

# **SSBC Manual**

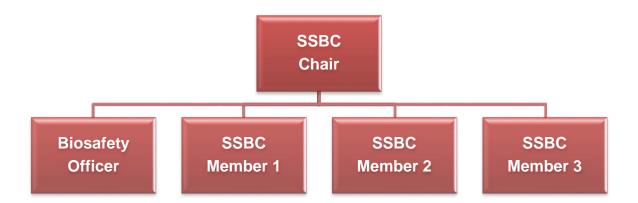
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Reviewed by:
Swinburne Sarawak Biosafety Committee
(SSBC)

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# 1. Swinburne Sarawak Biosafety Committee (SSBC) Structure



# 2. Purpose

The purpose of this SSBC Manual is to serve as guidelines and information for Swinburne Sarawak's staff and students to ensure the correct and smooth workflow of handling and dealing with the living modified organisms (LMOs) and biohazardous materials.

Please note that this manual will be periodically reviewed and updated when additional information is required to develop and implement appropriate and better biorisk and biosafety workflow system. Hence, it is important that the readers assure themselves that they are using the latest version.

The latest version of SSBC manual can be obtained from G:\FECS\Biosafety.

### 3. Responsibilities

#### 3.1 Swinburne Sarawak Biosafety Committee (SSBC)

- a) To assist Swinburne Sarawak in its commitment to provide a safe and healthy environment in relation to LMOs, biohazardous materials or facilities.
- b) To assist Swinburne Sarawak in meeting its legislative and contractual obligations concerning the safe production, handling, storage and disposal of biohazardous materials, particularly LMOs.
- c) To ensure compliance to Malaysia's Biosafety Act 2007, the Biosafety (Approval and Notification) Regulations 2010 and associated guidelines provided by the National Biosafety Board (NBB) of Malaysia and the Occupational Health and Safety Committee (Swinburne Sarawak).
- d) To review applications for conducting activities which pose biosafety risks to Swinburne Sarawak researchers, teaching staff or students in regards to risk identification, operating procedures and facility requirements prior to their submission to the NBB of Malaysia.
- e) To assess, approve, inspect or monitor activities or facilities relating to or involving LMOs and/or biohazardous materials, including advising and assessing whether the proposed activity or facility complies with guidelines set out by the NBB of Malaysia, Occupational Health and Safety legislation or other relevant safety boards.
- f) To advise Swinburne Sarawak in relation to national and international professional codes of conduct, and community standards and expectations concerning LMOs, biohazardous materials or facilities.
- g) To advise on, revise and approve policies, guidelines and procedures for the safe handling, storage or disposal of LMOs and/or biohazardous materials, including the training and qualifications of personnel involved.

#### 3.2 Biosafety Officer (BSO)

- a) Serve as a liaison officer between Swinburne Sarawak and external regulatory agencies concerning the use of LMOs and/or biohazardous materials.
- b) Provide guidance for matters related to biosafety in both teaching and research (e.g. handling, using, storing and disposal of LMOs and/or biohazardous materials).
- c) Periodically inspect all laboratories where LMOs and biohazardous activities are being conducted to monitor that laboratory biosafety standards are being followed.
- d) Provide guidance to PI and lab personnel in developing emergency response plan for handling and investigating laboratory accidents or illness involving LMOs and/or biohazardous materials.
- e) Report to the SSBC any significant problems, non-compliance of the Biosafety Act 2007, and any significant research-related accidents or illnesses involving LMOs and/or biohazardous materials.
- f) Submission of SSBC annual report to the NBB, on behalf of the Swinburne Sarawak.

#### 3.3 Project Investigator (PI)

- a) The PI is accountable to the SSBC and is required to comply with the appropriate research guidelines and all applicable laws related to biosafety.
- b) The PI involved in export, import, contained use and field experiment of LMOs shall comply with relevant requirements of the Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and other related regulations.
- c) The PI should submit all LMOs and biohazards applications for review and approval to SSBC.
- d) PI cannot modify the approved research project involving LMOs and biohazardous materials. Example of modifications includes change of the biosafety level (BSL) and/or Risk Group or change of premise. Such modifications have to be assessed by SSBC before the modifications of research project are allowed.
- e) Immediately notify the BSO and SSBC of any significant research related accidents that have resulted or could result in human illness, unanticipated plant or animal disease, or in the unintended release of LMOs and biohazardous materials under study from an intended confinement.
- f) Develop and obtain SSBC approval for Risk Assessment, Risk Management Reports and Emergency Response Plan to handle accidental spills and personnel contamination, and to adhere strictly to such plans.

#### 3.4 Laboratory Personnel (lab staff, students, research assistants)

- a) Follow all safe work practices and establish good biosafety laboratory techniques. They must work within the assigned biological safety containment level and use appropriate personal protective equipment (PPE) and engineering control as recommended by the PI, BSO and lab staff.
- b) Immediately notify the PI and BSO of any research related accidents and health conditions that may be due to their work in the laboratory or any health conditions that may be compromised prior to the initiation of a research project (e.g. pregnancy, immunosuppression).
- c) Follow all practices and procedures as provided by the PI and BSO, and ensure strict compliance with all required biosafety regulations and guidelines.
- d) Report problems, procedural mistakes, spills, etc. to the PI and BSO as soon as they occur.
- e) Report to the PI and BSO on non-compliance of biosafety guidelines or policies.

#### 4. Overview of the Biorisk Workflow

Submit the application(s) for all types of LMO and biohazard activities (teaching and research) to BSO.

#### **Living Modified Organisms (LMOs)**

- 1. Living Modified Microorganisms
- 2. Living Modified Plants
- 3. Living Modified Animals
- 4. Living Modified Aquatic Organisms

#### **Biohazards**

- 1. Microorganisms (RG 1, 2, 3 and/or 4)
- 2. Human Tissue or Blood Products
- 3. Cultured Primary Mammalian Cells / Mammalian Cell Lines Likely to Contain Infectious Agents
- 4. Biological Toxins



Submit the purchasing and inventory of all types of LMOs and biohazardous materials to BSO.



Arrange for Biosafety Briefing from PI, BSO or Science Lab Officer.

Request to access to science laboratories and science facilities from Science Lab



Submit annual report of the approved LMO and biohazard activities (teaching and research) to BSO.

Notify BSO for modifications, extension or termination of approved project(s).

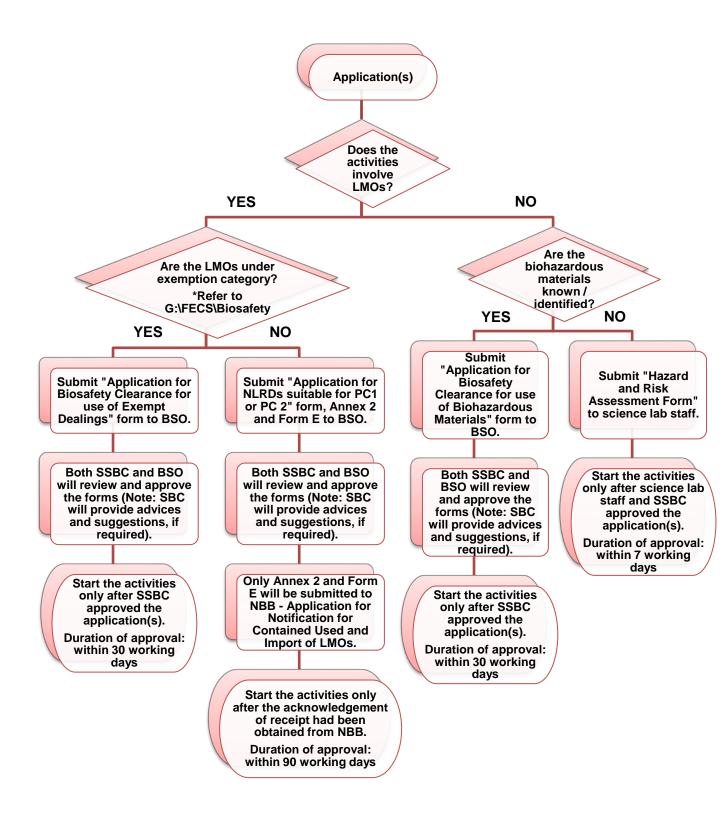


Report any LMO and biohazard related incidents to PI, HSO, BSO and/or any lab staff.



Consult PI or BSO first before the export or shipping of LMOs and/or biohazardous materials.

# 5. Application Process 5.1 Flowchart



# 5.2 Application Review: Criteria

The application(s) for LMOs and/or biohazardous activities or research will be reviewed by SSBC and proceed for further approval according to the criteria as below:

No.	Criteria					
1.	Do the science lab facilities meet the biosafety level of the LMOs and/or biohazard					
١.	activities?					
2.	Is the research or activity a dual use research?					
	The information as below must be adequate:					
	a) Source of gene / inserted DNA sequence (e.g. common and scientific name of					
	the donor organism, common and scientific name of the parent / recipient organism)					
3.	b) Nature of inserted DNA sequence (e.g. structural gene, oncogene)					
	c) Hosts and vectors to be used					
	d) Agent characteristics (e.g. virulence, pathogenicity, environmental stability)					
	e) Modified trait					
	f) Function of the modified trait					
4.	Detailed and proper risk assessment.					
5.	Detailed and proper risk management.					
6.	Detailed and proper emergency response plans (e.g. spills, occupational exposure,					
0.	unintentional release etc.).					
	Detailed and proper Standard Operating Procedures (e.g. step-by-step protocol					
7.	including experiment steps, safety steps, risk highlighted, proper containment steps					
	etc.).					
8.	Qualifications of the involved laboratory personnel.					
9.	Proper storage of the LMOs and/or biohazardous materials.					
10.	Proper record keeping of the LMOs and/or biohazardous materials.					
11.	Details of the suppliers: for the purchased LMOs and/or biohazardous materials.					

# **5.3 Modifications of Approved Project**

The PI cannot initiate or implement any significant changes or modifications to SSBC and/or NBB approved projects without the prior review and approval of the SSBC and NBB. This includes, but is not limited to:

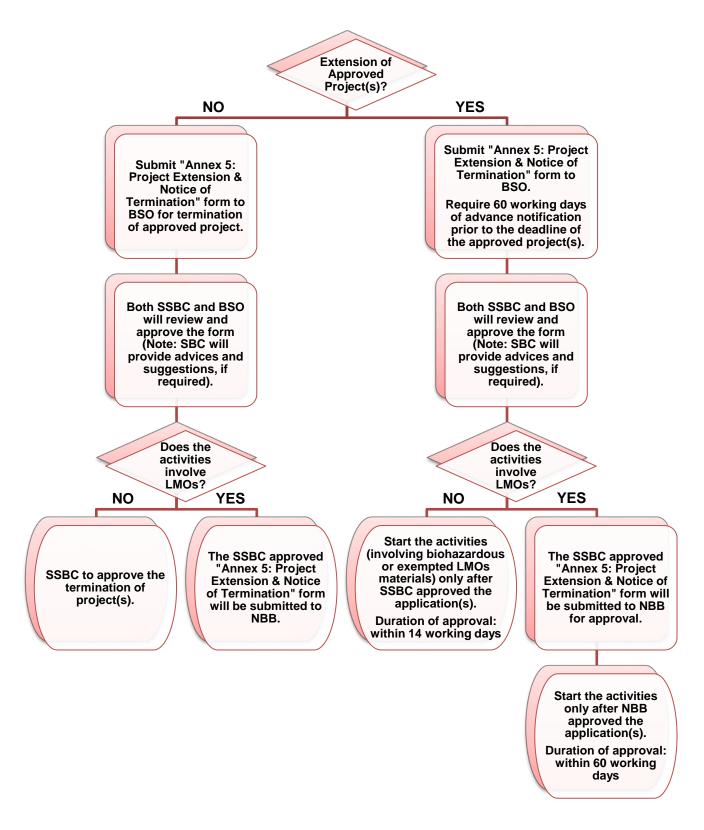
- Modification of LMOs and/or biohazardous materials
- Procedural changes
- Changes in laboratory personnel and/or adding of new personnel
- Change in laboratory location
- Any or all of which may change or increase the Risk Group and/or BSL of the project

PI or applicants must revise and submit the previously approved application form to SSBC for approval before making any of these changes.

Refer to Section 5 Application Process; Subsection 5.1 Flowchart.

#### 5.4 Extension or Termination of Approved Project

PI or applicants must obtain approval from SSBC before any extension or termination of the activities and research involving LMOs and biohazardous materials.



#### 5.5 Annual or Final Report of Approved Project

Annual or Final Report of Approved Project(s).

Submit "Annual/Final Report for use of Biohazardous Materials" form to BSO.

Both SSBC and BSO will review and approve the form (Note: SBC will provide advices and suggestions, if required).

PI will be notified on the SSBC decision, within 14 working days.

#### 5.6 Submission of SSBC Annual Report to NBB

BSO will compile the information as below for submission of SSBC annual report:

- 1. LMOs/rDNA activities for Notifications/Approvals
- 2. Modifications to Approved Projects
- 3. Exempted Activities in the Facilities
- 4. Exposure Investigation Incidents and Occupational Disease Records
- 5. Facilities Inspection
- 6. SSBC Meetings
- 7. Internal Institutional Training Related to Biosafety
- 8. Record of LMOs Stored in Facilities

SSBC will review and approve the annual report.

(Note: DVC, OHSC and SBC will provide advices and suggestions, if required)

BSO will submit the approved SSBC annual report to Direct General, Department of Biosafety through

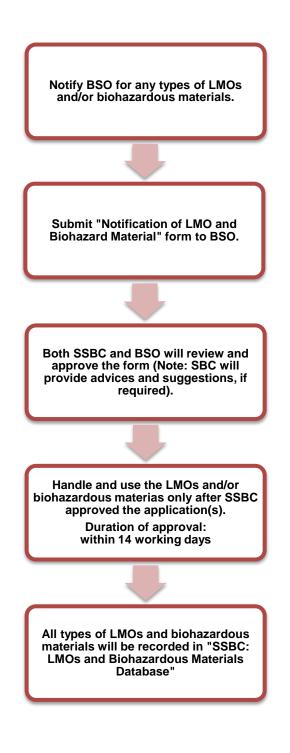
biosafety@nre.gov.my

#### 6. Procurement Process

Consideration to purchase LMOs and/or biohazardous materials. Submit "OHS-F-4.18.X Pre-Purchase Material Risk Assessment Form" and "Quotation Summary Form" to BSO. Note: Attach also the "Pathogen Safety Data Sheet" as supporting document. BSO and/or lab staff will review the submitted forms. Faculty Manager or Director of RCFP will approve the reviewed forms. Submit the approved forms to finance for further processing. Notify BSO when LMOs and/or Biohazardous Materials had arrived.

Refer to Section 7: Notification of LMO and Biohazardous Material.

#### 7. Notification of LMOs and Biohazardous Materials



# 8. Laboratory Access and Safety Briefing

PI or Unit Convenor to inform the Science Lab Officer.

Lab personnel to fill in these forms:

- 1. Science Lab Access Request Form
- 2. Equipment Glassware Chemical Booking Request Form (for undergraduate only)
- 3. Online Lab Safety Orientation & Assessment (for research only)
- 4. Hazard and Risk Assessment Form

Lab personnel to submit the completed forms to the supervisor for approval.

Supervisor(s) to submit the approved forms to Lab Officer.

Both Lab Officer and BSO will review the forms. Duration of review: within 14 working days.

Lab personnel to attend these briefings:

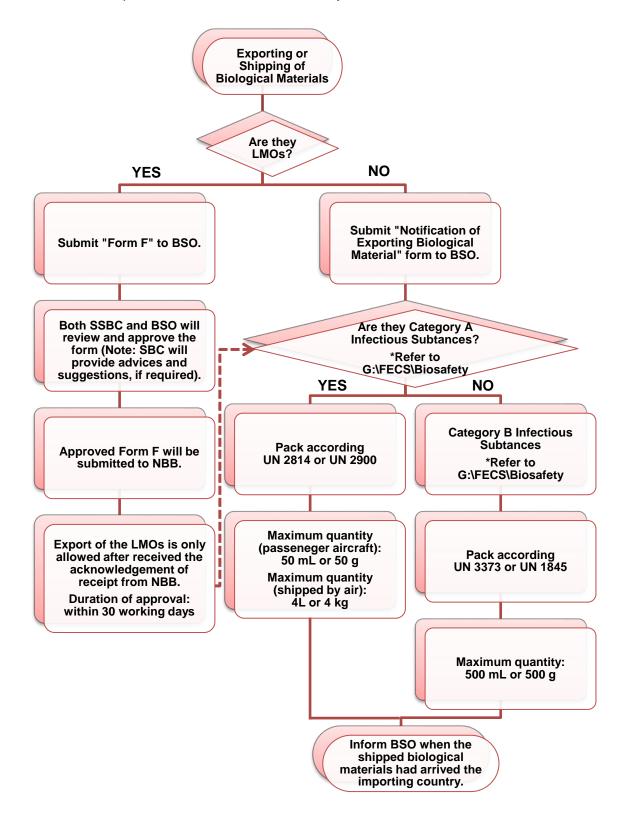
- 1. Lab Safety Briefing and Lab Tour
- 2. Equipment Briefing

(e.g. Hirayama Autoclave and/or SWAN air compressor).

Lab personnel can only access to the science labs and facilities after the approval of the submitted forms and had attended the briefings.

# 9. Exporting or Shipping of Biological Materials

PI or lab personnel must obtain approval from SSBC before exporting or shipping of biological materials especially the export of LMOs from the approved projects. Submission of notification for export of LMOs to NBB is necessary.



# 10. Facilities Inspection

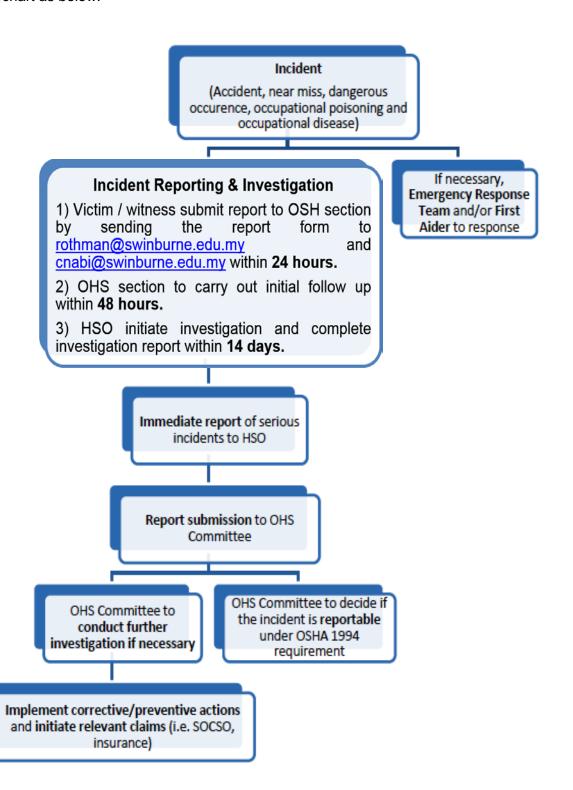
SSBC and BSO will monitor and inspect the facilities involving LMOs and biohazardous materials to ensure that the facilities are in compliance to Malaysia Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010. Facilities that are appropriate and safe for activities involve LMOs and biohazardous materials are essential.



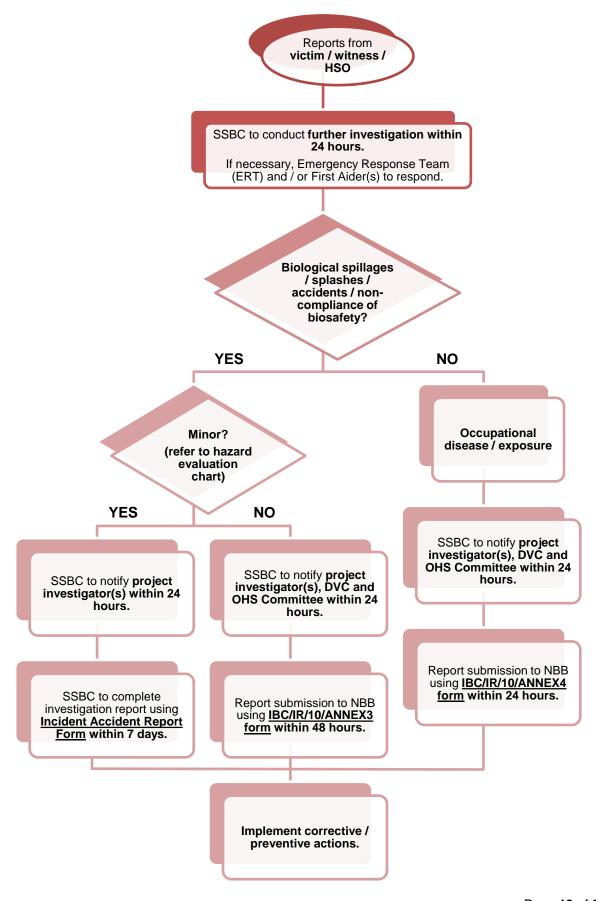
# 11. Incident Reporting Process Flow

#### 11.1 Overview

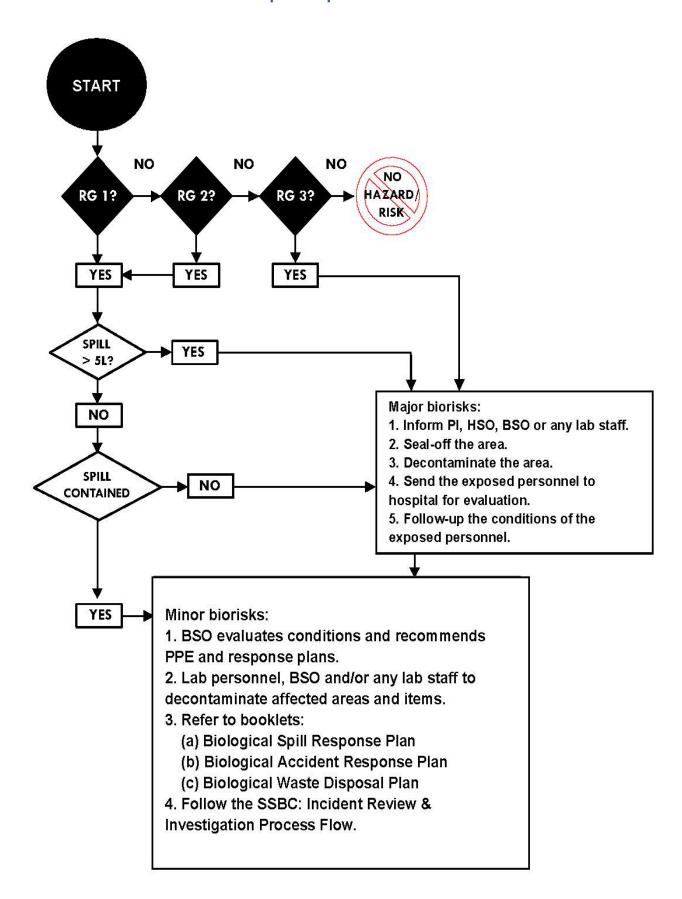
Lab personnel must immediately report (within 24 hours) any LMOs and biohazards related incidents to PI, health and safety officer (HSO), BSO and/or any lab staff. Refer to the flowchart as below.



#### 11.2 SSBC: Incident Review and Investigation Process Flow



#### 11.3 Hazard Evaluation Chart & Spill Response in Containment Facilities



# 12. Appendices

### **Appendix 1: Acronyms**

BSC Biosafety Level BSO Biosafety Officer

DVC Deputy Vice-Chancellor
HSO Health and Safety Officer
LMOs Living Modified Organisms
NBB National Biosafety Board
NLRDs Notifiable Low Risk Dealings
OHS Occupational Health and Safety
PC Physical Containment Level

PI Project Investigator

PPE Personal Protective Equipment

RG Risk Group

SBC Swinburne Biosafety Committee (Melbourne)
SSBC Swinburne Sarawak Biosafety Committee

# **Appendix 2: Staff Directory**

Name	Designation	Building Location	Room	Contact No.	E-mail
Awang Azman	Lab Tech (Electronic)	E	E502	260753	ahasmah@swinburne.edu.my
Bennard Merudi	Lab Tech (Civil)	E	E003A	260729	bmerudi@swinburne.edu.my
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Cinderella Sio	Lab Tech (Science)	В	B701	260953	csio@swinburne.edu.my
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Dayang Rafika Atiqah Abang Othman	Health and Safety Executive	G	G617	260679	rothman@swinburne.edu.my
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Fadilah Johari	Lab Tech (Mechanical)	E	E003A	260751	fjohari@swinburne.edu.my
Faizal Sufri Sukor	Lab Tech (Robotics & Mechatronics)	E	E217	260774	fsukor@swinburne.edu.my
Hwang Siaw San	SSBC Member 1	E	E206	260825	shwang@swinburne.edu.my
Liz Leonara	Lab Tech (Civil)	E	E110A	260971	lhowell@swinburne.edu.my
Marciana Jane Richard	Lab Tech (Science)	В	B609A	260695	mrichard@swinburne.edu.my
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Ng Sing Muk	SSBC Member 3	Α	A401D	260848	Smng@swinburne.edu.my
Nurul Arina Salleh	Lab Officer (Science)	В	B701	260953	nasalleh@swinburne.edu.my
Si Yan Eng	Lab Officer (Engineering) cum Lab Coordinator	Е	E402	260716	yesi@swinburne.edu.my
Thomas Manggie	Lab Tech (Mechanical)	E	E110A	260688	tmanggie@swinburne.edu.my
Usha Devi Nair	Lab Tech (TNE)	E	E402	260711	udnair@swinburne.edu.my
Victor Peter	Lab Officer (Engineering)	E	E107	260645	vpeter@swinburne.edu.my
Wallace Wong	SSBC Chair	В	B409	260628	wwong@swinburne.edu.my

# 13. References

Name	Location / Link		
Department of Biosafety	http://www.biosafety.nre.gov.my/		
Guidelines for Institutional	http://www.biosafety.nre.gov.my/guideline/guidelines%20f		
Biosafety Committee (2010)	or%20institutional%20biosafety%20comittees.pdf		

# 14. Responsibility

# 15. Version Control and Change History

Version Number	Approval Date	Approved By	Amendment
2	August 2017	SSBC	<ol> <li>Update of the SSBC members, SSBC and BSO responsibilities, application flow for activities involving unidentified biohazardous materials, duration of the approval from the Department of Biosafety, incident reporting process flow, file location and Appendix 2: Staff Directory.</li> <li>Changes in the application flow for the modifications of the approved projects, submission flow of the SSBC annual report to Department of Biosafety and facilities inspection flow.</li> <li>Addition of the criteria for the application review process.</li> <li>Addition of the "Responsibility" and "Version Control and Change History" sections.</li> </ol>
1	November 2015	SSBC	New SSBC manual.