

1. Commitment from Senior Management to manage and control biosafety and biosecurity risks at the institution/organization.

Memorial University of Newfoundland's (Memorial) Health and Safety Policy was approved by the University Health and Safety Committee (UHSC) with the authority of the President and sponsored by the Vice President Administration Finance and Advancement (VPAFA) – also Memorial's biosafety licensee (license # L-R2-13784-23-AD-00) on February 7, 2013 and is accessible through the university website (<https://www.Memorial.ca/policy/site/policy.php?id=213>). This policy is also available in [Memorial's Biological Safety Manual \(BSM\)](#), which was approved by the Institutional Biosafety Committee (IBC) on November 19, 2015. The BSM outlines Memorial's biosafety program (including biosecurity) and defines the roles and responsibilities of all stakeholders involved in the management and control of biosafety and biosecurity. This manual also provides information on the specific procedures developed to effectively manage the biosafety and biosecurity risks at Memorial.

2. Delineation of the roles and responsibilities for committees, individuals, departments etc., that have a role in the control/management of biosafety and biosecurity risks.

The roles and responsibilities of all partners (from laboratory workers and students to senior executives) involved in the management of biosafety and biosecurity risks are defined in Memorial's BSM. The specific reporting structure for biosafety/biosecurity is provided in the attached flowchart (Appendix 1). In summary, the Biological Safety Officer (BSO) administers and manages Memorial's biological safety program and reports to the Industrial Hygienist, who reports to the Director, Environmental Health and Safety (EHS). The Director, EHS reports to the VPAFA. By reporting to VPAFA, EHS can make unbiased decisions on safety issues while eliminating any perceived or real conflicts of interest which may arise by reporting to the VP (Research) or VP (Academic).

The BSO sits on the Institutional Biosafety Committee (IBC) and is also a member of the University Radiation Safety Committee (URSC) and Institutional Animal Care Committee (IACC). As a result of these memberships, the BSO is immediately made aware of biosafety and biosecurity issues identified by these committees. However, on both the URSC and IACC, the BSO is the subject matter expert with respect to the control/management of biosafety and biosecurity risks. In general, the URSC and IACC are not directly involved in the control/management of biosafety and biosecurity risks. However, individuals from both of these committees are represented on the IBC and are therefore involved in the control/management of biosafety and biosecurity risks as IBC members. Similarly, the IBC chair sits on the UHSC. As a result, biosafety and biosecurity risks that are not addressed at the IBC level can be escalated to the UHSC by the IBC representative. The authorities of the BSO during high-risk situations (i.e. work stoppage) are outlined in the BSM, as are the reporting obligations in the event of such incidents.

IBC membership and appointment

The IBC is composed of not less than six (6) members ([see IBC member profile page](#)) and administratively manages Memorial's biological safety program and functions according to its [Terms of Reference \(TOR\)](#). The TOR includes information about the membership appointment

process, requirements for membership eligibility, IBC responsibilities, IBC meeting requirements and the roles and responsibilities of IBC officers. The IBC meets bi-monthly to review internal biosafety permit applications/risk assessments, discuss biosafety/biosecurity issues and advise the BSO, as necessary. The biosafety permit application and approval process is outlined in the BSM. The IBC reports to the UHSC whose membership includes the VPAFA, Director of EHS and the Chair of the IBC, allowing for information flow regarding biosafety/biosecurity issues to the senior management group. As indicated in the UHSC terms of reference (Appendix 2), UHSC membership includes one individual from the URSC and IBC with indefinite terms.

Financial resources for biosafety are managed by Environmental Health and Safety and units with biosafety permits.

The BSO prepares and submits funding proposals outlining the specific needs for biosafety enhancements to environmental health and safety's senior leadership team. This involves providing clear documentation of how the requested funds will improve biosafety and biosecurity, particularly in the context of the university's research activities. Funding proposals could be for professional development, personal protective equipment and or management software, for example.

Regulatory Compliance: The Office of the Vice President Research must remain compliant with relevant legislation (e.g., biosafety standards, regulations, etc.). When non-compliances are observed by the BSO, the University's risk framework is used and the timeframe stated for corrective action must be applied. Corrective actions resulting in enhancements to infrastructure or equipment are the responsibility of the lab owner's department.

Emergency Funding: biosafety enhancements may require immediate action, such as addressing a significant biosafety risk or responding to regulatory changes. While most funding is planned and allocated in advance, the lab owners/BSO may request emergency funds if an urgent need arises. Availability of emergency funding is subject to institutional approval by senior management.

EHS works in conjunction with Facilities Management (which also reports to VPAFA) to ensure that all spaces (i.e. containment zones: including chemical, biological and radiation laboratories) are compliant with applicable legislation. Although retrofitting of existing spaces may be the responsibility of the laboratory owner, priority is given to high-risk areas such as biocontainment and radiation laboratories.

3. Establishment of a single point of contact to provide guidance on the Plan and a senior level 'champion' who can represent biosafety issues at a senior level on his/her behalf.

The BSO is the point of contact for all matters relating to biosafety and biosecurity at Memorial. The BSO is responsible for providing guidance and updating plan elements as necessary. The BSO reports indirectly to the Director of EHS who, as a member of the UHSC, reports on all health and safety issues (including biosafety) at senior management meetings. In addition, the Chair of the IBC, also a member of the UHSC provides updates to senior executives on biosafety/biosecurity-related issues. Both the Director of EHS (Ms. Barbara Battcock, bbattcock@mun.ca, 709-864-6126) and the Chair of the IBC (Dr. Rodney Russell, rodney.russell@mun.ca, 709-864-2875) act as biosafety "champions" at Memorial.

4. Overview of how biosafety and biosecurity risks, including those from research with dual-use potential, are identified at the institution/organization.

Overarching Risk Assessment: In 2014, a review of all biosafety permits was conducted to identify the departments that utilize biological hazards, as well as the various types of biohazards [and associated risk groups and work types (i.e. *in vivo*, *in vitro*, etc.)] that are used at Memorial. This original risk assessment was completed **by the BSO and IBC** and covered not only PHAC-regulated biohazards, but also those covered by other agencies (e.g. plants and aquatic animal pathogens, plant pests, etc. CFIA) as well as those not regulated in Canada (e.g. Human blood and tissues). This satisfied Memorial's requirement for an **Overarching Risk Assessment (ORA)** (CBS 4.1.4).

This ORA provided the basis for development of a second version of Memorial's BSM (2015), which was tailored to the work that was currently underway at Memorial. This manual is updated, when necessary, as new areas of work are identified.

Internal Biosafety Permits: Researchers are also responsible for identifying all biological hazards and participating in the assessment of RG (when necessary) as part of their biosafety permit application (as per **Local Risk Assessment (LRA)** requirements; CBS 4.1.6). The application process consists of submission of an application form as well as a biohazard procedures risk assessment which describes the specific procedures/techniques that utilize the biohazards in question. The intention of this procedures RA is to identify and control for biosafety and biosecurity risks associated with the specific biohazards and protocols in use. The permit application is an online form available through Memorial's my.mun portal, while associated documents can be found at [Biosafety Permit Application | Environmental Health & Safety | Memorial University of Newfoundland \(Memorial.ca\)](#)). On the biosafety permit application form, researchers are provided the PHAC "dual use" flow chart and asked to identify whether their research has dual-use potential. If dual-use potential is identified, the potential risk is evaluated by the IBC in conjunction with the applicant (see below), and relevant controls are mandated to mitigate the risk to an acceptable level.

Biosecurity risk assessment (BRA): A formal biosecurity risk assessment has been **developed by the BSO and IBC** and stands as a living document which is reviewed by the BSO and IBC members at bi-monthly IBC meetings (as per **Biosecurity Risk Assessment (BRA)** requirements; CBS 4.1.6). Additions/revisions (e.g., biosecurity scenarios, targeted assets, controls, etc.) are added/edited by the BSO when necessary.

In summary, biosafety and biosecurity risks are identified by researchers, the BSO and IBC members.

Biosafety permits are valid for two years and require renewal prior to the expiry and amendment prior to any changes to biohazards, procedures and/or locations. As a result, local and dual-use risks are identified at least bi-annually (sooner in the event of amendment requests). The ORA and biosecurity RA are living documents and are reviewed whenever there is a change to the scope of the biosafety program (e.g., addition of a new location or type of biohazard, or changes to scope of work). In all cases, investigation outcomes resulting from incidents or non-compliances can also result in the review/updating of one or more of these RA's.

5. Overview of how biosafety and biosecurity risks, including those from research with dual-use potential, are assessed once they have been identified at an institutional/ organizational level.

Memorial's [health and safety management system \(HSMS\) Hazard Identification & Risk Management element](#) outlines the process for identifying hazards and steps required to manage associated risks. Within this element, a standardized risk assessment scoring matrix is utilized to evaluate the overall risk based on the likelihood and consequence of its occurrence. At Memorial, the risk tolerance threshold is set a “moderate,” as described in the element. All biosafety-related risk assessments (ORA, LRA, BRA, dual-use risk assessment) follow this HSMS element.

The initial ORA described in element 4 allowed the BSO and IBC to develop and/or modify elements of the biological safety program in order to reflect the types of work that were underway at that time. This also resulted in the development of the current version of the BSM. This program is continually monitored by the BSO and IBC and when new areas of research involving biohazards arise, the program is/will be modified to reflect these changes.

LRA's are conducted for all work involving biohazards at Memorial, and involve the researcher, BSO and IBC. This involves a concerted effort by all involved to identify all of the biohazards that will be used, the specific procedures/techniques that will be used as well as the security/safety measures that may be required. This process is initiated through Memorial's biosafety permit application (required for all work involving biohazards at Memorial), must be approved by the IBC, and thereby ensures that appropriate work practices are in place prior to the commencement of work.

During the internal permitting process, a “procedures risk assessment (RA)” is **completed by the applicant**. In this RA, all of the procedures that utilize biological hazards are described in order to identify and assess the hazards (safety and security) associated with each step of the process, the risk level associated, as well as the controls required to mitigate these hazards. Upon submission, the procedures RA is **evaluated by the BSO and IBC**, with modifications (e.g., elimination of hazards, when possible, implementation of additional controls, etc.) added prior to final approval. The expertise of IBC members ensures that a robust review is completed, and that the resulting RA adequately mitigates the biosafety and biosecurity risks associated with the proposed work. Similarly,, identified dual-use potential is evaluated by the **BSO and IBC** (using the PHAC “considerations for risk assessment and mitigation of research with dual-use potential” document as a guide) and approval of the biosafety permit is conditional upon implementation of additional safeguards (if required).

In addition, the IBC has created, and continually updates a biosecurity risk register. This register is modelled after the PHAC biosecurity risk assessment template and is intended to identify potential biosecurity scenarios, as well as the mitigation strategies required to adequately reduce the risks identified. This is a living document that is reviewed and updated regularly by the IBC.

Biosafety permits are valid for two years and require renewal prior to the expiry and amendment when there are changes to biohazards, procedures and/or locations. As a result, local and dual-use

risk assessments are reviewed at least bi-annually (or sooner in the event of amendment requests).

The ORA and BRA are living documents and are reviewed whenever there is a change to the scope of the biosafety program (e.g., addition of a new location or type of biohazard, or changes to scope of work). In all cases, investigation outcomes resulting from incidents or non-compliances can also result in the review/updating of one or more of these RA's.

6. Overview of how the biosafety and biosecurity risks, including those from research with dual-use potential, are managed and controlled at an institutional/organizational level.

At Memorial we use a combination of methods to ensure that our biosafety and biosecurity risks are adequately managed and controlled:

- a. **Internal biosafety permitting process** – an internal biosafety permit is required for all work that is conducted by Memorial personnel, takes place on Memorial premises or funded through Memorial-administered funding before the work can commence. This includes off-site work (e.g., field work). During the application review process, the IBC and BSO, in consultation with the researcher, determine whether elimination and/or substitution of higher risk pathogens/toxins is a viable option for controlling the risk.
Memorial
- b. **Biological Safety Manual (BSM)** - An institutional BSM has been developed to provide researchers with the information necessary to appropriately manage the risks associated with their own work involving biohazards. This manual includes such topics as: biosafety permit application process, biohazard risk assessment procedure, biosafety training requirements, medical surveillance program, risk management options (engineering vs. administrative controls) in addition to a number of stand-alone standard operating procedures (SOPs) for common Memorial biosafety-related issues. The manual can be found at https://www.Memorial.ca/health_safety/media/production/memorial/administrative/environmental-health-amp-safety/media-library/ohsms/bsms/Memorial_Biosafety_Manual.pdf
- c. **Biosafety Training** – A comprehensive biosafety training program has been developed and is mandatory for all faculty, staff and students who work in authorized biohazard laboratories or under active biosafety permits (i.e. work in non-Memorial labs, fieldwork, Memorial-affiliated locations), as well as all ancillary workers who may require access to Memorial labs for their work duties.
- d. **Institutional Biosafety Committee (IBC)** – the IBC meets bi-monthly to review all biosafety permit applications, which includes determination of the appropriate CL and work practices for the work proposed. Detailed information on the IBC can be found at [Welcome | Environmental Health & Safety | Memorial University of Newfoundland \(Memorial.ca\)](#)
- e. **Committee cross-appointments** - As the BSO and certain members of the IBC are cross appointed on other committees (i.e., IACC, URSC, UHSC) any biosafety or biosecurity-related issue can be identified and rectified before potential unsafe work is initiated.

- f. **Internal inspection/audit program** – routine inspections of areas where biohazards are handled allows the BSO to identify areas of non-compliance to relevant regulations/policies/guidelines, etc. and to ensure that these deficiencies are adequately corrected. The fact that non-compliance issues can impact the status of a researcher’s biosafety permit, and potentially funding, promotes self-awareness by the researcher in order to avoid the potential for permit suspension.
- g. **Biosafety Standard Operating Procedures (BSOPs)** – a suite of BSOPs have been developed by the BSO/IBC and allow for certain common work types to be standardized across the university, thereby reducing the variation between research groups and therefore the likelihood of incidents during these activities.
- h. **Memorial Incident Management System (MIMS)** – This system facilitates the reporting of all health and safety related incidents (hazards, accidents and near misses) including biosafety-related incidents (i.e. LAI’s, potential exposures, spills, etc.). The reporting capabilities of this system allow EHS to identify areas where additional controls may be required.
- i. **Dual-use considerations** – In the event that dual-use potential is identified as described previously, a number of strategies are used to mitigate the risk. These strategies include the implementation of specific conditions of certification by which the researcher must comply in order to maintain their biosafety permit (imposed by the IBC during biosafety permit review), corrective action requirements identified by the BSO during periodic inspections (e.g. security improvements) as well as modifications to experimental design/methods which can come about as a result of discussions between the researcher/applicant and IBC members after the identification of dual-use potential.

7. Description of all work areas covered by the Plan

As indicated in element 6a, all work involving biohazards that is conducted by Memorial personnel, takes place on Memorial premises or funded through Memorial-administered funding must be approved by the IBC in the form of a biosafety permit before the work can commence. For research permits, each PI would have their own biosafety permit which would cover all biohazards (and locations) that the PI works with (in). For teaching permits, the department offering the course(s) (e.g. Biology) would maintain a biosafety permit which would include all courses that utilize biohazards, the inventory of biohazards handled and the laboratory locations where biohazards are handled.

When a researcher applies for a biosafety permit, the proposed biohazards that will be handled/stored, along with the procedures involving them will be assessed by the IBC, BSO and researcher in order to determine the appropriate CL and work practices that must be in place for the proposed work. As indicated previously, laboratory areas are inspected for compliance to relevant regulations/standards/guidelines, etc. by the BSO before they are approved for biohazard work (and listed as an approved location on a biosafety permit).

The following areas have been identified at Memorial:

- Research, teaching and animal challenge areas (i.e. small and large animal zones) at CL2 and AQC3 (there are currently no activities involving RG3 pathogens/toxins at any Memorial location).
 - Health Science Centre/Faculty of Medicine

- St. John's campus
 - Animal Resource Centre
 - Core Science Facility
 - S.J Carew (Engineering) Building
 - Biotechnology Building
 - Ocean Sciences Centre
 - Cold-Ocean Deep-Sea Research Facility (CDRF) –AQC3 certified with CFIA.
 - Marine Institute
- Grenfell Campus
 - Off-site areas (field work, Health Science Centre – regional hospital)

When new areas are identified (e.g. locations identified on a biosafety permit application), the Plan for Administrative Oversight is updated by Memorial's BSO in consultation with the IBC.

8. Description of all individuals covered by the Plan

As previously indicated in element 6a, all work involving biohazards that is conducted by Memorial personnel (this includes all faculty, staff and students), takes place on Memorial premises or funded through Memorial-administered funding must be approved by the IBC in the form of a biosafety permit before the work can commence. Through this permitting process, all personnel conducting research with human and terrestrial animal pathogens and toxins are captured within the PAO (this includes off-site locations).

It is the individual department's responsibility to provide an orientation to new staff, which includes information on applying for funding, training requirements and relevant internal permits that may be required. Some departments have developed welcome packages that include this information (an example can be provided upon request), and the IBC is working on expanding this initiative to all departments. In addition, new researchers are made aware of their biosafety responsibilities through peers. To facilitate this, most departments where biohazards are used are represented on the IBC. Finally, our internal granting department, Research Initiatives & Services (RIS) communicates the requirements for internal permitting during the funding application process. This includes biosafety permitting, which would capture these individuals into the PAO.

The PHAC-approved Plan for Administrative Oversight is available on the EHS >[Biosafety website](#) which is publicly accessible and promoted to the University community as the primary resource for biosafety-related information at Memorial.

9. Summary of how the Plan is communicated.

The PAO is communicated through a number of mechanisms at Memorial:

- j. **Environmental Health and Safety (EHS) annual report** – this report is submitted to senior management (Board of Regents and President's Executive Council) followed by university-wide dissemination and outlines the accomplishments of EHS during the preceding year. Included in this report are specific sections dealing with the major safety programs (e.g. Biosafety) which describe relevant milestones for the programs as well as program statistics (number of permits, inspections completed, non-compliances observed, personnel training, etc.).

- k. **UHSC meetings** – The UHSC meets regularly to discuss health and safety issues relevant to the university. As previously mentioned, the Director of EHS and the Chair of the IBC are members of the UHSC, and act as biosafety “champions” for Memorial. This environment provides an opportunity for biosafety issues to be relayed to the senior executive group as well as an opportunity for senior executives to provide input into the biosafety program in general.
- l. **EHS** – The EHS website lists all safety programs individually and provides a central repository for all program information. This includes the current versions of all Biosafety Standard Operating Procedures (BSOP’s), BSM, biosafety permit application package, IBC membership listing, etc. http://www.Memorial.ca/health_safety/OHSMS/
- m. **BSO/biosafety permit holder interactions** – The BSO is in frequent contact with biosafety permit holders, staff and students either through in-person lab visits or telephone/email. This interaction ensures that IBC directives are relayed to the people on the front lines.

10. Overview of the procedures to review and monitor the Plan.

All EHS documents are maintained under a document control program, which includes unique document identity and set review schedules. All biosafety-related materials (BSOP’s, biological safety manual, manual appendices, Plan for Administrative Oversight, etc.) are managed via the document control inventory and reviewed according to the review schedule. Besides the scheduled review process, the interaction between the BSO and biosafety stakeholder often results in the identification of aspects of the program that require revision/modification/addition or removal. These suggestions are discussed at IBC meetings and if approved, amended as soon as possible. Other trigger to amend the Plan for Administrative Oversight include:

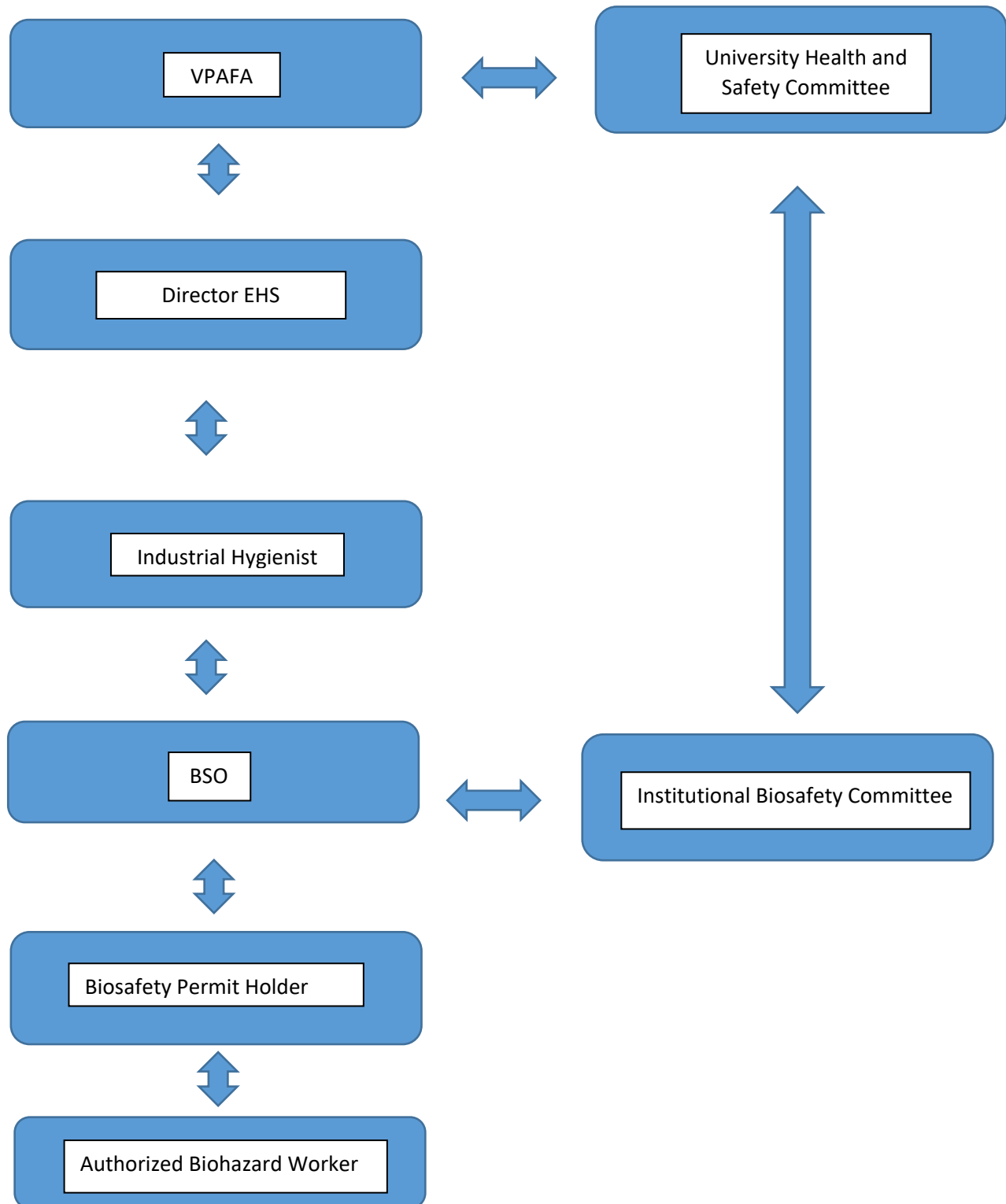
- a. Addition of work locations.
- b. Recommendations arising from incidents.
- c. Changes to relevant legislation.
- d. Changes in administrative control.
- e. Observed trends in non-compliance identified through inspection program.

Through the inspection program, the BSO’s review of non-compliance patterns allows for the identification of emerging needs for training, increased monitoring, SOP development, etc.

Once approved by the IBC, changes to the biosafety program are communicated to all biosafety permit holders through a regularly updated email list as well as through updates to the previously described EHS Biosafety website.

Appendix 1

Reporting Structure for Biosafety at Memorial



Appendix 2

Terms of Reference: University Health and Safety Committee (UHSC)

Terms of Reference: University Health and Safety Committee (UHSC)

1.0 Purpose (Roles and responsibilities)

The purpose of this advisory committee is to provide oversight and development of a University wide health and safety management system.

Specifically, this committee will:

- 1.1 Inform and advise the President on matters relating to Health & Safety.
- 1.2 Review the overall health and safety performance of the University based on input from MUN Workplace Health & Safety Committee (WHSC) representatives and subcommittees.
- 1.3 Recommend to the Vice-President (Administration and Finance) policies and programs which are designed to promote the health, safety and well-being of students, faculty and staff.
- 1.4 Review occupational health and safety matters as may, from time to time, come to its attention or be directed to it and formulating recommendations for action to the appropriate department.
- 1.5 Promote health and safety awareness to the university community.
- 1.6 Establish and promote health and safety educational programs for members of the university community and identify resources and make recommendations for improvement in health and safety training.
- 1.7 Review and make recommendations concerning any health and safety reports, quarterly summaries of MUN incidents and other reports as may be submitted.

2.0 Membership of the University Health and Safety Committee

The University has established and shall maintain a committee comprising of members of the University community, representatives of employee and student groups. The membership will consist of equal numbers of employee/student and management members. A voting member can send an alternate in their absence.

The UHSC shall consist of:

- 1 from CUPE (representing all locals)
- 1 from NAPE (representing all locals)
- 1 from MUNFA (co-chair)
- 1 from LUMUN (representing all locals)
- 1 from TAUMUN

- 1 from Biosafety Committee
- 1 from University Radiation & Safety Committee
- 1 from MUNSU
- 1 from GSU

- Senior administration
- Senior executive VP AF (co-chair)
- Marine Institute
- Grenfell Campus
- Human Resources
- Student Services
- Facilities Management
- Campus Enforcement and Patrol

- Add (4) Ex-Officio – Non-Voting
- Communications
- Chief Risk Officer
- Director EHS
- Administrative Coordinator

Recording Secretary – OCRO

3.0 Roles and Responsibilities

3.1 Co-Chairs

The Co- Chairs shall:

- be appointed by their respective group.
- alternate chairing of meetings and work with the recording secretary to plan the meeting agenda and prepare meeting minutes.
- be entitled to participate as a member of the Committee in discussion, decisions and recommendations.
- appoint one member of the Committee to act on his or her behalf in their absence

- appoint members of the Committee to act on issues and report back to the Co-Chair and the Committee.

3.2 Recording Secretary

The Recording secretary:

- a. is not a member of the Committee
- b. shall be responsible for recording the minutes of the meetings and for issuing notices of the meeting after consultation with the Chair. The Recording Secretary shall distribute copies of the minutes to the Committee members,
- c. shall prepare and distribute the agenda of the next meeting to the Committee members
- d. shall post approved minutes on the University web site.

4.0 University Health and Safety Committee Meetings

1. Committee meetings shall be held four (4) times per year or at the joint call of the co-chairs or at the request of three (3) or more members.
2. The quorum for the Committee shall be one half of the voting members.
3. The meetings shall be governed by Robert's rules of Order.