# BI Risk Assessment Policy

1. Risk assessments are required when there is a new hazard in the laboratory, when there is a change to an existing hazard, when a new procedure or piece of equipment is employed, when an incident or injury has occurred with existing hazards, procedures or equipment or when it is deemed necessary by supervisors.
2. BI user risk assessments and procedural SOPs pertaining to specific biohazardous work are the responsibility of the BI user’s supervisor and not kept on file in the BI.
3. BI risk assessments, review and SOPs written to capture biological work will be maintained by BI staff and users trained as required.
4. BI risk assessments and supporting documentation will be kept within the BI office area. If applicable, risk assessments will be made available to BI users electronically via the BI website. Refer to the BI Documentation Policy.

## Performing a Risk Assessment

1. Compile relevant safety information (e.g. SDS/PSDS) for the hazard.
2. Assess how the hazard, procedure or equipment has changed.
3. Determine relevant assets, potential threats and vulnerabilities.
4. Determine appropriate countermeasures or mitigation strategies, and control measures to reduce biohazardous material exposure risk.
5. Ensure there is adequate biosecurity measurements.
6. Consider whether these changes increase risk of injury or incident.
7. Assess increased exposure risks and whether PPE or engineering controls need to be modified.
8. Consult with external experts, such as safety offices, for additional safety information.

## Approving Risk Assessments

1. Risk assessments must be reviewed and approved by supervisors.
2. Supervisors must ensure the risk assessment process is repeated if information changes or new information becomes available.
3. Amendments must be communicated to workers.

## Amending Risk Assessments

1. For existing SOPs, assess each step for risk of spill, harm or exposure and provide actions to prevent or mitigate the risk.
2. Rewrite the SOP to include amendments.
3. Ensure the amended risk assessment is approved by supervisor.
4. Workers must be retrained.

## PHAC Overarching Risk Assessments

1. McMaster University has an overarching risk assessment to be conducted and documented to identify the hazards and appropriate mitigation strategies for the proposed activities involving infectious material or toxins, as per the Canadian Biosafety Standards (CBS) and to the Public Health Agency of Canada (PHAC).
2. The overarching strategies include the identification of hazards and mitigation of risks.

### Identification of Hazards

1. McMaster University researchers undertake controlled activities with pathogens form Risk Groups 1, 2 and 3 via purchase or acquirement of pure cultures or through clinical, environmental or other samples. Research includes genetic modification of wildtype pathogens. Also present at the University are risk group 1 and 2 materials regulated by the Canadian Food Inspection Agency. Materials are handled according to the highest level of risk deemed across all agencies. Materials may be handled or combined with hazardous chemicals or radioisotopes.
2. Containment laboratories are provided for work involving controlled activities with pathogens from Risk Groups 1, 2 and 3. Human resources are provided for auditing of containment zones on a regular basis. Repair to containment laboratories can be arranged through the University Facilities Services or if hospital-hosted, through the hospital engineering work-order system.
3. Containment laboratories are located on campus throughout various buildings and also within various hospitals across the city of Hamilton.
4. Workers and persons using the identified hazards include undergraduate students, graduate students, postdocs, research associates and research scientists. Activities may be undertaken as part of an undergraduate academic lab course or as part of an academic research laboratory program. Workers may also be hospital employees.
5. Activities undertaken with hazardous materials includes aerosol generating procedures, closed processing systems, in vivo use and intentional aerosolization. There are risks of splash and spills, inoculation, scratch and bite, ingestion, inhalation and mucous membrane exposure.

### Mitigation of Risks

1. Senior Management’s commitment to support the work of the biosafety committee and the biosafety program includes provision of resources necessary. This documented is part of the Risk Management Manual (RMM) and is signed by the President and Vice President, Research.
2. McMaster’s Presidential Biosafety Advisory Committee (PBAC) reviews projects and prescribes the appropriate containment level, reviews audit reports, assists in the performance of local risk assessments where necessary and contributes to the improvement of the biosafety program. PBAC members are appointed by the President and sit on the committee for terms of three years. The committee meets each month and performs the functions listed above.
3. McMaster’s biosafety program provides a framework of reporting and responsibilities for all persons involved in the use of biohazardous materials in order to meet the minimum standards articulated in the Canadian Biosafety Standard, Human Pathogens and Toxins Act/Regulations, Health of Animals Act/Regulations, Plant Protection Act/Regulations and other applicable legislations.

### Training

1. At this time, McMaster does not possess any human pathogens or toxins which require security clearances. Personnel suitability and reliability assessments are left with the Supervisors to manage. Training is provided in three compartments: (1) organizationally required training (WHMIS, TDG, Fire Safety etc), (2) through SOPs generated by the Supervisor and the Biosafety Office and (3) through experimental protocols generated by the Supervisor. Training consists of two parts: knowledge and practice. Workers take online trainings and read standard operating procedures and are to sign off that they have read and understood. Then, a competent delegate from the laboratory assesses the worker’s performance and mentors them until they are deemed proficient. This method of managing training is a module in core biosafety training taken by all supervisors and all workers.
2. The university provides the resources for auditing containment laboratories on a fixed schedule. Reports are sent back to the laboratory supervisor. Egregious deficiencies are followed up until resolved. A student has been hired year round to follow up on audits after 6 months. Unaddressed or repeat deficiencies are reported on the audit and reviewed by the institutional biosafety committee. Recommendations to withdraw biohazard approval for grants is communicated to the office of the Vice President, Research where necessary.
3. Pathogen risk assessments are carried out by filling out the Biohazard Utilization Protocol which is reviewed prior to the commencement of work. Standard operating procedures are assessed for risk on a regular basis or whenever recommended by the institutional biosafety committee. Supervisors are encouraged to send their SOPs for review by the biosafety office when non-standard experiments or protocols are to be implemented. Any piece of equipment is reviewed for the risk of aerosol generation. Guidance for performing a local risk assessment is provided as an SOP posted on the biosafety webpage.
4. There is an institutional program for incident and exposure reporting. If the incident includes a biohazard (whether or not regulated by HPTA), a copy of the report is sent to the Biosafety Manager and reviewed by the biosafety committee. The Biosafety Manager then reports the incident or exposure through the biosecurity portal. It is not necessary for the workers or supervisors to report to PHAC directly. It is the responsibility of the license holder (Associate Vice President, Research), the biosafety officer (Dr. Jennifer Robertson) and the biosafety alternate (TBA) to submit incident and exposure reports through the biosecurity portal.