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2.0 BIOSAFETY PROGRAMME

2.1 Biosafety Regulations

This facility is governed under the following laws and regulations:

1. Malaysia Biosafety Act 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

2. Australian Government Guidelines for Certification of a Physical Containment Level 2 Plant Facility

The Commonwealth Act and the Commonwealth regulations, together with corresponding state legislation, provide the legislative foundation for Australia's national scheme laws for the regulation of gene technology. The objectives of the national scheme laws are to protect the health and safety of people, and to protect the environment, by identifying risks posed by, or as a result of, gene technology, and by managing those risks by regulating certain dealings with GMOs.

The purpose of certification is to satisfy the Regulator that the containment facility:

- prevents release of GMOs into the environment;
- protects persons outside the facility from exposure to GMOs; and
- protects the safety of people working with GMOs inside the facility

3. OGTR Guidelines for the Transport, Storage and Disposal of GMOs

The *Gene Technology Regulations 2001* (the Regulations, as amended 1 September 2011), require that any notifiable low risk dealing (NLRD) involving transportation, storage or disposal of a GMO outside of certified facilities be conducted in accordance with the *Guidelines for the Transport, Storage and Disposal of GMOs* unless the Gene Technology Regulator ('the Regulator') has agreed otherwise in writing

4. WHO Laboratory Biosafety Manual (Third Edition)

For more than 20 years, since it was first published in 1983, the *Laboratory Biosafety Manual* has provided practical guidance on biosafety techniques for use in laboratories at all levels. For this new edition, the manual has been extensively revised and expanded. The manual now covers risk assessment and safe use of recombinant DNA technology, and provides guidelines for the commissioning and certification of laboratories. Laboratory biosecurity concepts are introduced, and the latest regulations for the transport of infectious substances are reflected. Material on safety in health-care laboratories, previously published elsewhere by WHO, has also been incorporated

5. Malaysia Guidelines for Contained Use Activity of Living Modified Organism (LMOs)

This guideline gives details on the Biosafety Levels (BSL) for containment as well as the safe practices for working with different types of LMO. Types of LMO outlined in the guideline are genetically modified microorganism, plant, animal, arthropod and aquatic. Other information found in this guideline are biological safety cabinet, disposal of LMO and related waste, movement, transport and storage of LMO. This guideline should be used in addition to the relevant legislations, guidelines and references that involve containment facilities

2.1.1 Other Relevant Regulations

1. Malaysia Factories and Machinery Act with Regulations 1967

Factories and Machinery Act (FMA) 1967 or Act 139, is to provide for the control of factories on matters relating to the safety, health and welfare of persons, and the registration and inspection of machinery. Some high risk machinery such as boilers, unfired pressure vessels, passenger lifts and other lifting equipment such as mobile cranes, tower cranes, passenger hoists, overhead traveling cranes and gondolas, must be certified and inspected by DOSH. All factories and general machinery must be registered with DOSH before they can be installed and operated in Malaysia

2. Malaysia Occupational Safety and Health Act and Regulations 1994

The Occupational Safety and Health Act (**OSHA**) 1994 - Act 415 provides the legislative framework to promote, stimulate and encourage high standards of safety and health at work. The aim is to promote safety and health awareness, and establish effective safety organisation and performance through self-regulation schemes designed to suit the particular industry or organisation. The long-term goal of the Act is to create a healthy and safe working culture among all Malaysian employees and employers

In addition to the above regulations, the practices done in this facility should also comply with the following general laboratory regulations:

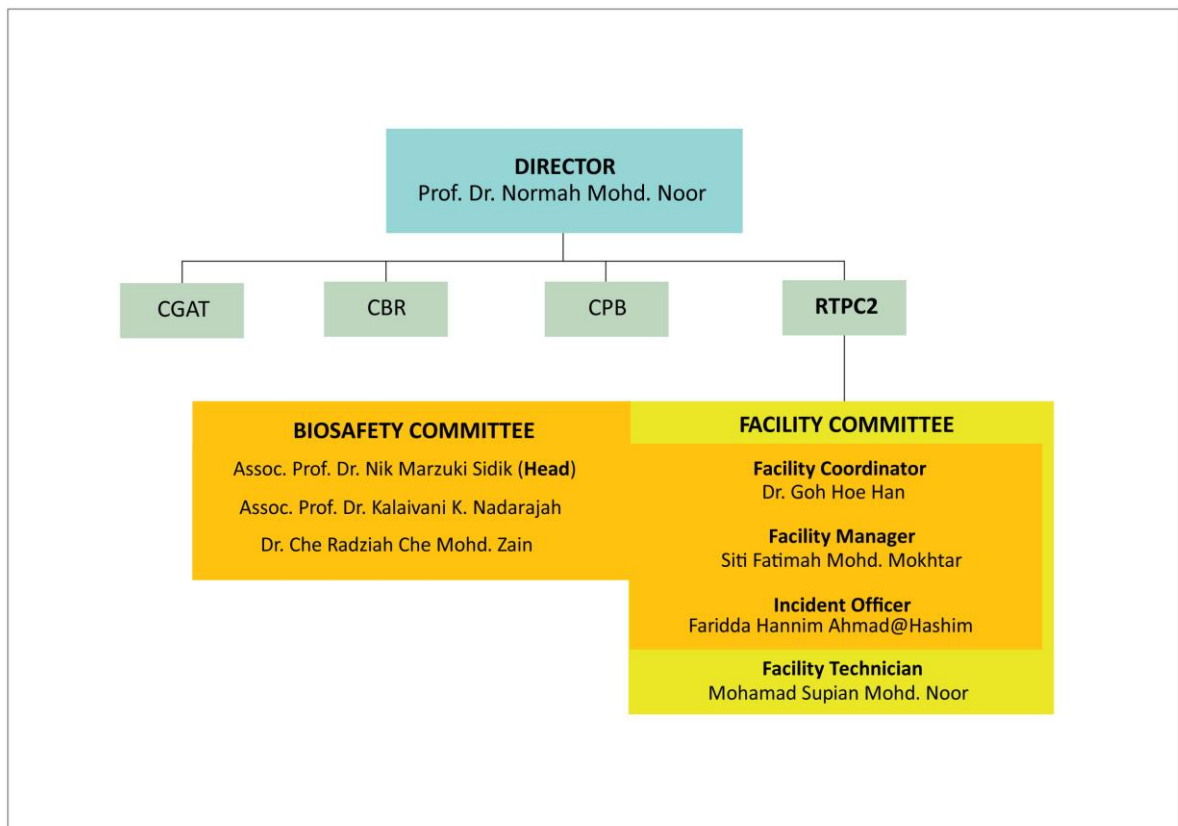
1. Access to the plant facility is limited to authorised personnel only
2. All work done should obtain permission from the facility manager and the IBC
3. All doors to the plant facility should be locked during the experimentation except for the periods in which the personnel are working inside
4. Personnel are required to read and understand the biosafety manual of the greenhouse prior to entering the facility

5. Protected clothing, gloves and footwear should be worn during work and removed before leaving the facility
6. Eating, drinking, smoking and storage of food for human consumption is not permitted in the facility
7. All personnel handling the GM plants or plants associated GM organisms should wash their hands after removing gloves and before leaving the facility
8. Work surfaces should be cleaned daily and any spill should be decontaminated
9. Experimental organisms should be rendered biologically inactive by appropriate methods before disposal outside the facility
10. A living plant should not be taken out from the plant facility except when they are being transferred to another containment facility or to an appropriate release site. Plants taken out should be carried in covered containers
11. All plants should be treated as LMO. Therefore, any waste plants, tissues, soil, soil substitutes and the containers should be decontaminated before disposal

2.2 BIOSAFETY COMMITTEE

2.2.1 Organization Chart

PC2-CERTIFIED GREENHOUSE (RTPC2)



2.2.2. Roles, Duties and Responsibilities

1. INBIOSIS Biosafety Committee (INBIOSIS-BC)

- a. A formal expert committee undertaking modern biotechnology work which involves the use of any LMO/rDNA materials that only involved with this facility
- b. Provide guidance to PI; with the help from the UKM Institutional Biosafety Committee on biosafety policies and issues in the use of LMO/rDNA research, including safety of laboratory personnel and other members of the organisation
- c. Review of all research conducted at this facility through independent assessment of the risks associated with the research and verification of containment levels assigned by the PI(s)
- d. Assess and monitor the facility, procedures, practices, training and expertise of personnel involved in LMO/rDNA research
- e. Ensure all the research activities of the facility comply with the referred guidelines and regulations as stated in the biosafety regulations (Section 2.1)
- f. Determine and approve whether a project can be carried out in this facility or not
- g. Review and approve any changes to the SOP every 2 years

2. Facility Coordinator

- a. Coordinate and monitor the operation of the facility
- b. Acting as a Biosafety Officer of RTPC2 to ensure all research activities and operation of facility comply with the stated rules and regulations
- c. Provide guidance to PI in developing emergency response plan for handling and investigating laboratory accidents involving LMO/rDNA materials
- d. Responsible for submitting all applications for approval and notifications
- e. Ensure all rules and regulations relevant to biosafety are up to-date
- f. Periodically inspect all laboratories where LMO/rDNA research are being conducted to monitor that laboratory standards are being followed in accordance to the biosafety regulations.
- g. Investigate and report all incidents occurring at the facility
- h. Report to the IBC any significant problems, non-compliance of the Biosafety Act 2007, and any significant research-related accidents or illnesses of which the BSO becomes aware, unless the BSO determines that a report has already been filed by the PI

3. Facility Manager

- a. Ensure all work done in the facility are authorized and have obtained appropriate approval through BSC
- b. Ensure all personnel adhere to the rules and regulation of the facility and exercises good laboratory practice all the time during the experimentation
- c. Ensure that all personnel using the facility and visitors are registered and have the approval to enter the facility
- d. Notify the BSO of any health condition or incidents occurring in the plant facility
- e. Report to the BSO on non-compliance of biosafety guidelines or policies

4. Facility Technician
 - a. Operate, monitor and perform periodic maintenance of equipment at the facility
 - b. Deal with any technical issue
 - c. Report any technical breakdown occurring at the facility

5. Incident Officer
 - a. The designated officer who assists in assuring compliance to the Biosafety Act 2007 and the Biosafety (Approval and Notification) Regulations 2010 pertaining to LMO/rDNA research conducted at an organisation
 - b. Acting as a Safety Coordinator to ensure safe working environment
 - c. Assist Facility Coordinator in ensuring that all regulatory aspect related to the researches done in the facility are fulfilled

6. Investigator/Scientist/Laboratory personnel
 - a. Anyone involved in conducting modern biotechnology research in an organisation/institution
 - b. Accountable to the IBC and must comply with the appropriate research guidelines and all applicable laws and guidelines related to biosafety
 - c. Follow all safety practices and establish good laboratory techniques. Use personal protective equipment as required
 - d. Notify the PI or BSO any health condition that may be due to their work in the laboratory or any health condition that may be compromised prior to the initiation of a research project (e.g. pregnancy, immunosuppression)
 - e. Follow all practices and procedures and ensure strict compliance with all required biosafety regulations and guidelines
 - f. Report to PI or BSO on problems, procedural mistakes, spills, etc. as soon as they occur
 - g. Report to the PI, BSO or IBC on non-compliance of biosafety guidelines or policies

2.3 Personnel Training

Access to the PC2-Certified Greenhouse is restricted to authorised persons. Personnel working in a certified facility must be trained in accordance with the facility guidelines. The Biosafety Committee (BSC) requires that all personnel (staff, students, visitors), irrespective of whether they are working with genetically modified organisms (GMOs), must complete the required training to be recognised as an authorised person. Personnel must provide evidence for their training record (Appendix 5.6) and demonstrate that they fully understand their training to the facility manager

2.3.1 Training Programmes

Any person handling GM plant(s) must receive instruction and training in the safe handling, storage, transport and disposal of such material, and in emergency procedures in the event of exposure and spills

1. Compulsory Training Course for facility users:
 - i. An Introduction to Biosafety
 - a. OGTR Guidelines:
 - Guidelines for Certification of a Physical Containment Level 2 Plant Facility; Behavioural Requirement
 - Guidelines for the Transport, Storage and Disposal of GMOs
 - b. Malaysian Biosafety Act & Guidelines
 - c. GM-biosafety training
 - d. Risk Assessment
 - ii. Hands-on training (on individual basis)
 - a. Handling of GMOs (Transport and disposal of GM Plants)
 - b. Waste disposal
 - c. Emergency procedures
2. Additional Reading:
 - i. PC2 Facility Regulations
 - ii. Risk assessment relating to work to be undertaken
 - iii. Standard operating procedures and protocols of PC2 facility:
 - a. SOP 1 Signage and Labeling of the Facility
 - b. SOP 2 Project-specific Risk Assessment and Application Process
 - c. SOP 3 Project Application and Approval Process
 - d. SOP 4 Greenhouse Control and Monitoring System
 - e. SOP 5 Greenhouse Entry & Exit
 - f. SOP 6 Transfer of GM Plants (in and out)
 - g. SOP 7 Transfer of Non-GM Plants (in and out)
 - h. SOP 8 Inventory of GM Plant(s)
 - i. SOP 9 Operation of Autoclave
 - j. SOP 10 Waste Management
 - k. SOP 11 Chlorination System
 - l. SOP 12 Spill Management
 - m. SOP 13 Emergency Management
 - n. SOP 14 Cleaning and Housekeeping
 - o. SOP 15 Usage of Tools
 - p. SOP 16 Disinfection of Equipment, Tools, and Surfaces
 - q. SOP 17 Pest Management
 - r. SOP 18 Maintenance and Monitoring
 - s. SOP 19 Record Keeping and Document Management
 - t. SOP 20 Incident and Accident Reporting
3. All persons must indicate their completion of the appropriate training by signing the "Training Record Form" and submit to the Facility Manager
4. This procedure must be completed before any staff/student commences work at RTPC2
5. Refresher courses may be appropriately conducted either formally or informally

2.3.2 Personnel

Permanent Staff and Students

All persons must indicate their completion of the appropriate training by signing the “Training Record Form” and lodging it with the Safety Co-ordinator. This procedure must be completed before any staff/student commences PC2-Certified Greenhouse work

Temporary Staff and Students

All persons wishing to do any work, or use any equipment, in any of the PC2 areas must be recorded on the complete the required training and lodge in the “Training Record Form”. This includes persons from other institutions. Research Supervisors must report all such persons to the Facility Manager

Staff and Students from other institutions: As above

Cleaning Staff: The Facility Manager provides an appropriate document to guide cleaning staff. Supervising cleaning staff will attend appropriate training provided by the Facility Manager. These two measures are to ensure cleaning staff is competent to perform their duties in a PC2 area

Security Staff: Will be given documentation and training as for cleaners

Service & Repair Staff – University: Property Services are informed that entry into PC2 areas is dependent on gaining the permission of the Facility Manager. Dependent on the work to be done the Facility Manager will make appropriate safety arrangements

Service & Repair Staff – Non-University: The Facility Manager must be informed of all such work and he will make appropriate safety arrangements

NOTE: Emergency situations – as all PC2 material is safely stored in our PC2 facilities, work can start on remedying most emergency problems immediately but the Facility manager should be consulted

Other training

All users might be required to complete any additional training deemed necessary by the Biosafety Committee (IBC)

2.4 VISITOR POLICY

Visitor notice. Welcome! Institute of Systems Biology (INBIOSIS) is committed to making your visit a safe and healthy one for you and others in the workplace. It is for that reason that we require all visitors to INBIOSIS grounds, facilities and workplaces to abide by the following safety rules while they are here

It takes the efforts of everyone working together - including visitors - to RTPC2 facility a safe & healthy workplace

1. **Visiting procedure.** All visitors may make appointments by emailing a Visit Form through our website (<http://www.inbiosis.ukm.my/rtpc2>). Please note that a minimum of two weeks advance notice is required to arrange your visit. Facility Manager will schedule an appointment for visitors based on date and time availability
2. **Logging in.** All visitors shall come to the reception desk at the main office and fill in the visitor's log. The form records each visitor's name and company affiliation, as well as the purpose and duration of their visit
3. **Hazard/emergency plan notification.** As part of the log-in process, you will be given a sheet describing the hazards of the workplace and the procedures to follow in case of an emergency
4. **Personal protective equipment.** All visitors must use and wear the following personal protective equipment at all times while visiting the plant facility: [*gloves, laboratory coat, laboratory shoes*]
5. **Visitors will be accompanied by a sponsoring employee at all times.** All visitors must be accompanied by the employee(s) that they are visiting for the duration of their stay. This requirement does not apply to users of the plant facility. Special arrangements may also be made to accommodate contractors on long-term assignments. Any special arrangements must be cleared with the Facility Manager
6. **Rules of conduct** All visitors must obey the following rules of conduct at all times:
 - Follow all verbal instructions and signs
 - Do not touch or attempt to operate any machine, device or equipment unless instructed so
 - Do not talk to or distract workers who are operating machines, devices or equipment or engaging in safety-related functions like traffic control
 - Do not engage in any pranks, horseplay, contests, feats of strength, running or rough and boisterous conduct
 - Stay out of restricted areas
 - Report all injuries or problems immediately, no matter how minor
7. **Photographs.** No photographs may be taken by visitors without prior approval from the Facility Manager. Furthermore, any permitted photographs may not be published without prior approval from the Facility Manager
8. **Logging out.** Visitors must leave through the same reception area in which they entered and log out