**BioCOSHH Risk Assessment**

A BioCOSHH risk assessment is required by law for the possession or use of biological agents or hazards. Managers and principal investigators are responsible for BioCOSHH risk assessments. The possession or use of high hazard biological agents (Hazard group 3 agents and the Hazard group 2 agents *Bordetella pertussis, Corynebacterium diphtheriae* and *Neisseria meningitidis*) requires permission from the University Biological Safety Committee (BSC). If you wish to do any work with these agents you must apply for permission from the University BSO. A BioCOSHH risk assessment must be submitted by the principal investigator by email to the University BSO. The University BSO issues advice and approval for these high hazard BioCOSHH risk assessments on behalf of the University BSC. Enquiries on BioCOSHH risk assessment and biological agents or hazards should be directed to your School Biological Safety Supervisor or School Safety Officer.

**BioCOSHH Risk Assessment Form**

[BioCOSHH Risk Assessment Form - Biological Agents and Hazards](#)

**Guide to BioCOSHH Risk Assessment**

The Control of Substances Hazardous to Health Regulations (COSHH) require employers to protect people, animals, plants and other aspects of the environment against risks from work activities with biological agents and hazards. Managers and principal investigators must ensure that work is not undertaken with biological agents and hazards unless a suitable and sufficient assessment of the risks created by that work has been undertaken and suitable and sufficient control measures identified and implemented so as to reduce the risk to the lowest level reasonably practicable. BioCOSHH risk assessments must address the routine and non-routine aspects of the work and there must be emergencies procedures. All workers including staff and students must be properly informed, trained and supervised to enable them to safely and competently perform the work. BioCOSHH risk assessments must be carried out by competent persons. The manager or principal investigator of the work is responsible for ensuring the risks associated with the work are properly assessed and recorded. The requirements of other legislation such as those relating to work with animal pathogens, plant pathogens and pests which are regulated by the Department for Environment, Food and Rural Affairs (DEFRA) must also be taken into account for work with biological agents and hazards. This guidance briefly summarises duties which apply to work with biological agents and hazards and describes how to carry out a BioCOSHH risk assessment for humans, animals, plants and other aspects of the environment. It is not a comprehensive overview of the law and it does not include all of the legal requirements. Detailed guidance on work with biological agents and hazards is given in the HSE COSHH Approved Code of Practice and Guidance, ACDP Biological Agents: Managing the Risks in Laboratories and Healthcare Premises, ACDP Approved List of Biological Agents and ACDP Management, Design and Operation of Microbiological Containment Laboratories.

- [HSE Control of Substances Hazardous to Health Regulations: Approved Code of Practice and Guidance](#)
- [ACDP Biological Agents: Managing the Risks in Laboratories and Healthcare Premises](#)
- [ACDP Approved List of Biological Agents](#)
- [ACDP Management, Design and Operation of Microbiological Containment Laboratories](#)

These guidance documents can be obtained from the HSE website. See guidance on the HSE and DEFRA websites.
Biological Agents and Hazards

The COSHH Regulations defines biological agent as a microorganism, cell culture or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health. A microorganism is defined as a microbiological entity, cellular or non-cellular, which is capable of replication or of transferring genetic material, and a cell culture is defined as the in-vitro growth of cells derived from multicellular organisms. The definition of biological agents includes microorganisms (e.g., bacteria, viruses, fungi and transmissible spongiform encephalopathy agents), parasites (e.g., malarial parasites, amoebae and trypanosomes), the microscopic infectious forms of larger parasites (e.g., ova and infectious larval forms of helminths), cell cultures (e.g., primary or continuous human or animal cell lines) and nucleic acids (e.g., oncogenes or viral infectious clones). Other legislation applies to animal and plant pathogens and pests. Biological agents include pathogens, toxins, allergens and carcinogens. Biological hazards include biological agents, any material which contains biological agents or any other hazardous biological substances which are not classified as biological agents.

There are two broad types of work with biological agents intentional work which involves deliberate work with or exposure to specific biological agents and unintentional work which involves work with or exposure to materials which might contain biological agents. The COSHH Regulations cover only those circumstances where the risks of exposure to biological agents are work related but not where they have no direct connection with the work. COSHH applies to intentional exposure resulting from a deliberate intention to work with biological agents (e.g., research, development, teaching or diagnosis) and unintentional exposure which arises out of the work activity but does not involve a deliberate intention to work with biological agents (e.g., maintenance, healthcare, gardening, agriculture, waste or sewage handling). However, COSHH does not apply to exposure which does not arise out of the work activity itself such as where an employee catches a respiratory infection from another employee whilst at work. There is other legislation that also applies to certain animal and plant pathogens and pests. Biological agents include pathogens, toxins, allergens and carcinogens. Biological hazards include biological agents, any material which contains biological agents, and any other type of harmful biological substances or products.

Essentials of BioCOSHH Risk Assessment

Essential steps to protect humans, animals, plants and the environment from risks associated with biological agents or hazards.

1. Assess risks to humans, animals, plants and other aspects of the environment arising from the use of the biological agents and hazards in the work.
2. Responsibility of managers and principal investigators.
3. BioCOSHH risk assessments must be done in advance and by competent persons.
4. Consult and communicate with workers and safety officers.
5. BioCOSHH risk assessments and controls must be suitable and sufficient and proportionate to the risks.
6. Consider the biological agents or hazards and the work activity.
7. Decide who or what might be harmed and how.
8. Assess risks relating to biological agents and hazards.
9. Decide on hazard group (HG 1-3).
10. Decide on containment level (CL 1-3).
11. Decide what control measures are necessary to prevent or adequately control exposure and minimise the risks.
12. Control measures must be implemented, monitored and maintained.
13. Decide whether health surveillance and monitoring of exposure is required.
14. Ensure there are plans and procedures to deal with emergencies.
15. Ensure workers are properly informed, trained and supervised to enable them to safely and competently perform the work.
16. Obtain DEFRA licence if required.
17. School Biological Safety Committee and University Biological Safety Committee permission required for hazard group 3 and several hazard group 2 activities.
18. HSE notification required for hazard group 3 and a few hazard group 2 activities.
19. HSE consent required for hazard group 3 activities.
20. BioCOSHH risk assessments and other relevant records must be kept by managers and principal investigators.
21. BioCOSHH risk assessments must be reviewed and revised where they are no longer valid or where there are significant changes to activity or risks.

Rules for Work with Biological Agents

The University has specific rules for work with biological agents and hazards which are determined by the hazard group. These rules are obligatory and you must comply with them in your work. Please read these rules carefully and you can obtain advice on BioCOSHH risk assessments and controls from your School Biological Safety Supervisor, Biological Safety Officer and School GM Chair.

Hazard Group 1

The possession or use of hazard group 1 biological agents and hazards is subject to the following requirements.


2. **Monitoring** - The PI must monitor the work to ensure that the controls are effective and all workers comply with the controls identified in BioCOSHH risk assessments.

3. **Review** - BioCOSHH risk assessments must be reviewed and amended immediately where there are any changes to the activity or the risks. Do not make changes to the original BioCOSHH risk assessments. To amend a BioCOSHH risk assessment the PI must save a copy and revise the new version of the form (eg v1, v2, v3).

4. **Records** - The PI must keep all BioCOSHH risk assessments and other relevant records. Keep electronic versions of all records.
Hazard Group 2

The possession or use of hazard group 2 biological agents and hazards is subject to the following requirements.


2. **Pathogen registration** - Hazard group 2 biological agents must be registered with the University Safety Office using the Pathogen Registration form.

3. **Monitoring** - The PI must monitor the work to ensure that the controls are effective and all workers comply with the controls identified in BioCOSHH risk assessments.

4. **Review** - BioCOSHH risk assessments must be reviewed and amended immediately where there are any changes to the activity or the risks. Do not make changes to the original BioCOSHH risk assessments. To amend a BioCOSHH risk assessment the PI must save a copy and revise the new version of the form (e.g., v1, v2, v3).

5. **Records** - The PI must keep all BioCOSHH risk assessments and other relevant records. Keep electronic versions of all records.

Hazard Group 3

The possession or use of hazard group 3 biological agents or hazards which contain hazard group 3 biological agents and the hazard group 2 agents *Bordetella pertussis, Corynebacterium diphtheriae* and *Neisseria meningitidis* or hazards which contain these hazard group 2 biological agents is subject to the following requirements.

1. **BioCOSHH risk assessment** - A BioCOSHH risk assessment is required for hazard group 3 biological agents or hazards and the hazard group 2 agents *Bordetella pertussis, Corynebacterium diphtheriae* and *Neisseria meningitidis* or hazards. Complete a BioCOSHH risk assessment form.

2. **BSC permission** - Hazard group 3 biological agents or hazards and the hazard group 2 agents *Bordetella pertussis, Corynebacterium diphtheriae* and *Neisseria meningitidis* or hazards BioCOSHH risk assessments require permission from the School Biological Safety Committee (School BSC), University Biological Safety Committee (University BSC) and Health and Safety Executive (HSE) before bringing any biological agents and hazards into the University or starting work. The principal investigator (PI) must email the BioCOSHH risk assessment form to the School GM Chair. The GM Chair will review and advise on the BioCOSHH risk assessment and may request amendments. The PI must act on the advice and make the requested amendments. The GM Chair will approve satisfactory BioCOSHH risk assessments on behalf of the School BSC. The GM Chair will then email the BioCOSHH risk assessment form to the University BSO for submission to the University BSC. The University BSC will review and advise on the BioCOSHH risk assessment and may request amendments. The University BSO will email all BSC advice to the PI and School GM Chair. The PI must consider the advice and make the requested amendments. The PI must email the amended BioCOSHH risk assessment form back to the School GM Chair who will check it and then email it to the University BSO. The University BSC will provisionally approve satisfactory BioCOSHH risk assessments. Approval will only be issued once HSE permission has been obtained.
3. **HSE notification** - The BioCOSHH risk assessments must be notified to the HSE. The University BSO will email an HSE CBA1 notification form to the PI. The PI must complete the form and then email it to the University BSO. The University BSO will advise the PI on completion of the form. The University BSO will then email the completed CBA1 form and the approved BioCOSHH risk assessment to HSE. The HSE may request further information about the work or request changes to the risk assessment. The University BSO will email all HSE advice and requests to the PI and School GM Chair. The PI must act on the advice and make the requested amendments. The PI must email amended forms back to the University BSO who will review them and if satisfactory will email them to the HSE. The University BSO will inform the PI of all HSE requests and advice. HSE will notify the University BSO in writing when they are satisfied.

4. **BSC permission** - The University BSC will approve satisfactory BioCOSHH risk assessments on receipt of HSE permission. The University BSO will email the approval certificate and copy of the HSE approval letter to the PI and School GM Chair. The PI may then commence the work.

5. **Pathogen registration** - Hazard group 3 biological agents or hazards and the hazard group 2 agents *Bordetella pertussis*, *Corynebacterium diphtheriae* and *Neisseria meningitidis* or hazards must be registered with the University Safety Office using the Pathogen Registration form. Pathogen registration must be done before the agents or hazards are acquired but they must not be acquired until the University BSO informs the principal investigator that HSE have given consent.

6. **Monitoring** - The PI must monitor the work to ensure that the controls are effective and all workers comply with the controls identified in BioCOSHH risk assessments.

7. **Review** - BioCOSHH risk assessments must be reviewed and amended immediately where there are any changes to the activity or the risks. Do not under any circumstances make changes to the original BioCOSHH risk assessments. To amend a BioCOSHH risk assessment the PI must save a copy and revise the new version of the form (eg v1, v2, v3). Email the revised BioCOSHH risk assessment form to the School GM Chair. The GM Chair will review and advise on the BioCOSHH risk assessment and may request amendments. The PI must act on the advice and make the requested amendments. The GM Chair will approve satisfactory BioCOSHH risk assessments on behalf of the School BSC. The GM Chair will then email the BioCOSHH risk assessment form to the University BSO for submission to the University BSC. The University BSC will review and advise on the BioCOSHH risk assessment and may request amendments. The University BSO will email all BSC advice to the PI and School GM Chair. The PI must act on the advice and make the requested amendments. The PI must email the amended BioCOSHH risk assessment form back to the School GM Chair who will check it and then email it to the University BSO. The University BSC will approve satisfactory revised BioCOSHH risk assessments. The University BSO will notify any significant changes to the project or risks to HSE. The University BSO will inform the PI of all HSE requests and advice. On receipt of HSE permission the University BSO will email the approval certificate and copy of the HSE approval letter to the PI and School GM Chair. The PI may then commence the work.

8. **Records** - The PI must keep all BioCOSHH risk assessments and other relevant records. Keep electronic versions of all records.

**Hazard Group 4**

The possession or use of hazard group 4 biological agents and hazards is prohibited at Newcastle University.
Human or Animal Cells and Tissues

The possession or use of human or animal cells and tissues is subject to the following requirements.


2. **Monitoring** - The PI must monitor the work to ensure that the controls are effective and all workers comply with the controls identified in BioCOSHH risk assessments.

3. **Review** - BioCOSHH risk assessments must be reviewed and amended immediately where there are any changes to the activity or the risks. Do not make changes to the original BioCOSHH risk assessments. To amend a BioCOSHH risk assessment the PI must save a copy and revise the new version of the form (eg v1, v2, v3).

4. **Records** - The PI must keep all BioCOSHH risk assessments and other relevant records. Keep electronic versions of all records.

Other Biological Hazards

The possession or use of other biological hazards (eg allergens, animals, plants, soils) which are harmful to human health or the environment is subject to the following requirements.


2. **Monitoring** - The PI must monitor the work to ensure that the controls are effective and all workers comply with the controls identified in BioCOSHH risk assessments.

3. **Review** - BioCOSHH risk assessments must be reviewed and amended immediately where there are any changes to the activity or the risks. Do not make changes to the original BioCOSHH risk assessments. To amend a BioCOSHH risk assessment the PI must save a copy and revise the new version of the form (eg v1, v2, v3).

4. **Records** - The PI must keep all BioCOSHH risk assessments and other relevant records. Keep electronic versions of all records.
Stage 1: Complete a BioCOSHH Risk Assessment Form

A suitable and sufficient BioCOSHH risk assessment is required by law for work involving the possession or use of biological agents and hazards or exposure to biological agents and hazards. The principal investigator or manager may delegate the preparation of a risk assessment to any competent member of the team but responsibility for approving the risk assessment remains with the principal investigator or manager. Firstly you need to download a BioCOSHH risk assessment form.

BioCOSHH Risk Assessment Form - Biological Agents and Hazards

The BioCOSHH risk assessment should be completed using a computer and should not be written by hand. The terms hazard and risk have specific meanings in relation to biological agents and hazards. The hazard of a substance is the intrinsic property to cause harm. The risk in relation to exposure to biological agents and hazards means the likelihood of harm under the conditions of use and the severity of that harm. It is important to understand the difference between hazard and risk. The main purpose of your BioCOSHH risk assessment is to identify the biological agents and hazards, decide who and what is at risk, assess the level of risks to human health, animals, plants and other aspects of the environment, and decide on suitable controls to ensure that the work with the biological agents and hazards can be done safely. BioCOSHH risk assessments are expected to be of a high standard, particularly in respect to clarity, justification of statements on hazards and risks and the identification of control measures. The BioCOSHH risk assessment will enable valid decisions to be made about what needs to be done to prevent or control adequately exposure to biological agents and hazards. The work must be categorised on the basis of risks taking into account the biological agents and hazards, the type of activity, appropriate containment level and controls. Examples of completed BioCOSHH risk assessment forms for human tissues and pathogens are given below. These are not generic risk assessments and you must do your own risk assessments for your work.

EXAMPLE - BioCOSHH Risk Assessment Form - Human Tissues - EXAMPLE

EXAMPLE - BioCOSHH Risk Assessment Form - Hazard Group 2 Pathogen - EXAMPLE

BioCOSHH risk assessments need to be sufficiently specific but should be understood by non-experts (eg workers, safety officers or HSE inspectors). It is very important that the risk assessment is clear and statements about risks and controls are properly justified. Avoid being unnecessarily restrictive and try to anticipate future changes and incorporate these into the risk assessment. The introduction should outline the background but be kept as brief as possible and focused on information needed to understand the risk assessment. Remember that you are writing a risk assessment not a grant application so you do not have to justify doing the work only that it will be done safely. Statements about risks should be explicitly justified. Probably the easiest way to justify most statements is to either cite an appropriate reference or provide sufficient information and explanation. Appropriate references can include scientific publications, official guidance documents which are very useful but specify section and paragraph numbers and commercial catalogues.

Basic Information

In this section you need to give basic information about the project or work and who is in responsible for management of the work.

Title of project or activity

You should provide the title of the project or activity in this section. The title should specify the nature of the work and the biological agents and hazards.

Principal investigator / Responsible person

You should provide the name of the principal investigator or the manager who is in charge of the activity in this section.
School
You should provide the name of your School (eg School, Institute or Unit etc).

Date of assessment
You should provide the date on which the assessment was carried out.

Location of work
You should provide the name of the building and room numbers or details of location for field work.

Section 1 Project or Activity

In this section you need to describe the work that you will be doing.

1.1: Brief description of the project or activity
You should provide a brief but sufficiently detailed description of the work to enable workers, other people and non-experts to understand the exact nature of the work. You should consider all of the relevant characteristics including the pathogenic, toxic, allergenic, carcinogenic and environmental properties of the biological agents and hazards.

Information resources

Proper assessment of the risks from biological agents and hazards requires sufficient information on the hazards and risks. Useful information can be found in the following resources.

- University Safety Office website.
- University Occupational Health Service website.
- Health and Safety Executive website.
- Department for Environment, Food and Rural Affairs website.
- Department of Health website.
- Health Protection Agency website.
- Centre for Disease Control and Prevention website.
- HSE, ACDP, DH, HPA and DEFRA publications.
- Microbiology and biology textbooks.
- Scientific papers.
- Information from other research centres.
- Microorganism and cell culture collections (eg ATCC, ECACC and UKNCC).
- Internet searches. A simple search using a search engine will often produce valuable information and links to useful websites.

These websites provide important and useful information on biological agents and hazards.

HSE Biological Agents

DEFRA Animal Pathogens

DEFRA Pests and Diseases

DH Immunisation Against Infectious Disease

Health Protection Agency

Centre for Disease Control and Prevention
There are two basic means of exposure to biological agents and hazards at work. These are intentional work with biological agents or hazards (eg work with a specific pathogen) and unintentional work with biological agents or hazards (eg work with cells, tissues, organs, bodies or materials that may contain pathogens).

**Section 2 Hazards**

In this section you need to describe the biological agents and hazards which will be used or to which people could be exposed in the work.

**2.1: Biological agents or hazards**

You should provide details of the biological agents and hazards. The COSHH Regulations apply to a very wide range of bacteria, viruses, fungi, parasites and infectious materials. They apply to individual biological agents or hazards wherever exposure might occur whether relating to scientific research, laboratory work, field work, building maintenance or cleaning etc. The biological agents and hazards are classified into the following types.

- Pathogens (ACDP/DEFRA Hazard Group 1).
- Pathogens (ACDP/DEFRA Hazard Group 2).
- Pathogens (ACDP/DEFRA Hazard Group 3).
- Toxins.
- Carcinogens.
- Allergens.
- Human primary or continuous cell cultures.
- Animal primary or continuous cell cultures.
- Human cells or tissues.
- Animal cells or tissues.
- Human blood.
- Patient contact.
- Animals.
- Plants.
- Soils.
- Other biological hazards.

**Classification of biological agents**

Biological agents are officially classified by ACDP or DEFRA according to the risks to human health, animals, plants and the environment. ACDP classifies human pathogens into four ACDP hazard groups while DEFRA classifies animal pathogens into four DEFRA hazard groups and classifies plant pathogens and pests into complex groups.

**ACDP classification of biological agents**

Human pathogens are classified by ACDP into four hazard groups (HG1-4) according to the following.

- Ability to cause infection.
- Severity of the disease that may result.
- Risk that infection will spread to the population.
- Availability of vaccines and effective treatment.

The four hazard groups of human pathogens and the basis of their classification are as follows.
Hazard group 1 (HG 1): Biological agent that is unlikely to cause human disease.
Hazard group 2 (HG 2): Biological agent that can cause human disease and may be a hazard to employees but it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available.
Hazard group 3 (HG 3): Biological agent that can cause severe human disease and may be a serious hazard to employees and it may spread to the community but there is usually effective prophylaxis or treatment available.
Hazard group 4 (HG 4): Biological agent that causes severe human disease and is a serious hazard to employees and it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

Human pathogens in hazard groups 2, 3 and 4 are classified in the ACDP Approved List of Biological Agents.

**ACDP Approved List of Biological Agents**

The list is not exhaustive so if a biological agent is not included it does not automatically fall into hazard group 1 and it should be classified according to its level of risk using the definitions given in Schedule 3 of COSHH. If there is any doubt as to which of two alternative hazard groups is the most appropriate then the agent must be assigned to the higher one. Biological agents that are classified as hazard group 1 are not necessarily safe since they may cause harm under specific circumstances. The list also provides the following additional information on pathogens.

- A: Known to have allergenic effects.
- T: Toxin production.
- V: An effective vaccine is available.

In some cases such as for attenuated vaccine strains it is possible to reclassify a biological agent to a lower hazard group than that given for the agent on the list. This should only be done in consultation and agreement with the HSE unless they have issued specific guidance indicating what to do in specific circumstances.

**DEFRA classification of animal pathogens**

Animal pathogens are classified by DEFRA into four hazard groups (HG 1-4) according to the following.

- Ability to cause infection.
- Severity of the disease that may result.
- Risk that infection will spread to the population.
- Risk of damage to the environment or economic loss.
- Availability of vaccines and effective treatment.

The four hazard groups of animal pathogens and the basis of their classification are as follows.

- Hazard group 1 (HG 1): Disease producing organisms which are enzootic and do not produce notifiable disease.
- Hazard group 2 (HG 2): Disease producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.
- Hazard group 3 (HG 3): Disease producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.
- Hazard group 4 (HG 4): Disease producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.
Rabies: There is also special accommodation for rabies and rabies related viruses.

Animal pathogens in hazard groups 1, 2, 3 and 4 are classified on the DEFRA website.

DEFRA Animal Pathogens

DEFRA classification of plant pathogens and pests

Plant pathogens are classified by DEFRA into complex groups depending on their role in disease in the UK. Plant pathogens and pests classified on the DEFRA website.

DEFRA Pests and Diseases

The ACDP and DEFRA classifications are not complementary and the requirements are very different for the classification, containment and control of human and animal pathogens, plant pathogens and pests. Compliance with one does not absolve employers and their workers from their responsibilities under the other and in all cases where there is any discrepancy between ACDP or DEFRA requirements then the higher requirements must be followed. Where an agent is listed by ACDP and DEFRA then both sets of requirements for risk assessment and control must be satisfied. See guidance on the HSE and DEFRA websites.

Section 3 Risks

In this section you need to describe the risks relating to the biological agents and hazards which will be used or to which people will be exposed in the work. You must consider the ways by which harm could be caused from exposure to the biological agents and hazards in your work. You will then need to make an assessment of the overall level of risk of harm to human health and the environment from exposure to biological agents and hazards in the work.

3.1: Human diseases, illnesses or conditions associated with biological agents or hazards
You should provide details of any human diseases, illnesses or conditions associated with exposure to the biological agents or hazards. Infection and disease are complex processes affected by multiple agent, host and environmental factors (e.g., agent or host genotype, virulence, host immunity) and humans have many physical, chemical and biological and immunological defence mechanisms. Exposure to biological agents or hazards may lead to asymptomatic, subclinical, acute, chronic, persistent or fatal infections or other diseases. Some biological agents or hazards may cause harm only to an exposed individual while others may constitute a serious risk of infection to other people, close contacts or the community. For example, human blood may contain bloodborne viruses such as HIV, HBV, or HCV which can cause acute or chronic infections such as AIDS, hepatitis and cancer. The effects of exposure to some pathogens may be delayed (e.g., HIV, HBV, TB). Use the sources of information given above to find out as much as you can about any diseases, illnesses or conditions associated with the biological agents and hazards in your work. Don’t assume that an agent is safe if there is no information available or any uncertainty especially if you are dealing with a novel agent or isolate. In these cases you should adopt the precautionary principle and always assume that any biological agent or hazard is potentially harmful until proven otherwise.

3.2: Potential routes of exposure
You should provide details of the potential routes of exposure to the biological agents or hazards. The potential for biological agents or hazards to cause ill health will depend upon the manner in which the substance can harm the body (target organs, or systems, at risk), route of entry to the body by which the substance is hazardous (hazard route) and the route of entry which leads to exposure to the substance (exposure route). Biological agents or hazards may be harmful by one or more of the
following exposure routes. For example, could the agent or hazard could enter by inhalation (eg microorganisms, toxins, allergens, dusts or aerosols), ingestion (eg microorganisms, toxins, allergens, soil, contaminated food or drink), injection (eg microorganisms, toxins, allergens, wounds, arthropod bites, sharps injuries such as hypodermic needlestick, scalpels, broken glass, animal bites or scratches), or by absorption (eg microorganisms, toxins, allergens, direct or indirect contact, intact skin, mucus membranes). Exposure may result from direct contact with a laboratory culture, an infected host, tissue, body fluid, secretion or excretion or indirect contact with an infected object (fomite). Routes of exposure and infection in the laboratory may be different from the natural route. Atypical routes of exposure may lead to unusual symptoms or misdiagnosis by medical practitioners. In some cases the route of exposure may be unknown.

3.3: Use of biological agents or hazards
You should provide details of the use of biological agents and hazards or how people will be exposed to the biological agents and hazards. For example will the work be small, medium or large scale or will it involve laboratory work, fieldwork, animals or plants. Fieldwork may lead to exposure to pathogens, toxins or allergens. Fieldwork in this country may lead to exposure to endogenous biological agents whereas fieldwork overseas may lead to exposure to unusual biological agents which cause exotic diseases. Environmental samples can contain pathogenic organisms which may be unintentionally concentrated or propagated in the laboratory. Culture conditions will influence selection and survival (temperature, pH, water activity etc). Microorganisms isolated from the environment should be treated as potentially pathogenic until shown to be otherwise. Harmful microorganisms may be present in some working environments (eg maintenance or cleaning activities). For example, the microorganism which causes Legionnaires disease may be found in cooling towers, plumbing systems, water baths etc. Experimental animals from reputable sources will normally be screened for specific pathogens. The risks are much greater in wild animals or experimental animals that have been in contact with wild animals. Cages, excreta, bedding and equipment used to trap or handle animals may be contaminated with biological agents and hazards.

Pathogens
Pathogens are microorganisms such as bacteria, viruses, fungi and parasites which can colonise humans and cause infection and harm to health. Microorganisms may be obligate human pathogens, opportunist pathogens, zoonotic pathogens capable of infecting humans and animals, or environmental pathogens.

Pathogens vary greatly in their ability to cause infection and may be weakly or highly infectious. Infectious doses may be very small but vary enormously depending on the pathogen, strain and physical condition of the organism, route of entry and host resistance. In some cases it is not the microorganism which is harmful but microbial products. For example, HBV infection may produce asymptomatic transient carriage, acute or chronic infection and liver cancer.

Toxins
Some microorganisms produce powerful toxins which are harmful to humans. Toxigenic microorganisms can be transmitted by many routes although they do necessarily not need to be viable for their toxins to cause harm since the microbial toxins can be hazardous (eg botulinum and tetanus toxins). Inhalation (eg Bacillus anthracis) or ingestion (eg Vibrio cholerae) of toxigenic microorganisms can cause infection and toxigenicity. Ingestion or injection of microbial toxins produced by microorganisms (eg Clostridium botulinum, Clostridium tetani, cyanobacteria and fungi) can cause toxigenicity. Not all toxigenic microorganisms are human pathogens, for example many fungi and cyanobacteria produce powerful toxins (eg aflatoxin, tetrodotoxin, saxitoxin).

Allergens
Many biological agents or hazards including animals, plants, microorganisms or their products can be allergenic and cause hypersensitivity reactions (eg occupational asthma, dermatitis or anaphylaxis). Hypersensitivity reactions can be mild or severe (eg fatal). Once sensitized, very low concentrations
of allergens may elicit allergic hypersensitivity reactions. Sometimes the consequences of an exposure may be sufficiently severe for the person to be unable to safely continue working in areas where they might be exposed to the agents or hazards.

**Carcinogens**
Some biological agents are carcinogens and can cause cancer (eg HBV, HCV or HDV). Most carcinogenic microorganisms are viruses but some are bacteria. Humans and animal tissues especially cancer cells and cell lines may contain cancer viruses and although there are normally strong immune rejection reactions to non-self cells and tissues there is no such protection against any cancer causing agents in the cells.

**Virulence**
Virulence is the measure of the degree of harm that may be caused by a pathogen. Some pathogens have highly virulent strains and avirulent or attenuated strains (eg vaccine strains). Note that attenuated strains may still be harmful and there have been many laboratory infections involving vaccine strains. Harmless strains may also act as opportunist pathogens or revert to virulence.

**Host specificity**
Some pathogens infect a wide range of species while others infect very few or are species specific. For example Salmonella spp will infect most vertebrates, rabies virus will infect most mammals, whereas HIV infects only humans and chimpanzees. Sometimes humans are end hosts and do not normally transmit infection to other humans. Some pathogens including many parasites have complex life cycles involving more than one host species and some stages but not others may be infectious for humans.

**Tissue specificity**
Some pathogens may infect a variety of tissues (eg Staphylococcus aureus or Mycobacterium tuberculosis). Others may be restricted in their routes of entry. Some may infect by unusual routes in unusual circumstances (eg Salmonella normally infects by the oral route but skin infections occasionally occur). Others are tissue specific (eg Vibrio cholerae normally only colonises the upper intestinal tract).

**Human and animal tissues**
Human and animal cells, tissues, organs and bodies, samples, blood, body fluids or faeces etc may contain biological agents. Clinical samples could include samples from patients, volunteers or post mortem specimens. Human and animal tissues are potentially hazardous because they may contain adventitious biological agents.

**Human and animal cell cultures**
Human and animal cell cultures include primary or continuous cell lines and cancer cell lines. Human and animal cell cultures are potentially hazardous because they may contain adventitious biological agents. The cells or medium may be contaminated.

**Animals and plants**
Animals may have zoonotic agents which are harmful to humans. For example, Chlamydia spp (birds, sheep), Salmonella spp (vertebrates eg mice), Mycobacterium bovis or tuberculosis (cattle), E. coli 0157 (cattle), Herpesvirus simiae (primates), rabies virus (vertebrates eg dogs), parasites (vertebrates eg pigs, mice) and ringworm (mammals eg cattle, mice). Laboratory animals may be screened (specific pathogen free) but only for a few common pathogens. Plants may also have agents which are harmful to humans or the environment. For example, fungal pathogens, allergens, plant toxins, plant pathogens or pests.
3.4: Frequency of use
You should provide details of how often the biological agents and hazards will be used or the activity carried out or how often people will be exposed to the biological agents and hazards.

3.5: Maximum amount or concentration used
You should provide details of the maximum amount or concentration of the biological agents and hazards used or to which people will be exposed.

3.6: Levels of infectious aerosols
You should provide details of the levels of any infectious or harmful aerosols which might be produced by the work. Aerosols are any airborne substances including solids (eg microorganisms, dusts, soils or spores) liquids (eg microbial cultures or liquid samples) and gases. You should assume that no control measures are in place when assessing the potential levels of aerosols produced in the work. Note the scale of your proposed operation and the significant risks of harmful exposure if things go wrong such as in the absence or failure of control measures or a catastrophic event. Airborne agents can be potentially dangerous especially if an agent can be infectious or harmful by the inhalation route. Some microorganisms and especially spores are readily spread by the airborne route but others do not survive well and may die once the fluid in the droplet has evaporated.

3.7: Potential for exposure to biological agents or hazards
You should assume that no control measures are in place when assessing the overall potential for exposure to biological agents and hazards in the work. Note the scale of your proposed operation and the significant risks of harmful exposure of humans or the environment if things go wrong such as in the absence or failure of control measures or a catastrophic event.

3.8: Who might be at risk
You should provide details of who will be doing the work and if any other people will be affected by the work. Specify which persons might be directly at risk of exposure to the biological agents and hazards in the work (eg staff, students) and who might be indirectly at risk (eg porters, cleaners, or maintenance workers). Consider whether any particular groups of people might be at increased risk or adversely affected by the work and might not be able to do the work. These include new or expectant mothers, young persons under 18, disabled workers, those allergic to particular biological agents and hazards, and employees who may be more susceptible to some illnesses because of their individual health status. Immunosuppressed people may be very susceptible to infection. Some groups such as pregnant women may be more at risk from certain biological agents than others. ACDP recommends special caution for work on Chlamydia psittaci, Listeria, Toxoplasma, cytomegalovirus, parvovirus, hepatitis viruses, rubella virus, HIV and varicella-zoster virus. See the University Occupational Health Service website for information on these risks.

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If you need advice on these risks contact the University Occupational Health Service. There may also be stages in the process where other workers who are not members of your team are involved and who may be affected (eg the stores person receiving the goods, the autoclave operator, those disposing of the waste). Their line managers should of course ensure they are trained and that their own work is assessed.

3.9: Assessment of risk to human health (Prior to use of controls)
You need to decide on the overall level of risk of harm to human health from exposure to biological agents and hazards in this work. Please note that this is the level of risk without the use of controls. In the controls section you will specify the necessary control measures which are required to reduce the level of exposure to the lowest level that is reasonably practicable and in any case to a level which is adequate to protect human health. To help you estimate the level of risk you should use the information below and the risk estimation matrix. This will give you an estimate of the potential risks
to human health of the work. Select only one of the following terms: Effectively zero, Low, Medium/low, Medium or High.

3.10: Assessment of risk to environment (Prior to use of controls)
You need to decide on the overall level of risk of harm to the environment from exposure to biological agents and hazards in this work. Please note that this is the level of risk without the use of controls. In the controls section you will specify the necessary control measures which are required to reduce the level of exposure to the lowest level that is reasonably practicable and in any case to a level which is adequate to protect the environment. This will give you an estimate of the potential risks to the environment of the work. Select only one of the following terms: Effectively zero, Low, Medium/low, Medium or High.

Estimating the level of risk
The risk of the activity is determined by the hazardous substance and how it’s used in the work. The level of risk of harm is calculated from a combination of the likelihood and severity of harm caused in given circumstances.

Risk of harm = Likelihood x Severity (Effectively zero, Low, Medium/low, Medium or High)

- Severity of harm were it to occur (severe, moderate, minor, negligible).
- Likelihood of harm occurring (high, medium, low, negligible).

In practice an estimate of the level of risk of harm can be calculated using a risk estimation matrix.

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<thead>
<tr>
<th>Severity of harm</th>
<th>Likelihood of harm</th>
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<tr>
<td></td>
<td>High</td>
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<td>Severe</td>
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<td>Moderate</td>
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<td>Minor</td>
<td>Medium/low</td>
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<tr>
<td>Negligible</td>
<td>Effectively zero</td>
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Section 4 Controls to Reduce Risks as Low as Possible

In this section you need to describe the control measures which will be used to protect people, animals, plants and other aspects of the environment from exposure to biological agents and hazards in the work. The COSHH Regulations require that the risks of exposure to biological agents and hazards is either prevented or where this is not reasonably practicable then adequately controlled. Control measures are actions taken or systems used to reduce the risks of exposure to biological agents and hazards. These include engineering controls (eg containment laboratories and microbiological safety cabinets), management controls (eg safe operating procedures, training, supervision) and personal protective equipment (eg lab coats, gloves, spectacles). The purpose of the BioCOSH risk assessment process is to enable you to select the most suitable controls or combination of controls that are proportionate to the risk. Where practicable, non-harmful or less harmful substances must be substituted for harmful ones and only if it is not reasonably practicable to prevent exposure to substances, should employers select control measures to reduce the risk of exposure to an acceptable level. DEFRA requires specific control measures for biological hazards which could be harmful to the environment. Detailed guidance on controls for work with biological agents and hazards is given in the HSE COSHH Approved Code of Practice and Guidance, ACDP Biological Agents: Managing the Risks in Laboratories and Healthcare Premises, ACDP Approved
List of Biological Agents and ACDP Management, Design and Operation of Microbiological Containment Laboratories. See guidance on the HSE and DEFRA websites.

- **HSE Control of Substances Hazardous to Health Regulations: Approved Code of Practice and Guidance**
- **ACDP Biological Agents: Managing the Risks in Laboratories and Healthcare Premises**
- **ACDP Approved List of Biological Agents**
- **ACDP Management, Design and Operation of Microbiological Containment Laboratories**

The COSHH Regulations specify principles of good practice for the control of exposure to substances hazardous to health which employers must follow to protect their employees. To achieve the appropriate level of control you should select and apply the appropriate control measures from those approved by the COSHH Regulations.

(a) Design and operate processes and activities to minimise emission, release and spread of substances hazardous to health.

(b) Take into account all relevant routes of exposure, inhalation, skin absorption and ingestion, when developing control measures.

(c) Control exposure by measures that are proportionate to the health risk.

(d) Choose the most effective and reliable control options which minimise the escape and spread of substances hazardous to health.

(e) Where adequate control of exposure cannot be achieved by other means, provide, in combination with other control measures, suitable personal protective equipment.

(f) Check and review regularly all elements of control measures for their continuing effectiveness.

(g) Inform and train all employees on the hazards and risks from the substances with which they work and the use of control measures developed to minimise the risks.

(h) Ensure that the introduction of control measures does not increase the overall risks to health and safety.

**Containment levels and controls**

Specific control measures and containment levels are required for activities with biological agents and hazards and these are described in Schedule 3 of the COSHH Regulations and extensive guidance is given by ACDP. The appropriate containment level is derived from the hazard group classification of the biological agent or what is suspected about the possible presence of a biological agent. The activities referred to are the following.

(a) Research, development, teaching or diagnostic work in laboratories which involves working with a hazard group 2, hazard group 3 or hazard group 4 biological agent or material containing such an agent.

(b) Working with animals which have been deliberately infected with a hazard group 2, hazard group 3 or hazard group 4 biological agent or which are or are suspected of being naturally infected with such an agent.
Industrial processes which involve working with a hazard group 2, hazard group 3 or hazard group 4 biological agent.

Details of the control measures that should be considered and applied where indicated by the risk are given in Parts II and III of Schedule 3. The COSHH Regulations specify minimum containment levels required for different types of work as follows.

- Containment level 2 (CL 2) for work with a hazard group 2 (HG 2) biological agent.
- Containment level 3 (CL 3) for work with a hazard group 3 (HG 3) biological agent.
- Containment level 4 (CL 4) for work with a hazard group 4 (HG 4) biological agent.
- Containment level 2 (CL 2) for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a biological agent but work with materials in respect of which it is unlikely that a hazard group 3 (HG 3) or hazard group 4 (HG 4) biological agent is present.
- Containment level 3 (CL 3) or 4 (CL 4), where appropriate, for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a hazard group 3 (HG 3) or hazard group 4 (HG 4) biological agent but where the employer knows, or it is likely, that such a containment level is necessary.
- Containment level 3 (CL 3) for activities where it has not been possible to carry out a conclusive assessment but where there is concern that the activity might involve a serious health risk for employees.

In some cases depending on the nature of the biological agents or hazards or the particular activity, additional control measures may also be necessary. In some other cases there are provisions for derogations and less stringent control measures may be applied. Even where a non infectious biological agent does not fall into hazard group 1 substantial control measures may still be needed for it depending on its other harmful properties. The regulations include specific additional measures for controlling exposure to biological agents. These include displaying appropriate hazard warning sign including the biological hazard sign which is specified in Parts IV of Schedule 3, specifying appropriate decontamination and disinfection procedures, having systems for safe collection, storage and disposal of contaminated waste and specifying procedures for working with, and transporting, biological agents or biological materials. Where an effective vaccine is available the employer is required to offer immunisations to individuals who may be exposed to biological agent at work.

The COSHH Regulations require that the HSE must be notified and consent obtained for the possession or use of any biological agent specified in Part V of Schedule 3 which are the following.

- Any hazard group 3 or 4 biological agent.
- The hazard group 2 biological agents Bordetella pertussis, Corynebacterium diphtheriae and Neisseria meningitidis.

Notifications must be made to the HSE and work may not commence until an acknowledgement has been received. The HSE must also be informed of changes to processes, procedures or agents that are of importance to health and safety and which render the original notification invalid. Notifications do not have to be made if an intention to use the agent has already been notified under the Genetically Modified Organisms (Contained Use) Regulations. Employers must keep a list of employees exposed to hazard group 3 or 4 agents, including details of the type of work involved, the agents to whom they have been exposed (if known) and records of exposures, accidents or incidents. There is an exemption to this requirement if the risk assessment indicates the activity does not involve a deliberate intention to work with or use the agent or that there is no significant health risk to exposed employees. The list must be kept for at least 40 years from the last known exposure. The Employment Medical Advisor (EMA) or appointed doctor and any employee with specific responsibility for the health and safety of other employees may have access to the list. Individual employees may have access to information relating to them personally. This list is not the same as a health record kept in relation to health.
surveillance.

Animal and plant pathogens and pests are covered by specific legislation and in certain cases require licences from DEFRA for possession, use, consignment, importation and exportation. DEFRA specifies containment conditions for licensed pathogens. The ACDP and DEFRA classifications are not complementary and the requirements are very different for the containment and control of human and animal pathogens, plant pathogens and pests. Compliance with one does not absolve employers and their workers from their responsibilities under the other and in all cases where there is any discrepancy between ACDP or DEFRA requirements then the higher control requirements must be followed. Where an agent is listed by ACDP and DEFRA then both sets of requirements for containment and control must be satisfied.

**Controls**

Control measures will predominantly reflect the potential routes of exposure or release. Broadly, the control of risks involves a systematic approach which requires the application of the most effective control measures which are reasonably practicable and the selection of risks control measures should be done using a hierarchical approach. The most effective control measures must be used in preference to the least effective ones starting with elimination, followed by substitution, engineering controls, management controls and lastly PPE. Once you have decided that you cannot eliminate or substitute less hazardous substances, you are required to implement control measures that prevent or minimise exposure to risk. Control measures should be selected in this order of priority according to the level of risk identified in the BioCOSHH risk assessment.

1. **Elimination.**
   Redesigning the work to remove the hazardous substance. For example, changing the process, technique or activity so that the biological agent or hazard is not needed or generated. If hazard elimination is not successful or practical then the next control measure is considered.

2. **Substitution.**
   Replace the hazardous substance or material or process with a less hazardous one. For example, the use of an attenuated strain instead of a virulent one or a non-carcinogen instead of a carcinogen. If no suitable replacement is available then the next control measure is considered.

3. **Engineering controls.**
   Installing or using additional machinery such as local exhaust ventilation to control the risk. For example, separating the biological agents and hazards from workers by methods such as using microbiological safety cabinets. If this method is not effective then the next control measure is considered.

4. **Administrative controls.**
   Procedures to organise and do the work safely. For example, reducing the time the worker is exposed to the biological agents and hazards. It could also include safe work practices, the prohibition of eating and drinking in laboratories, the provision of training and the performance of risk assessments. The scale or frequency of the procedure or quantities used could be reduced. Only after all the previous measures have been tried and found to be ineffective in controlling the risks should personal protective equipment be considered.

5. **Personal protective equipment.**
   This is the last control measure to be considered. If chosen, personal protective equipment (PPE) should be selected and fitted to the person who uses it. In most cases a combination of engineering controls, management controls and PPE are chosen to effectively control the risks. Where PPE is the main control method it should where practical be used in conjunction with another method of PPE and safe work practices.
General control measures should include systems and procedures for safe use, handling, storage and transport of biological agents and hazards, sharps, maintenance of equipment, reducing numbers of exposed persons, duration of exposure and quantities to the minimum, controlling the working environment, appropriate disinfection and decontamination, safe collection, storage and disposal of contaminated waste, displaying hazard warning signs and using appropriate hygiene measures. Where an effective vaccine is available the workers may need to be offered immunisations to individuals who may be exposed to biological agent at work. When deciding on the sort of control measures that you intend to use the most important requirement is that control of exposure should be achieved by the most effective means and this must not be only by the use of personal protective equipment where more effective measures can be used. In practice a combination of control measures are often used to reduce the risks of exposure to the biological agents and hazards. In some cases depending on the activity additional control measures may also be necessary or in other cases less stringent control measures may be applied. Once you have decided on the appropriate controls then they must be implemented and used. The controls must be used to reduce the level of exposure to the lowest level that is reasonably practicable and at least to a level which is adequate to protect human health, animals, plants and other aspects of the environment.

Control measures which are used to prevent or control exposure to biological agents and hazards are properly maintained, examined and tested to ensure that they are working efficiently. The control measures subject to detailed examination and testing include engineering controls, local exhaust ventilation (LEV), which includes microbiological safety cabinets and extract ventilation for equipment, and respiratory protective equipment (RPE). The precise nature of the maintenance, examination and test and degree of competence of the tester will vary depending on the nature of the equipment. Controls must be visually inspected periodically and maintained according to the manufacturer’s instructions. LEV must be regularly maintained and thoroughly examined and tested at least once every 14 months. Respiratory protective equipment must be thoroughly examined and tested at suitable intervals. People carrying out examinations and tests must be competent. Where equipment is simple and its operation easily checked a local examination might be sufficient. However, where more complex systems are in use an examination by an external specialist is likely to be required. This will be undertaken by the institution where such systems form an integral part of a buildings fabric such as the air handling systems in containment level 2 and 3 laboratories and microbiological safety cabinets which are externally ducted to the roof of a building. Personal protective equipment (PPE) used to protect workers should be stored, checked and cleaned in such ways as to prevent the equipment being a contaminated by biological agents and hazards. There must be an effective fault reporting system established. The requirement to inspect and test extends to administrative controls where it may be work practices that ensure adequate control and in these circumstances such systems should be subject to regular monitoring and inspection. Suitable records of any testing and examination of controls must be kept.

4.1: Containment
You should provide details of where the work will be done and how the biological agents and hazards will be properly contained. It’s important to consider the potential routes of exposure in deciding what sort of control measures will be required. Consider if the work can be done in a laboratory, animal facility, plant facility or will specialised facilities be required. Will the work require total enclosure (e.g. glove box, anaerobic cabinets, flexible film isolators or Class 3 safety cabinets), partial enclosure (e.g. Class 1 or 2 safety cabinets or cage cleaning cabinets), local exhaust ventilation (e.g. exhaust ducting for laboratory equipment) or general ventilation (e.g. containment laboratories, animal or plant facilities). You should also consider whether you will need to control access to the area where the work will be done by limiting it to authorised persons only.

4.2: Containment level
You must decide on the appropriate containment level that will be required for your work with biological agents or hazards according to ACDP or DEFRA requirements. Biological laboratories,
animal and plant facilities must be classified into one of the three containment levels (CL 1-3). Containment level 1 is for negligible to low risk work, containment level 2 is for low to medium risk work, and containment level 3 is for medium to high risk work. The relevant containment level must be used for the equivalent hazard group for the biological agent as follows. The minimum ACDP/DEFRA containment levels required for different types of work as follows.

- Containment level 1 for work with ACDP/DEFRA hazard group 1 biological agents.
- Containment level 2 for work with ACDP/DEFRA hazard group 2 biological agents.
- Containment level 3 for work with ACDP/DEFRA hazard group 3 biological agents.

There are minimum and recommended control measures which are required for work at each containment level and these are specified in the relevant ACDP and DEFRA guidance documents. It is possible to obtain permission for derogation from HSE to apply less than the full containment measures in the containment level corresponding to the class of the activity. Requests for derogations must be made to the University BSO and must be fully justified on the basis of risk assessment and may only be applied on receipt of written agreement from the HSE.

4.3: Microbiological safety cabinets (MSC)
You should provide details of microbiological safety cabinets which will be required to control infectious aerosols and dangerous biological agents and hazards. There are three basic types of MSC which offer different types of protection to the operator, work and environment.

- Class 1 (operator and environment protection).
- Class 2 (operator, work and environment protection).
- Class 3 (operator, work and environment protection).
- Class 1/3 hybrid (operator and environment protection only or operator, work and environment protection).

Microbiological safety cabinets function by using airflows to capture hazardous aerosols generated during manipulations, transferring microorganisms away from the operator before trapping them in a high efficiency particulate air (HEPA) filter. Selection requires an assessment of the work and operator protection requirements but also the proposed location as draughts or physical obstacles may compromise cabinet performance. Following installation MSC are tested to ensure they meet performance criteria (eg operator protection tests). Commissioning tests need to be repeated whenever an MSC is moved or there is a major change to the local environment. MSC show resemblance to fume cupboards, but they have very different functions and characteristics and should never be used instead of a microbiological safety cabinet. MSC should be selected, installed and maintained according to the British Standards.

4.4: Other controls
You should provide details of any special control measures that you intend to use for this work (eg avoidance of use of sharps, hygiene measures etc).

When selecting the appropriate measures for controlling the risks of carcinogens, the potential for long term and possibly fatal effects must be taken into account. Priority should be given to the elimination or substitution of the carcinogenic biological agents or hazards in question with a non-carcinogen. If alternatives are not reasonably practicable then this must be stated with explicit reasons in the risk assessment. If no suitable alternative to the carcinogen is available, exposure to the carcinogenic biological agents or hazards must be prevented by the best practicable means and following the hierarchy of control measures. Because of the nature of the risks posed by carcinogens, it is particularly important to select the most effective measures possible. Strict control measures should be adopted including for example, totally enclosed process and handling, extensive cleaning and disinfection procedures, safe storage and disposal and prohibition of eating and drinking. The storage, use and disposal of carcinogenic substances require careful control. Carcinogenic substances used in the workplace should be kept to the minimum needed for the process. Clearly identify the
areas in which exposure to carcinogens may occur and take measures to prevent the spread of contamination within and beyond these areas. The number of people likely to be exposed to carcinogenic agents and the duration of their exposure must be kept to the minimum necessary for the work. Non essential personnel must be excluded. Where appropriate, store and transport them on site in closed containers, clearly labelled and with clearly visible warning and hazard signs. Clearly label and securely store carcinogenic waste products until they are removed according to the proper procedures for removal of hazardous waste.

4.5: Storage of biological agents or hazards
You should consider at this stage the quantity you need and the facilities required to store the biological agents and hazards. Special conditions may also be required such as ventilation and security.

4.6: Transport of biological agents or hazards
You should provide details of how you will safely transport the biological agents and hazards. For example will the substances or materials need special packaging or multiple containment.

4.7: Inactivation of biological agents or hazards
You should provide details of how you will inactivate the biological agents and hazards used in the work. The proper inactivation and disposal of waste is very important part of work. There are chemical and physical methods of inactivating biological agents and hazards. Hazardous biological agents must be inactivated by a validated means and this needs to be explicit by using effective procedures for both validation and monitoring and keeping adequate records of these for inspection on request by the HSE. The effort involved in effective validation and monitoring varies considerably depending on the risks and inactivation method used.

Disinfection
Disinfectants must be validated for the particular biological agent under conditions matching those of intended use, and there must be appropriate procedures in place for regularly monitoring effectiveness. You need to be aware that the effectiveness of many disinfectants can vary considerable depending on the species of agent, the concentration, time since dilution (efficacy of some diminishes very rapidly on dilution to working concentrations), exposure time, and the nature of the material being disinfected (eg liquid or solid surface, pH, presence of organic or particulate matter). Achieving acceptable validation and monitoring procedures for disinfectants is in most cases a lot more difficult than autoclaving all biological agent or hazard contaminated waste. Published or manufacturers data can be cited as validation, but only if you can verify that these data are valid for your species and experimental conditions. If adequate data are not available then you will need to produce sufficient data on kill rates yourself. In either case, you will need to devise effective monitoring procedures which will probably require occasional testing of kill rates. The use of disinfectants does not always require validation and monitoring. In most though not all cases where disinfectants are used as an additional control measure rather than the sole means of inactivating biological agents then validation and monitoring may not be required. This might be the case where disinfectants are used to inactivate hazards prior to autoclaving. If you use a disinfectant for this purpose, you need to be aware that regular autoclaving of material containing certain disinfectants might, over time, cause corrosion that damages the autoclave. If in doubt, check with the manufacturer or supplier.

Autoclaving
Autoclaving is the most effective inactivation method and by far the easiest and least time consuming to both validate and monitor. For these reasons it is strongly recommended that all hazardous biological waste including all liquid waste and waste destined for incineration be autoclaved unless there is a very good reason to use another method. It is accepted by HSE that any biological agent, except TSE which are a special case, will be inactivated by autoclaving under conditions that maintain 121°C for at least 15 min with full steam penetration. Note, the minimum 15 min excludes the time required to reach 121°C, and the above conditions must be maintained even in the most inaccessible positions of the load. TSE will be inactivated by autoclaving at 134°C. In the present context,
inactivation is defined as achieving a sufficient % kill commensurate with the risks although 100% kill is normally required. The % kill to be achieved must be defined and appropriate methods of validation and monitoring that demonstrate this is achieved need to be specified and employed. Records must be maintained for possible inspection.

Validation of autoclaving should be carried out using thermocouple mapping. This involves placing multiple independent thermocouples at various sites, including the most inaccessible, within a typical load and recording output during a standard run to determine if all sites maintain the required temperature for the required time. This is usually done by a maintenance engineer as part of the annual maintenance contract and the printout recording the output from each thermocouple will be provided and should be kept as a record. Because steam penetration varies it is important that validation be conducted using a load that represents the most difficult encountered in normal use.

Monitoring of autoclaving should be carried out on each run to confirm that both the correct temperature and time has been employed. This is very easy if your autoclave includes a built in thermocouple linked to a chart or digital recorder which monitors each run and provides a printout or you can download the information electronically that can be kept as a record. If your autoclave lacks this then you have two options. Install a suitable digital recorder linked to a thermocouple that can be fitted to many but not all older or small autoclaves, but make sure you choose one that provides a continuous printout, recording the temperature throughout the run. Alternatively you could place a suitable commercially available autoclave indicator in each load and keep a log book that records the results of each run. Most commercially available indicators including standard autoclave tapes are not adequate for monitoring inactivation of waste, because they change colour either at temperatures considerably lower than 121°C, or within minutes of reaching 121°C, or in the absence of steam penetration, and therefore do not confirm that the appropriate conditions have been maintained for a sufficient time. A suitable indicator is TST (Time, Steam, and Temperature) test strips produced by Albert Browne Ltd. Note that there are several versions of these and you need to ensure you are using the appropriate strips, which are TST class 6 emulating indicators for monitoring 121°C for 20 min. These indicators can be obtained from Fisher Scientific (Sterilisation Indicators, TST). These can be obtained from commercial laboratory supply companies.

You should provide a brief statement in this section about the disinfection or autoclaving methods including and validation and monitoring which will be used in your work. For autoclaving you should use one of these standard examples.

‘All contaminated materials, including waste destined for incineration, will be inactivated by autoclaving (100% kill) prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual thermocouple mapping and each run will be monitored by continuous chart (or digital) recording of the temperature/time profile.’

or

‘All contaminated materials, including waste destined for incineration, will be inactivated by autoclaving (100% kill) prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual thermocouple mapping and each run will be monitored using TST (Time, Steam, and Temperature) test strips (Albert Browne Ltd., TST class 6 emulating indicator 121°C for 20 min).’

4.8: Personal protective equipment (PPE)
You should provide details of the personal protective equipment (PPE) which will be required to protect the body, hands, eyes, face etc (eg laboratory coats, gloves or eye protection). The risk assessment may specify that PPE is required to control exposure to a biological agent or hazard when it is not possible to achieve adequate control over exposure by any other means and then it should be used only in addition to other appropriate measures. The PPE must be suitable to adequately protect against particular biological agents or hazards. Consider the potential routes of exposure to the
biological agents and hazards when deciding on appropriate PPE. All PPE must be carefully selected and properly maintained including cleaning and workers should be fully trained in its use and limitations. It is important that the PPE is used appropriately.

4.9: Respiratory protective equipment (RPE)
You should provide details of the respiratory protective equipment (RPE) which will be required to protect the respiration (eg disposable masks, respirators or breathing apparatus). The RPE must be suitable to adequately protect against a particular biological agents and hazards and this is particularly important for respiratory protection. Consider the potential routes of exposure to the hazardous substances when deciding on appropriate RPE. RPE which relies on a tight-fit to the face for protection (disposable filtering dust mask, reusable half face and full face masks, and breathing apparatus) must be face-fit tested for each individual wearer. Testing must be carried out by trained competent persons. Once face fit tested to a particular respirator (type and manufacturer) a certificate of test must be obtained and this recorded. The worker must only wear that type and manufacture of respirator on which they were tested and do not require to be retested unless their facial characteristics change significantly (eg weight loss, major dentistry). Wearers of respirators that rely on a tight fit to the face for protection must be clean shaven in the area of the respirator face seal. Facial hair, or stubble, compromises the face seal and such people must not be supplied with a tight fitting respirator as a means of exposure control. A respirator option for those with beards is a powered hood which supplies filtered air at positive pressure to the breathing zone of the wearer by a soft or hard top hood that encompasses the head.

Disposable respirators (eg dust masks) do not provide protection against biological agents and hazards. Disposable respirators or filtering face piece (FFP) masks are available in three classes P1, P2 and P3 providing differing protection factors. For protection against biological agents and hazards reusable half or full face respirators require to be fitted with filters suitable to protect against the particular hazard present in the work. Detailed advice on this should be sought from the respirator manufacturer. All RPE must be carefully selected to be appropriate, properly maintained and serviced including cleaning and workers should be fully trained in its use and limitations. RPE must be thoroughly examined and tested at suitable intervals.

4.10: Health surveillance or immunisation
Health surveillance is required for certain occupational diseases or adverse health effects (eg infection, cancer, allergy, asthma, dermatitis) to check that people exposed to biological agents and hazards are not made sick from their work (eg work with pathogens, carcinogens, allergens or asthmagens). This is usually where there is an identifiable disease or adverse health condition related to work, valid techniques are available for detecting indications of the disease or condition, there is a reasonable likelihood that the disease or condition will occur under the particular work, and where surveillance is likely to further the protection of health of workers. Health surveillance may involve preliminary and ongoing surveillance, questionnaires, interviews, examination, tests, monitoring or referrals. See the University Occupational Health Service website for information on health surveillance.

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Health surveillance is required for all workers exposed to hazard group 3 biological agents or working at containment level 3 and may be required for workers exposed to animals and animal allergens. Immunisation may be useful as a control measure to protect people against infection by certain biological agents. For example, hepatitis B vaccine can offer valuable protection against infection for those people who work with human blood and tetanus vaccine is important for protecting against the risks of tetanus in the environment. Vaccines should not be considered as a primary defence against infection but as additional control measures. If you need advice on whether your work requires health surveillance or immunisation contact the University Occupational Health Service or University Safety Office. Guidance on where health surveillance is required can be found in the COSHH Approved
4.11: Instruction, training and supervision
You should provide details of special instructions, training, and supervision that are required to do the work safely. Employers must provide workers with adequate information, instruction and training on health hazards created by exposure to biological agents and hazards to enable them to carry out their work safely. This should include local rules, safe working practices, standard operating procedures and the effective application of routine and emergency control measures and procedures. Suitable information and instruction should also where required be provided to other persons such as contractors and visitors. It is important that information, instructions and training is appropriate to the level of risk and in a form which will be understood by those involved in the work. It is also vital to keep the information up to date, taking into account any significant changes in the type of work or the methods used. The control measures will not be effective if those involved in the work do not know their purpose, how to use them properly or the importance of reporting faults. Records of information, instruction and training should be kept. All workers must be adequately supervised and this is especially important where highly hazardous biological agents or hazards, specialist facilities or equipment are concerned. The principal investigator or manager must decide on the level of supervision required to do the work. Some work may not be carried out without direct personal supervision, some work may not be started without the advice and approval of supervisor while other work can be carried out without direct supervision.

4.12: HSE consent or DEFRA licence
The possession or use of high hazard biological agents requires written permission from the University Biological Safety Committee (BSC). You must obtain permission from the School BSC and University BSC if you wish to do work with any COSHH notifiable biological agents which includes all HG 3 and 4 agents, and the HG 2 agents Bordetella pertussis, Corynebacterium diphtheriae and Neisseria meningitidis. The possession or use of any of these agents requires consent from the Health and Safety Executive. The University BSO will submit your completed BioCOSHH risk assessment and a completed CBA1 form to the HSE with a request for consent. The biological agents must not be acquired or used unless the University BSC gives permission and consent is obtained from the HSE. Note that all work requiring containment level 3 requires explicit approval from the University BSC. Many animal and plant pathogens and pests are covered by specific legislation which may require a DEFRA licence. It is the responsibility of principal investigators and Schools to determine whether a licence is required and to obtain the licence from DEFRA. Enquiries can be directed to the School GM Chair or University BSO. Guidance is given on the HSE and DEFRA websites.

HSE Biological Agents - Notification Forms
The University BSC must be informed of all proposed changes to notified projects and will decide whether these are significant and will deal with the HSE. You can modify a BioCOSHH risk assessment which has been notified under the COSHH Regulations, but you must first reassess the risks of the project and make the appropriate changes to the BioCOSHH risk assessment. You must keep every amended version of your risk assessment for your records, so always keep the original version and save the modified risk assessment as a new version (ie v1, v2 etc). If the modification is within the scope of the original notified project and there is no significant increase in the risks of the work, then you only need to make the changes to the risk assessment and obtain approval from the University BSC and no further action is required. If the modification is within the scope of the original notified project but will significantly increase the risks of the work, then you must not carry out the work until consent for these changes has been obtained from the HSE. This will require making changes to the risk assessment and obtaining approval from the University BSC which will send the modified risk assessment and an updated CBA1 form to the HSE. Note that you cannot change the scope of the original notified project. If the modification is outside the scope of the original notified project, whether or not it changes the risks, then you must not carry out the work.
until consent has been obtained from the HSE. This will require a new request for consent for this project to the HSE. This will require a separate new BioCOSHH risk assessment and CBA1 form. In all cases all versions of the BioCOSHH risk assessment must be approved in writing by the University BSC. When you have finished an HSE notified biological agents project then it should be closed. To close the project you must request permission from the University BSC which will then notify the HSE that the project has ceased and all of the biological agents have been destroyed.

Section 5 Emergency Procedures

In this section you need to describe the emergency control measures and procedures which will be used to protect people and the environment from exposure to the biological agents and hazards in the work in an emergency.

5.1: Emergency procedures

You should provide details of the procedures that will be required to deal with accidents, incidents and emergencies that could cause any employee or other person to be exposed to a biological agent or hazard or an accidental release of biological agents or hazards. The manager, principal investigator and workers are responsible for ensuring that accidents and emergencies are properly dealt with since these are the experts in the biological agents and hazards and the work. You need to assess the potential for accidental exposure and implementing emergency procedures for your work. Emergency procedures and plans must be prepared in advance.

The primary objective of the emergency procedures is the containment of the biological agents and hazards and the minimisation of risks to health. You should consider all of the relevant factors which may include assessing situations, instructions, informing others of accidents, isolation of area, evacuation, seeking assistance, PPE, RPE, preventing spread of contamination or spills, decontamination of work area or laboratory, safe waste disposal, first aid treatment and medical treatment if required. Anyone not concerned with the emergency action should be excluded from the area. Only people essential for carrying out repairs and other essential work may be permitted in the affected area and they must be provided with appropriate personal protective equipment and any necessary equipment or plant. Emergency and spillage procedures should also be specified in any standard operating procedures (SOP) and laboratories may require spillage kits. In addition, it is often very useful to provide important emergency procedures as bullet pointed instructions on a laminated A4 sheet which can be placed where the hazardous work is done (eg stuck on the wall above the lab bench or on a piece of equipment). Appropriate training must be provided in the accident and emergency procedures. All workers must understand and be able to implement the emergency procedures. If an emergency occurs, procedures must be put into effect as soon as possible to minimise harm and return the situation back to normal as quickly as possible. Accidents, incidents and emergencies must be reported immediately or as soon as practicable to supervisors, safety officers or managers and using the accident, incident or near miss reporting form on the Safety Office website.

You should provide details of the first aid procedures which would be needed to deal with the specific biological agents and hazards in this work in case of an accident or emergency. Training must be provided in these emergency procedures. You should consider all of the relevant factors to establish effective emergency first aid procedures. This may include removing contaminated clothing as quickly as possible, removing contamination from skin, eyes and mouth by thorough washing with water, dealing with minor cuts and small puncture wounds, washing wounds with soap and water and dressing wounds. Use PPE if required when helping injured persons. Seek help where required from first aiders, GP or hospital. Emergencies should be taken straight to hospital and call ambulance if necessary (Call Security on campus 6666 or else 999). Explain the incident and biological agents or hazards to medical staff and if possible give them with a copy of the BioCOSHH risk assessment.

5.2: Emergency contacts

You should provide the names and contact details of people to contact in case of an accident or emergency. This must include the name of the principal investigator or manager who is in charge of
and understands the work together with details of other relevant persons including the workers doing 
the work and colleagues involved in the work. Your emergency contacts should not normally include 
the names of safety officers since they are not responsible for the work or for implementing your 
emergency procedures and are unlikely to know about the specific work or biological agents and 
hazards involved. The information and contract details of managers, safety officers, security, and 
emergency services etc are provided separately in emergency arrangements posters and websites etc.

Section 6 Approval

In this section the assessor and principal investigator or manager must sign and date the form to state 
that they have assessed the risks and reviewed and approved the risk assessment. The manager, 
principal investigator or person in charge of the work is responsible for ensuring the risks associated 
with their work are properly assessed and recorded. The principal investigator or manager may 
delegate the work of preparing a risk assessment to any competent member of the team but 
responsibility for approving the risk assessment remains with the principal investigator or manager.

6.1: Assessor
The person who carries out the risk assessment on behalf of the principal investigator or person 
responsible for the work must sign this part of the form. The assessment must be carried out correctly 
and to a suitable and sufficient standard identifying the hazards, risks, who might be at risk and the 
selection of appropriate controls for the work. Guidance on risk assessment can be obtained from 
School Safety Officers. You should consult with other people who might be adversely affected by the 
biological agents and hazards in your work where it is necessary (eg colleagues, other groups or 
workers).

6.2: Principal investigator / Responsible person
The principal investigator or person responsible for the work (eg manager, supervisor or course 
leader) must sign this part of the form to confirm that they have reviewed and approved the risk 
assessment. You must check that the assessment has been carried out correctly and to a suitable and 
sufficient standard identifying the hazards, risks, who might be at risk and the selection of appropriate 
controls for the work. Guidance on risk assessment can be obtained from School Safety Officers. You 
should consult with other people who might be adversely affected by the biological agents and 
hazards in your work where it is necessary (eg colleagues, other groups or workers).

Stage 3: Notification of Activities

The possession or use of hazard group 3 biological agents or hazards and the hazard group 2 agents 
*Bordetella pertussis, Corynebacterium diphtheriae and Neisseria meningitidis* or hazards requires 
written permission from the University BSC and requires notification to and consent from the Health 
and Safety Executive. You must obtain permission from the University BSC if you wish to do work 
with these biological agents and hazards. The University BSO will submit your completed 
BioCOSHH risk assessment and a completed CBA1 form to the HSE with a request for consent. The 
biological agents and hazards must not be acquired or used unless the University BSC gives 
permission and consent is obtained from the HSE. Many animal and plant pathogens and pests are 
covered by specific legislation which may require a DEFRA licence. It is the responsibility of 
principal investigators and Schools to determine whether a licence is required and to obtain the 
licence from DEFRA. Enquiries can be directed to the University BSO. Guidance is given on the HSE 
and DEFRA websites.

- HSE Notification Forms

The HSE must be notified of premises and certain higher risk activities in advance of commencement 
of the work. Hazard group 3 biological agents or hazards and the hazard group 2 agents *Bordetella 
pertussis, Corynebacterium diphtheriae and Neisseria meningitidis* or hazards activities have to be
notified in advance to the HSE on an individual basis and appropriate approvals or consents obtained to carry out the work. Any subsequent changes in the work must also be notified. The information required to be provided with an activity notification is set out in the regulations and HSE produce a CBA1 form for this purpose. A copy of the BioCOSHH risk assessment for the work has to be provided as part of the notification. HSE will send acknowledgement of the notification and there are then various notification periods before work can start depending on the particular activity and whether that hazard group of work has been done at the premises previously. Work may not start until HSE has given written consent. Information submitted to HSE as part of a notification is placed on the public register on the HSE website. However, in certain circumstances it is possible to claim confidentiality and exemption from public disclosure for some information but any claim has to be fully justified against stringent criteria and is subject to agreement by HSE and subject to the requirements of freedom of information. The HSE examines notifications and may request additional information, impose conditions and time limits to consents and revoke or vary them. Significant changes in activities or new information which may have a bearing on the BioCOSHH risk assessment must be immediately notified to the HSE. The HSE does not charge any fees for processing CBA1 notifications. HSE will issue consent once they are satisfied.

The HSE must be notified of any accident involving a significant and unintended release of biological agents and hazards present an immediate or delayed hazard to either human health and safety or the environment. This requirement is in addition to any notification requirements under Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR). HSE notification must provide information on the circumstances of the incident, identity and quantity of biological agents and hazards concerned information necessary to assess the risk and any measures taken to deal with the accident. RIDDOR accident reports are done by the University Safety Office.

The University BSC must be informed of all proposed changes to notified projects and will decide whether these are significant and will deal with the HSE. You can modify a BioCOSHH risk assessment which has been notified under the COSHH Regulations but you must first reassess the risks of the project and make the appropriate changes to the BioCOSHH risk assessment and apply for University BSC approval. If the modification is within the scope of the original notified project and there is no significant increase in the risks of the work, then you only need to make the changes to the risk assessment and obtain approval from the University BSC and no further action is required. If the modification is within the scope of the original notified project but will significantly increase the risks of the work, then you must not carry out the work until consent for these changes has been obtained from the HSE. This will require making changes to the BioCOSHH risk assessment and obtaining approval from the University BSC who will send the modified risk assessment and an updated CBA1 form to the HSE. Note that you cannot change the scope of the original notified project. If the modification is outside the scope of the original notified project, whether or not it changes the risks, then you must not carry out the work until consent has been obtained from the HSE. This will require a new request for consent for this project to the HSE. This will require a separate new BioCOSHH risk assessment and CBA1 form. In all cases all versions of the BioCOSHH risk assessment must be approved in writing by the University BSC. To close the project you must request permission from the University BSC which will then notify the HSE that the project has ceased and all of the biological agents and hazards have been destroyed.

Stage 3: Monitor the Work
The manager and principal investigator must carefully monitor the work. Monitoring is necessary to meet two main objectives. The first is to ensure compliance in the implementation of all the control measures identified as necessary through the BioCOSHH risk assessment. If your BioCOSHH risk assessment is suitable and sufficient for the work then each identified control measure is necessary to prevent or control exposure of people, animals, plants and other aspects of the environment to risk. Compliance is therefore both necessary and a legal requirement. The second objective is to ensure that the control measures and procedures continue to be appropriate. The review process discussed below will provide a point of reference to decide if the risk assessment remains valid but regular monitoring
can identify problems in the interim period. You should regularly check what people are doing and the activities to ensure that the work is done safely. The type of monitoring needed is proportional to the risks with higher risk work requiring a higher level of monitoring than lower risk work. Where problems are identified such as with the BioCOSHH risk assessment, controls or the need for additional training or supervision then action must be taken and the necessary changes or improvements must be to the risk assessment, procedures, instructions, training or supervision.

Stage 4: Review and Revise the BioCOSHH Risk Assessment
BioCOSHH risk assessments must be reviewed regularly and immediately if there is any reason to suspect the assessment is no longer valid such as if there has been a significant change to the work or to the risks of the work (eg as a result of changes to the work or monitoring). When reviewing the risk assessment the effectiveness of the preventative or control measures should be carefully re-examined. BioCOSHH risk assessments should in any case be reviewed at least annually. If review of the risk assessment concludes that changes are required then those changes must be made. Never make any changes directly to the original BioCOSHH risk assessment form but always to a new version (eg v1, v2, v3 etc) of the form. When you have finished a notified BioCOSHH risk assessment project it can be closed. However, by law a notified BioCOSHH risk assessment project can only be closed if you destroy all biological agents and hazards or transfer the biological agents and hazards to another appropriate notified and approved BioCOSHH risk assessment. BioCOSHH risk assessment projects can be closed by notifying the School BSC and University BSC.

Stage 5: Records of the BioCOSHH Risk Assessment
The principal investigator or manager must keep their BioCOSHH risk assessments and any other relevant records. The BioCOSHH risk assessment should always be completed by computer so that you will have electronic records, other people can easily read it, and the risk assessment can be easily reviewed and amended where required and communicated. All changes to BioCOSHH risk assessments should be made electronically. Always save the original version for your electronic records and make the changes to another version. Electronic and paper copies can be distributed to anyone who needs a copy. A copy of the BioCOSHH risk assessment should always be available in each defined area where the work is done. Employers must keep proper records relating to the work such as risk assessments, training records, maintenance and testing records. Records must be kept for at least 10 years after the activity to which the assessment relates has ceased. In some cases records must be kept for 40 years. Records must be comprehensible and readily retrievable for inspection. They must be available for examination at any reasonable time by the employer, managers, safety officers, safety representatives and HSE inspectors.