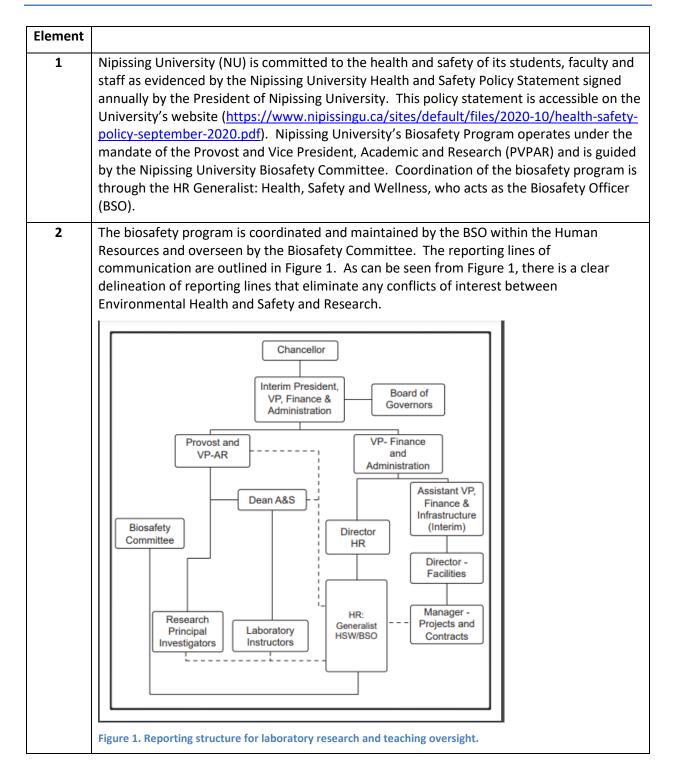


Plan for Administrative Oversight

Nipissing University Biosafety Program

Revised: May 2021

Nipissing University Plan for Administrative Oversight



There is an institutional Biosafety Committee comprised of members who are appointed by the PVPAR representing departments and areas that conduct biological activities as outlined in the Biosafety Committee Terms of Reference. The BSO also sits on this Committee. The Committee meets as required to review biosafety and biosecurity policy, discuss biosafety/biosecurity issues and review permit applications for projects involving biohazardous materials (see Appendix 1). The Biosafety Committee is advisory to and reports directly to the PVPAR. The BSO also sits on the University Joint Health and Safety Committee (JHSC) and the University Animal Care Committee in order to provide continuity and consistent oversight for biosafety aspects. The University Animal Care Committee does not oversee biosafety aspects but refers any project that may have related biosafety or biosecurity concerns to the BSO via the PVPAR's office. At present time, there are no *in* vivo pathogen projects.

For projects that require Research Ethics Board (REB) approval, the following instructions are part of the REB application form: "Does your research involve bio-hazards (i.e. Biohazardous material includes the following: 1) microbial and other organisms that are human, animal or plant pathogens; 2) human or animal tissues, blood or bodily secretions; 3) animals or plants that could contain on or in their body human, animal or plant pathogens; 4) toxins derived from microorganisms, plants and animal species; 5) genetically modified organisms, including viruses, bacteria, plants or animals.

Yes - you must obtain a permit from the Bio-Safety Office No ".

The BSO has an open line of communication to the four Deans and the PVPAR on matters dealing with laboratory safety (including biosafety). The biosafety program is meant to be collaborative; however, when there is an imminent health and safety risk, the Human Resources department can stop work as appropriate under the Ontario Occupational Health and Safety Act. The BSO would report major non-compliance issues directly to the PVPAR. The BSO would also report major non-compliance issues to the federal, provincial and municipal authorities as appropriate with the legislated requirements of the Biosafety Officer position. Minor non-compliance issues are handled directly between the BSO and the individuals engaged in biohazardous activities. If a biosafety enhancement (i.e. containment zone deficiency) is realized, the BSO will contact the appropriate administrative department head to have the deficiency dealt with within a reasonable time-frame. If the requirement is not within the budgetary resources of the administrative department, the matter will be reported through Human Resources and to the VP Finance and Administration.

The BSO actively collaborates with Facilities Services (who report directly to the VP Administration and Infrastructure) in order to ensure that any new buildings/laboratories or renovations of these spaces include input from a safety perspective. In all cases, if modifications will affect an area where biohazardous materials are being manipulated, the BSO will review the impact the modifications will have on biosafety and biosecurity. This may also require the researcher or laboratory instructor to initiate the biosafety permit application process either before or upon completion of the renovations, but before operations begin.

The Office of Graduate Studies and Research is responsible for grant funding and ensuring that the safety aspects of a research project have been met prior to releasing funding to

the researcher. Principal Investigators would liaise directly with the Office of Graduate Studies and Research, who in turn report directly to the PVPAR. Any projects dealing with potentially biohazardous materials are referred to the BSO and the Biosafety Committee for vetting and approval prior to being approved for funding. Those faculty involved in teaching courses that include the handling of biohazardous materials report directly to their respective Deans, i.e. Dean of Arts and Science, Dean of Education and Professional Studies.

- The BSO is the point of contact (linkage) that provides guidance and updates to this Plan.

 The BSO reports to the Director of Human Resources, who represents and reports on safety related aspects at senior management meetings. The Director of Human Resources acts as the 'champion' on safety issues in this forum in order to ensure that senior management continues to be informed, engaged and committed on all safety aspects.
- A comprehensive review of all biohazardous activities was completed at the inception of Nipissing University's Biosafety Program (CBS 4.1.1), to identify which departments were working with, or could potentially work with biohazardous materials (see the Overarching Risk Assessment document in Appendix 1). This was all-encompassing and included human, animal and plant pathogens and toxins, plus potentially infectious materials, such as blood and other potentially infectious material that would not be cultured.

The assessment makes up part of the overall risk mitigation strategy that is incorporated into Nipissing University's emergency management strategy.

With regard to possibility of dual-use research, all research is assessed, as part of a local risk assessment as outlined in element 5, to determine whether or not the results of that research can be misused to pose a biologic threat to public health and/or national security. The researcher/instructors are engaged in the dual-use research assessment through the use of the biohazard permit application process. The researcher must fill out a "Biohazardous Materials Use Risk Assessment and Permit Application" form which includes a section with an explanation of 'Dual-Use' and the decision tree diagram from page 8 of the "Plan for Administrative Oversight for Pathogens and Toxins in a Research Setting" guidance document provided by PHAC.

A risk identification process for personnel working with biohazardous materials has been developed as part of the medical surveillance program. This ensures that all hazards are identified and assessed, and applicable work practices are in place for those working with infectious material as required under CBS 4.1.7.

As part of the risk management strategy at Nipissing University, all laboratory and laboratory ancillary areas are jointly inspected at least quarterly by the Joint Health and Safety Committee and the BSO. These inspections look for safety hazards and security risks in both the chemical and animal laboratories as well as the biology and microbiology laboratories. If there are any deficiencies noted with regard to biosafety or biosecurity, the area supervisor is notified in writing with an explanation of the non-compliance issue, preferred corrective action and a suggested time frame for the corrective action. If the corrective action has not been taken within the time frame suggested, the issue is raised via the Director of Human Resources to the appropriate Faculty Dean and/or PVPAR for correction. Non-compliance could lead to loss of funding and/or laboratory privileges.

- 5 The overarching risk assessment (Appendix 2) outlines the risk management strategy at the institutional level, incorporating all types of risk including biological, chemical, and environmental hazards. The overarching risk assessment is only one element of the risk management strategy at Nipissing University. Once the departments that use biohazardous materials are identified, a determination of the Risk Group and Containment Level required to handle biohazardous material is done as part of the Overarching Risk Assessment program. These determinations as well as the assessment process outlined below are in line with CBS 4.1.5. Within the scope of the risk management strategy, every project or activity that involves biohazardous material undergoes a local risk assessment (LRA) by the BSO and the Biosafety Committee prior to being granted approval (as per requirement CBS 4.1.7). The LRA takes into account the following factors: personnel training and suitability; basic biohazard information (organism risk group, proposed containment level, etc.); proposed containment strategies; type of material utilized (blood or tissues; purified pathogens, GMO, radioisotopes, etc.); animal use requirements; biosecurity strategy (including dual-use considerations), including signage, access and inventory management; and decontamination and waste management . All approved biosafety permit applications are reviewed by the BSO on an annual basis to ensure compliance with all current and updated regulatory requirements.
- A number of biosafety control components have been incorporated into the biosafety and biosecurity structure at Nipissing University to limit non-compliance and the potential for accidents/incidents. Those areas that are now, or will be in the future, using RG2 or higher pathogens in teaching or research activities are captured by the biosafety control components.

To that end, the Biosafety Program incorporates the following components: 1) Risk Assessment and Risk Management; 2) Laboratory inspections and audits; 3) Biosecurity (including inventory control); 4) Laboratory and biosafety training; 5) Biosafety Policies and Procedures manual; 5) Laboratory Safety manual; 6) Guidelines for the Safe Use of Autoclaves; 7) Spills and Incident Management Procedures; and 8) Waste Management Guidelines.

The overarching control mechanism is the University's biosafety program and includes many of the control mechanisms that are in use. These include the Biosafety Manual, Research Services, linkages with the Animal Care Committee and the Research Ethics Board, internal Inspection and Audit program, and laboratory training program, including biosafety training. An overview of the controls:

• Safety Manuals: Nipissing University has developed a number of manuals and guidelines for use in a biocontainment facility. The first is the Laboratory Safety Manual that outlines protocols and procedures to be followed in chemistry and biology laboratories and identifies the major hazards and outlines the methods used to deal with those hazards. Building on the procedures contained within the Laboratory Safety Manual is the Biosafety Manual (CBS 4.9), which specifically outlines the legislative requirements for the Nipissing University Biosafety program, an overview of the institutional biosafety and biosecurity program, the medical surveillance program, emergency response and incident reporting. A comprehensive Spills Management Program document was developed to provide guidance in the event of a hazardous chemical or biohazardous spill. To deal with hazardous materials disposal, including biohazardous waste a Hazardous Materials

Disposal Guide was developed. All of these manuals and guides are available in pdf format on the Health and Safety website.

- The Biosafety Manual is considered a living document that is reviewed at least annually by the BSO. The BSO will revise the Biosafety Manual as needed, based on legislated changes, updated best practices and/or inspection reports or incidents within the containment zones. The revisions are then reviewed by the Biosafety Committee and the Joint Health and Safety Committee before being published on the Nipissing University Health and Safety website.
- Pathogen Inventory Control: At the present time, there is only one laboratory, the Microbiology teaching laboratory, which stores and maintains an inventory of human and animal pathogens. As part of the Pathogen Inventory Control program at Nipissing University, it is a requirement for all laboratories that maintain an inventory of pathogens, to submit an up-to-date listing of pathogens and quantities to the BSO at least annually or earlier in the event of changes to that inventory. The BSO maintains a campus-wide record of the pathogen inventories on a secure SharePoint server.
- Biohazardous Materials Use Risk Assessment and Permit Application form: The application form is the first official point of contact a researcher or laboratory instructor with the BSO. The BSO is responsible for reviewing the submission to ensure that the proposed project or teaching program meets the current regulations and policies. As part of the review by the BSO, the BSO has meetings (virtual, telephone or in person) with the applicant in order to more fully understand the project and to assist the applicant in making changes to the project that will lessen or eliminate risks associated with the project, if possible. Examples of biosafety changes that have been suggested include using a BSC when working with aerosolisable protocols such as centrifugation; using RG1 instead of RG2 pathogens in teaching situations; ensuring the use of loop furnaces instead of an open flame, etc. Examples of biosecurity changes are: key fob based locks on doors that only open to authorized personnel; ensure refrigerators and freezers are locked, etc. If Dual-Use is identified, the BSO works with the researcher, the Director of H and PVPAR's office to develop a comprehensive risk mitigation plan to ensure the safety and security of the intended research.
- Biosafety Committee: This committee is mandated to meet as required to review biohazardous materials use approval applications submitted through the BSO to ensure the correct containment levels have been identified and the appropriate biosafety practices are in place. Once the protocols have been vetted and approved, the Biosafety Committee, via the BSO, issues either a permit (RG2 or RG1 activities at CL2) or a letter (for RG1 activities at CL1) that allows the researcher to proceed with research activities with biohazardous materials. Biosafety permits and letters are valid for 5-years, subject to an annual review and regular laboratory inspections and audits. Minor changes or amendments to a research program (e.g. personnel changes) are reviewed by the BSO. Major changes or amendments (e.g. changes in protocol, biohazardous agent, etc.) must be submitted through the BSO and vetted and approved by the Biosafety Committee. Changes must be approved prior to the continuance of the project. Once approved, a new permit or letter is issued. If a research program will

continue beyond the 5-year term, a new biohazardous materials use approval application must be submitted.

The Biosafety Committee also functions to develop and maintain draft University policies for handling biohazardous materials in compliance with internal and external standards and ensuring that all users of biohazardous materials are fully aware of the policies and regulations required for teaching and research activities. In addition, the Biosafety Committee is responsible for reviewing and providing policy direction to the PVPAR for all matters pertaining to the use of biohazardous materials in research and teaching.

- Linkages with the Office of Grad Studies and Research: All funding requests are
 reviewed for compliance with regard to ethics, animal care and biosafety. With
 regard to biosafety and biosecurity, any projects that involve the use of or
 potential exposure to biohazardous materials are forwarded to the BSO by the
 PVPAR for review and inclusion into the biosafety review process if warranted. If
 the principal investigator does not hold a valid biosafety permit (RG2 work) or
 letter (RG1 work), grant funding can be stopped until a permit or letter has been
 issued.
- **Animal Care Committee:** The BSO sits on the Animal Care Committee to ensure any biosafety or biosecurity issues can be identified and rectified before any potential unsafe work is initiated.
- Internal Inspection/Audit Program: The BSO in conjunction with the institutional JHSC, performs monthly and quarterly inspections of all laboratory spaces at Nipissing University to ensure compliance with internal, municipal, provincial and federal safety requirements. All inspections generate a report. If non-compliance is realised, this report is shared with the Director of HR and respective Deans. The role of the inspection/audit program is to promote safety in the laboratory and the inspection reports are used as a tool to educate laboratory personnel and prevent non-compliance. The biosafety program is meant to be collaborative; however when there is an imminent health and safety risk, the Human Resources department can stop work as appropriate under the Ontario Occupational Health and Safety Act.
- Training Program: Nipissing University has a comprehensive training program that is clearly laid out with information provided as to which EHS training courses are required for different employee, student groups, visiting scientific personnel and volunteers. At a minimum, all laboratory workers and supervisors are required to take WHMIS 2015 training, as well as complete the Basic Laboratory Safety training certification course. With respect to Biosafety, there are core courses that are mandatory for all personnel supervising or working with biohazardous materials. The training consists of on-line in-house based training, with the type of training offered depending on the actual type of biohazardous work being performed (i.e. blood borne pathogen training for anyone working with blood or other potentially infectious material). Specialized training is mandatory for certain equipment (biological safety cabinets and autoclaves) and personal protective equipment (respirator fit testing). Aspects of biosecurity and biosafety are reviewed by laboratory personnel on an annual basis. Departments and individual laboratory supervisors are also responsible for providing their own specific activity related

- training. All training done through EHS is kept on file on a SharePoint based Access database.
- Incident/Accident Reporting System: All incidents at Nipissing University must be
 reported to the Human Resources department and are then provided to the JHSC.
 Incidents involving biohazardous or chemical material must also be reported to the
 BSO. This provides a mechanism by which LAI's can be reported by the BSO to the
 federal and provincial agencies as required. It also provides an indicator of the
 areas where more safety training or equipment may be required.
- The Departments of Biology and Psychology and the School of Physical and Health Education Research have been identified as conducting (or having the potential for conducting) controlled activities with pathogens and/or toxins in research, teaching, and animal testing areas, all at CL2 or CL1. All of these areas are covered under the University's Biosafety program. Biosafety permits are issued by the Biosafety Committee based on the types of activities being performed and the results of a LRA for each specific activity. At present time there are no studies ongoing or anticipated that use *in vivo* work with human pathogens or toxins.
- Nipissing University safety policies cover all researchers, professors, technologists, graduate and undergraduate students, and volunteers who handle and/or store human and terrestrial animal pathogens and toxins (and other chemical or biohazardous materials). Each biosafety permit includes the person responsible for the area as well as anyone who works under the permit.

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When new laboratory-based staff, faculty, students are hired by Nipissing University, Human Resources notifies the BSO to coordinate safety training that is applicable to the type of research activities that are to be anticipated by the new member. Human Resources also notifies the BSO regarding new laboratory-based volunteers to ensure they receive applicable training. An integral part of the Basic Laboratory Safety Training is an overview of other training requirements, including work with biohazardous materials. An overview of the training requirement was provided in element 6.

The Biosafety Program and elements within this plan are communicated to all impacted individuals using a variety of mechanisms. One avenue for the communication of plan elements is through the laboratory safety training program. All personnel who will be working in or supervising a laboratory facility are required to attend Basic Laboratory Safety Training. During this training session all aspects of the Biosafety Program are communicated to the participants, including any requirements for further training, biosafety control mechanisms and where to find further information and resources relating to the Biosafety Program. A second avenue of communication is the Laboratory Safety webpages on the Health and Safety web-portal. These pages outline the Biosafety Program, the training requirements, and links to online biosafety resources including PHAC and CFIA biosafety regulations.

Laboratory inspection/audit reports are an important tool for communicating biosafety issues and potential concerns to Senior Administration (i.e. Deans), Principal Investigators, and laboratory staff. The reports are designed to outline potential issues realized as well as provide a proposed solution to the issue. Since these reports are also communicated to the JHSC, they provide an additional communication channel since middle and senior administrators (managers and directors) also sit on the JHSC.

There is continual interaction/communication from the BSO and Human Resources department to the faculty, staff and students. This interaction takes place during regular laboratory safety inspections, inspection follow-ups and email correspondence.

Linkages to relevant committees (i.e. Animal Care Committee and Research Ethics Board) are handled via the research Coordinator to the PVPAR by providing relevant information relating to research activities to the BSO and hence to the Biosafety Committee. The Biosafety Committee, through the BSO, provides an annual report to the PVPAR that outlines the number of permits and letters issued by the Biosafety Committee, the number and type of incidents involving biohazardous material and/or non-compliance and any other information the Biosafety Committee deems relevant.

The BSO utilizes a number of other communication tools to ensure information being relayed is always current including: safety bulletins; email communications; safety manuals and guides; an easily navigable website that includes all forms, policies and training requirements in addition to relevant safety information.

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The entire Nipissing University safety program (of which biosafety is an integral part) is under continual review in order to ensure it remains consistent with federal, provincial and municipal regulations and is following accepted best practices. This Plan, as part of the safety program, is part of the review process. Recommendations for improvement are gathered from all members of the University community, including researchers, biosafety committee, JHSC members and senior administrators. Biosafety recommendations are reviewed and discussed by the Biosafety Committee, and the BSO in order to determine impacts on the program and options for incorporation or change.

The BSO conducts inspections and continually reviews incidents of non-compliance in order to identify trends and gaps in biosafety oversight. The gaps identified may lead to changes or enhancements in inspection frequency, training and awareness programs, or the development of new methods of information dissemination.

In order to stay current with accepted best practices in Laboratory Safety and Biosafety, the BSO networks with Provincial, Federal and International biosafety officers and biosafety professionals via email list servers, safety webinars and regular meetings, thus ensuring that the most up-to-date information is available to the stakeholders. Any new developments or changes to the program are communicated to affected researchers, departmental chairs and Deans through the BSO.

Nipissing University Biosafety Committee Terms of Reference

Mandate

The University has an obligation to its community, funding agencies and the public at large to conduct its teaching and research activities in a responsible and accountable manner. To that end, the Nipissing University Biosafety Committee is mandated by the office of the Provost and Vice President, Academic and Research and administered by the office of Graduate Studies and Research to provide policy direction and make recommendations to the Provost and Vice President, Academic and Research for all matters pertaining to the use of biohazardous materials in research and in teaching.

Membership

The Biosafety Committee has representation from members who have expertise and/or interest in biosafety at Nipissing University. Members are appointed for a two-year period with the possibility of renewal by the Provost and Vice President, Academic and Research as follows:

- Human Resources Generalist Health, Safety and Wellness/BSO
- Laboratory Technician
- Two (2) faculty** members who represent two different academic departments
- Senior administrator reporting to the Provost and Vice President, Academic and Research;
- One (1) member at large from the community

Reporting Structure

The Biosafety Committee is advisory to the Provost and Vice President, Academic and Research. The committee, through the chair shall report at least annually to the Provost and Vice President, Academic and Research, summarizing the activities of the year.

^{**} The chair will be a member of faculty who is elected by the membership and appointed by the Provost and Vice President, Academic and Research

Meetings

Meetings shall be held twice a year in the spring and the fall. The chair reserves the right to call additional meetings as required. Quorum consists of at least three members of the biosafety committee and decisions will be made by consensus. If consensus is not achieved, outside advice may be requested by the Chair.

Duties

The Committee monitors the use of biohazardous material in teaching and research by performing the following duties:

- Develop and maintain University policies for handling biohazardous materials in compliance with internal and external standards including: Public Health Agency of Canada (PHAC), Canadian Food Inspection Agency (CFIA), National Institute of Health (NIH), Occupational Health and Safety Act and Regulations (OHSA), and Nipissing University's policies;
- To ensure that all users, are fully aware of the guidelines and of the nature of containment required for research/teaching;
- Review and approve applications for use of biohazardous materials.
- Advise the Provost and Vice President, Academic and Research on matters relating to biohazards;

Note: The biosafety committee will review and amend the terms of reference annually at the spring meeting

Appendix 2

Overarching Risk Assessment for Nipissing University Biosafety Program

Introduction

Nipissing University has developed a robust biosafety program that takes into account the number and types of pathogens manipulated and/or stored on-site; where biohazardous materials are utilized and stored; and the protocols and procedures used when manipulating biohazardous materials, whether *in vivo* or *in vitro*. In addition, the role of various stakeholders in the use, control, and regulation of biohazardous materials has also been taken into account. To that end an overarching risk assessment as required under Canadian Biosafety Standard 4.1.6 was performed.

Risk Management Strategy

Identification of hazards

Nipissing University, being a teaching and research institution, conducts activities that pose a potential avenue for students, faculty and staff to come into contact with potentially biohazardous materials. A comprehensive survey of all activities with the potential to perform biohazardous activities or research was conducted and the activities were assessed for their potential to cause harm. These activities range from experiments on living systems, such as plants, soils, terrestrial animals (e.g. rats, salamanders, fruit flies) and aquatic animals. Some teaching and research activities may also involve purified strains of risk group 1 and 2 pathogenic bacterial cultures. The areas surveyed included: terrestrial and aquatic animal holding rooms; terrestrial and aquatic animal research laboratories; plant holding rooms, including greenhouses; plant research laboratories; chemistry research laboratories; and teaching laboratories.

Assessing hazards and risk

In most cases, with the exception of a limited number of courses and experiments, the activities associated with teaching and research at Nipissing University would be conducted at a containment level 1 (CL1) using good laboratory practices. For those activities involving human pathogens and/or other potentially infectious materials, a detailed local risk assessment (LRA) is undertaken by the Biosafety officer and vetted by the Biosafety Committee, before the activities can begin. Based on the risk assessment, protocols for mitigating the hazards associated with the activities are proposed and developed in consultation with the Biosafety officer. Mitigation strategies include training, physical

containment strategies (i.e. access control, biological safety cabinets, etc.), protocol development, personal protective equipment, waste disposal considerations, etc.

Monitoring and control of hazardous activities

Biosafety Committee

In order to properly monitor and control the risks associated with biohazardous activities, Nipissing University has developed a comprehensive biosafety program that involves senior administration, Joint Health and Safety Committee and the University Biosafety Committee. The Biosafety Committee reports directly to the Provost and Vice President, Academic and Research (PVPAR) and is composed of a senior administrator reporting to the PVPAR, the Biosafety officer, Faculty and laboratory technicians from departments involved with biohazardous activities.

Training

As part of the management of hazardous activities, Human Resources, in consultation with the Biosafety Committee and the Joint Health and Safety Committee has developed a hazard-based training program for all laboratory research and teaching personnel. The first level of training involves all provincially mandated training (i.e. WHMIS 2015) and Basic Laboratory Safety training. Depending on the type of biohazardous activity, Blood-Borne Pathogen Safety training and CL1 and CL2 Biosafety training may also be required. Other common equipment specific training (i.e. autoclave and biosafety cabinet) is offered if required.

In addition, a Laboratory Safety Manual, a Biosafety Manual and a Hazardous Materials Spill manual have been developed and made available in pdf format on the EHS website. These manuals collectively describe the basic operational practices and procedures that are required in order to safely work with biohazardous materials. These manuals are reviewed at least annually and updated as new information becomes available.

Medical Surveillance

A medical surveillance program has been developed for those individuals who are working directly with RG1 and RG2 pathogens in teaching or research laboratories. The program is outlined in the Biosafety Manual. The program includes two main components: prevention and education of the risks associated with the pathogens; and a post exposure plan.

Biosecurity

Nipissing University's biosecurity program is outlined in the Biosafety Manual and delineates the requirements for inventory control (including receipt, transport, storage and disposal of RG2 materials), laboratory visitors and protocols to deal with missing pathogen cultures.

Monitoring

Laboratory activities are routinely monitored through the Joint Health and Safety committee and biosafety officer initiated monthly inspections of laboratory areas. Detailed inspection

reports are forwarded to the Department Chair(s) or Deans, Director of Human Resources and the Joint Health and Safety Committee. The Chair of the JHSC and biosafety officer follows up with further site visits in order to assist in resolving any safety issues.

Conclusion

Based on the risk assessments and initiatives it can be concluded that biohazardous activities can be conducted safely Nipissing University. There are sufficient oversight and controls (i.e. biosafety committee, training programs and laboratory inspections) in place to limit the potential for harm posed by the use of biohazardous material by research and teaching personnel at Nipissing University.