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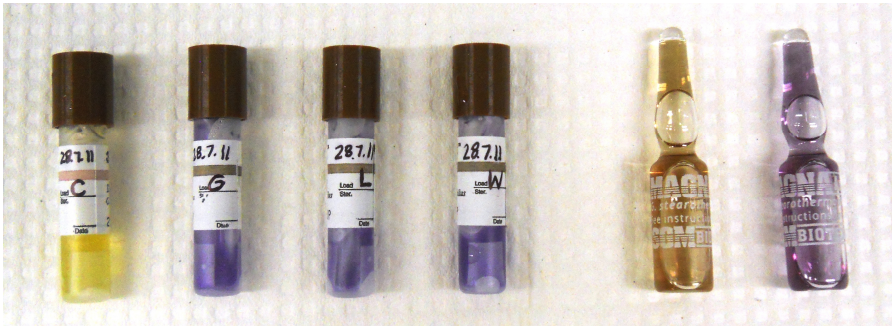
Great Lakes Forestry Centre
Insect Production Services

STANDARD OPERATING PROCEDURE

Number: IPS/032/003

Bio-Safety Officer Responsibilities



Effective Date: 4 September 2014

Canada

TITLE: Bio-Safety Officer Responsibilities

APPROVING OFFICIAL:

DD/MM/YY

Manager, Insect Production Services (IPS) _____ ___/___/___

SIGNIFICANT CHANGES FROM PREVIOUS VERSION:

-This Standard Operating Procedure (SOP) has been modified to include a procedure for autoclaving intact log bolts.
-An annual validation procedure has been added for intact log bolts.
-A new form has been added.

1.0 INTRODUCTION

1.1 Purpose

This SOP has been established to ensure that responsibilities of the BSO are clearly defined and are conducted timely, consistently and in support of maintaining the established IPS quality management system.

1.2 Scope

This SOP shall be followed by the BSO in the performance of her/his duties. The IPS manager shall provide back-up for the BSO and follow the duties described herein.

1.3 Definitions

Biological Safety Cabinet (BSC) – A class 2 containment cabinet designed for both worker and sample protection; room air is drawn into the front of the unit; the unit is designed in such a way that room air is HEPA filtered before blowing over the work area; air-borne hazardous particles coming off samples in the work area are pulled away from the worker and the air is vented back into the room after HEPA filtration; this type of unit is not suitable for worker protection from chemical fumes.

Bio-Safety Manual – A manual containing only those IPS SOPs that relate specifically to the IQ facility.

Bio-Safety Officer (BSO) – A member of IPS who has supervisory authority over the daily operation of the IQ facility and who provides technical/research support to users of the facility.

Controlled Copy – A copy of an SOP distributed to select GLFC personnel having a unique copy number and dated signature of the IPS manager. Controlled copies are intended to ensure that GLFC personnel follow the most recent version of the SOP.

Delta System – Hardware/software system used by GLFC engineering personnel to program, monitor and track environmental conditions within the facility and to provide an alarm when tolerance limits are exceeded.

Effective Date – The date from which the procedures given in an SOP are to be implemented.

Great Lakes Forestry Centre (GLFC) – One of five Canadian Forest Service (CFS) research facilities in Canada.

Insect Production Services (IPS) – A GLFC work team consisting of the Insect Production Unit (IPU), the Quality Control Unit (QCU) and insect quarantine (IQ) personnel who perform insect rearing, quality control and quarantine activities in support of forest pest research activities internal and external to the CFS.

Insect Production Services Manager – The individual who has overall responsibility for activities of the IPS team.

Insect Production Unit (IPU) – A work unit of IPS consisting of personnel who perform insect rearing, diet making and methods development activities at GLFC.

Insect Quarantine (IQ) – A general-use facility under the control of IPS used for rearing exotic forest insects and conducting associated research activities.

Insectary – A multi-species rearing facility under the control of IPS used exclusively by the IPU for maintaining insect colonies and preparing artificial diets.

Invasive Insects – Insects that adversely affect the habitats and bioregions they invade economically, environmentally, and/or ecologically and have become newly established in that area. They can be domestic (i.e., native to Canada) or introduced (i.e., exotic, non-indigenous, alien).

NIST Traceable Thermometer/Hygrometer – A thermometer/hygrometer with a manufacturer's certificate of accuracy verifying that it was calibrated and tested against standards traceable to the National Institute of Standards and Technology (NIST).

Principal Investigator (PI) - An individual internal or external to GLFC who has the responsibility for the overall conduct of the phase(s) of a study performed within the IQ facility.

Quality Control Lab – An analytical laboratory under the control of IPS used by the QCU for monitoring production, process and product control for all IPU insect colonies, and for developing new QC methods and procedures.

Quality Control Unit (QCU) – A work unit of IPS consisting of personnel who conduct routine production, process and product control testing and develop new QC methodology in support of IPU activities.

Standard Operating Procedures (SOPs) – Directives describing routine administrative or technical procedures conducted by IPS personnel or users of the IQ facility.

Voucher Specimen – A representative insect sample obtained from a batch of exotic insects brought to GLFC under a *Permit to Import* or a *Movement Certificate* and provided to the BSO for archiving.

1.4 Safety

1.4.1 The BSO must exercise health precautions to minimize risk to her/himself and to co-workers.
1.4.2 The BSO shall have access to, and be familiar with, the MSDS for all chemicals used in the IQ facility.
1.4.3 The BSO shall maintain a chemical/hazardous substance inventory for the IQ facility following current GLFC policies.

1.5 Materials

1.5.1 IPS Form Number 0108/005 (*Weekly Checklist for IQ Facility*, Appendix 1).
1.5.2 IPS Form Number 0109/005 (*Monthly Checklist for IQ Facility*, Appendix 2).
1.5.3 IPS Form Number 0110/002 (*IQ Training Log*, Appendix 3).
1.5.4 IPS Form Number 0111/001 (*IQ User Access Level,* Appendix 4).
1.5.5 IPS Form Number 0081/002 (*Equipment Logbook,* Appendix 5).
1.5.6 IPS Form Number 0082/001 (*Maintenance and Repair Log,* Appendix 6).
1.5.7 IPS Form Number 0083/001 (*Cleaning log,* Appendix 7).
1.5.8 IPS Form Number 0084/001 (*Calibration Log,* Appendix 8).
1.5.9 IPS Form Number 0112/002 (*IQ Insect Receipt Log,* Appendix 9).
1.5.10 IPS Form Number 0113/001 (*IQ Insect Transfer Log* Appendix 10).
1.5.11 IPS Form Number 0114/001 (*IQ Autoclave Log*, Appendix 11).
1.5.12 Insect Quarantine Autoclave Settings.
1.5.13 IPS Form Number 0115/002 (*IQ Facility Inspection Checklist*, Appendix 13).
1.5.14 IPS Form Number 0116/002 (*IQ BSC Flow Rates,* Appendix 14).
1.5.15 Validation of Autoclave Sterilization using Biological Indicators (Appendix 15).
1.5.16 IPS Form Number 0142/002 (Air Pressure Monitor Validation, Appendix 16).
1.5.17 IPS Form Number 0156/001 (Autoclave Validation for Whole Log Bolts, Appendix 20).

2.0 PROCEDURES

2.1 Approving Requests to Use IQ Facility

2.1.1 Upon receipt of a written request for using the IQ facility (i.e., refer to the current version of IPS Form Number 0103; *Request to Use IQ Facility*), the BSO shall review the form and may request a meeting/discussion with the PI to modify the request to better accommodate multiple users of the facility. The BSO shall provide specific instructions for pest-associated hazards to prevent the accidental release of pests. Agreed changes shall be documented on the form by the BSO. Approval shall be granted by dated signature of the BSO only if: 1) criteria for scheduling facility use are met (refer to the current version of SOP Number IPS/030, *IQ Facility Access Authorization*), and 2) upon determination that the IQ facility is currently approved by the CFIA for receiving the requested insect species from the specified source (refer to CFIA directive D-12-03). If the BSO is in agreement that scheduling criteria are met, but not CFIA approval, she/he shall apply for written authorization from the CFIA as per the procedure identified in D-12-03.

2.1.2 The BSO may approve entry of non-exotic invasive species (e.g., mountain pine beetle) into the IQ facility.

2.1.3 When space or conflicting activities within the facility become problematic, the IPS manager will assign priority. Disagreements will be forwarded by the IPS manager to the Director, Integrated Pest Management, for resolution.

2.1.4 The BSO shall provide a copy of the approved request form to the PI and shall maintain the original with facility records.

2.1.5 The BSO shall try to accommodate changes to the original request upon notification by the PI (or representative) during the conduct of the research project.

2.1.6 The BSO may revoke access privileges at any time.

2.2 Training

2.2.1 Upon approval of a written request for using the IQ facility (i.e., current version of IPS Form Number 0103. *Request to Use IQ Facility*), the BSO shall compare the names of identified potential users with the *IQ Training Log* (refer to 2.2.4) to determine the need for provision of training in new or revised SOPs.

2.2.2 The BSO shall provide *Bio-Safety Manual* training as follows:

a) Upon receipt of a signed *IQ Facility User Agreement* (i.e., refer to the current version of IPS Form Number 0104), the BSO shall meet with the potential facility user(s) and provide a detailed overview of the contents of the *Bio-Safety Manual* through presentation of a PowerPoint slide-show or by reading aloud each applicable SOP, provide verbal clarification where necessary and provide explanations of the intent of every procedure specified.

b) The BSO shall request the user to review the *CFIA Containment Standards for Handling Plant Pests* as well as applicable SOPs in the

Bio-Safety Manual (located on the GLFC intranet) and instruct them to read the material prior to commencing work in the IQ facility.

2.2.3 Whenever new or revised SOPs have been approved for use, the BSO shall inform all applicable/current users of the facility and provide/document training as soon as possible.

2.2.4 The BSO shall maintain a record of all training that she/he provides to users of the IQ facility using IPS Form Number 0110/002 (*IQ Training Log*, Appendix 3). A separate form shall be initiated for each facility user. The BSO shall maintain a historical file of these records.

2.2.5 The BSO shall provide new users with an on-site demonstration of access procedures (including when, where and how to don/doff lab wear), followed by a tour of the facility whereby she/he describes the physical operation and design of the facility. Prior users shall be provided with a demonstration of any procedures that have been revised since their last use of the facility.

2.2.6 Demonstration of the location of the following safety items shall be provided to new users of the facility:

a) fire extinguishers
b) telephones (including emergency contact numbers)
c) emergency exits
d) first aid kit
e) MSDS
f) eyewash stations
g) emergency shower
h) chemical spill kit
i) biological spill kit

2.2.7 The BSO shall monitor users (new and prior) closely as they perform procedures identified in the SOPs for the conduct of their research program in the IQ facility. New users must be accompanied by the BSO at all times (except as stated in 2.3.9). The level of monitoring required will be determined by the BSO on a case-by-case basis and will likely diminish over time.

2.2.8 Facility maintenance personnel shall be trained by the BSO (or IPS manager) in the use of applicable SOPs (or pertinent sections of SOPs) before being allowed to enter or work in the facility. Maintenance personnel are required to read applicable portions of the Bio-Safety Manual and to sign the IQ Facility User Agreement (IPS Form Number 0104). Training shall be documented by the BSO (or IPS manager, if applicable) as specified in 2.2.4.

2.2.9 The BSO shall train facility users in the use of the biological spill kit.

2.3 Assigning Level of Access

2.3.1 The BSO shall designate IQ users with one of the following levels of access for the facility, based on her/his assessment of the user's qualifications/experience in IPS IQ procedures:
   a) *Newcomer* - those individuals having little or no experience in the IPS IQ facility.
   b) *Restricted Access* - those individuals having limited experience.
   c) *Full Access* - those individuals having significant experience.

2.3.2 The BSO shall accompany and monitor the activities of *Newcomers* at all times within the IQ facility (except as stated in 2.3.9).

2.3.3 Individuals designated as having *Restricted Access* shall be escorted into the facility each time they require entry. The BSO shall monitor their activities as needed (i.e., they may be left unattended for short periods of time).

2.3.4 Individuals designated as having *Full Access* shall be permitted un-restricted access to the facility and the BSO may conduct sporadic monitoring of their activities. These individuals shall have their swipe card re-programmed for entry into applicable portions of the IQ facility as specified in 2.33.

2.3.5 Based on the assessment of the BSO, facility users may progress through the various levels of access.

2.3.6 Facility users must be trained in IPS IQ procedures (refer to 2.2) before being assigned any level of access.

2.3.7 The BSO shall document facility user names, level of access and date of competence for each level on IPS Form Number 0111/001 (*IQ User Access Level*, Appendix 4). This form shall be maintained with facility records.

2.3.8 The date when access is terminated (either at the end of the research program or when access privileges are revoked) for any facility user shall be documented by the BSO on the *IQ User Access Level* form. Swipe card access will be terminated as specified in 2.33. Subsequent access privileges may be reinstated as specified in 2.33.

2.3.9 The BSO may assign any facility user previously designated as having *Full Access* to monitor/accompany the activities of those having *Newcomer* or *Restricted Access*.

2.4 Visitors

2.4.1 Tours of the IQ facility shall be kept to a minimum to reduce the entry of contaminants and to reduce the risk of escape of controlled insects.

2.4.2 The BSO (or IPS manager) shall escort and monitor visitors at all times within the IQ facility. Upon request, the BSO may approve a PI (only those having *Full Access* privileges) to provide a tour.

2.4.3 The BSO (or IPS manager/PI as specified in 2.4.2) shall provide visitors with basic training on entry and exit procedures and shall provide them with the garments specified in 2.8.2.

2.4.4 Prospective facility users shall be provided a tour, upon request, to determine whether or not the facility will meet their needs.

2.4.5 Regulatory inspectors shall be allowed access to the facility without prior notice. The BSO (or IPS manager) shall provide basic instruction on facility entry and exit procedures. Inspectors shall be provided with the garments specified in 2.8.2. Inspectors shall be escorted at all times.

2.5 BSO Contact Information

2.5.1 The BSO shall ensure that signage is installed on facility entry doors indicating the level of containment (e.g., PPC-2A) and contact information for the BSO and IPS manager during and after normal working hours.

2.5.2 Each telephone or telephone docking station in the IQ facility shall be posted with the contact information for both the BSO and the IPS manager during and after normal work hours.

2.5.3 The BSO shall ensure that each environmental chamber/room in the IQ facility is posted with her/his contact information during and after normal work hours. The BSO will normally be identified as the primary contact and the user of the unit identified as the alternate contact.

2.6 Maintaining Facility Access Logs

2.6.1 The BSO shall post an *Insect Quarantine Access Log* (refer to the current version of IPS Form Number 0106) at the door to each anteroom and replace it at least monthly. Completed forms shall be maintained by the BSO with facility records.

2.7 Breach in Security/Access

2.7.1 The BSO shall immediately notify the IPS manager when any breach in the security/access of the IQ facility becomes evident. The BSO and IPS manager shall take corrective action to ensure the integrity of the containment barrier and to revise procedures to prevent future breaches. Breaches shall be documented on an *Insect Quarantine Incident Report* as specified in section 2.18.

2.8 Provision of Equipment and Supplies

2.8.1 The BSO shall ensure that the IQ facility is stocked with basic laboratory equipment, instruments and supplies as specified in the current version of SOP Number IPS/033 (*Conducting Research in Insect Quarantine*).

2.8.2 The BSO shall ensure that sufficient quantities and sizes of lab wear are always available in the change area for facility users, visitors and maintenance personnel. At the start of each research program, lab wear of the appropriate size shall be labeled with the name of potential facility

users and hung in the applicable lockers and areas having heightened bio-safety requirements. A sufficient number of lab wear shall be labeled for visitors and hung in the applicable lockers. Lab wear shall be labeled with the names of maintenance personnel and shall be stored in the applicable locker. The BSO shall ensure that a laundry hamper is available in the change area to store soiled lab coats.

2.8.3 The BSO is responsible for laundering lab coats as specified in 2.27.1f.

2.9 Maintenance and Repair of Facility and Equipment

2.9.1 The BSO is responsible for ensuring IQ equipment and facilities are maintained in good working order and that the biological security envelope is always maintained.

2.9.2 Requests for *Work Orders* shall be completed and submitted by the BSO or IPS manager (i.e., not by facility users). Copies of *Work Orders* shall be maintained with facility records. The BSO shall follow up on all maintenance activities to ensure that the work is completed as required.

2.9.3 Any maintenance, repair, calibration, or major cleaning action performed on IQ equipment or environmental chambers/rooms, either by the BSO or by maintenance personnel, shall be documented by the BSO on the applicable form in the equipment logbook (refer to 2.10) i.e., actions performed by maintenance personnel and documented on IPS Form Number 0141 shall be transcribed by the BSO into the applicable logbook.

2.9.4 The BSO shall ensure that defective equipment is labeled as “out of service” until such time that it is repaired, replaced or discarded.

2.9.5 Upon request by maintenance personnel to open mechanical access panels in walls or ceilings of the IQ facility, or to breach the containment barrier in any way (e.g., drill holes through the barrier), the BSO shall ensure that facility users in that area are not handling insects at the required time (i.e., halt all work), the immediate area is visually examined for free insects, and the duration of the breach is kept to a minimum. The BSO shall be on-site for the duration of the breach in order to monitor activities. Upon completion of the work, the BSO shall verify the integrity of the containment barrier by smoke pencil or other visual aid and include relevant documentation in the next facility recertification submission. The BSO shall consult the CFIA prior to commencing extensive changes to the IQ facility.

2.10 Equipment Logbooks

2.10.1 The BSO shall create and maintain a specific logbook (3-ring binder) for each piece of equipment and environmental chamber in the IQ facility.

2.10.2 Logbooks shall be located in the QC lab to facilitate easy access by the BSO. Records shall be made available to facility users upon request.

2.10.3 Each logbook shall be labeled on the front cover and/or spine to identify, by simple name or number, the specific device to which it pertains.

2.10.4 The first page of each logbook shall be a title page (IPS Form Number 0081/002, *Equipment Logbook*, Appendix 5) that identifies the specific name or number of the device to which it pertains and provides additional information including the type of device, manufacturer and serial number.

2.10.5 The remainder of the logbook shall be divided into sections applicable to the device, including:

(a) *Maintenance and Repair Log* (IPS Form Number 0082/001, Appendix 6)
(b) *Cleaning log* (IPS Form Number 0083/001, Appendix 7)
(c) *Calibration Log* (IPS Form Number 0084/001, Appendix 8)
(d) References (this section shall include any additional information such as certificates of calibration, operator manuals, etc.)

2.11 Environmental Chambers and Rooms

2.11.1 The BSO is responsible for the maintenance, operation, sanitation and historical tracking of each environmental chamber/room.

2.11.2 The BSO shall document required parameters for an environmental chamber (as determined by the facility user on the *Request to Use IQ Facility)* on the *Set Parameters for Environmental Chambers/Rooms* form (IPS Form Number 0005/002, Appendix 18) and attach it to the front of the unit. Expired forms shall be maintained in the equipment logbook for the associated unit.

2.12 Maintaining IQ Computer Workstation

2.12.1 The BSO shall ensure the availability of a computer work station (including laptop, docking station, monitor and scanner) for facility users to scan datasheets for immediate availability outside of the containment barrier, to access the *Bio-Safety Manual*, or to record/store data electronically if the user wishes to do so. Facility users shall be permitted to take the laptop to their assigned research module.

2.12.2 Electronic records for the IQ facility shall be stored by the BSO on the QC network drive, which is routinely backed-up by the GLFC IT department. Hard drives on computers in the IQ and QC facilities shall only be used for temporary storage of files not essential to daily operations or for maintenance of historical records.

2.13 Storage

2.13.1 The BSO shall approve all materials and supplies for entry into the IQ facility.

2.13.2 Bulk quantities of materials and supplies (e.g., rearing containers, lids, etc.) destined for use in the IQ facility shall be stored where they are protected from deterioration and contamination (i.e., they are not be stored in other GLFC laboratories/facilities where they may be exposed to pathogens).

2.13.3 The BSO shall designate storage locations for smaller quantities of materials and supplies within the IQ facility. These items shall be kept in enclosed cupboards, shelves or bins, where feasible, and shall be stored in a manner that will maintain their cleanliness and the cleanliness of the facility.

2.13.4 The BSO shall designate locations within the IQ facility where instruments/equipment are to be used and/or stored.

2.13.5 Maintenance personnel may store a minimal inventory of tools, equipment and spare parts in the IQ facility janitor room, or any other space designated by the BSO.

2.14 Movement of Pests

2.14.1 Import and/or movement of live exotic or domestic invasive insects into or out of the IQ facility shall be conducted as specified in the current version of SOP Number IPS/031 (*Movement of Exotic Forest Insects*), including the maintenance of files for copies of applications, permits and certificates.

2.15 Control of Materials and Supplies Entering Facility

2.15.1 The BSO shall monitor users of the facility to ensure that only those materials and supplies previously identified by the PI (refer to the current version of SOP Number IPS/030, *IQ Facility Authorization*) are brought into the facility and have been removed (where feasible) from their original packaging boxes outside of the IQ facility access door. The BSO may approve additional items upon request.

2.15.2 Upon notification of the arrival of live exotic or domestic invasive insects to the IQ facility, the BSO shall:

a) Examine the packaging/containers to ensure that containment has been maintained. If containment has been breached, determine if insects have escaped by comparing numbers remaining with numbers shipped (if available). If insects have escaped (or if unknown), report and document the occurrence as specified in section 2.18.

b) Document the arrival/receipt of insects on the *IQ Insect Receipt Log* (IPS Form Number 0112/002, Appendix 9) and maintain with IQ records.

c) Notify the applicable PI and/or their support personnel, if required.

2.15.3 The BSO shall ensure that domestic invasives (e.g., mountain pine beetle) approved for entry into the IQ facility are handled as though they are

exotic. i.e., procedures specified in the *Bio-Safety Manual* apply to any insect species brought into the IQ facility.

2.15.4 The BSO shall examine plants and plant materials to ensure that they are relatively free of insects, fungi, etc. before being brought into the facility.

2.15.5 The BSO shall ensure that soils and/or peat moss (excluding potted plants) have been autoclaved (refer to the current version of SOP Number IPS/033, *Conducting Research in Insect Quarantine*) prior to entering the IQ facility even when the material has been advertised as already being sterilized.

2.15.6 The BSO shall ensure that equipment and instruments entering the facility have been autoclaved or sterilized using a bleach working solution (refer to 2.34.1, 10 min. contact time), where feasible.

2.15.7 The BSO shall ensure that paperwork entering the facility from offices or administrative areas in the building is kept to a minimum. She/he should recommend to facility users that they make required documentation available on the GLFC computer system that can be accessed using the IQ computer.

2.15.8 The BSO shall monitor facility maintenance personnel to ensure that they limit the tools, equipment and parts (beyond those specified in 2.13.5) to only those items necessary for the task at hand.

2.16 Archiving Voucher Specimens

2.16.1 Upon receipt of voucher specimens of exotic or domestic invasive insects from facility users, the BSO shall:

a) Document the date of receipt of archival samples on the *IQ Insect Receipt Log* (IPS Form Number 0112/002, Appendix 9).
b) Ensure that samples are stored in sealed vials containing 70% ethanol (archived samples should be checked periodically and topped-up as needed).
c) Ensure that samples are labeled with the name of the insect species and movement certificate/import permit number.
d) Maintain samples for easy retrieval.

2.16.2 The BSO shall confirm the identity of archival samples, either independently or with the assistance of other qualified personnel, and shall document the date of confirmation on the *IQ Insect Receipt Log* (IPS Form Number 0112/002, Appendix 9).

2.17 Bio-safety Containment Procedures

2.17.1 The BSO shall maintain the physical biological containment barrier of the facility, including all items listed on IPS Form Number 0115/002 (*IQ Facility Inspection Checklist*, Appendix 13). Formal inspection/documentation shall be performed as specified in 2.30.1,

however the BSO shall be cognizant of maintaining the physical containment barrier on a daily basis.

2.17.2 Upon becoming aware that a break in the IQ containment barrier (e.g., broken door seal) has occurred, the BSO shall take the following corrective actions:

a) If possible, temporarily seal the break in the barrier using readily available materials (e.g., tape).
b) Instruct users of the affected area to cease insect handling operations until repairs have been made.
c) Contact facility maintenance personnel to make the appropriate permanent repair.
d) If timely repair cannot be made, remove all insects from the affected area but retain within the quarantine zone.
e) Post the affected area as being off limits.
f) Document and report incidents as specified in *2.18*.

2.17.3 The BSO shall ensure that any item that is to be removed from the facility has been sterilized and/or closely examined as specified in 2.22.

2.17.4 The BSO shall ensure that facility users comply with requirements for handling/rearing exotic insects as specified by the CFIA on the movement certificate or import permit.

2.17.5 Upon arrival of insects at the IQ facility, the BSO shall inspect materials as specified in 2.15.2 and 2.15.3.

2.17.6 Upon arrival of insects at the IQ facility, the BSO shall instruct facility users on appropriate procedures for opening packages/containers, which are to:

a) Ensure that the door to the room is closed and the air pressure monitor is not in alarm (i.e., inward directional air flow is maintained). Post sign on door indicating “do not enter, transfer in process”.
b) Examine packages/containers to ensure that containment has been maintained as specified in 2.15.2a.
c) Open small packages/containers within a sleeved cage and/or BSC.
d) Open large packages/containers in a room where there are no other insect handling operations being performed.
e) Open packages slowly; where feasible, use forceps to transfer insects and count insects before and after the transfer.

2.17.7 The BSO shall ensure that shipping packages/containers are autoclaved/sterilized immediately upon removal of the contents. Facility users shall be monitored to ensure that re-useable containers (e.g., Rubbermaid bins) are sterilized as specified in 2.20.5. The method and date of sterilization shall be documented on the IQ Insect Receipt Log (IPS Form Number 0112/002, Appendix 9).

2.17.8 The BSO shall ensure that insect handling and experimentation is conducted only in areas previously authorized by the BSO (refer to the current version of SOP Number IPS/030, *IQ Facility Access Authorization*).

2.17.9 The BSO shall monitor facility users to ensure that their experimental protocols and data sheets for use in the facility include methods to account for the whereabouts of each and every insect during its entire life cycle. The BSO shall hold users of the facility accountable for being excruciatingly stringent in correlation of actual numbers of insects with those identified/expected on the data sheets. The BSO shall routinely review data sheets for confirmation of numbers since it is unacceptable to have missing insects.

2.17.10 The BSO shall ensure that users do not remove data sheets from the facility until the rearing and/or the experiment is complete and the facility is sufficiently sanitized. When required sooner, datasheets may be scanned and saved to a common/personal drive where they can be retrieved by the user from outside of the facility.

2.17.11 Upon becoming aware of an incident whereby there is an actual or potential escape or release of insects from the facility, the BSO shall take immediate action to prevent the situation from escalating, which is to:

a) Place a patch on broken holding cage, if applicable, and arrange for permanent repair when time permits.
b) Instruct users of the affected area to cease insect handling operations in the area until free insects have been collected.
c) Close the door to the affected area and post the are as being off limits.
d) Collect all of the free insects using applicable collection devices (e.g., forceps, insect nets, etc.), or render non-viable (e.g., sticky traps).
e) Count the number of insects collected to ensure that all are accounted for.
f) Document and report the occurrence as specified in section 2.18.

2.17.12 The BSO shall ensure that all materials to be discarded are placed in garbage containers lined with autoclave bags. Living insects shall be killed by either of the following methods before being discarded:

a) place insects in an escape-proof vented container and autoclave at 121°C for 30 minutes, or
b) place insects in a vial containing either methanol or ethanol (minimum 70%) for at least 24 hours.

2.17.13 The BSO shall ensure that log bolts are sterilized and disposed using either of the following methods:

a) Autoclaving split wood:
    i) Autoclave log bolts for 60 minutes (include a steam indicator strip) and allow to cool (Note: this first of two autoclave cycles should kill all living organisms including fungal contamination and insects, except perhaps any insects that may have penetrated to the core).
    ii) Cut log bolts to a maximum length of 20” and diameter of 12” using the electric chain saw (when log bolts exceed these specifications, the BSO shall insist that the facility user responsible cut them to size); log bolts may stored in sealed bins and held in the walk-in cold room until subsequent splitting and autoclaving).

iii) Split to kindling size (i.e., sufficiently small such that steam will not need to penetrate more than 1'' during subsequent autoclaving) using the electric log splitter (Note: any insects that are found shall be removed and killed by placing in 70% ethanol for at least 24 hours; when there are large quantities of material to be split, the BSO shall obtain assistance of the individual responsible for generating the waste).

iv) Autoclave split wood for 60 minutes (include a steam indicator strip).

v) Once cool enough to handle, remove from the facility using the autoclave door on the outside of the quarantine envelope (i.e., autoclave cleanout room AA105) and dispose with regular waste.

b) Autoclaving intact log bolts:

i) Ensure that log bolts are not larger than 10" in diameter (this is the diameter at which the annual validation procedure is to be conducted) and 36" in length (this is the maximum length that can be accommodated in our autoclave); when necessary, use the electric chain saw or hand saw to cut the log bolts to the required size.

ii) Autoclave the log bolts (and steam indicator strip) for three hours (pre-vac cycle) at 121°C (plus an additional 5 min dry time to reduce moisture in the surrounding work room after autoclaving). This cycle will take 3hr 26 min to complete (including evacuation of the chamber).

iii) Allow the log bolts to remain in the chamber (with the door sealed) for an additional 60 minutes to allow the heat to penetrate deeper (total time in the autoclave is 4hr 26min).

iv) Log bolts may be discarded after an additional 60 minutes of standing time either on the floor (room AA105) or within the chamber (i.e., 5hr 26min after the initiation of the autoclave cycle).

v) Dispose with regular waste.

2.17.14 The BSO shall ensure that sticky traps are positioned in each anteroom as well as strategically throughout the facility and are replaced as needed.

2.17.15 The BSO shall ensure that a black-light trap is positioned in each anteroom and the bulb is replaced as needed.

2.17.16 The BSO shall ensure that procedures specified in 2.22 are followed for the removal of any item from the facility.

2.17.17 The BSO shall ensure that procedures specified in 2.19 are followed when unintentionally introduced organisms are found by facility users during the conduct of their rearing/experimentation.

2.17.18 Upon approval of IPS Form Number 0103 (*Request to Use IQ Facility*), the BSO must determine whether or not heightened bio-security requirements are necessary, and to which part(s) of the facility these requirements apply. The BSO may consult the CFIA for assistance. For example, when a researcher will be working with a very small insect (e.g.,

mountain pine beetle) in one of the research modules, additional lab wear (i.e., bunny suits, shoe covers and beard covers, if applicable) must be worn. The BSO must:

a) Discuss the heightened bio-security requirements with applicable personnel.
b) Post notices in the change rooms and at each applicable module indicating which part(s) of the facility require additional protective lab wear.
c) Ensure that the researcher(s) and maintenance personnel comply with lab wear requirements.
d) Ensure that all waste coming from these restricted areas is placed in sealed containers and taken directly to the autoclave for immediate sterilization.

2.17.19 The BSO shall ensure that the entry door to each research module is posted with signage indicating the nature of the plant pest/organisms contained within.

2.17.20 The BSO shall take corrective action whenever a differential air pressure monitor alarm is triggered. If an alarm is triggered due to a door being held open too long, the BSO shall provide applicable instruction to the facility user. If there is a mechanical breakdown of the air supply/return system thereby causing an alarm, or if the wall-mounted monitor is faulty, the BSO shall:

a) Instruct users of the affected area to cease insect handling operations until repairs have been made; when air pressure to the whole containment zone is affected, work shall cease throughout the IQ facility.
b) Contact facility maintenance personnel to make the repair.
c) If timely repairs cannot be made, remove all insects from the affected area but retain within the quarantine zone.
d) Post the affected area as being off limits.

2.17.21 The BSO shall take corrective action whenever damaged insect screens are found on air supply or return ducts, which is to:

a) Immediately seal the duct opening using a nearby blast gate.
b) Instruct users of the affected area to cease insect handling operations until repairs have been made.
c) Contact facility maintenance personnel to make the repair.
d) If timely repairs cannot be made, remove all insects from the affected area but retain within the quarantine zone.
e) Post the area as being off limits.

2.18 Incident Reporting

2.18.1 Facility users are required to immediately report to the BSO any incidents that occur in the IQ facility, or during transport, resulting in actual or potential escape of insects. Serious breaches are first reported verbally to

the BSO who shall determine corrective action and notify appropriate authorities. The BSO shall ensure that the facility user documents the incident on an *Insect Quarantine Incident Report* (refer to the current version IPS Form Number 0107) in a timely manner and provides the completed form to the BSO for facility records and for dissemination to the CFIA, if required.

2.18.2 If incidents are discovered by the BSO, she/he shall document the occurrence and corrective action on the *Insect Quarantine Incident Report* (refer to the current version of IPS Form Number 0107).

2.18.3 The BSO shall determine the effectiveness of corrective actions taken prior to approving the *Insect Quarantine Incident Report* by means of her/his dated signature.

2.18.4 When deemed necessary by the BSO, she/he shall investigate the root cause of an incident and implement revisions to SOPs and/or applicable training of personnel.

2.18.5 The BSO shall maintain *Insect Quarantine Incident Reports* with facility records.

2.19 Unintentionally Introduced Organisms

2.19.1 The BSO shall ensure that facility users immediately render unintentionally introduced exotic organisms (e.g., other insects, parasitoids, hyper-parasitoids, pathogens, nematodes, etc. found during the conduct of rearing/experimentation with regulated materials imported from another country) non-viable, either by autoclaving or placing in 70% ethanol for at least 24 hours.

2.19.2 The BSO shall obtain prior authorization and bio-safety requirements from the CFIA upon notification from facility users that they intend to maintain unintentionally introduced exotic insects or nematodes within the IQ facility, or to send pathogens to a level 3 facility for further experimentation.

2.19.3 Upon detection of unintentionally introduced exotic organisms, the BSO shall determine the need for decontamination of the facility and ensure that these actions are performed.

2.19.4 The BSO shall solicit advice from the CFIA and/or the scientific community, as required.

2.20 Sanitation and Autoclaving

2.20.1 The BSO shall ensure that users of the facility:

a) Keep it meticulously clean and free of clutter.
b) Clean work areas (e.g., bench tops) after each use by spraying with the provided bleach working solution (refer to 2.34.1) and allowing 10 minutes of contact time before wiping with sterile paper towel.

Surfaces can be sprayed with Windex and wiped with sterile paper towel to remove residue left by the cleaning solution.

c) Clean floors of their assigned work areas (including reach-in and walk-in chambers) whenever they become visibly soiled. Floors shall not normally be swept or dry mopped. They shall be vacuumed using the facility central vacuum cleaning system.
d) Handle materials in a manner that minimizes dispersion of particulates through the air. The BSC shall be used when there is risk of particulates becoming air-borne (e.g., dismantling cages or chambers with fungal spores).
e) Maintain a garbage bag (i.e., autoclave bag) within the rear part of the chamber when working in the BSC. Do not discard materials in containers outside of the cabinet. Avoid movement of materials or excessive movement of hands and arms through the front access opening during use. When personnel must enter or exit the cabinet, do so from straight on and allow the cabinet to stabilize before resuming work.
f) Clean the interior of the BSC after each session using the method specified in 2.20.1b. (The bench-top access panel of the BSC shall be removed and cavity below shall be cleaned on a weekly basis by the BSO).
g) Clean up spillage in environmental chambers as it occurs by collecting all insects (or rendering them non-viable), accounting for all insects, autoclaving waste, cleaning up debris using the central vacuum system and sanitizing the unit using the provided bleach working solution (refer to 2.34.1).
h) Always position screens in the sink drains.
i) Maintain order of equipment and supplies.

2.20.2 The BSO shall perform and document routine daily, weekly, monthly and annual cleaning/sanitation actions as specified in 2.26 through 2.29.

2.20.3 The BSO shall ensure that cleaning supplies are readily available to facility users, including:

a) bleach working solution (refer to 2.34.1), prepared daily
b) autoclaved paper towel
c) vacuum hose and wand
d) scouring pads

2.20.4 The BSO shall ensure that all garbage pails are lined with autoclave bags and are replaced as needed.

2.20.5 The BSO shall ensure that any item that is to be removed from the facility is autoclaved whenever possible. Items that are not autoclavable shall be cleaned with hot soapy water followed by sanitation with the bleach working solution (refer to 2.34.1) and visual inspection before leaving the facility. Items that can not be autoclaved or cleaned with the bleach solution shall be meticulously inspected before being removed from the facility.

2.20.6 The BSO shall conduct all autoclaving of materials that are to be removed from the facility. Required autoclave settings for common materials are identified on the table in Appendix 12; standard loads are described in Appendices 15 and 19. Refer to the operator manual for settings to be used with other materials and/or volumes. A biological indicator shall be included with all non-standard loads and the materials shall not be removed from the facility until validated as being sterile. The lot number of the biological test indicator and the results for the positive control and test indicator shall be recorded in the description of materials on the IQ Autoclave Log.

2.20.7 Waste materials may be left in sealed autoclave bags within the sealed autoclave chamber or in the cold room until it is convenient for the BSO to run the autoclave. Autoclave bags and containers are not to be overfilled. Prior to autoclaving, the BSO shall loosen the bag closures so that sufficient steam will be able to penetrate all areas of the autoclave bag.

2.20.8 The BSO shall ensure that log bolts are sterilized and disposed as specified in 2.17.13.

2.20.9 The BSO shall ensure that all autoclaving is conducted with a steam indicator test strip/tape enclosed within the chamber (i.e., within the deepest part of the load) to give a visual indication that the contents passed through a steam sterilization cycle. The BSO shall initial the strip chart recorder on the autoclave for each cycle. When applicable, the BSO shall conduct a visual inspection of materials following an autoclave cycle to ensure that all insects were rendered non-viable.

2.20.10 All autoclaved materials destined for disposal shall be removed from the chamber door on the outside of the quarantine barrier (i.e., autoclave cleanout room AA105).

2.20.11 Every cycle of the autoclave shall be documented on IPS Form Number 0114/001 (*IQ Autoclave Log*, Appendix 11) and shall be maintained in a binder within the IQ facility. Records shall include:

a) date
b) cycle # (transcribed from the autoclave strip chart recorder)
c) description of material autoclaved (e.g., waste, packaging materials, etc.)
d) test strip indicator (i.e., salvaged from chamber and attached to form)
e) initials

2.20.12 The BSO shall validate autoclave performance against the standard test loads identified in Appendix 15 at least once per year and after each breakdown/mechanical repair, using a Biological Verification Test Pack. Autoclave performance against whole log bolts shall be validated annually as per Appendix 19 and shall be documented on IPS Form Number 0156/001 (Autoclave Validation for Whole Log Bolts, Appendix 20). Additionally, the autoclave shall be validated monthly against a standard "waste" test load. Procedures specified by the manufacturer of the Test Pack shall be followed. Verification shall be documented in the equipment

logbook for the autoclave. The lot number of the biological test indicator and the results for the positive control and test indicator shall be recorded in the description of materials in the IQ Autoclave Log.

2.20.13 The BSO shall ensure that cleaning equipment is dedicated for use in the IQ facility only.

2.20.14 After the receipt of air sample results with high air particle counts, the BSO shall conduct intensive cleaning and sanitation of areas specified on the report.

2.21 Project Completion

2.21.1 Upon completion of a project/study in the IQ facility, the BSO shall clean and disinfect all areas that were used by the researcher, prior to allowing the next researcher to commence activities.

2.21.2 Equipment and materials supplied by the facility user but not intended for use in the near future shall be removed from the facility following procedures specified in 2.22 and returned to the facility user, or discarded.

2.21.3 All exotic insects shall be destroyed at the completion of their intended use, either by autoclaving or in killing jars.

2.22 Materials Exiting the Facility

2.22.1 No material of any kind shall be removed from the IQ facility until it has been autoclaved, sanitized and/or inspected by the BSO as specified in 2.20.5.

2.22.2 Materials shall normally be removed from the IQ facility when the experiment is complete, there are no active rearing activities, and the facility has been sufficiently sanitized. Upon request, the BSO may grant approval for the removal of items at other times after sufficient sterilization and inspection. The BSO shall inspect all items before removal from the facility.

2.22.3 Living insects shall be killed by autoclaving or in killing jars before being discarded. Removal of live exotic insects from the facility shall be conducted as specified in the current version of SOP Number IPS/031 (*Movement of Exotic Forest Insects*). The BSO shall document such removal on the *IQ Insect Transfer Log* (IPS Form Number 0113/001, Appendix 10) and maintain it with IQ records.

2.23 Provision of Assistance

2.23.1 Rearing activities and experimentation conducted within the IQ facility are the responsibility of the facility user. Upon request, the BSO shall strive to be available to assist users during times of excessive work load.

2.23.2 Assistance may be provided when sufficient notice is given, however researchers shall be informed that they should not expect this service unless it was agreed upon prior to commencement of the project.

2.23.3 The BSO will not be available to provide vacation leave replacement, however, when given sufficient notice, the BSO may (pending her/his work load) perform basic maintenance of rearing operations (e.g., misting cages, etc.) during these absences. The BSO will not take responsibility for experimental conduct.

2.23.4 The BSO shall strive to be available to assist facility users during periods of unavoidable leave (e.g., illness).

2.24 Contingency for Fire or Chemical Spill Alarm

2.24.1 The BSO shall ensure that the GLFC Floor Emergency Officer, Deputy Floor Emergency Officer and Floor Monitors are aware of IQ entry and egress practices.

2.24.2 Floor emergency personnel shall be instructed not to enter the IQ facility during an alarm situation.

2.24.3 Monitors shall be instructed to check the sign-in/out log on the door to ascertain that the area has been vacated. When there is a record of someone entering but not exiting, the monitor shall use a telephone to call into the facility and demand that personnel vacate the area. If there is no answer, the monitor shall inform the Floor Emergency Officer, who will report to the Emergency Control Center that it has not been confirmed that the facility is clear (it will then be the responsibility of the Fire Department to clear the area if deemed necessary).

2.25 Power Outage

2.25.1 Even though all essential systems within the IQ facility are connected to the emergency generator, the BSO (upon determination that a power outage has occurred in the IQ facility) shall immediately:

a) Determine the status of the insects housed in the environmental chambers/rooms.
b) Do a visual check of the NIST thermometer/hygrometer that is located in the environmental chamber/room to ensure that parameters have not been exceeded.
c) Reset/reprogram chamber(s), if required.
d) Reset/reprogram timer(s) for lighting, if required.
e) Review Delta System records and notify users of the facility, indicating the extent and duration that environmental parameters were exceeded, if applicable.
f) Confirm that air pressurization has returned to normal.

2.26 Daily Work Schedule

2.26.1 At the start of each work day, the BSO shall check Delta System records for each environmental chamber, rearing room and cold room to ensure that environmental conditions have been appropriately maintained since last being checked.

2.26.2 The BSO shall enter the IQ facility daily (excluding weekends and holidays) and conduct a visual check of each room. She/he shall avoid entering other laboratories in GLFC prior to entering the IQ facility, when possible, thereby reducing the potential introduction of pathogens and microbial contaminants.

2.26.3 If an alarm has been triggered for a reach-in or walk-in chamber/room, the BSO shall transfer the contents (i.e., insect/plant material) to the alternate environment posted on the unit, contact the maintenance department for repair, notify applicable facility users, and document the maintenance/repair action in the equipment log.

2.26.4 If a differential air pressure alarm has been triggered, the BSO shall immediately visit the location to determine the cause and to ensure that the integrity of the facility bio-safety envelope has been maintained. The BSO shall take corrective action as specified in 2.17.20.

2.26.5 Each time the BSO enters a reach-in or walk-in chamber/room, she/he shall make a crude assessment of the environmental conditions (i.e., temperature, relative humidity, light regime) against the NIST traceable thermometer/hygrometer and against the required settings posted on the door of the unit. If there are discrepancies, she/he shall contact facilities maintenance personnel to repair the unit.

2.26.6 Upon each entry to the IQ facility, the BSO shall be cognizant of the integrity of the containment barrier and take corrective action as specified in 2.17.11.

2.26.7 The BSO shall monitor facility users to ensure that they comply with all established IQ SOPs.

2.26.8 Each day, the BSO shall:

a) Ensure that change rooms are maintained in an orderly fashion.
b) Prepare fresh bleach working solution (refer to 2.34.1).
c) Vacuum areas that are visibly soiled.
d) Replace autoclave bags in waste receptacles, as needed.

2.27 Weekly Work Schedule

2.27.1 The BSO shall perform the following weekly tasks, document the event on IPS Form Number 0108/005 (*Weekly Checklist for IQ Facility*, Appendix 1) and maintain the completed form with facility records:

a) Print out and review Delta System environmental records and maintain with historical records.
b) Check sticky traps and replace when no longer tacky or when numerous insects have been caught. When insects have been caught,

take remedial action to determine their source and nature (refer to 2.17.11).

c) Check black light to ensure that it is functioning. When insects have been caught, take remedial action to determine their source and nature (refer to 2.17.11).
d) Autoclave waste and remove from facility.
e) Check sink drains to ensure that screens are in position.
f) Launder soiled lab coats. Lab coats shall be autoclaved prior to removal from the facility and laundered by the external contractor.
g) Flush the autoclave following procedures indicated in the operator's manual.

(Note: tasks a, b, c and e are to be performed by the BSO only on Level 1 of the facility; conduct of these tasks on Level 2 of the facility are the responsibility of IPU personnel and are included on their check lists, however the BSO is responsible for reviewing their work on a monthly basis as specified in 2.28.1-l)

2.27.2 The BSO shall perform the following weekly cleaning/sanitation actions, document the event on IPS Form Number 0108/005 (*Weekly Checklist for IQ Facility*, Appendix 1) and maintain the completed form with facility records:

a) Vacuum and bleach (refer to 2.34.1) facility floors (Level 1 and stairwell) including walk-in chambers (only those that are set above freezing temperature) and the cold room. The facility HEPA filtered central vacuum system shall be used to clean floors (i.e., they shall not normally be swept or dry mopped).
b) Reach-in chambers shall be checked to ensure that they are being kept clean by the user. The BSO shall vacuum and bleach the chambers as needed.
c) Clean the following items using the bleach working solution (refer to 2.34.1) and Windex (where required to remove the bleach residue):
   - door handles (rooms and chambers)
   - bench tops
   - light switches
   - keyboard, mouse, scanner
   - telephones.
d) Clean bathroom AA122.
e) Clean all BSCs and fume hood by vacuuming and using the bleach working solution. Remove the access panels in the BSCs to clean under the bench top.
f) Scrub sinks with scouring pad, if required.

(Note: all tasks above are to be performed by the BSO only on Level 1 of the facility; conduct of these tasks on Level 2 of the facility are the responsibility of IPU personnel and are included on their check lists, however the BSO is responsible for reviewing their work on a monthly basis as specified in 2.28.1-l)

2.28 Monthly Work Schedule

2.28.1 The BSO shall perform the following monthly tasks, document the event on IPS Form Number 0109/005 (*Monthly Checklist for IQ Facility*, Appendix 2) and maintain the completed form with facility records:

a) Verify the accuracy of the Delta System for the following rooms/chambers by comparison with a NIST traceable thermometer/hygrometer:
   - Environmental Rooms AA121, AA123
   - Chambers AA12301, AA12501, AA12601, AA12602, AA12701, AA12702
   - Cold Room AA128

b) Test the panic bar alarms on doors AA116B, AA136 and AA4, and replace the batteries as needed, i.e., panic bars shall be depressed sufficiently to set off the alarm, but not pushed to the point where the door seal is broke and containment is lost (the panic bar alarm is to be reset using a grand master key).

c) Assess supply inventories and re-stock as needed.

d) Validate the autoclave using bio-indicators as specified in 2.20.12.

e) Ensure that air sampling is conducted by facility QC personnel. The BSO shall take corrective action as specified by QC personnel.

f) Record air flow rates for BSCs #11, 12 and 13 on *IPS Form Number 0166/002* (Appendix 14) and maintain with facility records. Compare flow rates to previous results to determine if performance of the unit is decreasing. Arrange for servicing as required.

g) Check each fire extinguisher within the IQ facility to ensure that they are fully pressurized as indicated on the gauge. Sign and date the attached tags. Arrange for servicing as required.

h) Check the eyewash located in room AA125 to ensure that it is functioning properly. Sign and date the attached tag. Arrange for servicing as required.

i) Check the emergency shower in room AA125 to ensure that it is functioning properly (i.e., hold a bucket under the nozzle and pull the chain). Sign and date the attached tag. Arrange for servicing as required.

j) Replace the *Insect Quarantine Access Log* (refer to current version of IPS Form Number 0106) at the start of each month and maintain the completed log with facility records.

k) Test emergency light battery packs (i.e., by pressing test button) to ensure that they are functioning properly. Battery packs are located in rooms AA106B, AA102, AA202, AA206 and stair AA3. Arrange for servicing as required.

l) Review IPU check lists for their assigned work space on Level 2 (and conduct on-site spot checks as needed) to ensure completion of the following tasks for that part of the quarantine facility:
- chambers, floors, telephones, door handles, bench tops, sinks, light switches, BSCs and windows all cleaned
- black light checked
- electrical plug covers inserted
- sticky trap checked
- Delta system printouts taken and filed
- Delta system compared with NIST thermometers
- pressure taken for BSC #10
- fire extinguisher checked
- eyewash checked
- emergency shower checked
- panic bar alarms checked
- screen in floor drain
- screens in sinks
- screens on air supply/return vacuumed

m) Ensure that electrical plug covers are inserted into every outlet not occupied by an electrical cord.

2.28.2 The BSO shall perform the following monthly cleaning/sanitation actions, document the event on IPS Form Number 0109/005 (*Monthly Checklist for IQ Facility*, Appendix 2) and maintain the completed form with facility records:

a) Use bleach working solution (refer to 2.34.1) to clean shelves in:
- walk-ins AA12601 and AA12701
- reach-ins AA12301, AA12501, AA12602 and AA12702
- refrigerator.

b) Vacuum the screens on all air supply and return grills.

c) Check floor drain screens (located in rooms AA122, AA124 and AA125) and clean as required.

d) Empty the two facility HEPA vacuum canisters (located in rooms AA120 and AA131) and clean with the bleach working solution (refer to 2.34.1). Autoclave the waste from canisters prior to disposal.

e) Clean microscopes and balances.

f) Clean windows with Windex (including module doors) when required.

(Note: all tasks above are to be performed by the BSO only on Level 1 of the facility; conduct of these tasks on Level 2 of the facility are the responsibility of IPU personnel and are included on their check lists, however the BSO is responsible for reviewing their work on a monthly basis as specified in 2.28.1-l).

2.28.3 Prior to each monthly test of the GLFC fire alarm system by GLFC emergency committee personnel, the BSO shall post a notice at each entrance to the IQ facility prohibiting entry during the test to ensure that

there are no ongoing insect handling activities (Note: during an alarm, the facility ERV shuts down and facility air pressurization is lost).

2.29 Annual Work Schedule

2.29.1 The BSO shall conduct a formal inspection of the containment barrier at least annually as specified in 2.30.

2.29.2 The entire IQ facility (i.e., walls, ceilings, cupboard interiors, light fixtures, etc.) shall be cleaned annually by the BSO using the bleach working solution (refer to 2.34.1).

2.29.3 The BSO shall ensure that BSCs, balances and chemical fume hood are serviced and certified as needed (typically on an annual basis) and records are maintained as specified in 2.9.3.

2.29.4 The BSO shall meet with the IPS manager annually to discuss her/his training and development plan.

2.29.5 The BSO shall inspect the facility freezer and defrost it, if required.

2.29.6 The BSO shall validate and document the performance of the autoclave as specified in 2.20.12.

2.29.7 The BSO shall validate each air pressure monitor within the facility following the procedure outlined in Appendix 16 and document the testing on IPS Form Number 0142/002 (Appendix 17).

2.29.8 In addition to the routine cleaning/sanitation actions performed on environmental chambers as described throughout this SOP, the BSO shall conduct an annual thorough cleaning of each chamber using the bleach working solution (refer to 2.34.1). The BSO may request users of the chambers to remove contents from the storage compartment for cleaning/sanitation of the unit.

2.29.9 The BSO shall check the actual contents of the first aid kit against the list of required contents and requisition/add supplies as needed.

2.29.10 The BSO shall replace batteries in panic bar alarms on facility doors (whether required or not) and document in the comments section on IPS Form Number 0115/002 (*IQ Facility Inspection Checklist*, Appendix 13).

2.29.11 In collaboration with facilities engineering staff, the BSO shall have the main power to the facility turned off to ensure that the back-up generator starts as required and powers the following essential systems:

a) ERV (i.e., maintains pressurization and environmental controls throughout containment area)
b) BMS/Delta system (i.e., controls for environmental chambers and cold rooms)
c) BSCs in Rooms AA123, AA126, AA127, AA227 and AA228.
d) chemical fume hood (Room AA125)
e) emergency lighting
f) air pressure monitors
g) walk-in environmental chambers (temperature, lights, humidity) numbers: AA12601, AA12701, AA22701, and AA22801.

h) reach-in environmental chambers (temperature, lights, humidity) numbers: AA12301, AA12501, AA12602, AA12702, AA22702 and AA22802.
i) cold room #1 AA128 (temperature, lights).
j) alarms for doors AA122B/C, AA116B, AA136, AA4, AA238A/B AA249A and AA249B.
k) door interlocks (Doors AA122B/C, AA238A/B).
l) air curtains for doors AA122C and AA238B.
m) swipe card readers at doors AA122B, AA122C, AA238A, AA238B, AA244 and AA250.
n) egress buttons at doors AA122B, AA122C, AA238A and AA238B.
o) sliding doors AA126, AA127, AA227 and AA228.
p) sump pump.
q) IT Closet (i.e., computer network, telephone system, paging).
r) fire alarm (fire alarm is also on battery back-up).

(Note: BacNet Gateway for Delta System is located in the main GLFC building and is on back-up power in that location)

2.29.12 The BSO shall conduct an annual inspection of the containment barrier as specified in 2.30.

2.29.13 The BSO shall contact the GLFC emergency committee to obtain a list of dates for testing of the fire alarm system.

2.30 Facility Inspection

2.30.1 The BSO shall conduct a formal inspection of the containment barrier at least annually. The BSO shall notify the IPS manager to request assistance with the inspection. All items listed on IPS Form Number 0115/002 (*IQ Facility Inspection Checklist*, Appendix 13) shall be inspected and checked as being compliant or not. Smoke pencils shall be used to check for leaks in the barrier, however, facility maintenance personnel must first be notified in order to turn off fire/smoke alarms for the IQ facility. The smoke pencil shall slowly be passed by each penetration (e.g., electrical, plumbing, etc.) and door opening and the swirl of smoke examined for turbulence caused by air penetration. Smoke pencils will also be used to confirm inward directional air flow at each door along the containment barrier; door alarms shall be temporarily turned off and the door cracked open with the pencil held in that location; the direction of movement of the smoke will indicate directional air flow.

2.30.2 Upon completion of the inspection, the BSO shall determine if any findings warrant documentation and reporting of “incidents” as specified in 2.18.

2.30.3 Corrective action required following inspection shall be implemented as soon as feasible and the date of completion shall be documented on the facility inspection checklist.

2.31 CFIA Certification

2.31.1 The BSO shall arrange for inspections of the IQ facility by the CFIA at intervals requested by them.

2.31.2 Prior to an inspection by the CFIA, the BSO shall perform a facility inspection as specified in 2.30 (if one has not recently been conducted) and implement required corrective actions prior to the arrival of the inspector(s).

2.31.3 The BSO shall ensure that corrective actions are taken for all findings identified by the CFIA, documentation relating to the inspection is maintained with facility records, and the IPS manager is kept current of all activities associated with the inspection.

2.31.4 Upon receipt of an approved *Permit to Import* or *Movement Certificate* for an insect species new to our quarantine facility, the BSO shall co-ordinate with the CFIA for facility certification for working with that species, if requested by them.

2.32 Future Facility Expansion

2.32.1 Upon determination by the BSO that IQ facility user requests will exceed the capacity of the current facility, she/he shall consult the IPS manager for approval to expand the facility into lab modules formerly occupied by the domestic species area of the building. CFIA approval must be obtained prior to expansion.

2.32.2 Upon approval by the IPS manager to expand the IQ facility, the BSO shall perform the following actions prior to opening the connection between the old and new work areas:

a) Conduct an intensive cleaning (as per 2.29.2) of the work area that is to be incorporated into the quarantine zone, if required.
b) Conduct a visual inspection of the new containment barrier and repair any seals (e.g., screens, drains, caulking, etc.) requiring maintenance.
c) Instruct facility maintenance personnel to change air pressurization of the new lab space from “positive” to “negative”. Air pressurization of the new hallway shall be equal to that of the adjacent existing IQ hallway. Air pressurization of the new lab modules shall be lower than the adjacent hallway.
d) Conduct a facility inspection (as per 2.30) as it pertains to the newly acquired lab space.

2.32.3 Upon completion of 2.32.2, the BSO shall ensure that door alarms are turned off on those doors now fully incorporated within the quarantine zone, and turn on the door alarms at the new quarantine barrier. The BSO shall test the newly alarmed doors by breaching them and checking for applicable audible messages and email notifications. Signage on doors shall be changed, as applicable.

2.33 Swipe Card Building Passes

2.33.1 Upon approval of a *Request to Use IQ Facility* form by the BSO, she/he shall provide the IPS manager with the name(s) of individuals [i.e., only those persons designated as *Full Access* (as per 2.3.1)] who require swipe card access, the applicable door numbers, and the start/end dates for their access.

2.33.2 The BSO shall notify the IPS manager whenever individuals progress from *Restricted Access* to *Full Access* and require changes to the programming of doors to facilitate swipe card access.

2.33.3 The BSO shall notify the IPS manager if the end date for swipe card access for an individual needs to be extended (i.e., provide name of individual, door numbers, and new end date).

2.33.4 Researchers will not normally be given access to the upper level of the IQ facility (i.e., swipe card access through door AA250) unless deemed necessary by the BSO.

2.33.5 The BSO shall notify the IPS manager whenever facility access privileges need to be revoked for any individual.

2.33.6 The IPS manager is responsible for implementing changes to IQ facility swipe card access and for maintaining a historical file of those changes.

2.34 Calculations

2.34.1 The bleach working solution for general cleaning shall have a final sodium hypochlorite concentration of 0.3%. Bleach stock material with a 5.25% sodium hypochlorite concentration (e.g., Javex®) shall be diluted by combining 60ml bleach and 940ml water (i.e., 6% dilution). Bleach stock material with a 6.0% sodium hypochlorite concentration (e.g., Ultra Javex®) shall be diluted by adding 53ml bleach and 947ml water (i.e., 5.25% dilution). If another brand of bleach is used, volumes may need to be adjusted to provide a 0.3% sodium hypochlorite working solution.
[Note: minimum contact time of 10 minutes is required for effective sanitation]

2.35 Documentation and Reporting

2.35.1 Compliance to this SOP shall include completion of the following forms:

a) IPS Form Number 0005/002 (*Set Parameters for Environmental Chambers/rooms*)
b) IPS Form Number 0108/005 (*Weekly Checklist for IQ Facility*)
c) IPS Form Number 0109/005 (*Monthly Checklist for IQ Facility*)
d) IPS Form Number 0110/002 (*IQ Training Log*)
e) IPS Form Number 0111/001 (*IQ User Access Level*)
f) IPS Form Number 0081/002 (*Equipment Logbook*)
g) IPS Form Number 0082/001 (*Maintenance and Repair Log*)
h) IPS Form Number 0083/001 (*Cleaning Log*)
i) IPS Form Number 0084/001 (*Calibration Log*)
j) IPS Form Number 0112/002 (*IQ Insect Receipt Log*)

k) IPS Form Number 0113/001 (*IQ Insect Transfer Log*)
l) IPS Form Number 0114/001 (*IQ Autoclave Log*)
m) IPS Form Number 0115/002 (*IQ Facility Inspection Checklist*)
n) IPS Form Number 0116/002 (*IQ BSC Flow Rates*)
o) IPS Form Number 0142/002 (*Air Pressure Monitor Validation*).

2.35.2 Compliance to this SOP may include completion and/or maintenance of current versions of the following forms referred to herein:
a) IPS Form Number 0103 (*Request to Use IQ Facility*)
b) IPS Form Number 0104 (*IQ Facility User Agreement*)
c) IPS Form Number 0106 (*Insect Quarantine Access Log*)
d) IPS Form Number 0107 (*Insect Quarantine Incident Report*)
e) IPS Form Number 0141 (*Insect Production Services Sign-in Form*)
f) CFIA application for Written Authorization

3.0 DISTRIBUTION AND ARCHIVING

3.1 Distribution

This SOP shall be distributed by the IPS manager to the BSO and to any other potential facility users (e.g., GLFC personnel) who request a controlled copy. Controlled copies are monitored for chain of custody to ensure that current versions are distributed timely and that outdated versions are destroyed. A current version of this SOP may be viewed in the *Bio-Safety Manual* maintained within the IQ facility or through the GLFC intranet.

3.2 Archiving

3.2.1 The IPS manager shall maintain a historical file of this SOP when it is replaced by a new version.
3.2.2 The BSO shall maintain historical files for all forms specified in *2.35*.
3.2.3 The BSO shall maintain a historical collection of voucher specimens of exotic insects brought into the IQ facility.
3.2.4 The BSO shall maintain copies of *Work Orders* for the IQ facility.
3.2.5 The BSO shall maintain files for copies of applications, permits and certificates.
3.2.6 The BSO shall maintain all facility records for a period of at least 3 years.

3.3 Destruction of Outdated SOPs

When a new version of this SOP is available for distribution, all persons in possession of a controlled copy shall ensure that the retired version is returned to the IPS manager upon request.

4.0 ASSURING SOP VALIDATION AND COMPLIANCE

4.1 Responsible Individual

4.1.1 The BSO is responsible for assuring that this SOP is valid.
4.1.2 The BSO is responsible for assuring that she/he complies with this SOP.
4.1.3 The BSO is responsible for complying with procedures specified on a *Controlled Copy* of this SOP and shall never use non-controlled copies (which could be outdated).

5.0 REVISION OF THE SOP

5.1 Responsible Individual

The BSO is responsible for assuring that this SOP is current. If necessary, the BSO shall initiate the revision process.

5.2 Revision Schedule

This SOP shall be revised when its provisions no longer agree with current practices, GLFC policies or CFIA requirements, and shall be approved by the IPS manager and the CFIA Office of Biohazard Containment and Safety.

6.0 CONTINGENCIES

When facility users find circumstances that do not permit compliance with this SOP, the BSO shall be consulted.

7.0 CONFIDENTIALITY

IPS SOPs are not considered to be confidential documents and may be distributed to outside parties. *Controlled Copies* shall not be reproduced.

8.0 REFERENCES

Bio-Safety Manual
CFIA Containment Standards for Handling Plant Pests
CFIA Directive D-12-03
Current version of the following forms:
a) IPS Form Number 0103 (*Request to Use IQ Facility*)
b) IPS Form Number 0104 (*IQ Facility User Agreement*)
c) IPS Form Number 0106 (*Insect Quarantine Access Log*)
d) IPS Form Number 0107 (*Insect Quarantine Incident Report*)
e) IPS Form Number 0141 (*Insect Production Services Sign-in Form*)
Current version of the following SOPs:
a) SOP Number IPS/030 (*IQ Facility Access Authorization*)
b) SOP Number IPS/031 (*Movement of Exotic Forest Insects*)
c) SOP Number IPS/033 (*Conducting Research in Insect Quarantine*)

9.0 APPENDICES

Appendix 1: IPS Form Number 0108/005 (*Weekly Checklist for IQ Facility*)
Appendix 2: IPS Form Number 0109/005 (*Monthly Checklist for IQ Facility*)
Appendix 3: IPS Form Number 0110/002 (*IQ Training Log*)
Appendix 4: IPS Form Number 0111/001 (*IQ User Access Level*)
Appendix 5: IPS Form Number 0081/002 (*Equipment Logbook*)
Appendix 6: IPS Form Number 0082/001 (*Maintenance and Repair Log*)
Appendix 7: IPS Form Number 0083/001 (*Cleaning Log*)
Appendix 8: IPS Form Number 0084/001 (*Calibration Log*)
Appendix 9: IPS Form Number 0112/002 (*IQ Insect Receipt Log*)
Appendix 10: IPS Form Number 0113/001 (*IQ Insect Transfer Log*)

Appendix 11: IPS Form Number 0114/001 (*IQ Autoclave Log*)
Appendix 12: Insect Quarantine Autoclave Settings
Appendix 13: IPS Form Number 0115/002 (*IQ Facility Inspection Checklist*)
Appendix 14: IPS Form Number 0116/002 (*IQ BSC Flow Rates*)
Appendix 15: Validation of Autoclave Sterilization
Appendix 16: Air Pressure Monitor Validation Procedure
Appendix 17: IPS Form Number 0142/002 (*Air Pressure Monitor Validation*)
Appendix 18: IPS Form Number 0005/002 (*Set Parameters for Environmental Chambers/rooms*)
Appendix 19: Autoclave Validation Procedure for Whole Log Bolts
Appendix 20: IPS Form Number 0156/001 (Autoclave Validation for Whole Log Bolts)

Appendix 1

IQ Weekly Checklist
(Excluding modules assigned to IPU)

Week: DD/MM/YY to DD/MM/YY

	Task	Initials
Cleaning	Facility floors vacuumed and bleached (level 1 and stairwell)	
	Floors of Walk-ins vacuumed and bleached □AA12601 □AA12701	
	Floor of Cold Room (AA128) vacuumed and bleached	
	Reach-ins assigned to others checked/cleaned □AA12301 □AA12501 □AA12602 □AA12702	
	Door handles cleaned (rooms and chambers)	
	Bathroom cleaned	
	Bench tops bleached and windexed	
	Sinks scrubbed with scouring pad	
	Light switches cleaned	
	BSCs vacuumed and cleaned	
	Fume hood vacuumed and cleaned	
	Keyboard, mouse and scanner cleaned	
	Telephones cleaned	
Other	Delta System printouts taken, reviewed, filed	
	Sticky traps checked	
	Black light checked	
	Garbage autoclaved and removed	
	Screens in sink drains checked	
	Lab coats checked/laundered	
	Autoclave flushed	

IPS Form Number 0108/005

Appendix 2

IQ Monthly Checklist

Month:

Task		Initials	Date (DD/MM/YY)
Cleaning	Shelves of Walk-ins cleaned □AA12601 □AA12701		
	Shelves of Reach-ins checked/cleaned □AA12301 □AA12501 □AA12602 □AA12702		
	Shelves cleaned in fridge		
	Screens on air supply and return grills vacuumed		
	Floor drain screens checked/cleaned		
	HEPA vacuum canisters emptied and cleaned (2 units)		
	Microscopes cleaned		
	Balances cleaned		
	Windows (including module doors) checked/cleaned		
Other	Panic bar alarms tested □AA4 □AA136 □AA116B		
	Supply inventory assessed and re-stocked		
	Autoclave validated using bio-indicators		
	Electrical plug covers checked		
	Air sampling conducted		
	BSC flow rates recorded		
	Fire extinguishers checked		
	Eyewash checked		
	Emergency shower checked		
	IQ Access Logs replaced (both levels)		
	Maintenance personnel sign-in form filed		
	Compare Delta System with NIST — Walk-ins □AA12601 □AA12701		
	Compare Delta System with NIST — Reach-ins □AA12301 □AA12501 □AA12602 □AA12702		
	Compare Delta System with NIST — Cold Room AA128		
	Compare Delta System with NIST — Environmental Rooms □AA121 □AA123		
	Test emergency light battery packs □AA106B-left □AA106B-right □AA102 □AA202 □AA206 □AA3		
	IPU check list for level 2 modules reviewed; spot check conducted		

IPS Form Number 0109/005

Appendix 3

IQ Training Log

Name: __________________

Date of Training (DD/MM/YY)	Description of Training	Initials of BSO	Initials of Trainee

IPS Form Number 0110/002

Appendix 4

IQ User Access Level

Name	Access Level			Access Terminated (DD/MM/YY)
	Newcomer (DD/MM/YY)	Restricted Access (DD/MM/YY)	Full Access (DD/MM/YY)	

IPS Form Number 0111/001

Appendix 5

Equipment Logbook

Instrument Location: _____

Instrument Type: _____

Manufacturer: _____

Model Number: _____

Serial Number: _____

EDR (GLFC ID) Number:
_____

IPS Form Number 0081/002

Appendix 6

Maintenance and Repair Log

Equipment ID: _____ Location: _____

Date (DD/MM/YY)	Description of Maintenance or Repair Action	Initials

IPS Form Number 0082/001

Appendix 7

Cleaning Log

Equipment ID: _____ Location: _____

Date (DD/MM/YY)	Description of Cleaning Action	Initials

IPS Form Number 0083/001

Appendix 8

Calibration Log

Equipment ID: _____ Location: _____

Date (DD/MM/YY)	Description of Calibration Action	Initials

IPS Form Number 0084/001

Appendix 9

IQ Insect Receipt Log

Date Received: _____ (DD/MM/YY)

Insect Species: _____

Movement Certificate#: _____

Received From: _____

Import Permit #: _____

Intended User(s): _____
_____
_____
_____

Phytosanitary Certificate #: _____

Condition Upon Receipt:

_____
_____
_____

Description (including quantity):

_____
_____
_____
_____
_____
_____
_____
_____

Decontamination of Packaging Materials:
Method_____ Date_____ (DD/MM/YY)

IQ Storage Location(s): _____
_____
_____

Archive Samples: Rec'd _____ (DD/MM/YY)

ID'd _____ (DD/MM/YY)

Completed by: _____ Printed Name _____ Signature

IPS Form Number 0112/002

Appendix 10

IQ Insect Transfer Log

Date Distributed: _____ (DD/MM/YY)

Insect Species: _____

Movement Certificate#: _____

Person Responsible For Transport: _____

Recipient: _____

Description (including quantity):

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Completed by: _____ Printed Name _____ Signature

IPS Form Number 0113/001

Appendix 11

IQ Autoclave Log

Date (DD/MM/YY)	Cycle #	Description of Materials Autoclaved	Test Strip	Initials

IPS Form Number 0114/001

Appendix 12

Insect Quarantine Autoclave Settings

Material	Type of Cycle	Temperature (°C)	Sterilizing Time (minutes)	Drying Time (minutes)	Print Interval (minutes)
Waste	Pre-Vac	121	30	2	15
Glassware	Pre-Vac	121	30	30	15
Wood (split)	Pre-Vac	121	60	2	15
Wood (whole bolts)	Pre-Vac	121	180*	5	15
Lab Coats	Pre-Vac	121	30	10	15
1000ml Liquid	Liquid	121	45	0	15
500ml Liquid	Liquid	121	40	0	15
2000ml Liquid	Liquid	121	55	0	15

*Sterilized log blots shall remain in the sealed chamber for an additional 60 minutes, plus another 60 minutes in the chamber or on the floor prior to disposal.

[Refer to the operator manual for settings to be used with other materials and/or volumes]

Appendix 13

IQ Facility Inspection Checklist

Date of Inspection: DD/MM/YY

BSO Signature:

Area/Item Inspected	Compliant (✓)		Comments	Corrective Action Implemented	
	Yes	No		Date (DD/MM/YY)	Initials
Sign at entrances (e.g., containment area, unauthorized entry prohibited, contact information)					
Sign at exits (e.g., unauthorized removal of organisms prohibited)					
Entrances kept locked					
Anteroom lights controlled by door					
Air curtains controlled by door					
Door closures (i.e., self-closing, close quickly)					
Weather stripping on doors (i.e., tight fitting)					
Inward directional air flow					
Emergency exit alarms					
Access log					
Black lights					
Sticky traps					
Screens on air supply and return vents					
Screens in sink drains					
Screens on chemical fume hood					
Supplies stored in closed bins/cupboards					
Cages/containers secure against escape					
Integrity of walls, floor and ceiling					
Seals maintained [i.e., all seams, cracks or openings around service outlets (electrical, plumbing, heating, ventilation), floor drains, furnishings (benches, cupboards), door frames, etc.]					
Autoclave validated against standard loads					

IPS Form Number 0115/002

Appendix 14

IQ BSC Flow Rates
(Inches W.C.)

BSC #11 SN 100660-2879	BSC #12 SN 801-7591	BSC #13 SN 12242	Date (DD/MM/YY)	Initials

IPS Form Number 0116/002

Appendix 15

4 November 2013

Validation of Autoclave Sterilization using Biological Indicators

Two types of biological indicators (3M™ Attest™ and MagnaAmp®) are used to validate sterilization of five load types in the IPQL autoclave (Amsco Lab 250, Serial Number 0305610-08).

The 3M™ Attest™ biological indicator is used to validate sterilization of glassware, lab coats, waste or wood within the autoclave chamber when using the "prevacuum" (i.e., vacuum-assisted) cycle. It consists of a sealed glass ampoule containing a disc inoculated with *Geobacillus stearthermophilus* spores, growth medium and a Bromocresol Purple pH indicator, which changes colour when the sterilization process fails. The ampoule is placed in the autoclave load type and autoclaved as per one of the procedures indicated below.

The MagnaAmp® biological indicator is used to validate sterilization of water within the autoclave chamber when using the "liquid" cycle. It also consists of a sealed glass ampoule containing *Geobacillus stearthermophilus* and a specially formulated culture medium that changes colour to indicate failure of the sterilization process. The ampoule is suspended directly in the vessel of water to be autoclaved as per the procedure indicated below.

Both types of biological indicators are fitted with a steam indicator strip to provide preliminary indication that steam sterilization has occurred. It turns from pink to brown when exposed to steam (indicating a *positive* assessment), however successful sterilization cannot be validated using this indicator alone.

Upon the completion of applicable autoclave cycle for the load type, the ampoule is removed from the load and immediately incubated for 48h at 55-60°C. Prior to incubation, the 3M™ Attest™ ampoule is crushed in middle (while wearing safety gloves) to expose the inoculated disk to the growth medium, and is lightly shaken to ensure proper mixing. Both types of indicators should remain purple, resulting in a *negative* assessment and acceptance of the sterilization validation test. They will turn yellow when spores have survived the autoclave process, resulting in a *positive* assessment and failure of the test. Positive control ampoules (i.e., biological indicators from the same lot of each type) are not to be exposed to the autoclaving process but are to be incubated along with each test batch. These should turn yellow to show that the associated lot of indicators, as well as the incubation process, function as intended.

Five typical load types may be encountered in the quarantine facility. Descriptions and validation procedures for each are as follows:

1) **Glassware**: Place laboratory glassware (cylinders and beakers) in a large autoclavable plastic bin. Insert the 3M™ Attest™ biological indicator in the interior of a cylinder, wrap the end loosely with tin foil and place in the centre of the bin surrounded by other cylinders. Autoclave for 30 minutes using the "prevacuum" cycle, followed by a 30 minute dry-time within the chamber.

Page 1 of 4

Appendix 15 (continued)

4 November 2013

2) **Liquids**: The largest volume of water sterilized in the IPQL is 2000ml, therefore validation is to be performed using this volume in a Pyrex bottle. Suspend a MagnaAmp® biological indicator in the middle of the bottle using a wire as shown in the attached photo. Cap the bottle loosely with tin foil since the bottle cap will no longer fit due to the presence of the wire. Include the bottle cap in the chamber during the sterilization process. Autoclave for 55 minutes using the "liquid" cycle. Do not use any dry-time.


3) **Lab coats**: Place at least five lab coats in a mesh autoclavable bin. Insert a 3M™ Attest™ biological indicator in the pocket of a lab coat positioned in the middle of the group. Autoclave for 30 minutes using the "prevacuum" cycle, followed by a 10 minute dry-time within the chamber.


4) **Waste**: Place a typical sample of laboratory waste (e.g., paper, cardboard and paper towel) in an autoclavable bag. Tie string to a 3M™ Attest™ biological indicator and put the ampoule in the centre of the waste with the free end of the string protruding through the bag opening. Tie the bag loosely. Autoclave for 30 minutes using the "prevacuum" cycle, followed by a 2-minute dry-time within the chamber.

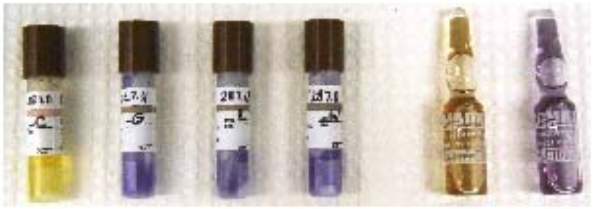

Page 2 of 4

Appendix 15 (continued)

4 November 2013

5) **Wood:** Place split wood (approximately one-inch in diameter) in an autoclavable bin. Place a 3M™ Attest™ biological indicator in the middle of the load (not visible from the top). Autoclave for 60 minutes using the "prevacuum" cycle and no dry-time. Allow the material to cool within the chamber for 24h then autoclave again using the same settings.


Expected results (after incubation) for sterilization of glassware, lab coats, waste and liquids:



A B C D E F

A. 3M™ Attest™ Biological control (positive control vial)
B. 3M™ Attest™ Biological control for the Glassware prevacuum cycle
C. 3M™ Attest™ Biological control for the Lab coat prevacuum cycle
D. 3M™ Attest™ Biological control for the Waste prevacuum cycle
E. MagnaAmp® Biological control (positive control vial)
F. MagnaAmp® Biological control for the 2000ml Liquid cycle

Expected results (after incubation) for sterilization of wood:

G H

G. 3M™ Attest™ Biological Control (positive control vial)
H. 3M™ Attest™ Biological control for the Wood prevacuum cycle

Page 3 of 4

Appendix 15 (continued)

4 November 2013

Recording of results

Post-incubation results of biological indicators are to be recorded as follows:

Incubation Date	Load-Type	Biological Indicator Used	Lot #	Chemical Indicator Strip (+/ -)	Colour	Success of Sterilization (Yes/No)
	Glassware	3M™ Attest™				
	Liquids	MagnaAmp®				
	Lab coats	3M™ Attest™				
	Waste	3M™ Attest™				
	Wood	3M™ Attest™				

Post-incubation results of positive controls are to be recorded as follows:

Incubation Date	Biological Indicator Used	Lot #	Colour	Success of Incubation (Yes/No)
	3M™ Attest™			
	MagnaAmp®			

Page 4 of 4

Appendix 16

Air Pressure Monitor Validation Procedure
Version: 10 October 2013

Purpose:

This procedure is intended to ensure that wall-mounted air pressure monitors throughout the quarantine facility and the domestic production facility are yielding accurate data and to ensure that this data is transmitted accurately to the Building Management System (i.e., Delta System).

Equipment Required:

Hand-held Air Pressure Monitor
Adaptor
Extension cord
Rubber tubing (approx. 5ft)
1-ml disposable pipette (with tapered end removed)
V-shaped Spatula
IPS Form Number 0142
2 Walkie-talkies

Page 1 of 4

Appendix 16 (continued)

Methodology:

(CAUTION: Do not blow into either of the ports of the hand-held sensor or the unit will become damaged)
-Conduct validation testing when other workers are not present in the facility (i.e., ensure that facility users are not opening and closing doors or operating exhaust fans).
-Perform validation of monitors in the order shown on IPS Form 0142.
-Connect the adapter to the hand-held air pressure monitor.
-Plug the adaptor into the extension cord.
-Plug the extension cord into a power source near to the location of the wall monitor being checked.
-Ensure that the reading on the wall monitor is relatively stable prior to conducting the validation procedure.
-Insert the 1 ml pipette into the rubber tube and connect the other end of the tube to the applicable port on the hand-held monitor; attach the tube to "LO" port when the air pressure on the opposite side of the door being tested is at a lower air pressure than the air space where the monitor is located; attach the tube to the "HI" port when the air pressure on the opposite side of the door being tested is at a higher air pressure than the air space where the monitor is located.

-Hold the open end of the pipette next to the open port of the monitor and wait for the read-out to stabilize (about one minute).

Page 2 of 4

Appendix 16 (continued)

-If the reading does not equal zero, use a pen tip to press the "zero" button on the front of the unit.

-Ensure that the unit now reads zero.
-Where required, use a spatula to create a temporary opening between the rubber door sweep and the floor of the door associated with the wall monitor being validated.

-Slide the open end of the pipette through the gap created by the spatula until it is fully inserted into the room but the rubber tube does not touch the door sweep.

Page 3 of 4

Appendix 16 (continued)

-Remove the spatula (i.e., the rubber door sweep should re-seal against the pipette).
(Note: the pipette may be slid between the two centre door panels of the sliding doors rather than underneath)

-Ensure that the rubber tube is not restricted by the door sweep or pinched anywhere else along its length.
-Wait for the reading on the hand-held monitor to stabilize (approximately one minute).
-Contact the facility engineer using the walkie-talkie and relay the readout from the wall-mounted monitor; ensure that it corresponds to the Delta system reading (±1 Pa); if they do not correspond, initiate repair and/or calibration and repeat the test.
-Take simultaneous readings from the hand-held monitor and the wall-mounted monitor; record the data on IPS Form Number 0142 [Note: readings from the wall-mounted monitor are stated in Pascal (Pa) whereas the readings from the hand-held monitor are stated in Inches of Water].
-Withdraw the pipette from under the door and ensure that the door sweep closes the gap.
-Once all readings are documented, convert hand-held monitor readings from Inches of Water to Pascal by multiplying by 248.8 and record on the form.

i.e., (Inches Water) x 248.8 = Pascal

-Ensure that the read-out from the hand-held monitor corresponds to the wall-mounted monitor within 3 Pa; if they do not correspond, initiate repair and/or calibration and repeat the test.
-The person conducting the validation procedure shall apply her/his name and dated signature to IPS Form Number 0142 and maintain the form with facility records.

Page 4 of 4

Appendix17

Air Pressure Monitor Validation

Conducted by: _____ (Name) _____ (Signature) ___/___/___ (DD/MM/YY)

Monitor Location		Reading on Wall-Mounted Monitor (Pa)	Reading on Delta System (Pa)	Hand-held Monitor	
Zone	Door Transition			Reading on Monitor (Inches Water)	Conversion to Pa*
Domestic	AA209/Q2				
Domestic	Q2/AA220				
Domestic	AA220/AA217				
Domestic	AA220/AA218				
Domestic	AA220/AA219				
Domestic	S3/AA222				
Domestic	S3/AA223				
Domestic	S2/AA224				
Domestic	S2/AA225				
Quarantine	S2/S1				
Domestic	Stair AA1/Outside	NA	NA		
Quarantine	U/AA125				
Domestic	U/AA118A				
Domestic	Q2/AA213				
Domestic	Q2/AA212				
Quarantine	AA211/AA211C				
Quarantine	AA211C/AA226				
Quarantine	R1/R2				
Domestic	Q/T				
Quarantine	AA105/AA130				
Quarantine	AA106/AA106A				
Quarantine	AA106A/AA129				
Quarantine	AA129/AA125				
Quarantine	AA125/AA127				
Quarantine	AA125/AA126				
Quarantine	AA125/AA123				
Quarantine	AA125/AA121				
Quarantine	Stair AA3/Outside				
Quarantine	R2/Stair AA3				
Quarantine	S1/AA228				
Quarantine	S1/AA227				
Quarantine	AA226/S1				

* Inches Water x 248.8 = Pa

IPS Form Number 0142/002

Appendix 18

Set Parameters for Environmental Chambers/Rooms

Chamber/Room ID:

Temperature: °C

Limits: ±

Relative Humidity: %

Limits: ±

Photoperiod:

On

off

Alternate Environment:

After Hours Contact:

Name
Phone
Cell

Alternate Contact:

Name
Phone
Cell

Effective Date:_____
DD/MM/YY

IPS Form Number 0005/002

Appendix 19

8 April 2014

Autoclave Validation Procedure for Whole Log Bolts

Autoclave performance against whole log bolts shall be validated annually under the most difficult scenario that we might ever encounter within our bio-containment facility (i.e., preliminary tests showed that sugar maple was the species most resistant to heat penetration; 36 inches is the maximum capacity of our autoclave). Therefore, validation shall be performed using a recently cut (i.e., prior to cracking caused by drying) sugar maple log 10±0.5 inches in diameter (i.e., mean of the diameter at each end), 36±0.5 inches long, and free of penetrations caused by wood boring insects thus providing test material with the greatest resistance to steam penetration during the autoclaving process.

The log bolt shall be autoclaved at 121°C for three hours using the pre-vac cycle and a five minute dry time (dry time reduces moisture in the surrounding work room after autoclaving). A steam indictor strip shall be included with the log to ensure that the required chamber temperature is achieved. The total autoclave cycle will last approximately 3hr 26min, including generator warm-up and chamber evacuation time.

Upon completion of the autoclave cycle, the log bolt shall be left in the sealed chamber for an additional one hour since preliminary tests revealed that heat continues to be driven from the sapwood deeper into the heartwood. Immediately upon completion of this one hour waiting period, the log bolt shall be removed and holes drilled in a straight line along the central axis to a depth of five inches (i.e., to the centre of the 10 inch diameter log). One of the holes shall be located at the middle of the central axis and additional holes shall be located at five inch increments toward each end of the log (i.e., the log will receive a total of 7 holes). The diameter of drill bit shall not be more than 1/16 inch larger than the diameter of the glass thermometers (calibrated and tested against thermometer standards traceable to the National Institute of Standards and Technology) that are to be immediately be inserted into the holes for taking temperature measurements, thus ensuring a snug fit and accurate readings. Each hole will be plugged with a thermometer for the duration of the subsequent sample period.

Core temperatures shall first be taken 15 minutes after the log is removed from the autoclave to allow sufficient time for drilling of holes and for the thermometer temperatures to stabilize, and again at 15 minute intervals thereafter for a three hour sampling period. All temperature measurements are to be recorded to the nearest 0.5°C on IPS Form Number 0156/001 (Autoclave Validation for Whole Log Bolts).

The autoclave validation procedure is deemed to be successful when all thermometers in the log measure at least 56°C for a minimum of one hour during the three hour sampling period.

No attempt shall be made to insert biological indicators into the core of the log bolt since they require a minimum temperature of 121°C for deactivation, whereas internal log bolt temperatures will not attain this level of heating when following this autoclaving procedure.

Appendix 20

Autoclave Validation for Whole Log Bolts

Date:

Autoclave Cycle Number: Steam Sterilization Time:

Wood Species:

Room Temperature:

Log Dimensions
Diameter: Length:

Time Post Autoclaving*	Core Temperature at Location #1 (°C)	Core Temperature at Location #2 (°C)	Core Temperature at Location #3 (°C)
15 min**			
30 min**			
45 min**			
60 min**			
75 min**			
90 min**			
105 min**			
120 min**			
135 min**			
150 min**			
165 min**			
180 min**			

*3hr steam sterilization at 121 °C + 5min dry time + chamber evacuation + 60min in sealed chamber= 4hr 26min total time in chamber
**additional time is at room temperature

IPS Form Number 0156/001

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