



Regulatory Compliance



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Learning Outcome

- ▶ To demonstrate fundamental awareness of international, national, and institutional legal requirements, laws and regulations, standards, and guidelines on Malaysian biorisk management
- ▶ To recognize the need for legislative requirements on effective biorisk management for the safety of all living things

Topics

► Biosafety & Biosecurity acts & regulations

- Biological Weapons Convention (BWC)
- Prevention And Control of Infectious Diseases Act 1988
- Biosafety Act 2007
- Biosafety Regulations (Approval and Notification)
- Biosafety (Compounding of Offenses) Regulations 2018
- Biosafety (Sampling Procedures) Regulations 2018
- Exceptions for Controlled Consumption Activities
- Malaysia Laboratory Biosafety & Biosecurity Policy & Guideline

► Biosafety & Biosecurity Standard, guidelines & manual

- ❖ WHO laboratory Biosafety Manual 4th edition and 6 monograph
- ❖ Laboratory Biosecurity
- ❖ Biosafety in Microbiological and Biomedical Laboratories
- ❖ Laboratory Biorisk Management Standard
- ❖ World Organisation for Animal Health (OIE)
- ❖ Malaysia Standard MS ISO 1042-3:2015
- ❖ Safety In Laboratories- Code of Practice Part 3: Biosafety & Biocontainment in Microbiology Laboratories
- ❖ ISO 35001 Biorisk Management

► Institutional policies & guidelines

- ❖ Universiti Malaya Laboratory Biosafety & Biosecurity Policy & Guideline

► Consequences of non-compliance (case study/ group discussion)

ACT

A bill that has passed through various required legislative steps and has become **law**.

Related Terms: Statutes, **Legislation**, **Law**, Regulation, Enactment, and Bill
Synonymous with the term enactment or statute.

REGULATION

Regulations are issued by various federal government departments and agencies to carry out the intent of legislation enacted by Congress. Administrative agencies often called "the bureaucracy" perform a number of different government functions, including rulemaking. The rules issued by these agencies are called regulations and designed to guide the activity of those regulated by the agency and also the activity of the agency's employees. Regulations also function to ensure uniform application of the law.

POLICY

- ▶ A **policy** is a set of **ideas** or plans used to make **decisions**, especially in **politics**, **economics**, and business
- ▶ An official organization's **policy** on a particular **issue** or towards a country is their **attitude** and actions regarding that issue or country

STANDARDS

International

- ▶ Laboratory Biorisk Management CWA 15793:2011
- ▶ ISO 15189:2007-Medical Laboratories

Malaysia

- ▶ Malaysian Standard MS 1042-3:2015 (Safety in Laboratories-Code of Practice-Part 3: Biosafety and biocontainment in microbiology laboratories, First revision)



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Exercise 4

- ▶ Each group is to spend 15 minutes listing the differences between regulations and policy
- ▶ Choose a representative from your group to share the outcome of your discussion with the class



LAWS OF MALAYSIA

► Related Regulations:

❖ Biosafety Regulations 2010 (Approval and Notification)

► Implementing Agent: Department of Biosafety

► Relevant Scope: GMOs and their products, import, export, release, containment, transport, occupational health



LAWS OF MALAYSIA

ACT 678
BIOSAFETY ACT 2007

Date of Royal Assent : 28 August 2007

Date of publication in
the Gazette : 29 August 2007

An Act to establish the National Biosafety Board; to regulate the release, importation, exportation and contained use of living modified organisms, and the release of products of such organisms, with the objectives of protecting human, plant and animal health, the environment and biological diversity, and where there are threats of irreversible damage, lack of full scientific evidence may not be used as a reason not to take action to prevent such damage; and to provide for matters connected therewith.

ENACTED by the Parliament of Malaysia as follows:

PART I - PRELIMINARY

Section 1. Short title and commencement

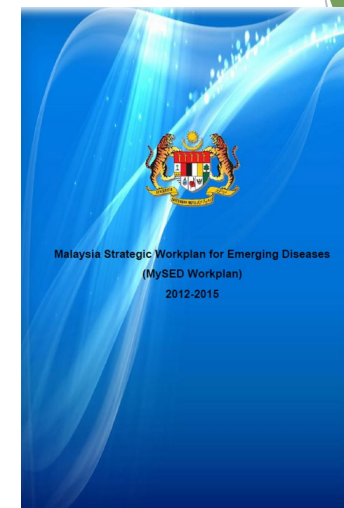
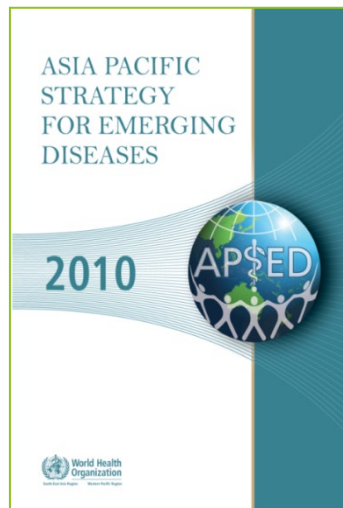
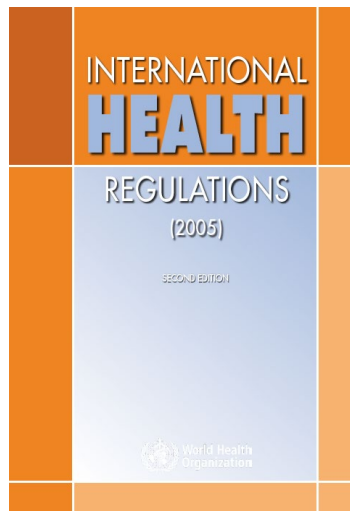
(1) This Act may be cited as the Biosafety Act 2007.



INTERNATIONAL HEALTH REGULATIONS 2005

- ▶ Adopted at the 58th World Health Assembly in Geneva in May 2005, the IHR (2005) entered into force on 15 June 2007
- ▶ The International Health Regulations 2005 (IHR 2005) is an International legally binding regulation in all WHO member states to protect global public health threats of infectious diseases and other Public Health Emergencies of International Concerns (PHEIC)
- ▶ Core capacity 8 – Laboratory Biosafety and Biosecurity

Component of core capacity	Country level Indicator	Development of IHR core capacities by capability level			
		<1 Foundational	1 Inputs and processes	2 Outputs and outcomes	3 Additional achievements
Laboratory biosafety and Laboratory Biosecurity	Laboratory biosafety and Laboratory Biosecurity (Biorisk management ¹¹) practices are in place and implemented	Biosafety guidelines are accessible to laboratories	An institution or person ¹² responsible for inspection (could include certification of biosafety equipment) of laboratories for compliance with biosafety requirements is identified Regulations, policies ¹³ or strategies for laboratory biosafety are available. A responsible entity ¹⁴ is designated for laboratory biosafety and laboratory bio-security (biorisk management). Relevant staff are trained on laboratory biosafety and laboratory biosecurity guidelines.	Biorisk ¹⁵ assessment is conducted in laboratories to guide and update biosafety regulations, procedures and practices, including for decontamination and management of infectious waste.	



THIS DOCUMENT IS IN LINE WITH THE NEED AS OUTLINED IN THE IHR 2005 AND APSED 2010

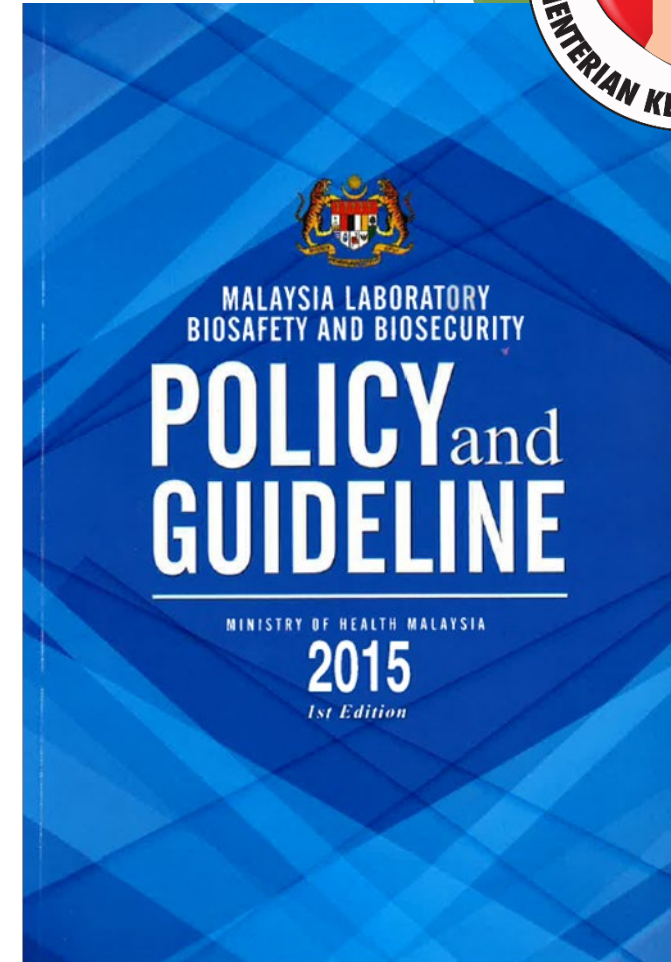


Focus Area 2: Laboratory

Key component	Target [Implementation Level]	Status of achievement
Biosafety	- Develop Biorisk SOP and Policy. - Conduct Biorisk assessment / inspection	- A Working Committee on Biorisk Management established - National Biorisk policy and guidelines developed - Implement & monitor National Biorisk policy and guidelines

POLICY AND GUIDELINE

This document consists of **basic concepts and approaches** in the form of policies and procedures that **govern all activities** involving the handling, manipulating, working, using, storing, and disposing of **infectious and potentially infectious agents/materials and biological toxins** in laboratories and containment zones of all forms and sizes



August 25, 2015



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POLICY

- ▶ It is the 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)**
 - ❖ provide **proper facilities** commensurable with the biosafety risk level of the infectious and potentially infectious agents/materials and microbial toxins being handled
 - ❖ ensure activities are performed by **trained and authorized personnel**
 - ❖ **comply** with all relevant national and international obligations and legal frameworks governing such activities

PREVENTION AND CONTROL OF INFECTIOUS DISEASES ACT 1988

- ▶ Related Regulations: Prevention and Control of Infectious Diseases (Importation and exportation of human remains and tissues and pathogenic organisms and substances) Regulations 2006
- ▶ Implementing Agent: Ministry of Health
- ▶ Relevant Scope: Import, export of pathogenic organisms
- ▶ Purpose: Prevention and Control of Infectious Diseases
- ▶ Main requirements under this Act: In Malaysia, a license is required to import and export pathogenic organisms or substances or part thereof

Biological Weapons Convention

- ▶ BWC or Biological and Toxins Weapons Convention (BWTC)
- ▶ Opened for signature on April 10, 1972
- ▶ Entered into force on March 26, 1975
- ▶ Currently, 163 countries have signed the treaty
- ▶ Multilateral disarmament treaty

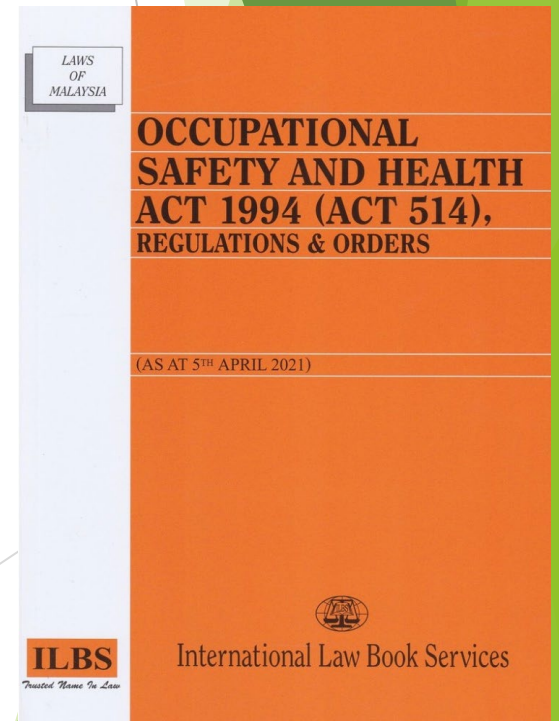
Ban the “Development, production and stockpiling of microbes or their poisonous products except in amounts necessary for protective and peaceful research”

BIOLOGICAL & TOXINS WEAPONS BILL

- ▶ Related Regulations: In progress
- ▶ Implementing Agent: Ministry of Defence/STRIDE
- ▶ Relevant Scope: Handling, import, and movement of biological agents, registration of facilities, and incident reporting
- ▶ Purpose:
 - ❖ Fulfill Malaysia's obligation under the Biological Weapons and Toxins Convention, to prohibit the development, production, and stockpiling of biological and toxin weapons, prevent the release of dangerous biological agents, and monitor facilities

OCCUPATIONAL SAFETY AND HEALTH ACT 1994

- ▶ Implementing Agent: Department of Occupational Safety and Health, Ministry of Human Resources, Malaysia
- ▶ Relevant Scope: Occupational Health
- ▶ Purpose: Securing the safety, health and welfare of persons at work, for protecting others against risks to safety or health in connection with the activities of persons at work
- ▶ Main requirements under this Act:
 - ❖ Establish Safety & Health Committee
 - ❖ Notify accidents, dangerous occurrences, occupational poisoning, and disease
 - ❖ Medical Surveillance



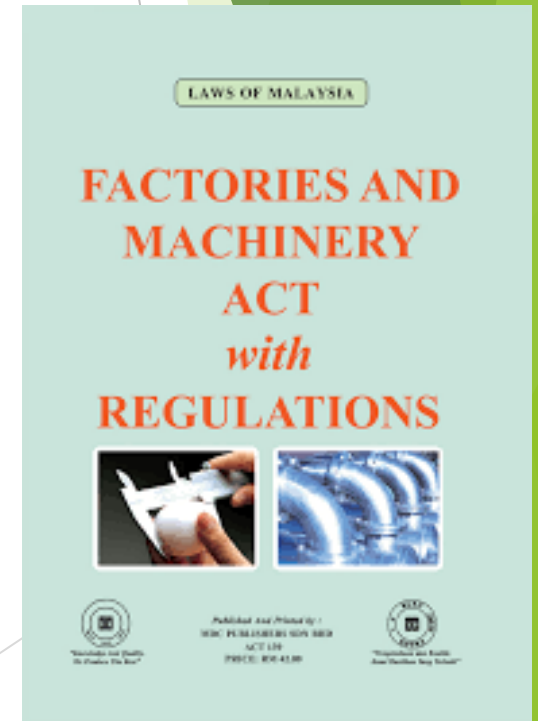
ENVIRONMENTAL QUALITY ACT 1974

- ▶ Related Regulations: Environmental Quality (Scheduled Wastes) Regulations 2005
- ▶ Implementing Agent: Department of Environment (DOE)
- ▶ Relevant Scope: Handling of Waste - SW 404 Pathogenic wastes, clinical wastes, or quarantined materials
- ▶ Purpose: Prevention, abatement, control of pollution, and enhancement of the environment, and for purposes connected therewith
- ▶ Main requirements under this Act:
 - ❖ Pathogenic wastes must be handled by registered waste disposal services
 - ❖ DOE must be informed of the disposal



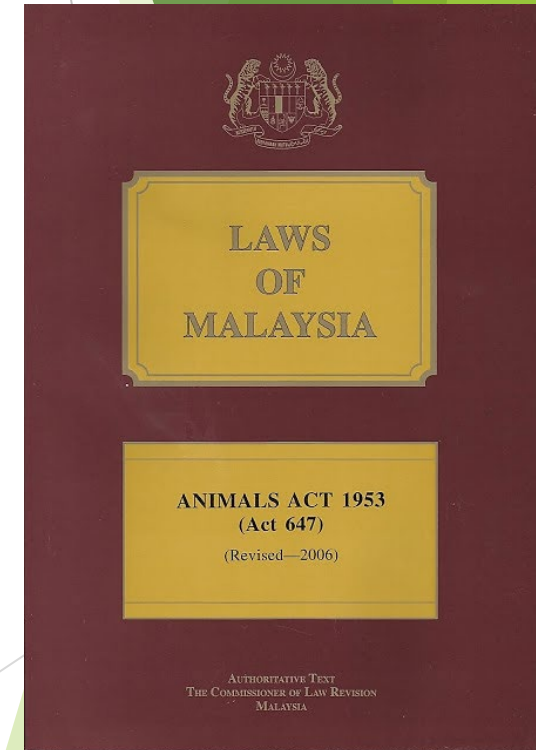
FACTORIES & MACHINERY ACT 1967

- ▶ Related Regulations: Factories and Machinery (Steam Boiler and Unfired Pressure Vessel) Regulations, 1970
- ▶ Implementing Agent: Department of Occupational Safety and Health, Ministry of Human Resources, Malaysia
- ▶ Relevant Scope: Maintenance of Laboratory Equipment - “Steam receiver”, an unfired pressure vessel used or intended to be used to contain steam or autoclave
- ▶ Purpose: To provide for the control of factories with respect to matters relating to the safety, health, and welfare of persons



ANIMAL ACT 1953

- ▶ Implementing Agent: Department of Veterinary Services (DVS)
- ▶ Relevant Scope: Animal welfare
- ▶ Purpose: to
 - ❖ control the import and export of animals and birds
 - ❖ prevent spread of diseases
 - ❖ prevent cruelty to animals
 - ❖ control the movement and slaughter of livestock
 - ❖ conserve and improve the general welfare of animals
- ▶ Main requirements under this Act: Import of animals for laboratory use requires a permit from the DVS

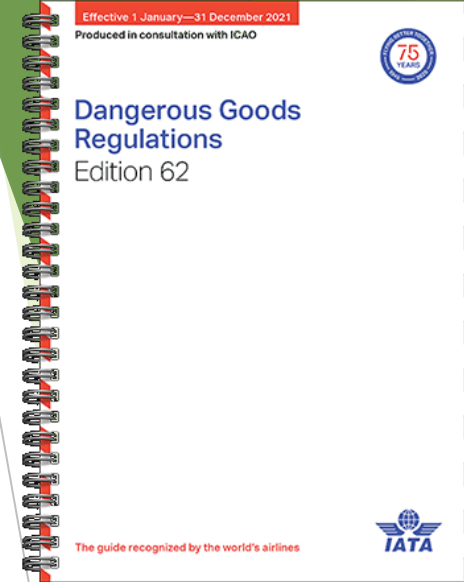


MAQIS - MALAYSIAN QUARANTINE & INSECTION SERVICES ACT 201

- ▶ Related Regulations: Malaysia Quarantine and Inspection Services (Issuance of permits, licenses, and certificates) Regulations 2013
- ▶ Implementing Agent: Department of Agriculture
- ▶ Relevant Scope: Import of plants, animals, fish, and microorganisms
- ▶ Purpose: Provide integrated services relating to quarantine stations and premises and certification for import
- ▶ Main requirements under this Act: Permit, license, or declaration is required to import plants, animals, fish, and microorganisms

IAT REGULATIONS

- ▶ International Air Transport Regulations - updated 2022
 - ❖ Govern national and international shipping of regulated materials by air
 - ❖ The guide is recognized by the world's airlines
- ▶ Implementing Agent: International Air Transport Association
- ▶ Relevant Scope:
 - ❖ Packaging and movement of dangerous goods/biological materials by air (DGR)
 - ❖ Transporting animals by air (LAR)
- ▶ Purpose:
 - ❖ Reference for shipping of dangerous goods by air
 - ❖ Global standard/guide for transporting animals by air in a safe, humane, and cost-effective manner (LAR)

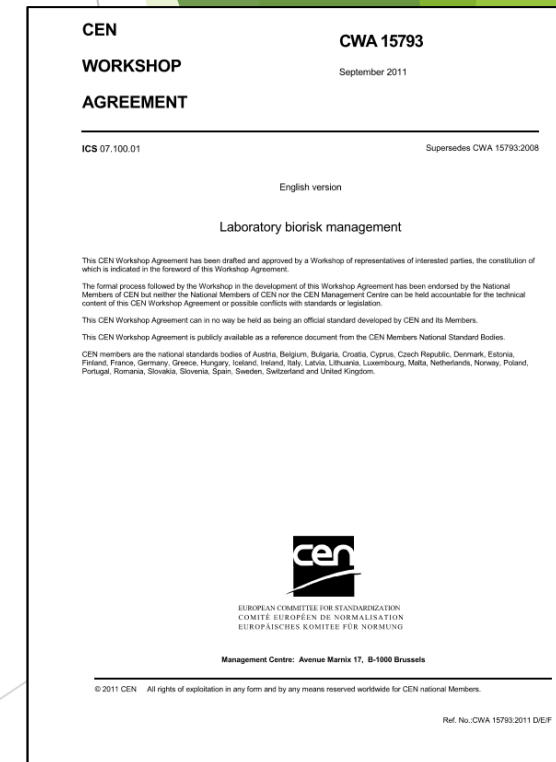


STRATEGIC TRADE ACT 2010

- ▶ Implementing Agent: Ministry of International Trade and Industry
- ▶ Relevant Scope: Export of infectious material
- ▶ Purpose: Control over the export, transshipment, transit, and brokering of strategic items, which can contribute to the proliferation of weapons of mass destruction
- ▶ Main requirements under this Act: Obtain a permit for the export, transship, or transit of strategic or unlisted items

LABORATORY BIORISK MANAGEMENT STANDARD

- ▶ International consensus document developed in 2007 by participants from 24 countries
- ▶ Various stakeholders from around the world (including IFBA and biosafety associations) drafted the document, facilitated by European Committee for Standardization (CEN) in Brussels through the CWA CEN Workshop Agreement process
- ▶ CWA15793 was published in 2008, and revised in 2011
- ▶ Due to a lapse in 2014, it was replaced by the Standard CWA16393: 2012 – Laboratory Biorisk Management: Guidelines for implementing CWA15793: 2008





ICS > 03 > 03.100 > 03.100.70

ISO 35001:2019

Biorisk management for laboratories and other related organisations

ABSTRACT

[PREVIEW](#)

This document defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials. This document is applicable to any laboratory or other organization that works with, stores, transports, and/or disposes of hazardous biological materials. This document is intended to complement existing International Standards for laboratories.

This document is not intended for laboratories that test for the presence of microorganisms and/or toxins in food or feedstuffs. This document is not intended for the management of risks from the use of genetically modified crops in agriculture.

GENERAL INFORMATION

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ICS : [03.100.70](#) Management systems | [07.100.01](#) Microbiology in general | [11.100.01](#) Laboratory medicine in general

BUY THIS STANDARD

FORMAT

LANGUAGE

☒ PDF + EPUB

English 

PAPER

English 

CHF **118**

 **BUY**



MALAYSIAN STANDARD

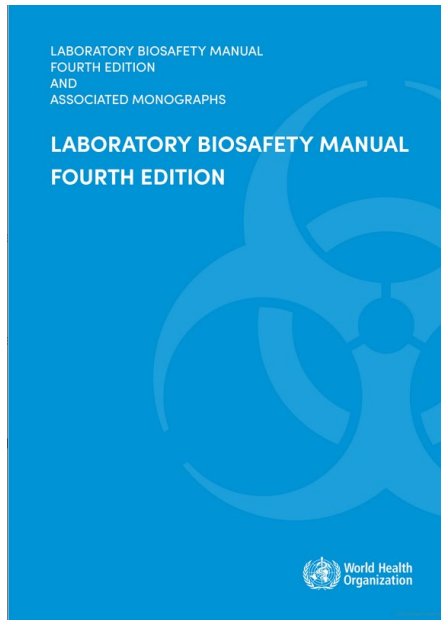
MS 1042-3:2015

**Safety in laboratories - Code of practice -
Part 3: Biosafety and biocontainment in
microbiology laboratories
(First revision)**

Guidelines

- ▶ Guidance documents, not legally binding
 - ❖ Used by some countries that lack their own national guidelines

<https://internationalbiosafety.org/resources/biosafety-biosecurity/biosafety-guidelines/>



Biosafety Guidelines	
Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition, USA	WHO Biorisk Assessment and Guidelines for the Production and Quality Control of Human Influenza Pandemic Vaccines
Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition, USA	WHO Five Moments for Hand Hygiene
Canadian biosafety guideline: Incident investigation	WHO Global Action Plan for Poliovirus Containment (GAPV)
Canadian Biosafety Standard	WHO Guidance on Hand Hygiene in HealthCare
Canadian Biosafety Handbook	WHO Guidance on Regulations for the Transport of Infectious Substances
Guiding Principles for Biosafety Governance, USA	World Health Assembly Resolution 58.29 – Enhancement of Laboratory Biosafety
Guidelines for Biosafety in Teaching Laboratories, USA	WHO Instructions for Storage and Transport of Suspected or Confirmed Human and Animal Specimens and Virus Isolates of Pandemic (H1N1) 2009
Guidelines for Biosafety in Teaching Labs – Appendix, USA	WHO Laboratory Biosafety Manual, 3rd edition
Handbook for Good Clinical Laboratory Practices, Pakistan	WHO Laboratory Biosafety Manual, 4th edition
Infection at Work: Controlling the Risks, UK	WHO Safe Management of Wastes from Health-Care Activities
Laboratory Biosafety & Biosecurity Policy Guidelines, Kenya	WHO TB Biosafety Manual
Laboratory Biosafety Guidebook, Pakistan	OIE Biosafety Guidelines for Handling Pandemic H1N1 2009 Influenza Viruses in Veterinary Diagnostic Laboratories
Microbiological Safety and Containment, Australia	
Practical implementation of LF-LAM for detection of active TB in people living with HIV, GLI, English, French and Portuguese	
TB Laboratory Safety Handbook, GLI, English, French and Portuguese	

Case study

- ▶ Divide yourself into groups
- ▶ Each group is to discuss the following scenario with respect to the regulations, standards, and guidelines and the consequences of non-compliance to the community, country, and humanity

SCENARIO:

You are planning to conduct a project involving a dengue virus. A nonvirulent gene will be inserted into the virus and the recombinant product will be sent to Singapore by air for animal testing. Waste generated from this project will be autoclaved before it can be disposed of by the contract vendor

References

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition
<http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>
- WHO Laboratory Biosafety Manual 3rd Edition
http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/
- WHO Laboratory Biosecurity Guidance
http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf
- Biological Weapons Convention
<http://www.unog.ch/>
- Laboratory Biorisk Management Standard
<ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf>
- Dangerous Goods Regulations, 56th edition, Division 6.2-Infectious Substances
<https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substance-classification-DGR56-en.pdf>
- WHO Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens
http://www.who.int/csr/emc97_3.pdf
- Act 342, Prevention And Control Of Infectious Diseases Act 1988 *Incorporating All Amendments Up To 1 January 2006*
- Malaysia Laboratory Biosafety and Biosecurity Policy and Guideline, Ministry of Health Malaysia, 2014, 1st Edition
- Universiti Malaya Policy and Procedure on Laboratory Biosafety and Biosecurity, University of Malaya, 2015, 1st Edition
- Act 678, Biosafety Act 2007

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Thank you

