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1.0 PURPOSE

Public Health Agency of Canada (PHAC) defines dual-use potential as pathogen or toxin that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused as a biological weapon to cause harm (e.g., bioterrorism). The definition of dual-use potential also encompasses any asset related to a biological agent that could be used for nefarious purposes, including knowledge, technologies, or products that contribute to the weaponization of a pathogen or toxin. In Canada, the pathogens and toxins that have been identified as having dual-use potential are referred to as security sensitive biological agents (SSBAs) and are described as "prescribed human pathogens and toxins" in the Human Pathogens and Toxins Regulations (HPTR) Biological agents have a dual-use potential.

The handling of bio-hazardous agents requires a biosecurity plan to ensure that biological agents are used as intended and stored securely. Biohazardous materials used in a Containment Level 2 facility, as is the case at Keenan Research Centre for Biomedical Sciences, are considered to be a low risk category for the purposes of biosecurity. In practice, this means far less stringent regulatory requirements. However, principal investigators are required to consider any biosecurity implications that a biohazardous agent may pose when submitting their biosafety permit applications.

2.0 PROCEDURE

Physical Protection

The KRCBS has a dedicated 24 security desk, located on the ground floor. Access to the sensitive areas of the building i.e. the wet bench labs, is restricted to authorized staff via the use of key cards. Access can be further restricted in areas where greater levels of security are required, for example within the viral vector lab. Access to higher security areas are granted only after appropriate training has been received. KRCBS does not currently hold any quantity of toxin (specified under the HPTA) that would require specific physical security measures to safeguard against misuse or theft.

Personnel Reliability/Suitability

Pre-employment background checks and security clearances are undertaken before employees are granted access to laboratory area. These checks are appropriate to the types and levels of pathogen used by researchers at KRCBS. The wearing of photo-identification badges for employees while on-site is absolutely required and all visitors must be escorted by an authorized worker in order to enter the research laboratory areas. New workers must undergo biosafety training before access is granted to restricted areas. Access to all restricted areas is controlled through the use of key cards, which limits workers to those areas for which they have the correct training level and approval. Access to these areas is disabled as soon as employment ends.

Pathogen and Toxin Accountability

Legislation requires tracking and documentation protocols at any facility handling pathogens or toxins, to enable rapid location and to aid in the identification of lost or misplaced biological materials. This requirement is less stringent in a facility, like the KRCBS, that primarily deals with Risk Group 2 pathogens. Where tracking is necessary e.g. when research groups send pathogens off-site, their biosafety permit will indicate the pathogen destination as well as the quantity sent, its intended use and the method of disposal. Under current regulations, facilities where certain trigger quantities of toxins are held, must undertake more strenuous inventory, control methods and a detailed response plans in the event of accidental release, loss or theft. KRCBS does not currently hold toxin levels that would require enhanced surveillance.

Incident and Emergency Response

Although primarily dealing with Risk Group 2 pathogens, any incidents or emergency situation that results in the loss, theft, or accidental release of any biohazardous material are to be reported to the Biological Safety Officer. Documentation and investigation of the incident will be undertaken, with the findings recorded and stored for reference. Where necessary, the Research Biosafety Officer will report the loss of material to the Federal Minister of Health.

Information Security

Consistent with the level of the risk posed by Risk Group 2 pathogens, access to electronic information that details any sensitive or confidential information must be safeguarded against accidental or deliberate attempts to access it. Sensitive material may include, but is not limited to, pathogen and toxin lists, the location of stocks of biohazardous material or passwords. Password and user name protected, individual network accounts are provided by Unity Health. Information can be further protected within specified network drives, accessed by specific permission granted by the St. Michael's Hospital IT department, after receiving permission from the drives supervisory user.

3.0 DEFINITIONS

Term/Acronym	Definition
KRCBS	Keenan Research Centre for Biomedical Sciences
SSBA	security sensitive biological agents
HPTA	Human Pathogens and Toxins Act

4.0 REFERENCES

Human Pathogens and Toxins Regulations (SOR/2015-44). (2015).

Human Pathogens and Toxins Act (S.C. 2009, c.24). (2015)

Government of Canada. (2016). Canadian Biosafety Handbook (2nd ed.). Ottawa, ON, Canada: Government of Canada. Available from https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines.html

https://lois-laws.justice.gc.ca/eng/regulations/SOR-2015-44/page-1.html#h-823271

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