have been contaminated with human material, or a hazard group 2 biological agent, medical assessment (for example in A&E or a walk-in clinic) is required, and post-exposure prophylaxis may be prescribed by a medical professional. Occupational Health should also be informed of any such incident on the next working day. For more details please see the Needlestick Policy.

21. Reporting of accidents and incidents

If any worker contracts a disease because of their work with a biological agent (i.e. an occupationally acquired disease), this could be regarded as de facto evidence of the failure to adequately control exposure. This would be reportable under the Reporting of Incidents, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995. The University Occupational Health service should inform H&S Services of any such case of occupationally-acquired disease, so that the circumstances could be investigated.

If a worker suspects that they may have contracted a disease as a result of their work, they should consult Occupational Health as soon as possible. If an occupationally-acquired disease is medically confirmed, H&S Services are responsible for reporting the disease under RIDDOR.

22. Further advice and information

H&S Services website on Biological Safety contains links to relevant forms, classification lists and guidance documents including:

- Control of Substances Hazardous to Health Regulations 2002 (as amended)
- The Approved List of biological agents. Advisory Committee on Dangerous Pathogens (ACDP).
- The Management, design and operation of microbiological containment laboratories. Advisory Committee on Dangerous Pathogens [ACDP]. HSE Books, Sudbury, 2001.
- List of Specified Animal Pathogens and notifiable pathogens and toxins under the Anti-terrorism, crime and security Act 2002.

Appendix 1 Sub Committee for Biological Safety – Terms of Reference

To advise on and oversee all activities involving the use of, or potential exposure to Biological Agents and other biological materials within the University, and to oversee University compliance with all regulations pertaining to activities involving genetic modification.

Key Functions

- To advise on risk assessments for activities involving genetic modification and the use of biological materials, including biological agents
- To approve all applications to undertake work involving genetic modification whether in contained use or deliberate release activities and to require that changes be made to proposed activities where the sub-Committee fails to approve such proposals;
- To receive, consider and advise on reports and information provided by inspectors of the enforcing authorities.
- To consider formal reports submitted by members of the University where appropriate.
- To monitor the effectiveness of the University's health and safety policy and procedures for genetic modification and biological safety.
- To consider and advise on Genetic Modification and Biosafety training and its effectiveness.
- To consider reports and statistics relating to incidents, work-related ill health and dangerous occurrences involving either genetically modified organisms or biological materials, and recommend remedial action where appropriate
- To submit regular reports via the Chairman to the main Health and Safety Committee, and to receive, consider and (where appropriate) act on reports from the parent committee in relation to the sub-Committee's activities.

Powers of the Sub-Committee

The Sub-Committee can:

- Require changes in experimental protocol to improve safety prior to approving projects;
- Advise on the drawing up of local rules to cover work involving hazardous biological agents and/ or genetic modification;
- Define and review laboratory practice with regard to safety in biological work, including activities involving the use of genetically modified organisms;
- Consider all relevant accidents/incidents and review University policy if necessary; and halt projects if breaches of University procedures or legislation occur.