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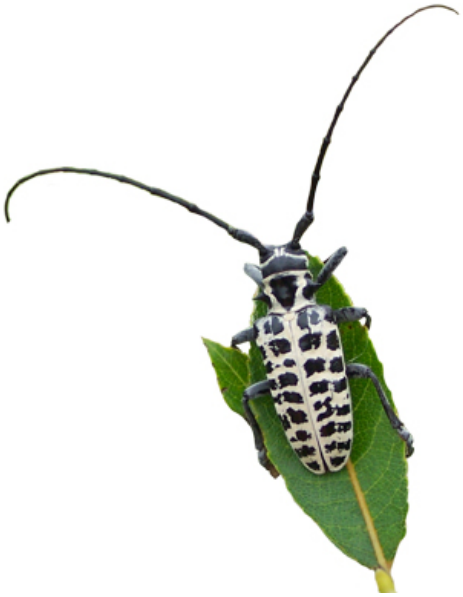
Great Lakes Forestry Centre
Insect Production Services

STANDARD OPERATING PROCEDURE

Number: IPS/020/004

Writing Insect Production Services Standard Operating Procedures



Effective Date: 15 October 2013

Canada

TITLE: Writing Insect Production Services (IPS) Standard Operating Procedures (SOPs)

APPROVING OFFICIAL:

DD / MM / YY

Manager, Insect Production Services _____ ___/___/___

SIGNIFICANT CHANGES FROM PREVIOUS VERSION:

-New definitions have been added; others have been revised.
-Confidentiality section has been revised to indicate that SOPs are no longer confidential documents.

1.0 INTRODUCTION

1.1 Purpose

This SOP has been established to assure that all IPS SOPs and associated reporting forms contain the required elements, follow a consistent format and adhere to the specified preparation and approval process.

1.2 Scope

This SOP shall be followed by all IPS personnel for the development of new or revised SOPs and/or reporting forms.

1.3 Definitions

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.

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.

Methods Development (MD) Lab – A research facility under the control of IPS used exclusively by the IPU for developing new rearing methods and for establishing new insect colonies.

Quality Control (QC) 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.

1.4 Safety

NA

1.5 Materials

a) *IPS SOP Distribution Log* (IPS Form Number 0007/003, Appendix 1).
b) *IPS SOP Template*

2.0 PROCEDURES

2.1 Format for SOPs

Every SOP prepared by IPS shall follow the format used in this SOP and shall address all of the critical elements listed below (refer to *2.1.1* through *2.1.14*). Where a particular issue is not appropriate or applicable to the SOP under development, "NA" shall be placed after the designated element addressed.

2.1.1 Unique SOP identifier as described in Section *2.2*.
2.1.2 Title of SOP, descriptive of the activity to be performed.
2.1.3 IPS manager dated signature (to be completed by the IPS manager upon approval of the SOP).
2.1.4 Effective Date (to be completed by the IPS manager).
2.1.5 *SIGNIFICANT CHANGES FROM PREVIOUS VERSION*; this element shall briefly describe major procedural changes from the previous version.
2.1.6 *INTRODUCTION* (Section *1.0*); shall include:
a) *Purpose* (Section *1.1*); provides the reason for having the SOP.
b) *Scope* (Section *1.2*); describes to whom or to what area the SOP applies.
c) *Definitions* (Section *1.3*); every SOP shall include a comprehensive list of definitions (i.e., those described in Section *1.3* of this SOP as well as any others specific to the SOP that is under development).
d) *Safety* (Section *1.4*); this element shall address precautions, required personal protective equipment, reference to MSDS, reference to other safety or emergency procedures, etc., that are required for the safe conduct of activities described in the SOP.
e) *Materials* (Section *1.5*); all materials required to conduct the activities described in the SOP shall be identified (e.g., equipment, forms, logs, chemicals, reagents, personal protective equipment, etc.). References to other SOPs are not to be included here but shall be identified in Section 8.0.
2.1.7 *PROCEDURES* (Section *2.0*); this element may be further subdivided into as many sections as are required to sufficiently describe methods, procedures, and/or processes for the conduct of activities described in the SOP. This element shall always include sections for:
a) *Calculations* (the section number for this element will vary between SOPs); this element shall include calculations, formulae, transformations, etc., required for the conduct of activities described in the SOP.
b) *Documentation and Reporting* (the section number for this element will vary between SOPs); this element shall identify documentation and reporting requirements described in the SOP, including forms and logs that are required to be completed and maintained.
2.1.8 *DISTRIBUTION AND ARCHIVING* (Section *3.0*); shall include:
a) *Distribution* (Section *3.1*); this element shall identify the potential recipients of the approved SOP.
b) *Archiving* (Section *3.2*); this element shall include the requirement that a historical copy of the SOP be maintained by the IPS manager, as well as archiving requirements (including the title of the individual responsible) and retention period for additional items identified in the SOP, if applicable (e.g., equipment logs, operator's manuals, etc.).
c) *Destruction of Outdated SOPs* (Section *3.3*); this element shall include the destruction procedure identified in Section *3.3* of this SOP.
2.1.9 *ASSURING SOP VALIDATION AND COMPLIANCE* (Section *4.0*); this element shall identify those persons responsible for assuring that the SOP is valid and for assuring that the SOP is followed.
2.1.10 *REVISION OF THE SOP* (Section *5.0*); shall include:

a) *Responsible Individual* (Section *5.1*); this element shall identify those persons responsible for assuring that the SOP is current and for initiating the revision process for the SOP.
b) *Revision Schedule* (Section *5.2*); this element shall include the revision schedule identified in Section *5.2* of this SOP.

2.1.11 *CONTINGENCIES* (Section *6.0*); this element shall identify those persons that shall be consulted when personnel find circumstances that do not permit compliance to the SOP.

2.1.12 *CONFIDENTIALITY* (Section *7.0*); this element shall include the SOP confidentiality policy statement identified in Section *7.0* of this SOP.

2.1.13 *REFERENCES* (Section *8.0*); this element shall include a list of references to current supporting documents identified in the SOP, e.g., other SOPs, test guidelines, manuals, etc. (version numbers for SOPs or supporting documents shall not normally be included).

2.1.14 *APPENDICES* (Section *9.0*); this element shall include a numerical list of all items attached to the SOP in the form of labeled appendices; appendices shall include, but not be limited to, copies of reporting forms required for completion during the conduct of activities described in the SOP; forms shall be included on separate numbered pages, each having a format consistent with the rest of the SOP (i.e., header and footer); forms may be reduced in size to fit the available space.

2.2 Numbering System for SOPs

2.2.1 SOPs shall be identified by four sets of identifiers composed of combinations of letter and number sets as described below:
a) The first set is composed of a combination of the letters **IPS**, indicating that the SOP is distinct from the GLFC Good Lab Practices program.
b) The second set is a three-digit number following a slash, which indicates a unique SOP number (e.g., IPS/**001**).
c) The third set is a three-digit number following a slash, which indicates the version number (e.g., IPS/001/**001**).
d) The fourth set is a three-digit number following a slash, which indicates the copy number of the SOP (e.g., IPS/001/001/**001**); the copy number is not to be filled in by the writer of the SOP but will be completed by the IPS manager at the time of distribution.

2.2.2 SOPs shall be paginated such that each page will indicate the appropriate individual page number and the total number of pages, including all appendices and attachments.

2.3 Format for Reporting Forms

2.3.1 Each IPS reporting form shall have a descriptive title located at the top of the page and a unique form identifier located at the bottom as described in Section *2.4* of this SOP.

2.3.2 The format for dates used on reporting forms shall be specified as DD/MM/YY.

2.4 Numbering System for Reporting Forms

IPS reporting forms shall be identified by the words "IPS Form Number" followed by two number sets as described below:

2.4.1 The first set is a four-digit number that indicates a unique form number (e.g., **0001**).

2.4.2 The second set is a three-digit number following a slash that indicates the version (e.g., 0001/**001**).

2.5 Preparation and Approval of SOPs and Reporting Forms

2.5.1 SOPs and associated reporting forms shall be written/revised by any qualified member of IPS, trained in the use of this SOP, when a new routine procedure is identified or an existing one needs to be revised.

2.5.2 Reporting forms shall be prepared by the same individual who is writing/revising the associated SOP.

2.5.3 Existing reporting forms do not necessarily need to be revised when the associated SOP is revised. Revision of the form is only required when changes to the SOP are carried through to the form.

2.5.4 When an existing reporting form is revised, the associated SOP must also be revised to reflect changes in the form and version number of the form. A reporting form may be used in several SOPs, thus all associated SOPs must be revised.

2.5.5 The writer of an SOP must first determine an appropriate SOP identification number (as well as reporting form identification numbers, if required) by consulting either the IPS manager or the IPU supervisor (who will in turn consult the lists of current SOPs and Forms on the QC&MD network drive).

2.5.6 To facilitate preparation of the new or revised SOP (and reporting forms), the IPS manager or IPU supervisor shall transfer electronic copies of the *IPS SOP Template* and/or applicable SOP(s) and reporting forms from the QC&MD network drive to the Insect Production network drive where the writer has read-write access and can edit the material as required.

2.5.7 The writer shall prepare a draft SOP (including associated reporting forms as appendices) following the requirements set forth in Sections *2.1* through *2.5* of this SOP.

2.5.8 The writer shall circulate the draft SOP to at least one other individual of his/her choice to be peer reviewed for technical merit.

2.5.9 The writer of the SOP shall make all necessary changes, then forward the draft to the IPS manager.

2.5.10 The IPS manager shall assure that the format and content adhere to the requirements of this SOP. If required, the IPS manager shall return the draft to the writer for revision. All requested changes to the draft SOP shall be written by the IPS manager directly on, or stapled to, the draft. Peer review shall not normally be required again, unless indicated by the IPS manager.

2.5.11 Once the IPS manager is satisfied that the format and content of the draft SOP meet the requirements of this SOP, the IPS manager shall then sign and date the revised draft, then add an appropriate *Effective Date*.

2.5.12 The writer shall provide the IPS manager or IPU supervisor, when requested, an electronic file of the approved version of the SOP, which will be maintained on the QC/MD network drive. Separate files for

each reporting form shall be placed by the writer in an appropriate file on the insect production network drive for IPS personnel to print as required.

2.5.13 The IPS manager shall make *Controlled Copies* of the approved SOP, apply a unique copy number to each, stamp each copy with the text "Do Not Duplicate" then distribute to personnel identified in Section *3.1* of the new SOP within one week of approval. Copy number 001 shall be retained by the IPS manager in a file of historical SOPs.

2.5.14 The IPS manager shall document the chain of custody of each copy of the new SOP in an *IPS SOP Distribution Log* (IPS Form Number 0007/003, Appendix 1), which shall be maintained with IPS records. Outdated versions of SOPs must be exchanged for the new ones.

2.5.15 When personnel leave the employment of IPS, the applicable supervisor shall ensure that SOPs held by the departing individual are returned to the IPS manager.

2.6 Calculations

NA

2.7 Documentation and Reporting

Compliance to this SOP shall include the maintenance of an *IPS SOP Distribution Log.* The IPS manager or IPU supervisor shall maintain electronic files of approved SOPs and Reporting Forms on the QC&MD network drive.

3.0 DISTRIBUTION AND ARCHIVING

3.1 Distribution

This SOP shall be distributed by the IPS manager to IPS personnel who may potentially write or revise an SOP or reporting form.

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.

3.3 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 IPS manager is responsible for assuring that this SOP is valid.

4.1.2 The IPS manager is responsible for assuring that this SOP is followed by IPS personnel and that these persons have been appropriately trained in the use of this SOP.

4.1.3 IPS personnel are 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 IPS manager is responsible for assuring that this SOP is current. If necessary, the IPS manager shall initiate the revision process.

5.2 Revision Schedule

This SOP shall be revised when its provisions no longer agree with current practices or GLFC policies, and shall be approved by the IPS manager.

6.0 CONTINGENCIES

When IPS personnel find circumstances that do not permit compliance with this SOP, the IPS manager 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

NA

9.0 APPENDICES

Appendix 1: IPS Form Number 0007/003 (*IPS SOP Distribution Log*)

Appendix 1

IPS SOP Distribution Log

SOP Title:

SOP Number (IPS/number/version/copy)	Distribution Date (DD/MM/YY)	Recipient		Return Date (DD/MM/YY)	Comments
		Name	Initials		

IPS Form Number 0007/003

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