1. Purpose:

The following information is provided by the Queen’s University Biohazard Committee to clarify how biohazardous agents are to be classified for the purposes of a Queen’s Biohazard Permit. Those wishing to use any biological material that is included in the risk groups below must obtain a permit from the Queen’s Biohazard Committee prior to importing or commencing work with the material.

2. Applicable Legislation, Standards, Guidelines:

Public Health Agency of Canada (PHAC) regulations
PHAC Laboratory Biosafety Guidelines 3rd edition, 2004
Canadian Food Inspection Agency (CFIA) regulations

3. Requirements:

Plant pathogens, soil, plants, or other material that might contain plant or animal pathogens exotic to Canada and/or Ontario: In addition to the biological material listed below, material source from outside Canada that might contain plant or animal pathogens exotic to Canada will be subject to regulation by the Canadian Food Inspection Agency (CFIA). Any CFIA-imposed containment requirements will be monitored by the Queen’s Biohazard Committee and will require a Queen’s Biohazard Permit Application and laboratory inspection. CFIA often requires containment similar to BSL2 and strict decontamination and inventory requirements for imported soil and associated plant or animal pathogens.

Movement of soil from certain areas within Canada to other areas in Canada is also prohibited because of plant pathogens that are present, unless a special permit is issued. Check with CFIA prior to moving soil from one area to another to determine whether a permit is required and provisions need to be made for appropriate containment and destruction of biohazards in the soil. If so, then a Queen’s Biohazard Permit is also required.

Note that culturing of any agents/microorganisms, even if obtained within Canada, will require a biohazard permit for work with a containment level of at least level 1 (see below).
3.1. Risk Group 1

The PHAC Laboratory Biosafety Guidelines (3rd edition, 2004) define Risk Group 1 (RG1, low individual and community risk) as, “Any biological agent that is unlikely to cause disease in healthy workers or animals.”

RG1 organisms usually require Containment Level 1 (CL1; also called Biosafety Level 1, BSL1), containment facilities and practices. These are equivalent to good general microbiological practices.

It should be noted that some agents in this category (termed opportunistic) may cause disease in compromised individuals (e.g. in the aged or in infants or in immunosuppressed individuals, such as those taking immunosuppressive drugs or undergoing cancer chemotherapy). Vaccine strains that have undergone multiple in vivo passages should not be considered non-virulent simply because they are vaccine strains.

It should also be noted that in some countries the classification of agents as Risk Group 1 or Biosafety Level 1 (RG1/BSL1) is solely based on the fact that they do not cause disease in healthy human adults, but these agents might still cause significant animal disease and be regulated by Canadian agencies (PHAC and/or the CFIA). To determine whether the containment level in Canada should be level 1 or higher, the agent’s pathogenicity for both humans and animals should be considered and indicated on the Queen’s Biohazard Permit application.

Risk Group 1 Biohazardous Material Includes:

1. Agents (bacteria, fungi, viruses and cell lines) classified as Risk Group 1 or as requiring Containment Level 1 or Biosafety Level 1 (CL1/BSL1) containment by the Public Health Agency of Canada (PHAC), the Canadian Food Inspection Agency (CFIA), the ATCC, or other recognized organizations
   a. Also agents derived from Risk Group 1 agents using methods or vectors that do not increase the risk group will be considered Risk Group 1.
2. Unidentified bacteria, fungi or viruses sourced from material in Canada (e.g. soil, healthy wild animals in Canada) that is unlikely to contain human or animal pathogens, provided that they are not cultured in a way likely to select for pathogens
   a. Such agents sourced from outside Canada require evaluation by the Canadian Food Inspection Agency prior to importation into Canada
3. The tissues of animals that are reasonably expected to carry quantities of Risk Group 1 agents similar to quantities found in bacterial cultures
   a. For example the small or large intestines, even from specific pathogen free animals
   b. Does not include animal by-products (eg. feces) because these are normally contained in cages and bedding and are disposed of through Queen’s Animal Care Services.

4. The relevant target tissues from animals intentionally infected with Risk Group 1 agents.

3.2 Risk Group 2

The PHAC Laboratory Biosafety Guidelines (3rd edition, 2004) define Risk Group 2 (RG2, moderate individual risk, low community risk) as, “Any pathogen that can cause human disease but, under normal circumstances, is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available, and the risk of spread is limited.”

For Risk Group 2 organisms the primary exposure hazards are through the ingestion, inoculation and mucous membrane routes. Risk Group 2 organisms usually require Containment Level 2 (CL2; also called Biosafety Level 2, BSL2) containment facilities and practices as described in the PHAC Laboratory Biosafety Guidelines. Particular care is taken to use equipment and practices to contain aerosols. Biosafety Level 2 conditions avoid splashes, environmental contamination and the generation of aerosols (aerosols can settle on bench tops and become an ingestion hazard through contamination of the hands). A risk assessment of the agent or biological material (including for example such information as diseases of risk in the population from which the biological material was obtained) and the experimental procedures to be performed will help to indicate what mitigating measures should be put in place, in particular which procedures require the use of a biological safety cabinet to contain aerosols.

Risk Group 2 Biohazardous Material Includes:

Agents (microorganisms) classified as requiring Biosafety Level 2 containment on MSDS forms found on the PHAC web site at [http://www.phac-aspc.gc.ca/msds-ftss/](http://www.phac-aspc.gc.ca/msds-ftss/). ATCC classifies the containment requirements for agents that they supply [http://www.atcc.org/](http://www.atcc.org/) and risk groups assigned by other countries can be found on the American Biological Safety Association website risk group database [http://www.absa.org/XriskgroupsX/index.html](http://www.absa.org/XriskgroupsX/index.html). If a risk group is not identified by these sources then a risk assessment will have to be performed to determine the risk group of the agent/material. The Queen’s Biosafety Officer, in consultation with PHAC or CFIA can assist with a risk assessment.
Human bodily fluids or tissues including mucous membranes (but not intact skin on live healthy human subjects) should be handled as if they contain a human pathogen unless they have been treated in some way that would destroy pathogens (e.g. fixation). Operational practices known as “Standard Precautions” or “Universal Precautions” are commonly used in health care settings. They are compatible with BSL2 containment practices, and may be useful guidance when determining appropriate precautions for projects at Queen’s that involve obtaining biological material directly from human subjects.

Live animals or animal tissues or bodily fluids that have the potential to contain zoonotic pathogens (microorganisms carried by animals that can cause disease when they infect humans) will be treated as biohazards requiring the containment level appropriate for the particular animal and microorganism. For example Macaque monkeys can carry Cercopithecine herpesvirus 1 (B-virus) which causes lesions like cold sores in the monkey, but can cause a fatal infection in humans if not properly treated. Despite the frequent contact of humans with monkeys these infections are rare, for reasons that are not known. Macaque monkeys are therefore treated as level 2 biohazards, level 2 operational practices are used in handling them or tissues derived from them and appropriate first aid and medial response is taught to all who work with these animals.

3.3 Risk Group 2+

Containment Level 2+ (Biosafety Level 2+) is defined by the PHAC as Containment Level 2 facilities used with Containment Level 3 operational practices as specified in their Laboratory Biosafety Guidelines, except for those level 3 practices that are not possible in a level 2 facility. Containment Level 2+ (BSL2+) may be required in some circumstances. This level of containment may be specified by the PHAC or the CFIA as a condition on an import permit, or may be determined by the Queen’s Biohazard Committee. For example work with certain viral vectors or viral vectors expressing oncogenes or biological toxins may require CL2+/BSL2+ containment.

3.4 Risk Group 3 and 4

There are currently no facilities to permit work with Risk Group 3 or 4 organisms on Queen’s University Campus.
4.0 Information and Enquires:

For further information regarding Biohazard Permits, contact the University Biosafety Officer (613-533-6000 ext. 77077).

Revision History:

1.0: Initial Release - March 11, 2008