



<b>College/Unit:</b>	<b>Safety Resources</b>
<b>Procedure Title:</b>	<b>Biosafety Permit Renewal Procedure</b>

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## Revision History

Revisions to this procedure are to be documented in Table 1, Revision History.

Table 1: Revision History

<b>Document Section</b>	<b>Details of Amendments</b>	<b>Date</b>	<b>Author (Initials)</b>

## 1 Purpose

This procedure outlines the processes to be followed by individuals to renew a biosafety permit at the University of Saskatchewan.

## 2 Applicable To

The *Biosafety Permit Renewal Procedure* is applicable to all university faculty, staff, students and visitors who hold active biosafety permits to work with organisms, biological materials or biohazardous materials.

## 3 Scope

The University of Saskatchewan is committed to providing a place of employment and learning that is as free as possible from recognized hazards. A safe and healthy environment is created and maintained through the development and maintenance of supporting programs, the provision of proper facilities, equipment, training, and services, and by promoting safety consciousness.

In accordance with the University of Saskatchewan *Biosafety Policy* and *Biosafety Code of Practice*, individuals intending to acquire, possess, use, store, transport or dispose of organisms, biological materials or biohazardous materials must obtain a biosafety permit.

Biosafety permits are valid for up to two years and must be renewed in accordance with the *Biosafety Permit Renewal Procedure*. Biosafety permits that are not renewed prior to the expiration date shall be suspended.

The biosafety permit renewal process is not a permit amendment process. Under the *Biosafety Code of Practice*, amendments to biosafety permits shall be made in accordance with the procedure, *Biosafety Permit Amendment Procedure*.

All procedures, documents, templates, and forms referenced in this procedure are in *italics*, and can be found on the Safety Resources website, <http://safetyresources.usask.ca/>.

## 4 Definitions

**Animal Pathogen:** A microbe or microorganism that can cause disease in animals. Zoonotic agents are animal pathogens that can cause disease in animals and humans.

**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.

**Biological Material:** Any material that originates from living organisms, which may be infectious or non-infectious.

**Biohazardous Material:** Any infectious agent or hazardous biological material that present a risk or potential risk to the health of humans, animals, plants, or the environment. The risk can be directly through infection or indirectly through damage to the environment. Biohazardous materials include certain types of recombinant DNA, proteins, organisms infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi, prions, protozoa) and biologically active agents (e.g. toxins, allergens, venoms) that may cause disease in other living organisms or cause significant impact to the environment.

**Biosafety Cabinet (BSC):** An engineering safety control device that is used to provide primary containment and an aseptic work area to protect the health of the worker, the product, and the environment.

**Biosafety Permit:** A biosafety permit is a formal authorization granted by the Biosafety Manager or the Biosafety Protocol Approval Committee (BPAC) to individuals requesting approval for the acquisition, use, storage, transportation and disposal of Risk Group 1 biological material, and Risk Group 2 and 3 biohazardous 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 prescribes the health, safety, and biosecurity measures supporting the responsible use and management of organisms, biological materials, and biohazardous materials. A biosafety plan is required under a biosafety permit at the University of Saskatchewan.

**Biosafety Officer:** The individual responsible for developing and administering the university's Biosafety Program in accordance with regulatory requirements and best practices.

**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, or exhausted laboratory air and strictly controlled laboratory access.

**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.

**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 or Organisms:** An infectious substance as defined in the *Human Pathogens and Toxins Act* means “a micro-organism or parasite that is capable of causing human disease or an artificially produced hybrid or mutant microorganism that contains genetically altered components of any microorganism capable of causing human disease”.

**Large Scale Production:** Processes normally greater than ten (10) litres such as fermenters and equipment that cannot be easily moved and sterilized in an autoclave, therefore requiring in situ sterilization.

**Microorganisms:** Any organism or consortium of organisms of microscopic size and can be unicellular or live in a colony of cellular organisms (e.g. virus, bacteria, protozoa, parasites, fungi, algae).

**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 microbe or microorganism such that can cause disease in an organism.

**Principal Investigator:** the person who takes direct responsibility for completion of a research project under a biosafety permit.

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

**Risk Group 1 Organisms:** A category of biological agents or microorganisms which are unlikely to cause disease in healthy workers or animals, or in plants. Risk Group 1 organisms pose a low risk to individuals and to the community.

**Risk Group 2 Organisms:** A category of human and/or animal pathogens that pose a moderate risk to the health of individuals and a low risk to public health. Risk Group 2 organisms are able to cause serious disease in a human but are unlikely to do so. Effective treatment and preventive measures are available and the risk of spread of disease caused by those pathogens is low.

**Risk Group 3 Organisms:** A category of human and/or animal pathogens that pose a high risk to the health of individuals and a low risk to public health. Risk Group 3 organisms are likely to cause serious disease in a human. Effective treatment and preventive measures are usually available and the risk of spread of disease caused by those pathogens is low.

**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.

**Toxin:** A poisonous substance produced by living cells or organisms.

**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.

## 5 Procedure

At the University of Saskatchewan biosafety permits are valid for up to two years. To facilitate permit administration, all permits, regardless of when issued, are renewed collectively on a two year cycle expiring on the 1<sup>st</sup> of May of the renewal year.

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

Permit holders intending not to renew, or to cancel their biosafety permit must notify the Biosafety Office at least one month prior to the expiry date or intended cancellation date of the permit. In accordance with the *Biosafety Code of Practice*, the permit holder must include a schedule to decommission all work and storage areas listed under the permit.

Safety Resources shall initiate and manage the renewal of biosafety permits in accordance with this procedure. Upon completion of the permit renewal process, the Biosafety Manager shall issue new biosafety permits to permit holders.

Safety Resources biosafety staff is available to assist permit holders at all stages in the biosafety permit renewal process.

1. Safety Resources shall send a biosafety permit renewal memorandum with a *Biosafety Operating Permit Renewal Form* to all active permit holders at least three months in advance of the permit expiry date.

The *Biosafety Operating Permit Renewal Form* includes the following information:

- Permit holder contact information;
  - Work locations;
  - Authorized workers;
  - Organisms, biological materials and biohazardous materials listed under the permit;
  - Permit conditions; and
  - Protocol title.
2. Permit holders shall review the *Biosafety Operating Permit Renewal Form* to ensure that the information listed under the biosafety permit is correct.

The biosafety permit renewal process is not a permit amendment process. Under the *Biosafety Code of Practice*, amendments to biosafety permits are to be made in accordance with the procedure, *Biosafety Permit Amendment Procedure*.

The permit holder shall notify the Biosafety Office immediately if there are anticipated amendments to a biosafety permit during the renewal process.

3. The permit holder shall sign the *Biosafety Operating Permit Renewal Form* confirming that the permit information is correct, there have been no changes to the permit, and that the permit holder wishes to renew the permit.
4. The permit holder must return the signed *Biosafety Operating Permit Renewal Form* to the Biosafety Office prior to the expiry date of the permit.
5. The Biosafety Office shall review the permit renewal application, and issue new a biosafety permit.
6. New biosafety permits shall be posted in permitted locations. Expired biosafety permits must be removed from permitted locations.

Biosafety permits that are not renewed prior to the expiration date shall be suspended.

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

## **6 Records**

Permit holders shall maintain copies of all information related to the biosafety permit as required under the *Biosafety Code of Practice*.

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.

## **7 Procedure Review**

This procedure shall be reviewed by Safety Resources at least once every three years. The procedure may, however, be reviewed by Safety Resources at any time, to correct errors or to make procedural changes.

## **8 Contact Information**

Following, is the primary contact information for the Biosafety Program.

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## 9 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.
- *Biosafety Code of Practice*, Safety Resources.
- *New Biosafety Permit Application Form*, Safety Resources.
- *Biosafety Plan Template*, Safety Resources.
- *Procurement of Organisms and Biological Material Procedure*, Safety Resources.
- *Saskatchewan Occupational Health and Safety Act*, 1993.
- *Saskatchewan Occupational Health and Safety Regulations*, 1996.
- *Human Pathogens and Toxins Act*, Public Health Agency of Canada.
- *Health of Animals Act*, Canadian Food Inspection Agency.
- *Human Pathogens Importation Regulations*, Public Health Agency of Canada.
- *Health of Animals Regulations*, Canadian Food Inspection Agency.
- *Plant Protection Act and Regulations*, Canadian Food Inspection Agency.
- *Laboratory Biosafety Guidelines*, Public Health Agency of Canada.
- *Containment Standards for Veterinary Facilities*, 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.
- *Memorandum of Understanding (MOU) on the Roles and Responsibilities in the Management of Federal Grants and Awards*, The Natural Sciences and Engineering Research Council of Canada (NSERC), with the Social Sciences and Humanities Research Council (SSHRC) and the Canadian Institutes of Health Research (CIHR).