

- 1. Memorial University of Newfoundland's (MUN) 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 and Finance [VPAF also MUN's biosafety licensee (license # L-R2-13784-16-HU-00)] on February 7, 2013 and is accessible through the university website (https://www.mun.ca/policy/site/policy.php?id=213). This policy is also available in MUN's Biological Safety Manual (BSM), which was approved by the Institutional Biosafety Committee (IBC) on November 19, 2015. The BSM outlines MUN'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 MUN.
- 2. The roles and responsibilities of all stakeholders (from laboratory workers and students to senior executives) in relation to the management of biosafety and biosecurity risks are defined in MUN's BSM (http://www.mun.ca/health_safety/OHSMS/BSMS/). 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 MUN's biological safety program and reports directly to the Associate Director, Environmental Health and Safety (EHS). The Associate Director, EHS reports to the Chief Risk Officer (CRO), who in turn reports to the VPAF. By reporting to VPAF, 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). The authorities of the BSO during dangerous situations (i.e. stop work) are outlined in the BSM, as are the reporting obligations in the event of such incidents.

The IBC is composed of not less than six (6) members (see IBC member profile page) and administratively manages MUN'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 certificate applications/risk assessments, discuss biosafety/biosecurity issues and advise the BSO, as necessary. The biosafety certificate application and approval process is outlined in the BSM. The IBC reports to the UHSC whose membership includes the VPAF, Associate Director of EHS and the chairman of the IBC, allowing for information flow regarding biosafety/biosecurity issues to the senior management group. Health and Safety Committee procedures (G-003) are available to the University community (University Health and Safety Committee (UHSC) terms of reference provided in Appendix 2).

EHS works in conjunction with Facilities Management (which also reports to VPAF) to ensure that all spaces (i.e. laboratories) are compliant with applicable legislation (including chemical, biological and radiation laboratories). Although retrofitting of existing spaces may be the



responsibility of the PI, priority is given to high risk areas such as biocontainment and radiation laboratories.

- 3. The BSO is the point of contact for all matters relating to biosafety and biosecurity at MUN. The BSO is responsible for providing guidance and updating plan elements as necessary. The BSO reports directly to the Associate Director of EHS who, as a member of the UHSC, reports on all 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 Associate Director of EHS (Ms. Barbara Battcock, bbattcock@mun.ca, 709-864-6126) and the Chair of the IBC (Dr. Rodney Russell, rodney.russell@med.mun.ca, 709-864-2875) act as biosafety "champions" at MUN.
- 4. In 2014, a review of all biosafety certificates 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 MUN. This scan 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 MUN's requirement for an Overarching Risk Assessment (ORA) (CBS 4.1.6). At that time, we had implemented an electronic management system to monitor our radiation and chemical hazards and the intention is to incorporate biological hazards into the system in the near future.

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

Researchers are also responsible for identifying all biological hazards and participating in the assessment of RG (when necessary) as part of their biosafety certification application (as per Local Risk Assessment (LRA) requirements; CBS 4.1.8). The application process consists of submission of an application form as well as a biohazard procedures risk assessment which outlines the specific procedures/techniques that utilize the biohazards in question (the complete certificate application package can be found at

http://www.mun.ca/health_safety/OHSMS/BSMS/BiosafetyCertificateApplicationp.php). On the biosafety certificate application form, researchers are provided the PHAC "dual use" flow chart and asked whether their research has dual-use potential on the application form. If dual-use potential is indicated, the potential risk is evaluated by the IBC in conjunction with the applicant (see below). During IBC review of biosafety certificate applications, dual-use potential is also evaluated (with the aid of the dual-use decision tree) by IBC members.

5. 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 (e.g. MUN has recently completed construction of a new aquatics facility and are in the early stages of the



CFIA Aquatic Containment (AQC) level 3 certification process. As a result, an aquatics specialist has been added to the IBC to reflect the need for his expertise in assessing the potential work that will be conducted in the facility once certified).

LRA's are also conducted for all work involving biohazards at MUN, 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 exact procedures/techniques that will be used as well as the security/safety measures that may be required. This process is initiated through MUN's biosafety certificate application (required for all work involving biohazards at MUN), must be approved by the IBC, and thereby ensures that appropriate work practices are in place prior to the commencement of work. During this process, identified dual-use potential is evaluated by the 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 certificate is conditional upon implementation of additional safeguards (if required). To date, no dual-use potential has been identified at Memorial University.

- 6. At MUN we use a combination of methods to ensure that our biosafety and biosecurity risks are adequately managed and controlled:
 - a. Internal biosafety certification process an internal biosafety certificate is required for all work that is conducted by MUN personnel, takes place on MUN premises or funded through MUN-administered funding before the work can commence. 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. For example, the two current teaching groups at MUN are in the process of evaluating all RG2 pathogens in use to determine if elimination/substitution is possible. Justification for maintenance of any RG2 biohazards for these groups is required.
 - 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 certificate 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 MUN biosafety-related issues. The manual can be found at http://www.mun.ca/health_safety/OHSMS/BSMS/
 - 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 certificates (i.e. work in non-MUN labs, fieldwork, MUN-affiliated locations).
 - d. **Institutional Biosafety Committee (IBC)** the IBC meets approximately bi-monthly to review all biosafety certificate applications, which includes determination of the appropriate CL and work practices for the work proposed. Detailed information on the IBC can be found at
 - http://www.mun.ca/health_safety/OHSMS/BSMS/InstitutionalBiosafetyCommittee.php



- 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 efficiently corrected. The fact that non-compliance issues can impact the status of a researcher's biosafety certificate, and therefore funding, promotes self-awareness by the researcher in order to avoid the potential for certificate suspension.
- g. **Biosafety Standard Operating Procedures (BSOPs)** these BSOPs 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. **Memorials Incident Management System (MIMS)** This system facilitates the reporting of all health and safety related incidents (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 certificate (imposed by the IBC during biosafety certificate 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. As indicated in element 6a, all work involving biohazards that is conducted by MUN personnel, takes place on MUN premises or funded through MUN-administered funding must be approved by the IBC in the form of a biosafety certificate before the work can commence. For research certificates, each PI would normally have their own biosafety certificate which would include all biohazards (and locations) that the PI works with (in). For teaching certificates, the department offering the course(s) (e.g. Biology) would maintain a biosafety certificate 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 certificate, 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 certificate). The following areas have been identified at MUN:



- Research, teaching and animal challenge areas (i.e. small and large animal zones) all at CL2 (there are currently no activities involving RG3 pathogens/toxins at MUN. However, upon approval of this plan, an application for an RG3 license will be submitted as one researcher currently has MT-2 cells [which shed HTLV (RG3)] in long-term storage with potential for re-activation in the future).
 - Health Science Centre
 - Science Building
 - o S.J Carew (Engineering) Building
 - Biotechnology Building
 - o Physical Education Building (human body fluids only)
 - Ocean Sciences Centre
 - Marine Institute
- Off-site areas (field work, Health Science Centre regional hospital)
- Cold-Ocean Deep-Sea Research Facility (CDRF) currently proceeding with AQC3 certification with CFIA.
- Note: There are no current activities involving RG2 or above biohazards at Memorial's Grenfell campus.

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

8. As previously indicated in element 6a, all work involving biohazards that is conducted by MUN personnel (this includes all faculty, staff and students), takes place on MUN premises or funded through MUN-administered funding must be approved by the IBC in the form of a biosafety certificate before the work can commence.

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/certificates 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.

Once approved by the PHAC, the Plan for Administrative Oversight will be made 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. The PAO is communicated through a number of mechanisms at MUN:
 - a. **Environmental Health and Safety annual report** this report is submitted to senior management (Board of Regents and Vice Presidents Council) followed by Universitywide 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 certificates approved, inspections completed, non-compliances observed, etc.).
- b. UHSC meetings The UHSC meets regularly to discuss health and safety issues relevant to the university. As previously mentioned, the Associate Director of EHS and the Chair of the IBC are members of the UHSC, and act as biosafety "champions" for MUN. 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.
- c. 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 certificate application package, IBC membership listing, etc. http://www.mun.ca/health-safety/OHSMS/
- d. **BSO/biosafety certificate holder interactions** The BSO is in continual contact with biosafety certificate holders, staff and students either through in-person lab visits or telephone/email. This constant interaction ensures that IBC directives are relayed to the people on the front lines.
- 10. 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

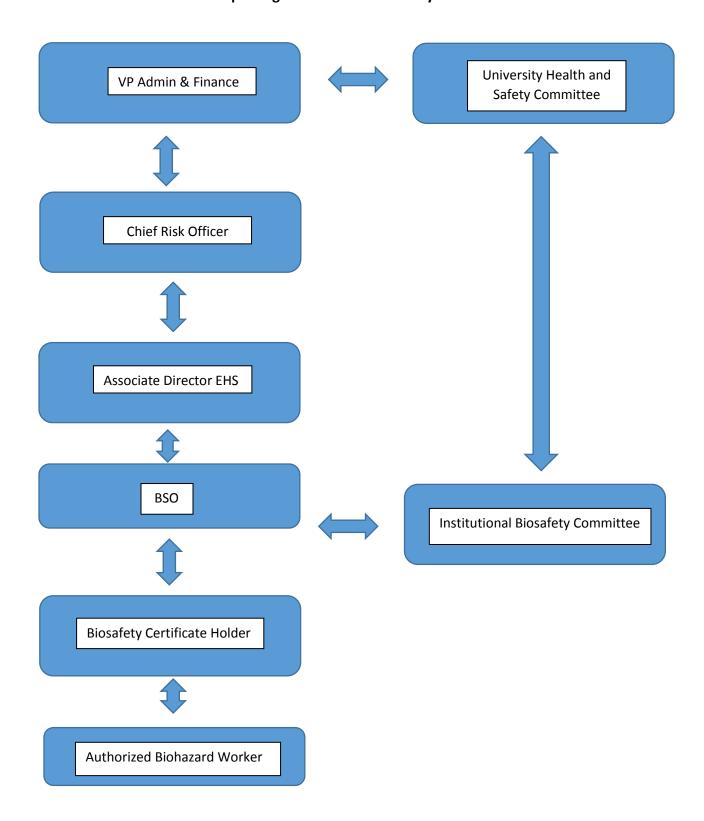
Through the inspection program, the BSO's constant review of non-compliance patterns allows for the identification of emerging needs for training, increased monitoring, SOP development, etc.

Once approved by the IBC, changes to the biosafety program are communicated to all biosafety certificate 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 MUN





Appendix 2

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

1.0 Purpose (Roles and responsibilities)

The purpose of this advisory committee is to provide policy oversight of the University wide health and safety management program.

Specifically this committee will:

- **1.1** Inform and advise the President on matters relation to Health & Safety.
- **1.2** Review the overall safety performance of the University based on input from MUN Joint Occupations Health & Safety Committee (JOHSC) 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 wellbeing of students, faculty and staff.
- **1.4** Review occupational health, safety and security 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 report, quarterly summaries of MUN accidents and incidents reports 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 member 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
- o 1 from LUMUN
- o 1 from TAUMUN



- o 1 from Biosafety Committee
- 1 from University Radiation & Safety Committee
- o 1 from non-bargaining
- o 1 from MUNSU
- 1 from GSU
- Senior administration
- Senior executive
- Marine Institute
- o Grenfell Campus
- o Human Resources
- Faculty Relations
- Academic
- Student Services
- o Facilities Management

Add (4) Ex-Officio - Non Voting

o Communications

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 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 five (5) times per year or at the joint call of the cochairs 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.