P B A C

presidential biosafety advisory committee

IMPLEMENTATION DIRECTIVE

WHICH ITEMS REQUIRE BIOHAZARD APPROVAL?

Approved: May 30, 2016
Rev: May 17, 2016

McMaster University

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INTRODUCTION

The following list is meant to streamline the biohazard approval process and to help faculty determine when biohazard approval is required. It is an interpretation of Section 2 of RMM#600 – Biosafety Program. If there is doubt as to which any of the below statements apply, please contact the Biosafety Office at x23453.

These interpretations may be amended from time to time, therefore please ensure the latest, posted reference is used as a guide.

Regulation of some items are only triggered if that item is imported. Please confer with the Biosafety Office to determine if your item is regulated.

ITEMS REQUIRING BIOHAZARD APPROVAL

HUMAN TISSUES, FLUIDS, CELLS OR OTHER SAMPLES

- If regulated by PHAC, CFIA or any other government body or;
- If reasonably[1] expected to contain infectious materials, organisms or toxins or;
- If cultured
- Please refer to PID - Use of Human Specimens in Research and Teaching Laboratories

TERRESTRIAL[2] ANIMALS

- If regulated by PHAC, CFIA or any other government body or;
- If intentionally infected

TERRESTRIAL ANIMAL TISSUES, FLUIDS, CELLS OR OTHER SAMPLES

- If regulated by PHAC, CFIA or any other government body or;
- If reasonably expected to contain infectious materials, organisms or toxins or;
- If cultured

AQUATIC ANIMALS

- If regulated by PHAC, CFIA or any other government body or;
- If intentionally infected

AQUATIC ANIMAL TISSUES, FLUIDS, CELLS OR OTHER SAMPLES

- If regulated by PHAC, CFIA or any other government body or;
- If reasonably expected to contain infectious materials, organisms or toxins or;
- If cultured

[1] Defined on page 4.
[2] Includes amphibians.

PLANTS

- If regulated by PHAC, CFIA or any other government body or;
- If intentionally infected

PLANT TISSUES, FLUIDS, CELLS OR OTHER SAMPLES

- If regulated by PHAC, CFIA or any other government body or;
- If reasonably expected to contain materials, organisms or toxins or;
- If cultured

SOIL

- If regulated by PHAC, CFIA or any other government body or;
- If reasonably expected to contain materials, organisms or toxins or;
- If cultured for isolation of an applicable item;

MICROORGANISMS, PROTOZOA, PRIONS, PESTS OR PARASITES

Defined for this purpose as ***bacteria, virus, fungi, protozoa, prions, pests or parasites***

- If regulated by PHAC, CFIA or any other government body
- If isolated from clinical, animal, plant or environmental sample or;
- If acquired in pure form or;
- If cultured or;
- If not in dosage[3] form (i.e. probiotic pills are exempt, cultures of probiotic organisms are not; GMP-produced doses of virus are exempt, a flask of virus culture is not)

TOXINS[4]

- If regulated by PHAC, CFIA or other government body or;
- If produced by a microorganism

ASSESSING INFECTIOUS STATE

REASONABLY EXPECTED TO CONTAIN INFECTIOUS MATERIALS, ORGANISMS OR TOXINS

This category shall be selected if any of the following[5] apply:

- the specimen was taken from a human, animal, plant or environmental locale whose history or current information indicates that the sample will be infectious;

[3] A format that is immediately ready for human clinical use.

[4] Toxic substances produced by microorganisms, animals, and plants that have the capability of causing harmful effects when inhaled, ingested, injected or absorbed

[5] Definition taken from RMM600 - Biosafety Programme

- the specimen was taken from a human, animal, plant or environmental locale that was intentionally infected;
- the specimen was proven to be infectious

PROVEN TO BE FREE OF INFECTIOUS MATERIALS, ORGANISMS AND TOXINS

This category shall be selected if any of the following apply:

- the sample was tested and proven free of infection at the manufacturer
- the sample was tested and proven free of infection after collection
- the sample was obtained from a donor or patient that was tested and proven free of infection at the time of collection

UNKNOWN

This category shall be selected if none of the above statements apply. If there is not enough information to rule out the above statements, use of the sample should be re-evaluated since such a lack of information indicates reasonable grounds re-evaluate the risk or otherwise handle the sample at BSL2.

INTENDED USE

If there is any intent to put the sample into culture for cell/tissue harvest or for pathogen isolation or to keep the sample alive, "culturing" must be selected. For the purposes of the biosafety programme, sealed container culturing i.e. were the sample is cultured in a closed/sealed container for diagnostic purposes and which is never opened prior to disposal, is not included in the definition of "culturing".

ASSESSMENT FOR BIOSAFETY PROGRAM APPLICABILITY

The PBAC has created an online tool that will help determine if any research laboratory, undergraduate lab course, central facility or on-campus company requires biosafety oversight.

https://biosafety.mcmaster.ca/assessment

It is intended that one survey be completed for each:

- research laboratory
- lab-course
- central facility
- on-campus company

A video demonstrating how to complete the assessment is posted on the above referenced website.

If there are any changes to legislation, regulation or policy that results in a change to this survey, it will be revised and re-posted.