Hong Kong University Biological Safety Policy and Guidance Document

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1. Introduction

This document forms part of the University of Hong Kong Health and Safety Policy and is issued with the approval of the University Biosafety Committee and the University Safety, Health and Environment Committee. All employees and students must observe those parts of the University Health and Safety Policy that are relevant to their own work as well as observing any additional local requirements.

This Biosafety Policy relates to the arrangements that must be made before working with hazardous biological materials and the precautions to be taken during the course of the work. The policy also includes arrangements for work with genetically modified biological materials.

The policy is intended to ensure standards within Hong Kong University match internationally accepted best practice. Extensive guidance produced by various expert technical advisory committees from the World Health Organisation, the United Kingdom, Australia and the United States of America has been incorporated into this document. A substantial contribution to the structure and content of this policy has been made by the University of Edinburgh biological safety policy (with permission).

2. Biological Hazards and the Law in Hong Kong

2.1 The Occupational Safety and Health Ordinance

In 1997 the Hong Kong government enacted The Occupational Safety & Health Ordinance – Chapter 509 (CAP 509). This states that:-

"Every employer must, so far as reasonably practicable, ensure the safety and health at work of all the employer's employees. This includes:-

- (i) maintenance and provision of equipment and machinery (plant) and adopting safe systems of work,
- (ii) arrangements for safe handling, and transport of plant and substances,
- (iii) the provision of appropriate information, instruction, training and supervision." The penalty for failing to comply with the legislation is a fine of up to HK\$200,000 and for flagrant violations can include up to 6 months imprisonment.

While biological hazards are not specifically mentioned in the ordinance they may be considered to be covered by the general duty of all employers to provide a safe place of work and the issues mentioned in (i), (ii), and (iii) (above) indicate the areas for particular concern specified by the legislation.

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2.2 Common Law

In the event of an accident involving personal injury the injured person (or his/her representative) can institute legal action to obtain compensation from the wrongdoer. In the circumstances of an accident on University premises it is most likely that it would be the University that was taken to court, but depending on circumstances, it is possible that members of staff or even students could be cited in legal action.

Liability for such a claim would probably be based on whether any one was negligent or required safety measures were ignored. While it would be up to the court to decide what constitutes negligence and what safety measures were required they would probably look to international best practice as a guide for their judgment. It is the specific intention of this Biosafety Policy and the University to meet international standards as specified in the WHO publication Laboratory Biosafety (Third edition) and the US NIH/CDC Biosafety in Microbiological and Biomedical Laboratories 5th Edition (BMBL).

It is worth noting that compensation payments in civil courts tend to be greater than the fines imposed after breaches of criminal law. While civil litigation in Hong Kong is not on the scale of that in the UK or USA compensation awards have been substantial in a number of cases.

2.3 Other Legislation and Biological Agents

Hong Kong, unlike most other industrialized countries, has little specific legislation in the area of recombinant DNA or biological agents. However various pieces of legislation have an impact on those within the University that work with, import, export or dispose of recombinant or wild type biological materials.

2.3.1 <u>The Import and Export Ordinance (Chapter 60)</u>

The Biological Weapons Ordinance (Chapter 491) prohibits the development, production, stockpiling, acquisition or retention of any biological agent or toxin of a type and in a quantity that has no justification for prophylactic, protective or other peaceful purposes. While the wording does not specify the agents this applies to, a specific list of Biological Agents controlled under the Import and Export Ordinance (Chapter 60) which has been drawn up to control agents capable of dual use (i.e. agents that can be exploited for legitimate peaceful aims or military purposes). Some of these agents are held by University departments and are actively studied; this includes Avian Influenza, Dengue

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virus, *B. pseudomallei and E.coli* O 157. For information see the strategic trade control circular no. 2/01. Interestingly this also includes the import and export of nucleic acids associated with pathogenic traits from any of the listed agents (see 1C353 list). Consequently to send or receive DNA plasmids encoding, for example, Avian Influenza haemagglutinin (HA) may require a license depending on the interpretation of the legislation. Please contact the Biological Safety Officer for further information.

2.3.2 <u>The Waste Disposal Ordinance (Chapter 354)</u>

On August 1st 2011 regulations governing the production and disposal of clinical waste came into force. The key points of the legislation are:-

- A licensing system for all clinical waste collectors and disposal facility operators.
- Clinical waste producers are required to manage their clinical waste by consigning it to licensed collectors for delivery to a licensed disposal facility.
- A consignment note (trip ticket) system tracks the movement of clinical waste from source to disposal facility. Copies must be kept for at least a year and if required they must be shown to the relevant authorities
- The Chemical Waste Treatment Centre (Tsing Yi) is designated as the facility for treatment of clinical waste. A disposal charge for use of the facility is levied.
- A Code of Practice to provide guidance for waste producers and collectors is promoted.

As a waste producer the University has a duty of care to manage the clinical waste produced and is required to:-

- Segregate clinical waste from other waste streams
- Package and label clinical waste properly for easy identification
- Provide safe and secure temporary storage areas
- Ensure staff take necessary safety measures and receive sufficient training

Clinical waste is defined as any substance matter or thing generated in connection with:

- any dental, medical, nursing or veterinary practice, or any other practice or establishment providing medical care and services for the sick, injured, infirm or those who require medical treatment;

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- any dental, medical, nursing, veterinary, pathological or pharmaceutical research; or
- any dental, medical, veterinary or pathological laboratory practice

and which consists wholly or partly of any of the materials specified in one or more of the groups of clinical waste listed in the EPD guidance. In brief these are: Group 1 - Used or Contaminated Sharps; Group 2 - Laboratory Wastes; Group 3 - Human and Animal Tissue; Group 4 - Infectious Materials; Group 5 -Soiled Dressings; Group 6 - Other Wastes.

For a fuller discussion of the issues involved and the University approved guidance on the disposal of clinical waste see the Biosafety section on the Safety Office website.

2.3.3 <u>The Cartagena Protocol</u>

The "Convention on Biological Diversity" is an international treaty that entered into force on 29 December 1993 and has been signed by over 190 parties. It has 3 main objectives: 1. the conservation of biological diversity; 2. the sustainable use of the components of biological diversity; 3. the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

As a means of furthering the aims of the treaty "The Cartagena Protocol on Biosafety to the Convention on Biological Diversity" was adopted as a supplementary agreement in 2000 to provide for the safe transfer, handling and use of genetically modified organisms (GMOs) [termed living modified organisms – LMO's by the protocol] that may have adverse effects on the conservation and sustainable use of biological diversity.

In September 2005 China ratified the Cartagena protocol and shortly after the Hong Kong government also announced its intention to ratify the protocol. The legislation (The Genetically Modified Organisms (Control of Release) Ordinance, Cap. 607, and its subsidiary legislation, the Genetically Modified Organisms (Documentation for Import and Export) Regulations) was introduced to implement the protocol and took effect on 1 March 2011.

The Ordinance controls the release into the environment and the transboundary movement of GMOs, and makes provision for a number of related matters such as a register of GMO's that have been approved for release and requirements for risk assessment. The focus of the ordinance is on the deliberate release of transgenic plants but also covers other organisms such as recombinant bacteria and transgenic mice. Almost all the various provisions for control of deliberate

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release do not apply to organisms intended for contained use. The one exception (see below) is that packaging of all GMO's imported into or exported from Hong Kong must carry appropriate labels detailing the contents of the shipment. The documentation requirements for the import and export of GMOs do not apply to a GMO that is a pharmaceutical product for use by human beings.

Clarifying Definitions:-

GMO: GMOs are living organisms that possess a novel combination of genetic material obtained through the use of modern biotechnology (e.g. recombinant DNA technology). GMOs cover a variety of food crops (such as BT corn, anti-frost tomatoes and herbicide-tolerance soya beans), GM seeds, GM fish, GM flowers, etc. However, GMOs do not include nonliving food products produced from GM crops, such as corn oil, soymilk and polished rice. Living organisms with genetic material altered through traditional breeding and selection techniques (e.g. hybrid rice and golden sweet corn) are also not GMOs.

Contained Use: A GMO is in Contained Use if : It is involved in an operation that is undertaken within a facility, installation or other physical barrier, and It is controlled by specific measures that effectively limit its contact with, and its impact on, the environment. For example, growing GM plants in a greenhouse with devices/ measures to effectively prevent the escape of pollen into the environment may be regarded as contained use.

Consequently almost all the various provisions for control of deliberate release do not apply to almost all of the Universities operations other than the appropriate labeling of living modified organisms imported or exported from Hong Kong. The following labeling requirements are taken directly from the legislation.

Documentation required for GMOs intended for contained use L.N. 171 of 2010 01/03/2011

- (1) For the purposes of section 26(1) of the Ordinance, a GMO that is intended for contained use must, when being imported into or exported from Hong Kong, be accompanied by a document that contains—
 - (a) a statement to the effect that the shipment in which the GMO is imported or exported contains a GMO that is intended for contained use;

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- (b) the safety requirements applicable to the GMO or, if there is no such requirement, a statement to that effect; and
- (c) the particulars specified in subsection (2).
- (2) The particulars are—
 - (a) the name, address and contact details of the consignee;
 - (b) the name, address and contact details of—
 - (i) if the GMO is imported into Hong Kong from another place, the importer of the GMO; or
 - (ii) if the GMO is exported from Hong Kong to another place, the exporter of the GMO;
 - (c) if available, the name, address and contact details of—
 - (i) if the GMO is imported into Hong Kong from another place, the exporter of the GMO; or
 - (ii) if the GMO is exported from Hong Kong to another place, the importer of the GMO;
 - (d) the common name and scientific name of the GMO and, if available, the commercial name of the GMO; and
 - (e) new or modified traits and characteristics of the GMO (including specification of use of the GMO and, if available, the transformation event code, unique identifier code and risk class of the GMO).

2.3.4 <u>The Dangerous Goods (Consignment by Air) (Safety) Regulations Chapter 384</u> <u>Subsidiary Legislation</u>

These regulations require consignors i.e. shippers and freight forwarders to ensure all dangerous goods are properly classified, packed, marked, labeled and documented before they are offered for air transportation. A person who contravenes these Regulations commits an offence and is liable to a fine of \$250,000 and to imprisonment for 2 years. Under Section 5 of Chapter 384, every director and every officer concerned in the management of the company maybe convicted of the offence!

For transport of infectious agents and clinical specimens to (or from) other countries it is recommended that a specialist firm is employed as import and

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export licenses may be required. Compliance with UN international regulations on packaging will also be required and this can be quite involved. The International Air Transport Association (IATA)'s Dangerous Goods Regulations have recently undergone significant changes that impact how specimens must be classified and packaged. For more information see Section 7.

2.3.5 <u>The "Prevention and Control of Disease Ordinance" (Cap. 599) and the</u> <u>"Prevention and Control of Disease Regulation" (Cap. 599 A)</u>

These regulations came into operation on the 14th of July 2008 and are operated by the Department of Health. They are the local implementation of the WHO International Health Regulations, 2005.

2.3.5.1 Importation of Biological Agents

Under Section 14 of Cap599A a permit in writing from the Director of Health, is required if any of the following biological materials are imported into Hong Kong:

- (a) a human corpse or any part of such a corpse;
- (b) an infectious agent;
- (c) any human or animal tissue, or tissue fluid, or any part of a human or animal body, that the person has the reason to suspect contains an infectious agent; or
- (d) any excreta, secretion, blood, or blood component, that the person has reason to suspect contains an infectious agent.

The application form for import (or transshipment – importation for subsequent export) of biological materials (Form DH2465) is accessible at (<u>http://www.dh.gov.hk/english/useful/useful_forms/useful_forms_qpd.html</u>) and the following explanatory table from the form gives some guide to the legislation.

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]	Items that generally do not require a permit
1. Infectious agent including 1 a parasite, a fungus, a fungus, a bacterium, a virus, a a prion or a any other agent that can cause an infectious 4 disease, in culture medium or in other 5 forms; 6 2. Human or animal 5 tissue, 5 tissue fluid, 5 body part, 5 excreta, 5	 Inactivated / sterilized tissues or materials Laboratory test reagents or test kits Synthetic substances Blood products for transfusion Cord blood Vaccines (These may require an import permit from the Pharmaceutical Service of the Department of Health) Animals or their body parts for human or animal consumption Insects and pests Human ashes

As is pointed out on the website the table is for reference only and the Department of Health reserves the right to make the final decision on whether a permit is required. (This license is in addition to any license that may be required under the import export ordinance CAP60 which is used to control "dual use" biological agents - this includes Avian Influenza, Dengue virus, pseudomallei and E.coli 157 appendix B. 0 see Π at http://www.stc.tid.gov.hk/english/circular_pub/2001_stc2.html for details)

Thus it may be necessary to obtain a permit from the department of health for a variety of activities where one was not previously required, these include:-

- i. Importing any infectious agent from overseas this includes those obtained from culture collections as well as those from personal or professional contacts.
- Obtaining from overseas cell lines containing infectious agents. This would include commonly cultured lines such as EBV transformed B-cells (e.g. lines such as B95-8, P3HR1 where EBV can be produced), HTLV1 transformed T-cells or HIV containing T-cells.

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- iii. Obtaining from overseas samples of any kind including clinical material where there is a reasonable expectation that an infectious agent could be present.
- iv. Importing to Hong Kong samples obtained from overseas field trips that might contain an infectious agent.
- v. Importation of infectious samples for laboratory accreditation exercises.

2.3.5.2 Reporting of accidents with scheduled agents

Under section 43 of CAP599A a laboratory is required to notify the Director of Health immediately of a leakage of scheduled infectious agents that may pose a public health risk. A list of the 31 scheduled agents can be found at http://www.hklii.org/hk/legis/en/ord/599/sch2.html and includes Dengue virus, Japanese encephalitis virus, Influenza H2, H5 and H7 subtypes, and SARS coronavirus all of which are worked on in various departments of the University.

Clarification of what is meant by the terms "leakage" and "may pose a risk" and how this relates to specific accidents will be sought from the department of health in the event of an incident. It should also be noted that under section 42 the university can be compelled to surrender any scheduled infectious agent if a health officer believes (a) the laboratory does not have sufficient facilities and equipment to handle the scheduled infectious agent; or (b) the person handling the agent in the laboratory does not have the necessary competency to do so; or (c) the agent is handled by the laboratory in a manner that may pose a public health risk.

3. Administrative Procedures

3.1 General

In common with other areas of safety it is ultimately the University Council that establishes and oversees the University's Biological Safety Policy. The Vice-Chancellor ensures the implementation of the standards and procedures outlined in the policy. The Vice-Chancellor has overall responsibility for safety and health within the University and has the authority to suspend or prohibit any operation that could give rise to imminent risk of serious injury or ill health.

The Safety, Health and Environment Committee (SHEC) is responsible to Council for overseeing the management of risks to safety and health at the University and has

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established a Biosafety Committee as a sub-committee (see 3.3) to oversee work with biological materials.

It is the duty of the Deans of Faculties to ensure that all aspects of the Councils Health and Safety Policy is implemented within their area of responsibility. Deans along with the Heads of Departments are expected to make all relevant persons aware of any hazards associated with biological materials encountered during the course of their work. They must also ensure that working procedures designed to minimise the risk are adopted. Decisions on how best to work safely with biohazards stem from risk assessments (see 3.4). The appropriate information and instruction contained within a risk assessment must be supplemented with the training required to carry out the work safely. Before commencing any work with biohazardous materials it is necessary to make such an assessment, which in almost all cases will require to be recorded in writing, and made available for inspection by interested parties such as Labour Department Inspectors, the University's insurers or members of the Safety Office.

In addition, each Head of Department must ensure the University Health and Safety Policy on safety in biological laboratories is supplemented by local departmental rules (see 5.5) relating to specific activities of the department, so that, when read in conjunction with this policy, the documents form an effective means of securing the safe use of biological materials, as well as potentially hazardous equipment and hazardous processes.

3.2 Advisory Appointments – BSO

The University has appointed a Biological Safety Officer (BSO), who is a member of the University Safety Office staff, to provide specialist professional guidance and advice on all aspects of biological safety to the University community, to ensure compliance with relevant legislation, University Health and Safety Policy and current international best practice. All contact and liaison with the enforcing authorities (primarily the Labour Department) on matters relating to biological safety should be via, or in consultation with, the University Biological Safety Officer.

3.3 The Biosafety Committee

The Biosafety Committee oversees the safe use of biological agents in the university. It is a sub-committee of the main university safety, health and environment committee and is comprised of a number of experts in relevant fields of work.

Terms of Reference

To oversee work in the university that may present a biological hazard with the aim of reducing risks and protecting people and the environment.

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- To undertake assessment and review of work which involves genetic modification, handling pathogens or potentially infected materials as well as any biological work involving carcinogens or teratogens. Projects will be approved initially for 3 years and subsequently reviewed regularly by the University Biological Safety Officer. This assessment and review will take into account the potential intrinsic risks involved in the experiments, the competence of the personnel and the safety/security of the laboratory facilities.
- To prescribe conditions for containment, housing, storage, transportation and procedures under which biohazardous research may proceed.
- To inspect and approve containment facilities before they are used for work with biohazardous materials.
- To report on a regular basis to the Safety, Health and Environment Committee.
- To co-operate with research granting agencies and with any committees on biohazards that may be established at governmental level.
- To collect and disseminate information and guidance, promote audit of facilities and the training of staff and students and in the area of biohazards and biosecurity.

3.4 Risk Assessment

It is University policy that all biological work that involves operating at Biosafety Level 2 or 3 as well as all work with virus vectors and clinical samples should be assessed for the risk involved.

The basic steps involved in carrying out any risk assessment can be found along with examples in the University risk assessment guidance document on the Safety Office website. The document also gives guidance on when an assessment is considered suitable and sufficient, who should carry out the assessment, the role of the PI or research group leader and other practical considerations.

3.5 Biosecurity

Biosecurity can be defined as the protection of high consequence pathogens or toxins, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse (Morbidity and Mortality Weekly Report December 6, 2002, Volume 51, No RR-19). The security of biological agents has become an important issue and the WHO has issued some general guidance in this area. A number of countries have also enacted specific legislation e.g. The Select Agent Rule in the USA; the Anti-terrorism, Crime and Security Act 2001 in the UK, which was updated in 2005, and The Biological Agents and Toxins Act 2006 in Singapore. Hong Kong has yet to

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enact similar legal requirements, however as mentioned in section 2.3.1 in order to meets its obligations under international biological and chemical weapons treaties Hong Kong has enacted legislation, Cap 491, intended to prevent the misuse of potential biological warfare agents or certain dual use technologies. A specified list of biological agents are detailed which require import and export licenses.

The Head of Department shall ensure that an adequate risk-based security plan is implemented and where appropriate security risk assessments are carried out. This should involve proactive measures to identify vulnerabilities and implementation of effective control and monitoring mechanisms. It is likely that organisms classified as Class 2 or below will not require specific biosecurity arrangements although there are a few exceptions and if there is any doubt the issue should be discussed with the Biological Safety Officer. A department that has in its possession an agent specified by Cap 491 should conduct a security risk assessment.

An area of particular concern for higher risk agents is specimen accountability. Detailed records must be kept for Class 3 agents. Heads of Departments may also wish to produce an inventory of Class 2 wild type and recombinant micro-organisms held in their department. This could include both those in use and in storage. To be of any value the information should be kept up-to-date and should identify the proper name and hazard group categorization of the micro-organism, where it is used or stored and the Principal Investigator/supervisor under whose area of responsibility it belongs.

4. Requirements for the different types of biological work

4.1 General

Detailed guidance on a range of biological safety topics is provided in the biosafety section of the Safety Office website. This includes guidance on risk assessment and the control measures required in order to work safely when carrying out various different types of biological work. University guidance is based on the legislative requirements in Hong Kong, and publications of various expert technical advisory committees in several countries including the WHO and US NIH/CDC. This website provides a single point of reference for University personnel and all personnel must refer to and follow the guidance relevant to their work. They should only take other measures after consultation with the University Biological Safety Adviser and with the agreement of their Head of Department.

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4.2 Work with Micro-organisms and their Genetic Modification

Micro-organisms are categorized into a hazard group. This forms the basis of the risk assessment which determines the level of containment under which the work must be undertaken. Additional control measures may then need to be assigned depending on the route of infection of the particular micro-organism and the nature of the work. The NIH/CDC list of categorisations of biological agents according to risk, is the approved list for work in the University.

All work with virus vectors and micro-organisms of hazard level 2 or 3, must be formally risk assessed and the assessment approved by the Biosafety Committee before the project commences.

The University Biological Safety Officer is the point of contact to submit all risk assessments to the Biosafety Committee. In most straightforward cases he/she can give provisional approval for a project which will then be looked at by the whole committee at a full meeting. In the case of more complex assessments and all Class 3 work the whole committee will be circulated by e-mail and consensus arrived at before approval.

Please note this is not just work being funded externally and encompasses all relevant biological agent work carried out by undergraduate students, research assistants, PhD students, Post Docs and PIs. Any format for a risk assessment will be considered, however, staff are encouraged to use the forms which will be provided on the Safety Office website. This includes copies of blank and model risk assessment forms are available for a variety of pathogens including work with viral vectors. The forms and associated guidance serve as an aide-memoir of the points to consider during the risk assessment procedure, as well as helping to keep information in a consistent manner.

Applicants for financial support from external granting agencies or university sources of finance can follow the approval procedures currently in place detailed on the Safety Office website under the Safety Manual and Research proposals – Safety Approval procedures subheading. The only additional requirement is that a risk assessment approved by the Biosafety Committee will be required in cases where virus vectors or micro-organisms of hazard level 2 or 3 are being worked on.

Risk assessment can be submitted at any time in the year and it would probably be prudent to avoid submission around the times RGC grants are due. It is the policy of the committee to give a response to the applicant within 7 working days. To assist in working to deadlines every effort will be made to reply within 48hrs although this may not always be possible.

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It should be noted that one risk assessment written to encompass an organism or a set of functional pathways in an organism may cover more than a single project.

Heads of Departments shall be responsible for ensuring that PIs carry out a risk for all biological work and where the agent used is a viral vector or a class 2 or 3 micro-organism they shall ensure that the approval of the Biosafety Committee is obtained before the work is started.

4.3 Work with Animals and Plants

The potential hazards associated with handling animals and plant materials must always be considered, and reference made to suitable sources of information to ascertain any precautionary measures required, before the work commences.

Persons working with animals must be aware of the risks of injury and ill-health to themselves, colleagues and the animals with which they work. (See Health and Safety Information for those working with animals in the University of Hong Kong on the Safety Office website). There is a range of different hazards associated with animal work that vary according to the type of work undertaken and the animals concerned. For example, allergy to laboratory animals used in research is a well-known and significant cause of occupational ill health in some countries. See the Laboratory Animal Unit (LAU) website for all matters concerning animal work, including requirements for ethical approval of any work undertaken. Please also see "Occupational health and safety in the care and use of research animals, NRC (1997)" http://www.nap.edu/catalog.php?record_id=4988 and "Guide for the Care and Use of Laboratory Animals, NRC, USA – Eighth Edition (2011)" for further information.

The Occupational Health Unit (see 10.1) undertakes a health surveillance programme of employees working in animal facilities. (See the document "Occupational Health Programme for Laboratory Animal Workers" available on the University Health Service (UHS) website). The LAU follow the policy and procedures for health surveillance as advised by the UHS. Heads of Departments, PIs and individual workers must also refer to and follow this policy.

For transgenic plants see Section 2.3.3 that deals with "The Genetically Modified Organisms (Control of Release) Ordinance, Cap 607" and its subsidiary legislation. Essentially it is a requirement of the regulations that effective measures are introduced which prevents exposure of the environment to Genetically Modified Organisms including transgenic plants, knockout or transgenic animals, recombinant bacteria etc. For transgenic plants this means that transgenic plants must be kept within a greenhouse so as to prevent their pollen from spreading to the external environment.

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5. Safe Systems at Work

5.1 General

Although much of the microbiological and biochemical work in University laboratories does not involve materials known to be infectious, it should be remembered that many biological materials may contain pathogens, laboratory procedures may support the growth of pathogenic contaminants and many micro-organisms whilst not generally regarded as human pathogens may, in certain circumstances, cause infections. Health and safety precautions are therefore essential in all forms of biological work because of the ever present possibility that laboratory workers, students and other personnel who access the facilities might be affected by accidental infections or allergic reactions. The approach used throughout the world is known as working in, or under, containment and is described in more detail below. This precautionary approach is well tried and tested having been successful for many years across multidisciplinary work areas.

All those who work with pathogenic micro-organisms and potentially biohazardous materials must do so within a framework which will provides the containment and protection appropriate to a reasonable and informed assessment of the risks involved. A safe system of work will generally arise naturally out of such a risk assessment because many of the necessary control measures should be incorporated as fundamental and routine parts of everyday working in biological laboratories.

It is the responsibility of all persons routinely engaged in work with potentially infective materials to give serious consideration to the possible effects of this work on the health of themselves, their colleagues and the community as a whole. A collective awareness of infective hazards should be fostered and prompt steps taken to investigate the unexpected absence from work of any co-workers.

5.2 Routes of Infection

In order to cause an infection a micro-organism must first gain access to the body. In the natural environment micro-organisms use several different routes of infection to gain access although these are often characteristic of, and specific to, the micro-organisms and the diseases they cause. For example, gastrointestinal diseases usually result from ingestion of contaminated food or drink whereas respiratory diseases usually result from inhalation of an infectious aerosol. In the laboratory setting, primary consideration must always be given to a pathogen's normal route of infection but it should also be remembered that laboratory manipulations might potentially give rise to exposures that would not normally be encountered in everyday life. For example, a high concentration of a respiratory pathogen could be injected directly into the body

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as a result of a needlestick injury and whilst this may not deliver the pathogen to its primary site of infection the potential for it to cause disease would still be significant.

All workers must be aware in general of the various routes of infection and the control measures necessary to block these and more specifically of the particular route(s) of infection of any micro-organism (or the micro-organisms that may be contained within any biological material) with which they work.

Working practices when handling biological materials should always follow the precautionary approach of routinely blocking routes of infection. The following summarises the routes of infection that may occur within the laboratory and the principal means of blocking them.

Ingestion route – never put anything in the mouth whilst in the laboratory and avoid subsequent transfer to items such as food by always washing hands before leaving.

Percutaneous route – avoid the likelihood of puncture wounds by careful handling procedures and always keep any breaks in the skin covered whilst in the laboratory. Care should be taken to ensure working practices do not contaminate mucous membranes by, for example, splashing or transfer. Sharps injuries are a significant concern and all workers in biological laboratories must receive instruction and training on safe working practices. Detailed guidance on avoiding sharps and needlestick injuries is available on the Safety Office website and all laboratory workers must refer to and follow these procedures.

Inhalation route – care must be taken to minimise the production of aerosols and where infectious aerosols may be generated the work should be carried out in a microbiological safety cabinet.

Instillation route – care should be taken to ensure working practices do not contaminate eyes by splashing or transfer. If these may be likely then the wearing of suitable eye protection is of paramount importance.

Further guidance on blocking routes of infection is given in the following sections (5.3 and 5.4) on good microbiological practice and containment. Further information on what to do in the event of an accident or incident involving a biological material is given below in section 9.

5.3 Good Microbiological Practice

The term "Good Microbiological Practice" is used in a number of different ways. In this document the phrase is taken to mean the basic safety precautions adopted in all

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laboratories where there is a risk of infection – even where the consequence of infection is minimal. The following is a hybrid of requirements written into UK legislation and recommendations on a core safety curriculum for students from the American Society for Microbiology.

- 5.3.1 Microbiological procedures are to include:-
 - (a) methods of aseptic transfer.
 - (b) minimizing or containing the production of aerosols.
 - (c) washing hands prior to and following laboratory activities and at any time contamination is suspected.
 - (d) disinfection of laboratory benches and equipment prior to and at the conclusion of each laboratory session, using an appropriate disinfectant and allowing a suitable contact time.
 - (e) identification and proper disposal of different types of waste.
 - (g) good laboratory practice, including returning materials to proper locations, proper care and handling of equipment and keeping the bench top clear of extraneous materials.
 - (h) reporting all spills and broken glassware to the instructor and receiving instructions for cleanup.
 - (i) using "standard" (universal precautions) with blood and other clinical samples.
- 5.3.2 Protective and Administrative procedures are to include:-
 - (a) tying long hair back, wearing personal protective equipment (eye protection, gloves, coats, closed shoes; glasses may be preferred to contact lenses) and using such equipment in appropriate situations. Laboratory coats belong in the laboratory, not the lecture theatre, office or refectory.
 - (b) always using appropriate pipetting devices and understanding that mouth pipetting is forbidden.
 - (c) never eating or drinking in the laboratory.
 - (d) never applying cosmetics, handling contact lenses, or placing objects (fingers, pens etc) in the mouth or touching the face. Mobile phones should not be answered while conducting procedures.
 - (e) testing equipment adequately and maintaining control measures.
 - (f) testing, where necessary, for the presence of viable process organisms outside the primary physical containment.

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- (g) formulating and implementing local codes of practice for the safety of personnel, as required. (In particular local rules/SOP's should minimise the use of sharp instruments and ensure their correct use and disposal as well as detailing what to do in the event of an accidental. Local codes should also outline procedures designed to protect the environment.)
- (h) displaying biohazard signs where appropriate.
- (i) keeping adequate records. This should include records indicating that an individual has read and understands the safety rules of the laboratory.
- (1) providing written standard operating procedures where appropriate to ensure safety.
- (m) having effective disinfectants and specified disinfection procedures available in case of spillage (or shedding).
- (n) providing safe storage for contaminated laboratory equipment and materials where appropriate (e.g. waste material before autoclaving/ disposal).
- 5.3.3 Emergency procedures are to include:-
 - (a) locating and properly using emergency equipment (eyewash stations, first aid kits, fire extinguishers).
 - (b) reporting all injuries immediately.
 - (c) following the proper steps in the event of an emergency (specified in the SOP).
- 5.3.4 Providing appropriate training and supervision of personnel.

5.4 Containment

Work with biological materials, including micro-organisms and genetically modified organisms, is undertaken in containment laboratories. There are 4 different levels of containment (levels 1–4 alternatively called Classes 1–4).

5.4.1 WHO Classification of infective microorganisms by risk group (with examples).

Risk Group 1 (no or low individual and community risk)

A micro-organism that is unlikely to cause human or animal disease – WHO. Not known to consistently cause disease in healthy human adults – NIH/CDC. *E.Coli K12, Saccharomyces cerevisae* Adeno-associated virus, *Bacillus subtilus*, Baculovirus.

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Risk Group 2 (moderate individual risk, low community risk)

A pathogen that can cause human or animal disease but is unlikely to be serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventative measures are available and the risk of spread of infection is limited. All 8 human herpesviruses – HSV, VSV, EBV, CMV, HHV6, 7 & KSHV, Enterotoxic E.coli including *E.coli* O157, Adenovirus (all 50+ human serotypes) *Stapylococcus aureus* (including MRSA), Ringworm, HIV and HBV.

Risk Group 3 (high individual risk, low community risk)

A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, directly or indirectly. Effective treatment and preventative measures are available. Vibrio cholera, *Shigella flexnerii, Mycobacterium tuberculosis* SARS, Rabies virus, Avian Influenza.

Risk Group 4 (high individual and community risk)

A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventative measures are not usually available. Marburg, Simian B virus, Ebola, Rift Valley Fever virus and Smallpox.

The level of containment under which particular work should be undertaken is determined as part of the risk assessment (see 3.4). Detail of the requirements of each containment level is described in supporting guidance on the Safety Office website.

5.5 Facilities and Working Practices Including Local Codes of Practice/ Laboratory Rules

The principles of containment are applied both in the basic design and facilities of the laboratory and in the working practices of all the people in the laboratory. The purpose of containment is not only to prevent the micro-organisms getting out of the laboratory but also to ensure that the workers are safe whilst in the laboratory. Heads of Department are responsible for ensuring that work with biological materials is undertaken in facilities that are suitable for the purpose and using appropriate working practices. Individual workers have a duty to work in accordance with the containment requirements for the activities they carry out.

Whilst working in containment laboratories it is also necessary to use the precautions indicated in the section on good microbiological practice (5.3).

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Each Head of Department has a responsibility to ensure that the level of containment required for a particular facility is correctly identified to those involved in the design and/or refurbishment of containment facilities, including the relevant Estates and Buildings Project Manager and the University Biological Safety Officer. The Head of Department should also ensure the requirements of the department and workers who will use the facility are made clear and taken into account in the design process. The Director of Estates and Buildings is responsible for ensuring that all new building and refurbishment work in containment laboratories meets the required/agreed specification.

Arrangements and responsibility for preparation of local rules must be included in the Departmental safety policy but this is expected to be within the following framework.

Each laboratory must have clear documented local rules indicating the working practices that must be followed for activities in that laboratory. Individual workers must have access to and adhere to local rules. The Research Group Leader/Principal Investigator of a given research group, or the supervisor/manager of a unit or work area, is responsible for ensuring local rules are in place and are complied with. These should be tailored for local conditions and activities.

When drawing up local rules and procedures note should be made of the following two points:

- (1) There should be no need for workers in laboratories to routinely disinfect their hands. It is very bad practice to spray hands with alcohol as this will damage the integrity of the skin and upset the balance of the normal skin microflora. 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 washing products are suitable for this and there is no need to use specialist antimicrobial products. Cloth towels must not be used in laboratories. Single use paper towels are recommended.
- (2) Procedures for the laundering of potentially contaminated clothing, e.g. laboratory coats, gowns, etc, must be clearly laid down in the departmental health and safety policy such items must never be worn, or otherwise taken, out of the School until they have been rendered safe. Laboratory coats from containment level 3 facilities must be autoclaved before laundering. Coats used in containment level 2 areas should be sent for laundering as soiled linen or if grossly contaminated (for example following an accident) be autoclaved first.

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Risk assessments should include cross-reference to the local rules. This pre-empts any need to write out or duplicate the information within the risk assessment and ensures consistency in standards.

Further information on the working practices that are fundamental to containment, and the reason for them, are described in the guidance on good microbiological practice and containment - see section 5.3.

5.6 Good Housekeeping

Good housekeeping is important in all types of laboratories but it is especially so in microbiological laboratories, and in other laboratories handling biological materials. Cleanliness is fundamental to minimising any contamination and ensuring a safe working environment. In order to facilitate cleaning, the laboratory should be tidy with no clutter or unnecessary items on benches and floors. It is also important that in the event of a spillage this does not seep into, onto or under items that need not be there.

Benches, floors and any items that may become contaminated should be easily cleanable. At the end of each working session or day, benches should be tidied and cleaned and, where appropriate, disinfected. Used culture plates and media should be disposed of as soon as they are no longer required to minimise growth of contaminants etc. Generally, items should not be stored in cardboard boxes, especially on floors, as these are impossible to clean. Cardboard boxes should never be used in cold rooms because they tend to become damp which encourages growth of moulds. Laboratory sinks should also be regularly cleaned and disinfected.

Day to day responsibility for housekeeping in shared or multi-user facilities should be assigned to a named member of staff to ensure satisfactory standards are maintained. Cold rooms are areas where housekeeping is often poor, often leading to mould contamination of walls and ceilings, equipment and experimental materials. This can result in unhealthy exposure to mould spores of workers entering the cold room. Attention should be paid to avoiding conditions where mould will result and any growth should be cleaned and disinfected as soon as it is observed.

Laboratories or similar facilities that are clean and tidy and have good standards of housekeeping are usually ones where there also is good management, organisation and working practices. Safety inspections often focus on housekeeping and workers should not underestimate its relevance to safety and should pay appropriate attention to this detail. As part of the housekeeping regime it should be ensured that hand wash sinks (including the taps) are regularly cleaned, and soap and paper towels are always available. If liquid soap is used in a containment laboratory this should be in a dispenser and, to prevent the multiplication of any contamination, dispensers should not

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be topped up from other bulk stocks. Single use paper towels are recommended for drying hands. Cloth towels must not be used.

5.7 Signs

To be effective safety signs must be used judiciously. Signs must indicate current conditions and be regularly checked for validity.

The Dean of Faculty together with the Head of Department is responsible for ensuring laboratories or other facilities where biohazardous micro-organisms or materials are present are labeled at the point of entry with:-

- an international biohazard sign, which comprises a black biohazard symbol in a black triangle on a yellow background (a hazard warning sign),
- the words Containment Level followed by the number of the level of containment at which the laboratory or facility is operating (this should be fixed immediately adjacent to the biohazard sign and also have markings/words in black on a yellow background), and
- a prohibition sign restricting access to authorised persons only.

Laboratories and similar facilities where blood and/or clinical samples are handled must operate as a minimum at Containment Level 2 and display the appropriate signs.

The following signs should also be considered and used as appropriate to reinforce local rules and procedures:-

- at the point of exit the mandatory sign indicating hands must be washed before leaving;
- in a prominent place the mandatory sign indicating laboratory coats must be worn;
- at a dedicated hand wash basin the mandatory sign indicating this sink is to be used for hand washing only.

The use of biohazard signs or labels within a containment laboratory or facility should not generally be required and should not be used unnecessarily. The displaying of a label on the door as described above indicates it is a containment area and restricts access to those persons authorised to enter. These people should have been instructed on the procedures that must be followed whilst in the area and any hazards they may encounter and they therefore know biohazards are to be expected. Only in exceptional circumstances, for example following an accident, should any area of benching or

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equipment be contaminated to such an extent that it requires to have a biohazard sign (label or tape) displayed on it and where used this should be taken to indicate a significant hazard or one greater than would normally be expected. The labeling of fridges and freezers for example is unlikely to serve a useful purpose, it is only to be expected that biohazardous material will be contained therein and in any case materials must be stored safely such that no exposure will occur to anyone using the fridge or freezer. In the case of storage it may however be prudent depending on usage, especially if shared or mixed or for higher risk materials, to use the biohazard sign on particular items for example on the outside of the secondary containment.

5.8 Fumigation

Fumigation of microbiological safety cabinets and some containment level 3 facilities is routinely carried out by the University Safety Office environmental team. This usually involves the use of formaldehyde vapor and even at low concentrations this has irritant and toxic properties and carries a risk of respiratory and/or skin sensitization reactions. At the higher concentrations used for room fumigations it is extremely hazardous and exposure to such levels, even for a short time, would likely result in very serious injury or death.

If the individual departments were to undertake fumigation it is the responsibility of the Dean of Faculty with the Head of Department to ensure appropriate systems are in place to provide safe and suitable procedures. In conjunction they must ensure adequate and appropriate instruction, training and supervision is provided for all workers undertaking fumigation procedures. They should also ensure that suitable arrangements are in place to monitor and review working practices.

5.9 Liquid Nitrogen

Cryogenic storage of biological materials in liquid nitrogen is commonplace and it is important that workers are aware of the potential hazards associated with the use of liquid nitrogen. These fall into three main areas:-

- Temperature the extremely cold temperature of –196°C means there is a very serious risk of cold burn on contact with the liquid. Items that have been in the liquid are cold and when touched may freeze to and stick to the skin. On evaporation, whilst unlikely to cause skin damage, the gas can cause damage to eyes and lungs.
- Explosion if samples are stored in tubes in the liquid phase of the vessel, liquid nitrogen may seep into the tube. When the samples are removed and warmed, the liquid nitrogen changes to a gas rapidly expanding in volume and may cause the

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tube to explode. Certain materials when immersed in liquid nitrogen become brittle and may shatter unexpectedly.

• Asphyxiation – when liquid nitrogen evaporates and changes from a liquid to a gas there is a huge expansion of nearly 700 times in volume (1 litre of liquid gives 0.7m3 of gas). A spillage of just a few litres of liquid in a poorly ventilated room would lower the oxygen concentration to such an extent that a person in or entering the room can lose consciousness and die.

Each Dean of Faculty along with the Head of Department is responsible for ensuring appropriate systems are in place to provide safe and suitable procedures for use of liquid nitrogen in biological laboratories and associated facilities. In addition, they must ensure adequate and appropriate instruction, training and supervision is provided for workers using liquid nitrogen. They should also ensure arrangements are in place to monitor and review working practices.

When drawing up local rules and procedures note should be made of the following points:-

- Eye protection, most appropriately in the form of a full face visor, thermal gloves and suitable footwear must always be worn when cryogenic liquids are being handled.
- Liquid nitrogen should be decanted into Dewar flasks which are designed for this purpose; if domestic thermos flasks are to be used as liquid nitrogen containers they should be made of stainless steel rather than glass.
- Ideally liquid nitrogen should not be carried in occupied lifts.
- Where significant volumes of liquid nitrogen are handled it is likely that additional low level, high volume ventilation will be required and the use of oxygen depletion monitors should be considered. Further advice can be obtained from the Safety Office.

It is worth noting that there have been at least three deaths from asphyxia in recent years in academic institutions as a consequence of the use of liquid nitrogen (in England, Australia and Scotland).

5.10 Disposal of Clinical Waste

Certain wastes arising from biological laboratories require specialist disposal as clinical waste because they may contain infectious micro-organisms. Some of the wastes may also have components that are regarded as unacceptable to be placed in the general waste stream and these, even if they are rendered non-infectious by some sort of

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pre-treatment, must always be disposed of as clinical waste e.g. sharps. The disposal of clinical waste is tightly regulated and must be carried out in accordance with strict legislative requirements (see section 2.3 and Guidance on Clinical Waste on the Chemical safety tab of the Safety Office website).

The Safety Office co-ordinates appointment of a licensed clinical waste collector and will assist in the management of the disposal of clinical waste but ultimately it is the responsibility of the heads of Department to ensure the safe disposal waste arising in areas under their control. They must ensure all biological wastes produced are disposed of in accordance with the University Code of Practice Workers must follow the local rules and procedures. Each worker in the University must ensure that waste is managed properly and disposed of safely and in accordance with legal requirements. Each Head of Department must ensure adequate instruction, equipment, training and supervision is provided to enable all workers to carry out their responsibilities.

Work in biological laboratories may also produce other hazardous wastes. Guidance, on the safe disposal of chemical substances is available on the Safety Office website.

6. Equipment

6.1 General

Adequate and appropriate instruction, training and supervision must be provided for workers using equipment. Individual workers must always closely follow instructions provided for use of equipment, use it only for the purpose it was intended and never tamper with or over-ride any safety related devices. Documented operating instructions should be available for all pieces of equipment. For some items of equipment the manufacturer's instructions will provide adequate systems of work whereas for others a local standard operating procedure should be drawn up applicable to the particular usage of the equipment.

Equipment must be maintained and, where necessary, tested to demonstrate it is working effectively. Further guidance on some of the common types of equipment used in biological laboratories can be provided by the Safety Office if required. The most significant safety related items are microbiological safety cabinets and autoclaves for which there are specific requirements as follows.

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6.2 Microbiological Safety Cabinets / Individually Ventilated Animal Cages (IVC's)

Cabinets and cages must be properly installed, commissioned and prior to use, a cabinet must pass the performance tests specified in an acknowledged standard. The test requirements are quite detailed and require competent persons to undertake the work for it to be carried out properly. Similar requirements apply when cabinets are moved or relocated. All microbiological safety cabinets and IVC's should be serviced on an annual basis and undergo examination and test at that time. A record should be kept by the department for at least 5 years of the examinations and tests and of any repair carried out.

Detailed information on microbiological safety cabinets is provided on the University's Safety Office website. Workers must refer to and follow this guidance. The requirement for a safety cabinet/IVC, and where required, the type or class, of safety cabinet, should be determined as part of a risk assessment of the work to be undertaken.

6.3 Autoclaves, Boilers and Pressure Vessels Safety

Chapter 56 "**The Boilers and Pressure Vessels Ordinance**" is administered by the government labour department and applies to establishments using boilers and pressure vessels including thermal oil heaters, steam receivers, steam containers, air receivers and pressurized cement tanks mounted on trucks and trailers. The legislation regulates the standards and operation of these boilers and pressure vessels, and requires them to be registered and examined before being put into use and periodically thereafter. This legislation includes autoclaves and pressure cookers.

Where an autoclave is used to decontaminate or make safe waste, the process should be validated at least annually and at any other times when the previous test may no longer be valid (such as part of re-commissioning after maintenance work). Records of validation should be kept for at least 5 years.

It is worth noting that the Labour Department, Boilers and Pressure Vessels Division, conducts regular spot checks on pressure equipment. It also conducts examinations associated with the issue of Certificates of Competency, investigates accidents and undertakes activities to promote safety.

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7. Transport

7.1 General

Certain biological samples, cultures and other materials fall within the description of dangerous goods for carriage and both national and international legislation demand stringent requirements be met if the goods are transported by any means. All workers in the University must ensure Regulations applicable to the transport of biological materials are complied with for each particular consignment and not carry, consign, package or play any other role in the transport chain if they are not competent to do so.

Heads of Departments must ensure that all persons undertaking any role in the transport chain are properly trained and have a detailed understanding of the relevant Regulations to ensure they are able to undertake their responsibilities to the required standards. The level of training should be commensurate with those responsibilities. Even if the particular biological material to be transported is not hazardous and does not fall under the description of dangerous goods, the item must still be packed safely for carriage.

Detailed guidance on the transport of biological materials is provided on the University's Safety Office website (also see 8.2 and 8.3 below).

Any problems occurring during transport, such as leakage or breakage, should be reviewed in order that corrective measures can be taken to prevent recurrence. If workers in the University receive packages that are not properly packaged or labeled they should contact the originator to advise of the problem and ask that any future packages meet the legislative standards.

When transporting samples particularly those of a potentially infectious nature (including bloods and clinical samples) a number of issues should be taken into account.

- Work should be organized in such a way as to minimise transport of samples around a building and they should only transported between buildings when absolutely necessary.
- When it is necessary to transport biological materials between buildings both primary and secondary leak proof containers must be used. The secondary container should hold enough absorbent material to surround and contain the sample should any breakage occur.
- Carrying unpackaged tubes on their own or in racks in public areas such as corridors and lifts should be avoided. For transport between laboratories, screw capped tubes are preferable to flip top eppendorf tubes and the use of open or

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stoppered glass tubes should discouraged because of the potential for breakage if dropped.

7.2 Transport on the University Campus.

For any transport between buildings of known or potentially biohazardous materials a sealed primary container must be placed into a sealed secondary container bearing a biohazard label on which the name of the material has been written. If the primary container is glass, a rigid, unbreakable secondary container must be used, as broken glass may penetrate a sealed plastic sample bag. Paper towels or other absorbent material should be used to separate primary glass containers from each other and from the secondary container to minimize the potential for breakage. The amount of absorbent used must be sufficient to absorb the contents of the primary container. Appropriate decontamination of the exterior surfaces of the primary and secondary containers should also be carried out.

For transport to other Universities in Hong Kong or journeys that involve crossing or navigating public highways, for example carrying material from the main campus to buildings on the Sassoon road site, rigid leak proof primary and secondary containers with absorbent material incorporated to contain any spill is required.

7.3 Transport within Hong Kong

Guidance for the transport of biological materials within Hong Kong is provided on the Safety Office website and includes sub-sections on using couriers and postal services. All University staff and students must refer to and follow the guidance relevant to their activities.

7.4 Transport Abroad

For transport of samples abroad, anyone sending biological materials by air must ensure they comply with the IATA Dangerous Goods Regulations. All information in these Regulations relevant to the transport of biological materials abroad has been summarized and supplemented with guidance on interpretation in University guidance available on the Safety Office website. All University staff and students must refer to and follow the guidance relevant to their activities.

For transport of infectious agents and clinical specimens to (or from) other countries it is recommended that a specialist firm is employed as import and export licenses may be required. Compliance with UN international regulations on packaging will also be required and this can be quite involved. Please also note that these regulations specify

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that anyone packing dangerous goods (including infectious organisms) must be trained by an accredited organization and will require re-certification on a regular basis.

8. Training and Supervision

8.1 General

As part of the induction procedures when first arriving, all persons working in the University should be made aware of the University Health and Safety Policy and of any other local health and safety policies made at Faculty and departmental level and below. All persons studying or working in biological laboratories must receive information, training and supervision appropriate for the work undertaken, so that risks to the health and safety of all persons involved are controlled.

The Research Group Leader/Principal Investigator of a given research group, or the supervisor/manager of a unit or work area, is required to give careful attention to the health and safety of those under their supervision. They should ensure all workers they are responsible for supervising receive the appropriate safety information and training and that this is suitably documented (see 9.2). In order to effectively discharge these responsibilities, those with supervisory or managerial roles must themselves be competent in safety related matters and, where necessary, should seek additional training (or refresher training) as appropriate.

To fulfill its function, the degree of supervision must have reasonable regard for the level of training and expertise of the staff or students being supervised. Young and inexperienced workers will require a greater level of supervision than those who are more experienced. Provision of adequate training and supervision applies not only to work on University premises but also to University work carried out elsewhere either in Hong Kong or abroad.

For all workers, specific laboratory training should as a minimum include familiarization with local rules and working practices, use of personal protective equipment (lab coat, gloves, eye protection), use of microbiological safety cabinets, disinfection procedures, waste disposal procedures, accident and emergency procedures and discussion of relevant risk assessments.

The University Safety Office offers training courses on various biosafety related topics and attendance at relevant sessions should be regarded as part of the training for workers handling biological materials. Further information on these biosafety training courses is available on the Safety Office website and in particular a three hour introduction to Biosafety course is recommended for all those new to the University.

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Under some circumstances specific sessions on topics of particular interest to a department can be arranged.

8.2 Training Records

While international practice varies in keeping records of training for work at containment levels 1 and 2 the Safety Office wishes to encourage Heads of Department to adopt a more systematic and thorough approach to training. The keeping of training records is one way of promoting this aim. Many of the basic procedures and control measures are common to all laboratories and a form can be tailored as appropriate for the different areas of work carried out. This proforma could be used as the basis of a training record for all biological workers at Containment Levels 1 and 2 including work with blood and human tissues, pathogens and genetically modified micro-organisms. For those undertaking work with pathogens or GM work at Containment Level 3, a more specific and detailed training programme will be required for the activities in a CL3 facility and a separate or supplementary record should be kept for this. The Research Group Leader/Principal Investigator or the supervisor/manager is responsible for maintaining the training record for each person for whom they have responsibility.

8.3 Single/Lone Working and Out of Hours Working

Each Dean of Faculty in consultation with Heads of Departments should ensure any work is prohibited which entails a risk of serious personal injury or fire by persons working alone in the evenings or at weekends, irrespective of the status and experience of the worker. Generally work with biological materials does not present an immediate risk of serious injury and there is no reason why work with high risk biological materials cannot be undertaken by lone workers or out of hours. However, it must be remembered that the work may be associated with other risks in the laboratory and these must be assessed against the restriction given above.

Where single/lone working and out of hours working occurs, there must be appropriate monitoring to ensure standards of working practices are maintained when individual workers are on their own without any immediate supervision.

8.4 Young Persons and Inexperienced Workers

The level of training and supervision required by young persons (16-18 years old) and inexperienced laboratory workers of any age will be greater than that required of more experienced workers. Supervisors should clearly identify training needs as part of induction procedures and work should be carried out under close supervision until it has been confirmed that individuals are competent to carry out their work safely.

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Undergraduates, young persons and inexperienced workers should only be allowed to carry out practical laboratory work in the evening or at weekends if explicit permission is given on each occasion by their supervisor and adequate supervision is employed. If the supervisor is not a senior member of the academic staff then one who is must agree to the granting of the permission and only do so after they have satisfied themselves as to the individual's competency.

9. Accidents and Incidents

9.1 General

Most accidents and incidents can be avoided with good management systems in place. All accidents and incidents that do occur should be reviewed by the individual(s) involved in conjunction with their immediate supervisor. The cause of the accident or incident should be established and it should be possible to identify what should be done to prevent any recurrence. Accidents and incidents should also be monitored and reviewed at Faculty level to identify any improvements that are necessary. Any remedial action identified must be implemented and any lessons learnt should be communicated widely within appropriate Faculties to others who may benefit from the information. However, care must be undertaken to protect the confidentiality of individuals involved in particular accidents.

The potential seriousness of accidents involving biological materials should not be underestimated. All workers must be made aware of the consequences should they be exposed to biohazardous materials. In some cases, for example blood carrying HIV or hepatitis B/C, a lifelong infection may develop that will have a serious detrimental effect on their health and quality of their life and that of their immediate family. Needlestick and sharps injuries are particularly serious and each Head of Department must ensure all workers handling needles and sharps receive instruction and training on safe procedures. Workers in the University must refer to and follow the guidance on avoiding sharps and needlestick injuries available on the Safety Office website. Particular care should be taken to ensure that others in the laboratory do not help with the clear up of accidental spillage (especially where there has been an accident that involves broken glass) unless they are aware of the potential risks and trained in safe working practices.

9.2 First Aid

In the event of an accident or incident in a biological laboratory, workers in the University must take immediate action to reduce the risk of infection developing. However this should not be at the detriment of treating other more serious injuries

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which should always take priority. The following should therefore be read in context of appropriateness to the particular accident or incident.

Immediately following ANY exposure to biological materials, irrespective of whether or not the source is known to pose a risk of infection, the site of exposure e.g. wound or non-intact skin should be washed liberally with soap and water but without scrubbing. Antiseptics and skin washes should not be used – there is no evidence of their efficacy, and their effect on the body's own defence systems is unknown. Free bleeding of puncture wounds should be encouraged gently but wounds should not be sucked. Exposed mucous membranes, including conjunctivae, should be irrigated copiously with water, before and after removing any contact lenses. In the event of a serious injury requiring medical attention, individuals should attend the Accident and Emergency Department/Minor Injuries Unit of the local hospital.

The University Health Service should be informed immediately in the event of any accident where exposure to a pathogen, genetically modified micro-organism or potentially infectious material may have occurred – it is important that the need for any prophylactic treatment or health surveillance be assessed on a case by case basis by medical personnel. Alternatively, for example out of normal working hours, the Accident and Emergency Department/Minor Injuries Unit of the local hospital should be contacted.

9.3 Accident Reporting

In the event of an accident or incident occurring, the individual(s) involved must inform the manager/person who has responsibility for the particular area and if this is not their immediate supervisor they must also inform them. The individual and the manager/supervisor have a responsibility to ensure an accident and incident, or occupational ill health, report is completed. All accidents and instances of occupational ill health (illness reliably attributed to a work activity) must be reported to the Director of Health and Safety as soon as possible after the incident has occurred, and in any case within seven days, so that the requirements of The Employees' Compensation Ordinance, Cap. 282 may be met. This ordinance requires an employer to report to the Commissioner for Labour any work accident or specified occupational disease in the University on an appropriate form within a specified time period. Any reporting required under these Regulations will be undertaken by the Safety Office. No accident should be considered too trivial to report although not all will be reported to the Labour Department. Near misses that could have had serious consequences should also be reported. Details of the accident etc. reporting system in the University and forms are available on the Safety Office website.

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10. Occupational Health

10.1 General

The University Health Service (UHS) has expertise in Occupational Health and advises both the University's managers and workers on all aspects of occupational health. It is totally independent, impartial and completely confidential. If individuals have concerns about the effect of any work activity on their health they should seek advice from the UHS or, if they prefer, from their own General Practitioner. A Dean of the Faculty or Head of Department may refer a worker to the UHS if they have concerns about an individual's health. Contact between an individual and the professional staff of the Unit is subject to medical confidentiality and medical information will only be disclosed to others with the consent of the individual concerned, irrespective of whether contact is by self-referral or by a supervisor or manager.

Where necessary and in consultation with the safety office the UHS will provide or arrange for any health surveillance identified as being required for a particular work activity.

The UHS must be informed immediately in the event of any accident or incident where exposure to a pathogen, genetically modified micro-organism or potentially infectious material may have occurred. This will enable the need for any prophylactic treatment or health surveillance to be assessed on a case-by-case basis by medical personnel. Alternatively, for example out of normal working hours, the Accident and Emergency Department/Minor Injuries Unit of the local hospital should be contacted.

10.2 Immunisation

The University offers immunisations to individuals who may be exposed to pathogens at work, where an effective vaccine is available. The UHS will provide any immunisations identified as being required for a particular work activity. They should be contacted for further advice.

The UHS undertakes a well-established immunisation programme which targets certain groups of workers. For example, those who may be exposed in the course of their employment to human blood or body fluids are required to receive Hepatitis B immunisation. Specific immunisations, travel and health advice will also be provided to workers at risk of developing disease while on University business abroad.

A minimum requirement for animal house staff and veterinary workers should be immunisation against tetanus, for those not already immune. It must be noted however,

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that immunisation against tetanus is part of routine childhood immunisations and therefore most adults are already immune. Boosters are not recommended other than at the time of tetanus prone injury since they have been shown to be unnecessary and can cause considerable local reactions.

If any member of the University chooses to reject advice to receive an immunisation, a signed declaration should be obtained to this effect. Immunisation must always be regarded as a backup rather than a control measure, and must never be regarded as a substitute for safe working practices.

11. Access to Biological Laboratories by non-laboratory personnel

11.1 General

Access to University laboratories and other facilities where biological work is carried out (containment laboratories) must be limited to those persons who have a valid reason to enter the laboratory. At containment levels 2 and above access should be restricted to authorised persons.

From time to time it will be necessary for persons other than laboratory personnel to require access to laboratory areas. Such access may be required regularly, for example by cleaners, or only intermittently, as would be expected for maintenance and repair work. Other individuals may visit for a variety of reasons. Each Head of Department is responsible for ensuring the health and safety of all persons on their premises and must have appropriate systems in place to control access to biological laboratories. They should also ensure that suitable arrangements are in place to monitor and review access controls and how they work in practice.

Appropriateness in terms of controlling access will vary depending on the nature of the access required. The different types of access likely to be required must be reviewed, the associated risks assessed and how each is to be managed addressed by incorporating procedures into local rules. Further guidance for departments, which they are expected to refer to and follow, is provided on the Safety Office website in the sections detailed below.

Anybody and everybody who enters a laboratory where biological work is carried out should be made fully aware of the hazards they may encounter in the area and be given information on what they should and should not do whilst in the laboratory in order to prevent and control any exposure to biohazardous materials.

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11.2 Repairs and Maintenance Work in Biological Laboratories

Entry of maintenance staff and contractors into biological laboratory areas must only be by agreement with those in charge of the area concerned and in the event of an accident only after the area is made safe. One way to control who enters the department including laboratory areas is to adopt a permit-to-work system. This is a well tried and tested system commonly used in industrial settings and building sites to control hazardous activities. If departments were interested in adopting this type of system please contact the Safety Office.

Entry to Class 3 laboratories must be tightly controlled and unauthorised persons should not be able to gain entry except by specific arrangement with one of the authorised laboratory workers and only after the area has been made safe. Workers carrying out repair or maintenance at Class 3 should be accompanied at all times.

In addition, the Head of Department must ensure that all maintenance staff and contractors whose job involves them entering and working in laboratory areas should be provided with information and guidance on the measures they need to take to ensure the safety of themselves and others whilst they are in the laboratory.

11.3 Cleaning of Biological Laboratories

Arrangements should put in place to ensure the safety of cleaners in laboratories.

11.4 Visitors

Only persons who have a valid, laboratory work related reason for entering a laboratory should be given access as a visitor. Casual access, for example by family, friends, office-based colleagues etc, should be discouraged.

Dogs and other pets are not allowed in University buildings, with the exception of assistance dogs. However, assistance dogs must be excluded from entering biological laboratories until risks have been assessed and specific control measures put in place to ensure the health and safety of the animal, and that safety standards in the laboratory are not compromised. The University Biological Safety Officer should be consulted for advice in such cases.

11.5 Children and Young Persons

Children (under 16 years of age) must be excluded from entering all laboratories where biological work is carried out. There may however be some occasions where access by children is required for a specific purpose, for example in the case of organised educational visits and open days. These would be regarded as exceptional cases and

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may proceed subject to agreement of the Dean of Faculty or Head of Department and specific arrangements being put in place to ensure the health and safety of the children whilst visiting the laboratories. The areas should be rigorously cleaned and disinfected and all infectious and potentially infectious material moved or otherwise made inaccessible. The children must be accompanied and supervised at all times when they are in biological laboratories. For group visits the level of supervision must be adequate for the numbers involved.

Young persons (16–18 year olds) who are not employees of the University must be accompanied and supervised at all times when they are in biological laboratories. Young persons on work experience or youth employment schemes and others not directly employed by the University should not work with blood, blood products or pathogens.

12. Monitoring and Inspection

12.1 General

The University has made various arrangements for ensuring the health and safety of its workers and others who may be affected by its activities. There is a need for procedures to be in place to confirm that these arrangements are effective and remain valid. For biological work the arrangements are supplemented by additional measures made at the faculty and departmental level and these are implemented within the various work areas.

12.2 Monitoring and Self-inspection

Monitoring tends to be on an informal basis but it has an important role in everyday activities. All persons with supervisory or managerial roles, and those appointed to safety related roles, should routinely monitor working practices and have a responsibility to identify any instances where the required safety standards are not met and ensure that appropriate corrective action is taken to improve the situation. If they are aware of any safety-related problem in an area for which they themselves are not responsible then they must bring this to the attention of the person whose responsibility it is or to a more senior member of staff.

A series of self-inspection checklists, including one for biological safety as well as an abbreviated, one page version covering most hazards, are available on the Safety Office website under the resources section of the "Training and Resources tab". These checklists can be used on a regular basis as a more formal way of monitoring safety.

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Departments may wish to modify them to better suit the needs of particular laboratories for which they are responsible.

All workers in the University are encouraged to take notice of what is going on around them and report to their supervisor, or to a more senior member of staff, any instances where University policy is not being followed or any other safety-related concern they may have.

12.3 Inspection

Regular inspections will be carried out by the Safety Office and mainly involve observation of facilities and working practices with a view to assessing whether standards are adequate when compared to those required for the particular work activities. The inspections, generally at the departmental, unit or institute level, look at implementation of the health and safety management system to verify whether the documented procedures and arrangements are being followed in practice – in other words, to check that the sentiments and intentions expressed in the various documents actually translate into what is happening in practice.

The Head of Department is responsible for ensuring that regular and systematic local health and safety inspections and audits are carried out in order to scrutinise health and safety standards and the effectiveness of the health and safety management systems in place. Inspections and audits should be recorded and included within the report should be the remedial action that may be required, who is to undertake it and in what timescale. Procedures should be in place to follow up and ensure any recommendations made are carried out.

The findings of audits and/or inspections should be recorded and these should be retained with a record of actions taken to address any recommendations. Interested parties, such as Labour Department Inspectors, the University's insurers or members of the Safety Office, may wish to see these documents and they should be made available on request.

12.4 Review

In order to ensure that health and safety arrangements remain valid it is necessary to undertake periodic reviews that take account of any changes in work activities, any new information on risks or technological advances in particular work areas, management and organizational changes, the results of inspections and audits, and any changes in relevant legislation and best practice recommendations.

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The University Biological Safety Officer is responsible for monitoring changes in legislation and expert guidance relevant to biological work and, where necessary, updating University Biosafety Policy and associated University guidance. Information on any changes shall be disseminated within the University to ensure any amendments required to local arrangements within Faculties and Departments are identified.

13. Frequently Asked Questions

⇒ What is Biosafety (Biological Safety)?

Biosafety is the application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards. Biosafety defines the containment conditions under which infectious agents can be safely manipulated. The objective of containment is to confine biohazards and to reduce the potential exposure of the laboratory worker, persons outside of the laboratory, and the environment to potentially infectious agents. (Definition from Medicine.net)

⇒ Why do we have a Biosafety policy?

The purpose of a policy is to formalize the Universities obligation to ensure that activities involving biohazardous material are conducted safely in accordance with applicable governmental regulations, laws, and guidelines. The policy is intended to ensure standards within Hong Kong University match internationally accepted best practice. It should also assist, support and inform staff, students and visitors enabling them to work more safely with potentially infectious materials or agents.

⇒ What does the policy mean for me?

The policy sets standards for work with infectious agents and potentially infectious materials that the University expects to be maintained. This involves all staff from Deans of Faculties to Research Assistants and Laboratory Aids. The key personnel in promoting a positive culture of safety are the Deans of the Faculties and the Heads of Departments. They have the responsibility of ensuring that any risks to safety and health within their area of responsibility are properly identified and controlled. In practice the duties arising from these responsibilities are often devolved to PI's, Senior Technical staff or Departmental Safety Officers. Whatever your position this policy hopefully clarifies how to manage and carry out work safely that involves infectious agents and potentially contaminated materials.

⇒ What are Biohazardous materials?

This includes all viable infectious, pathogenic, or toxin-producing agents, prions, biologically-derived toxins, or nucleic acid constructs that have the potential to affect the health of humans, animals, plants, or the environment (University of California, Davis, 2008).

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It includes vectors known to carry and transmit infectious agents, infected or potentially infected animals, infectious material, and recombinant DNA capable of producing deleterious effects in humans, animals, plants, or ecosystems "either directly through infection or indirectly through damage to the environment" (George Mason University Biological Safety Manual (February 2007). Fairfax, VA:

<u>http://labsafety.gmu.edu/BHAS-Resources/BiosafetyManual.pdf</u>). Samples from animal and human sources e.g. pathology specimens are also biohazardous as they may be incidentally infected with a viable agent.

⇒ What is meant by a Biosafety Level (BSL)

It is a description of the degree of containment (both procedural and physical) of infectious materials and agents to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment. In Wilson, D.E., & Chosewood, L.C. (Eds.). (2007). Biosafety in Microbiological and Biomedical Laboratories (BMBL). U.S. Department of Health & Human Services. (http://www.cdc.gov/biosafety/publications/bmbl5/index.htm) these are designated from BSL-1 the least stringent to BSL-4 the most stringent. In practice the Biosafety Level specifies a combination of practices and procedures, the facilities and safety equipment required at that level.

⇒ What is Biosafety Level 2?

Specific guidance on what facilities, safety equipment and policies and procedures constitute BSL2 can be found on the Safety Office website or the BMBL publication referred to above. Biosafety Level 2 builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that (i) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; (ii) access to the laboratory is restricted when work is being conducted; and (iii) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

\Rightarrow What is a risk group?

Classification, as defined by the World Health Organization (WHO), describes four risk groups (1-4, 4 being the most hazardous) based upon hazardous agent characteristics. These agent characteristics include the ability to cause disease in a susceptible human or animal host, virulence, route of transmission, and availability to prevent or treat the disease the agent causes. The BMBL classifies agents based upon their potential hazard to laboratory personnel and the environment, which includes the risk to plants. Hong Kong University regards the classification given in the BMBL as authoritative.

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⇒ Where can I find a list of agents classified for their risk?

The Biosafety in Microbiological and Biomedical Laboratories (BMBL). U.S. Department of Health & Human Services. (<u>http://www.cdc.gov/biosafety/publications/bmbl5/index.htm</u>) contains what it terms Agent Summary Statements which include the risk group and an indication of what Biosafety level would be appropriate to handle the organism.

⇒ When does a risk assessment need to be carried out?

All work with virus vectors and micro-organisms of hazard level 2 or 3, must be formally risk assessed and the assessment approved by the Biosafety Committee before the project commences. The University Biological Safety Officer is the point of contact to submit all risk assessments to the Biosafety Committee. In most straightforward cases he/she can give provisional approval for a project which will then be looked at by the whole committee at a full meeting. In the case of more complex assessments and all Class 3 work the whole committee will be circulated by e-mail and consensus arrived at before approval.

A guide on risk assessment and various forms are available on the Safety Office website. These resources are intended to assist in structuring the assessment and thinking through the various issues concerned.

⇒ Can we work with bacteria in an open laboratory?

The answer to this question will depend on the bacteria you wish to use, its route of transmission and the experimental procedures you wish to carry out. Any operations that would generate aerosols, for example sonication, should be contained. Generally operations such as streaking plates can be carried out on the open bench but where the agent can infect by the airborne route it would probably be more appropriate to contain the operation in a Biological Safety cabinet. To answer the question fully a detailed risk assessment might be carried out.

⇒ Does my lab need a code of practice or standard operating procedure?

Hong Kong University Biosafety policy states that each laboratory must have clear documented local rules indicating the working practices that must be followed for activities in that laboratory. Individual workers must have access to and adhere to local rules. The Research Group Leader/Principal Investigator of a given research group, or the supervisor/manager of a unit or work area, is responsible for ensuring local rules are in place and are complied with. These should be tailored for local conditions and activities.

⇒ We want to change the use of a room to work with infectious agents - what should we do?

The Safety Office and the Estates Office should be contacted and a site visit arranged to discuss the issues involved. Particular consideration should be given to the space available, the siting of any safety equipment such as a Biosafety Cabinet (BSC) and the air conditioning/ventilation in a room.

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⇒ I want to work with a virus/bacterium I've never worked with before – what should I do?

There are a number of issues involved in this question including ensuring the facilities available are appropriate and that sufficient training has been undertaken to handle the agent safely. Often the best way of receiving the appropriate training is to spend some time in a laboratory that routinely handles the agent you want to work with. For a more in depth discussion please contact the University Biological Safety Officer. It would also be appropriate to carry out a risk assessment on the work being proposed and the agent itself.

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