Guidance for Development of the Facility Administrative Oversight Plan

Background

The Ministry of Health (MOH) recognizes the importance of managing the risks to public health associated with the handling of First, Second and Third Schedule biological agents and Fifth Schedule toxins while permitting the handling of these dangerous biological agents and toxins for non-diagnostic activities. Depending on the sector and the intended work, institutions may face additional risk factors such as autonomous research and researchers, perceived diffuse accountabilities and varied and complex reporting and governance structures. Given the variations in operations and accountabilities, existing risk management framework at different institutions may or may not be sufficient to manage the risks posed by their intended work. As such, the Facility Administrative Oversight Plan (henceforth "the Plan"), aims to systematically guide the Applicant in developing a comprehensive institutional accountability structure for the governance and management of biosafety and biosecurity risks at facilities handling dangerous biological agents and toxins regulated under the Biological Agents and Toxins Act.

A. What is Facility Administrative Oversight Plan?

The Facility Administrative Oversight Plan (henceforth "the Plan"), is intended to be high level plan that provides an overview of the systems in place to manage and control biosafety and biosecurity risk.

B. Who needs to submit the Plan?

High containment facilities and facilities intending to handle First Schedule, Second Schedule, Third Schedule biological agents or Fifth Schedule toxins, including facilities applying to gazette their facilities as a Protected Place under the Infrastructure Protection Act. The Plan is to be submitted to MOH Biosafety Branch preferably during the planning stage, when the facility is seeking MOH's support to be gazetted as a Protected Place, or before the facility first certification

It is beneficial for facilities to prepare and submit the Plan early. The quality and completeness of the Plan submission is not expected to delay the issuance of the approval provided that all requirements under the Biological Agents and Toxins Act for the possession and handling are met, as MOH Biosafety Branch will work with the Applicant to finalize their plans as needed.

C. Why is it required?

The Plan provides a framework for institution/organization to guide the development or enhancement of the management of biosafety and biosecurity risks at the facility. The Plans can and will likely include references to other institutional/organizational documents and/or policies that are applicable. The detailed documents, e.g. biosafety manual, SOPs, emergency response plans, need not be provided with the Plan, as these shall be provided and be reviewed during the on-site inspection/certification.

The Plan also serves as an accountability system detailing the institution/organization's plans to mitigate the potential biosafety and biosecurity risks related to dual-use research work. In addition to the materials (biological agents and/or toxins) itself, considerations of the potential for dual-use shall also encompass the knowledge, technology that can be used for nefarious purposes. Accordingly, the Plan will demonstrate how institutions or organizations identify, assess and manage research activities with dual-use potential, including gain-of-function research. Gain-of-function research include activities that could result in the creation of a pathogen with increased virulence, pathogenicity, or communicability, that is resistant to preventative or therapeutic treatments, or produces a toxin with increased toxicity.

D. How does one go about developing the Plan?

The elements to be included in the Plan are provided below along with guidance and examples to help support development of the Plan. The Plan shall include an overview of how the following elements are managed or represented:

Elements to be included in the Plan

1) Institutional oversight on biosafety and biosecurity
2) Roles and responsibilities of various parties in managing biosafety, biosecurity and dual-use research work.
3) Scope of work that will be performed
4) Approval system for work conducted at the facility
5) Establishment of a single point of contact
6) Overview of biorisk management (includes biosafety, biosecurity and dual-use risk)
7) Plan for communication, staff engagement and adherence.
8) Plan for continuous quality improvement

Element	Requirements	Tips/Additional Info
1	Institutional oversight on biosafety, biosecurity and dual-use research work. This shall include: • Organizational chart providing an overview of the reporting structure; • Commitment from the senior management to identify, monitor, control and manage the risks associated with the work at the facility and to communicate this information to all personnel who are involved.	• The organizational chart need not identify specific individuals but shall minimally indicate the title/position associated with the working group/committees/role. • The information can be provided in the form of a Policy, Code, or reference to existing institutional/organizational document that is already available. • Where no existing document is available, a statement from the Senior Management declaring their commitment shall be provided.
2	Roles and responsibilities of committees, departments, individuals etc., in managing biosafety, biosecurity and dual-use research work. This shall include: • Areas of expertise of the committee members; • The terms of the appointment, including the authority and accountabilities associated with the appointment, the management of potential conflict of interest, and the approval mechanism; • Resources available to personnel and committee who have a role in the control and management of biosafety, biosecurity and dual-use risk.	• This can be provided in the form of diagrams, flow charts, job description of key personnel, Terms of Reference for the Institutional Biosafety committee (IBC), etc. • Resources may be in the form of financial, authority, e.g. withholding of research funding, authority to give stop-work orders.
3	Scope of work that will be performed. This shall include: • The biological agent(s) and/ toxin(s) that will be used, including the BATA Schedule; • Description of the type of work that will be conducted at the facility e.g. in-vitro research, animal-handling, production/manufacturing, diagnostic service; • The importance of the work including the need for continuity of service; • The acceptable downtime (outside of certification).	• The information can be provided in point form. • Where animal-handling is intended, list the types of animals that will be handled. • Where production/manufacturing is intended, include a description of the system that will be used. • In the case where the continuity of work is of importance, describe how the loss of the service will impact Singapore, and describe the business contingency plans to manage potential downtime.

Element	Requirements	Tips/Additional Info
4	Approval system for work conducted at the facility. This shall include: • Overview of the submission, review and approval process for new projects that will be conducted at the facility; • Overview of the submission, review and approval process for changes/amendments to existing projects; • The final approving authority e.g. IBC before commencement of work.	• This can be provided in the form of diagrams and flow charts. • Highlight the differences in the review and approval process between new projects and changes/amendments to existing projects, if any. • Highlight key processes in the system for monitoring dual-use research work.
5	Single point of contact to provide guidance on the Plan. This shall include: • Information of the person e.g. Biosafety Coordinator (BCo), who is responsible to provide guidance on the Plan; • The linkage and flow of information from the responsible person to the senior management and back.	• References can be made to existing reporting structures e.g., BCo reports to OHS Director who represents safety at senior level meetings.
6	Overview of biorisk management (includes biosafety and biosecurity). This shall include: • Overview of the biosafety management framework; • Overview of the biosecurity management framework; • Overview of dual-use management framework.	• This can be provided in the form of diagrams and flow charts, highlighting the key components of the biorisk management plans. The three frameworks can be combined, if relevant. • While there is a need to develop the biosafety manual, detailed SOPs, emergency response plans, etc., these do not need to be submitted with the Plan.
7	Plan for communication, staff engagement and adherence. This shall include: • How the information in the Plan is communicated to the relevant individuals, including new staff who join the facility subsequently; • How individuals are made aware of their responsibility to comply with requirements; • How individuals are informed of changes/updates to the biorisk management plans; • System for regular communication between the entities responsible for oversight of biosafety and biosecurity and the different user groups; • System for monitoring of staff adherence.	• This can be provided in the form of diagrams and flow charts and may include reference to existing mechanism for communication and training, e.g. on-boarding training for new employees, refresher training, regular meetings, info sessions, newsletters. • Identify the different user groups and their roles under the Plan. • Monitoring may be conducted through audits, user-cross-checking, etc.

Element	Requirements	Tips/Additional Info
8	Plans for continuous quality improvement. This shall include: • System in place to continually review and monitor the Plan and processes for improvements or gaps; • Indicators to trigger the review, update and communication of the Plan.	• This can include a chart to indicate the timeline for periodic review. • Examples of indicators that trigger review, updates and communication include a change in procedure for the release in funding, an incident that resulted in a change in the administrative controls, trends in non-compliances or near-miss, application process, inspection frequency, etc.