



Complete Program Title: Biosafety Programme	Risk Management Manual (RMM) Number: 600
Approved by:  Vice-President, Research and International Affairs  President and Vice-Chancellor	Date of Most Recent Approval: March 2014
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1 PURPOSE

- 1.1 To protect the University, stakeholders, public and environment from the risks which may arise from any controlled activities involving the use of infectious materials, organisms and toxins which affect humans, terrestrial animals, aquatic animals and plants.
- 1.2 To effect processes and policies which enable compliance and audit such compliance with PHAC and CFIA legislation and licenses which have relevance to biosecurity and controlled activities involving infectious materials, organisms and toxins.
- 1.3 To effect processes and policies which enable compliance and audit such compliance with any other federal, provincial or municipal legislation which may have relevance to biosecurity and controlled activities involving infectious materials, organisms and toxins.
- 1.4 To effect processes and policies which enable compliance and audit such compliance with funding agency policies as they pertain to biosecurity and controlled activities involving infectious materials, organisms and toxins.
- 1.5 To effect processes and policies which enable compliance and audit such compliance with all applicable best practices which may have relevance to

biosecurity and controlled activities involving infectious materials, organisms and toxins.

- 1.6 To support the Internal Responsibility System.

2 SCOPE

- 2.1 The biosafety programme applies to stakeholders conducting any controlled activity involving any risk group 1, 2 or 3 infectious material, organisms or toxins. No stakeholder shall conduct any controlled activity involving any risk group 4 infectious materials, organisms or toxins.
- 2.2 The biosafety programme applies to stakeholders conducting any controlled activity, involving any infectious materials, organisms or toxins, which affect humans, terrestrial animals, aquatic animals and plants.
- 2.3 The biosafety programme *may* apply to stakeholders using, in any manner, terrestrial animals, aquatic animals, plants or any derivations thereof. Such applicability will be determined based on a Committee review of the proposed work in the context of all relevant legislations, policies, guidelines and best practices.
- 2.4 The biosafety programme applies to stakeholders using, in any manner, any material derived from primates of the genus *Macaca*.
- 2.5 The biosafety programme applies to stakeholders using, in any manner, any material collected from any human, terrestrial animal, aquatic animal, plant or environmental locale which is reasonably expected to contain, infectious materials, organisms or toxins.
- 2.6 The biosafety programme applies to stakeholders culturing any material collected from any human, terrestrial animal, aquatic animal, plant or environmental locale.
- 2.7 The biosafety programme applies to stakeholders using, in any manner, any plants, arthropods or other invertebrates which are considered plant pests by the CFIA.
- 2.8 The biosafety programme does not apply to stakeholders using non-biohazardous material.
- 2.9 The biosafety programme applies to stakeholders who are, by OHS A definition, supervisors of those described above.
- 2.10 The biosafety programme provides all necessary policies, processes, procedures and training for conducting controlled activities at containment levels 1, 2, 2+ and 3.
- 2.11 The biosafety programme provides administrative resources to ensure PHAC certification of any level 3 containment zones owned by McMaster University or any part thereof.

3 Related Documents

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

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- 3.2 Human Pathogen Importation Regulations (SOR/94-558). (1994)
 - 3.3 Canadian Biosafety Standards and Guidelines, 1st Edition (2013)
 - 3.4 Health of Animals Act (S.C. 1990, c. 21) (2007)
 - 3.5 Health of Animals Regulations (C.R.C., c. 296) (2011)
 - 3.6 Reportable Diseases Regulations (SOR/91-2) (1990)
 - 3.7 Plant Protection Act (1990)
 - 3.8 Containment Standards for Facilities Handling Aquatic Animal Pathogens (2010)
 - 3.9 Containment Standard for Facilities Handling Plant Pests (2007)
 - 3.10 Agreement on the Administration of Agency Grant and Awards by Research Institutions
 - 3.11 McMaster University RMM #106 – Presidential Biosafety Advisory Committee Terms of Reference
 - 3.12 McMaster University RMM#600, Appendix C – Use of BSL 3 Biocontainment Unit
 - 3.13 McMaster University RMM #601 – Hepatitis B Policy
 - 3.14 McMaster University RMM #602 – Rabies Policy
 - 3.15 McMaster University RMM #603 – Medical Monitoring Program for Persons Working With Biological Agents
 - 3.16 McMaster University RMM #604 – Adenovirus Biocontainment Downgrade Criteria Policy
 - 3.17 McMaster University RMM #502 – Hazardous Waste Management Program

4 DEFINITIONS

- 4.1 **approved by the Chair on behalf of the Committee** – the status given to the Biohazard Utilization Protocol when all requirements for working at the requested or prescribed containment level have been met
- 4.2 **best practices** – processes or techniques that consistently show results superior to those by other means and are used as a benchmark
- 4.3 **containment level** - minimum physical containment and operational practice requirements for handling infectious material or toxins safely in laboratory and animal work environments
- 4.4 **containment zone** – the room or collection of rooms in which controlled activities take place

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- 4.5 **controlled activities** – possessing, handling or using; producing; storing; permitting any person access to; transferring; importing or exporting; releasing or otherwise abandoning; disposing
- 4.6 **individuals** – any person conducting any controlled activity involving an infectious material, organism or toxin
- 4.7 **non-biohazardous** – any material that is non-infectious and not cultured *in vitro*
- 4.8 **NSF49** – a national standard by which biological safety cabinets are certified
- 4.9 **reasonably expected to contain infectious materials, organisms or toxins** – the specimen was taken from a human, animal, plant or environmental locale whose history or current information indicates that the sample will be infectious; the specimen was taken from a human, animal, plant or environmental locale that was intentionally infected; the specimen was proven to be infectious
- 4.10 **plant pests** - Anything that is injurious or potentially injurious, whether directly or indirectly, to plants or to products or by-products of plants, and includes any plant prescribed as a pest in the Plant Protection Act (1990). This includes any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products including, but not limited to, arthropods, molluscs, bacteria, nematodes, fungi, phytoplasmas, viruses and viroids.
- 4.11 **reporting channel** – the route whereby the Committee Chair reports to the Associate Vice President, Research who then reports through the Vice President, Research and International Affairs to the President.
- 4.12 **risk group** - the classification of biological material based on its inherent characteristics, including pathogenicity, risk of spread, and availability of effective prophylactic and/or therapeutic treatments. Canadian risk group ratings take precedence over those from other countries.
- 4.13 **stakeholders** – McMaster University faculty, employees and students
- 4.14 **supervisor** - per OHS Act Section 1 (1), supervisor is a person who has: charge of a workplace, or; authority over a worker.
- 4.15 **toxins** – poisonous substances that are produced or derived from a microorganism and can lead to adverse health effects in humans, animals or plants
- 4.16 **the Committee** – the Presidential Biosafety Advisory Committee
- 4.17 **the University** - the legal entity represented by the President; the employer
- 4.18 **Acronyms:**
- BSC** – Biological Safety Cabinet
 - BUP** – Biohazard Utilization Protocol
 - CBSG** – Canadian Biosafety Standards and Guidelines
 - CFIA** – Canadian Food Inspection Agency
 - EOHSS** – Environmental and Occupational Health Support Services
 - HPTA** – Human Pathogens and Toxins Act

MILO – McMaster Industrial Liaison Office
NSF – National Standards Foundation
OHSA – Occupational Health and Safety Act
PHAC – Public Health Agency of Canada
RMM – Risk Management Manual
SOP – Standard Operating Procedure

5 RESPONSIBILITIES

5.1 Role of Vice President, Research and International Affairs:

The Vice President, Research & International Affairs shall:

- Provide the direction and resources necessary to support the activities of the Biosafety Office and the Committee.
- Shall appoint an Associate Vice President, Research to which the Biosafety Office and the Committee Chair shall report on a regular basis.

5.2 Role of Office of Research Finance / Health Research Services Office / MILO

Office of Research Finance / Health Research Services Office / MILO shall:

- Provide a mechanism to identify those projects describing any controlled activities involving infectious materials, organisms and toxins.
- Communicate with the Biosafety Office as needed in order to review such mechanisms where warranted.
- Create and implement processes which provide project specific information on a per-supervisor basis appropriate for conducting a risk assessment and maintain the structure of the Internal Responsibility System.

5.3 Role of Deans, Department Heads / Chairs

Deans, Department Heads and Chairs shall:

- Support implementation of policies and procedures related to responsible administration of biosafety and biosecurity.
- Be accountable for the dissemination of provided biosafety and biosecurity information on a departmental-wide scale to ensure all relevant stakeholders under their jurisdiction are aware of and have access to information, education and physical resources appropriate for working safely and in compliance.
- Be aware of all controlled activities in their department.
- Ensure that containment zones and projects describing controlled activities involving infectious materials, organisms and toxins in their department have

been approved by the Chair on behalf of the Committee prior to the start of such controlled activities.

5.4 **Role of Supervisors (Academic and Administrative):**

Supervisors shall:

- Submit a Biohazard Utilization Protocol (BUP) application prior to the commencement of any controlled activities for review by the Committee.
- Ensure that their containment zones and projects describing controlled activities involving infectious materials, organisms and toxins have been approved by the Chair on behalf of the Committee prior to the start of such controlled activities.
- Ensure they and their workers have all organizationally-required, project-specific and containment zone-specific training including training related to the procedures and the properties of the infectious materials, organisms and toxins in use prior to the commencement of any controlled activities.
- Amend their BUP in a timely manner when any part of any section has changed.
- Arrange for an annual audit of all SOPs relevant to biosafety and biosecurity and all containment zones listed on their BUP.
- Ensure all BSCs and enclosures are certified to NSF49 or manufacturer's specifications annually if used for containment level 2, 2+ or 3 protocols.
- Ensure all workers are aware of and understand any indications for medical monitoring and the medical monitoring programs.
- Maintain complete, detailed and up to date inventories of all infectious materials, organisms and toxins in their possession that may be produced upon request of the Committee, the Biosafety Auditor or any PHAC or CFIA inspector.
- Acquire and be accountable for all documentation required for importing, exporting and transferring of infectious materials, organisms and toxins prior to such import, export or transfer.
- Take measures to ensure and document biosecurity of their inventory and of their containment zone.
- Ensure compliance which meets or exceeds all relevant legislation, institutional policies, guidelines and best practices.
- Coordinate the maintenance/construction work that takes place inside the containment zone to ensure safety of maintenance/construction workers.
- Complete Injury/Incident Report forms as required.

5.5 **Role of the Committee**

The Committee shall:

- Carry out responsibilities as described in RMM #106 Biosafety Committee Terms of Reference

5.6 Role of the Biosafety Manager

The Biosafety Manager shall:

- Ensure implementation of those processes within the Biosafety Programme which allow or otherwise facilitate compliance.
- Ensure adequate administrative support to effect such implementation.
- Review efficiency, relevancy and suitability of such processes on a continual basis.
- Immediately suspend all controlled activities, or any subset thereof, by any stakeholder; which places any person immediately at risk of exposure or harm to their body or wellbeing and report such suspension through the reporting channel.
- Ensure fulfillment of the functions and duties as described in the Canadian Biosafety Standards and Guidelines and HPTA Regulations.

5.7 All Individuals

Individuals shall:

- Follow all facility-specific and project-specific SOPs as provided by the supervisor.
- Complete training as requested by the Supervisor.
- Complete training as provided by the Supervisor and the University.
- Comply with any conditions and restrictions listed on any import permits.
- Immediately report any exposure or suspected exposure, unsafe conditions, procedures or activities to the Supervisor and complete an Incident/Injury Report Form.
- Immediately seek medical attention for any symptoms or illness suspected of being related to work with infectious materials, organisms and toxins in the workplace.
- Immediately report any exposure or symptoms or illness suspected of being related to work with infectious materials, organisms or toxins to the supervisor and to:
 - Employee Health Services - for all employees and for those graduate students who have enrolled in the medical monitoring program
 - Student Wellness or their own family doctor - for all undergraduate students

- Their own family doctor – for all graduate students who are not enrolled in the medical monitoring program

6 RECORDS

- 6.1 The Biosafety Office is responsible for document retention related to the Biosafety Programme.
- 6.2 Training records shall be kept for 5 years.
- 6.3 Laboratory audits shall be kept in digital format for 5 years past the supervisor's employ at McMaster.
- 6.4 Individual Biohazard Approvals (short paper format) shall be kept 5 years beyond the expiration date.
- 6.5 Biohazard Utilization Protocols and all associated documentation shall be kept in digital format for 5 years past the supervisor's employ at McMaster.
- 6.6 Biological inventories shall be maintained by the individual supervisor.
- 6.7 Records of autoclave monitoring for autoclaves used to decontaminate waste or items contaminated with infectious materials, organisms or toxins shall be maintained by the individual supervisor.
- 6.8 Records of biohazardous waste disposal will be maintained as per RMM#502 - Hazardous Waste Management Program.
- 6.9 Medical monitoring records will be maintained by Employee Health Services for all employees and for those graduate students who have enrolled in the medical monitoring programme.

7 REVIEW

- 7.1 The Biosafety Programme shall be reviewed by the Committee on a regular basis.