# Accredited Seed Testing Laboratory Proficiency Monitoring Program (ASLPMP)

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#### 1.0 Introduction

The Canadian Food Inspection Agency (CFIA) Accredited Seed Laboratory Proficiency Monitoring Program is administered by CFIA Saskatoon Laboratory, Seed Science and Technology Section (SSTS) with the cooperation of the Canadian Seed Institute (CSI). The purpose of the monitoring program is to verify that accredited seed testing laboratories meet the minimum proficiency requirements and to ensure uniformity in testing and reporting of results. The monitoring program is based on principles outlined in ISO/IEC Guide 17025: General requirements for the competence of calibration and testing laboratories. The proficiency testing program is designed using ISO/IEC 17043: Conformity Assessment – General Requirements for Proficiency Testing as a guideline. One of the requirements of an ISO system is a proficiency testing program. The design of the CFIA Proficiency Test Sample Program closely parallels the ISTA Proficiency Test Program, which harmonizes with international standards.

There are approximately 30 to 35 accredited seed laboratories in Canada. The monitoring program is carried out in the scheme described as follows:

- The lab has an audit every three years (described in section 3)
- The lab conducts internal proficiency monitoring on an on-going basis (described in section 4)
- The lab participates in the CFIA Proficiency Test Program for all crop kinds under the scope of accreditation. (described in section 5)



#### 1.1 Scope

Seed testing laboratories accredited by CFIA must participate in the Accredited Seed Laboratory Monitoring Program (hereafter called monitoring program). The scope of this monitoring program includes post accreditation purity and germination tests regulated under the *Seeds Act and Seeds Regulations*. Non-accredited laboratories may participate in the proficiency test sample program voluntarily at their request to prepare themselves for accreditation.

#### 1.2 References

Current versions of:

Seed Laboratory Accreditation and Audit Protocol (Seed LAAP); Seeds Act and Seeds Regulations; Canadian Methods and Procedures for Testing Seed (M & P).

#### 1.3 Definitions

See the Seed LAAP for applicable definitions.

#### 1.4 Outline

The monitoring program facilitates the continued accreditation of seed testing laboratories who are conducting tests regulated under the *Seeds Act and Seeds Regulations*. It aims to identify methodology deficiencies, non-conformances and training needs for a lab to maintain its performance standards; and to monitor laboratory performance in following the *Canadian Methods and Procedures for Testing Seed* in an operating environment. For the purposes of three year audit cycle, laboratories are assigned to one of three groups based on the year of the laboratory's accreditation such that they are placed in the lab group requiring an audit in that same year (e.g. a laboratory accredited in 2017 will join the group of laboratories requiring an audit in 2020).

#### 2.0 Monitoring Program Requirements

A laboratory performance rating is established for each post accreditation monitoring program except the audit and review of results reporting part of the program. To maintain accreditation, laboratories must participate and meet minimum performance standards in each program. The following table describes the performance ratings.



**Table 1. Performance Ratings** 

Rating	Action Required
Α	Acceptable, no action required, except as otherwise indicated.
В	Review of methods is recommended. Preventative measures shall be taken.
С	Lab must investigate possible causes.
BMP Below Minimum Performance	The lab must investigate possible causes and take corrective action, a follow-up retest is required.

#### 2.1 Non-Participation

Laboratories that fail to participate in each part of the program or fail to meet deadlines without reasonable cause will be suspended until corrective actions are taken and evidence of implementation of the corrective action are confirmed by SSTS (e.g. completion of a PT panel and submission of results to SSTS, or implementation of an internal proficiency monitoring program).

#### 2.2 Suspension

Laboratories will have their accreditation suspended as a result of significant non-conformances and lack of appropriate and timely corrective action. Failure to participate in the monitoring program will result in suspension.

# 3.0 Audit and Review of Results Reporting Monitoring

#### 3.1 General Overview

During the audit, the auditor obtains 10 random sets of sample documentation (worksheets and reports of analyses) from the accredited lab. This documentation is submitted to SSTS for review of results and reporting procedures and compliance to the Seed Laboratory Accreditation and Audit Protocol (Seed LAAP). SSTS generates a report with a summary of the review of the reporting procedures and identification of



non-conformances and improvement ideas. The accredited lab submits corrective actions in response to identified non-conformances to the SSTS for confirmation that the corrective action will address the non-conformance. The accredited lab maintains the correspondence on file. During the audit the auditor ensures corrective actions related to previous sample documentation have been kept on file and have been implemented.

# 3.2 SSTS responsibilities

The review of worksheets and reports of analysis will be completed by SSTS for compliance with the *Seeds Regulations*, M & P and the Seed LAAP. Non-conformances and the applicable section of the Seeds Regulations, M & P and/or Seed LAAP will be identified on the corrective action requests. SSTS will issue a report including the corrective action requests generated from the review of worksheets and reports of analysis within 60 days of receipt. Communication with the accredited labs subsequent to the issuance of the report/corrective action requests will be made in a timely manner.

## 3.3 Accredited Laboratory responsibilities

The accredited laboratory, at the request of the auditor, copies 10 random sets of sample documentation (worksheets and reports of analyses) for submission to SSTS. Once receiving the report/corrective action requests, responds to SSTS by the date specified on the report indicating the corrective action taken and providing documented evidence of the corrective action implemented to address the non-conformances with the *Seeds Regulations*, M & P and/or Seed LAAP. The accredited lab must maintain the remainder of auditor submitted samples until SSTS has confirmed that the corrective actions are satisfactory. As required by the Seed LAAP the accredited lab must maintain the documents related to these samples for not less than five years so that they are available to the auditor during the next audit.

# 3.4 Auditor responsibilities

The auditor must limit their choice of sample records to those that are within the lab's scope of accreditation; were tested in accordance with the M & P; and were tested at the lab within the last year. The sample documentation must be clearly identified with the lab name, accreditation number and date of audit. The auditor submits the sample records (worksheets and reports of analysis) obtained from the accredited labs during the audit within 5 working days to SSTS. It is acceptable to send by mail or email a pdf copy to SSTS@inspection.gc.ca.





## 4.0 Internal Proficiency Monitoring

#### 4.1 General Overview

The accredited lab must conduct internal monitoring to verify the proficiency of each analyst performing seed tests related to the lab's purity and germination scope of accreditation. Internal monitoring must be planned and conducted on an on-going basis. Records of the internal proficiency monitoring and any corrective action taken to improve analyst proficiency must be maintained on file for verification by the auditor during the audit. Failure to conduct acceptable internal proficiency monitoring will result in a performance rating of BMP. There will be no assignment of A, B or C ratings for various levels of participation.

#### 4.2 Accredited Laboratory responsibilities

The accredited lab responsibilities for internal proficiency monitoring include:

- 1. Setting a proficiency standard or goal for purity and germination testing.
- 2. Describing in their quality system documents their internal monitoring procedure.
- 3. All analysts having an impact on test results must participate in the internal proficiency monitoring program.
- 4. Corrective actions must be taken if it is found that analyst(s) proficiency does not meet the established standard or goal.
- 5. Documentation of analyst participation, proficiency results and corrective action must be kept on file for the auditor to review during the assessment visit.

In general terms, acceptable germination and purity analyst proficiency monitoring procedures are described below:

- 1. Re-analysis of the same working sample by another analyst and comparison of results.
- 2. Analysis of two (or half of the) working sample(s) by different analysts and comparison of results.
- 3. Analysis of samples and comparison to a known result.

Failure to conduct internal monitoring as described above will result in corrective action request(s) from the auditor during the audit. SSTS will assign the lab a performance rating of BMP upon notification from CSI that a lab is not conducting internal proficiency monitoring.





#### 4.3 Auditor responsibilities

The auditor must review the files related to internal proficiency monitoring during the audit. Corrective action requests will be issued if the auditor identifies that the lab is not fulfilling the responsibilities as stated above. The auditor will notify CSI according to normal procedures that a corrective action has been issued to the lab for failing to conduct internal proficiency monitoring. CSI will immediately notify SSTS when a critical non-conformance is issued to the laboratory.

### 5.0 Proficiency Test Program

#### 5.1 General Overview

The design of the program includes 6 crop groups for a three year cycle and two panels of samples per year, each panel consisting of three samples of the same crop kind. A crop kind from each of two crop groups will be selected for two panels each year and the selected crop kind represents the grade table it belongs to. SSTS designs the panels, selects, prepares and distributes samples, and analyses the results. Participating laboratories may be required to test for purity, percentage purity, germination or all tests according to their scope of accreditation. In the case of purity samples, known numbers of contaminant species are added to the samples and the participating laboratories are given a score based on the percentage of these added seeds they retrieve and correctly identify. The expectation for monitoring the proficiency of accredited laboratories in impurity retrieval and identification will be based on the Minimum List of Species for Seed Identification by Canadian Accredited Seed Analysts and Laboratories (Minimum List). For pure seed percentage and germination tests, the results from all laboratories are analysed statistically. The evaluation of each laboratory's performance is based on this analysis, in particular, whether or not their results show any significant trend away from the mean value from all laboratories. Reports of performance on each panel will be distributed to each participating laboratory.

# 5.2 Program Schedule

Two panels of proficiency test samples are sent out within a calendar year. The target for distribution of the two proficiency test panels in each year is March and September. These panels are sent to the laboratories that have the testing for the crop kinds within their scope of accreditation.



Crop groups for a three year cycle of proficiency test samples are:

Year 1:

Group 1: Panel a): Grade Tables VIII-X

Group 2, Panel b): Grade Tables XVI to XX

Year 2:

Group 3, Panel a): Grade Tables I-IV

Group 4, Panel b): Grade Tables VII

Year 3:

Group 5, Panel a): Grade Tables V-VI and XVIII

**Group 6, Panel b): Grade Tables XI-XV** 

The six crop groups may be re-organized for any three year cycle to address any concerns with sample availability, laboratory performance, training needs, or testing methods. Accredited laboratories will be informed about the three year plan at the beginning of each cycle.

Laboratories that have a narrower scope of accreditation may only be required to participate in one panel in three years and the majority of the laboratories will participate in two panels per year. See Appendix 1 for an example of a three year plan. Voluntary participation is allowed when resources permit. Labs or analysts that are seeking to expand their scope of accreditation or status will be given priority for voluntary participation.

#### 5.3 SSTS Responsibilities

Samples for each PT panel will be prepared by SSTS according to CFIA Standardized Protocol: Administration of a Proficiency Test Sample Program Protocol. According to this protocol sample homogeneity for germination and pure seed will be verified by analysis before sending the panels to participating laboratories. Samples are randomly assigned to the participating laboratories using a random number allocated to each laboratory.

Every sample is packed in a sealed envelope for the security and integrity of the seed sample. An instruction letter accompanies each panel, indicating the test and reporting requirements, test initiation date and reporting deadline.

# **5.3.1 PT Advisory Committee**

The CFIA-SSTS is the chair of the PT Advisory Committee which is made up of representatives of CSAAC, CSI, Accredited Seed Labs and SSTS. The role of



the PT Advisory Committee is to facilitate communication between the PT program participants and the provider, so that program objectives and participant concerns can be discussed or addressed. The PT Advisory committee reviews the PT program procedures and instruction and provides input for improvements. The committee also deals with complaints and appeals from participants to assist in resolving them as appropriate. The terms of reference for the PT Advisory Committee is available upon request.

## 5.3.2 Filing of the Reports of Proficiency Test Program

CFIA-SSTS delivers proficiency test reports directly to the participating laboratories after the data is processed for each panel. An annual report will be provided to all accredited seed labs, the Commercial Seed Analysts Association of Canada (CSAAC), the Canadian Seed Institute, the PT Advisory Committee and CFIA Seed Section. Accredited laboratories shall keep all proficiency test sample reports on file for at least five years. Those reports shall be readily accessible to internal and external auditors.

## 5.4 Accredited Laboratory Responsibilities

Each year, an accredited seed laboratory must participate in the proficiency panel(s) that is within their scope of accreditation. The participating laboratory is expected to initiate the tests within two weeks of the receipt of the samples. When a damaged sample is received, e.g. opened seed packets, leakage of seeds, SSTS must be informed immediately and asked for a replacement. A new deadline may be arranged to address this situation. Complaints of inadequate sample status will not be considered once the reporting deadline is closed.

# 5.4.1 Reporting of Results

The laboratory shall send raw data of testing results on the provided datasheet by email or fax to CFIA-SSTS before the reporting deadline. The reporting deadline is indicated in the instruction letter and based on: sample distribution date, plus one week of mailing, maximum germination testing time of the crop kind, and two weeks for initiating the germination test. Additional time for conducting the purity test may be given. Prior to or at this deadline, the laboratories that have not reported the testing results will receive a deadline reminder that indicates the final date for reporting.

Mandatory participants will be scored with a BMP (below minimal performance) if the laboratory has failed to report the results by the deadline.



The participants are responsible for reporting the results correctly; no results will be corrected after the reporting period has ended.

#### 5.5. Evaluation of Test Result

#### 5.5.1 Germination

A statistically based procedure is used for evaluating germination results to determine the performance of each participating laboratory. The interpretation of values in statistical term is described in Appendix 2. The method is based on Z-scores that are calculated according the given formula: Zi = (Xi-X) / sd

Where the laboratory mean (average germination of three seed lots, Xi) correlated with the overall mean (average germination of all participating laboratories after outliers have been removed, X), which represents the true value of the sample. The outlier is identified by the laboratory Z-score if it is greater than 2. The standard deviation (sd) calculated from the data of participating laboratories, indicating the variations among testing laboratories.

The sum of absolute values of Z-scores for normal seedlings of three seed lots will be used for the rating of a laboratory performance (see Table 2):

Table 2. Rating system for germination and pure seeds

Performance	Sum of absolute	
Rating	Z- scores in three sample lots	
А	0.00 - 3.49	
В	3.50 - 5.29	
С	5.30 - 6.99	
BMP	7.00 and over	

#### 5.5.2 Purity Analysis

The percentage of pure seeds is evaluated and rated the same as germination rating system using the sum of Z-scores (see Table 2).

The rating of impurity retrieval and identification for each panel is based on the percentage of actual identified impurities calculated against the known number of



impurities added (see Table 3). The laboratory's retrieved impurities are requested to be returned for the identifications to be verified by SSTS.

Table 3. Rating threshold for impurity retrieval and identification rate

Performance Rating	Correct identification of retrieved impurities
A	≥ 90%
В	85 - 89%
С	80 - 84%
ВМР	< 80%

# 5.6 Auditor responsibilities

The auditor must review the reports of proficiency test panels during the audit. The auditor must review the improvement, preventative and corrective actions identified and verify that the lab implemented and continues to implement these actions. The auditor shall issue corrective action requests if the auditor identifies that the lab is not fulfilling the responsibilities as stated in the report. The auditor will notify CSI according to normal procedures that a non-conformance has been identified for failing to provide evidence on corrective actions for "C" rating and preventative actions for "B" rating from the proficiency monitoring. CSI will notify SSTS in the annual report.

**Appendix 1. Examples of Panels of Proficiency Test Program** 

Test Round	Crop Kind	Crop Kind Scientific name		Crop Group
PT18-01	Sweet clover	Melilotus officinalis/albus	IX	1
PT18-02	Dill	Anthemum graveolens	XX	2
PT19-01	Argentine canola	Brassica napus	VII	4
PT19-02	Barley	Hordeum vulgare	II	3
PT20-01	Creeping red fescue	Festuca rubra	ΧI	6
PT20-02	Pea	Pisum sativum	V	5



## Appendix 2. Statistical Terms used in Reports of PT Panel Results

- a. **Z-score.** The Z-score compares the distance of the participant's result from the overall sample mean, to the average difference from the mean of all participants. A Z-score of zero indicates the participant's result equalled the overall mean. A high number indicates the participant's result was far away from the mean.
- b. **Bias.** The bias is the average Z-score for a lab, and is an indicator of a systematic error which is causing results to be consistently high or low. A value of zero indicates no bias. As the value gets farther from zero the possibility of a bias towards high or low results increases. No significant value has been identified, but a value greater than **1.5** (ignoring the sign) should cause a lab to review its procedures.
- c. **Precision.** Precision is a measure of consistency. A lab which has consistent results will have a low precision value, regardless of how far from the mean these results are. A low precision value indicates consistent performance, while a high value indicates variable performance.
- d. **Accuracy.** Accuracy, as used here, is a combination of bias and precision. Low values indicate the lab is consistently near the overall mean. Increasing values indicate that the lab has a bias in one direction and/or is inconsistent. A value greater than **1.5** is cause for concern; a value greater than **2.0** is an indication that the lab may have a serious problem.

# Appendix 3. Revision Table

Previous Version	Previous Version	Paragraph revised, deleted,	Reason for Update
	Revision Date	added	
Version 2	January 2012	Throughout	Update SSTS phone number and fax
			number
		Throughout	Replace the word assessment with the word audit
		1.0	Add reference to ISO/IEC 17043
			Update number of accredited labs
			participating in the program
		2.0	Add an exception to the rating system as
			the audit and review of results reporting part
			of the program is not assessed in this
			manner
		3.0	Update program name to review of results
			reporting from split sample monitoring
			program
		3.1	Update overview of program to remove split
			sample monitoring program and replace with
			review of results reporting.
		3.2	Update SSTS responsibilities due to
			removal of the split sample monitoring
			program.
		3.3	Update accredited lab responsibilities due to
			removal of split sample monitoring program.
		3.4	Update auditor responsibilities due to
			removal of split sample monitoring program
			Update to state samples testing in last year.
		4.3	Update auditor responsibility regarding
			issuance of critical non-conformances.
		5.2	Update section regarding date of distribution
			of first PT panel, organization of crop groups
			and addition of volunteer participation.
		5.3.1	Add description of PT Advisory Committee

Previous	Previous	Paragraph	Reason for Update
Version	Version	revised, deleted,	
	Revision Date	added	
		5.4.1	Clarify how the reporting deadline is
			calculated for PT panels
		5.6	Clarify auditor responsibility for follow-up of
			"B" and "C" ratings from proficiency testing
			panel results as issued in the CSI Annual
			Report.
		Appendix 3	Add revision table