Biosafety Code of Practice

2017

University of Saskatchewan

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Definitions

Animal Pathogen: Any pathogen that causes disease in animals; including those derived from biotechnology. In the context of the Canadian Biosafety Standard and the Canadian Biosafety Handbook, “animal pathogen” refers only to pathogens that cause disease in terrestrial animals; including those that infect avian and amphibian animals, but excluding those that cause disease in aquatic animals and invertebrates.

Authorized Worker: A University of Saskatchewan employee, student, visitor, or contractor who has acquired the appropriate biosafety training and is approved to work with biological materials and/or biohazardous materials specified under an active biosafety permit.

Biohazardous Material: Materials of biological origin that have the capacity to produce deleterious effects on humans and/or animals. Examples, but not limited to, include:

- Recombinant DNA molecules that are transferred into human research participants (human gene transfer);
- Recombinant DNA that is introduced into animals (transgenic animals);
- Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or pharmacologically active agent);
- Microorganisms where there is a deliberate transfer of a drug resistant trait or of recombinant DNA containing genes for the biosynthesis of products potentially toxic for vertebrates;
- Microorganisms classified as Risk Group 2 (RG-2) or Risk Group 3 (RG3) agents (Risk Group 4 agents are not allowed on the University of Saskatchewan campuses) whether infectious or defective;
- Microorganisms where more than two-thirds of the DNA from RG-2 or RG-3 agents is cloned into other nonpathogenic agents;
- Biological products derived from RG-2 or RG-3 microorganisms;
- Clinical/medical waste (e.g., diagnostic specimens), that are used in research and known, or reasonably expected to contain pathogens classified as RG-2, RG-3, or toxins;
- Prions;
- Human bodily fluids, blood, tissues, and cell lines; and/or
- Large scale cultures of a biological material.

Biological Material: Pathogenic and non-pathogenic microorganisms, proteins, and nucleic acids, as well as any biological matter that may contain microorganisms, proteins, nucleic acids, or parts thereof. Examples include, but are not limited to, bacteria, viruses, fungi, prions, toxins, genetically modified organisms, nuclei acids, tissue samples, diagnostic specimens, live vaccines, material derived synthetically, and isolates of a pathogen (e.g. pure culture, suspension, purified spores).

Biosafety: Containment principles, technologies, and practices that are implemented to prevent unintentional exposure to infectious material and toxins, or their accidental release.

Biosafety and Environmental Officer: The individual responsible for developing, overseeing, and managing all facets of the U of S Biosafety Program. Serves as an expert resource on biosafety to the campus community and acts as the primary liaison between the University's Biosafety Advisory Committee and the Biosafety Protocols Advisory Committee, regulatory agencies, and the campus community.

Biosafety Cabinet (BSC): A primary containment device that provides protection for personnel, the environment, and the product (depending on the BSC class), when working with biological material.

Biosafety Permit: A biosafety permit is a formal authorization granted by the Biosafety Group or the Biosafety Protocol Approval Committee (BPAC) to individuals requesting approval for the acquisition, use, storage, transportation and disposal of select Risk Group 2 and 3 biological materials. A biosafety permit is only granted to individuals meeting the requirements as stipulated in the *Biosafety Code of Practice*.

Biosafety Plan: A written document that acts as an individualized biosafety manual for the permit holder. The plan describes the hazard assessment and the health, safety, and biosecurity measures supporting the responsible use and management of biological materials. A biosafety plan is required under a biosafety permit at the University of Saskatchewan.

Biosafety Officer (BSO): The individual responsible for administering and supporting biosafety programs, processes, and services at the University. Serves as an expert resource on biosafety to the campus community.

Biosafety Manual: A facility-specific manual that describes the core elements of a biosafety program (e.g., biosecurity plan, training, personal protective equipment).

Biosecurity: Security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens, toxins, and other related assets (e.g. personnel, equipment, non-infectious material, and animals).

Biotechnology: The application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.

Containment Level 1: Containment Level 1 laboratories/facilities require no special design features beyond those suitable for a well-designed and functional laboratory. Biological Safety Cabinets (BSCs) are not required. Work may be done on an open bench top, and containment is achieved through the use of practices normally employed in a basic microbiology laboratory.

Containment Level 2: The primary exposure hazards associated with organisms requiring containment level 2 are through the ingestion, inoculation and mucous membrane route. Agents requiring containment level 2 facilities are not generally transmitted by airborne routes, but care must be taken to avoid the generation of aerosols (aerosols can settle on bench tops and become an ingestion hazard through contamination of the hands) or splashes. Primary containment devices such as BSCs and centrifuges with sealed rotors or safety cups are to be used as well as appropriate personal protective equipment. As well, environmental contamination must be minimized by the use of hand washing sinks and decontamination facilities (autoclaves).

Containment Level 3: Agents requiring containment level 3 may be transmitted by the airborne route, often have a low infectious dose to produce effects and can cause serious or life-threatening disease. Containment level 3 emphasizes additional primary and secondary barriers to minimize the release of infectious organisms into the immediate laboratory and the environment. Additional features to prevent transmission of organisms requiring containment level 3 are appropriate respiratory protection, HEPA filtration of exhausted laboratory air and strictly controlled laboratory access.

Dual-use potential: Qualities of a pathogen or toxin that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused as a biological weapon to cause disease (e.g., bioterrorism).

Emergency Response Plan (ERP): A document outlining the actions to be taken and the parties responsible in emergency situations such as a spill, exposure, release of infectious material or toxins, animal escape, personnel injury or illness, power failure, fire, explosion, or other emergency situations (e.g., flood, earthquake, hurricane).

Good Microbiological Laboratory Practices: A basic laboratory code of practice applicable to all types of activities with biological material. These practices serve to protect workers and prevent contamination of the environment and the samples in use.

Genetically Modified Organism (GMO): An organism whose genetic material has been altered using genetic engineering techniques.

Genetically Modified Microorganisms (GMMO): Any organism or consortium of organisms of microscopic size, including bacteria, protozoa, fungi, algae, and viruses, whose genetic material has been altered using genetic engineering techniques.

Human Pathogen: A microbe or microorganism that can cause disease in humans.

Importing: The activity of bringing (e.g., transferring or transporting) pathogens, toxins, or other regulated infectious material into Canada from another country.

Incident: Any undesirable or unplanned event or sequence of events that has had an unintended effect on the health and safety of University of Saskatchewan employees, students or contractors, or the safety and security of facilities, operations, and property, or on legal or regulatory compliance.

Infectious Materials: Any isolate of a pathogen or any biological material that contains human or animal pathogens and, therefore, poses a risk to human or animal health.

Large Scale: Activities generally involving volumes of toxins or the in vitro culture of infectious material on a scale of 10 litres or greater. This could be a single vessel with a volume of 10 litres or greater, or based on the processes and pathogen used, could be multiple vessels with a total volume of 10 litres or greater. It is determined in consultation with the Public Health Agency of Canada and/or the Canadian Food Inspection Agency on a case-by-case basis, whether or not particular activities conducted in a containment zone are required to follow the increased or unique requirements for large scale production areas.

Microorganisms: A cellular or non-cellular microbiological entity, capable of replication or transferring genetic material and that cannot be reasonably detected by the naked eye. Microorganisms include bacteria, fungi, viruses, and parasites, and may be pathogenic or non-pathogenic in nature.

Notifiable Biological Substances: Are substances listed in the *Saskatchewan Occupational Health and Safety Regulations* requiring written notice and permission from the Director of Saskatchewan Ministry of Labour Relations and Workplace Safety to acquire, use, store and dispose. Notifiable biological substances also include those GMMO's or 'Biotechnology Substances' requiring permits from the PHAC, CFIA or the Canadian Environment Protection Agency (CEPA) under the *New Substance Notification Regulations*.

Organism: Any living entity (e.g. animals, plants, cell (tissue) cultures, microorganisms).

Pathogen: A microorganism, nucleic acid, or protein capable of causing disease or infection in humans or animals. Examples of human pathogens are listed in Schedules 2 to 4 and in Part 2 of Schedule 5 of the Human Pathogens and Toxins Act, but these are not exhaustive lists. Examples of animal pathogens can be found through the Automated Import Reference System on the Canadian Food Inspection Agency website.

Principal Investigator (PI): The individual who takes direct responsibility for completion of a research project under a biosafety permit.

Permit Holder: A PI authorized to work with organisms, biological materials, or biohazardous materials under the *Biosafety Policy* and *Biosafety Code of Practice*.

Prion: Small proteinaceous infectious particle generally considered to be responsible for causing a group of neurodegenerative diseases in humans and animals known as transmissible spongiform encephalopathies.

Risk Group (RG): The classification of biological material based on its inherent characteristics, including pathogenicity, virulence, risk of spread, and availability of effective prophylactic or therapeutic treatments, that describes the risk to the health of individuals and the public as well as the health of animals and the animal population.

Risk Group 1 (RG1): A microorganism, nucleic acid, or protein that is either a) not capable of causing human or animal disease; or b) capable of causing human or animal disease, but unlikely to do so. RG1 organisms capable of causing disease are considered pathogens that pose a low risk to the health of individuals or animals, and a low risk to public health and the animal population. RG1 pathogens can be opportunistic and may pose a threat to immunocompromised individuals. Neither of the RG1 subsets is regulated by the Public Health Agency of Canada (PHAC) or the CFIA due to the low risk to public health and the animal population.

Risk Group 2 (RG2): A pathogen or toxin that poses a moderate risk to the health of individuals or animals, and a low risk to public health and the animal population. These pathogens are able to cause serious disease in a human or animal but are unlikely to do so. Effective treatment and preventive measures are available and the risk of spread of diseases caused by these pathogens is low. Examples of RG2 human pathogens are included in Schedule 2 of the HPTA.

Risk Group 3 (RG3): A pathogen that poses a high risk to the health of individuals or animals, and a low risk to public health. These pathogens are likely to cause serious disease in a human or animal. Effective treatment and preventive measures are usually available and the risk of spread of disease caused by these pathogens is low for the public. The risk of spread to the animal population, however, can range from low to high depending on the pathogen. Examples of RG3 human pathogens are included in Schedule 3 of the HPTA.

Security Sensitive Biological Agents (SSBAs): The subset of human pathogens and toxins that have been determined to pose an increased biosecurity risk due to their potential for use as a biological weapon. SSBAs are identified as prescribed human pathogens and toxins by Section 10 of the Human Pathogens and Toxins Regulations.

Supervisor: A person who is authorized by the university to oversee or direct the work of employees and students. The authority to supervise employees and students is inherent in their job function. Although the university recognizes the ultimate responsibility of performing work in a safe manner lies with the individual employee, supervisors have additional responsibilities, which arise from their role as persons responsible for providing competent supervision and managing the workplace under their authority.

Terrestrial Animal Pathogen: A pathogen that causes diseases in terrestrial animals, including avian and amphibian animals, but excluding aquatic animals and invertebrates.

Toxin: A poisonous substance that is produced or derived from a microorganism and can lead to adverse health effects in humans or animals. Human toxins are listed in Schedule 1 and Part 1 of Schedule 5 in the Human Pathogens and Toxins Act.

Transgenic Plants and Animals: The results of the transmission of genes within the same species or into other animal or plant species.

Worker: A person who is engaged in an occupation in the service of an employer.

1 Purpose

In accordance with the University of Saskatchewan *Biosafety Policy*, the *Biosafety Code of Practice* is the governing document in the administration of the Biosafety Program at the University of Saskatchewan.

The *Biosafety Code of Practice* specifies the minimum requirements, roles, and responsibilities for individuals working with organisms and biological materials for academics, research, or other activities.

2 Scope

Under the *Biosafety Policy*, individuals working with organisms or biological materials must meet all legislative requirements and must adhere to the administrative procedures and operational rules for their acquisition, use, storage, transportation, abandonment, transference, releasement, and/or disposal as set forth in the university's *Biosafety Code of Practice* and supporting documentation.

The *Biosafety Code of Practice* applies to all university employees, students, contractors, and visitors.

3 Regulatory Considerations

The University of Saskatchewan is responsible for ensuring compliance with applicable legislation governing the use of organisms, biological materials and biohazardous materials, and for taking every precaution reasonable for the protection of employees, students, contractors, visitors, the public, and the environment.

In Canada, the acquisition, use, storage, transportation, abandonment, transference, releasement, and/or disposal of biological materials in Canada are governed collectively by a number of federal and provincial agencies:

- Public Health Agency of Canada (PHAC) (Human Pathogens and Toxins Act and Regulations (HPTA/R));
- Canadian Food Inspection Agency (CFIA) (Animal Health Act and Regulations);
- Environment Canada (Canadian Environmental Protection Act and New Substances Notification Regulations);
- Transport Canada (Transportation of Dangerous Goods Regulations); and
- Saskatchewan Ministry of Labour Relations and Workplace Safety (Saskatchewan Employment Act and Occupational Health and Safety Regulations).

The *Biosafety Code of Practice* reflects current best practices, which is outlined by:

- PHAC and CFIA *Canadian Biosafety Standard (2nd Ed., 2015)* and *Canadian Biosafety Handbook (2nd Ed., 2016)*; and the
- CFIA *Containment Standards for Facilities Handling Aquatic Pathogens* (1st Ed., 2010) and *Containment Standards for Facilities Handling Plant Pests* (1st Ed., 2007);

All work conducted by individuals working with biological materials on University premises or under University control are to be performed in accordance with the requirements set forth in this code of practice.

In accordance to PHAC's HPTA/R, the University of Saskatchewan, including the International Vaccine Centre, has obtained blanket licences, which allows controlled research activities being conducted with:

- All Risk Group 2 pathogens, prions, and all toxins that are not identified as Security Sensitive Biological Agents (SSBA);
- Specific list of prescribed toxins that are identified as SSBA; and/or
- Specific list of Risk Group 3 pathogens in a defined laboratory space (list may or may not include SSBA).

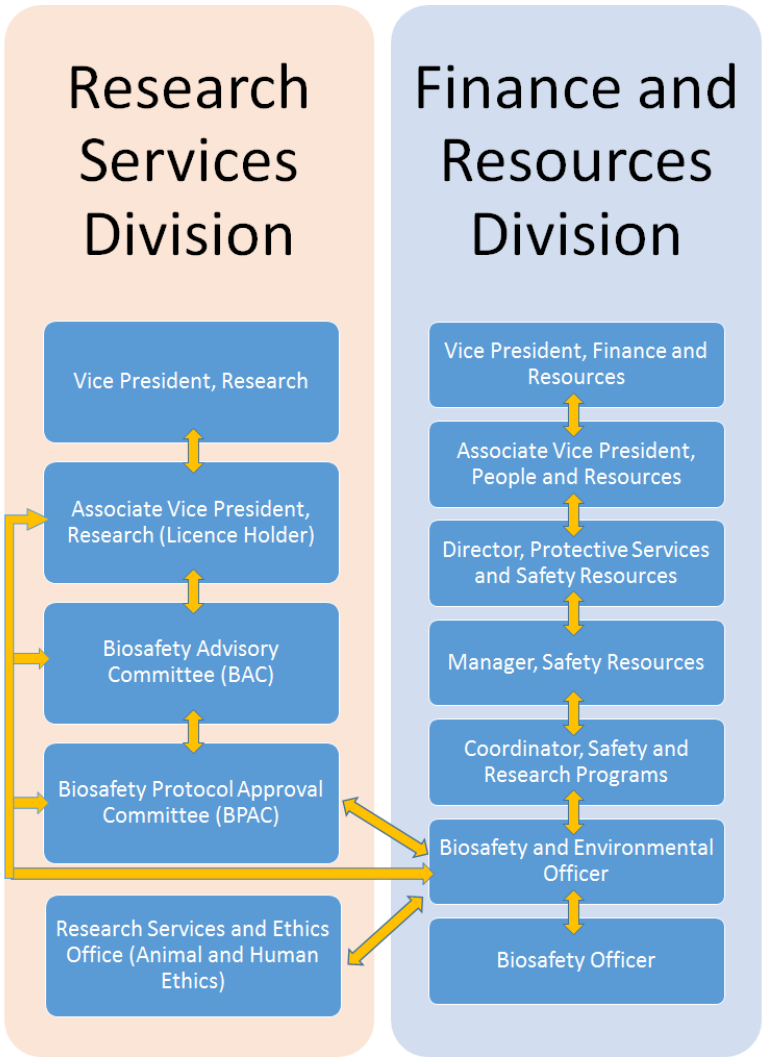
Therefore, all permit holders under the U of S Biosafety Program will not require an individual licence.

All supporting documents are listed in the reference section of this document.

4 Program Authority Roles and Responsibilities

The U of S has the following regulatory structure for administrating the Biosafety Program as shown by Figure 1.

Figure 1: The Regulatory Structure for the U of S Biosafety Program



The program authority roles and responsibilities of the BAC, BPAC, Safety Resources, and Research Services and Ethics Office are outlined below.

4.1 Biosafety Advisory Committee

The Biosafety Advisory Committee (BAC) is responsible for monitoring the university's Biosafety Program and for providing advice and guidance on policy, procedures and guidelines in support of biosafety and legislative compliance. The BAC also participates in investigations of serious incidents involving biohazardous materials, and serious infractions under the *Biosafety Code of Practice,* the *Human Pathogens and Toxins Licence,* or other current legislation.

The subcommittee of the BAC, the Biosafety Protocol Approval Committee (BPAC), is authorized to review and approve protocols involving organisms and biological materials in accordance with the *Biosafety Code of Practice*.

The composition and specific responsibilities of the BAC and BPAC are outlined in the supporting documents, *BAC Terms of Reference* and the *BPAC Terms of Reference*.

4.2 Safety Resources

In accordance with the Workplace Safety and Environmental Protection Policy, Safety Resources has overall authority over occupational health and safety at the university.

Safety Resources develops, manages, and supports comprehensive health and safety programs and processes, such as laboratory safety, radiation safety, and safety management system, to direct and provide guidance to the University community with respect to health and safety, including biosafety.

Under the *Biosafety Policy*, Safety Resources is responsible for developing, administering, and delivering biosafety programming for the university in accordance with the *Biosafety Code of Practic*e, current legislation, and best practices. Safety Resources is also responsible for supporting the activities of the BAC and the BPAC.

Reporting to the Associate Vice-President, People and Resources, the Director, Protective Services and Safety Resources, holds primary responsibility for the operations and resources (human, physical, and financial) of the unit. The Director provides strategic vision, leadership and stewardship of the unit in a manner that enables the achievement of the university's strategic and operational goals.

Reporting to the Director, the Manager, Safety Resources provides guidance to the Coordinator, Safety and Research Programs.. The Coordinator leads in the development and delivery of health and safety, and environmental programs, processes and systems to create and promote a culture of enterprise risk management to ensure a safe and healthy work and learning environment at the university.

Reporting to the Coordinator, Safety Resources and Research Programs, the Biosafety and Environmental Officer provides oversight and manages the the U of S Biosafety Program. Under the supervision of the Biosafety and Environmental Officer, the Biosafety Officer supports biosafety processes, manuals, procedures, and audit requirements. Both of these positions constitute the U of S Biosafety Group and serve as the expert resource to the university community on biosafety. The Biosafety Group is responsible for applying for the University's licence under the Human Pathogens and Toxins Act (HPTA) and communicates with the Minister on behalf of the licence holder, as required. This group also acts as a resource for the BAC and BPAC, and is the primary liaison with provincial and other federal and research granting agencies, as relating to biosafety.

The Biosafety Group is responsible for conducting periodic inspections and biosafety audits, developing and maintaining training programs, manuals and procedures, overseeing import, export, and transfer of biohazardous materials, and incident investigation and exposure reporting involving biohazardous materials. The group reviews permit applications and amendments submitted by the permit holders/principal investigators and recommends authorization to the BPAC.

Information on Safety Resources programs and services, including biosafety, can be found on its website, http://safetyresources.usask.ca/.

4.3 Research Services and Ethics Office

Research Services and Ethics Office is the main administrative unit of the Office of the Vice-President Research. This unit was established to both provide support and help facilitate research activity at the University of Saskatchewan. The office is responsible for all pre- and post-award administration of grants (individual, collaborative, and institutional) and contracts. This unit also administers a number of institutional programs including the Canada Research Chairs and Canada Foundation for Innovation Programs, as well as international activity related to research.

The university requires that all research conducted by its members conform to the highest ethical standards and federal and provincial regulations for the use of human subjects, animals, and biological materials. Research Services and Ethics Office ensures that all researchers have a proper biosafety and/or human/animal ethics approval prior to releasing the funding for grants or contracts.

Information on Research Services and Ethics Office, their roles and responsibilities, including policies on human and animal research, and supporting information can be found on their website at http://research.usask.ca/ .

5 Biosafety Permits

5.1 Biological Materials Requiring Biosafety Permits

The University of Saskatchewan requires that all individuals who intend to acquire, use, store, transport, abandon, transfer, export, release, and/or dispose of biological materials of Risk Group 2 and 3 organisms or biological materials must obtain or be operating under a biosafety permit.

Individuals who intend to acquire, use, store, transport, or dispose of Risk Group 1 organisms or biological materials do not require a biosafety permit with the exception of some select organisms and biological materials. Instead, the principal investigator must complete a *Biological Materials Declaration Form*, which is reviewed by the Biosafety Group and then recorded and kept track of internally.

The use of Risk Group 4 biological materials are not permitted at the University of Saskatchewan.

5.2 Biosafety Permit Application and Approval

Individuals seeking a biosafety permit shall submit an application and supporting documentation to the Biosafety Group, in accordance with the *New Biosafety Permit Application Procedure* (http://safetyresources.usask.ca/).

The Biosafety Group shall review the biosafety permit application for completeness and conduct an inspection of all work areas identified in the permit application to ensure proper containment, and that all necessary health and safety measures are in place.

A biosafety permit shall be granted only when all university, legislative, and granting agency requirements have been met.

Biosafety permit applications for the use of Risk Group 2 or 3 biological materials shall be reviewed and approved by the BPAC.

Upon approval of a biosafety permit application, the Biosafety Group shall issue a University of Saskatchewan biosafety permit to the individual who is designated as the permit holder. As deemed necessary, the Biosafety Group and BPAC may stipulate conditions on the biosafety permit which must be adhered to by the permit holder.

Before work is initiated, a member of the Biosafety Group shall meet with the permit holder to review responsibilities under the *Biosafety Code of Practice*, and the biosafety permit.

Biosafety permits are valid for a period up to two years and may be renewed.

Safety Resources shall maintain records of all permit applications, associated documents, and related correspondence, and biosafety permits. All information provided by the applicant shall be treated as confidential.

5.3 Amendment of a Biosafety Permit

An amendment to an active biosafety permit is required whenever there are changes to information contained within the permit. This includes:

- Changes to the Risk Group 1, 2, or 3 organisms, biological materials or biohazardous materials listed on the biosafety permit;
- Addition of a new research protocol and/or changes to an existing research protocol, includes expiring of a permit;
- Changes to quantities of organisms, biological materials, or biohazardous materials;
- Changes to authorized workers under the biosafety permit;
- Changes to locations listed under the biosafety permit; and
- Changes to contact information under the biosafety permit.

A permit amendment is also required when a permit holder intends to go on sabbatical or a leave of absence greater than three months, and is no longer able to oversee the research protocol or activities under the biosafety permit. The permit must assign an individual who will be responsible for the permit during the absence.

All amendments to an active biosafety permit shall be submitted to Safety Resources and/or the Biosafety Group in accordance with the *Biosafety Permit Amendment Procedure* (http://safetyresources.usask.ca/).

All amendments to active biosafety permits require approval by the Biosafety Group, Safety Resources designate, and/or the BPAC prior to implementation. Upon approval, an amended biosafety permit shall be issued to the permit holder.

5.4 Biosafety Permit Renewal

Biosafety permits are valid for up to two years. To facilitate permit administration, all biosafety permits have the same expiry date and are renewed at the same time.

Safety Resources shall initiate and manage the renewal of biosafety permits in accordance with the *Biosafety Permit Renewal Procedure* (http://safetyresources.usask.ca/). Upon completion of the permit renewal process, the Biosafety Group shall issue new biosafety permits to permit holders.

Research Services and the Research Ethics Office shall be notified of individuals who have not renewed their biosafety permit prior to the expiry date.

5.5 Cancellation of a Biosafety Permit

An active biosafety permit may only be cancelled by the permit holder or by the Biosafety Group.

The permit holder must notify the Biosafety Group at least one month prior to the intended cancellation date of a biosafety permit. The notification must include a schedule to decommission all work and storage areas listed under the permit in accordance with the University of Saskatchewan *Facility Decommissioning Standard* (http://safetyresources.usask.ca/). Once the decommissioning process has been fulfilled by the permit holder, the Biosafety Group, or Safety Resources, designate will verify that the process has been completed and issue a *Facility Decommissioning Certificate* (http://safetyresources.usask.ca/).

6 Procurement of Biohazardous Materials

Permit holders who wish to procure any organisms, biological materials, or biohazardous materials must notify the Biosafety Group prior to the procurement of the biological materials. For Risk Group 2 and 3 biohazardous agents, the permit holder must also complete the *Biohazardous Agent Transfer Notification Form* (http://safetyresources.usask.ca/) and submit the completed form to the Biosafety Group. The Biosafety Group will then determine if any other import permits and/or certifications are required for the procurement of the biological material (e.g. an import permit from CFIA).

Permit holders are only authorized to acquire only those organisms, biological materials, or biohazardous materials listed under their biosafety permit. If the permit holder wishes to add a new Risk Group 2 or 3 biological agent to their permit, it is subject to approval by the Biosafety Group and BPAC.

The importation of biological materials, including Risk Group 1 materials, Risk Group 2 and 3 biohazardous materials into Canada shall be carried out in accordance with all legislative requirements.

7 Transfer of Biohazardous Materials

University of Saskatchewan

Risk Group 1, 2, or 3 biohazardous materials may only be transferred to another permit holder at the University of Saskatchewan with appropriate approvals by the Biosafety Group or the BPAC and in accordance with the *Biosafety Permit Amendment Procedure* (http://safetyresources.usask.ca/).

Principle Investigators who wish transfer Risk Group 1 biological materials must complete and submit a *Biological Material Declaration Form* (http://safetyresources.usask.ca/) to the Biosafety Group.

Within Canada

Risk Group 2 and/or 3 materials may only be transferred to another PHAC licence-equivalent facility/institution within Canada. The permit holder must notify the Biosafety Group and complete the *Biohazardous Agent Transfer Notification Form* (http://safetyresources.usask.ca/) prior to transferring the material.

Outside of Canada

Risk Group 2 and/or 3 materials may only be transferred to another containment level 2 or 3 facility outside of Canada. The permit holder must notify the Biosafety Group and complete the *Biohazardous Agent Transfer Notification Form* (http://safetyresources.usask.ca/) prior to transferring the material.

The transfer of Risk Group 1, 2 or 3 biohazardous materials shall be performed in accordance with the regulations set forth by PHAC, CFIA, and Transport Canada.

8 Export of Biohazardous Materials

In addition to following the transfer process outlined above, some biohazardous materials and associated equipment that are destined for export from Canada may require an export permit from the Department of Foreign Affairs and International Trade Canada.

Permit holders intending to export biohazardous materials shall contact the Biosafety Group prior to export to determine if an export permit is required.

9 Biosafety Permit Holder Obligations and Responsibilities

The permit holder is ultimately responsible for ensuring the safe use, storage, and disposal of organisms, biological materials, or biohazardous materials listed under his/her biosafety permit. The specific responsibilities of a permit holder are outlined in the following sections, and are intended to form the contents of a biosafety plan as prescribed in the *New Biosafety Permit Application Procedure* and other supporting procedures referenced in the *Biosafety Code of Practice*.

9.1 Safety Management

It is the responsibility of the permit holder to provide competent supervision of all authorized workers and work activities under the biosafety permit. In providing competent supervision, the permit holder shall:

- Comply with legislative and granting agency requirements;
- Comply with university health, safety and environmental protection requirements;
- Comply with requirements set forth in the *Biosafety Code of Practice*;
- Comply with all biosafety permit conditions;
- Implement appropriate safety measures commensurate with the identified risks;
- Ensure that instruments, equipment and facilities are properly maintained and tested in accordance with university, regulatory requirements, and/or manufacturer specifications;
- Ensure staff and students adhere to procedures, rules and health and safety program requirements under the biosafety permit; and
- Monitor and review work locations and activities and take appropriate action to rectify areas of non-compliance, unsafe acts, or conditions.

The permit holder shall cooperate with Safety Resources and any other person exercising duties imposed by university policies or regulatory agencies.

The permit holder shall notify the Biosafety Group of any planned changes to a biosafety permit in accordance with the biosafety permit amendment process.

9.2 Training

The permit holder shall provide workplace training to authorized workers specific to the work they will be engaged in.

The permit holder shall inform authorized workers of the specific workplace hazards, risks and symptoms of exposures to biohazardous materials, and ensure that all authorized workers receive appropriate health and safety training.

All authorized workers are required to take the Safety Resources Workplace Hazardous Materials Information System (WHMIS) course, Laboratory Safety Course, and Biosafety Course. Other safety training may also be required depending on the particular activities engaged in under the permit. Safety Resources shall inform the permit holder of any additional training requirements for health and safety.

Site-specific training is the responsibility of the principal investigator, supervisor, and/or permit holder and determined by a training assessment which is done in consultation with the Biosafety Group. The results of the assessments are documented in their Biosafety Plan. All site specific

training is documented by the PI or Permit Holder completing *the U of S Site Specific Training Record template* (http://safetyresources.usask.ca/procedures_forms/index.php).

Each PI or permit holder also provides site specific training on the emergency response plan (ERP) for their specific location/area, which is documented and conducted annually.

9.3 Biosecurity

The permit holder shall implement and maintain biosecurity measures commensurate with the identified Risk Group and Containment Level of the biohazardous materials under the biosafety permit and legislative requirements. This includes, but is not limited to:

- Physical protection of the permitted facility to minimize unauthorized access to facilities, laboratories and storage areas;
- Personnel authorization and clearance of authorized workers to work in the facility;
- Inventory management of organisms, biological materials, and biohazardous materials used and stored under the biosafety permit;
- Assessment on research with dual-use potential; and
- Incident reporting, response, and investigation into suspected criminal activity including the loss or suspected theft of organisms, biological materials, or biohazardous materials under the biosafety permit.

The permit holder conducts a biosecurity assessment in consultation with the Biosafety Group, which is documented in the Biosafety Plan, and then reviewed and approved by the Biosafety Group and the BPAC.

9.4 Health and Medical Surveillance

Immunizations and/or medical surveillance programs may be required or recommended for individuals working with potentially infectious biological materials. This is dependent on the type, area, and hazards associated with the individual's particular work. Immunizations are available for agents; for example, Rabies, Hepatitis A and B viruses, Influenza, and Tetanus.

Permit holders are responsible for providing information regarding the risk versus benefits of any immunization that is available for the authorized workers and retaining documentation of all discussion and copies of all hand-outs.

The permit holder shall conduct an assessment in consultation with the Biosafety Group to determine if any immunizations and/or medical surveillance program is required for their research. The assessment is documented in *U of S Biosafety Plan (www.safetyresources.usask.ca)*.

The permit holder ensures that a health and medical surveillance assessment is implemented (if required) for all authorized workers prior to the initiating the research. The health and medical surveillance assessment may include, but is not limited to:

- Medical examination;
- Immunization;
- Medical surveillance; and
- Serum screening.

Immunizations and medical surveillance are conducted through the individual's medical practitioner. Individuals can waiver vaccinations by completing the *U of S Vaccination Waiver Form* (www.safetyresources.usask.ca). The individuals must be encouraged to address any concerns with their personal physician prior to completion of the Waiver Form.

9.5 Incident Reporting and Investigation

Permit holders and authorized workers must complete an incident report if they are involved in an incident or near miss incident while engaged in activities, or conducting work on campus. Incident reports are documented online through the Safety Resources website: www.safetyresources.usask.ca (for faculty, staff, and graduate students), or through the completion of a paper version (for undergraduate students, non-U of S personnel). Incident Reports are intended to provide formal records of all incidents that have occurred at the University.

Permit Holders are responsible to follow up with the incident and provide immediate and long-term corrective actions. Once reported, the Biosafety Group, or designate, conducts an investigation into the incident, or near miss, to follow-up and ensure the proper corrective actions have been completed.

The Biosafety Group, or designate, is responsible to report any incidents or near misses with biohazardous materials in accordance to the Human Pathogens and Toxins Regulations.

9.6 Disposal of Hazardous Materials

The permit holder shall ensure that all hazardous waste generated under the biosafety permit is disposed of in accordance with the *Hazardous Waste Disposal Standard* (http://safetyresources.usask.ca/).

The permit holder shall ensure that any viable biohazardous materials or waste is inactivated prior to its release into the environment unless otherwise specified and approved under the conditions of the permit, or by Safety Resources.

9.7 Emergency Response

The U of S is committed to having the structures, plans, and resources in place for effective emergency response management by means of optimal co-operation with service providers, emergency responders, and other key stakeholders. Safety Resources develops and maintains policies and procedures related to the building/facility-specific, or local Emergency Response Plan (ERP).

Each local ERP addresses the following emergency measure:

- Major and minor medical emergencies, which include injuries and confirmed or suspected illness from exposure to hazardous materials;
- Spills of hazardous materials, including biohazardous materials;
- Evacuation;
- Flood;
- Suspicious people and activity;
- Lockdown procedures and violence;
- Severe weather;
- Bomb threats;
- Containment equipment failure, including biosafety cabinets;
- Personnel or students in crisis;
- Loss or theft of hazardous materials;
- Power outages; and
- Fire.

If an area/location requires a specific emergency response measure, such as an animal escape or a modified evacuation plan, they are added to the local ERP as required.

The permit holder is responsible to ensure all authorized workers have reviewed and provide training on the current building ERP annually. The ERP training is to be documented using the *U of S Site Specific Training Record template* (http://safetyresources.usask.ca/procedures_forms/index.php).

The permit holder shall immediately report to Safety Resources all incidents including confirmed or suspected illnesses resulting from exposures to hazardous materials, spills, containment equipment malfunctions, or loss or suspected theft of permitted materials.

9.8 Decommissioning of Permitted Facilities

When a biosafety permit is to be cancelled or will not be renewed, the permit holder is responsible for decommissioning all work and storage areas listed under the biosafety permit.

All decommissioning must be completed prior to the permit expiry/cancellation date in accordance with the *University of Saskatchewan Facility Decommissioning Standard* (http://safetyresources.usask.ca/).

The Biosafety Group shall advise permit holders on the proper decontamination of work areas and equipment and shall confirm that facilities are decontaminated to accepted levels. Safety Resources shall support the removal and disposal of hazardous materials including biological, chemical, and radioactive.

9.9 Documentation and Records

It is the responsibility of the permit holder to ensure the all relevant documents pertaining to the biosafety permit are regularly reviewed and updated as required. The permit holder must also maintain all records associated with a biosafety permit. The relevant documents includes, but are not limited to:

- A copy of the biosafety permit;
- Biosafety permit application documentation;
- Biosafety permit amendments;
- Research protocol(s);
- Work procedures and standard operating procedures;
- Biosafety Plan;
- Authorized worker training records;
- Site specific training records;
- Up-to-date inventory of organisms, biological material and biohazardous material listed under the permit;
- Procurement records for organisms, biological material and biohazardous material;
- Transport and transfer records for organisms, biological material and biohazardous material;
- Equipment maintenance and certification records;
- Disposal of hazardous waste;
- Decommissioning records;
- Copy of the local emergency response plan; and
- Reported incidents.

Safety Resources shall maintain copies of records associated with all biosafety permits at the university.

10 Authorized Worker Responsibilities

Following are the responsibilities of authorized workers under a biosafety permit.

- Conduct work in a safe and responsible manner to protect the individual's health and safety, as well as others that may be affected by the individual's acts or negligence;
- Comply with legislative and granting agency requirements;
- Comply with university health, safety, and environmental protection requirements;
- Comply with requirements set forth in the *Biosafety Code of Practice*;
- Comply with all biosafety permit conditions;
- Follow rules and procedures established by the permit holder under the biosafety permit;
- Immediately report to the permit holder any deviations from or changes to the biosafety permit;
- Immediately report to the permit holder all incidents including confirmed or suspected illnesses resulting from exposures to biohazardous materials, spills, containment equipment malfunctions, loss or theft of permitted materials; and
- Cooperate with Safety Resources and any other person exercising duties imposed by university policies or regulatory agencies.

11 Compliance Enforcement

Safety Resources is authorized to conduct inspections and audits of permitted facilities and activities to ensure compliance with the *Biosafety Code of Practice*, legislative, and granting agency requirements. The permit holder is responsible for rectifying deficiencies identified during said inspections and audits.

In accordance with *Compliance Enforcement Pertaining to Hazardous Agents Policy*, the University of Saskatchewan will take specific and prompt action in order to enforce compliance with the terms and conditions of various licences issued to the university, and also with the applicable federal and provincial statutes pertaining to the use, handling, storage, and disposal of hazardous agents.

Individuals failing to adhere to the requirements contained within the *Biosafety Code of Practice*, university policies, and legislative requirements, are subject to compliance enforcement up to and including suspension of privileges to work with organisms, biological materials, or biohazardous materials at the university.

When, in the opinion of Safety Resources, there is unacceptable risk to employees, the public, the environment, or university property, Safety Resources is authorized to take appropriate action which may include the immediate suspension of research activity, prohibited entry to a laboratory, and/or the removal of hazardous material from the premises.

Compliance enforcement related to biosafety permits shall be carried out in consultation with the Biosafety Group and the BAC.

The Biosafety Group shall notify the U of S Human Pathogen and Toxins Regulations Licence Holder, regulatory agencies, and research granting agencies of compliance issues in accordance with their respective reporting requirements.

12 Review of Code of Practice

The *Biosafety Code of Practice* may be reviewed at any time on the recommendation of the BAC, but shall be reviewed at least every three years.

13 References

References listed herein are available on the Safety Resources website, http://safetyresources.usask.ca/.

- *Workplace Safety and Environmental Protection Policy*, University of Saskatchewan.
- *Biosafety Policy*, University of Saskatchewan.
- President's Biosafety Advisory Committee Terms of Reference, University of Saskatchewan.
- President's Biosafety Protocol Approval Committee Terms of Reference, University of Saskatchewan.
- *New Biosafety Permit Application Procedure* and forms, Safety Resources.
- *Biosafety Permit Amendment Procedure* and forms, Safety Resources.
- *Procurement, Export, and/or Transfer of Organisms and Biological Materials Procedure*, Safety Resources.
- *Biohazardous Agent Transfer Notification Form*, Safety Resources.
- *Biosafety Permit Renewal Procedure*, Safety Resources.
- *Biosafety Plan Guide* and *Biosafety Plan template*, Safety Resources.
- *University of Saskatchewan Facility Decommissioning Standard and Certificate*, Safety Resources.
- *Hazardous Waste Disposal Standard*, Safety Resources.
- *Laboratory Safety Manual,* Safety Resources.
- *Saskatchewan Occupational Health and Safety Act*, 1993.
- *Saskatchewan Occupational Health and Safety Regulations*, 1996.
- *Human Pathogens and Toxins Act and Regulations*, Public Health Agency of Canada.
- *Health of Animals Act*, Canadian Food Inspection Agency.
- *Health of Animals Regulations*, Canadian Food Inspection Agency.
- *Plant Protection Act* and *Regulations*, Canadian Food Inspection Agency.
- *Canadian Biosafety Standard (2nd Ed., 2015)*, Public Health Agency of Canada and Canadian Food Inspection Agency.

- *Canadian Biosafety Handbook (2nd Ed., 2016)*, Public Health Agency of Canada and Canadian Food Inspection Agency.
- *Containment Standards for Facilities Handling Plant Pests*, Canadian Food Inspection Agency.
- *Containment Standards for Facilities Handling Aquatic Animal Pathogens*, Canadian Food Inspection Agency.
- *Transportation of Dangerous Goods Act*, Transport Canada.
- *Transportation of Dangerous Goods Regulations*, Transport Canada.
- *Laboratory Biosafety Manual*, World Health Organization.
- *Biosafety in Microbiological and Biomedical Laboratories (5th. Ed., 2009),* Centers for Disease Control and Prevention.