Biosafety Program

1. Introduction:

The Biosafety Program focuses on regulatory and contractual compliance issues involving the receipt, use, storage, shipment and disposal of biohazardous materials at the University. Biohazardous materials include infectious agents, (i.e., pathogens), or materials produced by living organisms, (i.e., biological toxins), which may cause disease in other living organisms. Recombinant DNA is also encompassed by this policy.

2.0 Definitions:

**Authorized Worker**
A person who by education, training, and experience has been authorized by the Biosafety Committee to work on a project with biohazardous materials.

**Barriers, Primary**
Good microbiological technique and appropriate safety equipment used for the protection of personnel and the immediate work environment from exposure to biohazardous materials.

**Barriers, Secondary**
Facility design, layout, and construction and operational practices used for the protection of the environment external to the work environment from exposure to biohazardous materials.

**Biohazardous Material**
Ontario Occupational Health and Safety Act, WHMIS Regulation.

[http://www.e-laws.gov.on.ca/DBLaws/Regs/English/900860_e.htm](http://www.e-laws.gov.on.ca/DBLaws/Regs/English/900860_e.htm)

The WHMIS regulation defines biohazardous materials as material which contains organisms that have been shown to cause disease in persons or animals and the toxins of such organisms. Biohazardous materials are assigned to Class D, Division 3, under WHMIS. The WHMIS symbol for biohazardous material is:
Biohazardous material (continued)  

Transportation of Dangerous Goods Act and Regulations.

The Transportation of Dangerous Goods regulation, http://www.tc.gc.ca/tdg/clear/part1.htm#sec14, defines an infectious substance as a substance known or reasonably expected to contain viable micro-organisms that are known or reasonably expected to cause disease in human beings or animals, and that

(a) is included in Risk Group 2, 3, or 4, in Appendix 3 of Part 2, Classification, See http://www.tc.gc.ca/tdg/clear/part2.htm#app3; or

(b) meets the criteria in section 2.36 of Part 2, Classification. See http://www.tc.gc.ca/tdg/clear/part2.htm#sec236.

The Transportation of Dangerous Goods Regulations assign two different labels for infectious substances and their toxins:

Infectious substances  

Toxins
Biohazardous material
(continued)

Human Pathogens Importation Regulations

The Human Pathogens Importation Regulations define *human pathogen* as (a) an infectious substance, (b) the toxin of an infectious substance, or (c) any diagnostic specimen or other material that contains, or that its importer has reasonable grounds to believe contains, an infectious substance or the toxin of an infectious substance.

*Infectious substance* means (a) a micro-organism or parasite that is capable of causing human disease, or (b) an artificially produced hybrid or mutant micro-organism that contains genetic components of any micro-organism capable of causing human disease.

Biohazardous material
(continued)

Health of Animals Regulations

The Health of Animals Regulations define *animal pathogen* as including any animal pathogen derived through biotechnology.

Biohazard Restricted Area

Containment Level 2 (CL-2), Containment Level 3 (CL-3), or Containment Level 4 (CL-4) facility as defined in the Public Health Agency of Canada Laboratory Biosafety Guidelines. http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/ch2_e.html#22

Biosafety

A program of administrative controls, medical surveillance, vaccination, and containment strategies to reduce or eliminate exposure of laboratory workers, other persons, animals, plants and the outside environment to biohazardous materials.

Biosafety Coordinator

A University employee knowledgeable by virtue of education, training, or experience in the handling of biohazards and is responsible for all aspects of biosafety in a laboratory or workplace.
Biosecurity
Policies and measures taken to prevent the theft, misuse, or intentional release of biohazardous materials.

Competent person
A person who,
(a) is qualified because of knowledge, training and experience to organize the work and its performance,
(b) is familiar with the Occupational Health and Safety Act and regulations that apply to the work, and
(c) has knowledge of any potential or actual danger to health or safety in the workplace.

Conflict of Interest
A situation in which someone in a position of trust has competing professional and/or personal interests.

Containment, Biological
Use of host organisms that limit the survival or establishment of recombinant genes outside the controlled laboratory environment (Host-Vector system).

Containment, Physical
Use of physical facilities and equipment and good working techniques to reduce the probability of the release of biohazardous materials into the outside environment. Containment is achieved through the use of primary and secondary barriers.

Containment Level
A containment classification based on level of risk or hazard to be encountered while handling biohazardous material. There are four levels of containment based on the Public Health Agency of Canada Laboratory Biosafety Guidelines. Containment Level 1 (CL-1) has the least level of risk; Containment Level 4 (CL-4) has the highest level of risk.

http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/ch2_e.html#22

The United States Department of Agriculture (USDA) also includes Biosafety Level 3 Agriculture (BSL3-Ag) for working with organisms that affect plants and animals of agricultural importance.

**Containment Level (continued)**

Biosafety Level 5 (BSL-5), a term which is no longer used, was used for animal disease organisms which are forbidden entry into the United States, e.g., foot and mouth disease.


**Dual use research**

Biological research with legitimate scientific purpose, the results of which may be misused to pose a biologic threat to public health and/or national security.

**Emergency Response Plan**

A detailed plan that describes strategies to be implemented in the event of a spill, fire, medical emergency, loss of power, or other unanticipated occurrence which threatens safety and health and requires immediate action.

**Engineering controls**

Measures to reduce exposure to potential hazards either by isolating the hazard or by removing it from the work environment. Fume hoods and biocontainment cabinets are typical engineering controls.

**Genetically modified micro-organism**

Under Transport of Dangerous Goods regulations, a micro-organism in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

[http://www.tc.gc.ca/tdg/clear/part1.htm#sec14](http://www.tc.gc.ca/tdg/clear/part1.htm#sec14)

**Medical surveillance**

On a group basis, analysis of health information to look for hazards in the workplace that require targeted prevention. For individuals potentially exposed to known work-related health risks, detection of early disease followed by intervention steps to prevent further exacerbation.

**Micro-organism**

An organism of microscopic or submicroscopic size including bacteria, fungi, protozoa, algae, viruses, mycoplasma, rickettsia, chlamydia, and prions.

**Oncogenic Biological Material**

A biological material that induces cancer, i.e., malignant tumours. Oncogenic viruses are a typical example of this material.

**Parasite, internal**

An organism which lives within another living organism at whose expense it obtains some advantage.
**Principal Investigator**  
A University faculty, managerial, or professional staff member knowledgeable by virtue of education, training, or experience in the handling of biohazards and who is responsible all aspects of biosafety for a project, program, and/or teaching activity utilizing biohazardous materials.  
*See also “Biosafety Coordinator”.*

**Recombinant DNA**  
(i) DNA molecules which are constructed outside living cells by joining natural or synthetic DNA molecules that can replicate in a living cell; or  
(ii) DNA molecules that result from the replication of those described in (i) above.

**Risk Assessment**  
The qualitative or quantitative estimation of the likelihood of adverse effects that may result from exposure to specified hazards.

**Risk Group**  
A system of classification of infective micro-organisms by severity of individual and community risk. Risk Group 1 (RG-1) presents the least risk and Risk Group 4 (RG-4) presents the most risk. Risk groups are not to be confused with Containment Levels. The University shall adhere to the following definitions:

- Public Health Agency of Canada Laboratory Biosafety Guidelines:  

- NIH Guidelines for Research Involving Recombinant DNA Molecules:  

- World Health Organization Laboratory Biosafety Manual:  
Standard Operating Procedure

A written document which describes the steps necessary to conduct a task or respond to a given situation; an established procedure to be followed in carrying out a given operation or in a given situation.

3.0 Application.

3.1 Jurisdiction.

3.1.1 Programs. The Biosafety Policy shall apply to teaching programs, research projects, and diagnostic facilities at the main campus, Guelph-Humber campus, OAC regional campuses, research stations, and field sites.

3.1.2 Remunerative External Activities and Service Agreements. The Policy shall apply to:

(a) activities involving the use of University facilities conducted under Section 3.01 of the Faculty Policy on Employment in Remunerative External Activities, http://www.uoguelph.ca/hrfacpol/sectc.htm#SECTION%20C:%20Part%203; and

(b) activities conducted by other organizations involving the use of University facilities under a service agreement with the University.

3.2 Regulated Biohazardous Materials. The Policy applies to:

(a) cultures or concentrated forms of potentially pathogenic Risk Group 2 and Risk Group 3 micro-organisms and internal parasites potentially infectious to humans, animals, or plants in research, teaching, and diagnostic/analytical laboratories;

(b) human and simian (non-human primate) cell cultures, tissues, and bodily fluids (e.g. blood, urine);

(c) potentially infectious cell cultures, tissues, and bodily fluids (e.g., sheep amniotic fluids);

(d) potentially oncogenic biological materials;

(e) micro-organisms which are pathogenic to plants;

(f) transgenic or genetically-modified micro-organisms which may be
hazardous to humans, animals, or plants;

(g) plasmids, phage, or other vectors which may be hazardous to humans, animals, or plants;

(h) recombinant DNA which may be hazardous to humans, animals, or other life forms;

(i) biological toxins and venoms; and

(j) any potentially infectious material or biological toxin deemed to require an import permit by the Public Health Agency of Canada or the Canadian Food Inspection Agency.

3.3 Prohibited materials.

Risk Group 4 (RG 4) biohazardous materials are prohibited in University facilities.

3.4 Exclusions. The policy does not include:

(a) experiments involving recombinant DNA molecules that meet the criteria listed in Section III-F of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*; http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261577

(b) transgenic organisms which are not micro-organisms, e.g., plants, mammals; http://www.ec.gc.ca/substances/nsb/eng/biotech_e.shtml. Contact the Director, Research Risk Management, Office of Research.

(c) live vaccines which are prepared in accordance with the requirements of the *Food and Drugs Act* and are used in the course of normal animal husbandry or human clinical practice; http://www.hc-sc.gc.ca/dhp- mps/vet/index_e.html ; http://www.hc-sc.gc.ca/dhp- mps/brgtherap/index_e.html

(d) human bodily fluids and other potentially infectious materials as might be encountered in normal clinical practice in Student Health Services, Occupational Health Services, and the rendering of first aid (See safety policy *Bloodborne Pathogens*, 851.13.13) http://www.uoguelph.ca/ehs/policies/13-13.pdf;
(e) consumer products for testing which have been obtained from retail outlets;

(f) infection control procedures covered by the Veterinary Teaching Hospital Infection Control Policy, www.ovc.uoguelph.ca/vth/documents/InfectionControlManual2005update.pdf;

(g) procedures associated with the control of zoonotic infections (See safety policy Working with Animals, Policy 851.06.15) www.uoguelph.ca/ehs/policies/06-15.pdf;

(h) management of manure in the course of normal animal husbandry practices; (Nutrient Management Act and Regulations). http://www.e-laws.gov.on.ca/DBLaws/Statutes/English/02n04_e.htm ; http://www.e-laws.gov.on.ca/DBLaws/Regs/English/030267_e.htm


4.0 Biohazardous Materials Registration.

4.1 Principal Investigators shall obtain a permit for activities involving the use and storage of biohazardous materials. Permits are obtained by submission of a Biohazard Permit Application.

4.2 Principal Investigators responsible for activities as described in the NIH Guidelines for Research Involving Recombinant DNA Molecules, Section III-E. Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation
shall submit a registration document, Biohazard Permit, Level One only, to the Biosafety Officer at the initiation of the activities.

4.3 Permits are issued for two years and may be renewed prior to expiry.

5.0 Biosafety Committee (BSC) Terms of Reference.

The Biosafety Committee reports to the Vice-President, Finance and Administration. The committee is mandated to

(a) offer advice on the safe use of biohazardous materials;

(b) ensure compliance with the Occupational Health and Safety Act and Regulations;

(c) ensure adherence to the Public Health Agency of Canada’s Laboratory Biosafety Guidelines, the Canadian Food Inspection Agency Veterinary Containment Standards, the National Institutes of Health NIH Guidelines for Research Involving Recombinant DNA Molecules and any permits issued by these agencies; and

(d) communicate with Ministry of Labour inspectors on matters concerning biohazardous materials.

5.1 Membership

Biosafety Committee members are appointed by the Vice-President, Finance and Administration in consultation with the Vice-President, Research, the Vice-President, Academic, and the respective employee or student groups; the membership shall be appointed as follows:

(a) one faculty member from each college in which biohazardous materials are used;

(b) one faculty member from each regional campus at which biohazardous materials are used

(c) one faculty member from a non-user college;

(d) Managing Director, Lab Services Division or designate;

(e) Director, Animal Health Laboratory;
(f) Director, Research Risk Management, Office of Research;

(g) Director, Animal Care Services or designate;

(h) Technical Operations Manager, CRIFS/Level 3 Facility; a faculty member engaged in research in the CL-3 laboratory shall serve as alternate;

(i) Manager, Health and Well-Being, Occupational Health and Wellness, who shall serve as Medical Advisor;

(j) one member from the Technical Staff who works with biohazardous materials;

(k) one graduate student whose current research project involves the use of biohazardous materials;

(l) University Biosafety Officer, Environmental Health and Safety Department, who shall serve as Secretary to the Committee;

(m) Two local community members (i.e., not employed by and at arm's length from the University) knowledgeable in biohazards who represent the interest of the surrounding community with respect to health and protection of the environment.

Each member of the committee shall have an alternate appointed by the Vice-President, Finance and Administration in consultation with the Vice-President, Research and the Vice-President, Academic.

Members shall be appointed such that the committee has a broad range of expertise in many types of biohazardous materials, techniques and procedures utilizing these materials, and infection control. Members shall collectively have experience and expertise to meet the requirements of the NIH Guidelines for Research Involving Recombinant DNA Molecules.

5.2 Term of Office.

The University Biosafety Officer; Manager, Health and Well-Being; Director, Animal Care Services; Managing Director, Lab Services Division; and the Director, Research Risk Management shall be permanent members of the Committee.

The term of office for all other members and alternates shall be three years. A member or alternate may normally serve up to two consecutive terms.

5.3 Chair and Vice-Chair.
The Chair and a Vice-Chair shall be elected annually from among its members who are employed by the University. The University Biosafety Officer may not serve either as Chair or as Vice-Chair.

5.4 Procedures.

5.4.1 Voting.

All members shall have voting privileges. Decisions shall normally be made by consensus. If unable to reach consensus, then the decision shall be by majority vote.

5.4.2 Meetings.

Meetings shall be held at least quarterly or as frequently as the Chair deems necessary to fulfil the responsibilities of the Committee. If a member is unable to attend, then the member shall arrange for his/her alternate to be present. Nothing shall preclude both the member and his/her alternate from attending the same meeting; however, the alternate may neither speak to an issue, unless requested by the Chair, nor cast a vote.

5.4.3 Quorum.

Quorum shall be one-half or the smallest whole number exceeding one-half of the voting members. At least one-half of the faculty members must be present.

5.4.4 Minutes.

Minutes shall be recorded by the University Biosafety Officer and distributed to members, the Vice-President, Finance and Administration, and the Vice-President, Research.

5.4.5 Records.

Records of the Committee shall be maintained by the University Biosafety Officer.

5.4.6 Conflict of Interest.

Where a member has an actual, potential, or perceived conflict of interest regarding the approval of a project, the member shall not be present during the discussion and decision.
5.5 **Subcommittees.** The Biosafety Committee may establish subcommittees as it deems appropriate.

6.0 **Appeals.** A Principal Investigator who disagrees with the decision of the Biosafety Committee may appeal the decision. Appeals may be made on either, or both, of the following grounds:

(i) the decision was inappropriate or unreasonable in light of the evidence presented to the Biosafety Committee; and

(ii) the review of the Committee lacked procedural fairness.

6.1 **Appeals Committee.** The Vice-President, Research, shall convene an Appeals Committee. The Committee shall report to the Vice-President, Research, and shall be composed of three members as follows:

(i) one person named by the Principal Investigator;
(ii) one person named by, but not currently a member or alternate of, the Biosafety Committee; and
(iii) one person, mutually agreeable to the Principal Investigator and the Biosafety Committee, who shall be Chair. Failing such agreement, the person shall be appointed by the President.

Any question concerning the composition of the Appeals Committee shall be referred to the Vice-President, Academic whose decision shall be final. If the Vice-President, Academic is a party to the case or declares a conflict of interest, the question shall be heard by the Vice-President, Finance and Administration.

6.2 **Appeals Committee Procedures.**

(a) The Committee shall meet *in camera* and shall maintain confidentiality;

(b) the Vice-President, Research shall forward all documentation concerning the case to the Appeals Committee;

(c) the following types of evidence shall be considered:

(i) signed and dated written submissions including e-mail communications;
(ii) printed material with attribution;
(iii) published information;
(iv) verifiable records; and
(v) personal testimony;
(d) both parties to the appeal shall be given full opportunity to present all relevant information to the Appeals Committee;

(e) the decisions of the Appeals Committee shall be by majority vote. Abstentions count as a negative vote;

(f) the Appeals Committee shall deal with the appeal in a timely manner;

(g) records of an appeal shall be held by the Vice-President, Research for the length of the permit or two years whichever is longer.

6.3 Powers of the Appeals Committee.

The Appeals Committee may confirm or modify the decision of the Biosafety Committee and may impose its own conditions in relation to the appeal including termination of the project.

7.0 Responsibilities

7.1 The Vice-President, Finance and Administration shall:

(a) appoint members of the Biosafety Committee;

(b) provide administrative support to the Committee; and

(c) receive and act upon recommendations of the Biosafety Committee and its Chair and provide a written response to the Committee.

7.2 The Vice-President, Research shall:

(a) notify the University Biosafety Officer of any research which utilizes biohazardous materials;

(b) approve terms and conditions for research involving biohazardous materials conducted by other organizations involving the use of University facilities under a service agreement with the University; such research shall also be approved by the Biosafety Committee;

(c) approve projects involving dual use research;

(d) approve projects to be conducted at Containment Level Three;

(e) administer Material Transfer Agreements involving biohazardous materials. Copies of such agreements shall be forwarded to the Biosafety Officer;
(f) administer the peer review process;

(g) establish and administer the appeal procedure;

(h) receive and act upon recommendations of the Biosafety Committee and its Chair;

(i) order corrective actions for cases of non-compliance;

(j) ensure that research funds are not released until the appropriate biosafety project permit has been submitted and approved by the Biosafety Committee or Chair of the Biosafety Committee as appropriate;

(k) suspend funding for research projects that contravene the Public Health Agency of Canada Laboratory Biosafety Guidelines, violate applicable federal, provincial or municipal laws or regulations, or are not in compliance with the permit or this policy;

(l) rescind the suspension of funding once the contravention is rectified to the satisfaction of the Biosafety Committee;

(m) advise the relevant granting Agency of any changes in eligible status of Grant Holders and Award Holders and/or of serious problems in the use of research funds as required by the Memorandum of Understanding between the University and the The Tri-Council (NSERC, SSHRC and CIHR). The Biosafety Officer shall also be advised of such changes of status;

(n) prepare and submit New Substance Notifications as required by the New Substances Notification Regulations of the Canadian Environmental Protection Act with a copy to the Biosafety Officer;

(o) register the Biosafety Committee with the National Institutes of Health and file annual membership updates; and

(p) provide administrative support to the CL 3 laboratory associated with the Canadian Research Institute for Food Safety.

7.3 Occupational Health and Wellness and Student Health Services shall:

(a) offer advice regarding infection control, medical treatment, and prophylactic measures available regarding biohazardous materials and zoonotic diseases;
(b) provide medical surveillance programs for employees and students, respectively, working with biohazardous materials;

(c) report any cases of lab-acquired infections to the Biosafety Committee; and

(d) ensure that the local Medical Officer of Health is informed of any lab-acquired reportable diseases as required by Regulations promulgated under the Health Protection and Promotion Act.

7.4 Biosafety Committee (BSC) shall:

(a) establish in consultation with Environmental Health and Safety, the University Biosafety Program governing activities involving the use of biohazardous materials. The Committee shall review the program annually;

(b) review and approve the Committee's Terms of Reference annually;

(c) review and approve all activities involving the use of biohazardous materials, determine the level of containment required, and assess the biosecurity measures before the initiation of the activity;

(d) at the discretion of the Chair of the Committee ensure that scientific merit has been demonstrated for research projects that have not received peer review by the funding agency. Such scientific merit shall be determined by means of an independent peer review, such reviews to be administered by the Vice-President, Research;

(e) assess the Principal Investigator's qualifications, training, and experience in relation to the biohazardous materials to be used;

(f) ensure that facilities in which biohazardous materials are used are inspected to ensure satisfactory containment measures are available and in use;

(g) ensure that there are procedures for the acquisition, secure storage, transport, handling, and disposal of biohazardous materials;

(h) ensure that there are methods of recordkeeping;

(i) ensure that persons who are potentially exposed to biohazardous materials are trained in the risks and procedures associated with such materials;
(j) ensure that a medical surveillance program is available for the biohazardous materials in use and that such surveillance program is communicated to anyone who may be potentially exposed to such materials;

(k) ensure that an emergency response plan for biohazardous material incidents has been established;

(l) review any incidents involving biohazardous materials including lab-acquired infections;

(m) interpret policies, standards, and guidelines where necessary and provide information to Principal Investigators as appropriate;

(n) respond to concerns and complaints under this policy and make recommendations to the Vice-President, Finance and Administration as appropriate; and

(p) recommend disciplinary action when a Principal Investigator is found to be in non-compliance with this policy or any federal, provincial, or municipal legislation. Such actions may include but are not limited to the following:

(i) informing the Principal Investigator and the Department Chair or Director of the non-compliance;

(ii) referring continuing issues of non-compliance to the Vice-President, Finance and Administration for further action;

(iii) to recommend to the Vice-President, Finance and Administration, the immediate closure of facilities that are in serious non-compliance.

7.5 The Chair of the Biosafety Committee shall:

(a) provide leadership and advice to the University Community regarding biosafety issues;

(b) liaise on behalf of the Committee with the Vice-President, Finance and Administration, the Vice-President, Research, the University Biosafety Officer, and representatives of regulatory agencies;

(c) set the agenda in consultation with the members and chair meetings of the Biosafety Committee;

(d) review compliance audits and incident investigations and report the
findings to the Biosafety Committee, the Vice-President, Finance and Administration, and the Vice-President, Research;

(e) submit an annual report on biosafety activities to the Vice-President, Finance and Administration, a copy to be retained at the Department of Environmental Health and Safety; and

(f) sign approved biohazard permits.

7.6 The Vice Chair shall:

(a) fulfil the duties of the Chair in the absence of the Chair; and

(b) sign approved biohazard permits where there is an actual, potential, or perceived conflict of interest on the part of the Chair.

7.7 The University Biosafety Officer shall:

(a) serve as the audit and control manager for the Biosafety Committee;

(b) provide secretarial services to the Biosafety Committee;

(c) assist Principal Investigators to assess facilities and prepare the biocontainment permit application;

(d) co-sign approved biohazard permits;

(e) in consultation with the Chair of the Biosafety Committee, approve and sign Biohazard Permits, Level One only;

(f) maintain and provide information on all elements of the biosafety program;

(g) provide advice on biohazardous materials and work procedures;

(h) provide general biosafety training;

(i) liaise with the Public Health Agency of Canada, the Canadian Food Inspection Agency, Animal Care Services, Occupational Health and Wellness, Student Health Services, Security Services, and Physical Resources personnel on biohazard issues;

(j) liaise with the Technical Operations Manager, Level Three Laboratory, CRIFS;

(k) audit work areas for compliance with certificate requirements,
legislation, codes, and guidelines and submit compliance reports to the Chair;

(l) perform inspections and sign documentation for import permit applications;

(m) approve purchase orders and co-sign material transfer agreements for the acquisition and/or transfer of biohazardous materials;

(n) investigate incidents involving biohazardous materials including exposures and lab-acquired infections and report the findings to the Chair;

(o) maintain project files including permits and associated materials;

(p) coordinate and maintain records of the annual certification of biocontainment cabinets;

(q) order, on advice of the Vice-President, Finance and Administration or the Vice-President, Research, the suspension of any activity involving biohazardous materials when there is reason to suspect that the health and safety of University personnel, the public, and/or the environment is at risk or that regulatory conditions of the project have been breached;

(r) liaise with local health and safety committees as applicable;

(s) serve on the Animal Care Committee and the Research Ethics Board.

7.8 The Department Chair shall:

(a) ensure that any activities involving the use of biohazardous materials in his/her department has received approval prior to the acquisition of the biohazardous materials and the commencement of the activities;

(b) ensure that Principal Investigators in his/her department are fully aware of the University policies and guidelines regarding biohazardous materials;

(c) co-sign all permit application forms confirming the validity of the information;

(d) advise the Biosafety Officer when a Principal Investigator is no longer employed by the University;

(e) ensure that current inspection certificates for steam sterilizers in the
department are posted, that sterilization cycles are verified using biological indicators on a regular basis, and that records of users, cycles, and verification are maintained; and

(f) ensure the activities involving biohazardous materials in the department are in compliance with the permits;

(g) report issues regarding non-compliance to the Chair of the Biosafety Committee and the University Biosafety Officer.

7.9 Director, Canadian Research Institute for Food Safety (CRIFS) shall:

(a) liaise with the Vice-President, Finance and Administration, Vice-President, Research, Chair of the Biosafety Committee, and the University Biosafety Officer regarding issues involving the CL-3 laboratory;

(b) ensure that any activities involving the use of biohazardous materials in the CL-3 Laboratory has received approval prior to the acquisition of the biohazardous materials and the commencement of the activities;

(c) ensure activities in the CL-3 Laboratory are in compliance the legislation, guidelines, and standards set by regulatory and granting agencies, University policies, and permit terms and conditions; and

(d) in consultation with the Chair of Biosafety Committee and/or the Director, Environmental Health and Safety, order the suspension of any activity involving the use of biohazardous materials in the CL-3 Laboratory when there is reason to suspect that the health and safety of University personnel, the public, and/or the environment is at risk or that regulatory conditions of the project have been breached.

7.10 The Technical Operations Manager, Level Three Laboratory, CRIFS shall:

(a) assist Principal Investigators with procedures and SOPs involving the use of the CL-3 Laboratory;

(b) coordinate scheduling of the facility for users;

(c) manage the daily operation of the facility;

(d) maintain the security system and issue access cards to authorized workers;

(e) ensure that the work area is secured against unauthorized access at all
times, that biosecurity measures are followed, and that any breaches of security are reported immediately to Security Services;

(f) report unsafe conditions and unsafe work practices to the University Biosafety Officer and the Director, CRIFS;

(g) liaise with emergency response personnel in the event of an alarm and advise appropriate personnel;

(h) coordinate the maintenance and repairs of the facility;

(i) coordinate the annual certification of the facility; and

(j) liaise with Public Health Agency of Canada and Canadian Food Inspection Agency personnel on issues regarding the CL-3 Laboratory.

7.11 The Principal Investigator shall:

(a) apply to and receive approval from the BSC before obtaining and/or commencing work with biohazardous material;

(b) obtain approvals from the Animal Care Committee if working with animals and/or the Research Ethics Board if working with human subjects;

(c) obtain approvals and submit such approvals to the Biosafety Committee if conducting work at another facility which requires such approvals;

(d) obtain approvals from the Vice-President, Research if working with biohazardous materials that require notification under the Canadian Environmental Protection Act, New Substances Notification Regulations;

(e) if working in the field, submit a Field Work plan as required by the University of Guelph Safety Policy 851.06.04, http://www.uoguelph.ca/ehs/policies/06-04.pdf;

(f) comply with and enforce the legislation, guidelines, and standards set by regulatory and granting agencies, University policies, and permit terms and conditions;

(g) cooperate with the Environmental Health and Safety Department, Office of Research, the Joint Health and Safety Committee, and any person exercising duties as required by regulatory agencies;

(h) ensure that amendments to the permit including termination of the
project are submitted in a timely manner;

(i) when acquiring biohazardous materials, obtain written approval from the Biosafety Officer before the purchase of such materials. When acquiring such materials gratis, obtain a Material Transfer Agreement through the Office of Research;

(j) maintain a current inventory of biohazardous materials including the source;

(k) obtain written approval from the Biosafety Committee before transferring biohazardous materials to another party;

(l) provide competent supervision and ensure that all persons working under his/her control have received appropriate training in working with the biohazardous materials. Such training shall be documented;

(m) ensure that a competent designate is appointed in his/her absence;

(n) inspect the work area routinely;

(o) take appropriate action to remedy unsafe acts and conditions;

(p) ensure the safety of any service personnel, contractors, or visitors and advise them of any potential hazards in the work area;

(q) ensure all visitors are supervised;

(r) consult with Occupational Health and Wellness and/or Student Health Services regarding the components of the medical surveillance program;

(s) ensure that all persons working with the biohazardous materials are aware of and been offered access to the medical surveillance program. This program shall be at no cost to the participants;

(t) ensure that appropriate engineering controls are functioning and personal protective equipment is available;

(u) continually review all Standard Operating Procedures associated with the permit;

(v) develop and continually review site-specific emergency response plans for the work areas and ensure that appropriate spill response supplies are available;
(w) post project documentation, equipment certificates, emergency response plans, and door signage;

(x) ensure that the work area is secured against unauthorized access at all times, that biosecurity measures are followed, and that any breaches of security are reported immediately to Security Services;

(y) report all incidents involving biohazardous materials including all confirmed or suspected illnesses resulting from possible exposure to biohazardous materials to the University Biosafety Officer in a timely manner. Such incidents shall be documented;

(z) ensure significant unanticipated problems or complications are reported to the Biosafety Committee; and

(aa) ensure the work area is decontaminated and/or decommissioned at the end of the project.

7.12 Authorized workers shall:

(a) comply with the legislation, guidelines, and standards set by regulatory and granting agencies, University policies, and permit terms and conditions;

(b) participate in training;

(c) cooperate with the Department of Environmental Health and Safety, Office of Research, the Joint Health and Safety Committee, and any person exercising duties as required by regulatory agencies;

(d) report unsafe conditions, unsafe work practices, and breaches of security to the Principal Investigator immediately;

(e) notify the Principal Investigator of any incidents, spills, or confirmed or suspected illnesses resulting from a possible exposure to biohazardous materials; and

(f) seek advice when working with unfamiliar materials or procedures.

8.0 Resources

Applicable Legislation:

http://www.labour.gov.on.ca/english/about/leg/ohsa_regs.html 9 November 2005

Occupational Health and Safety Act of Ontario (OHSA) - Control of Exposure to Biological or Chemical Agents Regulation, O. Reg. 833, R.R.O. 1990;
http://www.e-laws.gov.on.ca/DBLaws/Regs/English/900833_e.htm


Human Pathogens Importation Regulations (SOR / 94-558);

Plant Protection Act and Regulations (1990 / 95-212);

Transportation of Dangerous Goods Act and Regulations (1992, c. 34);

Health Protection and Promotion Act and Regulations (R.S.O. 1990, Chapter H.7);
http://www.e-laws.gov.on.ca/DBLaws/Statutes/English/90h07_e.htm#BK29

Canadian Environmental Protection Act, 1999

New Substance Notification Regulations (Organisms)

Applicable Standards and Guidelines:


Containment Standards for Veterinary Facilities, 1996. Agriculture and Agri-Food Canada, Canadian Food Inspection Agency:
www.inspection.gc.ca/english/sci/lab/convet/convete.shtml

http://www.ene.gov.on.ca/envision/gp/425e.pdf

Guideline C-17, Non-Incineration Technologies for Treatment of Biomedical Waste (Procedures for Microbiological Testing).
www.ene.gov.on.ca/envision/gp/4321e.pdf

Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th Edition.  

NIH Laboratory Safety Monograph, 1979  

National Science Advisory Board for Biosecurity  
http://www.biosecurityboard.gov/index.asp

Tri-Council Memorandum of Understanding:  

Memorandum of Understanding between the University and the Granting Agencies.  
http://www.nserc.ca/institution/mou_doc_e.htm

Related University of Guelph Policies and Guidelines:  

Animal Care Policies and Guidelines.  
http://www.uoguelph.ca/research/acs/acs/guidelines/index.shtml

Research Involving Human Participants.  
http://www.uoguelph.ca/research/humanParticipants/index.shtml

Veterinary Teaching Hospital Infection Control Manual.

Environmental Health and Safety Policies:  


Occupational Health and Medical Surveillance Programs.  
http://www.uoguelph.ca/ehs/policies/13-03.pdf


http://www.uoguelph.ca/ehs/policies/07-05.pdf

Autoclaves, Boilers and Pressure Vessels.  
http://www.uoguelph.ca/ehs/policies/07-09.pdf
Other Resource Material:

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31990L0679&model=guichett