



MALAYSIA LABORATORY
BIOSAFETY AND BIOSECURITY

POLICY and GUIDELINE

MINISTRY OF HEALTH MALAYSIA

2015

1st Edition



**MALAYSIA LABORATORY BIOSAFETY AND BIOSECURITY
POLICY AND GUIDELINE**

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2015
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This document was developed by the Biosafety and Biosecurity Sub-Committee, Laboratory Technical Advisory Committee (LTAC), Ministry of Health Malaysia.

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FOREWORD BY THE DIRECTOR GENERAL OF HEALTH MALAYSIA



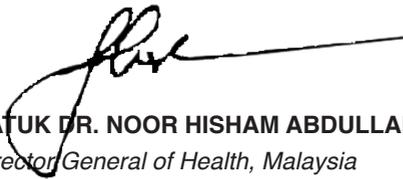
Working with pathogens in the laboratory is vital to ensuring that the Malaysia and the global community able to apply effective tools in treatment, control and prevention to counter the ever evolving threat of infectious diseases. This critical role of the laboratory has exposed laboratory workers to the potential health risks of using biohazardous materials. Unfortunately, there were several reports on laboratory incidents within the country and internationally indicating the need to strengthen overall biosafety and biosecurity at laboratory facilities. In fact, the provision of a healthy and safe laboratory working environment has become the cornerstone in laboratory practices highlighted in Malaysia Workplan Strategies in Emerging Diseases 2011-2015 Document.

For that, I am happy to announce the first publication of the Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline as an advisory document recommending best practices for the safe conduct of work in laboratories from a biosafety perspective. However, this document is not intended as a regulatory document though we recognize that it will be used that way by some. I believe all laboratory managers will find this document useful enough to equip the managers on the knowledge, competence, confidence and capacity to deal effectively with health and safety issues in relation to biological materials and toxin.

The development of this document is aligned with the country responsibility to provide adequate laboratory capacity including biosafety issues as a prerequisite for compliance to the International Health Regulation. The process of formulating this policy and guideline begun in the year 2013 and involved wide consultations with both Government and Non-Governmental Institutions. The Subcommittees of Biosafety and Biosecurity Laboratory has been given a mandate by the National Technical Advisory Committees on Laboratory Services for coordinating the formulation of Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline. At last count, a scientific and professional colleagues from thirteen government sectors, academicians as

well as privates contributed in technical working groups, serving as reviewers and guest editors, and as subject matter experts. The document, therefore, is based on stakeholder consensus on a comprehensive framework for development and safe application of biosafety in Malaysia. I wish to thank them all for their dedication and hard work for without them the 1st edition of the Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline would not be possible.

We hope you find this first edition of Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline is complete, timely and most of all, easy to use. I believe you will find it was well worth the wait.



DATUK DR. NOOR HISHAM ABDULLAH
Director General of Health, Malaysia

PREFACE

Timely, accurate laboratory diagnosis in a safe environment is a cornerstone of any surveillance and response system for emerging diseases and other public health events. Safe laboratory environments and safe practices are required to avoid staff members and other people from becoming infected with the hazardous agents that they are handling or if there is an accidental release of the agent and microbial toxin. In fact, strengthening laboratory biosafety activities has become one of the essential strategic actions outlined by the Asia Pacific Strategy for Emerging Diseases (APSED) which was initially launched in 2005 with an updated strategy in 2010. The APSED 2010 has been endorsed by the 5th Meeting of the Asia Pacific Technical Advisory Group for Emerging Infectious Diseases in July 2010 and the WHO Regional Committee Meeting for the Western Pacific in October 2010. It provides a framework for member states, WHO, donors and partners with strategic direction and priority actions for managing health security threats arriving from emerging diseases and other acute public health events.

The International Health Regulations (IHR) are a legally-binding international agreement designed to prevent the spread of disease. This regulation has been revised for the third time and adopted in their new form by the 58th World Health Assembly (WHA) on 23 May 2005. The purpose and scope of the IHR (2005) are “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade”. The revised IHR apply to diseases (including those with new and unknown causes), irrespective of origin or source, that present significant harm to humans, and offer the international community new opportunities to strengthen the public health capacities and collaborate with other countries and with the World Health Organization (WHO).

Coming after the entering into force of the IHR (2005) in 2007, Malaysia is required to fulfill the core content requirements as soon as possible, but no later than five years from the entrance into force of the Regulations. In response to this, Malaysia has adopted the APSED workplan and developed a Malaysia Strategy for Emerging

Diseases or MySED as a road map to guide the country towards meeting the IHR 2005 core capacity requirements. By 2011, Malaysia has successfully complied with at least minimal capacities in all core capacities according to the Regulation.

One of the core capacities is Core Capacity 8 which is on laboratory whereby biosafety is outlined for laboratory. In order to be comprehensive and ensure effective implementation on biosafety practices, in 2013, the Biosafety and Biosecurity Subcommittee of the National Technical Advisory Committee of Public Health Laboratory has gathered inputs and expertise of local experts from multi-sectorial agencies, public and private, as well as academic institutions, from various field, namely clinical, animal, food and environment to produce a Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline. This document sets out the scope, objectives and implementation procedures for a range of biosafety activities which together create the framework for a national biosafety regime. This policy applies to all public, agricultural and environmental laboratory personnel and facilities. The policy is also designed to meet not only international obligations, specifically those set out in the IHR 2005 on Biosafety, but also the peculiar needs and requirements of Malaysia as it seeks to benefit from the advantages of the current diagnostic technology.

This policy is to be read and implemented in conjunction with a range of existing complementary national laws and policies, including the National Biosafety Act. The Ministry of Health acknowledged contributions from all parties in the development of the first Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline.

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ABBREVIATIONS

BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSC	Biological Safety Cabinet
BSL1	Biosafety level 1
BSL2	Biosafety level 2
BSL3	Biosafety level 3
BSO	Biosafety Officer
CDC	Centre for Disease Control and Prevention
CSDS	Chemical Safety Data Sheet
ERP	Emergency Response Plan
GMT	Good Microbiological Technique
HVAC	Heating, Ventilation and Air-Conditioning
IATA	International Air Transport Association
IBBC	Institutional Biosafety and Biosecurity Committee
IHR	International Health Regulation
LAI	Laboratory Acquired Infection
MOH	Ministry of Health Malaysia
MSDS	Material Safety Data Sheet
PPE	Personal Protective Equipment
SOP	Standard Operating Procedure
WHO	World Health Organization

1.0 INTRODUCTION

The field of microbiology has contributed significantly towards the development of modern medicine and biotechnology. Microbes including viruses, bacteria, fungi and parasites have been studied and utilized in the laboratory to help in our understanding of life and disease processes. While in most instances, innocuous or harmless microbes are used or encountered, there are instances in which there is a need to handle and identify potentially unknown infectious agents/materials and microbial toxins, or known virulent pathogens for research and the development of therapeutics, vaccines and preventive measures against the pathogens. Under these circumstances, it is of paramount importance that the environment in which the microbes or potentially unknown infectious agents/materials and microbial toxins are handled ensures safety to the personnel, public at large, protects the environment and in compliance to all the national and international obligations and legal frameworks which govern such activities. There is also a need to ensure that the microbes and potentially unknown infectious agents and microbial toxins are properly managed and safeguarded to prevent intentional and unintentional release that could cause harm.

1.1 SCOPE

This document consists of the basic concepts and approaches in the form of policy and guidelines that govern all activities involving the handling, manipulation working, using, storing and disposing of infectious and potentially infectious agents/materials and microbial toxins in all forms and sizes of laboratories in Malaysia. This document serves as a reference for the development and establishment of the respective institutional code of practice for good microbiological technique (GMT), biosafety and biosecurity in a laboratory and defined containment zone.

1.2 POLICY

It is a policy that all institutions with personnel performing activities involving the handling, manipulating, working, using, storing and disposing of infectious and potentially infectious agents/materials and microbial toxins must institute an organizational level Institutional Biosafety and Biosecurity Committee (IBBC).

It is a policy that all institutions with personnel performing activities involving the handling, manipulating, working, using, storing and disposing of infectious and potentially infectious agents/materials and microbial toxins must provide proper facilities commensurable with the biosafety risk level of the infectious and potentially infectious agents/materials and microbial toxins handled.

It is a policy that all activities involving the handling, manipulating, working, using, storing and disposing of infectious and potentially infectious agents/materials and microbial toxins can only be performed by trained and authorized personnel.

It is a policy that all activities involving the handling, manipulating, working, using, storing and disposing of infectious and potentially infectious agents/materials and microbial toxins must comply with all the relevant national and international obligations and legal frameworks which govern such activities.

2.0 GUIDELINES FOR WORKING WITH INFECTIOUS AND POTENTIALLY INFECTIOUS AGENTS/MATERIALS AND MICROBIAL TOXINS

This guideline specifies the basic administrative controls, engineering controls, standard operating procedures and personal protection control for handling, manipulating, working, using, storing and disposing of infectious and potentially infectious agents/materials and microbial toxins in the laboratories. It is the intention of this guideline to specify the minimum requirements and to be non-exhaustive in nature to allow for respective institutional and organizational variations while at the same time ensuring uniformity across the country.

2.1 ADMINISTRATIVE CONTROL

The institutional or organizational IBBC is the responsible entity that ensures the implementation of the policy and guidelines specified in this document. The IBBC will serve as the custodian for all the biosafety and biosecurity administrative controls for the institution and organization. The following describes the basic purpose and function of the IBBC and its role as the biosafety and biosecurity administrative controller;

- i. Responsible for all matters pertaining to policy, standard operating procedure (SOP), procedures and techniques. These encompass the development, evaluation, approval, monitoring and review.
- ii. Comprises of members with expertise in human pathogens, plant/animal pathogens (if relevant) and a Biosafety Officer (BSO). Other members such as medical personnel, veterinarian, representative of technical staff and representative of laboratory management may be included.
- iii. Advises and ensures that a biosafety risk assessment is conducted prior to the commencement of any activity involving infectious agents and potentially infectious agents/materials and microbial toxins.
- iv. Ensures personnel working with infectious and potentially infectious agents/materials and microbial toxins are trained in:-
 - a. Basic biosafety and biosecurity practices/ good laboratory practices

- b. Agent or toxin specific biosafety and biosecurity procedures
- c. Job specific training (such as the proper use of biological safety cabinet (BSC), waste management, equipment handling, etc.). The training it provides can be formal or informal but it is documented. The IBBC decides the training methods, content, duration and ensures a continuous job safety training and re-training program.
- v. Evaluates the implementation of the biosafety and biosecurity training program. These evaluation can be in the form of :
 - a. Measuring the trainees' understanding to the instructions provided
 - b. Measuring the trainees' re-recollection and/or performance
Methods for evaluation are to be defined by IBBC.
- vi. Introduces appropriate access control and levels for laboratory where activities involving infectious agents and potentially infectious agents/ materials and microbial toxins are performed. These include the following;
 - a. Proper signage, indicating any special condition for entry with names and emergency numbers of person-in-charge who controls access.
- vii. Ensures that the proper guidelines for transportation of infectious agents, which include traceability of movement, proper documentation, and appropriate packaging procedure, are in place. It observes that all domestic and international transportation of infectious and potentially infectious agents/materials and microbial toxins adheres to local regulation as well as World Health Organization (WHO) and International Air Transport Association (IATA) requirements.
- viii. Establishes and institutes administrative controls for appropriate waste decontamination, disposal and management policy which considers the following;
 - a. Proper decontamination of biological wastes as per recommended in the accepted reference document listed in this document (see References)
 - b. Adequate facilities and procedure for temporary storage of wastes prior to disposal.

- c. Proper scheduled waste collection or disposal of waste and noting to adhere to the policies and regulations stipulated by the Department of Environment, Malaysia.
- ix. Ensures that all laboratories involved in handling of infectious and potentially infectious agents/materials and microbial toxins have an emergency response plan (ERP), and that all laboratory personnel are aware of the plan.
- x. Establishes an emergency response team and engages local emergency authorities for the management of an incident.
- xi. Ensures that there are procedures for reporting and documenting of incidents.
- xii. Establishes an immunization program where applicable, necessary or required.
- xiii. Establishes a medical surveillance program based on the type of activity, the infectious agent involved and the health conditions of personnel.
- xiv. Ensures that biosecurity measures are in place and this include;
 - a. Physical security such as infrastructure, containment zone, and perimeter safety.
 - b. Information security - includes protection of the building security plan, passwords, material inventory and information of storage site of infectious and potentially infectious agents/materials and microbial toxins.
 - c. Personnel security - includes background checks or security clearances.
 - d. Accountability and traceability of all materials
- xv. Provides an annual report on biosafety and biosecurity activities in compliance with the International Health Regulation (IHR) to the Ministry of Health Malaysia (MOH).

2.2 ENGINEERING CONTROL

Physical containment of infectious and potentially infectious agents/materials and microbial toxins constitutes most of the engineering controls specified in this document. A minimum of BSL2 containment facility and/or practices is required for all activities that involve handling of infectious agents/material of risk group

2 and above. Details of the basic laboratory containment facility (BSL1, BSL2, BSL3 and etc.) with regards to specific infrastructure, design, safety and security requirements are as recommended and meeting the minimum requirement outlined in the WHO Laboratory Biosafety Manual 3rd Edition 2004 and the BMBL 5th Edition 2009 and the relevant national guidelines and regulations (see References). It is recommended that facility is externally certified for fitness by a third party registered certifier but it is not mandatory. This document however, stipulates that;

- i. Biosafety containment laboratory must be properly maintained and periodically checked. Preventive maintenance should be carried out for example on building integrity, ventilation, heating and air-conditioning (HVAC), pressure leakages rate, access door system, pest control, electronic sensors and general building upkeep. Documents of the maintenance activities must be properly recorded and maintained.
- ii. Laboratory equipment must be properly maintained, calibrated and periodically checked. This includes but is not limited to biological safety cabinet (BSC), autoclave and centrifuge. Any equipment that requires certification must be re-certified accordingly. Documents of the maintenance activities must be properly recorded and maintained.
- iii. A proper and secure storage and inventory system is in place for all biomaterials commensurately with the biosafety risk level. All biosecurity measures are taken into consideration to prevent unauthorized access to infectious agents and biomaterials consisting of potentially infectious agents and microbial toxins.
- iv. An appropriate and effective system for disposal of all biomaterials commensurately with the biosafety risk level is available and maintained.

2.3 STANDARD OPERATING PROCEDURE

Standard operating procedures are set of standard instructions for performing specific activity. It is meant to be reproducible when performed by any individual strictly following the instruction. There are generic procedures for performing routine laboratory activities and there are specific procedures for activities involving the handling of specific microorganism, pathogens and toxins. This

document recognizes the institutional and laboratory variations in procedures on how similar work is performed. In general, however, GMT must be adhered to when working with infectious and potentially infectious agents/materials and microbial toxins.

The IBBC ensures that general SOP (including SOP for every single activity involving work with infectious and potentially infectious agents/materials and microbial toxins for example; donning and doffing; collection, movement, transport and handling of infectious agents; receiving and storage of infectious agents; proper use of laboratory instruments and equipment; hand washing; entry and exit; disinfection, decontamination and sterilization; spill and waste management; accidents and incidents including loss, theft; and emergency response plan) as well as agent specific SOP are established. This guideline specifies that;

- i. SOP is written based on actual activity performed.
- ii. SOP is written in language that is understood well by the performer.
- iii. SOP is available and easily accessible to all laboratory personnel.
- iv. Appropriate and relevant SOP is used as basis for training of personnel.
- v. SOP is evaluated, validated, communicated, periodically reviewed and updated and documented by the IBBC based on the most acceptable recent reference guidelines.

2.4 PERSONAL PROTECTION CONTROLS

Personnel protective equipment (PPE; eg. respirators, goggles, gloves and clothing) is the last critical barrier to accord protection against possible exposure to infectious agents and microbial toxins. It is designed to further minimize the risk of accidental exposure after other controls including engineering, SOP and administrative controls are already in place. Appropriate use of PPE along with the proper SOP, hence, is paramount to ensure personnel are protected. This guideline specifies that;

- i. PPE is not to be used as substitute for other primary containment barriers.

- ii. Appropriate high quality PPE is used commensurably with the biological safety risk assessment category. The appropriate PPE is as per recommended in the accepted reference document listed in this document (see References).
- iii. Routine checks and maintenance of all PPE is performed. This includes identifying damaged PPE and hazard that might results from PPE failure, such as, impaired dexterity or visibility.
- iv. PPE is appropriately used even in training and for staff, visitors and contractors.
- v. Adequate quantities of PPE are always maintained.

3.0 LABORATORY BIOSAFETY CHECKLIST

3.1 Basic Laboratory – Biosafety Level 1

	YES	NO	N/A
3.1.1 Laboratory			
a. Limited access			
b. Proper signage: e.g. biohazard, ultraviolet light etc.			
c. Relevant SOP for work activities available and followed			
d. Laboratory equipment properly labelled (biohazardous, radioactive, toxic, etc.)			

3.1.2 Laboratory design

a. Facility designed for easy cleaning			
b. Corridors and exits are free from obstruction			
d. All storage shelves secured			
e. Bench-tops waterproof and resistant to acids, alkali, organic solvents, heat, chemicals used to decontaminate the work surface.			
f. Adequate illumination/lighting provided			
g. Adequate storage space available and appropriately used			
h. Adequate ventilation			
i. Windows fitted with insect-proof screen (when windows can be opened)			

3.1.3 Gas cylinders

a. All cylinders secured			
b. Caps on reserve cylinders			
c. Asphyxiating and hazardous gases only in designated ventilated rooms			
d. No excess or empty cylinders present in non-designated areas			

3.1.4 Chemicals

- a. Flammables stored in storage cabinet for flammables
- b. Chemicals segregated properly based on intrinsic properties when stored
- c. Hazardous chemicals stored safely and securely
- d. Working stock chemicals available in appropriate amount
- e. MSDS/ CSDS is available and easily accessible for all chemicals

3.1.5 Refrigerators/freezers/cold rooms

- a. No food for human consumption stored
- b. Flammables placed in explosion-proof/-safe units
- c. All material containing carcinogens, radioactivity and/or biohazards are labelled externally
- d. Cold-room has emergency release
- e. Cold-room has audible alarm or temperature monitoring system

3.1.6 Electrical equipment

- a. No overloaded extension cords or electrical strips
- b. Earths/grounds present on electrical outlets and cords
- c. No electrical connections in wet areas e.g. sinks, under showers, etc.
- d. All equipment and wiring in good working condition
- e. Power strips mounted off the floor
- f. Proper fuses in conduits

3.1.7 Personal protective equipment

- a. Eyewash available in laboratory
- b. Safety shower available
- c. Personal protective equipment available (gloves, gowns, goggles, etc.) and worn
- d. Occupants properly attired

- | | | | | |
|----|--|--|--|--|
| e. | Laboratory coats, gowns, smocks, gloves and other personal protective clothing not worn outside the laboratory | | | |
| f. | Personal protective equipment available for cryogenic storage | | | |

3.1.8 Waste management

- | | | | | |
|---|---|--|--|--|
| a | Wastes segregation implemented | | | |
| b | Chemical waste containers tagged, labelled, dated and kept closed/stored | | | |
| c | Biohazardous waste containers appropriately handled and disposed | | | |
| d | All sharps (needles, broken glass, scalpel blades) are disposed in sharps bin or designated durable puncture proof containers | | | |
| e | No trash on floor | | | |

3.1.9 Occupational health and safety programme available

- | | | | | |
|----|---|--|--|--|
| a. | Hazard communication (Lab personnel advised of all potential hazards) | | | |
| b. | Respiratory protection | | | |
| c. | Hearing conservation | | | |
| d. | Chemical Spill Kit available | | | |
| e. | Biological Spill Kit available | | | |
| f. | First Aid Kit available | | | |
| g. | Emergency response plan (ERP) in place | | | |
| h. | Reporting of Incidents, Accidents and Illness | | | |

3.1.10 General engineering controls

- | | | | | |
|---|---|--|--|--|
| a | Sink available for hand-washing | | | |
| b | No exposed machine parts (pulleys, gears) | | | |
| c | Water purification system in good condition | | | |

3.1.11 General practices and procedures

- a. Food for human consumption stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose
- b. Microwave oven(s) clearly labelled "Strictly to Laboratory Materials Only"
- c. Eating, drinking, smoking and/or applying of cosmetics not allowed in the laboratory
- d. Pressurized glass containers taped or shielded (i.e. vacuum traps)
- e. Mouth pipetting prohibited
- f. Mechanical pipetting devices available and used
- g. Protective laboratory clothing stored separately from street clothing

3.1.12 General laboratory housekeeping

- a. Bench-top cleaned and not cluttered
- b. Laboratory floor free from trip hazards
- d. Broken glassware handled by mechanical means (brush and dustpan, tongs, etc.)
- e. Chemical inventory system available
- f. Pest Control program implemented

3.1.13 Fire protection

- a. Sprinkler heads free and unobstructed
- b. No wiring or tubing through door openings
- c. Minimum passage width of 1 meter(m) in laboratory
- d. Minimum combustibles stored in laboratory
- e. Adequate fire extinguisher available
- f. Fire alarm available and drills for evacuation implemented

3.2 Basic laboratory – Biosafety Level 2

This form is used in addition to the Biosafety Level 1 laboratory safety checklist

YES NO N/A

3.2.1 Biological safety cabinet (BSC)

	YES	NO	N/A
a. Annually certified by qualified person			
b. BSC surface wiped down with appropriate disinfectant at beginning and end of each procedure			
c. Front grill and exhaust filter unobstructed			
d. No open flames used inside cabinet			
e. Vacuum lines have in-line filters and disinfectant traps in use			
f. Location of BSC not directly opposite entrance and below in-flow air vent			
g. BSC used when there is potential for creating infectious aerosols			

3.2.2 Administrative control

	YES	NO	N/A
a. Access limited and restricted to authorized personnel			
b. Appointment of BSO			
c. Laboratory biosafety training program implemented			
d. Proper documentation and records (material inventory, incident reporting, etc.)			
e. Immunization plan available			
f. Appropriate medical surveillance available			
g. Biosafety manual prepared and adopted			
h. Staff competency evaluated			

3.2.3 Laboratory

	YES	NO	N/A
a. Biohazard sign posted on laboratory door as appropriate			
b. Information on signage accurate, current and indicate emergency contact numbers			
c. Sign legible and not defaced			
d. All doors closed			

- g. All windows sealed or closed permanently
- e. Hand-washing sink available near laboratory exit

3.2.4 Decontamination

- a. Decontaminant appropriate to the organism(s) in use
- b. All spills and accidents involving infectious materials reported to the laboratory supervisor
- c. Appropriate disinfectant used during spill clean-ups
- d. Work surfaces decontaminated before and after each procedure, daily and after spills
- e. Biological spill kit available (content e.g. disinfectant should be periodically checked for expiry)

3.2.5 Handling of contaminated waste

- a. Infectious waste should be segregated and placed in autoclavable bags
- b. Waste containers or bags properly labelled and closed securely
- c. Culture stocks and other infectious waste properly decontaminated by autoclaving or chemical disinfectant before disposal
- d. Infectious waste containers not overfilled
- f. Materials decontaminated outside the laboratory transported in closed, durable, leak proof containers
- g. Co-mingled waste (biological waste mixed with chemical or radiological waste)/decontaminated prior to disposal according to local regulations

3.2.6 Personal protection

- a. Gloves worn when handling infectious material or contaminated equipment
- b. Face protection provided when working outside the BSC with infectious material

- c. Proper personal protective equipment available (gloves, gowns, goggles, etc.) and worn

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3.2.7 Practices

- a. BSC used when potential for creating infectious aerosols/splashes exists
- b. Personnel read, review and follow the instructions on practices and procedures, including safety or operations manual
- c. Procedure performed so as to minimize aerosols/splashes
- d. Needle-locking syringes/single-use needle-syringe units used with infectious agents
- e. Appropriate handling of centrifuge cups and rotors
- f. Infectious specimens transported outside a BSC in suitable containers
- g. Hands washed after removing gloves, after working with infectious agents, before leaving the laboratory
- h. Packaging and transportation of infectious materials within facility and between institution should follow local guideline and international regulations

3.2.8 Engineering control

- a. Autoclave is available and certified annually
- b. Preventive maintenance performed for equipment

3.3 Containment laboratory – Biosafety Level 3

This form is used in addition to the Biosafety Level 1 and Biosafety Level 2 checklist

YES NO N/A

3.3.1 Facility

- a. Laboratory separated from unrestricted traffic flow in building
- b. Access to laboratory through an anteroom with self-closing doors
- c. All penetrations in laboratory sealed or sealable for decontamination
- d. Room exhaust air single-pass and exhausted away from occupied areas
- e. Controlled ventilation system to monitor directional airflow available
- f. Air recirculated into the containment laboratory must be HEPA filtered
- g. Audible or clearly visible alarms for engineering controls available with a proper back up plan
- h. A dedicated autoclave is available and certified annually
- i. Vacuum line has filters and traps
- j. Backflow prevention to water supply
- k. Surfaces of floor, walls and ceilings should be easily cleaned

YES	NO	N/A

3.3.2 Administrative control

- a. Controlled access to authorized and trained personnel (e.g. Card key access or CCTV)
- c. Competency training program available on BSL3 practices
- d. Appropriate and adequate personal protective equipment available
- e. Medical surveillance program implemented
- f. Appropriate material inventory system available
- g. All infectious agents and materials secured (e.g. freezers are lockable)

YES	NO	N/A

3.3.3 Personal protection

- a. Closed-front gowns worn in laboratory
- b. Protective laboratory clothing worn only in laboratory areas
- c. Double gloves worn when handling infectious material, potentially contaminated equipment and work surfaces
- d. Respiratory protection worn by all personnel in the laboratory when aerosols are not safely contained in a BSC
- e. Sink with foot operated pump , elbow or automatically controlled faucet provided near exit

3.3.4 Practices

- a. Face shield provided when working with infectious material outside a BSC
- b. Personnel advised of special hazards associated with the agent(s)
- c. Personnel required to read and follow all instructions on practices and procedures, including safety or operations manual
- d. Personnel receive annual updates/additional training for procedural changes
- e. All contaminated waste autoclaved prior to disposal

3.3.5 Laboratory biosecurity

- a. A qualitative risk assessment been performed to define risks that a security system should protect against
- b. Acceptable risks and incidence response planning parameters been defined
- c. The facility including storage areas for infectious material are securely locked when unoccupied
- d. Doors and windows are intrusion proof
- e. Access to rooms, equipment and materials appropriately controlled and documented
- f. Facility is equipped to withstand known natural disasters

4.0 GLOSSARY

Activities - handling, manipulating, working, using, storing, transporting and disposing

Biosafety - the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release (adapted from: WHO/CDS/EPR/2006.6)

Biosecurity - 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 (adapted from: WHO/CDS/EPR/2006.6)

Bio-risk assessment - The process to identify acceptable and unacceptable risks (embracing biosafety risks (risks of accidental infection) and laboratory biosecurity risks (risks of unauthorized access, loss, theft, misuse, diversion or intentional release) and their potential consequences. WHO/CDS/EPR/2006.6

Containment zone – A designated area that allows for the containment, confinement and manipulation of animal, plant or organism that harbours infectious and potentially infectious agents/materials and microbial toxins, which requires good microbiological techniques within its perimeter.

Emergency response plan - measures to be taken in the event of situations such as a spill, exposure, release of infectious material or toxins, animal escape, personnel injury or illness, power failure, fire, explosion, flood, or other emergency situations (as defined by IBBC).

Good microbiological technique - as defined in WHO Laboratory Biosafety Manual 3rd Edition, 2004.

Institution – All registered organizations, Government laboratories; higher learning institutions, Hospitals, Schools, Private companies, Government-linked companies,

Incidents - An event or occurrence (including near miss) involving infectious material, infected animals, or toxins, including a spill, exposure, release of infectious material or toxins, animal escape, personnel injury or illness, missing infectious material or toxins, unauthorized entry into the containment zone, power failure, fire, explosion, flood, or other crisis situations (e.g., earthquake, flood). Incidents should also include laboratory acquired infection (LAI). Canadian Biosafety Standards and Guidelines First Edition, 2013

Medical surveillance programme - surveillance to monitor for occupationally acquired diseases.

Waste management - comprises policies, plans and procedures to address all aspects of waste management, including decontamination and disposal.

5.0 REFERENCES

- a) Laboratory Biosecurity Guidance, World Health Organization, September 2006
(http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf)
- b) Laboratory Biosafety Manual, Third Edition, World Health Organization, Geneva 2004, ISBN 92 4154650
(http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSRLYO_2004_11/en/)
- c) Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, U.S. Department of Health and Human Services, Public Health Service Centers for Disease Control and Prevention, National Institutes of Health, HHS Publication No. (CDC) 21-1112, Revised December 2009
(<http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>)
- d) Laboratory Biorisk Management CWA 15793:2011, European Committee For Standardization, **ICS** 07.100.0
(ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf)
- e) Canadian Biosafety Standards and Guideline, 1st Edition, 2013, ISBN: 978-1-100-22266-0 (<http://canadianbiosafetystandards.collaboration.gc.ca/>)
- f) Guidelines On The Handling And Management Of Clinical Wastes In Malaysia, Department Of Environment, Ministry Of Natural Resources & Environment, Third Edition August 2010
- g) Guidance on regulations for the Transport of Infectious Substances 2007–2008, World Health Organization, Applicable as from 1 January 2007
- h) International Health Regulations (2005) IHR Core Capacity Monitoring Framework: Questionnaire For Monitoring Progress In The Implementation Of IHR Core Capacities In States Parties 2011 Questionnaire

- i) Act 342, Prevention And Control Of Infectious Diseases Act 1988 *Incorporating All Amendments Up To 1 January 2006*, The Commissioner Of Law Revision, Malaysia Under The Authority Of The Revision Of Laws Act 1968, In Collaboration With Percetakan Nasional Malaysia Bhd 2006
- j) Tuberculosis Laboratory Biosafety Manual, World Health Organization 2012. www.who.int/tb/publications/2012/tb_biosafety/en/



