
IMPLEMENTATION DIRECTIVE

OPERATIONAL PROCEDURES FOR USE AT BSL2+

Implementation Directive

Operational Procedures for Use at BSL2+

CONTENTS

Introduction	3
BSL2 Operational Procedures	3
Additional Operational Procedures	3
BSL2+ Specific SOPs	3
Additional Operational Procedures for Use with Diagnostic Samples of HIV, Hepatitis C Virus and West Nile Virus and With Macaque or Rhesus Monkey Samples	4
Additional Operational Procedures for Use of Lentiviral Vectors	4
Additional Operational Procedures for Use With Influenza Virus and Diagnostic Samples of Mycobacterium Tuberculosis	5
Training Required for BSL2+	5
Documentation of Training	5
Corporate Matrix	6
BSL2 Training	6
Lab Specific Standard Operational Procedures Training (NEW)	6
N95 Mask Training and Fit Test	7
Spill Cleanup Procedures Training (NEW)	7
Reassigning a Laboratory from BSL2 to BSL2+	7
Reassigning a Laboratory From BSL1 to BSL2+	7
Reassigning a Laboratory from Non-Biohazard Work to BSL2+	8
Mechanism to Monitor PID Effectiveness	8
Contact Information for Assistance	8
Index	9

INTRODUCTION

The Public Health Agency of Canada (PHAC) provides operational practices for use at biosafety level 1 (Laboratory Biosafety Guidelines, 2004; LBG) and biosafety levels 2, 3, and 4 (Canadian Biosafety Standards and Guidelines, 2013; CBSG). There may be cases where certain features of the pathogen (virulence or oncogenic factors) or protocols (volumes or intentional aerosolization) may increase the risk of exposure and thus necessitate additional operational procedures. These additional operational procedures may be specified as a result of a local risk assessment performed by the Presidential Biosafety Advisory Committee (PBAC) or they may be specified directly from the government.

The implementation of “biosafety level 2+” (BSL2+) practices has changed over the course of time, predominantly due to the increased scope of knowledge pertaining to a particular pathogen or its use and due to data accumulated with respect to laboratory acquired infections (LAIs). The intent of the present PBAC Implementation Directive (PID) is to review and combine the various PBAC-approved and PHAC-mandated operational practices into one comprehensive document available to the McMaster research community.

In addition to external regulation by PHAC of operational procedures with respect to infectious materials, organisms and toxins, these are also regulated by the Canadian Food Inspection Agency (CFIA). The PHAC regulates human and terrestrial animal infectious materials, organisms and toxins in addition to prion disease agents whereas the CFIA regulates pathogens causing foreign animal disease, aquatic animal pathogens and plant pathogens. Together these two agencies effectively provide regulation and guidance for all forms of biohazardous work at McMaster University.

The operational procedures outlined below are in consideration of *in vitro* work only. If any *in vivo* work is to be undertaken with an infectious material, organism or toxin deemed to require BSL2+ the *in vivo* work must also comply with BSL2+ operating procedures.

BSL2 OPERATIONAL PROCEDURES

Operational procedures for BSL2 are outlined in the CBSG and the CFIA documents Containment Standards for Facilities Handling Aquatic Animal Pathogens and Containment Standards for Facilities Handling Plant Pests.

ADDITIONAL OPERATIONAL PROCEDURES

In the addition to the above operational procedures, the laboratory must incorporate those procedures described below when manipulating the specified samples. In the event that an operational procedure listed below is in conflict with the Pathogen Safety Data Sheet (PSDS), a risk assessment will be performed by the PBAC and the Supervisor to determine which procedures most appropriate to mitigate the risk of exposure.

BSL2+ SPECIFIC SOPs

The Occupational Health and Safety Act requires, and thus has the force of law, that all *Supervisors be competent because of knowledge, experience and training*. As such, the Supervisor identifies risks, creates or reviews created SOPs and deems them appropriate to mitigate the identified risks within their laboratory and during the course of the work they organize. This is effectively the “sign off” on the SOPs by the Supervisor and provides the documentation that the Supervisor is competent.

Implementation Directive

Operational Procedures for Use at BSL2+

The PBAC requires that all laboratories newly working at BSL2+ submit their Standard Operating Procedures (SOPs) while working in BSL2+ mode for review and approval prior to initiation of the BSL2+ work. These include Layout of the BSL2+ area when in BSL2+ mode, Laboratory Access, Biosecurity, PPE Required, Entry and Exit Protocols, Decontamination and Waste Handling, Housekeeping, Emergency Exit Protocols, Spill Protocols, Lab Specific protocols (experimental procedures done at BSL2+), Use of a Biological Safety Cabinet and Lab Specific Procedures for Transitioning Between BSL2+ and Other Containment Levels¹. Should there be any change to the BSL2+ SOPs for a laboratory, for example an increase in culture volume, higher titers to be used or new procedures which generate aerosols, those modified or new BSL2+ SOPs must be submitted to PBAC for review and approval before such changes are implemented.

ADDITIONAL OPERATIONAL PROCEDURES FOR USE WITH DIAGNOSTIC SAMPLES OF HIV, HEPATITIS C VIRUS AND WEST NILE VIRUS AND WITH MACAQUE OR RHESUS² MONKEY SAMPLES

These additional operational procedures are taken directly from a PHAC-generated document provided by the Pathogen Regulation Directorate. Most procedures listed are already required for work at BSL2.

1. All activities should be conducted in a Biological Safety Cabinet (BSC).
2. If no BSCs are available or if it is not possible to use a BSC, workflow and manipulations with the pathogen must be designed to minimize the spread of contamination. These must include:
 - a. Identifying dedicated work areas and equipment for use with the pathogen
 - b. The use of absorbent material to cover work surfaces
3. A solid-front gown with tight-fitting wrists must be worn when infectious materials are directly handled and must be removed after completion of work and kept by the dedicated work area.
4. Personnel must have demonstrated proficiency in microbiological practices and techniques applicable to the select pathogen.
5. Leak-proof containers must be used to transport infectious material within the laboratory.
6. Centrifugation of infectious materials must be carried out in closed containers placed in sealed safety cups or rotors that are unloaded in a BSC. If it is not possible to use a BSC, sufficient time must be allowed for aerosols to settle before safety cups or rotors are opened.
7. Pathogen-specific disinfection and decontamination procedures must be in place.
8. Infectious agents stored outside the containment zone must be kept locked in leak-proof containers. Emergency response procedures are to take into account the existence of such infectious agents outside the containment laboratory.

ADDITIONAL OPERATIONAL PROCEDURES FOR USE OF LENTIVIRAL VECTORS³

These additional operational procedures are taken directly from a PHAC-generated document provided by the Pathogen Regulation Directorate. Most procedures listed are already required for work at BSL2.

¹ Includes lab signage, lab access and lab decontamination steps

² The genus Macaque is not limited to Rhesus monkeys and therefore this directive is applicable to all species of monkey in the genus *Macaca*.

³ Lentiviral vectors to be handled using BSL2+ operational procedures are those which are described in *PBAC Implementation Directive – Risk Assessment of Lentiviral Vectors*

Implementation Directive

Operational Procedures for Use at BSL2+

1. All activities must be conducted in a Biological Safety Cabinet.
2. A solid-front gown with tight-fitting wrists must be worn when infectious materials are directly handled and must be removed after completion of work and kept by the dedicated work area.
3. Personnel must have demonstrated proficiency in microbiological practices and techniques applicable to the select pathogen.
4. Leak-proof containers must be used to transport infectious material within the laboratory.
5. Centrifugation of infectious materials must be carried out in closed containers placed in sealed safety cups or rotors that are unloaded in a BSC.
6. Pathogen-specific disinfection and decontamination procedures must be in place.
7. Infectious agents stored outside the containment zone must be kept locked in leak-proof containers. Emergency response procedures are to take into account the existence of such infectious agents outside of the containment laboratory.

ADDITIONAL OPERATIONAL PROCEDURES FOR USE WITH INFLUENZA VIRUS AND DIAGNOSTIC SAMPLES OF MYCOBACTERIUM TUBERCULOSIS

These additional operational procedures are taken directly from a PHAC-generated document provided by the Pathogen Regulation Directorate. Most procedures listed are already required for work at BSL2.

1. All activities must be conducted in a Biological Safety Cabinet.
2. A solid-front gown with tight-fitting wrists must be worn when infectious materials are directly handled and must be removed after completion of work and kept by the dedicated work area.
3. Personnel must have demonstrated proficiency in microbiological practices and techniques applicable to the select pathogen.
4. Leak-proof containers must be used to transport infectious material within the laboratory.
5. Centrifugation of infectious materials must be carried out in closed containers placed in sealed safety cups or rotors that are unloaded in a BSC.
6. Pathogen-specific disinfection and decontamination procedures must be in place.
7. Infectious agents stored outside the containment zone must be kept locked in leak-proof containers. Emergency response procedures are to take into account the existence of such infectious agents outside of the containment laboratory.

TRAINING REQUIRED FOR BSL2+

DOCUMENTATION OF TRAINING

All training must be documented⁴ and the responsibility for maintaining the training record for any worker rests with the Supervisor to satisfy legislated requirements. Templates for training records may be found on the Biosafety website under the section “SOPs, Docs, Forms & Templates” or custom templates may be created at the discretion of the Supervisor.

⁴ Hazard-specific training must be completed and documented prior to initiation of any work involving those hazards. The most convenient way for a Supervisor to maintain documentation of their worker’s training is to create a training record for each worker and themselves.

Implementation Directive

Operational Procedures for Use at BSL2+

All training documentation in the laboratory will be audited on a yearly basis by the Biosafety Auditor.

CORPORATE MATRIX

All persons are required to follow the training outlined in the corporate matrix. Depending on the training required, you may contact the FHS Safety Office (x24956; gemmelc@mcmaster.ca), EOHSS (x24352; eohss@mcmaster.ca) or the Biosafety Office (x22950; carte@mcmaster.ca). The corporate matrix is found at:

<http://www.workingatmcmaster.ca/med/document/Corporate-training-matrix-1-36.pdf>

Currently, the requirement for any biohazard work is that all persons must complete an annual update for Fire Safety, an annual update for WHMIS and Code Awareness (if located in a hospital). This is irrespective of the Faculty in which the person works.

BSL2 TRAINING

Provision of BSL2 training is the responsibility of the Biosafety Office. Maintenance of documentation of BSL2 training is the responsibility of the Supervisor. Supervisors and workers must complete specific training for work at BSL2. Information is provided online and the paperwork generated is submitted to the Biosafety Office in 1J11A. The content is found on the Biosafety website <http://www.mcmaster.ca/biosafety> under the tab marked "Training".

BSL2 training must be updated annually. This consists of the "BSL2 Update" also found on the Biosafety website. This training is to be documented in the training records which will be audited annually by the Biosafety Auditor.

LAB SPECIFIC STANDARD OPERATIONAL PROCEDURES TRAINING

Provision and documentation of lab-specific SOPs training (which includes the operational procedures while in BSL2+ mode) is the responsibility of the Supervisor. These SOPs include:

- Layout of the BSL2+ area when in BSL2+ mode
- Laboratory Access
- Biosecurity
- PPE Required
- Entry and Exit Protocols
- Decontamination and Waste Handling
- Housekeeping
- Emergency Exit Protocols
- Spill Protocols
- Lab Specific BSL2+ protocols
- Use of a Biological Safety Cabinet
- Lab Specific Procedures for Transitioning Between BSL2+ and Other Containment Levels

and shall be created and signed off by the Supervisor. Some sample SOPs and training records can be found on the Biosafety website in the section entitled "SOPs, Docs, Forms & Templates". Guidance from the Biosafety Office and the PBAC is readily available. More SOPs for equipment can be found on the FHS Safety Office website:

http://fhs.mcmaster.ca/safetyoffice/safety_equipment.html

Implementation Directive

Operational Procedures for Use at BSL2+

This training is to be documented in the training records and will be audited annually by the Biosafety Auditor.

N95 MASK TRAINING AND FIT TEST

Provision of N95 mask training and fit testing is the responsibility of either EOHSS or the FHS Safety Office. Documentation of N95 mask training and fit testing is the responsibility of the Supervisor. Supervisors and workers must be trained in and fitted for the use of an N95 respirator which is used during biohazardous spill cleanup. Information on the McMaster Respiratory Protection Programme can be found at:

<http://www.workingatmcmaster.ca/med/document/RMM-311-Respiratory-Protection-Program-1-36.pdf>

Please contact the relevant safety office to arrange for N95 respirator training and fit testing. For those persons in FHS, please contact the FHS Safety Office (x24956; gemmelc@mcmaster.ca) and for those persons not in FHS, please contact EOHSS (x24352; eohss@mcmaster.ca).

Respirator training requires an annual update by submitting a quiz to the relevant office. Fit testing is required to be done every 2 years. This training and fit testing is to be recorded in the training records and will be audited annually by the Biosafety Auditor.

SPILL CLEANUP PROCEDURES TRAINING

Provision and documentation of BSL2+ spill cleanup procedures training is the responsibility of the Supervisor. Using the guidance documents that can be found on the Biosafety website in the section entitled “SOPs, Docs, Forms & Templates”, the spill cleanup procedures shall be modified by the Supervisor to reflect the specific procedures implemented in their BSL2+ laboratory. Special attention is to be made with respect to the choice of disinfectant and its minimum contact time. Once approved by the PBAC, these BSL2+ spill cleanup SOPs are then used as the content for training in BSL2+ spill cleanup procedures. This training is to be documented in the training records and will be audited annually by the Biosafety Auditor.

REASSIGNING A LABORATORY FROM BSL2 TO BSL2+

For the laboratory which was formerly a BSL2 lab, who wishes to convert to BSL2+ requires a number of tasks to be completed:

- Updated Biohazard Utilization Protocol (BUP) for resubmission to PBAC
- BSL2+ SOPs to be generated and approved by PBAC
- BSL2+ SOP training and documentation
- N95 Training and Fit testing
- All BSL2 requirements up to date including annual lab audit

REASSIGNING A LABORATORY FROM BSL1 TO BSL2+

For the laboratory which was formerly a BSL1 lab, who wishes to convert to BSL2+ requires a number of tasks to be completed:

- Updated BUP for resubmission to PBAC
- BSL2 training

Implementation Directive

Operational Procedures for Use at BSL2+

- BSL2+ SOPs to be generated and approved by PBAC
- BSL2+ SOP training and documentation
- N95 Training and Fit testing
- All BSL2 requirements up to date including annual lab audit

REASSIGNING A LABORATORY FROM NON-BIOHAZARD WORK TO BSL2+

For the laboratory which was formerly a non-biohazard lab, who wishes to convert to BSL2+ requires a number of tasks to be completed:

- Complete BUP for submission to PBAC
- BSL2 training
- BSL2+ SOPs to be generated and approved by PBAC
- BSL2+ SOP training and documentation
- N95 Training and Fit testing
- All BSL2 requirements up to date including annual lab audit

MECHANISM TO MONITOR PID EFFECTIVENESS

- Use of BSL2+ operational procedures, #BUPs
- User feedback, qualitative quantitative

CONTACT INFORMATION FOR ASSISTANCE

Please use the following contact for assistance in training options and implementation of the above procedures.

Dr. Jen Robertson, University Biosafety Officer

- robertjv@mcmaster.ca
- X23453
- HSC 1J11A

Kristen Carrigan, Associate Biosafety Officer

Carol Carte, Research Compliance Auditor

- carte@mcmaster.ca
- X22950
- HSC 1J11A

FHS Safety Manager

- fhssso@mcmaster.ca
- X22402
- HSC1J11A

Environmental and Occupational Health Support Services (EOHSS)

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Implementation Directive

Operational Procedures for Use at BSL2+

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- X24352
- GH 304

INDEX

animal.....	3	Monkey.....	4
Biological Safety Cabinet.....	4, 5	N95	7, 8
BSC.....	4, 5	Pathogen Safety Data Sheet	3
CBSG	3	PHAC.....	3
CFIA	3	PSDS.....	3
exposure.....	3	Rhesus	4
Hepatitis C Virus	4	risk assessment.....	3
HIV	4	Spill	7
Influenza Virus.....	5	Supervisor.....	3, 5, 6, 7
LBG	3	training	5, 6, 7, 8
Lentiviral Vectors.....	4	West Nile Virus	4
Macque.....	4		