
IMPLEMENTATION DIRECTIVE

LOW RISK BIOHAZARD UTILIZATION PROTOCOL

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INTRODUCTION

The low risk biohazard utilization protocol applies to laboratories where the activities undertaken must follow prescribed conditions outlined in import permits or other regulatory directives which fall outside of the canonical containment level descriptions. For example, soil importing laboratories must adhere to the conditions prescribed in the specific import permit. This protocol does not apply to laboratories which already follow typical containment practices such as CL1, CL2, PPC1, PPC2, AQC1 or AQC2 etc. Low risk biohazard utilization protocols will be created to ensure adherence to conditions prescribed on import permits, there will be no grant review of the projects.

BUP

A new BUP will be opened for all low risk biohazard laboratories. The BUP will be designated as “Prescribed Containment Level: Other” to indicate the low risk BUP. As such, only certain sections of the BUP apply and PI will be instructed to complete only the relevant sections listed below.

- Section 1: Principle Investigator & Scope
- Section 2: Delegates
- Section 3: Laboratory Locations
- Section 7: Biological Inventory
- Section 9: Import Permits and Compliance Letters
- Section 13: Waste Assessment
- Section 14: Special Lab-Specific SOPs
- Section 15: Course Information (if applicable)

LAB SPECIFIC SOPs

The McMaster Biosafety Office (MBSO) will review import permit conditions and other regulatory requirements which apply to the work and determine appropriate lab specific SOPs which need to be in place. Required lab specific SOPs will be listed on the PI’s BUP in section 14: Special Lab-Specific SOPs. The PI must submit the required lab specific SOPs to the MBSO for review and approval.

Example:

Import permit condition: Imported aquatic animals shall not be released into natural waters.

MBSO determined a Tank Cleaning, Lab Security, Euthanasia and Disposal SOPs are required to ensure condition of no aquatic animals will be released into natural waters is met.

BUP APPROVAL

Once the MBSO has received the lab specific SOPs the PBAC will be notified during their monthly meeting of the new low risk BUP. The lab specific SOPs will be reviewed by the MBSO and PBAC will be notified of approval. If additional lab specific SOPs or modifications to existing SOPs are required the PI will be notified of the required changes and asked to resubmit. When the lab specific SOPs are approved the BUP will also be approved.

ANNUAL REVIEW

The low risk BUP is reviewed on an annual basis. One month prior to the annual review date, the PI will be sent the current BUP information.

The PI will attest to the fact that their project is still applicable under the low risk protocol. If imported materials have been destroyed and CFIA import conditions are no longer in place, the BUP will be closed. If the project scope has changed resulting in a prescribed containment level, the BUP will be changed to the appropriate containment level and removed as a low risk BUP.

The PI will also attest that they are still adhering to the import permit conditions and approved protocols are unchanged and being followed. If changes to the lab specific SOPs are required, they must be submitted to PBAC for review and approval.

Finally, the PI will attest that any import permits, compliance letters or communication with regulatory agencies will be forwarded to the MBSO office for record retention purposes.

The BUP is then approved and the annual renewal date is extended another year from the last approval date.

LAB AUDITS

Laboratories with low risk BUPs will not be audited by the MBSO. The lab space will be audited annually by the Health and Safety Committee.

NON-COMPLIANCE

Failure to complete the Annual Review will be considered non-compliance and escalated automatically at Day 0, Day 30, Day 60 and Day 90 per current procedures.