University College Dublin

Laboratory Biosafety Manual

Rev 1. Issued January 2008

University College Dublin Safety Office

Contents

1.0 Introduction

The *Safety Health and Welfare At Work (Biological Agents) Regulations 1994 (SI 146)* defines a biological agent as *'…a micro-organism including those which have been genetically modified, a cell culture and a human endoparasite, which may be able to provoke any infection, allergy or toxicity…'* The definition of biological agent in the legislation does not extend to include non microbiological biological entities therefore the specific provisions of this legislation do not apply to their usage / interaction with workers.

For example whilst a bull on a farm might pose a significant risk to farm workers it is not considered a 'biological agent' under the legislation and therefore the provisions of the various biological agents regulations do not apply to its handling. However as it poses a risk to the safety of farm employees it's presence on the farm would be subject to the same requirements for risk assessment as any other workplace hazard. As a rule of thumb if a biological agent is capable of causing an infection or a toxic response in a worker then it is covered by the biological agents legislation.

In the workplace there are two distinct types of worker exposure to biological agents. The first is *incidental exposure*, which is where workers are exposed to biological agents which happen to be present in the workplace but which are not deliberately handled or utilised, e.g. in diagnostic laboratories. The second is where workers are exposed to biological agents which are deliberately utilised, e.g. in research labs using *E. coli* bacteria.

This handbook is designed to provide University staff and students with guidance on the safe handling and usage of biological agents (including those which are genetically modified) in a laboratory or similar setting.

Users of genetically modified biological agents must also refer to the *UCD Use Of Genetically Modified Organisms Manual* for further information on the legal requirements for their use.

2.0 Types Of Biological Agent

There are a number of different types of biological agent that may be encountered within the University. These include but are not limited to:

2.1 Bacteria

These are single celled organisms that can cause a number of diseases in humans. Many types of bacteria pose no risk to healthy humans and live on and in the human body continuously. In some circumstances bacteria which are normally considered to be non pathogenic[*] can cause disease. Common diseases caused by bacterial infection include Tuberculosis (*Mycobacterium spp.)*; Tetanus (*Clostridium tetani*); and Cholera (*Vibrio cholerae*). Most bacterial infections are susceptible to antibiotics, whilst for destroying bacteria in the environment there a range of effective disinfectant agents available. It is possible to get vaccinations against some of the diseases caused by bacterial agents.

2.2 Viruses

Viruses are simple entities that can infect individual human cells causing the infected cell to produce more virus particles. Large scale viral infections in populations can lead to world wide epidemics. Some viruses have an ability to constantly change their characteristics leading to many strains of the same virus e.g. the influenza virus. Common diseases caused by viruses include Influenza (Orthomyxoviridae spp); Chicken Pox (*Varicella simplex*); and Cold Sores (*Herpes simplex*). Viral infections are not treatable with antibiotics although effective disinfectant agents are available for destroying viruses in the environment. It is possible to get vaccinated against some viral agents.

2.3 Prions

Prions are very simple biological agents made up of proteins. Prion infections are very difficult to treat and the prion agent itself can also be very difficult to destroy in the environment. There are no vaccinations available to prevent prion infection. Prions are the causative agents of *Creutzfeldt-Jacob Disease* and *Bovine Spongiform Encephalitis*.

[*] A *Pathogen* is defined as any organism capable of producing disease

2.4 Fungi

Fungi include yeasts, moulds and mushrooms. Some species of fungi have the ability to colonise and to grow on and in the body. These include *Candida spp* which can cause thrush infections and *Cryptococcus neoformans* which can cause lung infections. Fungal infections are usually treatable. There are no vaccinations available to guard against fungal infections.

2.5 Parasites

Parasites are defined as organisms that infect a 'host' and live on or in that host to the detriment of the host. Parasites can live inside the body (endoparasites) or on the outside of the body (ectoparasites). Parasites may come from a variety of biological families including nematodes (e.g. roundworms); protozoans (single celled organisms e.g. malaria); cestodes (tapeworms); insects (e.g. fleas); etc. Some parasitic infections are easily treatable whilst others cam be extremely difficult to treat. In some cases the parasite may have no noticeable negative effect in the body whilst in other cases such infections can be fatal.

3.0 Routes Of Infection

For biological agents to give rise to a negative affect in a person that person must be 'infected' by that agent. To infect a person a biological agent must either get onto or into a persons body. There are a number routes of infection for a biological agent.

i. *Ingestion Of The Agent*: This may happen through the consumption of contaminated water or food or through the insertion of contaminated fingers, pens, etc. into the mouth.

ii. *Inhalation Of The Agent*: Inhalation of an infectious agent can occur if an infectious aerosol* is present.

iii. *Entry Via Mucosal Membranes*: Some infectious agents can pass through thin body membranes on simple contact and can cause infection e.g. through the eyes, nose, ears or mouth. This route of entry can be further exacerbated if fingers or other items are inserted into the eyes, mouth, nose or ears whilst working with risk material.

iv. *Entry Via Damaged Skin*: Contact between infectious material and broken skin, e.g. skin abrasions, can allow an infectious agent to directly enter the body.

v. *Subcutaneous Entry:* This occurs when infectious agents are physically introduced into the body through the skin, e.g. through a needle stick injury with a contaminated syringe.

vi. *Physical Contamination:* A person may also become contaminated with a biological agent following a simple contact with infectious material. In such cases the agent may cause a disease at the site of contamination or may be spread about the body.

Once in or on a persons body a biological agent may give rise to a recognisable disease. However peoples' susceptibility to a biological agent varies greatly between individuals and depends on a range of factors including age, sex, general state of health, etc.

* An *aerosol* is defined in this instance as a suspension of biological agents in the air.

In order to prevent the infection of persons with a biological agent the potential routes of transmission between infectious materials and that person must be identified and eliminated or minimised to as low a level as is practicable. This is the ultimate aim of any Biosafety Risk Reduction measures implemented in the University.

4.0 Incidental Exposure To Biological Agents

4.1 Introduction

Incidental exposure to biological agents may take place when such agents are to be found in the University but are not directly or deliberately handled or utilised. In some workplaces materials are routinely handled or utilised that have the potential to contain or harbour biological agents whilst in other settings biological agents may be naturally present in the working environment.

For example persons working with human or animal waste or with bodily fluids (e.g. blood) are at risk of exposure to any biological agents that may be carried in those materials. Similarly all work with animals has the potential to place persons at risk of exposure to biological agents that may be carried by the animals (*Zoonoses* is the term used to describe diseases that can be transmitted from animals to man, e.g. Bovine Tuberculosis, Brucellosis, etc.).

The potential for harmful biological agents to be present in the workplace must always be considered, especially when persons are working with products of human or animal origin. In most cases it will be necessary to take specific steps to minimise the risk to workers from incidental exposure to biological agents.

4.2 Incidental Exposure To Biological Agents – Legal Requirements

The *Safety Health and Welfare At Work (Biological Agents) Regulations 1994 (SI 146)* are applicable to workplaces where there is a risk of incidental exposure of employees to biological agents. The regulations require that employers conduct a written risk assessment in order to identify the potential for employee exposure to a biological agent where the presence of a biological agent in the workplace is suspected or can be reasonably assumed given the nature of the work undertaken. Risk reduction measures designed to protect worker safety must be identified and implemented. At a minimum the implementation of good microbiological and hygiene practices as outlined in Section 6 below is legally required.

Where deemed necessary by said risk assessment the legal requirements for the deliberate use of a biological agents as outlined in Section 5.2 below should also be implemented.

Guidelines on risk assessment are outlined in Section 7.

5.0 Deliberate Use Of Biological Agents

5.1 Introduction

The deliberate use of named biological agents in the University may exposure persons to a risk of infection by that agent. Consequently the requirements of the legislation for those persons deliberately utilising named biological agents is much greater that that imposed on persons who may be incidentally exposed to such agents in the course of their work.

5.2 Deliberate Use Of Biological Agents – Legal Requirements

5.2.1 Classification

Where a named biological agent is deliberately used in the workplace it must be classified into one of four biohazard classifications. These are:

- **Hazard Class I:** a biological agent that is unlikely to cause human disease

- **Hazard Class II:** a biological agent which can cause human disease and might be a hazard to employees, although it is unlikely to spread to the community and in respect of which there is usually effective prophylaxis or treatment available

- **Hazard Class III:** a biological agent which can cause severe human disease and presents a serious hazard to employees and which may present a risk of spreading to the community, though there is usually effective prophylaxis or treatment available

- **Hazard Class IV:** a biological agent which causes severe human disease and is a serious hazard to employees and which may present a high risk of spreading to the community and in respect of which there is usually no effective prophylaxis or treatment available

A comprehensive list of biological agents and their classifications is given in the *Fourth Schedule* of the 1994 Biological Agents Regulations. However this list was updated by the *Biological Agents (Amendment) Regulations (SI No. 248 of 1998)*, and it is this updated list that should be referred to when assigning a biological agents it's hazard classification. The list as given in the 1994 regulations is no longer valid.

If the organism in question cannot be found within the listings contained within the relevant legislation then reference should be made to the UK Health and Safety Executive's *'The Approved Lists Of Biological Agents'* which can be downloaded free of charge from the internet. The latest edition was published in 2004. If an organism cannot be found in this listing then further enquiries should be made with other researchers to establish the internationally accepted classification for that organism. The classification system for biological agents is based on *World Health Organisation Guidelines* and is standard worldwide. In the eventuality that no classification for a biological agent can be found then the user must assign a classification themselves based on the properties of the organism and similar type organisms.

5.2.2 Containment

Within the 1994 regulations the **minimum legally binding containment measures** necessary for the safe use of each class of biological agent are laid down within the *Seventh Schedule* and *Eight Schedule* of the regulations. The *Seventh Schedule* lays down minimum requirements for health and veterinary care facilities, laboratories, diagnostic laboratories and rooms in which deliberately infected animals or animals suspected of being infected are being kept. The *Eight Schedule* lays down minimum requirements for industrial processes utilising biological agents (refer to Tables 1 and 2 below).

When a biological agent is intentionally used in the workplace then the minimum containment measures applicable to its hazard classification as outlined in the relevant schedule must be implemented. Containment levels are classified as Levels 1-4 in accordance with the hazard classification of the agents in question. An animal carrying or suspected to be carrying a biological agent must be classified in accordance with the hazard class of the agent it is carrying.

In work settings which are laboratories, diagnostic laboratories and rooms in which deliberately infected animals or animals suspected of being infected are being kept employers must:

- Determine the containment measures required in order to minimise infection
- Carry out activities involving the handling of a biological agent only in working areas corresponding to at least the minimum containment level required for that agent
- Adopt at a minimum Containment Level 2 in laboratories handling materials in respect of which there exists uncertainties about the presence of a biological

agent which may cause human disease, but which do not have as their aim working with a biological agent including cultivating or concentrating a biological agent and containment levels 3 or 4 as and when appropriate, where it is known or it is suspected that it is necessary.

5.2.3 Risk Assessment

A written risk assessment is required where biological agents are deliberately used or handled in the workplace. Guidelines on risk assessment are outlined in Section 7. At a minimum the implementation of good microbiological and hygiene practices as outlined in Section 6 below and the minimum containment measures applicable to the class of agent being handled are legally required. Where the deliberate use is of a Class 1 biological agent then the implementation of good microbiological and hygiene practices is sufficient – there are no specific containment measures outlined for the use of Class 1 agents in the legislation.

5.2.4 Notification To The Health and Safety Authority

Persons must inform the *Health and Safety Authority* (*HSA*) of the use of a biological agent:

- Thirty days prior to the commencement of work involving the use for the first time of a Group 2 or 3 or 4 biological agent
- Thirty days prior to the commencement of work involving the use for the first time of each subsequent Group 4 biological agent
- Thirty days prior to the commencement of work involving the use for the first time of any Group 3 biological agent where the user provisionally classifies that biological agent himself
- For the first time only in the case of laboratories providing a purely diagnostic service in relation to a Group 4 biological agent
- In any case where there are substantial changes of importance to safety and health at work to processes or procedures which render the notifications required above out of date

A standard notification form is available from:
www.hsa.ie/files/file_20040521120602notification_biological.pdf

Persons must also inform the *HSA* of any accident or incident which may have resulted in the release of a biological agent and which could cause both severe human infection and human illness or both.

Table 1. Extract From The Seventh Schedule Of The 1994 Biological Agents Regulations

Containment Measures At Different Containment Levels For Health And Veterinary Care Facilities, Laboratories, Diagnostic Laboratories And Rooms In Which Deliberately Infected Animals Or Animals Suspected Of Being Infected Are Being Kept.			
Containment Measures	**Containment Level 2**	**Containment Level 3**	**Containment Level 4**
1. The workplace is to be separated from any other activities in the same building	No	Recommended	Yes
2. Input air and extract air to the workplace are to be filtered using HEPA or likewise	No	Yes, on extract air	Yes, on input and extract air
3. Access is to be restricted to nominated workers only	Recommended	Yes	Yes, via airlock
4. The workplace is to be sealable to permit disinfection	No	Recommended	Yes
5. Specified disinfection procedures	Yes	Yes	Yes
6. The workplace is to be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
7. Effective vector control e.g. rodents and insects	Recommended	Yes	Yes
8. Surfaces impervious to water and easy to clean	Yes, for bench	Yes, for bench and floor	Yes, for bench, walls, floor and ceiling
9. Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
10. Safe storage of a biological agent	Yes	Yes	Yes, secure storage
11. An observation window, or alternative, is to be present, so that occupants can be seen	Recommended	Recommended	Yes
12. A laboratory is to contain own equipment	No	Recommended	Yes
13. Infected material including any animal is to be handled in a safety cabinet or isolator or other suitable containment	Where appropriate	Yes, where infection is by airborne route	Yes
14. Incinerator for disposal of animal carcases	Recommended	Yes (available)	Yes, on site

Table 2. Extract From The Eight Schedule Of The 1994 Biological Agents Regulations

Containment Measures At Different Containment Levels For Industrial Processes Utilising Biological Agents			
Containment Measures	**Containment Level 2**	**Containment Level 3**	**Containment Level 4**
1. Viable organisms should be handled in a system which physically separates the process from the environment	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to:	Minimise release	Prevent release	Prevent release
3. Sample collection addition of materials to a closed system and transfer of viable organisms to another closed system, should be performed so as to:	Minimise release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable organisms have been:	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimise release	Prevent release	Prevent release
6. Closed systems should be located within a controlled area	Optional	Optional	Yes and purpose built
(a) Biohazard signs should be posted	Optional	Yes	Yes
(b) Access should be restricted to nominated personnel only	Optional	Yes	Yes, via an airlock
(c) Personnel should wear protective clothing	Yes, work clothing	Yes	A complete change
(d) Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
(e) Personnel should shower before leaving the controlled area	No	Optional	Yes
(f) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
(g) The controlled area should be adequately ventilated to minimise air contamination	Optional	Optional	Yes
(h) The controlled area should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
(i) Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
(j) The controlled area should be designed to contain spillage of the entire contents of the closed system	No	Optional	Yes
(k) The controlled area should be sealable to permit fumigation	No	Optional	Yes
(l) Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means

5.2.5 Training And Information

Employers must provide all employees with sufficient and appropriate training and information concerning:

- Any potential risks to health
- The precautions to be taken to prevent exposure
- Any hygiene requirements
- Information on the wearing and use of personal protective equipment
- The steps to be taken by employees in the case of incidents and to prevent incidents

5.2.6 Records

Employers must keep records of all persons exposed to a Group 3 or a Group 4 biological agent (or both), indicating the type of work done by each employee, and, whenever possible, the biological agent to which they have been exposed, as well as records of exposures accidents and incidents, as appropriate. These records must be kept for at least 10 years.

5.2.7 Health Surveillance

Where necessary provisions for the Health Surveillance of employees should be made. Health Surveillance is defined as '*the periodic review, for the purpose of protecting health and preventing occupationally related disease, of the health of employees, so that any adverse variations in their health which may be related to working conditions are identified as early as possible'.* Health surveillance may include at least one of the following measures:

- Keeping records of an employee's medical and occupational history
- A personalised assessment of the employee's state of health
- Where appropriate, biological monitoring as well as detection of early and reversible effects
- Further tests may be decided upon for each employee, when he is the subject of health surveillance, in the light of the most recent knowledge available to occupational medicine

6.0 Good Microbiological / Hygiene Practices

At a very minimum the following biosafety precautions should be taken where relevant to avoid exposure to biological agents when working in University laboratories or similar:

1. The avoidance of the use of a harmful biological agent or if the nature of the activity permits it's replacement with a less hazardous agent
2. The implementation of good hygiene practices, e.g.
    - The provision of adequate welfare and washing facilities
    - The covering of all cuts and abrasions with a waterproof dressing
    - The prohibition of eating, drinking and smoking in areas where biological agents may be present
    - The washing of exposed skin following completion of work and before eating, drinking or smoking
    - Not inserting fingers into mouth or biting fingernails
3. The keeping of the number of potentially exposed persons to a minimum
4. The provision of adequate information and training to relevant persons particularly in the recognition of symptoms of infection
5. The provision of vaccinations free of charge if deemed necessary to affected persons
6. The provision and use of suitable personal protective equipment which is properly stored, cleaned as required, is replaced when defective and is separated from normal clothing
7. The design of work practices so as to minimise potential for contact with biological agents
8. Ongoing health screening for affected persons if deemed necessary
9. The formulation and implementation of local codes of practice for the safety of personnel where required, especially for the taking, handling and processing of samples of human or animal origin
10. The display of warning notices were necessary
11. The keeping of adequate records of persons potentially exposed to infectious agents where deemed necessary
12. The drawing up of plans to deal with accidents involving a biological agent.
13. The testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of a biological agent used at work.
14. The use of means for the safe collection, storage and disposal of waste by employees, including the use of secure and identifiable containers, after suitable treatment where appropriate.

15. The making of arrangements for the safe handling and transport of a biological agent within the workplace.

In addition where blood products are being handled then the implementation of a series of measures known as *Universal Precautions* should also be considered. *Universal Precautions* are a set of safety guidelines which are based around the *Universal Precautions For The Handling Of Blood And Blood Based Products*. The application of *Universal Precautions* requires that all blood and body fluids be regarded as potentially infectious and appropriate protective action taken. *Universal Precautions* include:

1. The assumption that all blood products are potentially infectious
2. The implementation of good personal hygiene practices and the avoidance of hand or equipment to mouth/eye/nose/ear contact
3. The use of vaccinations where necessary
4. The wearing of suitable personal protective equipment
5. The prevention of puncture wounds, cuts and abrasions in the presence of blood and body fluids
6. The protection of skin lesions and existing wounds on workers
7. The avoidance of the use of sharps and sharp objects when possible but, where unavoidable, taking particular care in their handling and disposal
8. The development of suitable working area decontamination procedures
9. The elimination or containment of any work practises that could give rise to aerosols or the uncontrolled release of material
10. The development of emergency response plans
11. The disposal of all contaminated waste safely
12. The provision of training and information to all employees engaged in handling potentially infectious material

7.0 Biological Agents Risk Assessment

The ultimate aim of a *Biological Agent Risk Assessment* is to assess the risk from the use / presence of the biological agent in the workplace to the health and safety of persons and to identify control measures designed to reduce the risk to as low a level as possible. In the case of biological agents risk reduction can be achieved through the use of procedural, management and physical controls.

'Hazard' is defined as the potential / ability to cause harm, and in the case of biological agents the organism / infectious material itself represents the hazard. 'Risk' is defined as the potential of the hazard, i.e. the biological agent concerned, to cause harm under the actual circumstances of use. The assessment of risk is based on the linkage of the probability of exposure / infection of workers with the biological agent with the severity of injury resultant from that exposure. The risk assessment matrix below (Table 3) can be used to assess risk from workplace hazards.

Table 3. University College Dublin Standard Risk Assessment Matrix

	Severity Of Outcome Of Exposure		
Probability Of Exposure	**Slightly Harmful**	**Harmful**	**Very Harmful**
Unlikely	***trivial risk***	***acceptable risk***	***moderate risk***
Likely	***acceptable risk***	***moderate risk***	***substantial risk***
Very Likely	***moderate risk***	***substantial risk***	***intolerable risk***

Severity Of Outcome Of Exposure

Slightly Harmful Outcomes:

- Superficial injuries
- Minor cuts and bruises
- Eye irritation
- Nuisance and irritation
- Temporary discomfort

Harmful Outcomes:

- Lacerations
- Burns
- Concussion
- Sprains
- Minor fractures

- Dermatitis
- Asthma

Very Harmful Outcomes:

- Fatality
- Amputation
- Major fracture
- Poisoning
- Cancer
- Life shortening disease
- Deafness
- Head injuries
- Eye injuries

Risk Rating

Risk assessments are thus graded as trivial risk, acceptable risk, moderate risk, substantial risk or intolerable risk.

Trivial Risk

- No action needed

Acceptable Risk

- No additional risk control measures required

Moderate Risk

- Implement further risk control measures if possible

Substantial Risk

- Further control measures must be implemented.
- If not possible then work must be strictly managed to ensure safety

Intolerable Risk

- Work must be prohibited until further control measures are implemented.

Risk assessments must be completed for all biological agents in use prior to those agents being used for the first time and for all workplace activities where there is a risk of exposure to biological agents. When carrying out the risk assessment in the

case of activities involving potential exposure to several types of biological agent then the danger presented by all hazardous biological agents present must be considered.

Risk assessments must be completed by a competent person. That person must have sufficient knowledge and experience to identify and classify the hazards associated with a biological agent and also how to reduce the risks from these hazards.

When completing any Biological Agents Risk Assessment the following should always be borne in mind:

- The use of a less hazardous biological agent.
- The keeping as low as possible of the number of employees exposed or likely to be exposed to a biological agent.
- The design of work processes and engineering control measures so as to avoid or minimise the release of a biological agent into the place of work.
- The use of both collective protection measures, and individual protection measures where exposure cannot be avoided by other means.
- The use of hygiene measures compatible with the aim of preventing or reducing the accidental transfer or release of a biological agent from the workplace.
- The use of the biohazard sign and other relevant warning signs.
- The drawing up of plans to deal with accidents involving a biological agent.
- The testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of a biological agent used at work.
- The use of means for the safe collection, storage and disposal of waste by employees, including the use of secure and identifiable containers, after suitable treatment where appropriate.
- The making of arrangements for the safe handling and transport of a biological agent within the workplace.

Risk assessments must be reviewed on a regular basis (it is recommended that *Biological Agents Risk Assessments* are reviewed at least annually) and when changes in work practices necessitate it. Written copies of the most up to date risk assessment must be maintained in the workplace and if deemed necessary extracts should be displayed prominently in or adjacent to the areas to which they refer. All risk assessments should be dated and have a section detailing their review history.

The name of the person who wrote or last reviewed the assessment must be clearly indicated also.

The University Safety Office recommends the use of the *UCD Pro Forma Biological Agents Risk Assessment Template* when conducting biological agents risk assessments.

8. UCD Pro Forma Biological Agents Risk Assessment Template

The University Safety Officer has developed a *pro forma* template to aid persons in completing a Biological Agents Risk Assessment.

1. Name & Status Of Person Carrying Out Assessment

Persons completing the risk assessment should insert their name and status here, e.g. academic, postgraduate students, etc.

2. Date Of Assessment

Insert the date of assessment here.

3. Location Of Work

The physical location of the work under review should be inserted here.

4. Detail The Process Involving The Use Or Risk Of Exposure To Biological Agents

A description of the process involving the risk of exposure to biological agents should be inserted here. Persons should indicate the frequency and duration of the process, the materials to be handled and who will be carrying out the process. If necessary a written procedure for the process should be attached.

5. Does The Work Involve The Deliberate Use Of A Named Biological Agent

If the work involves the use of a named biological agent persons should tick yes and move to section 6. If not they should tick no and move to section 7.

6. Deliberate Use Of Named Biological Agent

In this section persons should indicate the name and type of agent in use. They should also indicate its hazard classification and tick the relevant mandatory containment measures as outlined in Appendix 1 for that class. If the agent in question is a Class 1 organism then they should proceed to Section 8. When this section is completed persons should proceed to section 8.

7. Non Deliberate Use Of Biological Agent

The names of the agents that persons may be potentially exposed to in their work should be indicated here. In work settings which are laboratories, diagnostic laboratories and rooms in which deliberately infected animals or animals suspected of being infected are being kept Containment Level 2 measures must be implemented. See Appendix 1 for details.

8. Is specialist training required before this process commences

Is specialist training is required the it must be organised for relevant persons before the process can be undertaken .

9. List Persons Likely To Be Exposed To Biological Agents:

The persons who are likely to be exposed to the agent should be listed here. Apart from the user themselves these may include other persons in the laboratory, cleaners, etc.

10 Potential Likely Routes Of Exposure

The likely route of exposure of persons to the biological agents in question should be indicated here.

11. Potential Health Effects Of Biological Agent(s)

Detail the potential health effects of the biological agents under consideration here.

12. Control Measures Designed To Allow Safe Use Of Agent

In this section a range of information should be inserted.

A. PPE Required: insert required PPE in this section
B. Engineering controls required: state what engineering controls are required
C. Insert emergency responses for spillages and accidental exposure and indicate a suitable disinfectant
D. Indicate the good hygiene practices required
E Indicate if a vaccination is required and if so give details
F Any further risk control measures as deemed necessary should be indicated here.

13. Risk Rating

A risk rating for the biological agent under review should be assigned in this section. If the final assessment is acceptable then the document should be signed and dated by the assessor. If the risk from an agent cannot be reduced to an acceptable level then the work cannot be carried out. This section should also be used to ascertain whether or not the process is suitable for lone working.

Section 14. Notification To The Health and Safety Authority Required:

Indicate if notification is required to the HSA.

Section 15. Notification To The University Biosafety Committee

All work with biological agents that may result in exposure to a biological agent must be notified to the *University Biosafety Committee*. Users should submit a copy of their completed risk assessment to biosafety@ucd.ie as notification.

Section 16. Revision History

The assessment's revision history should be detailed here.

University College Dublin
Pro Forma Biological Agents Risk Assessment Template

Persons completing this assessment should refer to the UCD Biosafety Manual

1. Name & Status Of Person Carrying Out Assessment

_____ _____

2. Date Of Assessment **3. Location Of Work**

_____ _____

4. Detail The Process Involving The Use Or Risk Of Exposure To Biological Agents – indicate the frequency and duration of the process, the materials to be handled and who will be carrying it out - if necessary attach a written procedure for the process.

_____

_____

_____

_____

_____

_____

5. Does The Work Involve The Deliberate Use Of A Named Biological Agent

Yes ☐ if yes proceed to section 6

No ☐ if no proceed to section 7

6. Deliberate Use Of Named Biological Agent

Name Of Agent _____

Type Of Agent _____ (bacteria, virus, etc)

Classification of Agent: _____ (1-4) if Class 1 proceed to Section 8

Containment Required

Containment Measures	Implemented
1. The workplace is to be separated from any other activities in the same building	
2. Input air and extract air to the workplace are to be filtered using HEPA or likewise	
3. Access is to be restricted to nominated workers only	
4. The workplace is to be sealable to permit disinfection	
5. Specified disinfection procedures	
6. The workplace is to be maintained at an air pressure negative to atmosphere	
7. Effective vector control e.g. rodents and insects	
8. Surfaces impervious to water and easy to clean	
9. Surfaces resistant to acids, alkalis, solvents, disinfectants	
10. Safe storage of a biological agent	
11. An observation window, or alternative, is to be present, so that occupants can be seen	
12. A laboratory is to contain own equipment	
13. Infected material including any animal is to be handled in a safety cabinet or isolator or other suitable containment	
14. Incinerator for disposal of animal carcases	

Ticking a containment measure indicates it's implementation. Please see Appendix 1 for mandatory containment measures.

Proceed to Section 8

7. Non Deliberate Use Of Biological Agent
Detail potential infectious agents that persons may be exposed to:

_____ _____ _____ _____

In work settings which are laboratories, diagnostic laboratories and rooms in which deliberately infected animals or animals suspected of being infected are being kept Containment Level 2 measures must be implemented. See Appendix 1 for details. Have these measures been implemented where necessary ***yes*** _____

8. Is specialist training required before this process commences: yes ☐ no ☐

9. List Persons Likely To Be Exposed To Biological Agents:

* *
* *

10. Indicate Potential Routes Of Exposure

Ingestion Of The Agent	☐	*Inhalation Of The Agent*	☐
Entry Via Mucosal Membranes	☐	*Subcutaneous Entry*	☐
Entry Via Damaged Skin	☐	*Physical Contamination*	☐

11. Potential Health Effects Of Biological Agent(s)

_____

_____

12. Risk Control Measures Designed To Allow Safe Use Of Agent

A. PPE Required: Lab Coat: √ Safety Glasses: ☐ Safety Goggles: ☐

Face Shield: ☐ Gloves: ☐ Other: ☐ (give details) _____

B. Engineering Controls Required: Safety Cabinet ☐ Other: ☐ (give details) _____

C. Emergency Response
First Aid Responses

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-
-
-

Spill Response

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-
-
-

Suitable Disinfectant _____

D. Good Hygiene Practises:

No eating or drinking in work area ☐ Hand washing Facilities Available ☐

Mandatory washing of exposed skin after work completed ☐

Covering of cuts and abrasions ☐ No insertion of objects into mouth, etc ☐

E. Vaccination Required no ☐ yes ☐ (give details) _____

F. Further Risk Control Measures Required To Eliminate / Minimise Identified Routes Of Exposure (Section 10)

Consider the following:

1. The design of work practices so as to minimise potential for contact with biological agents
2. Ongoing health screening for affected persons if deemed necessary
3. The formulation and implementation of local codes of practice for the safety of personnel where required, especially for the taking, handling and processing of samples of human or animal origin
4. The display of warning notices were necessary
5. The keeping of adequate records of persons potentially exposed to infectious agents where deemed necessary
6. The drawing up of plans to deal with accidents involving a biological agent.
7. The testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of a biological agent used at work.
8. The use of means for the safe collection, storage and disposal of waste by employees, including the use of secure and identifiable containers, after suitable treatment where appropriate.
9. The making of arrangements for the safe handling and transport of a biological agent within the workplace.
10. The removal of sharps from the workplace
11. The implementation of Universal Precautions for handling blood products
12. The restriction of access to the workplace
13. Pregnant employees
14. Equipment requirements
15. Sharps issues
16. Lab animal issues
17. Additional hygiene control measures

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13. Risk Rating

Assessment of Severity
High (H) = Very Harmful
Medium (M) = Harmful
Low (L) = Slightly Harmful

Assessment of Likelihood Of Exposure:
High (H) = Very Likely
Medium (M) = Likely
Low (L) = Unlikely

Risk = Severity x Likelihood

RISK RATING: _____

Severity

Likelihood	L	M	H
L	1	2	3
M	2	3	4
H	3	4	5

Shaded Area = risk rating

1. **Trivial Risk:** No further action needed
2. **Acceptable Risk:** No additional risk control measures required
3. **Moderate Risk:** Implement further risk control measures if possible
4. **Substantial Risk:** Further control measures must be implemented. If this is not possible then work must be strictly managed to ensure safety.
5. **Intolerable:** Work must be prohibited until further control measures are implemented.

Is the risk rating acceptable: yes ☐ no ☐

If yes sign and date below and ensure all risk control measures have been implemented. If no identify further control measures and reassess risk. If the risk cannot be reduced to an acceptable level then process cannot be carried out.

Signed: **Date:** **Position:**

_____ _____ _____

Is the process suitable for lone working yes ☐ no ☐

Section 14. Notification To The Health and Safety Authority Required

yes ☐ no ☐

Section 15. Notification To The University Biosafety Committee

yes ☐ no ☐

Section 16. Revision History

Appendix 1. Extract From The Seventh Schedule Of The 1994 Biological Agents Regulations

Containment Measures At Different Containment Levels For Health And Veterinary Care Facilities, Laboratories, Diagnostic Laboratories And Rooms In Which Deliberately Infected Animals Or Animals Suspected Of Being Infected Are Being Kept.			
Containment Measures	**Containment Level 2**	**Containment Level 3**	**Containment Level 4**
1. The workplace is to be separated from any other activities in the same building	No	Recommended	Yes
2. Input air and extract air to the workplace are to be filtered using HEPA or likewise	No	Yes, on extract air	Yes, on input and extract air
3. Access is to be restricted to nominated workers only	Recommended	Yes	Yes, via airlock
4. The workplace is to be sealable to permit disinfection	No	Recommended	Yes
5. Specified disinfection procedures	Yes	Yes	Yes
6. The workplace is to be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
7. Effective vector control e.g. rodents and insects	Recommended	Yes	Yes
8. Surfaces impervious to water and easy to clean	Yes, for bench	Yes, for bench and floor	Yes, for bench, walls, floor and ceiling
9. Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
10. Safe storage of a biological agent	Yes	Yes	Yes, secure storage
11. An observation window, or alternative, is to be present, so that occupants can be seen	Recommended	Recommended	Yes
12. A laboratory is to contain own equipment	No	Recommended	Yes
13. Infected material including any animal is to be handled in a safety cabinet or isolator or other suitable containment	Where appropriate	Yes, where infection is by airborne route	Yes
14. Incinerator for disposal of animal carcases	Recommended	Yes (available)	Yes, on site

9. Biological Laboratory Safety – Key Aspects

9.1 Emergency Planning

All laboratories / facilities where biological agents are handled must have in place at all times an *Emergency Response Plan* which outlines the responses to be taken in the event of an emergency. Emergencies may include such things as fire, gas leak, chemical leak, failure of critical equipment, power failure, worker injury, exposure to a biological agent, unintentional release or spillage of a biological agent, etc.

The emergency response plan must detail the necessary steps to be taken to deal with such incidents. Key functionaries must be named and their responsibilities outlined in the plan. If any emergency response equipment is identified by the plan as being required to deal with an incident then this material must be kept readily available on site and if necessary training in its correct use must be given to the named functionaries.

Emergency Response Plans should be reviewed on a regular basis and when changes in work practices necessitate it. Response plans must be tested on a regular basis.

9.2 Spillages

A key part of the *Emergency Response Plan* is the procedure to be followed in the event of a spillage or loss of biological material. Key to the safe management of spillages is the use of appropriate disinfectants, personal protective equipment (PPE) and staff training.

For spillages where aerosols are not likely to be produced persons should don the necessary PPE and treat the affected area with an appropriate dry disinfectant or cover with tissue paper and apply a liquid disinfectant. The treated area should be allowed to remain long enough for the disinfectant to take effect before being cleaned and the waste material being disposed off accordingly. The contact time and the type of disinfectant to be used may vary depending on the biological agent in question and this should be clearly indicted in the *Emergency Response Plan*.

Where a spillage may give rise to aerosols, e.g. during the rupture of a sample tube in a centrifuge, the area must be evacuated and the droplets allowed time to settle. Persons then wearing appropriate PPE may enter the effected area treat the spillage. In some cases extensive decontamination of the working area may be required. If

deemed necessary testing for the presence of the biological agent can be done following the completion of the disinfectant procedure. Respiratory protection may be required when dealing with spillages that have generated aerosols.

9.3 Worker Training / Supervision

All persons working with biological agents must be adequately trained so that they can work with the material safely and without undue risk to their own or their co-workers safety. The extent of a workers training will depend on the nature of the work in which they are engaged and the type of biological agent which they are handling. All workers will require some form of supervision, especially undergraduate students and inexperienced postgraduates. Academic supervisors and facility managers must ensure that appropriate supervision is provided to all staff under their control.

Employers must provide all employees with sufficient and appropriate training and information concerning:

- Any potential risks to health
- The precautions to be taken to prevent exposure
- Any hygiene requirements
- Information on the wearing and use of personal protective equipment
- The steps to be taken by employees in the case of incidents and to prevent incidents
- All relevant risk assessments and laboratory procedures
- Any laboratory equipment that they are required or are likely to use

(refer to Table 4 below)

Employers must also provide written instructions and if appropriate display notices which must include the procedures to be followed in the event of a serious accident or incident involving the handling of a biological agent.

All training and information must be provided in a form, manner and language likely to be understood by the person receiving the training.

Training should not be limited to those working at the bench; managers, administrators, services staff, maintenance contractors and cleaners may require some form of training. Seniority of rank / grade is not an indication of competence. Similarly a lack of formal qualifications does not indicate a lack of competence. Competency should be viewed as a combination of training, experience and

knowledge which enables the user to handle and work with the biological agent safely. A minimum training / competency level for all relevant employees must be laid down within the risk assessment.

Table 4 Worker Training Requirements

Containment Level	*Key Competencies*
1 and 2	▪ Awareness of the nature of the biological agents in use and its health effects ▪ Awareness and understanding of all procedures and risk assessments ▪ Technical competency for work in question ▪ Knowledge and understanding of disinfection and hygiene requirements ▪ Knowledge of waste management provisions ▪ Knowledge of the emergency response plan ▪ Safe use of PPE
3 and 4	▪ As for Class 1 and 2 ▪ Safe evacuation, sealing and fumigation procedures

9.4 Lone Working

All laboratories or facilities must have in place a *Lone Working Policy*. This policy must outline the requirements for those persons who wish to work with biological agents during out of hours periods when they are may be alone in the laboratory. At a minimum persons wishing to engage in lone working should be required to produce a *Lone Working Risk Assessment* in order to identify any potential hazards associated with the work and to assign a risk rating to the lone work. This assessment must be reviewed and approved by the facility manager / academic supervisor before lone working can commence. Lone working must not be allowed for any *High Risk* activities, when working with Class 3 or 4 agents and when engaging in any activity the emergency response to which requires the presence of more than one person.

9.5 Record Keeping

The *1994 Biological Agents Regulations* requires that a range of records be kept when persons are working with potentially hazardous biological agents.

All risk assessments carried out for any work with a biological agent(s) must be kept in a written format in the workplace.

All vaccination records and training records for staff working with biological agents must be available within the workplace.

All records of any health surveillance undertake must be maintained by the university (these records must be made available to the individual employees concerned if requested).

Accident records must be available in the workplace

Employers must also keep a list of the employees who may have been exposed to a Class 3 or 4 biological agent (or both), indicating the type of work done by each employee, and, whenever possible, the biological agent to which they have been exposed, as well as records of exposures accidents and incidents, as appropriate. This list must be kept for at least 10 years following the end of exposure. Such records must be kept for 40 years in situations where:

- The work was with a biological agent known to be capable of establishing persistent or latent infections
- That in the light of present knowledge, are indiagnoseable until illness later develops
- That have particularly long incubation periods before illness develops
- That result in an illness which recrudesce at times over a long period despite treatment
- That result in illnesses that may have serious long-term sequelae

In addition to the above records which must be kept to comply with statutory requirements laboratory managers / project managers must also keep all records pertaining to equipment maintenance, waste disposal and staff training.

All users of genetically modified material must keep a written record of the work carried out on each contained use and such records must be submitted to the *Environmental Protection Agency* within one month of the end of each calendar year. Users of Class 1 material must keep a written record of each risk assessment and of the work carried out on each contained use, and such records must be submitted to the *EPA* within one month of the end of each calendar year.

9.6 Selection Of Personal Protective Equipment

Health and safety legislation requires that where the risk from a hazard cannot be controlled by other means then workers must be provided with suitable Personal Protective Equipment (PPE) designed to protect their safety. Whilst the use of PPE is generally considered to be the option of ‘last resort’ when controlling workplace

hazards in the case of working with biological agents the selection and correct use of appropriate PPE is key to controlling the risks presented by biological material. Employers must ensure that any necessary PPE supplied is properly stored in a designated place, is checked and cleaned if possible, before, and in any case after each use, and is repaired, where defective, or replaced, before further use.

Protective Clothing

All persons working in a biological laboratory must at a minimum wear a closed laboratory coat. Such coats must be removed when leaving the laboratory and must be laundered on a regular basis. In so far as is practicable such coats should be laundered in-house and not brought to the users home. Heavily soiled laboratory coats should be removed immediately and if necessary disposed off.

Gloves

Persons involved in the manipulation of biological material must also wear protective gloves. Disposable gloves which provide a mechanical barrier between the users skin and the material being handled are sufficient. Where possible latex gloves should be avoided due to the allergic reactions that such material can generate in wearers. If certain procedures are being undertaken then the use of specialist gloves may be required, e.g. when handling contaminated sharps, cleaning up broken glass, etc. In some cases 'double gloving' may be required.

Eye / Face Protection

Where there is a risk of material splashing or being ejected under pressure safety glasses must be worn by workers. Consideration should be given to the wearing of a full face shield when blood is being handled and there is a risk of splashing.

Respiratory Protection

Under normal conditions respiratory protection should not be required in laboratories handling Class 1 and 2 biological agents, although it may be required in laboratories handling Class 3 and 4 material. If a mask is required to protect the worker from the material being handled then the risk control measures have failed. However, respiratory protection may be required during the clean up following the spillage or unintentional release of biological material. If specialist respiratory protection is required in such instances then appropriate training must be given to the persons responsible for its use.

All required PPE must be clearly indicated in the risk assessment for the biological agent(s) / processes under consideration by that assessment.

9.7 Routes Of Exposure To Pathogenic Agents

For a pathogenic agent to cause a disease or elicit a response in a person it must enter into or onto that persons body. In order to prevent the infection of persons with a biological agent these potential routes of transmission between potentially infectious material and the host person must be eliminated or minimised to as low a level as practicable.

There are a number of ways in which a biological agent may enter the body. These are:

1. *Ingestion Of The Agent*: This may happen through the consumption of contaminated water or food or through the insertion of contaminated fingers, pens, etc into the mouth.
2. *Inhalation Of The Agent*: Inhalation of an infectious agent can occur if an infectious aerosol* is present.
3. *Entry Via Mucosal Membranes*: Infectious agents can pass through thin body membranes on simple contact and can cause infection e.g. through the eyes, nose, ears or mouth. This route of entry can be further exacerbated if fingers or other items are inserted into the eyes, mouth, nose or ears whilst working with pathogens.
4. *Entry Via Damaged Skin*: Contact between infectious material and broken skin, e.g. skin abrasions, can allow an infectious agent to directly enter the body.
5. *Subcutaneous Entry:* This occurs when infectious agents are physically introduced into the body through the skin, e.g. through a needle stick injury with a contaminated syringe.
6. *Physical Contamination:* A person may also become contaminated with a biological agent flowing a simple contact with infectious material. In such cases the agent may cause a disease at the site of contamination or may be spread about the body.

The ultimate aim of any risk reduction measures implemented in the workplace must be to guard against the occurrence of any of the above routes of exposure between the pathogenic organisms and the worker.

* An *aerosol* is defined in this instance as a suspension of biological agents in the air.

Further Reading

Infection at work: Controlling the risks: A guide for employers and the self employed on identifying, assessing and controlling the risks of infection in the workplace. Advisory Commission On Dangerous Pathogens / HMSO 2003.

9.8 Personal Hygiene In The Laboratory

All persons working in a biological laboratory must adhere to the highest standards of personal hygiene in order to minimise the spread of biological agents within and outside of the laboratory. The legislation requires that employers provide employees with suitable washing and toilet facilities, which may include eye washes and skin antiseptics (or both).

Persons working with biological materials must:

- Cleanse or wash their hands after handling material and prior to leaving the laboratory or using the telephone, computer or any other equipment in the laboratory.
- Not insert their hands or fingers or any pieces of equipment e.g. pens, into their mouth / eye / nose / ears whilst in the laboratory
- Cover all cuts, abrasion and skin lesions with a waterproof dressing at all times.
- Persons suffering from any condition that causes them to produce excessive mucosal secretions e.g. colds and flu; or which causes them to sneeze excessively e.g. hay fever; may not be suitable candidates for working with biological agents until their condition has improved.
- There must be no eating or drinking within the laboratory
- All persons protective equipment must be removed upon exiting the laboratory and must not be worn in common areas or on canteens / tea rooms.

9.9 Vaccinations

The use of vaccinations should be considered where workers are handling potential infectious agents and an appropriate and validated vaccine is available. The *1994 Biological Agents Regulations* requires that employers '*make effective vaccines available, when necessary, to those employees who are not already immune to the biological agent to which they are exposed or are likely to be exposed* '.

When offering vaccination employees should be informed of both the benefits and drawbacks of both vaccination and non-vaccination and be allowed to make an informed decision. If necessary employees should be encouraged to consult with

their own or the University's medical practitioner(s) for advice. Vaccinations must be offered free of charge with a vaccination certificate record kept.

Whilst vaccinations cannot be made compulsory for employees, working with certain biological agents can be restricted to those persons with appropriate vaccinations.

9.10 Waste Management

All wastes considered to be contaminated with biological material must be disposed of in an appropriate manner. There are severe penalties laid down within waste management legislation for those individuals and entities that fail to dispose of their wastes in accordance with the law. Under Irish legislation all waste which is potentially '*infectious*' is considered to be *hazardous waste* and must be disposed off accordingly. There are no definitions given in legislation for infectious wastes but they should be considered to be any wastes containing biological agents that may potentially give rise to a disease causing response in humans or animals. The following can be considered to be hazardous wastes:

- All human tissues, blood and related swabs and wipes from hospitals or laboratories
- Animal carcasses and dressings from veterinary hospitals / practices
- Contaminated needles, glass, instruments, etc.
- Microbiological cultures
- Potentially infected waste from pathology or research labs

Hazardous wastes must be collected and disposed by licensed waste management companies. All companies engaged in the collection of wastes from university premises must be in possession of a *Waste Collection Permit* issued by the local authority in whose functional area the waste is being collected and which is valid for the collection of the type of waste being collected. The final disposal / treatment plant must also be licensed by either the *Environmental Protection Agency* / Local Authority (Ireland) or the National / Local Competent Authority (EU).

It is recommended that an in-house segregation regime be implemented in every university facility in order to allow the clear identification of different waste streams. Colour coded bags should be used to separate infectious wastes (yellow bags) from non infectious wastes (black / clear bags). All sharps must go into suitable sharps bins for disposal. Sharps include broken glassware, blades and syringe tips. Sharps

must never be placed into normal bins. Full records of all wastes disposed should be kept for each laboratory.

The disposal of non infectious wastes which may appear to the untrained / uniformed person to be '*medical wastes*' must be undertaken with great care, e.g. swabs, wipes, syringe bodies, drips, etc. Very often these items are included in the hazardous waste removed from the university in order to avoid any confusion. If these items are to be disposed of as non hazardous wastes then the waste disposal service provider must be made aware of the nature of this waste so that when the material is encountered off site that it is not assumed to be infectious.

There is no legal requirement to treat non genetically modified biological waste before it leaves site. Genetically Modified Organisms of Category 1 do not require inactivation before leaving site, but all other categories of GMO do.

If biological waste is not treated before it leaves site it may come under the auspices of the *2001 Carriage Of Dangerous Goods By Road Regulations* (Refer to Section 6.19). This legislation requires that all materials, which are considered to be *hazardous for transport*, are carried on the road in a manner which limits the risk to persons and the environment. In general all infectious wastes containing biological agents (excluding Class 1 agents only) are considered to be hazardous for transport and must be packaged and transported accordingly.

Radioactive biological wastes must be treated and disposed of in accordance with the requirements of any RPII issued licence and the directions of the University Radiological Protection Officer.

Further Reading

Segregation, Packaging and Storage Guidelines For Healthcare Risk Waste 3rd Edition. April 2004. *Department Of Health and Children (available on the web).*

9.11 Selection And Use Of Disinfectants

The disinfection process is designed to reduce the number of micro-organisms present to an acceptable level such that the item being disinfected is safe to handle. Disinfection should not be confused with sterilisation, a process that renders an object free from all viable organisms.

There are several types of chemical and physical agents that can be used for disinfection, including chemicals, heat and irradiation. All university laboratories handling micro-organisms should have in place written disinfectant procedures for decontaminating surfaces and equipment and should ensure that all such working surfaces and equipment are treated on a regular basis.

The Target Organism

Disinfectants do not generally kill all the organisms which they come into contact with and do not disinfect against all organisms equally well, e.g. disinfectants do not normally kill bacterial spores. Disinfectant which is effective against bacteria may not be as effective against viruses. Some disinfectants are more effective against Gram positive than against Gram negative bacteria. Some disinfectants have a wide spectrum of performance against many organisms. There are many different commercial products available and these will vary in how effective they are against different micro-organisms. Manufacturers of disinfectants should provide advice on the specific antimicrobial activity of their particular products. If the types of micro-organisms in samples or materials handled are unknown then a general purpose disinfectant should be chosen. In some cases in-house validation may be required.

Presence Of Other Materials

The presence of other materials in or on the surfaces to be disinfected can have an effect on the activity of the disinfectant. The presence of organic material, other chemical agents including soaps and detergents and the pH and temperature can all reduce the effectiveness of the disinfectant. The concentration of disinfection to be used is likely to vary depending on whether it is used in "dirty" or "clean" conditions.

The Nature Of Surfaces And Equipment To Be Cleaned

Some disinfectants will chemically attack items being disinfected. Stainless steel can be damaged by strong acids and hypochlorite. Plastics may be affected by disinfectants containing organic solvents. Various metals may be attacked by strong acids or alkalis, halogen active substances, or disinfectants containing electrolytes. Manufacturers should provide advice on the suitability of using their products on particular surfaces or materials.

Safety Implications Of Disinfectants

Many disinfectants have toxic properties and some are also highly corrosive, causing damage if they come into contact with skin or eyes. Some disinfectants, e.g.

glutaraldehyde and hypochlorites, may also have irritant properties and so cause respiratory problems if used in poorly ventilated areas. Some disinfectants may react with other chemicals causing hazardous gases. A *Chemical Agents Risk Assessment* must be completed for all disinfectants in use. Material Safety Data Sheets for all disinfectants in use should be provided by the manufacturer and held within the laboratory.

When selecting a disinfectant both the efficacy of the product and the hazards associated with its use must be taken into account, e.g. given the hazards associated with the use of glutaraldehyde there are unlikely to be any grounds for selecting this agent for routine use within the university.

Some products have cleaning properties in addition to the disinfecting capacity and there can be significant benefits in use of these types of products e.g. Virkon™.

Working Dilutions

Disinfectants are usually provided in concentrated form and have to be diluted in water to the working strength. The manufacturers' instructions should be followed to ensure that the required concentration is achieved. Over dilution will render the disinfectant ineffective. Once made up the disinfecting capacity of diluted products tends to deteriorate rapidly with time, e.g. sodium hypochlorite solutions lose their efficacy rapidly (<24hrs). Manufacturers should recommend how long made up solution can be stored for and this be noted in the disinfection policy. Some products contain coloured indicators to show effective disinfecting capacity, e.g. Virkon™. If the disinfectant in use does not contain an indicator then a *use by* or *expiry date* should be clearly marked on the bottle when the solution is made up.

Discard Jars

A discard jar is a container of disinfectant into which contaminated items are placed to disinfect them prior to final disposal. Wherever possible, autoclaving of dry discards should replace the use of discard jars filled with disinfectant. The discard jar when freshly made up should be approximately half full to allow for increased fluid levels when items are added. If liquid waste is to be added to the disinfectant then the initial concentration should be proportionately increased to ensure the final concentration after additional waste liquids are added does not drop below the effective disinfection concentration. If liquid waste is aspirated into a container then

the amount of concentrated disinfectant added should allow for dilution to the final volume of the full receptacle. Items placed in discard jars must be completely submerged in the disinfectant. All surfaces of the item should come into contact with the disinfectant. Items must remain in the disinfectant for at least an hour and preferably overnight before disposal. The disinfectant can then be washed down a sink (not a hand wash basin) through a sieve or colander. The disinfected solids can then be disposed of.

Contact Time

Chemical disinfectants need to be applied to the item they are disinfecting for sufficient time to enable the disinfection to be effective. Manufacturers should recommend contact times (in combination with concentrations) for various applications and this should be clearly stated in the disinfection procedure. Objects should be fully immersed and air pockets should not be present. Disinfectants should always be used in accordance with the manufacturer's instructions.

Types Of Disinfectants

Hypochlorites

Examples: Sodium hypochlorite, Chloros, Presept

- Available as solutions of sodium hypochlorite or powdered tablets of sodium dichloroisocyanurate (NaDCC) Note: household bleaches should not be used.
- They have a wide range of bactericidal, virucidal, and fungicidal activity. They have limited activity against bacterial spores
- Rapid action
- Inactivated by organic matter, particularly if used in low concentration
- Corrosive to some metals and may damage rubber
- Compatible with anionic and non-ionic detergents
- Incompatible with cationic detergents
- Irritant
- Chlorine gas released when mixed with strong acids
- Carcinogenic products produced when mixed with formaldehyde
- One of disinfectants of choice for use against HIV and hepatitis B viruses
- Not very effective against Mycobacterium spp.
- Commonly used dilutions (expressed in parts per million available chlorine):
    - 1,000 ppm for general wiping of equipment and benches
    - 2,500 ppm for discard containers (if required)
    - 10,000 ppm for spillages

- 20,000 ppm for work surfaces, including microbiological safety cabinets, where material containing prions/TSE agents has been handled (NaDCC not effective in this context)

Clear Soluble Phenolics

Examples: Hycolin, Stericol, Clearsol

- Wide range of bactericidal activity
- Good fungicidal activity
- No activity against spores
- Variable virucidal activity - usually poor against non-enveloped viruses
- Compatible with anionic and non-ionic detergents and metals
- Not readily inactivated by organic matter
- May be inactivated by rubber and some plastics
- Contain detergents
- Concentrates are stable but stability is reduced on dilution
- Agent of choice for Mycobacterium spp.
- 20,000 ppm for work surfaces, including microbiological safety cabinets, where material containing prions/TSE agents has been handled (NaDCC not effective in this context)

Peroxygen compounds

Example: Virkon

- Wide range of bactericidal, viricidal and fungicidal activity
- Variable activity against bacterial spores and Mycobacterium spp.
- Corrosivity varies with different products, but less so than hypochlorites
- Made up dilutions have very low toxicity and no irritancy (powders are irritants)
- Built-in colour indicator
- Good detergent properties combines cleaning with disinfection
- Stable for seven days on dilution
- Due to its wide spectrum of activity, suitability for use in most applications, the pink indicator to show disinfectant capacity and the high degree of safety to users, Virkon is recommended as the disinfectant of choice for most university laboratory applications.

Alcohols

Examples: Ethanol, Isopropanol, Methanol, Industrial Methylated Spirits (IMS)

- Good bacterial and fungicidal activity

- No activity against spores
- Variable activity against viruses (ethanol less effective against non- enveloped viruses, propanol not effective against viruses)
- Only recommended for limited use (such as on clean surfaces and for flaming forceps etc) - seek alternative wherever possible
- Poor penetration into tissues
- Should only be used on physically clean surfaces as poor penetration of organic matter
- Rapid action
- Alcohols must be diluted to 70-80% before use (100% alcohol is not an effective disinfectant)
- Highly flammable
- Effective against Mycobacterium spp.

Aldehydes

Examples: Formaldehyde, Glutaraldehyde, Cidex

Chemicals such as formaldehyde and glutaraldehyde have irritant and toxic properties and are extremely hazardous. Therefore these types of chemical disinfectants should notbe used as a general disinfectant in the laboratory and only be employed only for specialised uses when no suitable alternative is available.

Other Disinfectants

There are many proprietary products available that are sold as disinfectants. Manufacturers should clearly specify the types of applications their product is useful for. Products sold as skin disinfectants eg. Hibiscrub, Hibitane, etc should not be used as a general laboratory disinfectant nor should products such as bleach or other household or domestic cleaning type disinfectants.

Skin disinfection

There should be no need for workers in laboratories to routinely disinfect their hands. Skin disinfectants are for use in clinical settings. All workers should wash their hands regularly whilst working in the laboratory, and always before leaving. Standard hand wash products are suitable for this and there is no need to use specialist antimicrobial products. If liquid soaps are used in containment laboratories they should contain a bacteriostatic agent to prevent the multiplication of any contamination. Cloth towels should not be used in laboratories. Single use paper towels are recommended.

Refer to Table 5 below for details on the types of disinfectants available and their general usage.

Fumigation

On occasion it may also be necessary to fumigate microbiological safety cabinets (MSC) or whole rooms, especially after the uncontrolled release of a Class 3 or 4 agent. When in use fumigation processes should be subjected to risk assessment and procedural controls. In many cases the agents used for fumigation may pose significant human health risks, e.g. formaldehyde, and they must be used in a safe manner.

Table 5. Some Common Classes Of Disinfectants And Their Activity

Disinfectant Type	Vegetative bacteria	Bacterial spores	Fungi	Enveloped viruses	Non-enveloped viruses	Myco-bacteria	TSE & Prion Agents
Phenolic	Generally Effective	Generally Ineffective	Generally Effective	Generally Effective	Depends On The Virus	Generally Effective	Generally Ineffective
Hypochlorites	Generally Effective	Generally Effective	Limited Activity	Generally Effective	Generally Effective	Limited Activity	Generally Effective
Alcohols	Generally Effective	Generally Ineffective	Generally Ineffective	Generally Effective	Generally Effective	Generally Effective	Generally Ineffective
Aldehydes	Generally Effective	Generally Effective	Generally Effective	Generally Effective	Generally Effective	Generally Effective	Generally Ineffective
Surface active agents	Generally Effective	Generally Ineffective	Limited Activity	Depends On The Virus	Depends On The Virus	Generally Ineffective	Generally Ineffective
Peroxygen compunds	Generally Effective	Generally Effective	Generally Effective	Generally Effective	Generally Effective	Generally Effective	Generally Ineffective

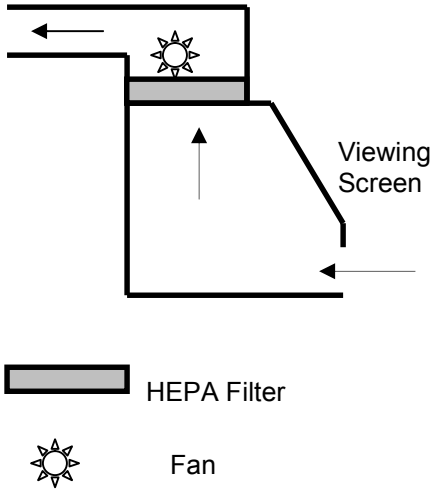
9.12 Microbiological Safety Cabinets

Introduction

Microbiological Safety Cabinets (MSC) are a basic tool in laboratories where biological agents are handled. A MSC is a ventilated enclosure intended to offer protection to the user and the environment from aerosols generated when handling biological agents. MSC are not designed to hold radioactive, toxic or corrosive substances. MSC should be used for the handling of all Class 3 and 4 organisms and where there is a risk of generating aerosols when handling Class 2 organisms.

There are three basic types of MSC.

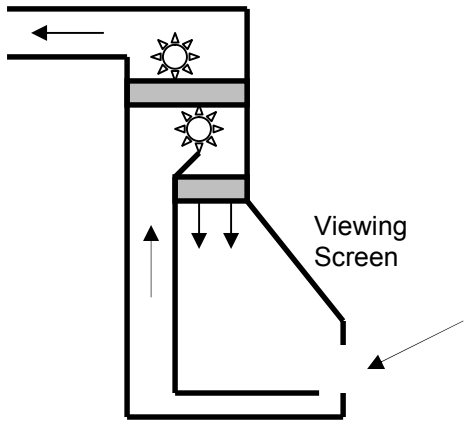
Class 1 Cabinet



An open fronted cabinet designed to protect the operator by continuously drawing air into the front o the cabinet.

This is the standard type of MSC used in most labs and is suitable for work with Class 1, 2 and 3 biological agents.

Class 2 Cabinet



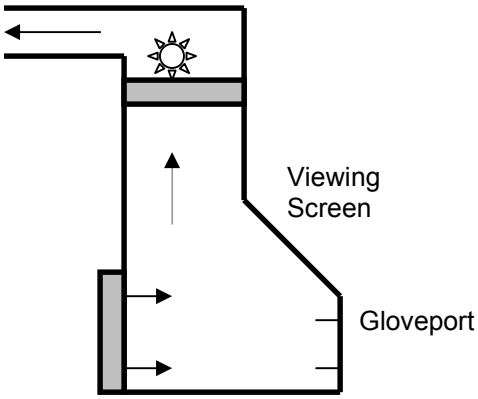
An open fronted cabinet designed to protect the operator and the work from external contamination.

Inward air is directed down below the work surface and is filtered before being redirected into the working area as a clean downward flow of air.

These cabinets achieve a high degree of sample protection. They are usually used for cell and tissue cultures where sample protection is important.

This MSC is suitable for work with Class 1, 2 and 3 biological agents.

Class 3 Cabinet



A totally enclosed cabinet in which operations are conducted through a gloveport.

Air enters the cabinet via a HEPA filter and is exhausted through a second HEPA filter.

These cabinets are generally used with high risk Class 3 and 4 biological organisms.

Laminar Flow Hoods / Cabinets

MSC's must not be confused with Laminar Flow Hoods / Cabinets. These type of units provide a filtered inward air flow and are designed for the protection of the sample only. They may only be used with non pathogenic material.

Maintenance

MSC must be subjected to a system of planned preventative maintenance. It is vitally important that the services of a competent service provider are engage to complete this maintenance. The suggested service and maintenance intervals for MSC are outlined below:

Table 6 Suggested Maintenance Schedule For Microbiological Safety Cabinets

Item		***Frequency***
Air Flow	Contractor Test	6 monthly
	Operator Test	Monthly
Filter Integrity		6 monthly
Mechanical and electrical function		6 monthly
Mechanical integrity (including visible ductwork)		Annually
Operator protection	Level 2	Annually
	Level 3	6 monthly

In some circumstances cabinets used in low risk activities with Class 1 Biological agents may be subjected to an annual frequency test for all operations but this should be subjected to a risk assessment.

Training

All persons working with MSC must receive safety training in its proper and efficient use. Training should cover such areas as:

- Classification of cabinets
- Appropriate and inappropriate use of cabinets
- Operational controls of cabinet
- Limitations of cabinet
- How to operate the cabinet safely
- How to decontaminate the cabinet after use and following a spillage
- How to perform regular efficiency tests where required

Decontamination Procedures

When using a MSC there must be written decontamination procedures in place which detail how to decontaminate the cabinet after each use and also how to decontaminate the cabinet following an unintentional spill of a biological agent. Particular care must be taken to ensure that the disinfectants selected for use in a MSC are compatible with the cabinet components. Generally speaking the use of UV light to disinfect safety cabinets is not an effective procedure unless the cabinet is completely empty.

Siting Of MSC

MSC should be sited in an optimal position where the likelihood of disruptive air flows at the front of the cabinet is minimised. This is particularly important for Class 2 cabinets. Particular care must be taken when locating cabinets that the exhaust air from one cabinet does not cause unwanted air flows to the front of another. Smoke testing may be required to determine the optimal position of an MSC within a laboratory. Cabinets should be located at least 300mm from any walls and corners.

Safe Use Of MSC

When using cabinets place the minimum amount of equipment as possible within the unit. Always work as near to the centre of the cabinet as possible in Class 1 and 2 cabinets. Large equipment such as centrifuges should not be used within MSC unless appropriate tests have been conducted to demonstrate no reduction in cabinet efficiency. Pre and post use checklists should be developed for all MSC's to ensure that the units are in a functioning condition before and after use.

Further Reading

- *BS EN 12469 2000: Performance Criteria For Microbiological Safety Cabinets*
- *The Management, Design And Operation Of Microbiological Containment Laboratories.* Advisory Committee On Dangerous Pathogens (2001). HSE Books.

9.13 Safe Use Of Autoclaves

The hazards associated with the use of autoclaves are burns from hot surfaces or liquids, slips on spilled liquids and exposure to any hazardous agent being loaded into the autoclave. To ensure the safe operation of autoclaves the following should be adhered to:

- No person should operate an autoclave without first receiving instruction in the safe use of that particular model / type of autoclave.
- Autoclaves must be visually inspected before each use and damaged units reported to the laboratory manager / supervisor. Damaged units must not be used until they have been examined by a competent person.
- Instructions for the use of the autoclaves should be clearly displayed on or adjacent to the unit.
- For non 'self filling' autoclaves the water levels must be checked before every use and topped up to the correct level as required.
- Lab coat and safety glasses must be worn when operating an autoclave. Gloves should also be worn when loading the unit and heatproof gloves and a face shield should be worn when unloading material – to be donned prior to opening the autoclave.
- The contents of the autoclave should be stacked carefully and baskets or buckets not overloaded.
- Safe manual handling techniques must be employed to prevent injury when loading and unloading the autoclave.
- The correct programme for the type of material to be treated must be selected.
- All spills and leakages must be mopped up immediately.
- All autoclaves must have a functioning interlock preventing the opening of the unit when it is in use.
- When in use appropriate signage indicating that the surface of the autoclave may be hot should be positioned adjacent to or on the unit.
- Users of autoclaves must be aware that items held in autoclaves will still be hot for a period following completion of the autoclave cycle. When removing material from an autoclave heat proof gloves and a face shield must be worn. Items should be removed with great care from the unit to prevent the boiling over of hot liquids.
- Lids of screw-capped bottles should be loosened before autoclaving to prevent pressure build-up.

- On occasion media in screw-capped bottles can become superheated and appear to still be boiling when removed from the autoclave. If this is the case do not shake as hot media can "erupt" from the bottle before the lid is fully tightened.
- Unprotected sharps should not be autoclaved, items such as scalpels, needles or pointed forceps must be adequately protected to prevent injury.
- Broken or cracked glassware should only be autoclaved if it is adequately protected / contained.
- Before opening an autoclave after a cycle users should make sure that the unit pressure gauge has returned to zero.
- Assistance must be obtained when moving bench autoclaves.
- Autoclaves must be switched off when not in use.
- Autoclaves must be subjected to a statutory inspection once every 26 months and records of such inspections maintained within the facility.
- All autoclaves must comply with a relevant CE; EN or BS standard.
- All autoclaves must be serviced and maintained in accordance with the manufacturers instructions.

9.14 Safe Use Of Centrifuges

Centrifuges can pose a variety of risk to both users and to persons in their immediate vicinity in the event of mechanical failure. If balanced or loaded incorrectly centrifuges may move about during use and possibly fall from laboratory benches. In addition to the risk posed by component parts of the unit any hazardous materials contained within the centrifuge may also pose a risk to operator safety during any failure of the unit. To ensure the safe operation of centrifuges the following should be adhered to:

- No person should operate a centrifuge without first receiving instruction in the safe use of that particular model / type of centrifuge.
- Centrifuges must only be used as per the manufacturers instructions. A copy of the instructions for each type of centrifuge should be readily available within each laboratory / facility.
- If deemed necessary a log of use should be kept for each centrifuge.
- Each unit must be serviced by a competent person as per the manufacturers suggested intervals.
- Units must be visually inspected before each use and damaged units reported to the laboratory or facility manager. Damaged units must not be used until they have been examined by a competent person.

- All centrifuges must be fitted with an interlocking device which cuts the power to the unit motor if the cover is opened. Persons must never try to open the cover when the rotors are still spinning and under no circumstances must persons attempt to slow down spinning rotors by hand.
- The correct rotors, buckets, adaptors and tubes for each centrifuge must be used.
- Sample containers must not be overloaded / overfilled.
- Material loaded into sample tubes must be compatible with the sample tube material, e.g. some solvents can cause tubes to swell and to crack.
- Swing out rotors must be examined before each use to ensure that the tube holders have been correctly positioned and will not move about during a run.
- Rotors must be installed correctly on the centrifuge spindle, and any fixing nuts must be tightened (but not over-tightened).
- The manufactures maximum rotor speed must not be exceeded. Maximum rotor speeds may require reduction as a unit gets older or following damage. Rotor speeds must be reduced when the rotor speed and temperature combination exceeds the solubility of a gradient material causing it to precipitate.
- The load within the centrifuge must be distributed evenly on the rotor.
- Where recommended by manufacturers instructions units should be bolted to a solid surface.
- If present keys must not be removed from centrifuges that are left running.
- Where applicable, once a refrigeration cycle is completed the centrifuge should be switched off and the cover left opened to allow any condensation to evaporate.
- All spillages within centrifuges must be cleaned immediately. Spills of hazardous material must be adequately decontaminated. Written procedures for the decontamination of centrifuges must be developed.
- Rotors must be cleaned, dried and stored upside down following use.
- Centrifuges and their component parts can be heavy, when being manoeuvred mechanical aids may be required and safe manual handling techniques must be employed.
- Only chemicals compatible with the rotors must be placed into centrifuges. Anything that may abrade or corrode rotor component parts must not be used in a centrifuge.
- Hazardous agents should be centrifuged in sealed tubes to prevent the generation of aerosols.

- In the event of rotor disruption the unit must be isolated from the electrical supply and left to stand for 30 minutes. In the event that non hazardous materials are contained within then the inside of the centrifuge should not be disturbed if at all possible until a representative of the manufacturer / supplier has examined the unit. If the material in the unit is hazardous in nature then cleanup should be performed whist wearing the appropriate personal protective equipment with a decontamination procedure suitable for the hazardous agent(s) in question. As much of the damaged unit should be retained as possible for future examination.
- All centrifuges must comply with a relevant CE; EN or BS standard.
- All centrifuges must be maintained in accordance with the manufacturers instructions.

9.15 Safe Use Of Sharps

Every laboratory in which sharps are used must have in place a *Sharps Policy* which is designed to minimise the risk from sharps to persons in lab. Sharps pose a particular risk to persons working with biological agents in that in the event of a sharps injury the biological agent may be introduced directly into the victims body.

Glassware

- Use plastic as an alternative to glass when possible
- Care must be taken when working with glassware. Particular care must be taken when:
  - Inserting pipettes into pipetting aids or Pasteur pipettes into teats
  - Attaching glass to or removing glass from rubber or plastic tubing
  - Removing "frozen" stoppers from glass bottles
  - Breaking glass tubing
  - Washing up glassware
  - Handling broken glassware
- All broken, cracked or chipped glassware must be disposed off immediately
- When handling glass items avoid applying force or excessive pressure in case the item slips or gives way suddenly and breaks. If inserting pipettes into pipetting aids or Pasteur pipettes into teats; attaching glass to rubber or plastic tubing; or removing "frozen" stoppers from glass bottles then the glassware should be held in a cloth to help prevent slipping.
- Do not run when carrying glassware.
- Carry glassware in suitable trays / cages where necessary.

Blades

- Always handle blades with care.
- Use the appropriate blade for the task. Do not use scalpel blades or razor blades unless absolutely necessary and when in use handle them with care.
- Wherever possible use single unit disposable scalpels rather than changing the blades on a re-useable holder.
- If not being disposed after use blades must always be placed in a safe position and orientation so as to avoid possible accidental injury to others. Do not leave scalpels pointing upwards from beakers or similar or sitting under water in a sink.
- Where a blade is used in a holder particular care must be taken when changing the blade. The blade should not be held in the fingers during the process and the use of excessive force must be avoided. A forceps should be used to hold the blade.

Needles

- Needles should only be used if necessary, and always for the purpose that they were designed. Always consider less hazardous alternatives wherever possible.
- There should be minimal handling of needles in the workplace. Once the seal on the sheath of a needle has been broken carry out any subsequent handling with extreme care and keep handling to a minimum.
- Used needles should be placed directly in a sharps bin at the point of use without either detaching the needle or re-sheathing – there should be no further unnecessary handling of a used unsheathed needle.
- If needles require re-sheathing never hold the sheath with your fingers as if the needle misses the sheath it will puncture a finger, always use a forceps.
- Do not detach the needle from the syringe unless absolutely necessary.
- Unsheathed and used needles must not be left on worktops or mixed with other items. They should be placed into a tray or similar container where they are clearly visible.
- When using needles to inoculate animals the following should be adhered to:
  - Restrain the animal to minimise any unexpected movement in so far as is possible
  - Position hands carefully such that the needle is not pointed either towards your hands or the hands of anyone who may be assisting
  - Ensure you are not likely to be disturbed during the procedure
  - Always wear eye protection.

- If more than one person is carrying out the procedure establish an agreed technique in advance to ensure the person holding the needle does not inadvertently stick the hand of the person assisting.

- Any needle stick injury caused by a implement contaminated with human, microbial, animal, chemical or radioactive material should be immediately reported to the *University Safety Office* and the victim must seek immediate medical advice.

Disposal

- Place used needles and syringes, or any other types of sharps, directly into a sharps bin for disposal.
- Have a sharps bin available at the point of use to enable immediate disposal.
- Dispose of used sharps only in an appropriate bin. Clearly label sharps bins as to their allowable content.
- Do not overfill sharps bins, fill only as far as the fill line.
- Never place sharps or sharps bins in plastic bags or a domestic refuse bin for disposal.

First Aid

- Cuts caused by sharps should be treated immediately. No attempt should be made to remove broken glass from wounds. Needle stick injuries from contaminated needles should be encouraged to bleed. Wash well under running water and cover with a dry dressing. An attempt should be made to identify any chemical or biological hazard in the needle that may have been injected.
- Apart from very minor injuries, a First Aider should be called.
- In the event of sustaining an accident resulting in a wound:
  - Immediately wash the wound liberally with soap and water but without scrubbing
  - Do not attempt to remove ay glass by hand
  - Gently encourage free bleeding of puncture wounds but do not suck the wound
  - Dry the area and apply a waterproof dressing
  - Seek medical advice if the sharp concerned was contaminated with any hazardous materials

There is no evidence available to show that using antiseptics or squeezing a wound will reduce the risk of transmission of a blood borne pathogen. Using a caustic agent such as bleach to wash a wound is not recommended.

9.16 Cell Cultures

Cell cultures can themselves pose a risk to worker safety or they may harbour potentially harmful agents. Cell cultures are included in the definition* of biological agents as given within the *1994 Biological Agents Regulations* are thus subject to the provisions of the regulations and their use requires a risk assessment. As with all biological agents cell cultures must be assigned a Hazard Classification based on their properties and their ability to infect / harm human health. The four hazard classifications are:

- **Hazard Class I:** a biological agent that is unlikely to cause human disease.
- **Hazard Class II:** a biological agent which can cause human disease and might be a hazard to employees, although it is unlikely to spread to the community and in respect of which there is usually effective prophylaxis or treatment available
- **Hazard Class III:** a biological agent which can cause severe human disease and presents a serious hazard to employees and which may present a risk of spreading to the community, though there is usually effective prophylaxis or treatment available
- **Hazard Class IV:** a biological agent which causes severe human disease and is a serious hazard to employees and which may present a high risk of spreading to the community and in respect of which there is usually no effective prophylaxis or treatment available

The hazard will depend on the type of cells being handled. Well characterised and known cell lines may assigned to Hazard Class 1, although it is worth remembering that even with cell lines such as these there is no absolute guarantee that these cell lines do not carry latent viral agents or viral genome. Unscreened cells or cells with a less well defined history should be handled at at least Containment Level 2. In reality due to the need to protect the cell lines from contamination most cell lines are used at Level 2 containment in a Class 2 Microbiological Safety Cabinet. When handling a cell line it is important to be aware of as much of its history as possible and

* A Biological Agent is defined as '*a micro-organism, including those which have been genetically modified, a cell culture and a human endoparasite, which may be able to provoke any infection, allergy or toxicity, classified into four risk groups according to their level of risk of infection*'.

particularly whether or not the cell line has been infected with a viral vector at any stage in its history. Human and primate cell lines must always be considered as having the potential to harbour human viruses. The geographical source of the cell lines should be examined as in some parts of the world Hepatitis B, HIV and similar viral infections are extremely prevalent.

Primary Cultures

When handling primary cultures there is an increased risk of spontaneous transformation. This happens relatively frequently with rodent cells and to a lesser extent with human and primate cells. Transformed cells isolated from a worker or a colleague can pose a significant risk to the donor due to the fact that if accidentally reintroduced into the donor body the cells may not be recognised as foreign matter by the body and may in theory form invasive colonies within the body. Therefore the following precautions must always be taken:

- Never culture your own cells and if possible avoid culturing cells from your immediate colleagues
- Never transform your own cells or those of your colleagues
- Whenever possible culture primary cells for short periods only. This reduces the probability of spontaneous transformation.
- If cell lines are unscreened for viral agents then further precautions may be required – Refer to Table 7.

Whenever possible only cell strains that have been authenticated and / or have a documented provenance should be used. These are best obtained from a culture collection or from the originator of the cell line. To avoid cross contamination handle only one cell line at a time and ensure appropriate decontamination procedures between the handling of cell lines. The generation of aerosols and the use of sharps should also be minimised.

Table 7 Containment Levels Appropriate For The Handling Of Cell Cultures

Hazard	Cell Type	Containment
Low	Non human, non primate cell lines that have been authenticated and have a low risk of infection with a human pathogen and present no apparent hazard to laboratory workers	Containment Level 1
	Well characterised, screened, and / or authenticated finite cell lines of human or primate origin	
Medium	Cell lines or cell strains that have not been fully characterised	Containment Level 2
High	Primary cells from blood, lymphoid cell, neural tissue of human or simian origin.	Containment appropriate to the potential risk
	Primary cell lines cultured for more than 100 hours	
	Cell cultures known, or strongly suspected, to harbour an endogenous pathogen	
	Cell cultures deliberately infected with a human pathogen	

9.17 Universal Precautions For The Handling Of Blood And Blood Products

Universal Precautions are a set of safety guidelines which are based around the *Universal Precautions For The Handling Of Blood And Blood Based Products*. The application of *Universal Precautions* requires that all blood and body fluids be regarded as potentially infectious and appropriate protective action taken. The relevant counter-infection measures outlined in *Universal Precautions* are listed below and should be implemented by all persons working with such materials in all settings:

- The implementation of good personal hygiene practices and the avoidance of hand or equipment to mouth/eye/nose/ear contact
- The use of vaccinations where necessary
- The wearing of suitable personal protective equipment
- The prevention of puncture wounds, cuts and abrasions in the presence of blood and body fluids
- The protection of skin lesions and existing wounds on workers
- The avoidance of the use of sharps and sharp objects when possible but, where unavoidable, taking particular care in their handling and disposal
- The development of suitable working area decontamination procedures

- The elimination or containment of any work practises that could give rise to aerosols or the uncontrolled release of material
- The development of emergency response plans
- The disposal of all contaminated waste safely
- The provision of training and information to all employees engaged in handling potentially infectious material

Further Reading

Protection against blood-borne infections in the workplace: HIV and hepatitis. Advisory Commission On Dangerous Pathogen / HMSO 1995.

9.18 Working Safely With Research Animals

Working with laboratory animals may expose workers to the risk from allergenic hazards and infectious hazards. The use of all lab animals should be subjected to a risk assessment before commencing work. All lab animals should be held in suitable containers with minimal risk of escape. The escape of any transgenic animals must be reported to the *Environmental Protection Agency* immediately.

Allergenic Hazards

Laboratory Animal Allergy (LAA) is a common condition in laboratory workers who work with lab animals. The most common symptoms of LAA are rhinitis, conjunctivitis, contact dermatitis and asthma which may develop following inhalation of and contact with animal excreta and secretions. The sources of animal allergenic hazards are outlined in Table 8.

Table 8. Common Lab Animals And Allergens

Animal	*Sources Of Allergens*
Rat	▪ Urine (especially that of adult males) ▪ Urine soiled bedding ▪ Saliva ▪ Pelt / Fur ▪ Dander ▪ Serum ▪ Faeces is not considered to represent a significant source of allergens
Mouse	▪ Urine ▪ Pelt / Fur ▪ Dander ▪ Soiled litter
Guinepig	▪ Urine ▪ Soiled litter ▪ Saliva ▪ Pelt / Fur ▪ Dander ▪ Serum
Rabbit	▪ Urine ▪ Saliva ▪ Pelt / Fur ▪ Dander ▪ Serum
Cats / Dogs	▪ Pelt / Fur ▪ Dander ▪ Urine ▪ Salive
Insects	▪ Faeces ▪ Secretions ▪ Hairs ▪ Setae ▪ Scales ▪ Discarded exoskeletons
Stored Bedding / Foodstuffs	Such material may be contaminated with mites.

It is essential that any person who develops any of the above symptoms during or after working with laboratory animals ceases such work immediately and informs their supervisor / *University Safety Office* so that allergy testing can commence.

The risk of exposure to allergens is greatest in animal containment rooms, especially when animals and materials are being disturbed such as in cleaning out operations. Persons should undertake such works with care and aim to generate as little disturbance as possible. To help in reducing personal exposure of laboratory workers to animal allergens animal holding rooms should have suitable ventilation in place in so far as is practicable; workers should be trained; strict personal hygiene practices should be adhered to; there should be regular health monitoring of staff; and if necessary respiratory protection should be worn by workers if deemed necessary and as a last resort.

Infectious Hazards

Laboratory animals may pose a risk from any micro-organism with which they have been deliberately infected and any potentially zoonotic agent that they may be carrying. Therefore all lab animals, including those not involved in infectious disease studies, should be considered as potential infection risks.

Common lab animal zoonotic hazards are outlined in Table 9.

Table 9. Common Lab Animal Zoonotic Hazards

Animal	***Sources Of Allergens***
Rats and Mice	▪ LCM Virus ▪ Bacterial Infections (rat bite fever; campylobacteriosis; gastroenteritis; etc) ▪ Leptospirosis ▪ Ringworm
Guinepigs	▪ Bacterial Infections (campylobacteriosis; gastroenteritis; etc) ▪ Leptospirosis ▪ Ringworm ▪ Tuberculosis
Rabbits	▪ Gastroenteritis ▪ Ringworm ▪ Septicaemia
Cats	▪ Septicaemia ▪ Meningitis ▪ Toxoplasmosis ▪ Ascarid infections (roundworms)
Dogs	▪ Rabies ▪ Leptospirosis ▪ Campylobacteriosis ▪ Ascarid infections (roundworms) ▪ Ringworm

To guard against worker infection all animals which are experimentally infected or are known to be infected with a biological agent should be contained in accordance with the Biological Containment Level relevant to the infections agent. Animal room work practices should be designed so as to prevent worker infection. Measures to reduce the risk of worker infection in animal containment facilities include:

- Limiting or eliminating the use of sharps. Sharps should be used in one hand at a time only and never be passed from hand to hand. It is good practice to use scalpels with integral blades and not the disposable type. If disposable blades are being used they must be changed using a forceps and not by hand.
- Allowing animal inoculation to be carried out by experienced operators only, and where necessary restraining / anesthetising animals to be inoculated. During inoculations the site of the injection should be swabbed with disinfectant both before and after the injection.

- When withdrawing contents from a sealed container of infectious material wrapping the needle and the top of the container in cotton wool soaked in disinfectant. When removing such contents air should not be blown into the sealed container.
- When adjusting the volume within a needle containing infectious material or eliminating air bubbled inserting the needle tip into disinfectant soaked cotton wool.
- Through the use of worker vaccination
- Through the wearing of suitable personal protective equipment (which must be removed before exiting the animal containment facility)

Further Reading

- *Working Safely With Research Animals: Management Of infection Risks.* Advisory Commission On Dangerous Pathogens / HSE Books 1997. ISBN 0 7176 1377 1.
- *Health And Safety In Laboratory Animal Facilities.* Laboratory Animals Handbook No. 13. Royal Society Of Medicine Press 1999.

9.19 Transport Of Infectious Materials

Potentially infectious material (including wastes and genetically modified materials) which is to be transported by road or air must be properly classified, labelled and packaged before it can be shipped. A qualified *Dangerous Goods Safety Advisor* (DGSA) must be engaged to advise on this process (the *University Safety Office* contains such expertise). Infectious material must be transported under the requirements of the *2001 Carriage Of Dangerous Goods By Road Regulations* where deemed necessary. This legislation lays down minimum transport provisions designed to prevent exposure of the public or the environment to hazardous materials whilst they are in transit. The transport of Class 1 biological agents and appropriately treated wastes, which are not deemed to be infectious, does not come under the control of this legislation.

For transport purposes infectious materials are classified as *Class 6.2* materials. This is a worldwide UN approved classification. 'Category A' is applied to known infectious agents capable of causing a life threatening or fatal disease in man and animals or in animals only. The former is labelled as *UN No. 2814* and the latter as *UN No. 2900*. The proper shipping name for UN No. 2814 is *"INFECTIOUS SUBSTANCE,*

AFFECTING HUMANS". The proper shipping name for UN No. 2900 is *"INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only*".

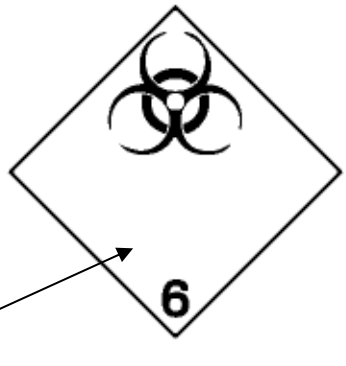
Infectious agents which do not come under 'Category A 'are assigned to 'Category B' and *UN No. 3373*. The proper shipping name of UN No. 3373 is *"DIAGNOSTIC SPECIMENS" or "CLINICAL SPECIMENS."*

Medical or clinical wastes containing 'Category A' infectious substances or containing 'Category B' infectious substances in cultures are assigned to *UN No. 2814* or *UN No. 2900* as appropriate. Medical or clinical wastes containing infectious substances in 'Category B' other than cultures, are assigned to *UN No. 3291.* Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances are assigned to *UN No. 3291.* The proper shipping name for UN No. 3291 is *"CLINICAL WASTE, UNSPECIFIED, N.O.S." or "(BIO) MEDICAL WASTE, N.O.S". or "REGULATED MEDICAL WASTE, N.O.S.".*

All infectious material must be properly labelled with the *Class 6.2* warning label and the relevant UN number when being transported (Refer To Figure 6.19.1 below). The legislation also lays down minimum requirements for the receptacles used to transport such items. Particularly strict requirements apply to the transport of 'Category A' agents. Further information should be obtained from the *University Safety Office* before transporting any infectious material from the university.
Blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to the provisions of the legislation.

It should be noted that *An Post* do not engage in the transport of infectious agents.

Figure 1. *Class 6.2 Infectious Substances Transport Label*



Insert appropriate UN number here

9.20 Accident Reporting

All accidents and near misses, whether they involve biological material or not, must be reported to the *University Safety Office* on using an official university *Accident Report Form*. The *University Safety Office* will then conduct an accident investigation if required and make recommendations where necessary.

9.21 Pregnant Employees

No pregnant or breastfeeding employee may work with a hazardous biological agent until a *Pregnant Employee Risk Assessment* has been carried out in order to determine if the work being undertaking poses a risk to the employee or her unborn or breastfeeding child's safety. The *University Safety Office* will arrange the completion of such an assessment once it has been informed of the presence of a pregnant employee in the workplace.

9.22 Sources Of Biosafety Information

There are numerous publications available which give advice on Laboratory Biosafety. Many of these publications are freely available on the web, whilst the *University Safety Office* also maintains a number of publications. There are also a large number of useful websites that give information on biosafety.

Websites

- www.irishstatutebook.ie – relevant legislation
- www.epa.ie – information on GMO's
- www.ebsa.be – European Biosafety Association
- www.cdc.gov – Centre For Disease Control, USA.
- http://www.hsa.ie/publisher/index.jsp?aID=1582&nID=97&pID=93#18 – Irish Health and Safety Authority FAQ on biological safety
- www.dohc.ie – Department of health and children
- www.hc-sc.gc.ca/pphb-dgspsp/ols-bsi/index.html - excellent site which include safety data information for a large range of organisms.
- www.hse.gov.uk – Health and Safety Executive (UK)
- www.hse.gov.uk/pubns/misc208.pdf - Approved lists of biological agents
- www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/ - Guidance notes on GMO

Publications

- *The management, design and operation of microbiological containment laboratories . ACDP / HSE, 2001* - available from the *University Safety Office*.

- *Working safely with research animals – Management of infection risks. ACDP / HSE, 1997.*
- *WHO Biosafety Manual; 2nd edition 2003.* Google Search – free download.
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10.0 Revision History

- Rev. 0 issued February 2007

- Rev. 1 issued January 2008.
    - *Part 8 Section 15 Page 22.* Change in mechanism of notification of Biosafety Committee by users of biological agents outlined.