

Complete Program Title: Biosafety Program	Risk Management Manual (RMM) Number: 600
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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 all federal, provincial and municipal legislation and/or licenses which have relevance to biosafety and biosecurity.
- 1.3 To effect processes and policies which enable compliance and audit such compliance with funding agency policies and all applicable best practices and guidelines adopted by the University which have relevance to biosafety and biosecurity.
- 1.4 To support the Internal Responsibility System as it relates to biosafety and biosecurity.

2 SCOPE

- 2.1 The biosafety program 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 program 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 program *may* apply to stakeholders using, in any manner, terrestrial animals, aquatic animals, plants, seeds, soil, fungi or any derivations thereof. Such applicability will be determined based on a Committee review of the proposed work in the context of all relevant legislation, policies, guidelines and best practices and in consultation with the University Veterinarian where applicable.
 - 2.4 The biosafety program applies to stakeholders using, in any manner, any material derived from primates of the genus *Macaca*.
 - 2.5 The biosafety program applies to stakeholders using, in any manner, any material derived from any human, terrestrial animal, aquatic animal, fungi, plant or related matter or environmental locale which is reasonably expected to contain, infectious or invasive materials, organisms or toxins.
 - 2.6 The biosafety program applies to stakeholders using, in any manner, smallpox DNA.
 - 2.7 The biosafety program applies to stakeholders culturing any material derived from any human, terrestrial animal, aquatic animal, plant or environmental locale.
 - 2.8 The biosafety program applies to stakeholders using, in any manner, any plants, fungi, arthropods or other invertebrates which are considered plant pests or invasive or alien species by the CFIA.
 - 2.9 The biosafety program applies to stakeholders using, in any manner, any microorganism, invertebrate or plant regulated by ECCC.
 - 2.10 The applicability of the biosafety program is irrespective of stakeholder location i.e. on campus or off campus or hospital-hosted.
 - 2.11 The biosafety program does not apply to stakeholders using non-biohazardous material. Please defer to the programs implemented by FHS Safety Office or EOHSS.
 - 2.12 The biosafety program does not apply to commercially-sourced lab animals, excluding those described in section 2.4, found to be positive for, and naturally infected with, human or terrestrial animal pathogens or toxins. Please defer to the University Veterinarian for procedures.
 - 2.13 Laboratories exclusively using human samples that are not reasonably expected to contain infectious materials, organisms or toxins and that are not propagatively culturing those samples are exempt from the biosafety program and must follow standard routine practices, good laboratory practices and must dispose of their human samples in accordance with RMM#502.
 - 2.14 The biosafety program applies to stakeholders who are, by OHS A definition, supervisors of those described above.

- 2.15 The biosafety program provides all necessary policies, processes, procedures and training for conducting controlled activities at PHAC and CFIA containment levels 1, 2 and 3 or any other type of containment or operational practices required by any applicable legislations.
- 2.16 The biosafety program 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)
- 3.2 Human Pathogens and Toxins Regulations (2015)
- 3.3 Canadian Biosafety Standard, 2nd Edition (2015)
- 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 (S.C. 1990, c. 22). (1990)
- 3.8 Invasive Species Act (S.O. 2015, c.22). (2015)
- 3.9 Canadian Environmental Protection Act (S.C. 1999, c. 33). (1999)
- 3.10 Guideline C-4: The Management of Biomedical Waste in Ontario, November 2009, Ministry of the Environment
- 3.11 New Substances Notification Regulations (Organisms) (SOR/2005-248). (2005)
- 3.12 Containment Standards for Facilities Handling Aquatic Animal Pathogens, 1st Ed (2010)
- 3.13 Containment Standards for Facilities Handling Plant Pests, 1st Ed (2007)
- 3.14 WHO Biosafety Manual, 3rd Ed (2004)
- 3.15 Laboratory Biosafety Guidelines, 3rd Ed (2004)
- 3.16 Biosafety in Microbiological and Biomedical Laboratories, 5th Ed (2009)
- 3.17 Agreement on the Administration of Agency Grant and Awards by Research Institutions
- 3.18 Ontario Occupational Health and Safety Act (R.S.O 1990, c. O.1)
- 3.19 McMaster University RMM #100 – Workplace and Environmental Health and Safety Policy
- 3.20 McMaster University RMM #101 – McMaster University Risk Management System

- 3.21 McMaster University RMM #106 – Presidential Biosafety Advisory Committee Terms of Reference
- 3.22 McMaster University RMM #601 – Hepatitis B Policy
- 3.23 McMaster University RMM #602 – Rabies Policy
- 3.24 McMaster University RMM #603 – Medical Monitoring Program for Persons Working With Biological Agents
- 3.25 McMaster University RMM #502 – Hazardous Waste Management Program
- 3.26 McMaster University RMM #1000 - Reporting & Investigating Injury/Incident/Occupational Disease Program
- 3.27 McMaster Faculty Leave Policies and Guidelines - <http://www.mcmaster.ca/policy/faculty/Leaves/>

4 DEFINITIONS

- 4.1 **authorized personnel** – an individual who has been granted access to the containment zone by the containment zone supervisor. This is dependent on completing training requirements and demonstrating proficiency in the SOPs, as determined to be necessary by the supervisor. This includes any person directly undertaking controlled activities involving infectious materials, organisms and toxins
- 4.2 **approved by the Chair on behalf of the Committee; approved** – the status given to the Biohazard Utilization Protocol when all requirements for working at the requested or prescribed containment level have been met
- 4.3 **best practices** – processes or techniques that consistently show results superior to those by other means and are used as a benchmark
- 4.4 **applicable biohazard** – any item deemed applicable under this policy; applicability is defined within the scope of the policy.
- 4.5 **biohazard utilization protocol** – a document which contains all information relevant to biosafety and biosecurity specific to one supervisor; an approved BUP signifies compliance with all responsibilities related to RMM600
- 4.6 **compliance** - achievement of all requirements derived from any legislation, external policy or institutional policy or directive which is relevant to undertaking work, teaching and research involving infectious materials, organisms and toxins.
- 4.7 **containment level** - minimum physical containment and operational practice requirements for handling and disposal of infectious material or toxins safely in greenhouse, laboratory and animal (both vertebrate and invertebrate; both aquatic and terrestrial) work environments
- 4.8 **containment zone** – the room or collection of rooms in which controlled activities take place

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- 4.9 **controlled activities** – possessing, handling or using; producing; storing; permitting any person access to; transferring; importing or exporting; releasing or otherwise abandoning; disposing
- 4.10 **non-biohazardous** – any material that is non-infectious and does not contain anything that is infectious and that does not require to be handled with infection control procedures and does not require to be disposed as infectious waste
- 4.11 **NSF49** – a national standard by which biological safety cabinets are certified
- 4.12 **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.
- 4.13 **Qualified Designated Authority (QDA)** – a person acting on behalf of the University for the purposes of reporting or notification under the New Substances Notification Regulations (Organisms) under the Canadian Environmental Protection Act (1999).
- 4.14 **reasonably expected to contain infectious materials, organisms or toxins** – the specimen was taken from a human, animal, plant, fungus 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
- 4.15 **reporting channel** – the route whereby the Committee Chair reports to the Associate Vice President, Research who then reports through the Vice President, Research to the President.
- 4.16 **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.
- 4.17 **stakeholders** – McMaster University Faculty, employees, students, visitors, volunteers and any contractors or consultants with interest towards any stakeholder or containment zone. This definition is irrespective of the stakeholder's workplace location.
- 4.18 **supervisor** - supervisor is a person who has: charge of a workplace, or; authority over authorized personnel as defined in this RMM
- 4.19 **toxins** – poisonous substances that are produced or derived from a microorganism and can lead to adverse health effects in humans, animals or plants; all toxins require level 2 containment and operational practices
- 4.20 **the Committee** – the Presidential Biosafety Advisory Committee
- 4.21 **the University** - the legal entity represented by the President; the employer
- 4.22 **Acronyms:**

AREB – Animal Research Ethics Board
BSC – Biological Safety Cabinet
BUP – Biohazard Utilization Protocol
CBS – Canadian Biosafety Standard
CFIA – Canadian Food Inspection Agency
ECCC – Environment and Climate Change Canada
EOHSS – Environmental and Occupational Health Support Services
FHS – Faculty of Health Sciences
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
QDA – Qualified Designated Authority
RMM – Risk Management Manual
SOP – Standard Operating Procedure

5 RESPONSIBILITIES

5.1 Role of Vice President, Research:

The Vice President, Research shall:

- Provide the direction and resources necessary to support the activities of the Biosafety Office and the Committee.
- Facilitate identification, where required, of all Faculties where controlled activities with infectious materials, organisms and toxins are undertaken and that are also within the scope of the Biosafety Program; ensure that such Faculties are captured under biosafety processes; a current Faculty breakdown report may be requested from the Biosafety Office at any time.
- Identify all distinct corporate entities with operations inside the University infrastructure whose activities fall within the scope of the Biosafety Program and ensure the following:
 - the corporation will obtain their own HPTA license and
 - the corporation will name their own biosafety officer and responsible person and
 - the corporation will design and implement their own biosafety program which meets or exceeds the standards set out in this policy or;
 - the corporation will exist as a stakeholder within the University's biosafety program and will participate in and be subject to all responsibilities therein

- a corporate inventory may be requested from the Biosafety Office at any time.
- Shall appoint an Associate Vice President, Research to which the Biosafety Office and the Committee Chair shall report on a regular basis.
- On reports received for documented non-compliance spanning 90 or more days, implement sanctions deemed appropriate, which may include suspension of access to research funding and/or access to laboratory facilities.

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

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

- Withhold the release of project-specific research funding until documentation of project-specific biohazard approval has been received, for any project where applicability to the biosafety program has been declared.
- Provide a mechanism to identify and track those projects describing any controlled activities involving infectious materials, organisms and toxins. Such a mechanism may include a section for declaration by the supervisor on any funding-release or project-related form.
- Consult the Biosafety Manager, where necessary, to determine the applicability of any project to the Biosafety Program in cases where there is no declaration of applicability, but applicability is suspected.
- Communicate with the Biosafety Office as needed in order to review such identification and tracking mechanisms where warranted.
- Implement processes which provide project specific information on a per-supervisor basis appropriate for conducting a biosafety and biosecurity risk assessment and supports the Internal Responsibility System as it relates to biosafety and biosecurity.
- Upon direction from the Vice President Research, suspend access to research funding in whole or in part.

5.3 **Role of Associate Deans, Research**

Associate Deans, Research shall:

- Support implementation of policies and procedures related to responsible administration of biosafety and biosecurity.
- Facilitate identification, where required, within their Faculty, departments undertaking controlled activities with infectious materials, organisms and toxins in research or teaching laboratories; departmental lists can be obtained from the Biosafety Office; notify the Departmental Chair and Biosafety Manager when any department has been identified where such activities are taking place, but does not appear on the departmental list.

- Ensure all identified Departmental Chairs in their area are aware of and execute their responsibilities under this program as demonstrated by the departmental rate of approved protocols and the departmental rate of non-compliance issues; such information can be obtained from the Biosafety Office.

5.4 **Role of Departmental Chairs**

Departmental 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 department-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.
- Facilitate identification, where required, all those supervisors and courses within their department who direct authorized personnel to undertake controlled activities with infectious materials, organisms and toxins and are within the scope of the Biosafety Program and ensure such supervisors have an approved BUP prior to the start of such activities; a departmental list of BUPs may be requested from the Biosafety Office at any time.
- Refer identified supervisors, who do not have either a BUP or an approved BUP, to the Biosafety Office to initiate or complete the BUP process, respectively.
- Ensure all identified supervisors in their department are aware of and execute their responsibilities under this program as demonstrated by the maintenance of an approved BUP; such information can be obtained from the Biosafety Office at any time.
- Ensure that any departmentally owned or managed autoclave is assessed for compliance with the Canadian Biosafety Standard.

5.5 **Role of supervisors:**

Supervisors shall:

- Meet the requirements of a supervisor as described in the OHS Act.
- Submit a biohazard utilization protocol (BUP) application prior to the commencement of any controlled activities that fall within the scope of this program and which have not previously been reviewed by the Committee. A BUP application is submitted once and amended thereafter. The BUP is meant to capture and maintain information appropriate for a risk assessment of biological inventories, operational practices, containment zones and biosecurity practices.
- Amend their BUP in a timely manner, when any part of any section has changed. Amendments are done using the online BUP portal.

- Maintain a laboratory-specific biosafety manual, to be audited during each biosafety lab audit, to consist of:
 - Reporting hierarchy listing reporting lines for all health and safety issues
 - all risk management manual programs relevant to the work, the authorized personnel and the workplace
 - incident and injury reporting program
 - biosecurity plan
 - lab training prescription
 - emergency response plan
 - standard operating procedures for all activities involving biohazardous materials
 - housekeeping program
 - maintenance program for equipment, especially primary containment devices
- Where possible, reduce higher risks to biosafety if a lower risk organism is available or a non-biohazardous method can substitute.
- Where possible, reduce higher risks to biosecurity (door signage and locks) if a lower risk location (key-carded entry and/or security patrolled) is available.
- Submit a project-specific biohazard approval (BHA) form for each new project involving infectious materials, organisms and toxins (not applicable to courses) for submission to the relevant funding office.
- 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 authorized personnel have all organizationally-required, project-specific, facility-specific and containment zone-specific training relevant to biosafety and biosecurity 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. This may be achieved by producing lab-specific training records combined with records from EOHSS, FHS Safety Office and Mosaic or other administrative offices.
- Ensure that authorized personnel are proficient in carrying out the work they are required to undertake; this may involve practical evaluation or observation on behalf of the supervisor to deem such proficiency.
- Prohibit any person under their supervision from undertaking any controlled activities where the person does not have the required training as prescribed by the supervisor or where the person is not deemed proficient by the supervisor.

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- Provide biohazard-work related accommodation for any authorized personnel in consultation with Student Accessibility Services or Employee Health Services where required.
 - Arrange for a regular audit of all SOPs relevant to biosafety and biosecurity and all containment zones listed on their BUP.
 - Ensure all BSCs, enclosures or HEPA filter-containing containment devices are registered with the biosafety office.
 - Ensure all BSCs, enclosures or HEPA filter-containing containment devices are certified to the most current applicable standards (including but not limited to NSF49 or manufacturer's specifications) on installation, on relocation or on repair. Certification must also occur annually if used for containment level 2, 2+ or 3 protocols.
 - Ensure all authorized personnel are aware of and understand any indications for medical surveillance and the medical surveillance program.
 - 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, ECCC 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.
 - Notify the Biosafety Office before arranging to import, export or transfer any infectious materials, organisms and toxins.
 - Prohibit any authorized personnel from purchasing or otherwise arranging to import, export or transfer of any infectious materials, organisms or toxins unless the supervisor has ensured that all regulatory documentation requirements are met and that the Biosafety Office has been notified.
 - Ensure that themselves and all authorized personnel adhere to all restrictions that are listed on the import permits or dossiers associated with any imported material.
 - Take measures to ensure and document biosecurity of their inventory and of their containment zone.
 - Immediately notify the Biosafety Office when Inadvertent Release of an inventory item has occurred. This may be in the case of an incorrect delivery, a theft or in the case of a release into the environment.
 - Ensure compliance which meets or exceeds all relevant legislation, institutional policies, guidelines and best practices.
 - Ensure that any autoclave which is used to decontaminate contaminated items for re-use or disposal is registered with the Biosafety Office and is associated with an appropriate load validation standard operating procedure. Results of such validations will be audited on an annual basis.

- Coordinate the maintenance/construction work that takes place inside the containment zone to ensure safety of maintenance/construction workers.
- Upon notification of injury or exposure by any authorized personnel they supervise, complete Injury/Incident Report forms as described in RMM1000.
- Upon notification by an authorized person of symptoms or illness suspected to be related to work with infectious materials, organisms or toxins, complete an injury/incident report per RMM #1000 - Reporting & Investigating Injury/Incident/Occupational Disease Program.
- Identify all inventory items for which immunization is available.
- Where applicable, strongly recommend immunization for authorized personnel who handle infectious materials or organisms for which immunization is available. Authorized personnel at risk cannot be denied immunization due to the cost of immunization and titers.
- Assign a substitute supervisor during leaves of absence according to the Faculty Leave Policies and Guidelines (does not apply to courses).
- Ensure all biological inventory items are disposed or otherwise transferred to another researcher prior to their departure from the University.
- Ensure all authorized personnel under their supervision are aware of and execute their responsibilities under this program.
- Ensure that any autoclave required for use is assessed for compliance with the Canadian Biosafety Standard.
- Register all biohazard storage or processing equipment located in hallways with the Biosafety Office.

5.6 **Role of the Committee**

The Committee shall:

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

5.7 **Role of the Biosafety Manager**

The Biosafety Manager shall:

- Ensure implementation of those processes within the Biosafety Program 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.

- Ensure relevant information is available to parties with responsibilities under this policy; such information must serve to demonstrate fulfillment of those responsibilities.
- Immediately suspend all controlled activities, or any subset thereof, by any stakeholder which place 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 Standard, 2nd Edition (2015) and Human Pathogens and Toxins Regulations.
- Fulfill the functions and duties of the QDA for all organisms not otherwise regulated by the Canadian Council on Animal Care as described in the New Substances Notification Regulations (Organisms).

5.8 University Veterinarian

The University Veterinarian shall:

- Prohibit *in vivo* biohazard use until approval for such use is given by the AREB and the PBAC.
- Oversee and be accountable for all biohazard animal facilities and their function.
- Provide a facility-specific biosafety training program.
- Provide or withhold facility access for any stakeholder as deemed necessary for the protection of animals, facility staff and other stakeholders from any issue relating to biosafety or biosecurity.
- Immediately suspend any controlled activity involving infectious materials, organisms or toxins within any animal facility by any stakeholder which place any person or animal immediately at risk of exposure or harm to their body or wellbeing and report such suspension to the stakeholder's Associate Dean, Research. Such activities leading to suspension shall also be reported to the Biosafety Manager and through RMM1000 – Injury/Incident Reporting.
- Immediately suspend any controlled activity involving infectious materials, organisms or toxins within any animal facility by any stakeholder where such *in vivo* use is not declared on the supervisor's approved animal utilization protocol (AUP).
- Immediately report any loss of biohazardous containment to the Biosafety Manager and through RMM1000 – Injury/Incident Reporting. Such a loss may be due to equipment malfunction, accidental release or divergence from the Standard Operating Procedures on behalf of any stakeholder.

5.9 Research Compliance Auditor

The Research Compliance Auditor shall:

- Maintain an inventory of all rooms in which controlled activities are carried out.
- Keep up to date a laboratory audit checklist that complies with containment standards, including but not limited to those listed in section 3.
- Perform laboratory audits, both on campus and off campus, according to the audit checklist on a schedule of every two years for containment level 2 and 2+ zones and every three years for containment level 1 zones.
- Perform and arrange for validation and verification testing annually for containment level 3 zones.
- Prepare audit reports for distribution to the laboratory supervisor and the Committee.
- Prepare annual summary reports of audit results for root cause analysis of deficiencies and make recommendations for program improvements.
- Implement the 'Monitoring of Non-Compliance' process as described in section 8.1 of RMM 106.
- Maintain an inventory of all primary containment or other HEPA filter containing devices for which NSF49 or other certifications are required, maintain copies of all certifications, send out reminders for annual certifications and schedule certification contractors.
- Maintain an inventory of all McMaster-owned autoclaves.
- Implement and audit a decontamination validation program for autoclaves being used to decontaminate infectious waste.

5.10 All Authorized Personnel

Authorized personnel shall:

- Follow all facility-specific and project-specific SOPs as provided by the supervisor and any facility manager or director.
- Complete training as requested by the supervisor in a timely manner.
- Complete training as provided by the supervisor and the University in a timely manner.
- Withhold from arranging to purchase, import, export or transfer any infectious materials, organisms or toxins until express consent has been given by the supervisor. (not applicable to courses)
- Comply with any conditions and restrictions listed on any import permits, as directed by their supervisor.
- Seek consultation with EHS (employees) or Student Accessibility Services (students) as soon as possible on the occasion:

- They have any limitation such that they cannot adhere to safe practices as described in work-related standard operating procedures.
 - They have a new or pre-existing medical condition that would increase the risk of disease or severity of disease if exposed.
- Notify their supervisor or course instructor that they have initiated the accommodation process with Student Accessibility Services or Employee Health Services.
- Refrain from engaging in any work activities until the accommodation process, if necessary, has been completed.
- Immediately report any injury to their supervisor and complete an Incident/Injury Report as per RMM#1000.
- Immediately report any exposure or suspected exposure, unsafe conditions, procedures or activities to the supervisor and complete an Incident/Injury Report as per RMM#1000.
- Immediately report to their supervisor any of the following:
 - any missing inventory items due to loss or theft or;
 - any loss of containment or failure of any primary containment equipment (BSC, centrifuge, process equipment) or;
 - any inadvertent release of pathogens or toxins to the environment
- 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 symptoms or illness suspected of being related to work with infectious materials, organisms or toxins to their supervisor.

6 RECORDS

- 6.1 The Biosafety Office is responsible for document retention related to the Biosafety Program.
- 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 in scanned form.
- 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 Lab-level 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.

7 REVIEW

- 7.1 The Biosafety Program shall be reviewed by the Committee on an annual basis.

8 PERFORMANCE INDICATORS

- 8.1 The performance of the Biosafety Program can be assessed by the following performance indicators:
 - **BUP Approval Rate:** This value is calculated as the number of approved BUPs per total number of BUPs. A rate of 100% indicates full compliance relevant to biosafety and biosecurity across the group.
 - **Audit Completion Rate:** This value is calculated as the number of completed audits per total required audits per unit time. A rate of 100% indicates full compliance with the target auditing schedule.
 - **User Feedback:** This data represents the quality of service delivered to the stakeholder group.
 - **Injury/Incident Rate:** This value is calculated as the number of injury/incident reports involving an infectious material, organism or toxin per the total number of stakeholders.