**Local Biohazard Risk Assessment**

**Requirements, Instructions and Template**

**For Risk Group 1 Material**

**Local Risk Assessment Requirements:**

The description of the requirements for a local risk assessment below also apply to material that is more hazardous than Risk Group 1 (RG1), but the example/template has been modified for RG1 material only. Less detail is usually required for RG1 material than for RG2 material.

It is a requirement of the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) that each laboratory performs a detailed **local risk assessment** (LRA) to determine the biohazard containment level required for both facilities and operational practices to mitigate the risks associated with the biohazardous agents in use.

The local risk assessment of all work with biohazardous material (Risk Group 1 and 2 and 2+), is to be documented as part of a Queen’s University Biohazard Permit Application.

**A local risk assessment will:**

* identify the Risk Group of the microorganism, (or tissue that might contain this microorganism)
* describe the potential hazard associated with the microorganism, including symptoms of disease if it is pathogenic (which it is important for all lab members to know so that they will be aware of any potential lab acquired infection so that it can be diagnosed and treated appropriately. Although disease is unlikely with RG1 microorganisms, if working with an RG1 agent that is other than a cloning strain of bacteria, determine if it has been pathogenic in immune-compromised individuals.)
* indicate whether the material will be used only *in vitro*, or also *in vivo*
	+ what is being done with the material and where; consider procedure’s potential for generating aerosols that might contain and spread infectious agents
	+ indicate whether or not sharps will be used and the precautions associated with them
	+ *in vivo* use of infectious materials increases the risk of exposure, so the facilities and operational practices for *in vivo* work must be described separately from that for *in vitro* work
* describe the overall risk mitigation strategy and details of this strategy including:
	+ physical containment and engineering controls (i.e. lab design) This can be indicated simply by stating the which of your containment level 1 or 2 laboratories (or shared facilities) will be used for the different types of work, because the Biohazard Committee inspects all laboratories.
	+ operational requirements
		- containment equipment and supplies
			* equipment might include e.g. Biological Safety Cabinet, centrifuge cups with aerosol resistant lids containing o-rings
			* supplies might include e.g. closed, screw-capped tubes
		- appropriate personal protective equipment (PPE)
		- decontamination and disposal methods
		- medical surveillance (e.g. immunization, titre checks, first aid and medical response to accidental exposure)
		- training needs (this will be supplied as a separate statement in the application)

At Queen’s the Principal Investigator’s local risk assessment is to be documented and appended to the Biohazard Permit Application along with any applicable risk assessments from reputable sources (e.g. PHAC PSDS) and lab specific procedures/SOPs.

* In general, more detail is required for material and activities that pose a greater risk.
* The local risk assessment and associated documents are reviewed and approved by the Biohazard Committee.
* After approval, these documents become an integral part of the training of lab personnel.
* Following approval of a Biohazard Application or a Biohazard Amendment that changes the type or risk group of material used in the lab (reviewed by the Biohazard Committee), each member of the biohazard lab team is required to:
	+ read the approved Biohazard application/amendment and associated documents that are posted on the TRAQ/Romeo site
	+ have any questions that they might have answered by their P.I. and/or the Biosafety Officer
	+ submit the Biohazard Team Member Attestation form through the TRAQ/Romeo system, to indicate that they understand and will abide by the requirements for working safely with the biohazardous material.
* **All new personnel** **must read the version of this local risk assessment** that has been approved by the Biohazard Committee as part of the lab specific training before they are added to the list of authorized individuals on your Biohazard Permit.

**Instructions regarding the use of the Template:**

***Italicized text is a comment, example, alternative or a question.***

*Examples or partial templates of local risk assessments are provided below to assist researchers in developing a local risk assessment for their laboratories.*

* *It is not required that this format be used and the examples are not exhaustive.*
* *The requirements for your Local Biohazard Risk Assessment are outlined above, and in the Queen’s Environmental Health and Safety SOP- Biosafety-04 which is available on the web site* [*www.safety.queensu.ca*](http://www.safety.queensu.ca) *.*
* *The material that is regulated as a biohazard through the Queen’s Biohazard Committee is described in SOP-Biosafety-05* [*https://www.safety.queensu.ca/policies-and-standard-operating-procedures*](https://www.safety.queensu.ca/policies-and-standard-operating-procedures) *.*

*Although some of the information required for the local biohazard risk assessment is contained in the biohazard permit application form, and in your biohazard inventory and risk group table, the local risk assessment is very helpful for the Biohazard Committee and for your personnel because the narrative form clarifies what is being done and demonstrates that the researchers have thought about the safety hazards and how to mitigate the risks.  In some cases the procedures being used affect the risk and this is much clearer in the local risk assessment than from looking at the form.*

The current version of the Canadian Biosafety Standards 2nd Edition (2015), is available on-line at <http://canadianbiosafetystandards.collaboration.gc.ca/index-eng.php>

***Abbreviations:***

PHACPublic Health Agency of Canada

CFIA Canadian Food Inspection Agency

ATCC American Type Culture Collection

PHAC PSDS Public Health Agency of Canada Pathogen Safety Data Sheet

***In the Template below, please remove my italicized comments and remove or alter any other text that does not apply to your lab.***

*If a Queen’s Biosafety SOP has been written for the biohazard, equipment, or procedure that you will be using then it should be mentioned in your local risk assessment, indicating that you and your personnel are aware of the contents of the SOP and will follow it* [*https://www.safety.queensu.ca/policies-and-standard-operating-procedures*](https://www.safety.queensu.ca/policies-and-standard-operating-procedures)*. Also, where appropriate, indicate deviations from the SOP (and briefly justify the change) or indicate where practices will be followed that are recommended but not required in the SOP. Please do not attach Queen’s EH&S SOPs.*

***P.I. name* Bioahazard Containment Level 1 Local Risk Assessment**

**Program Overview:**

*Start with one or two sentences or a short paragraph describing the research project goals and general approach.*

**Biohazardous Materials:**

*Then describe, first in general terms, what types of biohazardous material are used and the common techniques, and then more specifically with paragraphs for each type of biohazard e.g.:* The biohazardous material used in my research, *is what? Eg.* cloning strains of bacteria E. coli BL21, DH5, and Top10 &/*or* are established cell lines *from what species?*; *&/or* are *Xx* tissues or cells from *xx* species are used for \*\* analysis &/or are from the intestines and therefore contain large numbers of risk group 1 bacteria and so the tissues/cells are treated using level 1 biohazard procedures and containment *&/or* are the following species/strains of bacteria, virus, viral vector or parasite; *&/or* are numerous and listed on the appended table *&/or* are consortia of unidentified bacteria from soil *(or other source eg intestines of specific pathogen free animals))*

*In each of the sections below, remember to describe any in vivo work.*

**Bacteria and/or Fungi:** are classified as Risk Group 1 (Biosafety Level 1) by (*?authority eg. ATCC, PHAC, CFIA)* because they do not cause disease in healthy adult humans or animals.  *OR, in my opinion, should be classified as risk group 1 because the source is unlikely to contain human pathogens and nothing has been done to select for human pathogens (describe source… eg. soil contaminated by products from the petroleum industry).*

*For level 1 bacteria (cloning strains) or yeast strains commonly used for molecular biology, write something to the effect of:*  Cloning strains of bacteria derived from E. coli K12 (e.g. BL21, DH5) are classified as risk group 1. They do not carry the well recognized

pathogenic mechanisms required by strains of E. coli that cause the majority of

enteric infections. E. coli strains EQ1, DH5a, BLR and BL21 are considered to be non-pathogenic and unlikely to survive in host tissues and cause disease. (Chart, H., *et al.* 2000.Journal of Applied Microbiology 89, 1048-1058) Bacteria *and yeast cells* are cultured on the open bench using flame sterilization. Media, cells, and cell lysates are decontaminated using freshly diluted bleach (*or list another appropriate dissinfectant)* before disposal to ensure that the environment is not contaminated with plasmids carrying antibiotic resistance genes or other potentially harmful genes.

*For other types of level 1 microorganisms that might be more likely to pose a health risk to immunocompromised individuals, note this fact and indicate what medical conditions should be reported so that additional precautions can be taken alternative duties assigned.*

**Parasites:**

*Work with parasites is not common at Queen’s, so an example is not provided. If you will be working with parasites then a local risk assessment of the parasite and the work to be done with it, along with a description of mitigation measures must be provided.*

**Viruses or viral vectors:**

 *Describe the virus being used, its hazard, work to be done, and the precautions taken. Discuss the risks and precautions to mitigate the risks of in vitro and in vivo (animal) work separately.*

*The local risk assessment might be as simple as:* The only viral infectious agent being propagated and manipulated is a baculovirus that infects only insect cells and are therefore classified as risk group 1 and handled with general lab practices as described elsewhere in this risk assessment.

*If viruses/viral vectors are used that infect mammalian cells then they need to be described in more detail, especially noting if they are engineered to infect human cells (in which case they might be classified as RG2). Include the biology and associated risks of the viral vector itself and also the transgene.*

*If the vector system is supposed to be replication incompetent indicate how this is ensured eg. What generation is the vector system? What viral genes have been deleted? How many plasmids involved in generating the virus? Is there a deletion created in the LTR when it integrates into the genome?*

*What might the effect of the vector be if a person was accidentally infected? Anything beyond local transient inflammation?*

*What would the effect of the transgene be if a person was accidentally infected? Is the transgene hazardous enough that special precautions should be in place (possibilities include - no use of sharps; mandatory goggles so eyes cannot be touched)?*

*What medical surveillance is required? i.e. are any immunizations recommended? What should the response be if someone was accidentally exposed to the virus? Specify first aid and medical response including antiviral chemotherapy to prevent infection if available.*

**Cells or Tissues from animals:** *from* xx species are from purpose-bred specific pathogen free animals.  They are therefore not considered biohazardous but are treated with good general lab practices (*so this doesn't actually have to be reported to the Biohazard Committee, but sometimes it is helpful to clarify in the context of an application)........*

**Cultured cells, cell lines or microorganisms** are being used *for what? E.g. to grow plasmids for what purpose?....e.g. to express protein xxx in bacteria for purification and study by crystallization.* The host range of the plasmid vectors is bacteria and therefore the biohazard potential is low … These techniques includesmall volume sterile culture (< 10 L for bacteria and yeast cells, xxx for mammalian and insect cells) (*volume is important because risk increases with large volume culture >10 litres at one time)*;

 ***what proteins are of interest****, briefly what is their function and do they pose any health risk?...e.g. if someone ate them, got them in their eyes, or injected them accidentally?*

***For clarity, the following information about containment facilities and practices used to mitigate risk can be provided in each of the sections above for the different types of biohazardous agents if it differs among them. Alternatively, if there are common practices that are better described together that can be done here. If this information is included in your lab specific SOPs, then just make a general statement here about Physical and Operational Containment being CL1 as described in detail in the attached SOPs.***

**Physical containment and engineering controls:**

*Containment level 1 laboratories (or shared facilities) that are inspected by the Biohazard Committee will be used for the different types of work requiring CL1 containment.*

**Containment Equipment and Supplies:**

* Containment equipment used will be e.g. Biological Safety Cabinet, centrifuge cups with aerosol resistant lids containing o-rings (*not required for RG1 – just examples that might be used)*
* Containment supplies will include e.g. closed, screw-capped tubes

**Operational practices:** For Risk Group 1 material, we use standard microbiological and biochemical techniques and follow all the general operational practices for microbiological biosafety level 1 as described in the Queen’s Biosafety Manual.

**Personal Protective Equipment:**

* *describe the personal protective equipment (PPE) that will be used e*.g *lab coat , gloves, goggles, face shield if required for a splash hazard*

**Transport**

*If you will need to transport the material or waste outside of a lab, specify that it will be contained to prevent spills and how (e.g. double bagged, or tupperware container with lid, or ice box with latching lid).*

**Decontamination and Disposal:**

*Briefly describe decontamination:* Work surfaces are decontaminated using \_\_\_\_\_ *specify appropriate disinfectant, and if different for different material then clearly indicate that – see note at the end of this paragraph)* at the end of each work period. Any spills are decontaminated with freshly prepared 10% bleach for 30 minutes prior to clean­up (*or list another dissinfectant if it is more appropriate for the biohazardous material that you are using or the surface being decontaminated (bleach is cheap and effective against many pathogens, but remember that bleach corrodes stainless steel so it can create problems if used routinely and not rinsed well; bleach may be necessary if you are culturing bacteria that form spores). Note that 70% ethanol is a good dissinfectant for soaking instruments (10 minute contact time), and is good as a sterile rinse after other disinfectants, but it is not as effective on surfaces because it evaporates quickly, reducing the contact time. Examples of some alternative disinfecctants used on campus are:* Backdown detergent disinfectant, *a quaternary ammonium compound effective against viruses, bacteria, and fungi. BDD is available from Fisher Scientific*; Virkon S *a general purpose disinfectant instead of bleach.  It is inexpensive, highly effective against a broad range of microbes, and does not have the associated problems of metal corrosion or odour*. *Read the manufacturer’s instructions for any disinfectant carefully and specify the appropriate dilution and contact time.)*.

*If applicable:* Disposable plastic ware that has contacted biological material is placed in an autoclave bag inside the BSC, and the bag closed with tape prior to removal from the BSC or laboratory. Prior to disposal the bag is opened and autoclaved in \_\_\_\_ (*location*) following procedures specified in SOP-Biosafety-09 Autoclaves – Biohazard Waste Treatment. The efficacy of autoclave decontamination is determined by weekly tests with biological indicators and a log kept by \_\_\_\_\_\_\_. (*or other e.g.* disposed as biomedical waste by KGH*, or* sent for incineration via Queen’s EH&S*)*. Material that has been in contact with bleach is not autoclaved.

Contaminated sharps are placed in an approved plastic biohazardous sharps container which disposed of through Queen’s Department of Environmental Health and Safety (*or other e.g. disposed of through KGH)*.

Glassware (and reusable plastic items) are decontaminated using bleach (*or other specified disinfectant)* prior to washing (or disposal in glass garbage).

Contaminated PPE is disposed as biohazardous waste, or decontaminated by autoclaving or chemical disinfectant prior to being sent to the laundry.

**Medical Surveillance:**

*The Canadian Biosafety Standards specify that you must consider what medical surveillance is required for personnel working in your laboratory as part of the local risk assessment process. This could include but is not limited to: a medical examination; serum screening, testing and/or storage; immunizations; and possibly other tests as determined by the risk assessment process.*

*For Risk Group 1 the medical surveillance most commonly includes* *a simple warning about potential effects of the specific microorganisms in use on those who are pregnant or who have compromised immune systems. It might also include some of the following. Edit and add information as appropriate:*

* Specific immunizations (e.g. Hepatitis B, rabies), and serum titre testing to confirm response to the immunization.
* A plan of what first aid and medical response is to occur in case of an incident involving exposure must be written, approved, and posted in the laboratory. (eg. *If using virus/viral vectors, what should the response be if someone was accidentally exposed to the virus? Specify first aid and medical response including antiviral chemotherapy to prevent infection if applicable.)*
* Training to develop an awareness that changes in the health status of personnel can increase their personal risk from the biohazards in that laboratory. In particular, changes in health status that might affect immune responsiveness (immune-compromised) should be reported. For these individuals, some risk group 1 microorganisms which do not normally cause disease can be pathogenic and Risk group 2 microorganisms can cause much more severe disease than normal, or even death. *Personnel entering CL2 labs in which they do not work should be aware of what agents are used in the lab and if they have a medical condition that makes them potentially at a greater risk of infection. Be sure to state whether or not the micro-organisms that you use could be a particular health risk for immunocompromised individuals or pregnant women or their foetuses.*
	+ If the organism being worked with has been attenuated or genetically altered to be less hazardous than wild-type, you should be aware of the mechanism of attenuation (if known) and any conditions that might make the attenuated organism more pathogenic for you.
	+ Note that, without the need to reveal personal medical information, the occurrence of such a change should be reported to their supervisor so that, if necessary, appropriate adjustments in the operations or risk mitigation methods can be made in consultation with their personal physician and/or the Queen’s University Occupational Health Services provider or other medical experts as necessary.
	+ Conditions of concern include:
		- Pregnancy (pregnant women may need to take extra precautions or be reassigned to other duties early in their pregnancy because certain microorganisms can damage the fetus and because their own immune responsiveness may be altered)
		- Immune-deficiency
		- Immune-suppressive drugs (e.g. with organ transplantation)
		- Anti-inflammatory medications
		- Cancer
		- Treatment for cancer
		- Age (the elderly; also very young children are more susceptible to infection, which is one of the reasons that they are not permitted in research laboratories)
		- Other conditions as determined by your physician
	+ Cloning strains of E. coli are unlikely to be a health risk for immunocompromised individuals. Nevertheless anyone undergoing cancer chemotherapy or immunosuppressive therapy should tell their physician that they work with these bacteria to check their particular risk.
* Occupational Health services for personnel working in and around Queen’s research laboratories is available through Walsh and Associates Occupational Health Services. Details and a map are located at <https://www.safety.queensu.ca/biosafety/occupational-health-services-biological-hazards> . Charges will be billed to departments through the Department of Environmental Health and Safety and payment is the responsibility of the supervisor.

*If any specific first aid or medical response is recommended because of the biohazardous material in use then indicate that this information is included in the lab specific training and ensure that it is on the Emergency Response Procedure posted in your laboratory.*