UNIVERSITI MALAYSIA SARAWAK

Laboratory Biorisk Management Manual

Faculty of Medicine and Health Science

6th October 2016

Foreword

The Faculty of Medicine and Health Sciences, Universiti Malaysia Sarawak is proud to launch its own Biorisk Management Manual. The development of this manual was part of project (GTRX-14-60789-0) to Dr. Tan Cheng Siang under the Biosecurity Malaysia Enhancement Grant (BMEG) from the Biosecurity Engagement Program (BEP) US Department of State which was executed via CRDF Global.

The Biorisk Management Manual was carefully written by the Faculty's Biorisk Management Manual Committee and was based on the internationally recognized CWA15793 document. The manual provides a management system for both biosafety and biosecurity aspect and hope to help the Faculty of Medicine and Health Sciences to spearhead biorisk management in UNIMAS and beyond.

I believe the launching of our Faculty's Biorisk Management Manual in timely with the global development in biosafety and biosecurity.

TERMS AND DEFINITIONS

accident
unintended event giving rise to harm

audit
systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled
NOTE 1 Independent does not necessarily mean external to the organization. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

biohazard
potential source of harm caused by biological agents or toxins

biological agent
any microorganism including those which have been genetically modified, cell cultures and endoparasites, which may be able to provoke any infection, allergy or toxicity in humans, animals or plants.
NOTE: For the purpose of this agreement prions are regarded as 'biological agents'.

biorisk
combination of the probability of occurrence of harm and the severity of that harm where the source of harm is a biological agent or toxin NOTE The source of harm may be an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorized access or intentional unauthorized release.

biorisk assessment
process of evaluating the biorisk(s) arising from a biohazard(s), taking into account the adequacy of any existing controls, and deciding whether or not the biorisk(s) is acceptable.

biorisk control
actions implementing biorisk management decisions
NOTE: Biorisk control may involve monitoring, re-evaluation, and compliance with decisions.

biorisk management committee
institutional committee of individuals competent in biorisk control, and other representatives as appropriate

biorisk management system
part of an organization's management system used to develop and implement its biorisk policy and manage its biorisks
NOTE 1A: management system is a set of interrelated elements used to establish policy and objectives and to achieve
those objectives.
NOTE 2A: management system includes organizational structure, planning activities (including for example, risk assessment and the setting of objectives), responsibilities, practices, procedures, processes and resources.
Biosafety officer

individual who has expertise in the biohazards encountered in the organization and is competent to advise top management and staff on biorisk management issues.

biosafety
laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release.

biosecurity
laboratory biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release.
NOTE: In the context of this agreement biosecurity is restricted to laboratory biosecurity; laboratory includes animal and manufacturing facilities, and does not include all aspects of biosecurity in the sense of national or regional control measures to prevent the dissemination of alien species and pathogens.

calibration
correlation of the performance of equipment (e.g. readings of an instrument) to a standard

certification
systematic, documented process to ensure systems perform in accordance with available certification standards or applicable validation guidance

community
people outside the workplace potentially affected by the activities of the facility

competence
appropriate education, training, skills and experience

containment
system for confining microorganisms or organisms or other entities within a defined space

continual improvement
recurring process of enhancing the biorisk management system in order to achieve improvements in overall biorisk management performance consistent with the organization's biorisk management policy
NOTE: The process need not take place in all areas of activity simultaneously.

corrective action
action to eliminate the cause of a detected nonconformity or other undesirable situation
NOTE 1: There can be more than one cause for a nonconformity.
NOTE 2: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

decontamination
procedure that eliminates or reduces biological agents and toxins to a safe level with respect to the transmission of infection or other adverse effects

disinfection
process to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms

document
information and its supporting medium
NOTE: The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or a combination thereof.

event
occurrence of a particular set of circumstances

facility
operational unit and associated buildings and equipment used to manage biological agents and toxins
NOTE: This includes the laboratory, together with the supporting infrastructure, equipment and services including ancillary rooms such as airlocks, changing rooms, sterilizing rooms and storage rooms.

genetically modified microorganism
microorganism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

good microbiological techniques
working methods applied to eliminate or minimize exposure to biological agents via e.g. aerosols, splashes, and accidental inoculation

harm
adverse effect on the health of people, animals or plants, on the environment or on property

hazard
source, situation, or act with a potential for causing harm

hazard identification
process of recognizing that a hazard exists and defining its characteristics

incident
event with a potential for causing harm
NOTE 1: An accident is an incident which has resulted in harm.
NOTE 2: An incident where no harm is caused may also be referred to as a "near miss", "near hit", "close call" or
"dangerous occurrence".
NOTE 3: An emergency situation is a particular type of incident.

inspection
conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging

inventory
itemized record of stored supplies of biological agents or valuable biological materials

laboratory
room within a facility, designated for work on biological agents and/or toxins

microorganism
microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material including viruses, viroids, animal and plant cells in culture

nonconformity
non-fulfilment of a requirement
NOTE: A nonconformity can be any deviation from: relevant work standards, practices, procedures, legal requirements, etc.: biorisk management system requirements.

organization
company, corporation, firm, enterprise, authority or institution, or part or combination thereof, whether incorporated or not, public or private, that has its own functions and administration
NOTE: For organizations with more than one operating unit, a single operating unit may be defined as an organization.

personal protective equipment (PPE)
material, including clothing (e.g. gown, gloves, respirators, safety glasses), used to prevent exposure to or contamination of a person by chemical or biological matter

preventive action
action to eliminate the cause of a potential nonconformity or other undesirable potential situation
NOTE 1: There can be more than one cause for a potential nonconformity.
NOTE 2: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

procedure
specified way to carry out an activity or a process

record
document stating results achieved or providing evidence of activities performed

risk
combination of the probability of occurrence of harm and the severity of that harm

risk assessment
process of evaluating the risk(s) arising from a hazard(s), taking into account the adequacy of any existing controls and deciding whether or not the risk(s) is acceptable

safety
freedom from unacceptable risk

sharp
an object having an edge or point that is able to cut or pierce something

standard operating procedure (SOP)

set of written instructions that document a routine or repetitive activity followed by an organization

source
item or activity having a potential for a consequence

toxin
substance, produced by a biological system, which in small or moderate amounts produces an adverse effect in humans, animals or plants. This definition includes substances and materials which may be contaminated with toxins (see also biohazard)

validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

valuable biological materials (VBM)
Biological materials that require (according to their owners, users, custodians, caretakers or regulators) administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, and/or the population from their potential to cause harm. VBM may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, living modified organisms, cell components, genetic elements, and extraterrestrial samples.

verification
confirmation, through the provision of objective evidence that specified requirements have been fulfilled

workplace
any physical location in which work-related activities are performed under the control of the organization
NOTE: When giving consideration to what constitutes a workplace, the organization should take into account the occupational health and safety effects on personnel who are, for example, travelling or in transit (e.g. driving, flying, on boats or trains), working at the premises of a client customer, or working at home.

LIST OF ABBREVIATIONS

AMP	Assessment-Mitigation-Performance
ANSI	American National Standards Institute
BMBL	Biosafety in Microbiological and Biosciences Laboratories
BOMBA	Fire Department
BSC	Biosafety Cabinet
BSL	Biosafety Level
BSO	Biosafety Officer
CBMP	Certified Biorisk Management Professional
CCTV	Closed Circuit Television
CEN	The European Committee of Standardization
COPD	Chronic Obstructive Pulmonary Disorder
CWA	CEN Working Agreement
DBT	Design-Basis-Threat
DNA	Deoxyribonucleic acid
DOSH	Department of Occupational Safety and Health
FMHS	Faculty of Medicine and Health Sciences
GMP	Good Microbiological Practice
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HEPA	High Efficiency Particulate Air
HIV	Human Immunodeficiency Virus
IBC	Institutional Biosafety Committee
IFBA	International Federation of Biosafety Associations
IHR	International Health Regulation
JKKP	Occupational Safety and Health Committee
LMO	Living Modified Organism

MBBA	Malaysian Biosafety and Biosecurity Association
MCA	Material Control and Accountability
MSDS	Material Safety Data Sheet
MTA	Material Transfer Agreement
NRE	Department of Natural Resourse and Environment
NSF	National Sanitary Foundation
PDCA	Plan-Do-Act Check
PI	Principal Investigator
PIM	Potentially Infectious Material
PPE	Personal Protective Equipment
SOP	Standard Operating Procedure
UN	United Nation
UNIMAS	Universiti Malaysia Sarawak
VBM	Valuable Biological Materials
WHO	World Health Organization

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082-662 300

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082-581 999

Main UNIMAS Security Guard Post
082-583 904

UNIMAS CCTV control room
082-581 004

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CHAPTER 1 INTRODUCTION

The purpose of this manual is to provide basic biosafety and biosecurity resource for researchers and staff of the Faculty of Medicine and Health Sciences (FMHS), Universiti Malaysia Sarawak (UNIMAS). It aims to support and encourage their activities in a manner that:

a) protects all FMHS personnel and visitors from laboratory-acquired infections;

b) maintains the security and integrity of specimen and other research materials;

c) provides environmental protection to minimize risks to those outside the laboratory and beyond the confines of the campus;

d) ensures compliance with relevant international, national, and local regulations and guidelines pertaining to biorisk management.

The principle of this manual is to set requirement necessary to control risks associated with the handling, storage and disposal of biological agents and toxins in laboratories and facilities. The biorisk management system described herein will enable FMHS to:

a) establish and maintain a biorisk management system to control or minimize risk to acceptable levels in relation to employees, the community and others as well as the environment which could be directly or indirectly exposed to biological agent or toxin.

b) provide assurance that requirements are in place and implemented effectively.

c) provide a framework for training and raising awareness of laboratory biosafety and biosecurity guidelines and best practices for personnel.

This biorisk management system approach enables FMHS to effectively identify, monitor and control the laboratory biosafety and biosecurity aspects of its activities. An effective biorisk management system approach should be built on the concept of continual improvement through a cycle of planning, implementing, reviewing and improving the processes and actions that an organization undertakes to meet goals. This is known as the PDCA (Plan-Do-Check-Act) principle which also complements the AMP (Assessment-Mitigation-Performance) Model approach to biorisk management (Figure 1).

No single document can address every situation. When additional activity or agent-specific information is required, the Biosafety Officer will assist investigators in developing and implementing appropriate practices to minimize the risk of laboratory infection or environmental contamination. When indicated, the expertise of the Institutional Biosafety Committee or other resources may be called upon for additional input. Principal Investigators are responsible for seeking out these and other resources. They must also ensure that all personnel under their supervision are appropriately trained, informed of applicable regulations and guidelines and that they

are capable, based on academic background and hands-on experience, of working within these regulations and guidelines.

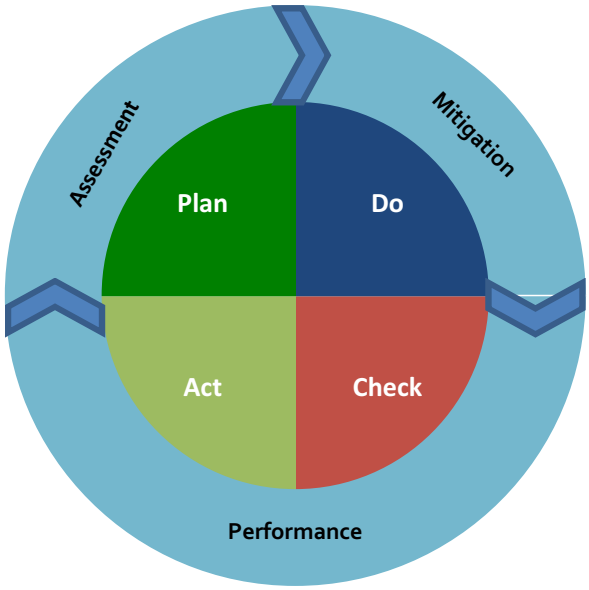

Figure 1 Illustration of Plan-Do-Check-Act Cycle aligned with Assessment-Mitigation-Performance (AMP) Model for Biorisk Management

Plan: Planning, identification of hazard and risk and establishing goals; Do: Implementing training and operational issues; Check: Checking, monitoring and corrective action; Act: Reviewing, process innovation and acting to make needed changes to the management system

CHAPTER 2 BIOSAFETY PROGRAMME

2.1 ROLES AND RESPONSIBILITIES

Each personnel or lab involved in the use of biohazardous materials has a defined degree of responsibility for implementation of the Biorisk Management Programme. Failure of any personnel to recognize this responsibility or to comply with established procedures may face disciplinary action.

2.1.1 Behavioral expectations

All individuals including the PIs should agree to prior to being given access to the laboratory. These behavioral expectations should be reviewed and signed annually.

The 5 Behavioral expectations:

1) I will follow all standard operating procedures (SOPs) to the best to my ability.

2) I will ensure others follow SOPs to the best of their ability.

3) I will report any near misses or incidents.

4) I will report any symptoms which match clinical presentation of pathogens found in the laboratory.

5) I will report any new medical conditions.

2.1.2 Faculty's Management Committee

The Faculty's Management Committee shall take ultimate responsibility for the organization's biorisk management system to ensure that roles, responsibilities and authorities are defined, documented and communicated and to demonstrate its commitment by ensuring the availability of resources to establish, implement, maintain and improve the biorisk management system. The Faculty's Management Committee is responsible to receive biosafety related advices and recommendations from the Faculty's Biosafety Officer and act upon it.

2.1.3 Principal investigator (PI)

The Principal Investigator (PI) is directly and primarily responsible for the safe operation of the laboratory. The PI's expertise and judgment are critical in assessing risks and appropriately applying the recommendations in this manual. Other responsibilities includes but not limited to:

a) Assess the risks of their experiments.

b) Ensure the safe operation of their laboratory.

c) Provide Good Microbiological Practice (GMP) training to his/her personnel.

d) Communicate biorisk and other experimental related risk to his/her staff to the relevant student/staff

e) Ensures the compliance of his/her personnel to FMHS's rules and regulations.

f) Ensures the compliance of his/or project(s) with all applicable state, national and international regulations and guidelines pertaining to biosafety and biosecurity.

g) Register the following experiments with FMHS's Biosafety Officer or IBC:

   i. Recombinant and synthetic nucleic acid activities,

   ii. Work with infectious agents,

   iii. Experiments involving the use of human blood or other potentially infectious material (PIM).

In cases where undergraduate teaching and Elective research is concerned, the lecturer in charge of the practical assumes the responsibility of the PI.

2.1.4 Faculty's Biosafety Officer (BSO)

The Faculty's Biosafety Officer (BSO) shall be appointed by the Vice Chancellor of the University on a 2-year service term. The BSO shall be designated to provide advice and guidance on biorisk management issues. The role and knowledge of the BSO is key to develop, implement, maintain and continually improve a biosafety and biosecurity program based on a management system. The BSO should be competent to perform the role and allocated sufficient time and other resources to do the job effectively

The overall responsibility of the BSO is to monitor the use of biohazardous materials in teaching and research facility at the faculty of Medicine and Health Sciences. The BSO acts as an advisor to the Faculty Management Committee and performs the following functions:

1. To monitor and promote compliance with the established policies and procedures as set out in the national Biosafety Act 2007, and other government and University guidelines related to biosafety.

2. To make recommendations to the Faculty administration on actions and/or policies related to safe utilization of biologically active materials at the Faculty.

3. To develop and recommend policies and procedures to meet the requirements for each biocontainment level as stated in most current version of the national Biosafety guidelines issued by Ministry of National Resources and Environment (NRE).

4. To advise on risk assessment for all proposed work with pathogenic microorganisms, recombinant DNA and human blood, tissues, or fluids and codes of practice.

5. To consult and review all matters pertaining to biosafety and biosafety facilities.

6. To advise on disinfection and waste disposal policy.

7. To prepare contingency plans for action following accidents and incidents involving biological agents.

8. To advise and assist the Faculty Management Committee in investigations following accidents and incidents involving biological agents.

9. To carry out periodic inspections of containments facilities.

10. To monitor the procurement, storage, utilization, and disposal of all biohazardous materials materials including human source tissues, blood and body fluids for both research and teaching facilities, and to recommend and monitor the appropriate safety precautions.

11. To recommend and identify training needs and assist in the development and delivery of biosafety training programmes.

12. To monitor the effectiveness of the biosafety programme and its associated management system on an annual basis.

Criteria of a BSO should include:-

i. At least a BSc (Hons) in Microbiology, Biomedical Sciences or any other relevant discipline.

ii. Minimum of 2 years intensive laboratory experience and familiar with methodology pertaining to handling and manipulation of biohazardous materials.

iii. Familiar with biorisk management system

iv. Well versed in the following documents but not limited to:-

- WHO Biosafety Manual 3rd Edition,
- Biosafety in Microbiological and Biomedical Laboratories 5th Edition (BMBL5) CDC, NIH
- CEN Workshop Agreement (CWA15793:2011 and CWA16393:2012)

v. A valid membership with the Malaysian Biosafety and Biosecurity Association (MBBA) http://www.mbba.org.my/webv/.

vi. Holds a valid Certified Biorisk Management Professionals (CBMP) credential from the International Federation of Biosafety Associations (IFBA). http://www.internationalbiosafety.org/. All fees associated with the certification and recertification of the appointed BSO shall be borned by the Faculty.

2.1.5 Occupational Health Officer

Occupational Health Physician or Occupational Health Nurse shall assume the role as the Occupational Health Officer. Upon the absence of a Occupational Health Physician, the Dean shall in his discretion appoints a Medical doctor or nurse to assume this role. The Occupational Health Officer should what good understanding of the chemicals, biological agents and toxins that are handled within the Faculty. The role of the Occupational Health Officer is to provide input of into the risk assessment from a worker health perspective, advising on first aid/emergency treatment measures and follow-up, liaising with external health care providers, and coordinating medical examinations, surveillance and coordinating vaccination programmes.

2.1.6 Facility Director

The Director, Service Management Division FMHS and Teaching Hospital shall assume the role of the Facility Director with responsibilities relevant to facilities and equipment, with knowledge of laboratory facilities, containment equipment and buildings, coordinating building and maintenance work, liaising with contractors.

The Facility Director may execute his role with the assistance from the Science Officer or Senior Medical Laboratory Technologists.

2.1.7 Science Officer

The Science Officer may be designating the role to assist the Facility Director in ensuring the smooth running of the Research Facility. This role is assumed by the Senior Medical Laboratory Technologist.

The Science Officer is in charge of the security access system of the facility and has the authority to change the pin number when necessary.

2.1.8 Radiation Protection Officer

Any biological work or experimentation utilizing radioisotopes shall be reported to the Radiation Protection Officer for risk assessment and advice.

2.1.9 Employees/ Laboratory Workers

All employees performing work with biohazardous materials must accept a shared responsibility for operating in a safe manner. Ultimately each individual is responsible for his/her own safety. They shall:

1) Ensure that all work is conducted in accordance with established policies and

guidelines described in this document or specific laboratory SOPs;

2) Report all hazardous conditions to the PI and/or BSO;

3) Promptly report any job related injuries, exposures or illnesses to the PI and/or BSO and seek medical treatment immediately;

4) Refrain from operating any equipment or instrument without proper instruction and/or training;

5) Request information and training when unsure how to handle potentially hazardous materials;

6) Wear and maintain appropriate PPE necessary to perform each task;

7) Use engineering controls properly eg. BSC, fume cabinet;

8) Practice Good Microbiological Techniques (GMT).

2.2 FACULTY'S BIOSAFETY POLICY

The Faculty of Medicine and Health Sciences is continually committed to

a) protecting staff, students, contractors, visitors, community and environment from biological agents and toxins that are stored or handled within the facility;

b) reducing the risk of unintentional release of, or exposure to biological agents and toxins;

c) reducing the risk to an acceptable level of unauthorized intentional release of hazardous biological materials, including the need to conduct risk assessments and implement the required control measures;

d) complying with relevant legal requirements applicable to the biological agents and toxins that will be handled or possessed;

e) ensuring that the need for effective biorisk management shall take precedence over all non "health and safety" operational requirements;

f) informing all employees and relevant third parties and communicating individual obligations with regard to biorisk to those groups;

g) continually improving biorisk management performance.

2.3 LEGAL REQUIREMENTS AND SCOPE

All researchers working in the Faculty of Medicine and Health Sciences must conform and comply with the relevant international, national and local biosafety and biosecurity regulations such as but not limited to:

1. The Biosafety Act 2007

http://www.nre.gov.my/English/MediaCentre/Pages/Policies%20and%20Act.aspx

2. The International Health Regulations (IHR) World Health Organization

http://www.who.int/ihr/en/

CHAPTER 3 BIOSAFETY REQUIREMENTS

3.1 WORKPLACE SAFETY AND HEALTH ACT

The Occupational and Health Act 1994 (amendment 2006) [Act 516] under the Department of Occupational Safety and Health (DOSH), Ministry of Human Resources was passed in 1994 and amended in 2006. The Act specifies the workplace safety and health obligations to be fulfilled, as well as responsibilities of every individual in the workplace.

Regulations under Occupational Safety and Health Act 1994 (Act 514) which is relevant to the Faculty are but not limited to:

1) Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations (2013)

2) Occupational Safety and Health (Notification of Accident, dangerous occurrence, Occupational Poisoning and Occupational Disease) Regulations 2004

3) Occupational Safety and Health (Use and Standards of Exposure of Chemical Hazardous to Health) Regulations 2000

4) Occupational Safety and Health (Safety and Health Officer) Regulations 1997

5) Occupational Safety and Health (Safety and Health Committee) Regulations 1996

6) Occupational Safety and Health (Control of Industrial Major Accident Hazards) Regulations 1996

7) Occupational Safety and Health (Employers' safety and Health General Policy Statements (Exception) Regulations 1995

The Occupational Safety and Health Act 1994 (Act 514) and its corresponding Regulations can be downloaded via the official portal of the Department of Occupational Safety and Health, Ministry of Human Resources webpage (http://www.dosh.gov.my/)

3.2 WORK INVOLVING BIOHAZARDOUS MATERIALS

All PIs who plan to use biohazardous agents, animals and transgenic animals are required to complete a thorough project risk assessment before any new research or task is to be implemented. The risk assessment and mitigation procedures should show that the risk can be reduced to an acceptable level. All risk assessment and mitigation procedures shall be approved by the PI and endorsed by the Biosafety Officer and reviewed annually if necessary.

All PIs are accountable for the inventory of the biohazardous agents including toxins in his/her lab and are responsible for ensuring safe operation of the laboratory. The inventory system must be updated at least annually and a biosecurity plan should be developed and implemented to prevent unintended misuse of biological materials.

3.3 RECOMBINANT DNA EXPERIMENTS

All PIs working on recombinant DNA experiments utilizing or potentially be generating a living modified organism (LMO) as stipulated in the Biosafety Act 2007 shall gain approval from the University's Institutional Biosafety Committee (IBC) and shall only commence work once the approval permit is received from The Ministry of Natural Resources and Environment (NRE).

Exemptions are available and PIs are encouraged to read and understand the Biosafety Act 2007 for details.

Nevertheless, higher mitigation procedures may be required when:

1. The expression of DNA sequences derived from pathogenic organisms may increase the virulence of the LMO;

2. Inserted DNA sequences are not well characterized;

3. Gene products have potential pharmacological activity;

4. Gene products code for toxins.

3.4 ANIMALS

All research experiments involving animals must be approved by the University's Animal Ethics Committee and be conducted in an Animal Biosafety Laboratory (A-BSL which offers containment level sufficient for the specific animal involved.

Authoritative references on animal ethics, welfare, work and care can be found in http://www.iacuc.org/index.htm

3.5 HUMAN SUBJECTS/HUMAN TISSUES

All research experiments involving human subjects or human tissues must be reviewed by the Faculty's Ethics Committee and received written approval before commencement.

3.6 TRAINING

Biorisk management training and refresher course shall be conducted by the BSO, internal/external experts or invited trainers.

CHAPTER 4 BIORISK MANAGEMENT

4.1 CLASSIFICATION OF BIOLOGICAL AGENTS

Malaysia has not published any guidelines for the classification of biological agents into risk groups as recommended by the WHO Biosafety Manual 3rd Edition. A guideline from WHO in the classification of biological agents is shown in Table 1.

4.2 PRINCIPLES OF CONTAINMENT

The principle of containment is to keep the agent of interest within a designated area in order to prevent the release of biological agents to the environment or accidental exposure to the user.

Table 1 Classification of Biohazardous microorganisms by risk group

Risk Group 1 (no or low individual and community risk) **A microorganism that is unlikely to cause human or animal disease.**
Risk Group 2 (moderate individual risk, low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
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. Effective treatment and preventive measures are available.
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 preventive measures are not usually available.

4.3 BIOSAFETY LEVELS

Laboratory facilities are designated as basic – Biosafety Level 1, basic – Biosafety Level 2, containment – Biosafety Level 3, and maximum containment – Biosafety Level 4. However, FPSK only house basic BSL2 facility thus, higher containment laboratory might not be discussed in this manual. Please refer to the WHO Biosafety Manual 3rd Edition for further information. However, each Biosafety level may be enhanced with additional features found in higher level containment facility and the term 'plus' or the symbol (+) may be indicated after the actual Biosafety Level (eg BSL2+).

Biosafety level designations are based on a composite of the design features, construction, containment facilities, equipment, practices and operational procedures required for working with agents from the various risk groups. The key requirements of each relevant biosafety level are summarized in Table 2.

Table 2 relates but does not "equate" risk groups to the biosafety level of laboratories designed to work with organisms in each risk group. A summary of the relationship between risk groups to biosafety levels, practices and equipment is summarized in Table 3.

Table 2 Summary of Biosafety Level requirements

	BIOSAFETY LEVEL			
	1	2	3	4
Isolation of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation: — inward airflow — controlled ventilating system — HEPA-filtered air exhaust	 No No No	 Desirable Desirable No	 Yes Yes No/Yes	 Yes Yes Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	No
Anteroom	No	No	Yes	-
Anteroom with shower	No	No	Yes/No	No
Effluent treatment	No	No	Yes/No	Yes
Autoclave: — on site — in laboratory room — double-ended	 No No No	 Desirable No No	 Yes Desirable Desirable	 Yes Yes Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring capability	No	No	Desirable	Yes

Biorisk assessment should take into account the risk group and the following:-

1) Pathogenicity of the organism.

2) Mode of transmission and host range of the organism. These may be influenced by existing levels of immunity in the local population, density and movement of the host population, presence of appropriate vectors, and standards of environmental hygiene.

3) Local availability of effective preventive measures. These may include: prophylaxis by immunization or administration of antisera (passive immunization); sanitary measures, e.g. food and water hygiene; control of animal reservoirs or arthropod vectors.

4) Local availability of effective treatment. This includes passive immunization, post-exposure vaccination and use of antimicrobials, antivirals and chemotherapeutic agents, and should take into consideration the possibility of the emergence of drug-resistant strains.

The assignment of an agent to a biosafety level for laboratory work must be based on a risk assessment. Such an assessment will take the risk group as well as other factors into consideration in establishing the appropriate biosafety level. For example, an agent that is assigned to Risk Group 2 may generally require Biosafety Level 2 facilities, equipment, practices and procedures for safe conduct of work. However, if particular experiments require the generation of high-concentration aerosols, then Biosafety Level 3 may be more appropriate to provide the necessary degree of safety, since it ensures superior containment of aerosols in the laboratory workplace. **The biosafety level assigned for the specific work to be done is therefore driven by professional judgment based on a risk assessment, rather than by automatic assignment of a laboratory biosafety level according to the particular risk group designation of the pathogenic agent to be used**. Thus the assignment of a biosafety level takes into consideration the organism used, the facility available, and the equipment practices and procedures required to conduct work safely in the laboratory.

When the risk assessment suggested the need for Biosafety Level 3 containment, the work must not be carried out within the FMHS facility.

In the event of discovering a novel agent (via routine surveillance screening) of which required a Biosafety Level 3 containment facility or higher, the PI shall:-

1. triple pack and store the agent in a secured freezer or location within the FMHS facility

2. inform the BSO and IBC immediately

3. conduct a thorough biorisk assessment

If the risk of the agent cannot be mitigated with the available controls the agent may be sent to another containment facility with a proper Material Transfer Agreement signed protecting the ownership of the agent. The PI may have the sole discretion not

to transfer the agent to another facility and choose to destroy it by autoclaving if the risk cannot be mitigated using the available controls to an acceptable level.

However, if the PI can demonstrates the feasibility to mitigate the biorisk involved within a Biosafety Level 2 plus facility (BSL2+ or also known as BSL2 enhanced), the work may be carried out but a written permission must be obtained from the Biosafety Officer and the University's Institutional Biosafety Committee.

Table 3 Biosafety Levels practices and equipment

BIOSAFETY LEVEL	LABORATORY TYPE	LABORATORY PRACTICES	SAFETY EQUIPMENT
Basic Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
Basic Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
Containment Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
Maximum containment-Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class 3 BSC, or positive pressure suits in conjunction with class II BSCs, double ended autoclave

4.4 PLANNING AND ASSESSMENT STRATEGIES

Proper planning of work activities is the first critical step in establishing and maintaining the biorisk management system. Hazards must be identified to facilitate proper selection of control measures and determination of risk acceptance. Specific elements of planning and acccessment strategies to ensure proper response and also continuity of operations include: hazard identification and risk assessment, identification of the work program, legal requirements and personnel needs, and emergency plans.

4.4.1 Biorisk Assessment

One universal biorisk assessment methodology is provided in the CWA 15793 (Figure 2) and can be used to conduct both safety and security assessments.

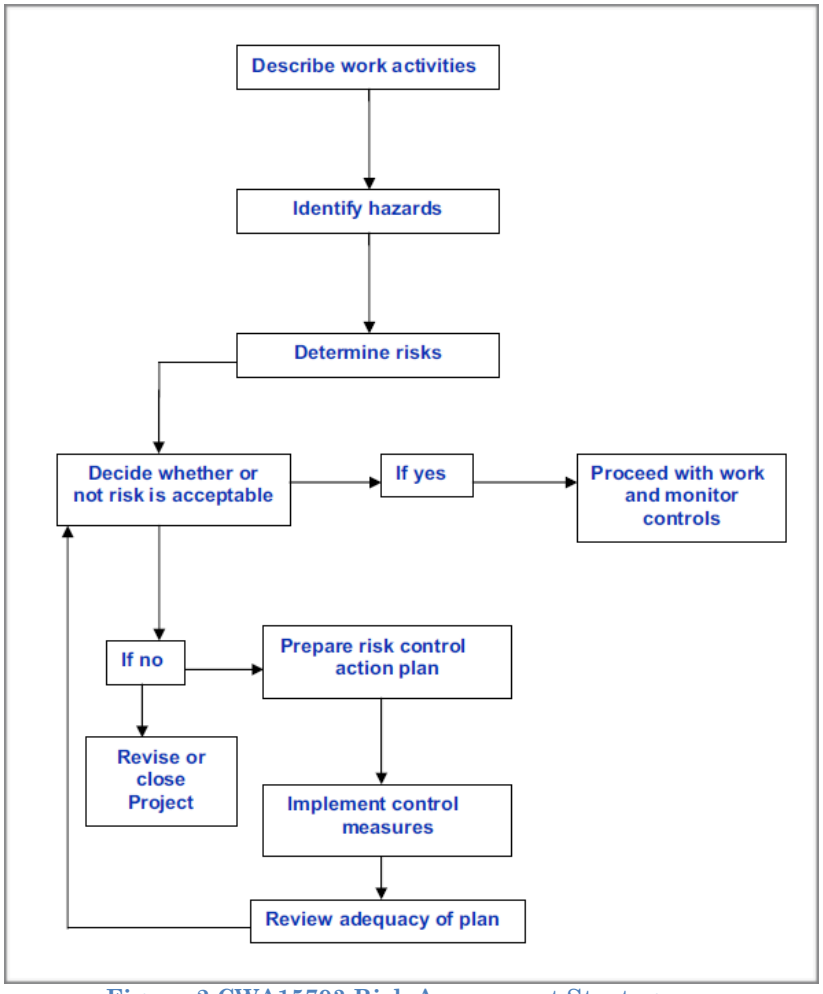

Figure 2 CWA15793 Risk Assessment Strategy

4.4.2 Biosafety Risk Assessment

Laboratories that work with biological agents must manage their safety risks to reduce the potential of accidental exposure of laboratory personnel, the general public, and the environment to biological agents from the laboratory or facility. Accepted biosafety best practices and international guidance span a wide variety of potential biosafety risk mitigation measures. These measures can be categorized as a hierarchy of controls to include substitution, engineering, procedural and administrative controls, and personnel protective equipment. Laboratories have an obligation to their staff and community to perform a risk assessment and choose appropriate mitigation measures to reduce the risk. The determination of which mitigation measures should be used to address the specific laboratory risks present in the work environment should be based upon a thorough a risk assessment. Ideally, a risk assessment should be conducted in a standardized and systematic manner that is repeatable and comparable. A thorough risk assessment should clearly define the risk being assessed and the results should clearly support making risk management decisions. By performing a risk assessment on an operation or event, it is possible to make a systematic evaluation of the exposure and infection potential and the possible consequences. The results of this risk assessment can then inform decisions on how the risk can best be avoided, reduced, or otherwise managed.

The biosafety risk assessment is an evaluation of the potential of an accidental exposure to or release of a biological agent (likelihood) and the subsequent severity of that exposure or release (consequences). The risk assessment process quantifies the risks that exist in a laboratory, and based on likelihood and consequence, allows for laboratory management to prioritize and determine which risks will/can be mitigated and to what degree. A repeatable, structured, analytical process should be identified and documented that can identify the risks associated with identified hazards and how those risks affect laboratory workers, the community, and the environment. Table 1 lists relevant factors to consider when conducting a facility biosafety risk assessment; however, not all of these factors will impact risk in the same manner.

Table 4 Facility-Level Biosafety Risk Assessment Factors

Identify Risks and Stakeholders To Be Assessed	Laboratory Workers • Researchers, Technicians etc • Custodial Staff • Vendors, Service Engineers Accidental Exposure to Community Accidental Exposure to Animal Community Potential For Secondary Exposure to Human or Animal Community
Determine Likelihood	Laboratory Procedures Route of Infection • Inhalation • Ingestion • Direct Contact • Percutaneous • Vector-Borne Infectious Dose Prophylaxis or Vaccine Availability Host Immune Status Personnel Competency
Consequences of Disease	Agent Properties • Morbidity • Mortality Consequence Mitigation Measure Availability • Therapeutics • Vaccines Potential for Secondary Transmission • Communicability • Transmissibility
Characterize the Risk	Risk Evaluation • Not Tolerable • Tolerable • Acceptable Available Risk Reduction Strategies • Mitigation Measures (Facility and Equipment Upgrades, Adapted Practices)

The selected risk assessment method should directly support the characterization, determination and ultimate acceptance of the (mitigated) risk. A separate assessment should be conducted for each work process or procedures and agent used; however, data collected for each work process can support many assessments to avoid misuse of resources and redundant efforts. The results of the assessments should be used to prioritize risks, evaluate the risk tolerance for the organization, and to determine what risk mitigation measures should be implemented to reduce risk to acceptable levels. After defining and implementing appropriate control measures, the identified risks and controls should be reviewed to confirm proper implementation provides system improvements.

4.4.3 Biosecurity Risk Assessment

Facility-specific biosecurity risk assessments follow the same principles outlined above for biosafety, but also are required to ensure adequate security measures are in place to reduce the risk of the theft and misuse of biological agents. The objective of a biosecurity risk assessment is to develop a strategy to manage biosecurity risk, including the likelihood of theft of a biological agent, and the severity of the consequences associated with an attack by that agent. Based on the risk identified, the vulnerabilities in a facility's current biosecurity program can be identified and adapted to ensure unacceptable biosecurity risks are reduced to levels deemed acceptable by facility stakeholders. The risk assessment should also include a clear definition of the threats the system is designed to protect against. These threats should be articulated in a Design Basis Threat (DBT) statement that details the threat and clarifies the mission and performance requirements of the physical security system. Relevant factors to consider when conducting a facility biosecurity risk assessment are listed in Table 5 however, not all of these factors will impact risk in the same manner.

Table 5 Facility-Level Biosecurity Risk Assessment Factors

Characterize Assets	Identify Malicious Use Properties of the Assets (Biological Agents)
Develop Design Basis Threat	Determine Which Assets Will be Assessed Determine Which Adversaries Will be Assessed • Characterize Threats (e.g., adversary type, capabilities and methods, motivation) Determine Which Scenarios Will be Assessed • Specify characteristics of event
Evaluate Scenarios	Assess Likelihood and Consequences of Malicious Use Assess Adversaries (Threat Assessment) Assess System Performance Identify and Assess Vulnerabilities
Characterize the Risk	Risk Evaluation • Not Tolerable • Tolerable • Acceptable Available Risk Reduction Strategies • Mitigation Measures (Facility and Equipment Upgrades, Adapted Practices) • Analysis of Alternatives • Cost-Benefit Analysis

In summary, when conducting biorisk assessments it is important to acknowledge that while biosafety focuses on keeping the workers, human and animal community safe, and biosecurity focuses on keeping the valuable assets inside the facility secure, these two goals might not always be synergistic. It is important to have both aspects in mind when deciding upon a relevant biorisk management strategy and actual mitigation measures.

4.4.4 Laboratory Emergency and Incident Planning

Even the most well prepared laboratory may experience accidental or intentional incidents or emergencies such as fire, biological release, chemical spill, or minor work place injuries despite existing prevention or mitigation measures. Effective incident response is a mitigation strategy that may reduce the consequences from these unknown events through planning, and preparing for potential incidents, as well as detecting, communicating, assessing, responding to and recovering from actual events. Laboratories should have a documented contingency plan for incident or emergency identification and response. Plans should be developed by the stakeholders and agreed upon by the PI.

Planning considers the potential incidents and designates resources to respond effectively and mitigate adverse effects. These potential incidents should take into account the risk assessment for an individual laboratory area and the facility as a whole. Common potential laboratory incidents to be included in a facility emergency and incident plan include, but are not limited to:

- Puncture wounds, cuts, needle stick, bites and abrasions;
- Personnel exposure to potentially infectious materials;
- Broken containers and spilled infectious substances;
- Biohazard spill outside primary containment (biosafety cabinet, centrifuge);
- Fire and natural disasters;
- Security breaches or incidents
- Incidents involving malevolent human adversaries (crime, arson, terrorism, vandalism, civil disobedience)

Acquisition of resources, storage, and equipment, and provision of personnel training and facility drills is essential in preparing for and managing an incident or emergency. FMHS shall furnished each laboratories with first aid kit, fire extinguisher, spill kit, burn kit and other relevant PPE to ensures appropriate emergency response can be executed during an actual accident/incident.

Table top exercise with the relevant first responder agencies such as the Fire Department should be carried out regularly.

Drills and exercises can also be used in the planning and preparation stages to test the

responses to simulated incidents or emergencies. They can help identify gaps and other improvement opportunities. Plans should be reviewed and updated at least annually incorporating the information garnered through drills and incident reports and investigations. Plans should take into consideration the steps between event occurrence and identification and reporting. A standard reporting chain should exist to facilitate reporting. Incident report forms are available to provide an opportunity for investigation, root cause analysis, corrective action, and process improvement.

CHAPTER 5 ENGINEERING CONTROLS

Engineering controls are tools or equipment that provides protection to the specimen, operator and the environment when used correctly. Examples include biological safety cabinets, autoclaves, sharps containers, personal protective equipment (PPE). Correct usage is critical. Engineering controls should never be used in place of protective behavior or administrative controls.

5.1 CLEAN BENCHES

Clean benches utilize HEPA filtered laminar flow directed over the product towards the user. There are horizontal and vertical laminar flow benches which offer only product protection. The horizontal laminar flow clean benches has large opening without window sash and allows the use of small equipment such as a microscope within the horizontal laminar flow cabinet. The vertical laminar flow cabinet comes with a window sash and the use of small equipment is limited.

Clean benches are NOT BIOSAFETY CABINETs and should only be used with non-hazardous and non-biohazardous work only.

5.2 BIOLOGICAL SAFETY CABINETS

Biological safety cabinets, also known as tissue culture hoods, are one of the most important engineering controls. Proper use provides a high level of containment that protects the operator from exposure while providing some protection from contamination of the material being handled within the work volume.

Biological safety cabinets are designed to contain aerosols generated through the use of laminar air flow and high efficiency particulate air (HEPA) filtration. Three types of biological safety cabinets (Class I, II and III) are used in laboratories. Open-fronted Class I and Class II biological safety cabinets are partial containment devices which provide a primary barrier offering significant levels of protection to laboratory personnel and to the environment when used in combination with good laboratory technique.

The Class I biological safety cabinet is suitable for work involving low to moderate risk agents, where there is a need for containment, but not for product protection. It provides protection to personnel and the environment from contaminants within the cabinet but does not protect the work within the cabinet from "dirty" room air.

The Class II biological safety cabinet protects the material being manipulated inside the cabinet (e.g., cell cultures, microbiological stocks) from external contamination. It meets requirements to protect personnel, the environment and the product. There are three basic types of Class II biological safety cabinets: Type A, Type B and 100% Exhaust. The major differences between the three types may be found in the percent of air that is exhausted or recirculated, and the manner in which exhaust air is removed from the work area.

The gas-tight Class III biological safety cabinet, or glove box, provides the highest attainable level of protection to personnel, the environment and the product. It is the

only unit which provides a total physical barrier between the product and personnel. It is for use with high risk biological agents (eg. Ebola virus) and is used when absolute containment of highly infectious or hazardous material is required.

It is important to note that horizontal laminar flow benches must not be utilized for work with biohazardous or chemically hazardous agents. These units provide product protection by ensuring that the product is exposed only to HEPA-filtered air. They do not provide protection to personnel or the ambient environment.

Proper operation and maintenance of a biological safety cabinet is essential for effective protection to be provided. Biological safety cabinets should be serviced and certified annually by a NSF certified service engineer to NSF/ANSI 49 standard or equivalent for the BSC.

5.3 AUTOCLAVES

Autoclaves are pressurized equipment used for heat sterilization. The autoclaving process commonly use steam heated to 121°C, at 15 psi above atmospheric pressure with the holding time of 15 minutes. Autoclaves are generally used to sterilize instruments, media and glassware, and to decontaminate biohazardous wastes prior to disposal.

There are two models of autoclave in FMHS, the side loading STERIS AMScoLab 110 and the top loading TOMY SS-325. The STERIS AMScoLab 110 model should only be operated by the Laboratory Attendant while other users may make use of the TOMY SS-325 after being trained by a competent personnel such as the BSO, PI, Science Officer and Laboratory Attendant.

As an autoclave uses saturated steam under high pressure to achieve sterilizing temperatures, proper use is important to ensure operator safety. Appropriate personal protective equipment must be worn when operating autoclaves and when handling potentially infectious materials to be autoclaved.

Preventative maintenance and quality control checks should be done to ensure proper performance of the equipment.

When necessary, spore strips containing *Bacillus stearothermophilus* can be included in an autoclave cycle as a biological control and assayed according to the manufacturer's instruction to test for the effectiveness of the autoclave.

All autoclaves must be serviced and certified by the Occupational Safety and Health Committee (aka Jawatankuasa Kesihatan dan Keselamatan Pekerjaan [JKKP]), Department of Occupational Safety and Health, Minstry of Human Resources. The servicing and and certification work is the responsibility of the Risk Management Committee (Jawatankuasa Pengurusan Risiko, UNIMAS).

5.3 OTHER SAFETY EQUIPMENT

a. Safety centrifuge cups and safety blenders are enclosed containers designed to prevent aerosols from being released during centrifugation or homogenization of infectious material.

b. Sharps containers or devices with engineered sharps injury prevention features are engineering controls used for safe handling of sharps for prevention of percutaneous injuries.

CHAPTER 6 ADMINISTRATIVE CONTROLS

Administrative controls are important in laboratory safety because they stipulate behaviors and actions that apply to and protect all members of the laboratory staff. They are also an important means of evaluating compliance with regulatory requirements.

Administrative controls include:

- personnel management
- placement of proper signs and labels in and about the laboratory
- medical surveillance programs,
- performance of training,
- laboratory inspections,
- development of standard operating procedures and the establishment of sound safety attitudes.

6.1 PERSONNEL MANAGEMENT

6.1.1 Personnel recruitment

Personnel including staffs and students working on pathogenic organisms and chemicals should have no criminal record and mental health condition.

6.1.2 Risky behavior

Personnel exhibiting abnormal behavior, which poses an unacceptable risk to self, others sharing the laboratory, the community or environment should be reported to the PI and BSO and referred to the Faulty's Management Committee for action.

6.2 SIGNS AND LABELS

6.2.1 Signage

a. A biohazard label is required for all areas or equipment, which contains biohazardous or toxic agents. The appropriate place for posting the label is at the main entrance door(s) to laboratories, on equipment like refrigerators, incubators, transport containers, and/or lab benches.

b. Each laboratory must have a sign at the entrance of the room that provides safety information to visitors and service personnel.

c. Entrance to laboratories that handle infectious or potentially infectious materials such as human blood must be posted with a BSL2 biohazard sign that contains the

universal biohazard symbol, the legend "Biohazard" Biosafety Level, Responsible Investigator and Emergency call number (refer Figure 2).

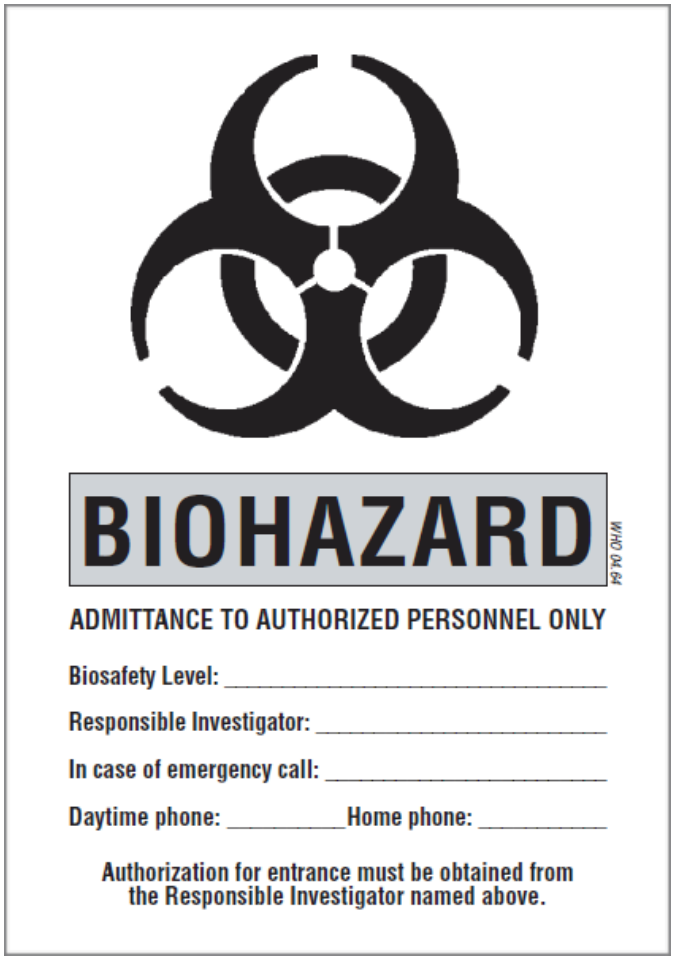

Figure 2 Door Biohazard Signage

6.2.2 Internal Laboratory signage

a. Room signage must contain information on all laboratory hazards in use within the laboratory (carcinogens, acutely toxic agents, biohazards, radioactive materials etc.), specific personal protective equipment (PPE) needed in the lab as well as the name and phone numbers of the principal investigator or other responsible person.

b. Certain areas and pieces of equipment within a laboratory may also require signs. Refrigerators, freezers, cabinets and other storage facilities require the biohazard symbol whenever used to store infectious agents of Risk Group 2 or higher or human blood or blood products, unfixed tissues, cell or organ cultures, body fluids or excreta.

6.3 MEDICAL SURVEILLANCE

Medical surveillance consists of preventive approaches and early diagnosis and treatment to reduce the consequence of an exposure. The need of having a medical surveillance should be discussed with the BSO and occupational health officer.

6.3.1 Immunizations

Employees shall be vaccinated against the known biohazardous agent if effective vaccine is available. Those working with body fluid should at least be immunized against Hepatitis B virus. The PI should factor in the cost of vaccination in the research grant.

6.3.2 Pregnancy

Exposure to certain infectious agents may adversely affect a foetus during pregnancy if the mother is infected with the agent. Therefore, if pregnancy is possible while you are working in an infectious disease laboratory or laboratory engaged in work with infectious agents you should consult your PI. Women that are pregnant or become pregnant are encouraged to inform their respective PI.

All staffs are urged to discuss exposure issues with their principal investigators regarding associated risks of research being conducted during pregnancy.

6.3.3 Medical Screening

Medical screening is essential either done periodically or on demand post-exposure. Periodic screening is important if the biological agent may not cause immediate symptoms such as brucellosis. The PI should factor in the cost of medical screening in the research grant proposal.

6.4 TRAINING

Good microbiological and laboratory practices are essential for a safe work environment. The purpose of training is to provide the understanding, technical knowledge and tools to the laboratory personnel to improve his or her daily laboratory safety practices.

All staff working in laboratories should undergo safety trainings based on their job scope and work hazards.

At the minimum, all personnel working with biological materials should be trained in the following areas prior to the start of their experiments:

- Knowledge of the Biosafety Manual and SOPs;
- Experimental procedures to be used;
- Decontamination and spill clean-up procedures;

• Safe handling methods for any infectious agent and/or recombinant DNA they might be handling;

• Proper methods for transporting infectious agents and other biohazardous materials.

In addition, they should receive adequate laboratory specific training from the Principal Investigator (PI) on:

- good laboratory and practices as applicable;

- site specific information on risks, hazards and procedures;

- laboratory or environment specific BSL-2 procedures as applicable.

The PI is responsible for ensuring that laboratory personnel in his/her laboratory receive proper training in the biohazards and controls specific to his or her laboratory and the safe conduct of the experimental procedures to be used.

6.5 INSPECTIONS

PIs should develop a system for internal audit to ensure that they have an appropriate safety management system in place for a safe laboratory working environment.

The minimum recommended checklist should be based on the WHO "Laboratory Biosafety Manual, 3rd edition" or its derivatives

Inspections and audits should be carried out periodically by the BSO. The BSO may with his/her discretion request each laboratory to carry out an internal audit and submit an audit report to the BSO for filing.

6.6 STANDARD OPERATING PROCEDURES (SOPs)

Standard Operating Procedures, (SOPs), are developed to establish a consistent, repeatable method for performing common, repetitive tasks. In practice, any procedure to be conducted by more than one personnel shall have a written SOP. Such tasks have been performed many times and most of the common errors and unsafe practices have been discovered and corrected. The set approach and methods presented in the SOP ultimately enhance both the efficiency and the safety of the procedure.

SOPs should be kept updated by routine evaluation and validation. Laboratory personnel should be alert for ways to improve the SOPs in use and to ensure that demonstrated improvements are incorporated into the documents.

CHAPTER 7 BIOSECURITY PROGRAMME

7.1 MATERIAL CONTROL AND ACCOUNTABILITY

When properly designed and implemented, inventory management systems can assist bioscience facilities in understanding, managing, optimizing, and securing flows of materials (including biological materials, reagents, consumables, supplies, etc.) into and out of the facility. An inventory management system will help enable the facility to monitor supply levels and order new supplies when needed while avoiding unnecessary costs or waste generation.

Laboratories that work with biological agents and/or toxins should develop a system to manage and oversee its inventory of these materials. This inventory may be integrated into a broader inventory of biological materials, reagents, supplies, and other property stored and used at the facility. A designated person should be assigned responsibility for overseeing the inventory. The level of oversight and access control imposed on biological agents and toxins, and associated inventory information (such as storage locations, quantities, etc.), should be based on a risk assessment that includes consideration of both safety and security, as well as any applicable laws, regulations, or policies.

In addition to helping better manage facility resources and improve overall facility performance and efficiency (e.g., by helping to better control the quantities of various supplies maintained on site), the inventory helps form the basis for material control and accountability (MCA) measures to help oversee the storage and use of biological agents and toxins, as well as other valuable biological materials.

The objectives of MCA are

- to establish internal oversight of biological agents and toxins,
- to discourage theft and/or misuse,
- ensure traceability and continuity of research in the absence of researcher (eg. resignation, retirement, death)

The inventory in general, and particularly the inventory of biological agents and toxins, should therefore be current, complete, accurate, and updated regularly to account for changes in inventory levels. Those personnel assigned responsibility for assembling and/or maintaining the inventory should ensure the inventory information meets these basic conditions. Based on risk, the facility should determine and document what type and level of information should be captured for each item. The following criteria/data but not limited to may be recorded.

- Name of agent/toxin;
- Passage number;
- Characteristics (e.g., strain designation, GenBank Accession number;
- Quantity acquired (e.g., containers, vials, tubes);

- Initial and current quantity amount (e.g., milligrams, milliliters);
- Date of acquisition;
- Source of acquisition;
- Storage location (e.g., building, room, and freezer);
- When removed and/or returned from storage and by whom;
- Purpose of use;
- Transfer records (e.g., name and quantity of agent, date of transfer, name of sender and recipient);
- Notification of theft, loss, or release records;
- Destruction records (e.g., name and quantity of agent, date, by whom);
- What training is provided to ensure compliance with the inventory management system?;
- Who is responsible for MCA (e.g., accountable individual for each item in the inventory: updates to the inventory system to include use, transfers and destruction);
- What are the inventory reconciliation processes (e.g., frequency of auditing, reporting and resolving discrepancies)?;
- How are materials handled and stored (e.g., appropriate temperature control, prevention of overcrowding, well organized, shelf-life management)?;
- Are inventory locations minimized and provided adequate protection so that only authorized personnel have access?;
- How is information protected?
- How are materials from suppliers validated?
- Are materials clearly labeled and tracked?

7.2 MATERIAL TRANSFER AGREEMENT (MTA)

No Valuable Biological Materials (VBMs) shall be shared/given to other institution outside of FMHS, UNIMAS without a MTA. The MTA should be signed by the sending researcher and endorsed by the Dean/Deputy Dean of FMHS and signed by the receiving scientist and endorsed by the receiver's Head of Institution.

A copy of the MTA should be kept by the Deputy Dean (Postgraduate and Research) Office for record.

7.3 PHYSICAL SECURITY SYSTEM

Physical security countermeasures are used to prevent unauthorized access from outside adversaries (i.e., those who do not have a legitimate presence in the facility and harbour malicious intent such as criminals, terrorists and extremists/activists) and also minimize the threat from insiders (i.e., those who have a legitimate presence in the facility such as employees and approved visitors) who do not require access to a particular asset. Physical security systems promote not only biosecurity objectives, but directly support biosafety by limiting access to the laboratories and other potentially hazardous areas. An effective physical security system incorporates a variety of elements to enhance a facility's capability to detect, assess, delay, respond to, and recover from a security incident. These elements include establishing boundaries, access controls, intrusion detection and alarm assessment, as described in more detail below, and are typically used in a graded manner. A graded protection system is achieved by increasing security incrementally and forming concentric layers of protection around the facility's assets in a risk-based manner. The highest level of protection should be given to those primary assets whose loss, theft, compromise, and/or unauthorized use will most adversely affect international or national security, and/or the health and safety of employees, the public, and the environment. In addition, these elements are selected and implemented following a site-specific biosecurity risk assessment to ensure that all elements are practical, sustainable and commensurate with identified risks.

7.3.1 Access Controls

The goal of an access control system is to allow authorized persons to enter secure areas, and prevent or delay the entry of unauthorized persons into secured areas. Access controls provide reasonable assurance that only authorized personnel are allowed to enter a restricted area. The type and number of controls depend on the level of security required. Access can be controlled with a variety of unique items (e.g., badges, physical or electronic keys, knowledge (code), biometrics). These items can be used in combination or sequentially to increase the probability that and individual is indeed authorized. Sharing of unique credentials is prohibited. Prior to granting an individual access to the laboratory, an assessment should be made to determine wether that person has demonstrated a need and received authorization for access.

The research facility of FMHS is protected by a two-tier system; password and card access systems. The access to the corridor requires a password which shall be given to the authorised personnels. The access to individual laboratory is protected by the card access system. To ensure the functionality of the card controlled access system, all valid laboratory users shall have the access to gain admission into the research facility.

As all laboratories within the facility house common-use equipment, all valid laboratory users shall have access to all laboratories during official office hour unless stated otherwise by the Faculty' Management Committee or justtified otherwise based on the PI's risk assessment.

- Undergraduate Elective 1 students is encouraged to make use of the teaching laboratory for their research work. However, their use of the research facility is

permitted with a written consent from the respective laboratory manager or PI in charge of the laboratory. Elective 1 students must always be supervised by a competent personnel (eg. PI, Medical Laboratory Technologists, postgraduate students etc)

- Tailgating is prohibited to ensure each individual presents their own unique identifier for access.

- Visitors access:

    a. All short term visitors such as official visitors and vendors registered with the Main Security Post with the appropriate credential tag may gain admission to the laboratory provided that they are escorted by a valid laboratory user.

    b. All mid- to long-term visitors (outside of UNIMAS) such as research partners, collaborators, exchange students etc must apply for access permission from the Facility Director. The PI shall have the responsibility to apply for access permission.

    c. UNIMAS researchers including postgraduate students from outside of FMHS who wished to make use of FMHS research facility is required to have permission from the laboratory PI and accompanied by a registered laboratory user. Mid to Long term or project based access will require permission from the Facility Director.

- In case of emergency, master access cards are available from the Dean's Office, Director's Office and the Science Officers in charge of the research facility.

7.4 AFTER HOUR WORK

After-hours work is defined as work conducted after the national legal working hours (excluding lunch break), weekends and public holidays.

a. If experimental work must be conducted after office hours, the PI or other lab personnel should be informed;

b. Certain types of work may not be undertaken outside of normal working hours, for example, working with highly toxic chemicals or hazardous biological materials. The PI should identify the activities that cannot be performed outside of normal working hours;

c. If experiments are to be run unattended overnight, it should be accompanied with a note containing information of the biological/chemical hazards involved, name of experimenter and contact number in case of an emergency;

d. Carrying out experimental laboratory work alone after hours is strongly discouraged. There should preferably be a "buddy-system" when work is to be carried out during the after-work hours. Buddy must be either affiliated with FMHS or a registered laboratory user.;

7.5 TRANSPORTATION AND SHIPPING

When not properly packaged or contained, infectious substances can pose both a safety and security hazard to the public when transported outside of the laboratory. Many countries have strict regulations that govern the transport of infectious substances on roadways, through the air and in other public venues. There are also international regulations and standards such as the International Air Transport Association (IATA) that apply when transporting materials across international borders. In the event that local or city regulations regarding shipment of infectious substances exist, a risk assessment of the material being shipped should be performed and considerations for packaging should made in accordance with nationally or internationally accepted practices. There may also be additional requirements to consider if using a refrigerant. In addition, most airlines follow strict international rules when accepting dangerous goods including infectious substances for transport. Fortunately, most countries, airlines and other carriers follow the same set of international guidelines published by the United Nations (UN) for the safe transport of dangerous goods. It is the policy of the Faculty of Medicine and Health Sciences to strictly adhere to all applicable standards when transporting infectious substances both domestically and internationally, namely the WHO Guidance on Regulations for the Transport of Infectious Substances. General steps for shipping include:

1. Classify - determining whether your shipment is a regulated dangerous good or not; Category A, Category B, exempt human/animal specimen, etc.

2. Identify - selecting a proper shipping name for your shipment. All dangerous goods must be assigned a proper shipping name and United Nations (UN) Identification number. These names and numbers are standard throughout the world.

3. Package - infectious substances have specific packaging requirements that include a triple package concept: a leak-proof primary, leak-proof secondary, sufficient absorbent, and sturdy outer packaging.

4. Mark and Label – proper marking and labeling helps identify the contents and describe the hazardous nature. The marks and labels required by international dangerous goods shipping regulations are the same in every country. Irrelevant marks and labels should be removed from any reused packaging.

5. Document - several international standardized documents are designed to accompany shipments of dangerous goods. The following documents may be necessary for shipments depending on the dangerous good, the mode of transport, and the destination:

    - Shipper's declaration for dangerous goods

    - Pro-forma invoice listing details about the shipment, contents, number of packages, etc.

    - Air waybill

- Import and/or export permits

Packing of dangerous goods may require a certified packer. The best approach is to engage a professional courier company such as World Courier (M) Sdn Bhd which will pack your VBM to international standard, prepare all documentations including AirWay Bill and ship it at from your doorstep for a fee.

CHAPTER 8 GOOD MICROBIOLOGICAL TECHNIQUES

Human error, poor laboratory techniques and misuse of equipment cause the majority of laboratory injuries and work-related infections. This chapter provides a reference of methods, practices and technical SOPs that are designed to avoid or minimize the most commonly reported hazards.

8.1 GOOD LABORATORY PRACTICES

a. Human factors and attitudes are important elements for considerations of biosafety in the laboratory. Factors compromising safety include:

- The lack of accident perception
- Inflexibility of work habits, that tends to preclude preventative action when an accident situation is recognized
- Working at an abnormal rate of speed
- Intentional violations of regulations
- Performance of routine procedures such as diluting and plating cultures is the most frequent task being performed at the time of laboratory accidents.
- Working when one is very tired
- Working at a disorganized and crowded laboratory bench

b. Each employee working with biohazardous agents must be aware of the importance of the proper attitude in preventing accidents in the laboratory.

c. Prudent practices and good technique are of primary importance in laboratory safety.

Both are based on sound technical knowledge, experience, common sense and an attitude of courtesy and consideration for others. At a minimum, the Seven Basic Rules of Biosafety (

Table 6) should be the basis of any personal laboratory work ethic:

Table 6 Seven Basic Rules of Biosafety

1.	Do not mouth pipette.
2.	Manipulate infectious fluids carefully to avoid spills and aerosol production.
3.	Use needles, syringes and other "sharps" carefully to avoid self-inoculation; and dispose of sharps in puncture-resistant and leak-proof containers.
4.	Use personal protective equipment such as laboratory coats, gloves and eye protection.
5.	Wash hands following all laboratory activities, following the removal of gloves, and immediately following contact with infectious materials.
6.	Decontaminate work surfaces before and after use and immediately after spills.
7.	Do not eat, drink, store food, apply cosmetics or smoke in the laboratory.

8.2 HOUSEKEEPING AND PERSONAL HYGIENE

Well-defined housekeeping procedures and schedules are essential in reducing the risks associated with working with pathogenic agents and leads to safe accomplishment of the research program.

Injuries and exposures are more likely to occur in poorly maintained, disorderly work areas than in neat, well-kept spaces. For those with the luxury of unshared work space, personal safety is greatly enhanced by keeping that space neat, clean and orderly. More often than not, work space is shared with others and good personal housekeeping in the laboratory becomes a cardinal rule. Leaving behind a jumbled mess after work exposes others to risks of which they may have little or no knowledge. In shared spaces, consideration for others and cleaning up after oneself is essential for maintaining a safe working environment.

8.2.1 Objectives of Housekeeping

a. To provide an orderly work area conducive to the accomplishment of the research program

b. To get rid of physical clutter that could interfere with the activities of laboratory personnel at a critical moment in a potentially hazardous procedure

c. To provide a work area that is free of physical hazards injury or background contamination

d. To prevent the accumulation of materials from current and past experiments that constitutes a hazard to laboratory personnel.

e. To ensure that locations of various hazards will be known

f. To prevent the creation of aerosols of hazardous materials

g. To prevent the accumulation of organic debris that may:

- harbor microorganisms that are potentially threats
- enhance the survival of microorganisms inadvertently released in experimental procedures.
- hinder penetration of decontaminates.
- be transferable from one area to another on clothing and shoes.
- with sufficient buildup, become a biohazard as a consequence of secondary aerosolization by personnel and air movement
- cause allergenic sensitization of personnel (e.g., to animal dander).

8.2.2 Housekeeping procedure

a. Housekeeping tasks should be carried out by lab personnel on an individual basis for their immediate work areas and on a cooperative basis for areas of common usage.

b. Housekeeping chores, both individual and cooperative, should be performed on a periodic basis. Routine housekeeping will provide a work area free of significant sources of background contamination.

c. Areas for which housekeeping should be carried out include but are not limited to:

- Corridors
- Lab Entrances and Exits
- Aisles
- Work Benches
- Floors
- Lab Equipment Cleanup
- Biological Safety Cabinets
- Lab reagents storage areas
- Refrigerators
- Cold Rooms
- Deep Freezers
- Incubators

- Waste Storage areas
- Cryogenic tanks
- Work Surfaces
- Lab SOPs

d. Housekeeping tasks should be assigned to personnel who are knowledgeable of the lab environment.

e. Keeping a housekeeping tasks schedule helps to ensure that work in the lab will not be interrupted.

f. Principal Investigators should carry out periodic inspections of the lab to assure compliance.

8.2.3 Good housekeeping practices

a. All areas of the laboratory must be kept clean and orderly. Keep the area as clean as the work allows throughout the day and all working surfaces should be decontaminated and cleaned at the end of each work day.

b. Stock solutions of disinfectants e.g. 70% ethanol, 10% household bleach should be maintained at each bench top and biological safety cabinet work area.

c. Shared workbenches or lab space should be cleaned prior to leaving it for the next user as a common courtesy.

d. Keep floors clean and free of tripping hazards or clutter. Unavoidable wirings on the floor should be securely tapped on the floor using a suitable masking tape.

e. Keep stairways, hallways, passageways/aisles and access to emergency exits dry and free of obstruction.

f. Store items so they do not block access to the fire extinguisher(s), safety equipment, electric panel boxes, or other emergency items such as an eyewash or safety shower.

g. Do not allow combustible material such as paper, cardboard boxes, or pallets to accumulate. Do not place these materials in hallways.

h. Minimize extraneous supplies and equipment. To the extent possible, restrict all work areas to only those items needed for the immediate experimental procedure.

i. Do not clutter fume hoods or biosafety cabinets with unnecessary items. The safety of these workspaces and the ventilation provided is compromised when excessive items and equipment are kept in this space.

j. Label all personal materials clearly for ease of identification. An inventory database should be available for common use freezers to ensure materials accountability.

k. Do not let materials accumulate. Dispose of materials, chemicals, and equipment

that are no longer needed.

l. Store chemicals in designated locations- Store flammable liquids in a flammable liquids cabinet. Do not store acids above shoulder height or in unprotected metal cabinets. Store water reactive materials away from water sources, such as sprinkler systems and sinks. Chemical products should be returned to their proper place after use.

m. Maintain a chemical inventory. Store only the amount of material reasonably needed. Do not over-purchase. Replace chemicals that have reached their expiration date.

n. Do not store frequently used or heavy items on top shelves. Locate supplies used daily close to the work area and place items used periodically in nearby storage areas.

o. Shelves should be equipped with doors or lips to prevent items from falling.

p. Keep an adequately stocked spill kit in the work area. Clean up all small spills immediately. Know what to do in the event of a hazardous material spill and take appropriate action immediately.

q. Always secure compressed gas cylinders with appropriate restraining tool.

r. Dispose of all laboratory wastes (e.g., radioactive, chemical, biohazardous and sharps wastes) properly. Ensure waste containers are placed near the point of use and are adequate of size. Do not over fill the collection containers.

s. Decontaminate all infectious materials, contaminated plasticware/glassware, and contaminated waste prior to washing or disposal.

t. Periodic inspections should be carried out by the PI.

8.2.4 Personal hygiene

a. Personal hygiene is an important means to enhance personal protection in the laboratory.

b. Personal protective equipment such as lab coats and gloves must be worn in the laboratory work areas and removed prior to leaving the laboratory after lab activities. Do not wear contaminated or potentially contaminated lab coats outside the laboratory.

c. Ideally, all lab coats from BSL2 laboratories should be laundered regularly by within the laboratory laundering facility. When this service is not available, the lab coat should be decontaminated within the laboratory (eg bleached) before being allowed to be taken out from the laboratory.

d. Wash hands with antiseptic soap immediately after removing gloves or on contact with infectious agents. This ensures that contamination of the hand by glove micro-puncture or prior exposure is neutralized before being spread.

e. Do not eat, drink or smoke in the lab. Do not store food or drinks in laboratory areas such as cold rooms or lab refrigerators.

f. Do not perform personal cosmetic tasks such as applying makeup, manipulating contact lenses, trimming fingernails, or combing hair. These activities provide opportunities for exposure to infectious agents.

CHAPTER 9 DECONTAMINATION AND DISPOSAL

Materials containing infectious agents must be decontaminated prior to reuse or disposal. The aim of decontamination is to reduce or eliminate the potential of infectious agents to cause disease.

Decontamination is a process that removes and/or kills microorganisms. It can be achieved by sterilization or disinfection. These terms are used synonymously but are distinct from one another:

Sterilization is the process that kills and/or removes all classes of microorganisms and spores.

Disinfection is a physical/ chemical means of killing microorganisms, but not necessarily spores.

A disinfectant is a chemical or mixture of chemicals used to kill microorganisms, but not necessarily spores and is usually applied to inanimate surfaces or objects.

An antiseptic is a substance that inhibits growth and development of microorganisms without necessarily killing them and is usually applied to body surfaces.

9.1 METHODS OF DECONTAMINATION

9.1.1 Heat sterilization

a. The application of heat, either moist or dry, is recommended as the most effective method of sterilization.

b. Dry heat at 160°C to 170°C for periods of 2 to 4 hours is suitable for destruction of viable agents on an impermeable non-organic material such as glass, but is not reliable in even shallow layers of organic or inorganic material that can act as insulation.

c. Incineration is another use of heat for decontamination. Incineration will burn any organism to ash. It serves as an efficient means of disposal for human and animal pathological wastes. Sharps and glasswares may be sent for incineration.

d. A widely-used method for heat sterilization is the autoclave. Autoclaves commonly use steam heated to 121°C, at 15 psi above atmospheric pressure with the holding time of 15 mins. Autoclaving is the most convenient method of rapidly achieving sterility under ordinary circumstances as moist heat causes the denaturation of proteins at lower temperatures and shorter times than dry heat.

Autoclaves can sterilize all items that are heat stable. Proper autoclave treatment will inactivate all fungi, bacteria, viruses and also bacterial spores, which can be quite resistant. Solid surfaces are effectively sterilized when heated to 121°C, at 15 psi for at least 15 minutes. Liquids and instruments packed in layers of cloth require a much longer time to reach a sterilizing temperature.

Position the items in the autoclave in a manner that allows steam to penetrate into all

the items. Autoclave bags must not be sealed tight to allow steam to penetrate into the contents. Alternatively water can be introduced into the autoclave bag with dry content before being secured for autoclaving.

Caution! Materials in tightly sealed or stoppered containers may not be effectively decontaminated and may become dangerously pressurized causing injury when removed from the autoclave.

Items containing flammables chemicals such as phenol or chloroform should not be placed in an autoclave. Caution must also be exercised when handling hot solids and liquids.

Laboratory personnel should be aware of the safe and proper operation of autoclaves.

9.1.2 Liquid decontaminants

Liquid chemical decontaminants can be used for surface decontamination and, at sufficient concentration, as decontaminants of liquid wastes for final disposal in the drainage systems. However, proper consideration must be given to such factors as temperature, contact time, pH, the presence and state of dispersion, penetrability and reactivity of organic material at the site of application in order for decontamination to be effective.

Most chemical decontaminants are not sterilizers and should not be relied on to destroy all organisms on a surface or piece of equipment. Simple wiping of the surface to be decontaminated with a liquid disinfectant does not kill all the organisms present.

Liquid decontaminants can be categorized as halogens, acids and alkalis, heavy metal salts, quaternary ammonium compounds, phenols, aldehydes, ketones, alcohols, and amines and are commonly available in a variety of trade names

Alcohols such as ethanol or isopropyl alcohol in concentrations of 70-90% are good as general use disinfectants. They are effective against bacteria and enveloped viruses, less active against non-enveloped viruses and not effective against bacterial spores.

Halogens: Chlorine-containing solutions commonly available as household bleach are active against bacteria, fungi and viruses. At higher concentrations and extended contact times, chlorine can inactivate bacteria spores as well. However, they are corrosive to metals and tissues. Iodophors, which are iodine containing formulations, are active against vegetative forms of bacteria, fungi and viruses.

Phenolic-based compounds are effective decontaminants against some viruses, fungi, and vegetative bacteria, including rickettsiae. Phenolics are not effective in ordinary use against bacterial spores. A common phenolic disinfectant is Lysol™.

Quaternary Ammonium Compounds are cationic detergents that are strongly surface-active. They are only effective against vegetative bacteria and enveloped viruses. They are easily inactivated by the presence of excess organic material.

9.1.3 Vapors and Gases

Chemical decontaminants that are gaseous at room temperature are useful as space-penetrating decontaminants. When employed in a closed system and under controlled conditions of temperature and humidity, excellent decontamination can result. The most common ones are formaldehyde, chlorine dioxide and vaporized hydrogen peroxide.

Vapor and gas decontaminants are primarily useful in decontaminating biological safety cabinets, bulky or stationary equipment that resists penetration by liquid surface decontaminants; instruments and optics that may be damaged by other decontamination methods; rooms, buildings and associated air-handling systems and air filters.

Formaldehyde as a gaseous sterilizing agent is prepared by heating of solid paraformaldehyde. Formaldehyde in solution form as formalin is used as a fixatives and liquid sterilizing agents, provided that the immersion time is sufficiently long.

Formaldehyde is effective against all bacteria, viruses and bacterial spores and is commonly used for the decontamination of BSCs. However, it is toxic and potentially carcinogenic so personnel exposure must be limited and considerable care is required when handling, storing and using formaldehyde.

Avoid inhalation of vapors of formaldehyde and ethylene oxide. Stock containers of these products should be air-tight and kept in properly ventilated chemical storage areas.

9.1.4 Radiation

Sterilization may be achieved using radiation such ultraviolet (UV) radiation.

Ultraviolet light irradiation is useful only for sterilization of surfaces and some transparent objects. UV irradiation is routinely used to sterilize the interiors of biological safety cabinets but has been overrated as an effective decontamination method. **UV has very low penetration and is ineffective in shaded areas, including areas under dirt**. The effectiveness of the UV sterilization works on a very narrow range of wavelength and the wavelength may change over the life of the UV lamp. In addition, due to its damaging and harmful effects, the use of UV for routine surface decontamination is not encouraged.

9.2 SELECTING CHEMICAL DISINFECTANTS

Microorganisms exhibit a wide range of resistance to inactivating agents. Most vegetative bacteria, fungi and lipid-containing viruses are relatively susceptible to chemical decontamination whereas non-enveloped viruses and bacteria with a waxy coating e.g. tubercle bacillus have mid-range resistance. Spores are most resistant to inactivation.

No single chemical disinfectant or method is effective for decontamination in all situations. The choice of chemical disinfectants should be made after consideration of the following factors:

- Target organism;
- Highest concentration of organisms;
- Amount of extraneous organic material present;
- The material to be decontaminated;
- Potential toxicity of disinfectant;
- Activity of disinfectant.

9.3 GUIDELINES FOR THE USE OF COMMON DECONTAMINANTS

Decontaminants/ disinfectants should be used in accordance with manufacturer's directions in order for effective decontamination to occur.

A decontaminant selected on the basis of its effectiveness against organisms on any range of the resistance scale will be effective against organisms lower on the scale (eg. disinfectants that effectively control spore forms can be assumed to inactivate any other organism).

High titers of microorganisms or presence of large amounts of organic materials such as agar, proteinaceous nutrients, and cellular materials can effectively retard or chemically bind the active moieties of chemical disinfectants. Such interference with the desired action of disinfectants may require higher concentrations and longer contact times.

Ineffectiveness of a decontaminant can also occur as a result of failure of the decontaminant to contact the microorganisms. Microorganisms under spots of grease, rust, dirt or dry areas of tiny bubbles on the surface of the item will not be contacted by the decontaminant.

The more active the disinfectant, the more likely it will possess undesirable characteristics such as corrosiveness. Particular care should be observed when handling concentrated stock solutions of disinfectants. Personnel should be aware of safety precautions to follow and appropriate personal protective equipment to use when handling them.

9.3.1 Alcohol

a. Ethanol or isopropanol should be used at concentrations of around 70 %(v/v) in water. They have less effective germicidal properties at higher or lower concentrations.

b. A contact time of ten minutes is generally employed in efficacy tests with disinfectants. Due to the high evaporation rate of alcohols, repeated applications may be required to achieve the required ten minute contact time for decontamination.

c. Isopropyl alcohol is generally more effective against vegetative bacteria; ethyl alcohol is a more virucidal agent.

d. 70% ethanol can be used on skin, for disinfecting work surfaces and for swabbing/ soaking small pieces of equipment.

e. Alcohols denature proteins and are somewhat slow in germicidal action.

f. Alcohols are not very caustic and are not significantly harmful to personnel using them.

i. As alcohols are flammable, do not use them near open flames.

j. They should be stored in proper containers to prevent evaporation as they are volatile. Alcohols in spray or squirt bottles should be replaced periodically to ensure sufficient concentration when used

9.3.2 Bleach

a. Bleach is a broad spectrum disinfectant used in many labs here. It is active against bacteria, fungi and viruses. At higher concentrations and extended contact times, bleach can inactivate bacteria spores as well.

b. Guidelines for use:

Household bleach contains approximately 5.25% w/v (52 500ppm) sodium hypochloride or lower.

Liquid wastes can be decontaminated with 1:10 dilution of household bleach (ie. one part bleach to 9 parts liquid) for 30 minutes. After decontamination, liquid waste can be disposed of in the public drainage system with copious amount of water provided no other hazardous materials are present (e.g., chemicals and/or radioactive materials).

c. Effective working concentrations of bleach for disinfection are:

“Dirty” conditions (eg. presence of large amounts of organic matter) – Sodium hypochlorite solution containing 0.5% available chlorine. (Also equivalent to 5g/litre or 5000 parts per million) “Clean” conditions (e.g. for disinfecting surfaces, rinsing protective clothing) -

Sodium hypochlorite solution containing 0.1% available chlorine. (or 1 g/litre or 1000 parts per million)

Domestic household bleach is typically made of 5.25% (52,500 ppm). Sodium Hypochlorite but can range from 3-6%. Industrial bleach solutions have a higher concentration (10-15% Sodium Hypochlorite). They have to be diluted accordingly to obtain the working concentration.

d. The efficacy of a bleach solution to act as a disinfectant is considerably reduced:

- by presence of organic material (e.g. Serum and protein in blood);
- with storage;

- by exposures to high temperature, oxygen and sunlight

e. Hypochlorite concentrations drop over time due to relative instability of the active chlorine component. As a general guide, solutions with high levels of organic matter should be changed at least daily, while those with less frequent use may last for as long as a week.

f. Chlorine solutions can also be made from:

Bleach powder- Chlorine compounds available in powder form (e.g. calcium hypochlorite or chlorinated lime) or Chlorine-releasing tablets-(Sodium dichloroisocyanurate, or commercial preparations e.g. Germisep tablets)

Solutions can be made fresh for use when required. Follow the manufacturer's instructions for preparation and usage of working solutions.

g. Many by-products of chlorine can be harmful to humans. Avoid indiscriminate use of chlorine-based disinfectants and follow safety precautions when using bleach:

- Chlorine gas is highly toxic. Store and use bleach in a well-ventilated area.

- Household bleaches containing 5% sodium hypochlorite is an irritant. More concentrated bleaches contain 10-15% sodium hypochlorite is corrosive. Avoid direct contact with skin and eyes. Skin contact will produce caustic irritation or burns. Splash goggles/face shield and protective gloves are recommended PPE.

- Hypochlorite and other chlorine-releasing disinfectants may cause corrosion of metals and this must be taken into account when decontaminating equipment.

- Do not mix bleach with other chemicals. For example, bleach mixed with acids or ammonium-containing materials rapidly generates the toxic chlorine and chloramine gas respectively. Check the incompatibility chart of bleach.

9.4 BIOLOGICAL WASTE DECONTAMINATION AND DISPOSAL

All biological waste should be placed in an autoclave bag, labelled with information (eg. User name, PI, Laboratory and Date), autoclave sterilized and disposed as regular waste. These information allows waste traceability and accountability.

Sharps in the sharps bin should be disposed by incineration by licensed biowaste collectors such as Faber Medi-Serve Sdn Bhd.

CHAPTER 10 PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment (PPE) are often used in combination with biological safety cabinets and other containment equipment to protect personnel from contact with biohazardous materials, animals, other materials such as toxic and corrosive chemicals, heat, cold, fire and other physical hazards. Appropriate PPE may also protect the experiment from contamination.

The extent and kind of clothing and equipment to be selected for any particular activity depends upon the research operations and levels of risk associated with the research. It should be understood that while PPE serves as a second line of defense. Good laboratory techniques, procedures and appropriate laboratory equipment are the primary barriers against potential exposure to hazardous agents.

10.1 LABORATORY CLOTHING

10.1.1 Laboratory Clothing

a. Laboratory clothing includes laboratory coats, scrub suits, and gowns.

b. The clothing should be durable and provide protection of the skin from exposure to harmful agents.

c. Long sleeved garments with elastic wrist cuff should be used to minimize the contamination of skin or street clothes and to reduce shedding of microorganisms from the arms. If proper precautions are not taken, contaminated clothing may carry infectious materials outside the laboratory and into other work areas, cafeterias, or the home.

d. Religious head scarf and long hair should be nicely tugged inside the protective clothing.

e. In procedures where splashes may occur, the lab clothing must be resistant to liquid penetration to protect clothing from contamination. When necessary, a waterproof apron should be worn in addition to the standard laboratory coat.

f. If the lab clothing is not disposable, it must be capable of withstanding sterilization, in the event it becomes contaminated.

g. Change the lab clothing as soon as feasible whenever it is contaminated, soiled or torn. Upon obvious exposure to agents at all level of risk, immediately decontaminate the lab clothing and change into a clean piece.

h. Remove protective clothing and leave it in the laboratory before leaving for non-laboratory areas.

i. Protective clothing worn within the laboratory should not be worn outside the facility to the library, cafeteria, hospital or other places accessible to the public.

j. Home laundering of protective clothing is not encouraged and provision should be made by FMHS to set up an in-house laundering service for this purpose. Otherwise

all protective clothing should be properly disinfected or decontaminated before bringing home to launder. Lab coats with extensive contamination may be placed in a biohazard bag and autoclaved before laundering.

k. Provisions should be made for PPE to be provided to visitors and maintenance or security personnel, if applicable.

10.1.2 Shoes

a. Shoes worn in the laboratory must be closed-toe. Sandals and stiletto heels are not allowed to be worn into the laboratory.

b. When working with infectious agents it is advisable to wear shoe covers over street shoes, which can be decontaminated (autoclaved) before disposal. Alternatively, shoes with surface which can easily be decontaminated can be worn in the absence of shoe covers.

c. For work in tissue culture laboratories it may be necessary to change from street shoes to specific laboratory shoes for protection of cultures from contamination.

10.1.3 Gloves

a. Disposable gloves must be worn when working with biohazardous and/or toxic materials and physically hazardous agents. Breaks in the skin barrier of the hand (damaged cuticles, scrapes, micro-cuts, dermatitis, etc.) are common.

b. Gloves should be comfortable and of sufficient length to prevent exposure of the wrist and/or forearm. When working with hazardous materials, the lower sleeve and the cuff of the laboratory garment should be overlapped by the glove. A long sleeved glove or disposable arm-shield may be worn for further protection of the garment.

c. Gloves may be fabricated of cloth, leather, natural and synthetic rubbers, or nitrile depending on the hazards involved and the activities to be conducted. Personnel who have known allergy against latex should use alternative glove material such as nitrile. MSDS of materials handled shall be consulted to select the appropriate type of glove.

d. Check gloves for visible tears before use.

e. Disposable gloves must not be washed or reused.

f. Change gloves periodically and when soiled. Gloves must be disposed of when contaminated, removed when work with infectious materials is completed. Always wash hands after removing gloves.

g. Gloves must never be worn outside the laboratory. Gloves shall be removed and hands washed before exiting the laboratory.

h. Use the one glove method, or an appropriate secondary container, when transporting materials through common use areas.

i. Do not touch door handles, elevator buttons, telephones, computers or other clean

surfaces or items with gloved hands.

j. Normal disposable gloves will not prevent needle sticks or other percutaneous injuries.

k. Surgical grade Kevlar gloves and stainless steel mesh gloves can provide protection against slices, scratches or cuts, but will not prevent direct puncture or needlestick injuries. Neoprene and other abrasive resistant gloves are cut resistant, but significantly reduce dexterity.

l. Temperature-resistant gloves must be worn when handling hot material, dry ice or materials being removed from cryogenic storage devices.

m. Chemical resistant gloves such as nitrile gloves must be worn when handling corrosive chemicals.

n. In some instances double gloving may be appropriate e.g. Work with highly infectious agents or cleaning-up of spills. A first layer of black coloured nitrile gloves followed by the regular light coloured external worn external gloves provides good visual contrast of tear on the external disposable gloves.

10.2 FACE AND EYE PROTECTION

a. Face protection are required for preventing splashes, sprays or splatters of infectious or other hazardous materials to the face.

b. Face protection devices includes goggles or safety glasses with solid side shields in combination with masks, chin length face shields or other splatter guards.

c. Shields should cover the entire face, permit tilting back to clean the face if desired, and be easily removed in the event of an accident.

d. Contact lenses do not provide eye protection. It is recommended that contact lenses not be worn when working around chemicals, fumes, and other hazardous material and dust particles since these items may become trapped in the space between the contact lens and the cornea. When contact lenses are worn, eye protection, such as tight fitting goggles, must be worn.

10.3 RESPIRATORS

a. Infection via the respiratory system can occur by inhalation of respirable-sized aerosols of less than 5µm.

b. HEPA filtered respirators (air purifying or powered air purifying) are worn to prevent exposure to potentially infectious aerosols. However, engineering controls, such as the use of biological safety cabinets, should always be considered as a first line of defense against respiratory infection when working with infectious organisms. Respirators should only be considered as a second line of defense after feasible engineering controls have been put into place and additional controls are still needed.

c. Personnel who require respiratory protection should consult the Biosafety officer for

assistance in the selection of respirator and proper use.

d. The use of respirators should require medical clearance and fit-testing. The need of medical clearance is necessary when the user has a history of respiratory problem such as asthma, chronic obstructive pulmonary disease (COPD), chronic smoker etc. Fit-testing can be carried out by the BSO with the proper fit testing equipment. Fit testing should be carried out at least annually.

CHAPTER 11 EMERGENCY RESPONSE

11.1 EXPOSURE MANAGEMENT

An "exposure incident" is a contact with potentially infectious materials via eye, mouth, other mucous membrane, respiratory tract via inhalation, non-intact skin, or parenteral contact)

If a known or potential exposure incident has occurred, remove gloves and treat the affected area immediately. General actions to take following exposure incidents are as follows:

11.1.1 Percutaneous Injury

a. Percutaneous injuries include puncture wounds, needlestick injuries, cuts, abrasions, animal bites/scratches.

b. For cuts and abrasions, wash area with soap and water for 1–2 minutes.

For injuries with contaminated sharps and needlesticks, wash the affected area with

antiseptic soap and warm water for **15 minutes**. Apply an appropriate skin disinfectant.

c. Cover injured area with clean gauze.

d. Obtain medical attention as necessary for cuts and abrasions. Obtain prompt medical attention if injuries involve contaminated sharps and needlestick exposures to human material (blood, body fluids, tissues); as well as animal bites and scratches.

e. Report injury to your supervisor and complete accident/incident report. Report cause of injury and organisms involved (if any).

f. Keep all medical records and accident/incident reports properly.

NOTE: Personnel who suffered percutaneous injuries caused by sharps which may be potentially contaminated with HIV should receive the first dose of anti-retroviral drug within 2 hours of exposure (refer to the Guidelines for The Occupational Exposure to HIV, HBV and HCV at the Ministry of Health Malaysia webpage (http://www.moh.gov.my/)

11.1.2 Splash to Face/Eye

a. Flush affected area in an emergency eyewash for **15 minutes**.

b. Forcibly hold eyes open to ensure effective wash behind both eyelids.

c. Obtain prompt medical attention. Bring along safety data sheets or other source of contaminant information to the clinic.

d. Report injury to your PI and complete accident/incident report.

e. Keep all medical records and accident/incident reports properly.

11.1.3 Contact on skin

a. Remove any contaminated clothing, jewelry, etc.

b. Wash skin thoroughly with water using a drench hose, emergency shower or faucet.

c. Take care not to break the skin.

d. Flush mucous membranes with soap and water.

e. Obtain medical attention if necessary. Bring along safety data sheets or other source of contaminant information to the clinic.

f. Report injury to your supervisor and complete accident/incident report.

g. Keep all medical records and accident/incident reports properly.

11.1.4 Ingestion of potentially infectious material

a. Remove protective clothing if any.

b. Seek medical attention. Provide information of material ingested and circumstances of the incident.

c. Report injury to your supervisor and complete accident/incident report.

d. Keep all medical records and accident/incident reports properly.

11.1.5 Aerosol Exposure

a. Hold your breath and immediately vacate the area.

b. Remove Personal Protective Equipment (PPE) carefully. When removing PPE make sure to turn the exposed areas inward. Wash hands well with soap and water.

c. Inform the PI and biosafety officer immediately.

d. Post spill sign on lab entrance and evacuate the lab for at least 30 minutes to allow aerosols to settle.

e. Carry out appropriate decontamination procedure after the appropriate time. The lab must be cleared for reentry by the PI, or biosafety officer depending on the extent of decontamination and agent involved.

e. Seek medical attention. Provide information of material inhaled and circumstances of the incident.

f. Report injury to your supervisor and complete accident/incident report

g. Keep all medical records and accident/incident reports properly.

11.2 MEDICAL ASSISTANCE

In the event of exposure to biological materials/infectious agents resulting in possible infection, disease or illness, please inform the PI immediately and seek medical help.

11.2.1 Medical Emergencies

If an injury is a medical emergency the lab personnel should be taken to the University Health Centre (during office hour) or the Accident and Emergency Department of the nearest hospital (off office hour) where initial assessment and emergency treatment will be provided.

a. Call for an ambulance or help (see USEFUL CONTACTS) in any life-threatening situation requiring immediate medical attention.

b. Provide the following information:

- Type of emergency and any injuries;

- Injured person's location, if applicable;

- Your name, location and telephone number;

c. Remain on line until the dispatcher disconnects the call. Whenever possible, get someone or the University security to wait for the ambulance at the main entrance to direct them to the right building, floor and laboratory.

d. Check for hazards before entering location where emergency occurred.

e. Initiate lifesaving measures if required and only if you are trained to do so.

f. Do not move injured persons unless there is an immediate danger of further harm.

g. Keep injured person warm.

h. Remain with victim until medical assistance arrives.

11.2.2 Laboratory-acquired illness

If a laboratory personnel who work or handle infectious materials suspected to have acquired a laboratory acquired illness:

a. Report to the Occupatinoal Health Physician immediately. Provide information on the infectious agent or material used in the laboratory.

b. Report the illness to the Principal Investigator.

c. Submit a report to the Biosafety Officer.

d. Consult with the medical care provider before to returning to work. PIs should also assess the risk of exposure posed to fellow lab workers and other persons encountered by the affected personnel and determine whether medical assessments are appropriate.

11.2.3 Non-Emergency Medical Treatment

If non-emergency medical treatment is required following exposure,

a. The medical treatment for the injury should be obtained as soon as possible following the injury.

b. Bring along with you any material/pathogen safety data sheets or information of any contaminant you were exposed to. If an incident report had been made prior, present it to the attending doctor.

11.3 SPILL RESPONSE

11.3.1 Spill response plan

In any spill scenario, the priority of actions should follow the order of People>Environment>Property. The highest priority is to provide aid to injured personnel and prevent spill area access to others. Following that, action should be taken to prevent environmental damage if it can be done without endangering personnel. An example would be to prevent a biomaterial from spreading by placing an absorbent in the flow path. Finally, action to prevent property damage should be taken if it can be done safely.

The basic rules for responding to a spill are:

a. Immediately report all spills and injuries.

b. Tend to the injury/ injured - Seek immediate medical assistance.

c. Isolate the spill - evacuate the immediate spill area or the entire room in the case of an aerosolizing (splashing or spraying) spill or a spill of volatile material; prevent others from entering the spill area with barricades or, if necessary, a sentry.

d. Contain the spill - place absorbent material around, on or in the flow path of the spilled material only if it can be done safely.

e. Proceed with cleanup – only if trained and properly equipped with personal protective equipment to clean up and disinfect spill safely. Otherwise, wait for assistance of trained spill clean-up personnel / spill response teams.

11.3.2 Biological Spill Kit

A biological spill kit is an essential safety item for labs working with infectious or potentially infectious agents classified at Biosafety Level 2 or higher and for groups working with large volumes (0.5> 1liter).

A basic spill kit should include:

a. Concentrated disinfectant appropriate for the infectious agent handled in the lab

e.g. Sterisorp stabilised chlorine absorbent, household bleach, Germisep tablets, Virkon tablets with appropriate dilution container.

b. Spray bottle for making dilutions of disinfectant

c. Forceps, autoclavable broom and dust pan, or other mechanical device for handling sharps

d. Paper towels or other suitable absorbent materials

e. Biohazard autoclave bags for contaminated items

f. Utility gloves and medical examination gloves

g. Face protection (eye wear and mask, or full face shield)

Each spill kit should be tailored to meet the specific needs of each lab. It is the responsibility of the PI to ensure a well thought out spill kit is readily available and maintained (e.g. periodic replacement of the disinfectant).

One-time-use spill kits are also available from several safety supply sources. These kits contain everything needed for cleaning up and disposing of biohazard spills.

Laboratories should have a supply of biological spill kits and trained laboratory staff that knows how to use them.

The spill kits should be strategically located close to the work areas so that they are easily accessible.

11.3.3 Chemical Spill Kit

A chemical spill kit is essential for every biological laboratory which uses corrosive and/or toxic chemicals such as phenol, concentrated acids and alkali, fuming chemicals etc. Risk assessment must be carried out taking into consideration the hazard, volume, concentration. The MSDS must be consulted while constructing the spill kit.

When necessary, consult your BSO to construct a fuctional chemical spill kit for the specific hazard.

11.5.4 Spill response plan

The fundamental rule in dealing with a biological and/or chemical spill is to be

prepared. Establish an emergency spill response plan. It should consist of a step-by-step procedure to follow if a spill occurs. Spill kit materials should be present in proximity to the area where biohazardous materials are handled.

Identify the biohazard risks involved on the site and the types of potential spills or emergencies which can occur.

11.4 ACCIDENTS AND INCIDENTS REPORTING

11.4.1 Events

Laboratory events that might create hazards, exposures, or accidents requiring reporting include:

- Accidents during work with biohazardous materials that result in physical injury,cuts, burns, abrasions, or fractures. The injured site could be contaminated with the biohazardous agent in use.

- Incidents occurring during the handling of biohazardous agents, infected specimens, or animals that could allow the undesired transfer of the agent to the lab personnel or release of the agent to the environment e.g. biological spills, exposure to aerosols and penetration of agents through the unbroken skin.

All accidents, known exposures, and potential hazards should be identified and reported in order to control the biohazards and contain the organisms involved as well as devise necessary measures to prevent such accidents from happening in the future.

11.4.2 Incidents and Accidents

All incidents or accidents have to be notified by the Reporting Person to the Biosafety officer, Principal Investigator.

11.4.3 Reporting person

In general, the reporting person is the PI of the lab. However, the reporting responsibility begins with the individual involved in an accident, exposure, or suspected hazardous situation. The individual should report as soon as practical to the PI and/or the Faculty Biosafety officer in order to begin the reporting process.

11.4.4 Report Investigation

Faculty's Biosafety Officer in cooperation with the PI and his/her staff will conduct the necessary investigation of any laboratory incident/accident. The goal of the investigation is to prevent similar incidents/accidents as well as to assess the circumstances and number of personnel who may have been exposed to the agent in question.

11.4.5 Publication of Report

The Faculty should allow the publication of the investigation results in safety/biosafety/biosecurity related journals or presentation in biosafety related

conferences as part of the Faculty's commitment in championing biosafety and biosafety in its laboratories.

11.5 EMERGENCY RESPONSE PLANS

11.5.1 Emergency response plan

Departments are encouraged to develop an emergency response plan which covers contingencies which may arise in the event of an accidental exposure.

The emergency response plan should carry the following information:

1. The type of ventilation system serving the lab, corridors and the building in order to enable you to know how aerosols or airborne particles would move;

2. Where the fume hoods and biological safety cabinet exhaust ducting goes after leaving the lab area;

3. Where the biohazard work areas and storage areas of biohazardous materials in order to assess what hazard could result in the event of a fire, flood, or explosion.

4. Evacuation routes and procedures to be used in the event of an emergency with biohazardous materials;

5. Established procedures for safe handling, storage and disposal of biohazardous materials to minimize accidental release and to avoid conditions which might lead to an accidental spill;

6. Procedures for dealing with exposure to biohazardous materials;

7. Any agent-specific post exposure treatment protocol; and

8. Procedures for reporting.

References

1. CEN Workshop Agreement (CWA15793) (2011) Laboratory Biorisk Management [http://www.uab.cat/doc/CWA15793_2011]

2. Laboratory Safety Manual (2004), 3rd Edition World Health Organization (WHO) [editionhttp://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/]

3. Biosafety in Microbiological and Biomedical Laboratories (BMBL) (2009) 5th Edition. [http://www.cdc.gov/biosafety/publications/bmbl5/]

4. EMORY University Biosafety Manual (2008)

5. NUS Laboratory Biorisk Management Manual (2008)

6. Biosafety Manual For University of Maryland (1997)

UNIVERSITI MALAYSIA SARAWAK

ACCIDENT/INCIDENT/INFECTION REPORT FORM

The report involves a ☐ Student ☐Employee ☐Visitor

The Accident/Incident/Infection Occurred: ☐ On Campus ☐Off Campus

This report is completed by ☐Injured person ☐PI ☐BSO

Section 1 PERSONAL DETAILS [Injured person]

Tick as appropriate ☐ Accident ☐Incident ☐LAInfection

FULL NAME:

SALUTATION:

ADDRESS:

MOBILE PHONE

DATE OF ACCIDENT/INCIDENT (DD/MM/YY): / /

TIME OF DAY: ☐am☐pm

DESCRIBE THE ACCIDENT/INCIDENT/LAI

WHERE DID THE ACCIDENT/INCIDENT/LAI OCCUR?

Building Floor Room

DESCRIBE ANY MEDICAL CONDITION/TREATMENT FOLLOWING THIS ACCIDENT/INCIDENT/INFECTION

THIS REPORT IS AGREED BY [WHEN APPROPR

FMHS BIORISK ASSESSMENT FORM

	Hazard Identification				**Risk Assessment**				**Mitigation**	
No	Description of steps	Equipment used	Hazard	Potential risk	Existing risk control	Likelihood	Consequence	Risk	Additional Risk Control	Additional resources required
Eg.	*Pelleting 50ml of Salmonella culture for plasmid midi-prep*	*Centrifuge*	*Salmonella*	*Aerosolization of culture during centrifugation*	*Gloves, facemask*	*Medium*	*Medium*	*Medium*	*Centrifuge with safety bucket and cap*	*Biosafety Cabinet. Opening safety cap in a BSC.*

Approved by

Endorsed by

_____

Principal Investigator

_____

Biosafety Officer