
# SSBC Manual

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**Reviewed by:**
**Swinburne Sarawak Biosafety Committee (SSBC)**

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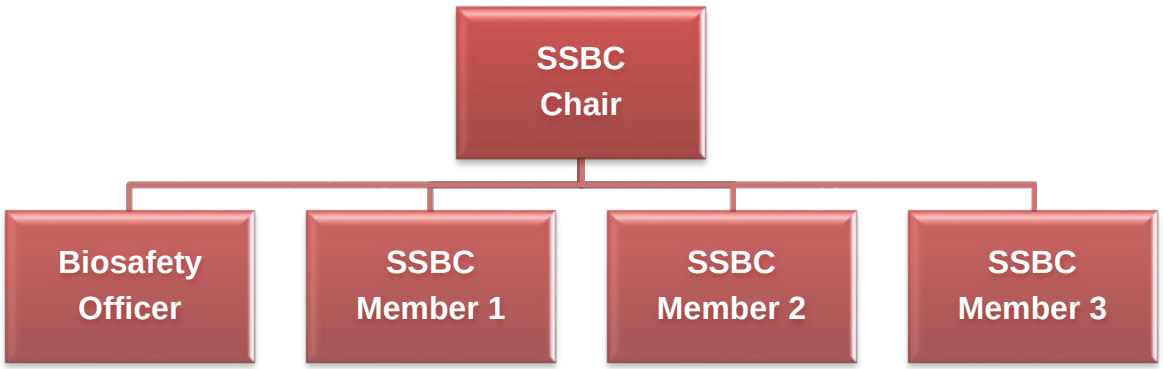
## 1. Swinburne Sarawak Biosafety Committee (SSBC) Structure




## 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.

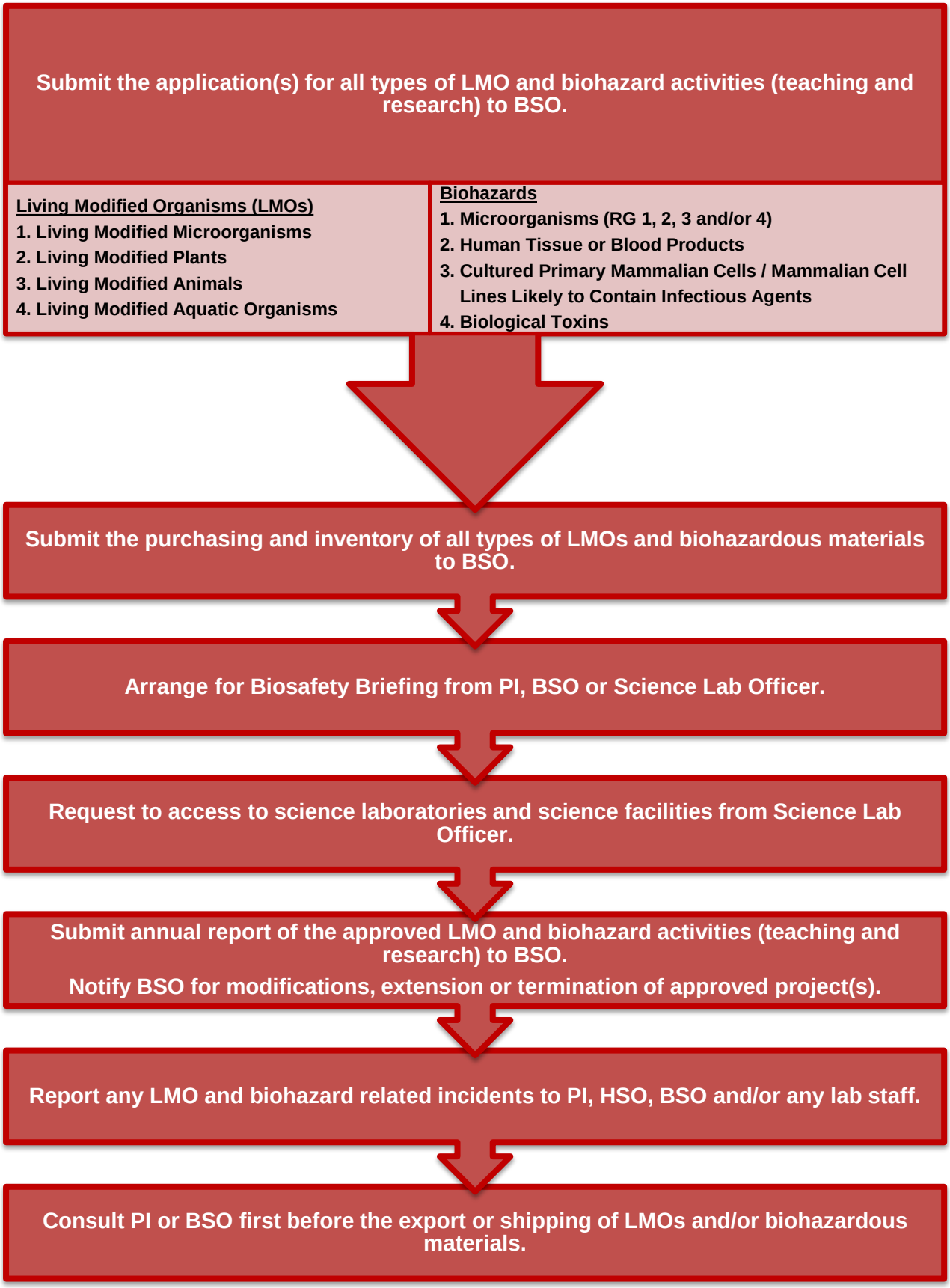
## 3.3 Project Investigator (PI)

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)

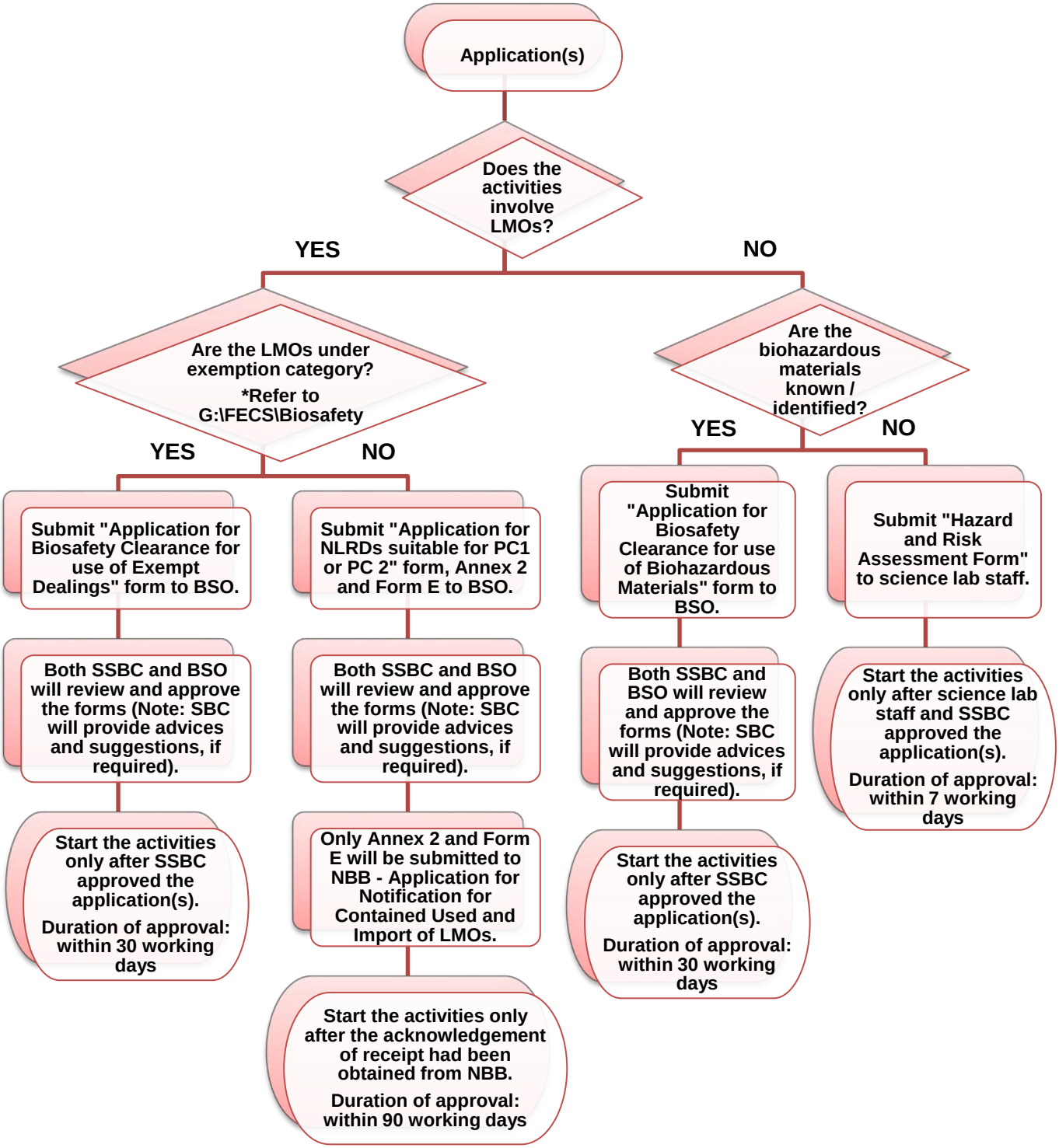
a) Follow all safe work practices and establish good biosafety laboratory techniques. They must work within the assigned biological safety containment level and use appropriate personal protective equipment (PPE) and engineering control as recommended by the PI, BSO and lab staff.
b) Immediately notify 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



# 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 activities? |
| 2. | Is the research or activity a dual use research? |
| 3. | The information as below must be adequate:<br>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)<br>b) Nature of inserted DNA sequence (e.g. structural gene, oncogene)<br>c) Hosts and vectors to be used<br>d) Agent characteristics (e.g. virulence, pathogenicity, environmental stability)<br>e) Modified trait<br>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, unintentional release etc.). |
| 7. | Detailed and proper Standard Operating Procedures (e.g. step-by-step protocol 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:

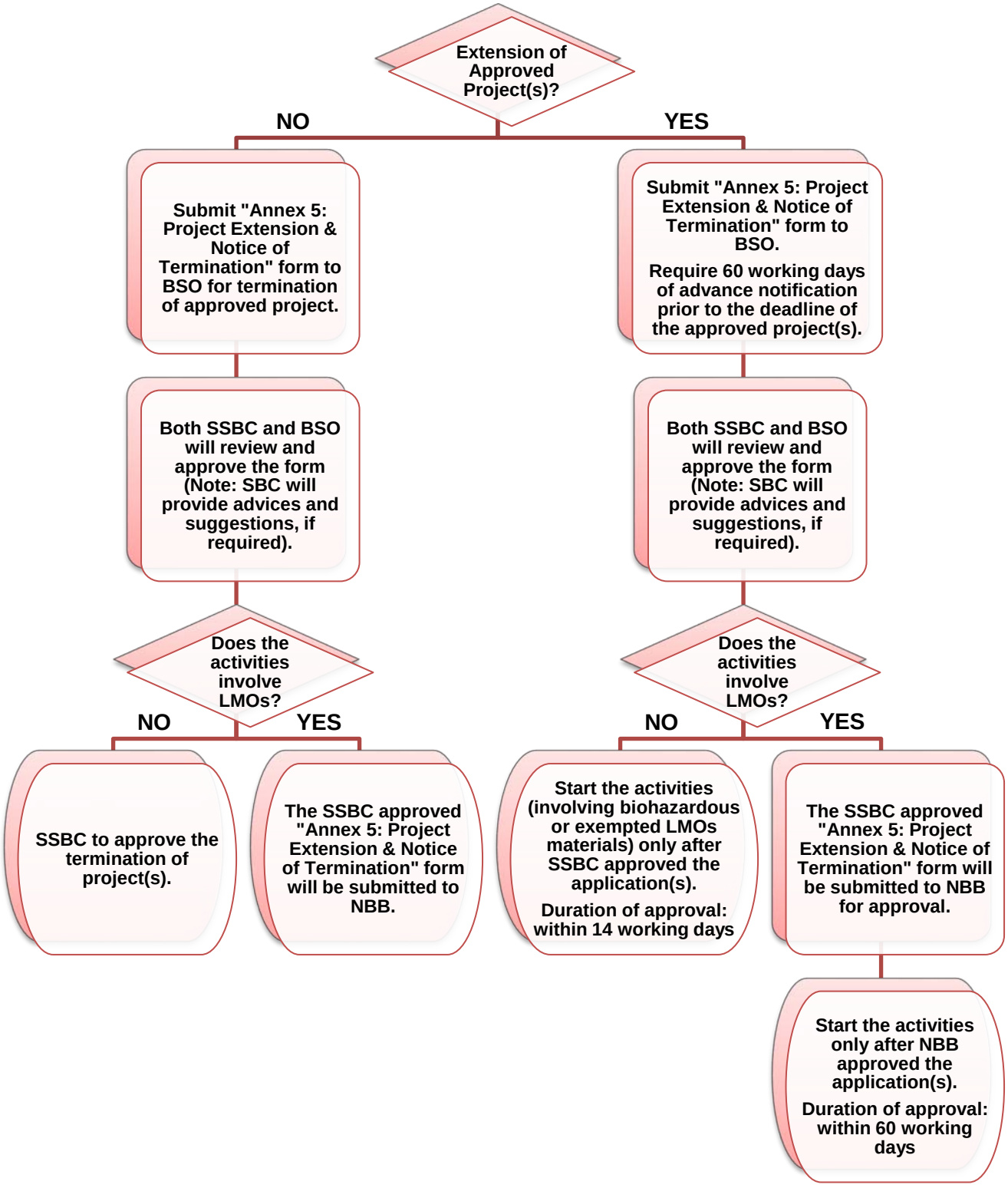
- Modification of LMOs and/or biohazardous materials
- Procedural changes
- Changes in laboratory personnel and/or adding of new personnel
- Change in laboratory location
- Any or all of which may change or increase the Risk Group and/or BSL of the project

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

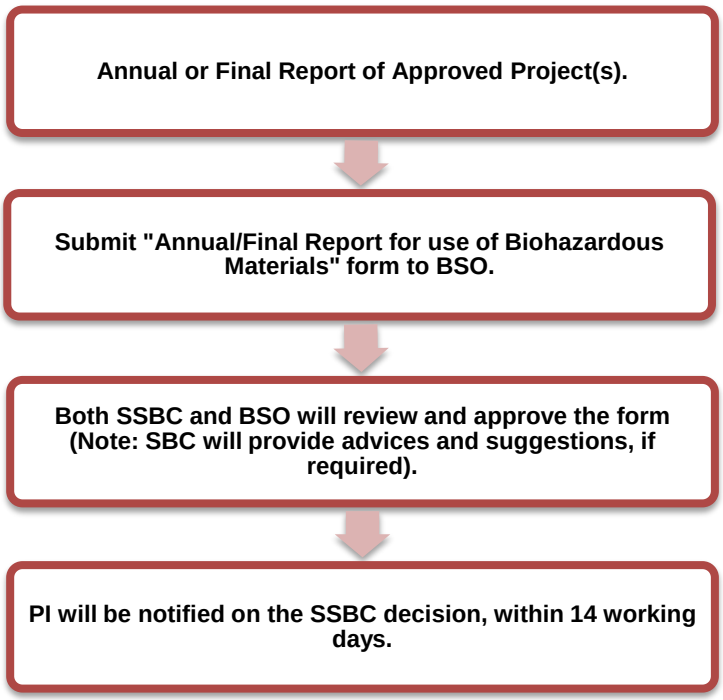
Refer to Section 5 Application Process; Subsection 5.1 Flowchart.

## 5.4 Extension or Termination of Approved Project

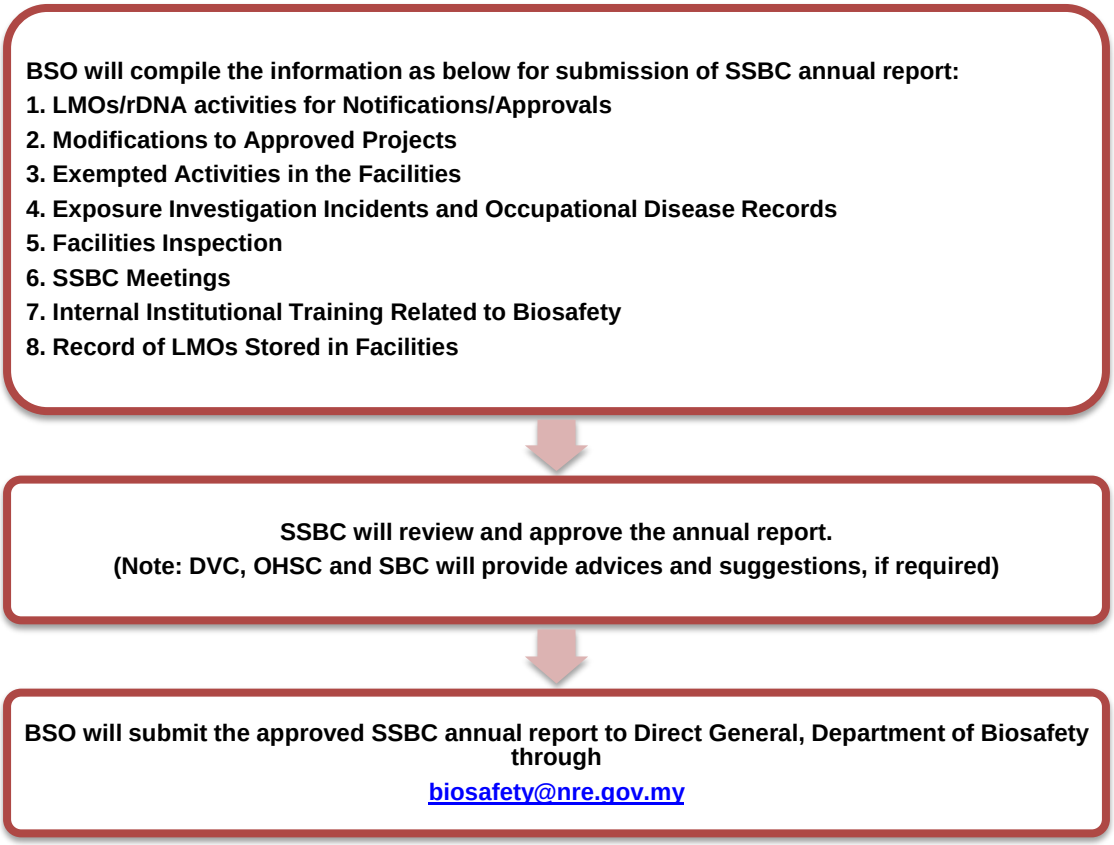
PI or applicants must obtain approval from SSBC before any extension or termination of the activities and research involving LMOs and biohazardous materials.



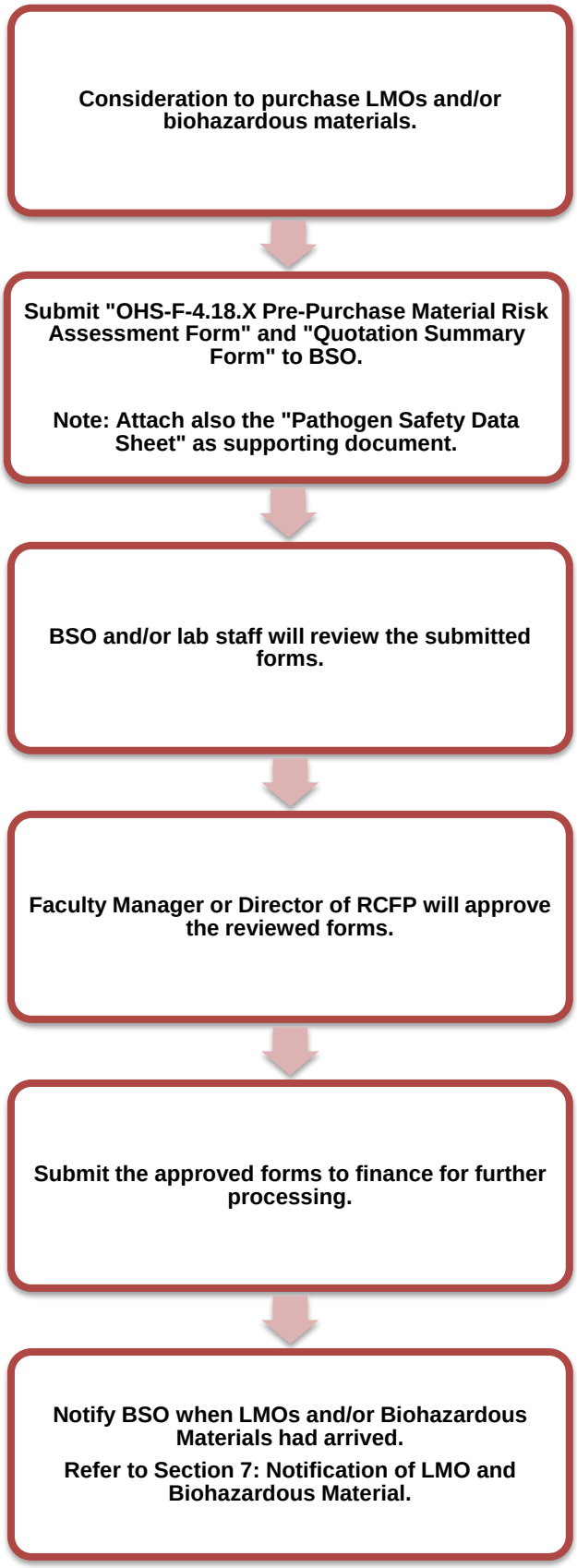
## 5.5 Annual or Final Report of Approved Project



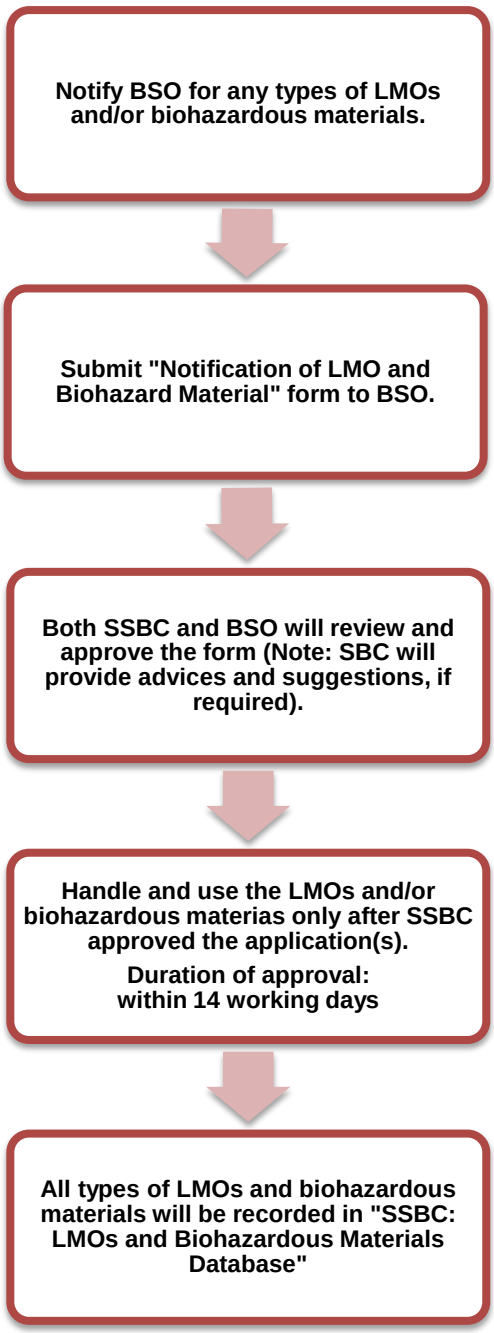

## 5.6 Submission of SSBC Annual Report to NBB



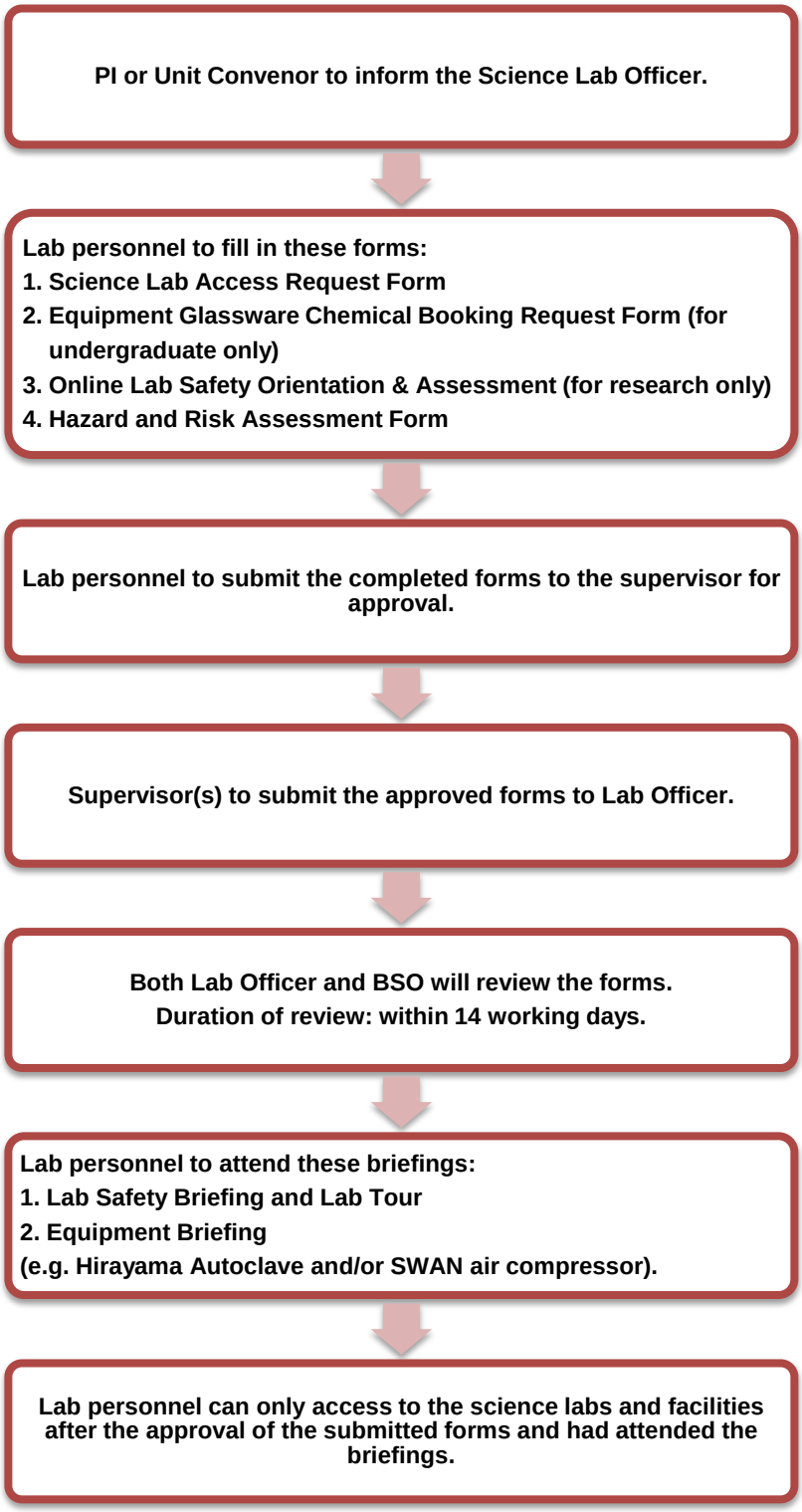
## 6. Procurement Process



## 7. Notification of LMOs and Biohazardous Materials

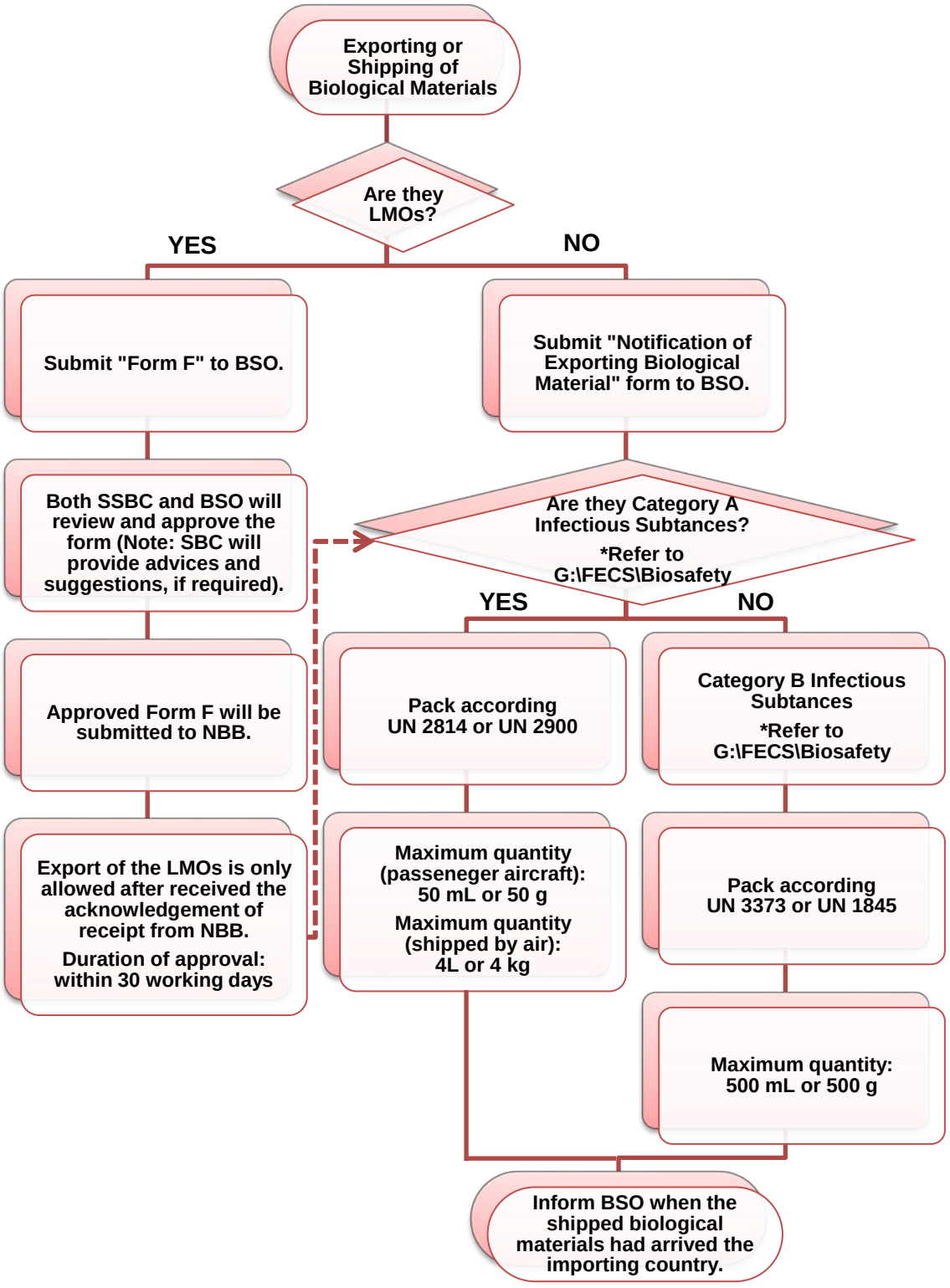


## 8. Laboratory Access and Safety Briefing



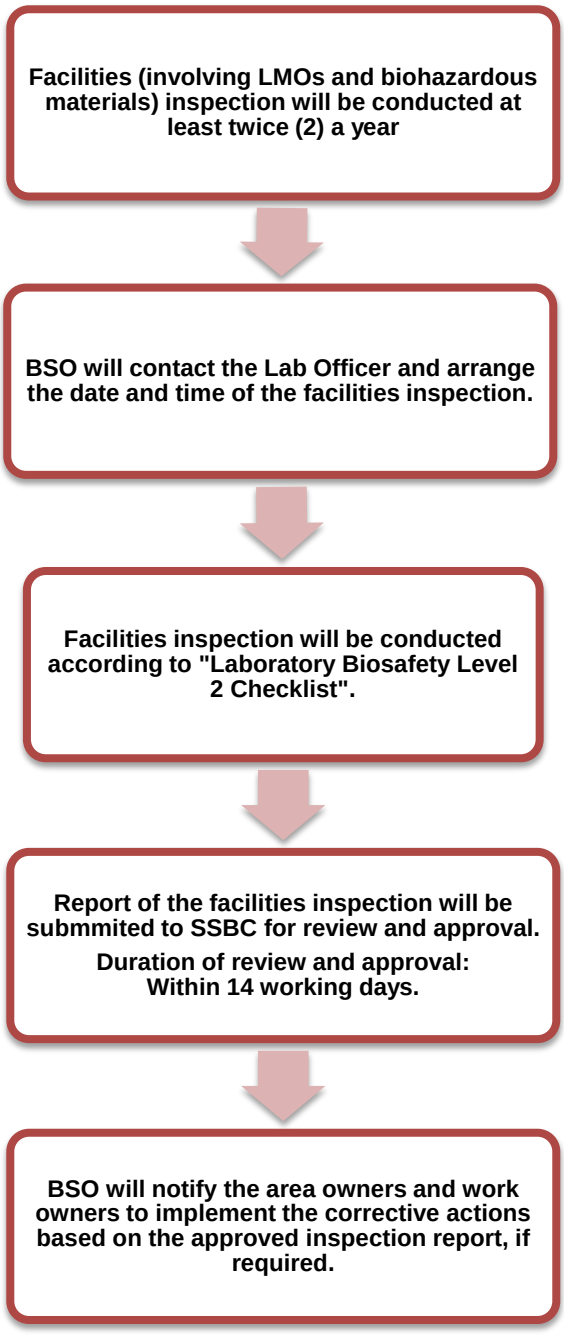
## 9. Exporting or Shipping of Biological Materials

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

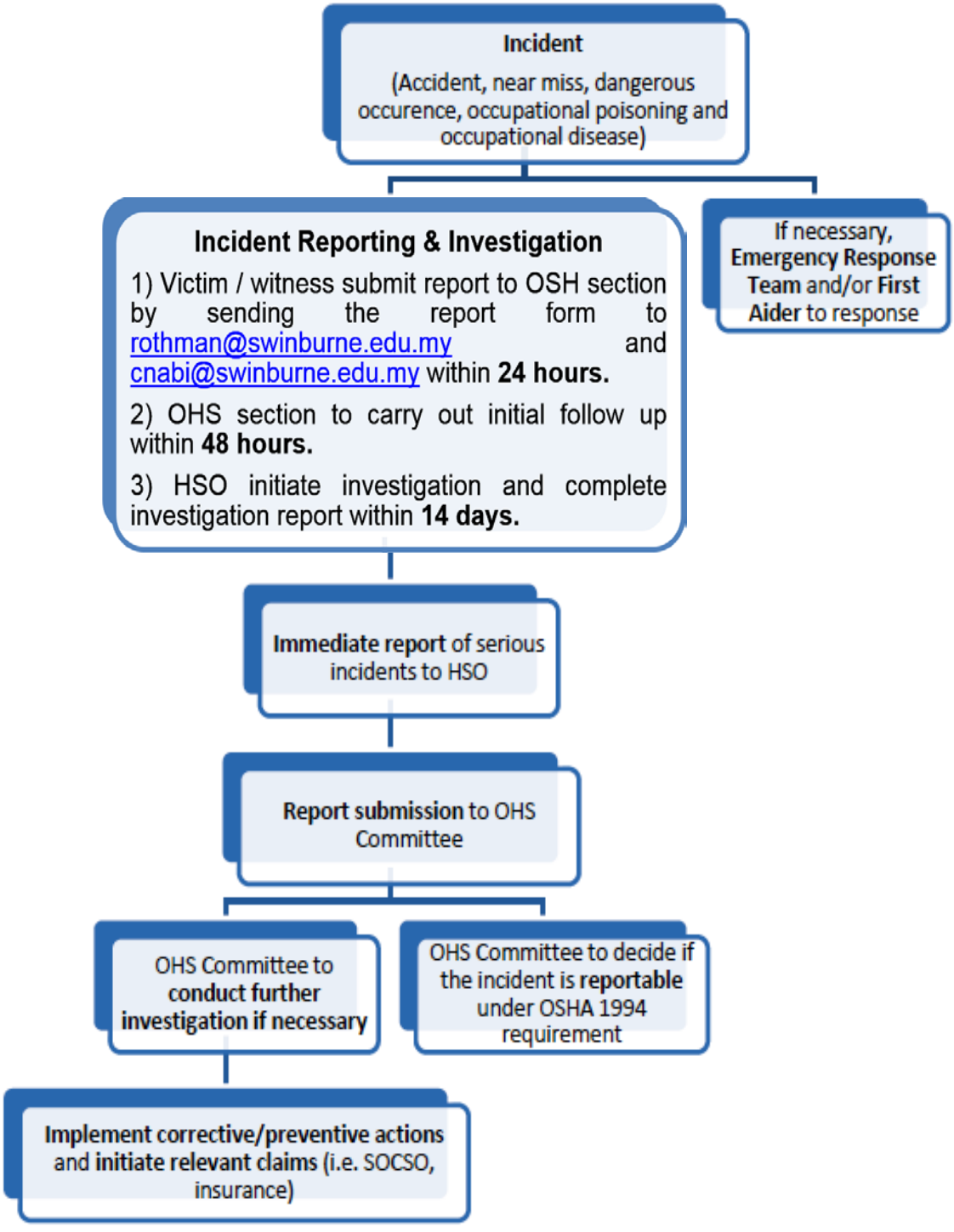
SSBC and BSO will monitor and inspect the facilities involving LMOs and biohazardous materials to ensure that the facilities are in compliance to Malaysia Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010. Facilities that are appropriate and safe for activities involve LMOs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



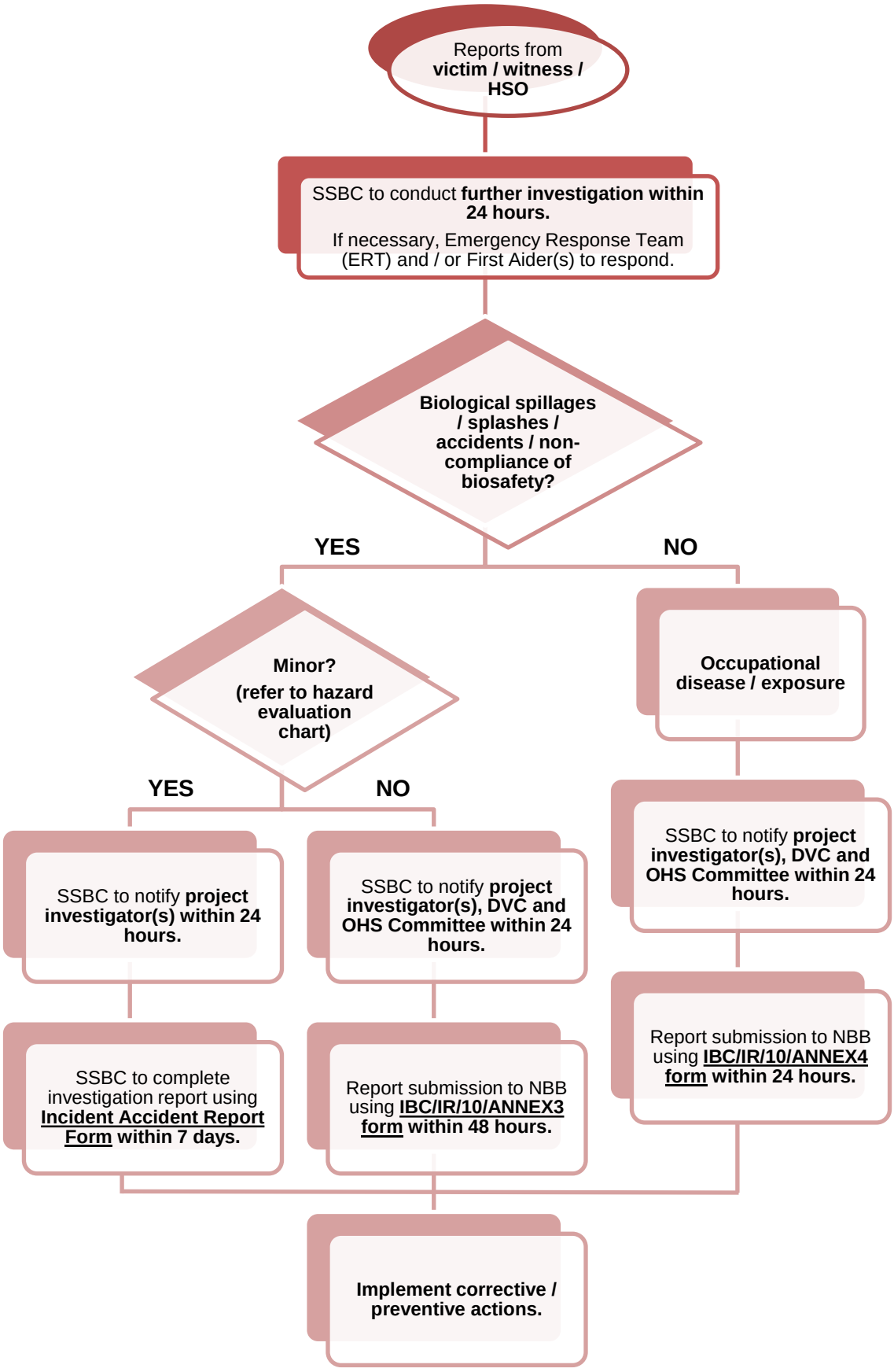
# 11. Incident Reporting Process Flow

## 11.1 Overview

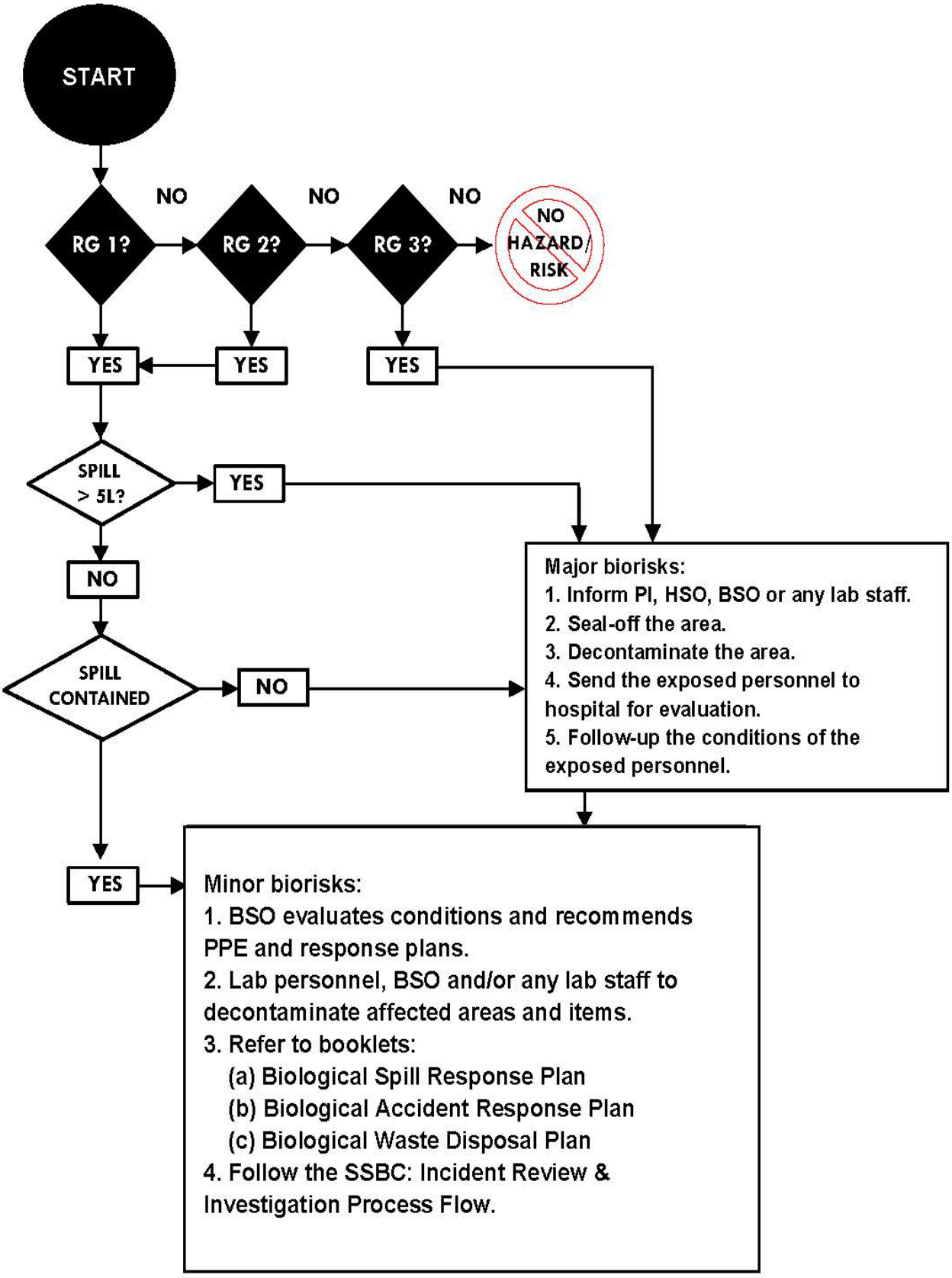
Lab personnel must immediately report (within 24 hours) any LMOs and biohazards related incidents to PI, health and safety officer (HSO), BSO and/or any lab staff. Refer to the flowchart as below.



## 11.2 SSBC: Incident Review and Investigation Process Flow



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



# 12. Appendices

## Appendix 1: Acronyms

| | |
|---|---|
| BSL | 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 |
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| Dayang Rafika Atiqah Abang Othman | Health and Safety Executive | G | G617 | 260679 | rothman@swinburne.edu.my |
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| Nurul Arina Salleh | Lab Officer (Science) | B | B701 | 260953 | nasalleh@swinburne.edu.my |
| Si Yan Eng | Lab Officer (Engineering) cum Lab Coordinator | E | 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 | B | B409 | 260628 | wwong@swinburne.edu.my |

## 13. References

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

## 14. Responsibility

| | |
|---|---|
| **Owner** | Swinburne Sarawak Biosafety Committee (SSBC) |

## 15. Version Control and Change History

| Version Number | Approval Date | Approved By | Amendment |
|---|---|---|---|
| 2 | August 2017 | SSBC | 1. 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.<br>2. 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.<br>3. Addition of the criteria for the application review process.<br>4. Addition of the "Responsibility" and "Version Control and Change History" sections. |
| 1 | November 2015 | SSBC | New SSBC manual. |