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1.	PPHRL Lab Staff on duty
2.	Quality Management Record
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Revise before:	After one year of approver/ as per need

Changes in this version compared to previous version:

To be done after revision as per international accreditation guidelines

Purpose:

The purpose of this document is to describe the laboratory biosafety and biosecurity risk assessment process and its conceptual framework.

Scope:

The scope of this document is to provide technical guidance to all personnel who work in a biological laboratory and who actively handle or manage biological agents and toxins, as well as other valuable laboratory material. This document is also intended for facility managers, administrative support, security forces, community stakeholders, oversight bodies, and policymakers, who want to learn more about risk assessment and the safety and security risks that are present in their laboratories.

Responsibility

It is responsibility of quality control team and all laboratory staff members to look for bio risk management.

Aim

Further, the risk assessment process does not provide specific recommendations regarding how to reduce the risks identified, but can rather be used to assist or guide individuals in the laboratory, the facility, and the community to make informed decisions how to mitigate risk.

Introduction:

In considering the nature of the operations, risks must be assessed by evaluating all laboratory situations that could reasonably and foreseeable (i.e. within the rule of reason and not based on pure conjecture) result in an adverse event, exposure or release. The risk assessment must considered potential effects on employees working in the laboratory and on members of the public outside the facility in the surrounding community. The assessment reviews both normal working operations and unforeseen internally or externally initiated scenarios. At following levels risk must be monitored and being taken care of.

At the engineering controls or secondary barriers level:

- Availability of primary containment such as biosafety cabinets, including maintaining current equipment certification;
- heating, ventilation, and air conditioning challenges to maintain and increase air changes per hour while using existing infrastructure;
- installation of additional transmission control barriers between workstations and, if applicable, in a way that is consistent with the equipment manufacturer's specifications; and
- Availability of hand washing stations in adapted spaces for laboratory activities.

At the administrative control level:

- Comprehensive and complete risk assessment process that accounts for changes in personnel, process, and/or other changing conditions.

- Personnel and training:
- Providing just-in-time and appropriate training;
- ensuring that surge capacity personnel are provided with appropriate safety and security training, including pathogen-specific training;
- training for use and doffing of personal protective equipment (PPE) such as gloves, gowns, Controlled Air Purifying Respirator (CAPR),or Powered Air Purifying Respirator (PAPR);
- maintaining staffing levels in the event of a positive employee and coworkers in quarantine;
- considering increased risks to lone workers outside normal operating hours;
- ensuring personnel adherence to established protocols including provisions for operating under emergent infectious diseases with high community transmission;
- considering additional supervision under surge capacity conditions; and planning for mental or physical health support for personnel responding to high-stress or high volume events

Procedures

- Standard operating procedures for novel products and techniques;
- validation of inactivation methods, especially when transferring samples from high-containment (Biosafety Level [BSL]-3) to lower containment levels;
- new reagents and diagnostic techniques for use at BSL-2 that may need to be validated by the manufacturer and the technicians or laboratory staff;

- ability to institute enhanced work practices and procedures (i.e., from BSL-3 in a BSL-2 facility, also known as BSL-2+ or BSL-2 enhanced) for non-inactivated materials such as blood or upper respiratory specimens, tissues, autopsy specimens, stool, other body fluids, waste water, and effluent;
- ensuring availability of test components or other critical supplies (e.g., lysis buffer, swabs, and other consumables.) and equipment;
- maintaining an accurate and up-to-date inventory of critical supplies and components;
- maintaining an inventory management system to assure integrity and security of biological
- materials and chemicals, especially for samples known to contain SARS-CoV-2 or suspected of containing novel pathogens; and
- adapting to a shortage of supplies and reagents
- and prioritizing work.

Disinfection and waste management:

- Ensuring availability of disinfectants/sanitizers that are proven to be effective in inactivating novel pathogens in the laboratory and office area as well as documenting and making available chemical safety data sheets in accordance with national standards and
- Ensuring that appropriate disposal methods for regulated biological and hazardous waste are in place and can be adapted for large volumes of

materials. These processes must be in accordance with local, regional, national, or international regulations.

Occupational Health

- Ensuring availability of occupational health surveillance to all workers;
- additional physical and mental stress on the workforce when working beyond normal duty hours due to colleagues in isolation or quarantine;
- symptom screening or administering questionnaires to staff before returning to the workplace, especially after a known illness; and
- Following applicable country-specific standards such as clinical clearance before N9 respirator fit testing or testing for hepatitis B antibody titers (respiratory protection standard and Blood borne Pathogen Standard in the United States).

Non pharmacological preventive measures directly to the pandemic:

- Ensuring clear guidance for personnel as to what respiratory precautions are required. Examples

  include demarcation of work and clean zones, clear delineation of the purpose of and requirement for different face coverings in different risk settings, and making its use consistent with overall bio containment initiatives and policies;
- the COVID-19 pandemic has strained the supply chain for PPE and other risk-reduction materials and, therefore, availability of prescribed equipment has

been limited. In these instances, a rigorous risk assessment will drive the minimal PPE needed by adjusting the engineering controls;

- wearing face covers (cloth or surgical mask) even when individuals are not handling hazardous biological materials in a laboratory environment for pandemic protection rather than protection of self from the work hazard; and
- Rearranging the laboratory set up to accommodate physical distancing (e.g., 6 feet or 2 m) and population density per institutional guidance.

At the PPE level:

- Selecting PPE according to the hazard assessment and equipment selection process conducted by the employer/supervisor;
- Availability of quality PPE due to the supply shortage. PPE must meet the country-specific manufacturing requirements and counterfeit materials must be avoided;
- providing medical clearance, fit testing, and training for correct use of respiratory protection such as N95 or powered air purifying respirator or controlled-air purifying respirator, or other PPE; and
- Implementation of PPE reuse procedures based on risk assessment and verified safe practices.