



Canadian Grain
Commission

Commission canadienne
des grains

Standard for Protein Testing

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1.0 Purpose

- 1.1** The Standard for Protein Testing provides guidance to licensees on how to develop a quality management system (QMS) for protein testing. Compliance with the standard will help ensure that results and practices are consistent, comparable and repeatable for applicable licensees.

2.0 Definitions

2.1 Calibration

The process of ensuring that an instrument provides accurate results.

2.2 Control sample

Material that is purchased, or made in-house, with a similar composition to the samples being analyzed. Control samples must be stable and have repeatable results over time with known tolerances. They are analyzed on a regular basis to monitor results, verifying that instruments are performing correctly and ensuring the laboratory is meeting quality standards.

2.3 Enhanced program

Optional procedures that exceed the minimum requirements of the standard.

2.4 Licensee

A company that holds a primary elevator, terminal elevator, process elevator, or grain dealer licence issued by the Canadian Grain Commission.

2.5 Proficiency testing

An external assessment of a laboratory's ability to perform tests to the required level of competence and quality using pre-established tolerances. A sample is received by a laboratory, analyzed and results are reported back to an accredited body. A report is sent to participants and the accredited body gives a pass, warning or fail based on all laboratories who submitted results.

2.6 Tolerance

The acceptable variation in the results of a particular test.

2.7 Verification

The process of confirming that an instrument operates according to its stated specifications and performs without any error.

3.0 General requirements

- 3.1** The licensee shall develop a quality management system (QMS) based on this standard and provide evidence that its protein testing procedure and instruments are producing reproducible and accurate results. The licensee may also show that its current QMS meets this standard.
- 3.2** The licensee shall meet the minimum requirements of this standard. Within the standard, there are enhanced procedures that are optional and allow the licensee to have a more robust QMS.
- 3.3** The licensee shall document and maintain records (electronically or in hard copy) and implement the process.
- 3.4** The licensee shall have a procedure that will be implemented when any aspect of its controls, instrumentation, testing activities or results do not fall within defined tolerances. The procedure shall ensure that the following occur and are documented:
 - 1. identification and description of the issue
 - 2. investigation of the cause
 - 3. immediate and corrective actions

4.0 Internal verification of instruments

- 4.1** The licensee must define suitable tolerances and demonstrate that its instruments provide repeatable results for identical samples.
- 4.2** The licensee must verify its instruments by running, at minimum, one sample in duplicate on each day an instrument is in use and must meet its defined tolerances.

5.0 Controls

- 5.1** The licensee must analyze control samples (purchased or developed in house) with known tolerances on a regular basis.
 - 5.1.2** One control at one protein level must be analyzed on a monthly basis at a minimum.
 - 5.1.3** Under the enhanced program, two or more controls at different protein levels must be analyzed each day that samples are analyzed.
- 5.2** Control samples must be stable and give repeated results over time with known tolerances.

- 5.2.2** Under the enhanced program, control charts to monitor trends and outliers must be developed.

6.0 External verification of instruments

- 6.1** Under the enhanced program, the licensee must verify its instruments using an external source that provides acceptable tolerances, at a frequency determined to be suitable by the licensee. The licensee must use one of the following methods:
1. proficiency testing
 2. submit analyzed samples with known results to the Canadian Grain Commission's fee for service program to receive a certificate of analysis that can be used for result comparisons
- 6.2** If the licensee is using the Canadian Grain Commission's fee for service program to verify its instruments, the licensee must define suitable tolerances and demonstrate that the instruments have comparable results.

7.0 Calibration

- 7.1** The licensee must verify calibrations using an external source and adjust bias as required.
- 7.2** The calibration provider must provide tolerances to ensure the licensee's instruments are within tolerance.

8.0 Maintenance and repairs

- 8.1** The licensee must maintain and repair its instruments according to the manufacturer's instructions. In addition:
1. instruments must be cleaned each month at a minimum
 2. instruments must be cleaned after infested samples have been tested
 3. instruments must be cleaned after receiving errors messages or if samples exceed suitable tolerances
 4. Under the enhanced program, instruments must be cleaned at least once a week during high volume testing
- 8.2** Following repair, the licensee must verify an instrument using a control sample with known tolerance prior to analyzing more samples.