



# **Seed Laboratory Accreditation and Audit Protocol (SEED LAAP)**

## **FOR PURITY, GERMINATION & TRUE LOOSE SMUT TESTING**

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## 1. Introduction

The Canadian Food Inspection Agency (CFIA), through a variety of acts and regulations, works with Canadian producers and importers to safeguard the health, safety, quality and wholesomeness of food and agricultural products. To be credible and fair in the assessment of these products, a laboratory's results must be accurate, reliable and reproducible. CFIA requires that laboratories which provide results for seed assessments through the various Canadian Food Inspection Agency programs, meet the requirements outlined in the Seed Laboratory Accreditation and Audit Protocol (Seed LAAP). The Seed LAAP has been developed to assess specific test competence in the scientific disciplines of chemistry, biology and microbiology. The Seed LAAP has been developed to be consistent with the CFIA's overall framework and policies for the oversight and recognition of laboratories testing in areas under our mandate. It is designed to meet international standards in a Canadian context.

The principle requirements for a seed testing laboratory wishing to be accredited and maintain its accreditation under this protocol are listed in Section 7 and are verified by an on-site audit. They include Management Requirements and Technical Requirements similar to those set out in the ISO/IEC 17025 Accreditation Standard.

In addition, the laboratory must demonstrate its capability to perform the specific tests for which accreditation is requested (pre-accreditation samples).

Laboratories, which meet and maintain the requirements of the Seed LAAP, will be considered to have demonstrated their ability to perform and maintain competence in seed testing by ensuring they:

- have technically competent staff with the requisite skills and knowledge;
- have a lab environment with the requisite facilities and equipment;
- follow the requisite procedures;
- implement the requisite quality management system.



## 2. Definitions

For the purposes of this document the following are defined:

### **Accreditation**

Recognition by CFIA that a laboratory is considered competent to carry out seed purity and/or germination and/or True Loose Smut tests according to the *Canadian Methods and Procedures for Testing Seed*.

### **Accredited analyst: Purity and/or Germination and/or True Loose Smut**

An analyst who has completed training in seed purity and/or germination and/or TLS testing and has passed the qualifying requirements set by CFIA.

### **Accredited laboratory**

Testing laboratory to which accreditation has been granted.

### **Accredited report or certificate of analysis**

A seed testing report/certificate of analysis, issued by an accredited laboratory, which meets the information requirements of the *Canadian Methods and Procedures for Testing Seed* and the Seed Laboratory Accreditation and Audit Protocol. It also contains a statement that the laboratory has been accredited under the CFIA testing accreditation program and states the accreditation number.

### **Accredited Seed Lab Proficiency Monitoring Program (ASLPMP)**

A program administered by SSTS to verify that accredited seed laboratories are maintaining a minimum proficiency level for the tests within their scope of accreditation.

### **Accredited test**

The test method and procedures conducted are those stated in the current *Canadian Methods and Procedures for Testing Seed*. The kind or species and the test method are stated on the scope of testing for which the laboratory is accredited.



## **Auditor**

A person, with qualifications recognized by CFIA, who undertakes to conduct a quality audit.

## **Agent**

Third party conformity body, e.g. Canadian Seed Institute (CSI).

## **Calibration**

Measurements taken and adjustments made traceable to a national or international standard, to ensure accurate operation of an instrument or piece of equipment throughout its working life.

## **Canadian Methods and Procedures for Testing Seed (M&P)**

The "recognized standard methods" required for carrying out "officially recognized tests" as defined in Section 2 of the current *Seeds Regulations*.

## **CFIA Directive D-02-10**

The directive that describes the Canadian Phytosanitary Certification Program for Seeds (CPCPS) to meet the phytosanitary import requirements of the United States. The issuance of APHIS seed analysis certificates must be commensurate with the purity accreditation granted to the laboratory. The USDA-APHIS is responsible for recognition of Canadian seed laboratories under this program and issues laboratories the *Reference Notebook for Canadian Seed for Export to the United States*.

## **Continuous Improvement**

Laboratories should demonstrate continual improvement of their management system. Continual improvement generally involves at least the analysis of the management review topics as well as customer feedback and feedback from the users of the management system e.g. customer surveys can be a source of ideas for continual improvements to the management system.

## **Corrective Action**

Investigation of cause and action taken to eliminate the causes of an existing non-conformity, defect or undesirable situation in order to prevent recurrence. This extends beyond the immediate problem corrected (remedial action) and is an investigation of a problem that has been evaluated to be either potentially



repetitive, or that there is a doubt of the procedures, and considers related systems and processes. The investigation is a root cause analysis which will ultimately expose all the potential causes of the problem allowing the laboratory the ability to evaluate different solutions and select the best one(s) to implement to prevent recurrence.

### **Internal Audit**

The laboratory shall audit every part of their management system annually. The annual audit must include an audit of the tests and techniques that are representative of at least the methods on the scope of accreditation and also include an audit of the implementation of the management elements to demonstrate compliance with the Seed Laboratory Accreditation and Audit Protocol.

### **Management Review**

A formal evaluation by top management annually of the status and adequacy of the laboratory's management system in relation to the quality policy and objectives. The management review shall cover all the management review topics stated in the Seed Laboratory Accreditation and Audit Protocol Section 7.1 j.

### **Non-accredited test**

A test conducted by a CFIA accredited seed testing laboratory that is not within the laboratory's CFIA scope of accreditation and/or is not conducted as prescribed in the *Canadian Methods and Procedures for Testing Seed*.

### **Proficiency test (PT)**

A seed sample or panel of seed samples of known quality, distributed to laboratories for the purpose of assessing proficiency.

### **Post-accreditation audit**

An assessment of a laboratory's compliance with the requirements stated in section 7 of this document as determined by an audit team during a quality audit.

### **Post-accreditation proficiency monitoring**



Proficiency test(s), internal proficiency monitoring and review of results reporting is used for determination of the laboratory testing proficiency as described in the Accredited Seed Laboratory Proficiency Monitoring Program document.

### **Pre-accreditation audit**

An examination and assessment of a laboratory which has applied for accreditation, as measured by pre-accreditation proficiency tests and an on-site quality audit.

### **Preventive Action**

Actions taken to eliminate the causes of a potential non-conformity, defect or undesirable situation in order to prevent occurrence. Preventive action highlights the need to look out for potential problems and opportunities for improvement before problems occur. A proactive approach rather than a reactive approach.

### **Quality Audit**

An independent review of a laboratory's quality system.

### **Quality Manual**

A document stating the quality policy, quality system and quality practices/procedures of an organization.

### **Quality Control**

The operational techniques and activities that are used to fulfill requirements for quality.

### **Quality Management System or Management System**

The collective activities and events that provide an organized plan to ensure that the quality of a product, process or service satisfies the needs of the users.

### **Review of Results Reporting**

Ten set of random sets of sample documentation (worksheets and reports of analyses) from the accredited lab are submitted for monitoring as described in the Accredited Seed Laboratory Proficiency Monitoring Program. CFIA reviews the documents for compliance to the Seed Laboratory Accreditation and Audit Protocol, *Seeds Regulations* and *Canadian Methods and Procedures for Testing Seed*.



## True Loose Smut (TLS)

True loose smut (*Ustilago nuda*). A seed borne disease of barley. The only disease test which CFIA accredits seed laboratories and seed analysts to conduct.

### Verification

Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

## 3. Canadian Food Inspection Agency Responsibilities

### 3.1 General

Canadian Food Inspection Agency will:

- a. Develop, update and amend the Seed LAAP, ASLPMP and any other related documents in response to the needs of the accreditation program.
- b. Consult with accredited laboratory representatives and representatives of the Commercial Seed Analysts Association of Canada (CSAAC) to discuss and resolve problems concerning the Seed LAAP or any aspect of the accreditation process.
- c. Prepare an annual report of activities, as required.
- d. Implement and administer the seed laboratory accreditation program.
- e. Follow up on documented complaints or concerns regarding the performance of accredited seed laboratories.

### 3.2 Inquiries

Any comments, concerns or inquiries about seed laboratory accreditation should be made to:

CFIA Saskatoon Laboratory Seed Science and Technology Section (SSTS)  
301 - 421 Downey Road  
Saskatoon, SK S7N 4L8

Phone: (306)385-4858 Fax: (306) 385-4944  
Email: [ssts@inspection.gc.ca](mailto:ssts@inspection.gc.ca)





#### 4. Purpose of the seed laboratory accreditation program

- a. To provide a standardized and technically sound process to ensure the validity of results which must be used for the grading of seed and may be used to assess whether imported seed lots meet minimum requirement.
- b. To identify laboratories which are deemed competent to perform accredited tests
- c. To add credibility and recognize competent laboratories.
- d. To facilitate laboratory continual improvement by promoting quality control practices such as:
  - Identification and correction of quality control deficiencies;
  - Identification and correction of methodology deficiencies;
  - Identification of training needs;
  - Confirmation of performance specifications in an operating laboratory environment.
- e. To promote the acceptance of an accredited laboratory's results.
- f. To facilitate international trade through acceptance of test data from accredited laboratories.

#### 5. Scope

This protocol applies to laboratories and companies which have chosen to become accredited to establish the acceptability of their laboratory's test results for the purposes of the *Seeds Act and Seeds Regulations*.

Relevant portions of other recognized accreditation programs in which a laboratory participates may be used to fulfill some or all of the requirements of this Seed LAAP.

Facilities, labour relations, safety and accident prevention are the responsibilities of other government agencies and the laboratory. The auditor may comment upon any such deficiencies. However the auditor will only request corrective action for deficiencies which are not in compliance with Section 7 of the Seed LAAP, M&P or the *Seeds Act and Seeds Regulations*.



## 6. Steps for accreditation

### 6.1 Application

Laboratories must apply in writing to the Section Head, Saskatoon Laboratory Seed Science and Technology Section (SSTS). Email – [ssts@inspection.gc.ca](mailto:ssts@inspection.gc.ca) or fax (306) 385-4944 is acceptable.

The Application for seed laboratory accreditation must clearly include the following information:

- a. The name and address of the laboratory;
- b. The scope of accreditation requested. The scope of accreditation must be described in terms of crop kind(s) (crop kinds are as listed in Schedule I of the *Seeds Regulations*) or Grade Table(s) (are as listed in Schedule I of the *Seeds Regulations*) or crop group(s) (crop groups are as specified in section 2 of the Candidates Guide to Seed Analyst Accreditation) and by test i.e. purity, germination, and/or true loose smut of barley;
- c. The name(s) of the laboratory manager, supervising analyst, the quality manager and all accredited analyst(s) and copies of their analyst accreditation certificates;
- d. The expected date of submission of the quality manual;
- e. A statement of the approximate number of samples tested by the laboratory at the time of application.

The application will be acknowledged and if found applicable to the program will be accepted.

The fee for lab accreditation is \$1100.00 (plus GST) payable to the Receiver General of Canada. The applicant will be invoiced for the fee when the application is received. The accreditation process will not proceed to the pre-accreditation audit unless the fee is received.

An application form is available for your convenience in Appendix C.

### 6.2 Submission and Review of the Quality Manual

The laboratory's quality manual should be submitted to CFIA for review within four months of submission of the application. A quality manual review will be conducted to verify compliance with Section 7. Comments will be provided to the applicant. A final



version of the quality manual will be required from the applicant prior to the pre-accreditation audit.

### **6.3 Completion of the Pre-accreditation proficiency testing**

The lab will be sent a set of pre-accreditation samples to be analysed within a given time period and according to the specified test protocols. The number and type of proficiency tests is dependent on the scope of accreditation. The laboratory must test all pre-accreditation samples, without reimbursement, and report the results to CFIA within the prescribed time period.

### **6.4 Completion of the Pre-accreditation Audit**

The laboratory must submit to audits by CFIA for the purpose of verifying that the laboratory meets the Management and Technical Requirements as stated in section 7 of the Seed LAAP, the M&P and the *Seeds Act and Seeds Regulations* and is operating in accordance with its own quality manual. **The laboratory must be fully functional at the time of audit.**

### **6.5 Issuance of the Audit Report**

- a. A copy of the audit findings and observations will be provided to the laboratory at the end of the audit or upon agreement within a few days after the audit.
- b. A final CFIA audit report is prepared within 30 days of the applicant laboratory satisfactorily completing the required corrective actions.

### **6.6 Correction of Non-conformances**

Any non-conformances identified during the audit will be verified, depending on the nature of the non-conformance, by another audit, site visit by a third party chosen by the audit team, or by documentation provided by the laboratory.

### **6.7 Accreditation**

Laboratories which have successfully completed the above will be granted accreditation. A letter of accreditation and a lab accreditation number will be issued by CFIA. The accredited laboratory will be identified on a list which will be made public and distributed on request to potential users of their services.

Laboratories accredited for purity can also request recognition under directive CFIA Directive D-02-10.



## 7. Requirements for accreditation

Before accreditation, the laboratory will be assessed for compliance with each of the following requirements. After accreditation the laboratory must continue to comply with the requirements to maintain their accreditation. Compliance with these requirements will be verified by on site audits.

### 7.1 Management requirements

#### a. Organization and Management

- i. The laboratory's organizational structure must have the capability to operate and maintain testing activities for the scope of accreditation requested.
- ii. Adequate facilities and equipment must be available to carry out testing activities.
- iii. The laboratory must have in place a documented and acceptable quality system.
- iv. The organization must be an entity that can be held legally responsible and have the capability to operate and maintain the testing activity for which accreditation has been requested. Management must be committed to the quality system policy.
- v. The laboratory must have a quality manual.
- vi. The laboratory must be fully operational, have all the required equipment including sample and results entry and quality procedures in place at the time of the pre-accreditation and subsequent audits.
- vii. The laboratory must promptly notify CFIA by contacting SSTS ([ssts@inspection.gc.ca](mailto:ssts@inspection.gc.ca)) of any changes in laboratory, such as the:
  - lab supervisor/manager;
  - quality manager;
  - accredited analysts;
  - laboratory name;
  - ownership;
  - address;
  - contact information;
  - lab closure.



## **b. Quality Manual**

The quality manual must document the quality system and clearly address all the management and technical requirements stated in the Seed LAAP. A member of the staff must be designated as the Quality Manager. The Quality Manager must ensure the quality manual is current, maintained and relevant.

## **c. Document Control**

All related requisite seed testing rules, regulations, handbooks, manuals and instructions must be maintained current and readily available to staff. See Appendix B for required references.

## **d. Purchasing of Services and Supplies**

The laboratory must have policies and procedures for the selection and purchasing of the services and supplies it uses that affect the quality of tests. The procedure for dealing with services and supplies that are not acceptable or adequate must be included.

## **e. Complaints**

The laboratory must have a policy and procedure for resolution of complaints received from customers or other parties.

## **f. Control of Nonconforming Testing and Corrective Action taken:**

Non-conforming testing or reporting errors within the laboratory must be reviewed and any corrective action identified must be implemented. Corrective actions are to be considered as part of the Management Review that is conducted periodically.

## **g. Preventive Action**

Actions taken to prevent errors within the laboratory's quality system are to be discussed/reviewed as part of the Management Review.

## **h. Control of Records**

The laboratory must keep records of:

- Qualifications and training for all personnel. These records are to include training received outside the laboratory and all in-house training;



- Laboratory and analyst proficiency (e.g. review of results reporting, inter-laboratory proficiency tests, external proficiency tests and internal proficiency monitoring);
- Subcontracts for accredited tests (if applicable);
- All records related to testing or reporting errors, and corrective action taken;
- Inspection and maintenance for each item of equipment significant to the tests performed which includes:
  - Records of calibration and verification;
  - Daily germination and pre-chill cabinet temperature measurements.

All quality records such as test results, corrective actions, maintenance and repair of equipment, calibration records and certificates, proficiency testing results (review of results reporting and proficiency test reports), subcontracts (if applicable), management reviews, internal and external audit reports must be kept for 5 years.

If quality records require changes to original data, the original data shall not be made illegible but shall be crossed-out by a single line and initialed and dated.

### **i. Internal Audits**

The laboratory must at a minimum annually conduct internal audits. Audits must be according to a predetermined schedule and follow procedures to verify that the laboratory continues to comply with the requirements of their quality system and the Seed LAAP.

### **j. Management Review**

Management reviews must be conducted at a minimum annually and according to a predetermined schedule to review the laboratory's quality system and testing activities to ensure the systems continuing suitability and effectiveness and to introduce necessary changes and improvements. The result of this review must be documented. The Management Review should identify responsibility and timelines for the implementation of identified action items.

The review must also take into account the following:

- i. Suitability of policies and procedures;



- ii. Reports from managerial and supervisory personnel;
- iii. Outcome of recent internal audits;
- iv. Corrective and preventative actions;
- v. Assessments by external bodies;
- vi. Results of proficiency monitoring;
- vii. Changes in the volume and type of work;
- viii. Customer feedback;
- ix. Complaints;
- x. Other relevant factors, such as quality control activities, subcontracts, resources and staff training.

## 7.2 Technical requirements

### a. Personnel

The laboratory must maintain knowledgeable, adequately-trained and proficient employees to:

- perform testing activities according to specified protocols (i.e. M&P);
- use and conduct verification of testing equipment;
- manage and maintain all documentation and reporting procedures. See the requirement for training records under the heading “Records” above.

An accredited test must be conducted by or under the supervision of, a seed analyst accredited for the test and the applicable species or group of species.

In addition to the above:

- Laboratories with a scope of accreditation for germination testing but not purity testing, where the crop groups in their scope of accreditation include Grade Tables VII to XVII and XIX to XX, must at a minimum have an analyst accredited to conduct purity tests of the crop kinds in these grade tables conducting or supervising these tests.
- Laboratories with a scope of accreditation for germination testing but not purity testing, where the crop groups in their scope of accreditation



include Grade Tables I to VI and XVIII, must at a minimum have an analyst or GB Grader accredited to conduct purity tests for Grade Tables I to VI and XVIII conducting or supervising these tests.

The intent of these requirements is to ensure that pure seed of the applicable crops are planted for germination tests.

The laboratory must ensure that accredited analysts participate in continuing education activities to ensure their proficiency is maintained at an acceptable level for at least the tests within the laboratories scope of accreditation. The continuing education programs required by the Commercial Seed Analysts Association of Canada (CSAAC), Association of Official Seed Analysts (AOSA) and Society of Commercial Seed Technologists (SCST) are acceptable. Analyst participation in continuing education activities will contribute to a lab's proficiency.

#### **b. Accommodation and Environmental Conditions**

Adequate facilities and equipment must be available to carry out testing activities for which accreditation is sought. Minimum specifications are given in Appendix A.

#### **c. Test Methods**

All accredited purity, germination and true loose smut tests must be conducted in accordance with the M&P.

#### **d. Equipment**

All equipment must be uniquely identified e.g. laboratory assigned number or manufacturer's serial number.

When a new piece of equipment is purchased, any laboratory staff that will be responsible to conduct tests using the equipment must receive instruction from the appropriate authorized personnel or the Instruction/Operation Manuals.

Copies of all equipment instruction/operation manuals are to be retained and readily available to the staff.

Malfunctioning equipment must be taken out of service and clearly labelled as "Out of Service" until it has been repaired and then shown by test or calibration to be performing its function satisfactorily again.

Minimum equipment requirements are given in Appendix A.





### **e. Measurement Traceability**

All measuring and testing equipment having an effect on the accuracy or validity of tests must be calibrated (e.g. balances, thermometers, anemometers) or verified (e.g. thermometers, germinators, precision blowers, herbariums, substrate, chemicals) before being put into service and thereafter, and records of the calibrations and verification must be kept. Calibration activities must be conducted by qualified personnel. The calibration records must be traceable to a National or International Standard.

### **f. Handling of Samples**

Each submitted sample is to be examined to ensure the integrity has not been compromised. The laboratory must have procedures for the acceptability criteria of submitted samples and documents, and the actions to be taken when samples do not meet the criteria. Samples must be uniquely identified to ensure there can be no confusion regarding identity or correspondence with worksheets and reports of analysis.

The condition and integrity of samples must be protected before, during and after analysis. Samples must be held for one year following analysis. In the case of purity analysis, each working portion analysed must be packaged separately, be uniquely identified and retained with the submitted sample. Samples must be stored in an environment that will ensure the integrity of the sample for the storage period.

Any impurities found and all impurities removed, as part of the analysis must be packaged separately from the working portions, uniquely identified and retained with the submitted sample.

### **g. Sampling**

The laboratory must have procedures and the appropriate equipment for obtaining samples for testing.

Working samples must be obtained according to the M&P.

### **h. Quality Control**

The laboratory must have in place a quality control program to ensure the integrity of accredited testing activities. This must include the following:



- i. Regular inspection and maintenance of equipment must be carried out and records kept by the responsible lab personnel.
- ii. Laboratories must maintain equipment and supply records e.g. balance verifications, pH verifications, substrate phytotoxicity tests and daily (work days only) records of germination and pre-chill cabinet temperature measurements.
- iii. Laboratories must participate in the CFIA Accredited Seed Laboratory Proficiency Monitoring Program (ASLPMP) which includes external proficiency test panels, internal proficiency monitoring and review of results reporting submitted on the lab's behalf by the third party conformity body (e.g. CSI assessor).

## i. Reporting Results

Results reporting must be in accordance with the M&P.

Reports of analysis containing accredited test results must include the address and contact information for the laboratory and a statement that the testing is in accordance with the M&P and the laboratory's scope of accreditation.

Option 1: The lab may choose to describe their actual scope of accreditation on the report of analysis to make that information more available to the customer. These specific statements must be approved by CFIA prior to use. Please submit them to [ssts@inspection.gc.ca](mailto:ssts@inspection.gc.ca) for approval.

Examples:

- A. A lab that has a full scope of accreditation for germination testing could state the following:

"Accredited by CFIA to conduct germination tests for all crop kinds represented in the Grade Tables of the *Seeds Regulations* in accordance with the *Canadian Methods and Procedures for Testing Seed*. CFIA Accreditation number XXXX."

- B. A lab that has accreditation for TLS of barley as well as purity and germination accreditation for all crop kinds except those that require the use of the blower and could state the following:

"Accredited by CFIA to conduct true loose smut test for barley and purity and germination tests for all crop kinds represented in Grade



Tables of the *Seeds Regulations* except crop kinds in Grade Table XII and Orchardgrass in accordance with the *Canadian Methods and Procedures for Testing Seed*. CFIA Accreditation number XXXX.”

Or

“Accredited by CFIA to conduct tests in accordance with the laboratory’s scope of accreditation (*insert link to laboratory’s website where the scope of accreditation is described*) and the *Canadian Methods and Procedures for Testing Seed*. CFIA Accreditation number XXXX.”

Option 2: Alternatively the following statement can be used on the report of analysis:

“Accredited by CFIA to conduct tests in accordance with the laboratory’s scope of accreditation and the *Canadian Methods and Procedures for Testing Seed*. CFIA Accreditation number XXXX.”

“CFIA Accreditation number XXXX” need not be in close proximity to the previous sentences related to scope.

All reports of analysis containing accredited test results must be signed by the lab manager or delegate taking responsibility for the analysis, or by the accredited analyst who conducted/supervised the analysis.

Results of tests must be reported accurately, clearly, unambiguously and objectively. Records for each test must contain sufficient information to permit satisfactory repetition of the test. Worksheets must clearly indicate who conducted the test or activity.

If it is discovered that there was a non-conformance in the analysis or reporting and the issuance of an amended report of analysis is authorized it must be clearly identified as an “Amended Report.”

Results of accredited tests that are reported on an Accredited Labs report of analysis must have been conducted at the Accredited Lab issuing the result or the name and accreditation number of the Accredited Lab that conducted the test must be stated in such a way that it is clear which tests were conducted by each Accredited Lab. The labs must have in place a subcontract agreement addressing the expectations for the testing lab and reporting lab. The subcontracted lab must be CFIA accredited for the tests which will be reported by the reporting laboratory. The reporting lab is responsible to the customer for all the test results (including the subcontractors) reported on their report of analysis.



Electronic data capture and results issuance, including electronic signature are permitted. The laboratory's quality manual or quality documents must describe the related procedures. These procedures must ensure that electronic data/documents/records are protected from inadvertent or unauthorized amendment and that they are directly correlated to the original data/documents/records. Common acceptable approaches include:

1. controlled access to use the electronic signatures;
2. specify the persons that have edit access;
3. use password protection;
4. use read only storage media (only authorized personnel allowed to make changes);
5. clear and simple procedures to modify data/documents/records and tracking of amendments and clear authority for doing the amendments;
6. backups of current versions so that data can be restored if normal access is lost.

All computer software developed by the lab must be validated as being adequate for use. All software modifications should be validated as fit for purpose (e.g. calculations of data, macros). The validation of software must include a test plan identifying a pre-defined series of inputs that are selected in such a manner to represent the range of inputs and to provide sufficient confidence on the outputs or performance of the software for the intended use. The pre-defined inputs are entered using the software being validated and the outputs are compared to the expected results obtained by alternative, proven methods. The records from the validation testing must provide objective evidence that the software works as expected over its specified range. The test plan and validation must be revised and repeated when there are changes to the algorithms. The validation test plan should also include robustness to ensure that the software responds as expected when invalid inputs are provided.



## 8. Pre-accreditation proficiency samples

Before a laboratory is accredited, it must successfully demonstrate its capability to perform the specific tests for which accreditation is requested. The laboratory must test all pre-accreditation proficiency samples, without reimbursement.

- a. Canadian Food Inspection Agency (CFIA) will provide pre-accreditation proficiency samples, and testing instructions for each of the accredited tests under consideration. CFIA will notify the lab by email when the pre-accreditation samples have been or will be sent.
- b. The laboratory will report non-receipt or delayed receipt of samples to CFIA.
- c. The laboratory will analyze the samples, following the provided testing instructions and report all results within the specified time period and keep records of results.
- d. If the results of the analysis and the samples are not forwarded to CFIA within the specified period, the accreditation request will be suspended. It is the laboratory's responsibility to contact CFIA and re-initiate the pre-accreditation process. The test results will be evaluated for test procedures, reporting and compared with the expected results.
- e. CFIA will prepare a pre-accreditation proficiency test report and provide a copy to the laboratory.

## 9. Pre-accreditation audit

The quality manual review will be completed by CFIA and a final version of the quality manual will be sent to CFIA by the laboratory prior to the pre-accreditation audit. The laboratory site will be audited by CFIA to verify that quality management practices, organization, facilities and that the quality system /control procedures are maintained as stated and in compliance with the Seed LAAP, the M&P and the *Seeds Act and Seeds Regulations*. A lead auditor is assigned by the CFIA to lead the audit team.



## 10. Failure to attain accreditation

Accreditation will not be granted if the applicant fails to meet the requirements stated in Section 7 or fails to describe how these requirements are met in a quality manual or related quality documents. If the laboratory is not operational or the audit team is presented with a new version of the quality manual at the audit the lead auditor may choose to terminate the audit. The laboratory will have to re-initiate the accreditation process including a new payment for the lab accreditation fee.

## 11. Annual recommendation by agent based on verification audit

The laboratory must submit to audits by CFIA, its agent (i.e. CSI) or an ISO/IEC 17025 accrediting body for the purpose of verifying that the laboratory continues to meet the Management and Technical Requirements as stated in section 7 of the Seed LAAP, the M&P and the *Seeds Act and Seeds Regulations* and is operating in accordance with its own quality manual. The frequency of audits/assessments can vary according to a laboratory's performance but with an anticipated frequency of once every three years. The agent will notify CFIA if a laboratory has not successfully completed a post-accreditation audit.

A re-accreditation audit by CFIA may be required under the following circumstances. The lab accreditation fee will apply if an on-site audit is conducted:

- Change of ownership and supervising analyst;
- Change of location and supervising analyst;
- Change of ownership and location;
- Proficiency or operational deficiencies indicating that the Laboratory is not meeting the requirements of the Seed LAAP.

Submission of a new or revised quality manual and any supporting quality documents is required if quality documents are revised due to the following circumstances:

- Change of supervising analyst;
- Change of ownership;
- Change of location.

**Note:** SSTS must be informed, in writing, of any personnel changes related to ownership, laboratory manager, supervising analyst or accredited seed analysts.



When there is a change of location, the lab manager must inform SSTS in writing in advance of the move. Contact information must be submitted to SSTS as well as a new floor plan. As stated, the lab will be required to update their quality manual; SSTS will provide the laboratory a checklist that must be returned to SSTS before the move takes place.

It is best practice for a laboratory to utilize a different auditor after two consecutive audits.

## 12. Post-accreditation proficiency monitoring

A laboratory's on-going capability to test is monitored by the post-accreditation testing program which is described in the ASLPMP document. The ASLPMP includes participation in CFIA proficiency tests, submission of documentation by the auditor for review of results reporting, and internal proficiency monitoring. Participation and a satisfactory rating in the ASLPMP is a mandatory requirement to maintain accreditation.

**Note:** Referee samples may be distributed to laboratories to verify methodology and/or to develop or confirm the performance of a method. These samples are not considered for proficiency monitoring purposes. Laboratories are requested to participate in these tests, but participation is voluntary and not a mandatory requirement for maintenance of accreditation status. However, participation in referees can contribute to an analyst's continuing education (see section 7.2).

## 13. Scope Expansion

Laboratories may apply to expand their current scope of accreditation at any time by informing the Section Head of SSTS, Saskatoon Laboratory in writing. Email – [ssts@inspection.gc.ca](mailto:ssts@inspection.gc.ca) or fax (306) 385-4944 is acceptable.

Scope expansion fees are dependent on the scope being requested. The fee for a scope expansion will be determined on an hourly basis of \$60/hour but will not exceed the original accreditation fee of \$1100 (plus GST). All fees are to be made payable to the Receiver General of Canada.

Pre-accreditation proficiency tests are required for a scope expansion, refer to Section 8.3.



## 14. Suspension or partial suspension of accreditation

Laboratories will have their accreditation suspended or have their scope of accreditation limited as a result of significant post-accreditation non-conformance and testing failures as determined through post-accreditation audits and/or post accreditation proficiency monitoring. Lack of appropriate and timely corrective action could also lead to removal of accreditation.

Removal of some Grade Tables may affect your scope of accreditation in other Grade Tables. For example, if a lab is no longer accredited to test Grade Tables VIII to X, this will affect Grade Table XIII; removal of Grade Tables V and VI will affect Grade Table XVIII, etc.

For laboratories that are recognized under CFIA D-02-10, notification will be given to USDA-APHIS if the laboratories purity scope of accreditation has changed.

## 15. Removal of accreditation

Laboratories will lose accreditation if there is evidence that the laboratory has willfully taken actions that are contrary to the Seed LAAP and thereby calls into question the credibility of the quality practices and results produced by the laboratory. Examples of such actions are the falsification of results or data or the willful destruction of evidence, samples or records that would demonstrate incompetence in testing. On-going failure to meet Seed LAAP requirements or failure to correct deficiencies in testing proficiency could lead to loss of accreditation which can be initiated by CFIA. Accreditation will also be removed at the request of the laboratory or when a laboratory is permanently closed.

For laboratories that are recognized under CFIA D-02-10, notification will be given to USDA-APHIS if the laboratories purity scope of accreditation has changed.

## 16. Complaint and appeal process

If a laboratory has a complaint or wishes to appeal an accreditation decision the process will require the following:

- a. Notify the Section Head of SSTS in writing. In the case of an appeal of an accreditation decision, notification must be within 30 days after the original decision was made. Notification can be emailed to [ssts@inspection.gc.ca](mailto:ssts@inspection.gc.ca).





Written notification must describe any allegations of errors or omissions that may have occurred to support the complaint or appeal.

- b. If the complaint or appeal is not resolved at the Saskatoon Laboratory level, the complaint may be raised the CFIA Complaints and Appeals Office.

## **17. Re-accreditation**

The manager of a laboratory can re-apply for accreditation by writing to the Section Head of SSTS, Saskatoon Laboratory. The accreditation fee and evidence of compliance with the requirements of the Seed LAAP will be required. In addition evidence of corrective action may be requested, prior to accepting a request for re-accreditation.



## Appendix A

### Accredited Seed Testing Laboratory: Minimum facility and equipment requirements

The equipment in the laboratory and the ability of the personnel to use it are essential factors which determine the scope of the germination, purity or true loose smut (TLS) testing which may be performed at an individual laboratory.

#### 1. General Lab Requirements

**Note: Equipment may be shared between a purity, germination and/or TLS laboratory**

##### General facility

- Testing must be conducted in an area dedicated to seed testing.
- The laboratory must be fully operational

**Mechanical mixer/divider:** At least one of the following, of a size appropriate for the kind(s) of seed included in accreditation.

- Centrifugal divider (Gamet)
- Riffle (soil) divider
- Any device which can be shown to randomly mix/divide seed (i.e. the lab must provide supporting evidence)

##### Sample storage area

- Capacity to store samples for one year following analysis.
- Storage system and facility adequate to maintain integrity of samples (e.g. pest free, germination.)

#### 2. Germination Lab Requirements

(See also General Lab Requirements)

##### Germination bench space

- Sufficient space for planting and evaluating samples.
- Sufficient illumination.

##### Germination chamber

- Capable of maintaining the temperature prescribed for the crop kind(s) included in the scope of accreditation,  $\pm 2^{\circ}\text{C}$ .
- If alternating temperatures are prescribed, then the lab must either have a chamber capable of automatically alternating temperatures, with the



- changeover being accomplished in one or less hour; or a second chamber capable of maintaining the second prescribed temperature,  $\pm 2^{\circ}\text{C}$ .
- The germination chamber system must be capable of maintaining high humidity around the seeds in the test, either with a humidified chamber, or by enclosing tests.
  - If accreditation covers species for which light is prescribed, the chamber must meet the specifications of M&P 4.5.5.

**Prechill chamber** (required only if accreditation includes crop kinds that require a prechill)

- Capable of maintaining a specified constant temperature  $\pm 2^{\circ}\text{C}$  at a temperature not lower than  $5^{\circ}\text{C}$  and not more than  $10^{\circ}\text{C}$ .

**Water for moistening substrate and cleaning equipment**

- Must meet the specifications of M&P Section 4.5.3.
- Must be reasonably free of chemical and organic impurities.
- There must be a source of running water within the laboratory, enough to allow for routine cleaning of trays, containers, housekeeping etc.

**Balance** (for preparation of chemical solutions)

- Capacity at least 100 g.
- At least two decimal places.
- Must have a valid calibration certificate.

**Thermometers**

- One for each germination and pre-chill chamber.
- Must be capable of measuring the range of the operating temperatures of the germinators.
- Must have a valid calibration certificate.

**Magnifier or Microscope** in the range of 3X to 7X

**\*Sand**, for use as a primary substrate and/or as a retesting medium

- Must meet the specifications given in Section 4.5.2 and 4.5.2.a of the M&P.
- Must be non-phytotoxic, as determined by the phytotoxicity test described in Section 4.5.6 of the M&P.

**\*Soil-less organic growing media**, for use as a retesting medium



- Must meet the specifications given in Section 4.5.2 and 4.5.2.c of the M&P.
- Must be non-phytotoxic, as determined by the phytotoxicity test described in Section 4.5.6 of the M&P.

**Paper substrata** (towels, blotters, filter paper), for use as a primary substrate. (Not required if accredited only for crop kinds for which sand is an allowed substrate).

- Type depends on M&P prescription and laboratory preference.
- Must meet the specifications given in Section 4.5.2 and 4.5.2.b of the M&P.
- Must be non-phytotoxic, as determined by the phytotoxicity test described in Section 4.5.6 of the M&P.

#### **Test containers**

- One or more of cardboard, aluminum, glass, plastic boxes, petri dishes, etc. Type depends on laboratory preference and must be appropriate for the use.
- Must be non-phytotoxic, as determined by the phytotoxicity test described in Section 4.5.6 of the M&P.

**\*Potassium nitrate** ( $\text{KNO}_3$ )

**\*Tetrazolium** (2,3,5-triphenyl tetrazolium chloride)\*

**Note\***: it is not mandatory for the lab to have these items at all times but they must be aware of the circumstances when they would be required to use them and be able to source them as/when required.

#### **Miscellaneous equipment**

- Calculator
- Mixing pans, at least four
- Forceps
- Purity knife
- Scalpel
- Dissecting needles, at least two
- Cleaning brush
- Containers/implements for mixing sand
- Sieve and pan set for separating seedlings from sand

### **3. Purity Lab Requirements**



(See also General Lab Requirements)

### **Seed specimen reference collection**

- Must contain all Schedule I crop kinds and all *Weed SeedS Order* specimens (picture references are acceptable for prohibited noxious and vegetable specimens that are difficult to obtain).
- In addition to species in Schedule I and the Weed Seed Order there must be at least 25 specimens from the *Minimum List of Species for Seed Identification by Canadian Accredited Seed Analysts and Laboratories*.

### **Purity workbench**

- Dedicated working surface
- Sufficient illumination

**Stereo microscope** (required if accreditation includes crop kinds of Grade Tables VII-XX)

- Magnification with a range of at least 10X to 30X
- Sufficient illumination

### **Balances**

- The required number of decimals is based on the significance of weighing stated in M&P Section 3.3.1, for example, if the balance is being used to weigh working samples that are less than 1 gram then the minimum number of decimal places is 4.
- The required capacity is based on the required working sample weights for the crop kinds in the laboratory's scope of accreditation, for example, if the lab's scope of accreditation includes crop kinds that have a working sample weight of 100 grams then the balance used for the crop kind(s) should have a capacity range that includes 100g.
- Both capacity and the required number of decimals are to be considered when selecting the appropriate balance.

**Seed blower, anemometer** (required only if accreditation includes crop kinds in Grade Table XII and/or Orchardgrass)

- Precision blower equivalent to the General blower
- Anemometer as set out in M&P
- Kentucky bluegrass master calibration sample as set out in M&P. Not required to have the master calibration sample at the lab but must be aware of how to source the master calibration sample from AOSA/SCST.



- Orchardgrass master calibration sample as set out in M&P. Not required to have the master calibration sample at the lab but must be aware of how to source the master calibration sample from AOSA/SCST.

**Diaphanoscope** (required only if accreditation includes crop kinds that are listed in Grade Table XI to XII)

**Ultra-violet light** (35 nm) (required only if accreditation includes wheatgrasses)

**Brassica boards**, at least two (or equivalent) (required if accreditation includes *Brassica spp.*)

**Screen/sieve set** to aid separation and retrieval

#### **Miscellaneous equipment**

- Calculator
- Seamless sub-sample containers (at least ten) e.g. cups
- Mixing pans, at least four
- Hand lens, or magnifier with a magnification between 3X and 10X
- Forceps
- Purity knife
- Scalpel
- Dissecting needles, at least two
- Cleaning brush

#### **4. True Loose Smut of Barley (*Ustilago nuda*) Lab Requirements**

(See also General Lab Requirements)

##### **TLS bench space**

- Sufficient space for the preparation and evaluating samples
- Sufficient illumination
- Sufficient ventilation

##### **Balance** (for preparation of chemical solutions)

- Analytical Balance with a minimum capacity of 100 grams and at least 2 decimals
- Balance with a capacity of least 1000 grams and minimum of 1 decimal if using NaOH pellets



- a. **Stereoscopic Binocular Microscope:** With magnification between 6X-50X equipped with 10X to 20X oculars. Either zoom or step wise magnification change is acceptable. Step wise change allows for exact magnification while zoom systems may be preferred by the inexperienced analyst as the field of view is not lost between magnification changes. Lighting should be available in both transmitted and substage incident modes. Transmitted light should be “cool” to prevent drying out of delicate specimens and come from two directions to eliminate shadows.
- b. **Containers and Glassware:** Petri dishes, a minimum of two enamel photographic pans or similar type of pan, graduated cylinders, 1000 ml beakers or measuring cups or similar containers, crucible or pyrex dishes (high sides) or similar container.
- c. **Other Equipment:** Tyler sieves (mesh size refer to M&P), pipettes, funnels, beakers, dropping bottles for reagents and stains, forceps, spatulas, stirring rods and seamless mesh screen.
- d. **Chemical:** Sodium Hydroxide, Lactic Acid, Trypan blue, Glycerin and Ethanol, distilled water (For detail on chemical requirements, refer to M&P Chapter 5.0).



## Appendix B

### Accredited Seed Testing Laboratory: List of reference documents

#### 1. Required References for all Accredited Labs

- a. *Canada Seeds Act and Seeds Regulations* (current edition)
- b. Seed Laboratory Accreditation and Audit Protocol (current edition)
- c. *Canadian Methods and Procedures for Testing Seed* (current edition)
- d. Accredited Seed Laboratory Proficiency Monitoring Program (current edition)

#### 2. Germination Lab References

##### a. Required References (in addition to Appendix B, section 1):

- i. AOSA Rules Volume 4, Seedling Evaluation, current version
- ii. AOSA Rules Volume 1, Principles and Procedures, current version (If testing species not listed in Schedule I of the *Seeds Regulations* and/or participating in the Authorized Exporter program using AOSA Rules, or testing coated seeds)
- iii. ISTA Rules, current version (If testing species not listed in Schedule I of the *Seeds Regulations* and/or participating in the Authorized Exporter program using ISTA Rules)
- iv. AOSA Tetrazolium Testing Handbook or ISTA Tetrazolium Handbook (for verifying whether ungerminated seeds are dormant or dead and if their scope of accreditation includes germination testing *Pascopyrum smithii*, Western wheatgrass or fall cereals).

##### b. Recommended References:

- i. AOSA Rules Volume 1 to 4, current version (also can be a required reference as stated above)
- ii. ISTA Rules current version (also can be a required reference as stated above)
- iii. ISTA Handbooks (see ISTA website for publications <http://seedtest.org/en/home.html>)
- iv. AOSA Handbooks (see AOSA website for publications <http://www.aosaseed.com/>)
- v. Seed Technologist Training Manual, (see SCST website <http://www.seedtechnology.net/publications.htm> )





### 3. Purity Lab References:

#### a. Required References (in addition to Appendix B, section 1):

- i. At least one flora reference, e.g. Gray's Manual of Botany, or access to the USDA/ARS/GRIN website on the internet (<http://www.ars-grin.gov/cgi-bin/npgs/html/index.pl>) AOSA Rules Volume 1, Principles and Procedures, current version (If testing species not listed in Schedule I of the *Seeds Regulations*, issuing APHIS Certificates and/or, participating in the Authorized Exporter program using AOSA Rules, testing coated seeds)
- ii. AOSA Rules Volume 2, Uniform Blowing Procedure (if testing species in Grade Table XII and/or Orchardgrass).
- iii. ISTA Rules, current version (If testing species not listed in Schedule I of the *Seeds Regulations*, participating in the Authorized Exporter program using ISTA Rules)

#### b. Recommended Purity Testing References:

- i. AOSA Rules Volume 1 to 4, current version (also can be a required reference as stated above)
- ii. ISTA Rules current version (also can be a required reference as stated above)
- iii. ISTA Handbooks (see ISTA website for publications <http://seedtest.org/en/home.html>)
- iv. AOSA Handbooks (see AOSA website for publications <http://www.aosaseed.com>)
- v. Seed Technologist Training Manual (see SCST website <http://www.seedtechnology.net/publications.htm> )

#### c. Recommended Seed Identification References:

- i. [www.idseed.ca](http://www.idseed.ca)
- ii. Seed Purity and Taxonomy: Application of Purity Testing Techniques to Specific Taxonomical Groups of Seeds, by Doris Baxter and Lawrence O. Copeland.
- iii. Seed Identification Manual, by Alexander C. Martin, William D. Barkley
- iv. Illustrated Taxonomy Manual of Weed Seeds, by Richard J. Delorit
- v. Weed Seeds of the Great Plains: A Handbook for Identification, by Linda W. Davis



- vi. Seeds and Fruits of Plants of Eastern Canada and Northeastern United States. By Montgomery, F. H. University of Toronto Press, Toronto, Ontario. 1977. (may be out of print)
- vii. Identification of Crop and Weed Seeds. Agricultural Marketing Service, Agricultural Handbook 219. U.S. Government Printing Office, Washington, 1963 (may be out of print)
- viii. Plant Identification Terminology: An Illustrated Glossary by James G. Harris, Melinda Woolf Harris

d. **Recommended Nomenclature Reference:**

- i. Common and Scientific Names of Weeds in Canada, S.J. Darbyshire, M. Favreau, M. Murray, AAFC, 2000 or newer.

**4. True Loose Smut Lab References**

a. **Recommended References:**

- i. ISTA Rules current version and Annexe to Chapter 7



## Appendix C

### Application for Seed Laboratory Accreditation

1. Name, address and contact information for the laboratory seeking accreditation:

2. Scope of accreditation requested: (describe in terms of crop kind(s) or Grade Table(s) and by test i.e. purity, germination, and True Loose Smut of barley).

3. Name of Laboratory manager:

4. Name of Supervising analyst:

5. Name of Quality Manager:

6. List all accredited analyst(s):

7. The expected date of submission of the quality manual:

8. The approximate number of samples currently tested by the laboratory:

\_\_\_\_\_  
Signature of Applicant

\_\_\_\_\_  
Date of Application

**Submit by email to SSTS @inspection.gc.ca or by fax to (306) 385-4944**

The applicant will be issued an invoice for the fee for lab accreditation, \$1100.00 payable to the Receiver General of Canada. See Section 6.1 of the Seed LAAP for more information regarding application and the fee for lab accreditation.



## Appendix D Revision Table

Previous Version	Previous Version Revision Date	Section revised, deleted, added	Reason for Update
Version 5	November 2011	Throughout	Update the SSTS phone and fax number
		Throughout	Replace the word assessment with the word audit
		Throughout	Remove all mention of split sample monitoring program and refer to review of results reporting instead (also updated in ASLPMP document)
		2.0	Add definition for CFIA Directive D-02-10 (re: APHIS-PPQ925 program) Add definition for review of results reporting Remove definition for split sample monitoring program Edit definition for post-accreditation proficiency monitoring
		6.1	Move scope expansion fee to Section 13
		6.7	Add information about lab recognition under the CFIA Directive D-02-10
		7.2.a	Added SCST acronym
		7.2.d	Change wording to clarify statement regarding malfunctioning equipment
		7.2.i	Change from amended certificate to amended report Add requirement for validation of lab developed software and software modifications
		11	Include the option for acceptance of ISO/IEC 17025 audits. Clarified the procedure when a lab relocates Suggested to limit the number of consecutive audits by the same auditor to 2 as best lab practice
		13 (new)	Add a new section to describe the process for scope expansion
		14	Re-number section from Section 13 Clarify removal of grade tables when they relate to grade tables containing seed mixtures. Add that APHIS is informed of all purity related scope removals
		15	Re-numbered from Section 14
		16	Re-numbered from Section 15 Clearly defined complaints and appeals process



<b>Previous Version</b>	<b>Previous Version Revision Date</b>	<b>Section revised, deleted, added</b>	<b>Reason for Update</b>
		17	Re-numbered from Section 16
		17 (old)	Removed section and incorporated into Section 15
		Appendix A	Add Soil-less organic growing mix Added Minimum List reference Updated section on germinators to refer to the light specifications in the M&P
		Appendix B	Add Seed LAAP and ASLPMP to the list required documents and clarify required references
		Appendix C	Updated application form
		Appendix D	Add revision table