Canadian Grain Commission | Commission canadienne des grains

Canada

# Canadian Grain Commission
# Review of testing at the Grain Research Laboratory

# 2006-2007

**TABLE OF CONTENTS**

**1.0 Introduction**

1.1 Background
1.2 Review objectives
1.3 Review scope
1.4 Approach and methodology

**2.0 Roles and responsibilities**

**3.0 Review findings and recommendations**

3.1 General findings
3.2 Validity, traceability, repeatability and objectivity of testing
    3.2.1 Validity
    3.2.2 Traceability
    3.2.3 Repeatability
    3.2.4 Objectivity
3.3 Quality management systems
    3.3.1 ISO/IEC 17025:2005 Standard
    3.3.2 Good Laboratory Practice – GLP
    3.3.3 Quality management systems discussion
3.4 Controls and processes

**4.0 Conclusion**

**5.0 Summary of recommendations**

## 1.0 Introduction

The review of Grain Research Lab (GRL) testing activities at Canadian Grain Commission (CGC) was undertaken in accordance with the 2006-2007 Risk- Based Audit Plan approved by CGC's Executive Management Committee.

## 1.1 Background

The GRL was established as part of the CGC in 1913. In December 1913 Dr. F.J. Birchard was appointed as the first director of GRL. Since its establishment the GRL has been developing grain testing methods that quantify the quality of Canadian grains, oilseeds and pulses as well describe and test the qualities of products made from those grains. In the 1960s and 1970s the GRL introduced testing for biological and chemical residues left on the grains by various biological and chemical agents.

Through the hard work of the GRL staff and management the GRL has become an internationally known and respected research and testing center on the quality of grain and grain products. Its scientists report on the processing quality of the grain that is harvested and shipped from Canadian ports. The GRL engages in research to expand the CGC's scientific knowledge of what constitutes grain quality.

The GRL consists of two sections:

- Crops
- Technologies

Both sections provide testing and assurance services to CGC's Industry Services division (internally) and to the grain industry (externally). The CGC has begun a process of reviewing its various services and associated fees and discontinuing those that do not fall under the department's mandate and / or mandate supporting activities. In addition, some of the testing services that used to be provided on fee for service basis are still provided, however the cost of the testing is either absorbed by the CGC or there is a specific contract between the CGC and service requester to recover the cost of performing the tests.

## 1.2 Review objectives

The objectives of this review are:

- To review the guidelines and methods used in ensuring that all standard tests performed by the GRL are valid, traceable, repeatable and objective.
- To review quality control processes and procedures.

## 1.3 Review scope

The scope of this review included the following activities within CGC related to GRL testing, specifically:

Technologies group:

- Variety Identification Monitoring (VID)
- Trace elements
- Microbiology
- Trace Organics
- Grain Biotechnology
- Image Analysis/Spectroscopy/Grain Biology

Crops group:

- Wheat
- Barley
- Oilseeds
- Pulses
- Analytical

### 1.4 Approach and methodology

The methodology followed in carrying out this review included the following:

- Review of program goals and objective with program managers
- Review of GRL testing information available on the CGC website
- Review of ISO 17025 standard
- Review of Good Laboratory Practice (GLP) standard
- Interviews with GRL program managers responsible for testing

The review was conducted from September 1 to October 31, 2006.

## 2.0 Roles and responsibilities

The GRL is a division within the CGC. The Chief Commissioner is responsible for the GRL and has delegated this responsibility to the Director, Grain Research Laboratory. The GRL is composed of two research sections plus administrative support.

The following programs provide services to outside parties and other divisions within the CGC.

The Section Head, Technologies group is responsible for:

- Variety Identification Monitoring
- Trace Elements
- Microbiology
- Trace Organics

- Grain Biotechnology
- Image Analysis/Spectroscopy/Grain Biology

The Section Head, Crops group is responsible for:

- Wheat
- Barley
- Oilseeds
- Pulses
- Analytical

**3.0 Review findings and recommendations**

**3.1 General findings**

The GRL is composed of eighteen labs of which six provide services directly or indirectly to external customers such as Canadian Wheat Board, grain seller and buyers and end users of the grain. The services provided range from sample variety composition to chemical, biological and biological contaminates testing.

The testing is provided either directly on the samples provided by the customer or Industry Services (VID testing) or the assurance is provided based on testing of samples provided by the cargo monitoring program and/or the harvest survey program.

The GRL labs focus on the specific areas of their expertise:

- VID lab focuses on testing of export cargo and railcar samples for ineligible varieties (non-registered and of other classes) in CWRS wheat shipments. The lab will also test (under contract) individual wheat and barley shipments based on the requests from customers to verify the purity of the grain for Identity Preserved (IP) shipments.
- Grain safety assurance focuses on sample testing for pesticides, trace elements, mycotoxins and bacteria that could be present in grain shipments. The labs test samples obtained from cargo monitoring, harvest survey programs and samples submitted by Industry Services. Programs provide scientific advice and assistance to the trade, CGC and other Federal Agencies on grain safety issues and provide letters of assurance to marketers and processors to reassure buyers about the safety of Canadian grains. The Trace Organics lab is also under contract with CWB to test shipments to United Kingdom (UK) for pesticide residues and shipments to EU member countries for Ochratoxin A to facilitate its requirements.
- The Wheat Enzymes lab focuses on sample testing for industry and producers. The lab does Falling Number tests, Amylograph viscosity tests and Rapid Viscosity Analysis (RVA) tests. All tests are designed to estimate the level of alpha- amylase enzyme in the grain. The alpha-amylase enzyme is produced during the sprouting of the grain and negatively affects the end use quality of

grain. In addition to testing the lab provides verification services and standard samples to all Industry Services labs performing the falling number and RVA testing.

- Grain biology tests a limited number of samples obtained from the export cargoes to provide general assurance to trade and producers on the levels of weed seeds in the grain shipments. The process is very labour intensive as it involves a manual inspection of the sample (250g). The test can take anywhere from 1 hour for a clean sample to 1 day (7.5 hrs) for highly contaminated samples. The lab does some limited testing for outside parties however it is limited by the time it takes to test each sample and number of qualified staff to perform the testing. Currently the lab has only one full time employee that is certified to perform weed seed analysis of the samples.

### 3.2 Validity, traceability, repeatability and objectivity of testing

#### 3.2.1 Validity

A test is valid if the outcome of the test is true and can be verified by either repeating the test itself on the same sample or compared to another test performed at the same time under the same conditions using certified reference materials.

The certified reference materials or in-house quality control materials that are used for the quality tests are either developed in-house (collaborative studies) or obtained from outside vendors. Another method of validating the tests is participation in the proficiency or "ring" tests with other laboratories located in Canada, North America or elsewhere in the World. In the proficiency or "ring" test the lab tests sample or samples and provide results back to the originating laboratory which in turn will grade the lab on its proficiency in testing. This grade is a validity check for the lab to determine whether all test methods are correct and utilized properly.

The GRL labs utilize a variety of methods to validate their test results. For example, the VID lab includes a sample of a known wheat variety in every test batch to ensure its quality. The grain biology lab relies on the technical knowledge of its staff to ensure the quality (professional certification as Certified Weed Seed analyst).

The trace elements and trace organic labs rely on the proficiency testing and stringent method validation to validate their results.

In general all labs within the CGC, GRL have and do utilize methods to validate the results of their test. All test methods are well documented and some of the methods are published.[1]

[1] - For example some of the methods utilized by GRL are published by American Association of Cereal Chemists.

### 3.2.2 Traceability

Traceability relates to the ability to follow up on tests performed by the GRL.
The review noted that all labs utilize methods of documenting every test performed on the samples, the method(s) utilized and the test outcome or data. This is important, since record keeping of the data and results is essential in cases where the results are challenged by the parties relying on them.

All lab results are provided back to parties requesting the tests. In cases of generic testing for general letters of assurance (trace elements, grain safety assurance and image analysis / microscopy labs), information is provided on case by case basis.

### 3.2.3 Repeatability

Repeatability of the test results is one of the most important factors in lab testing and depends largely on the test and samples being utilized for the test. For homogenous samples (i.e. ground samples of grain) the repeatability of the test results is based on the availability of sufficient samples to perform additional testing. For more diverse samples, such as those utilized in VID testing (i.e. whole grain kernels in mixed variety grain samples) the tests are repeatable. The statistics for single kernel analyses are well defined and there are confidence intervals around estimates. For quality control purposes, the VID lab relies on known varieties used as control samples in testing when required.

The tests performed in Trace Organics, Trace Elements, Grain Biotechnology, Microbiology, Grain Biology and Cereals laboratories are repeatable since all either utilize homogeneous samples or conduct testing that does not destroy the sample.

### 3.2.4 Objectivity

The definition of the word Objective is- *"undistorted by emotion or personal bias; based on observable phenomena"*[2].
The test performed by GRL appears to be objective and set on standards that are accepted by the scientific community. The GRL is in the forefront of the development of methods and techniques for testing of grain and grain products. Many methods used at GRL are methods developed and validated by the GRL and a number are published by American Association of Cereal Chemists (AACC). The GRL is viewed by many as a valuable independent source of testing data to grain industry and farmers[3]. The independence of the GRL allows for a high degree of objectivity and combined with solid scientific methods used at the lab enables provision of reliable testing data to grain producers, traders and buyers.

[2] - http://dictionary.reference.com/browse/objective
[3] - COMAPS review commissioned by AAFC for the Parliament.

### 3.3 Quality Management Systems

The quality management systems (QMS) are utilized by many organizations to formalize and document quality processes within the organization. The following two systems were reviewed:

#### 3.3.1 ISO/IEC 17025:2005 Standard

ISO/IEC 17025:2005[4] (International Organization for Standardization/ International Electro-technical Commission) specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

ISO/IEC 17025:2005 is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by ISO/IEC 17025:2005, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

ISO/IEC 17025:2005 is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. ISO/IEC 17025:2005 is not intended to be used as the basis for certification of laboratories.

Compliance with regulatory and safety requirements on the operation of laboratories is not covered by ISO/IEC 17025:2005.

#### 3.3.2 Good Laboratory Practice – GLP

The purpose[5] of the Principles of Good Laboratory Practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby saving time and resources. The application of these Principles should help to avoid the creation of technical barriers to trade, and further improve the protection of human health and the environment.

Organization for Economic Co-operation and Development (OECD) member countries has pursued international harmonization of test methods and good laboratory practice. In 1979 and 1980, an international group of experts established under the Special Program

[4] - ISO website
[5] - OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 1

on the Control of Chemicals developed the "OECD Principles of Good Laboratory Practice" (GLP), utilizing common managerial and scientific practices and experience from various national and international sources. These Principles of GLP were adopted by the OECD Council in 1981, as an Annex to the Council Decision on the Mutual Acceptance of Data in the Assessment of Chemicals
[C(81)30(Final)].

The GLP were again reviewed and updated in 1999.

### 3.3.3 Quality management systems discussion.

The GRL does not utilize a common quality management system at this time. The laboratories that are part of the GRL each have their own quality management systems that are not uniform or standardized across the lab.

**R.1 - It is recommended that GRL develop and implement a formal Quality Management System at the GRL.**

Every lab has its own methods manual, however those manuals are not standardized and do not follow any particular format. Although neither ISO 17025:2005 nor GLP prescribe any particular format for the methods documents, the labs that form the GRL should have a common way of formatting and maintaining the methods manuals.

**R.2 - It is recommended that GRL develop and implement standardized method document format.**

It is recommended that the method format at the very least contain:

1. Creation date
2. Update date
3. Name and signature of the person that created / updated the method
4. Name and signature of the person that validated / approved the method on behalf of GRL.

**R.3 - It is recommended that GRL update all method documents currently utilized to the new format above.**

### 3.4 Controls and processes

In general all areas reviewed have quality control procedures over the testing methods and processes utilized in their respective areas. Every section has either electronic and / or hard copy of testing procedures available to staff. The review has also found evidence[6] that the procedures themselves are updated in a timely fashion when new information is available.

[6] - Some of the procedures and methods have change controls implemented into the procedure. Those change controls include date the change has been approved and signature of approving scientist.

The control processes utilized during testing provide a sufficient degree of assurance that the test themselves are correct and within the acceptable margin of error. Lab management is actively involved in ensuring that the lab results are consistent and verifiable.

The risk of generating incorrect test results is mitigated by the use of verification techniques. The test verification is accomplished by method validation and verification procedures before, during and after performing the test (proficiency testing, test sample duplicates, control sample).

The testing control procedures at the labs reviewed by this review appear to be working as designed.

One of the risks facing the management of GRL is the acquisition and retention of qualified personnel to fill technical positions at the labs. For example, the Grain Biology lab currently has only one technician certified to perform the weed seed analysis. This poses a risk that in the event that this employee ceases to work at the CGC, the lab will have to rely on the results of testing performed by other labs providing same or similar services.

Other labs within the GRL face similar risks. The on job experience and expertise of the technical staff is one of the most important components of the controls at the GRL.

**R.4 – It is recommended that the GRL ensure that it has sufficient human resources to discharge its obligations relating to testing services provided to others, as well ensure adequate development and training of existing GRL staff.**

## 4.0 Conclusion

In conclusion, the GRL labs involved in the standard testing for IS and industry appear to be using well defined and reviewed testing procedures and manuals.

In addition each lab has developed assurance procedures and methods to assure that the tests they are performing are valid, traceable, repeatable and objective.

**5.0 Summary of recommendations**

R.1 - It is recommended that GRL develop and implement a formal Quality Management System.

R.2 - It is recommended that GRL develop and implement standardized method document format.

R.3 - It is recommended that GRL update all method documents currently utilized to the new format above.

R.4 – It is recommended that the GRL ensure that it has sufficient human resources to discharge its obligations relating to testing services provided to others as well ensure adequate development and training of its existing staff.

This report was prepared by:

Tom Jankowski, CGA – Internal Auditor
Geoffrey Govia, CMA – Accounting Controls and Reporting Officer

The review was substantially completed on November 3, 2006.

The review was approved on July 5, 2007 by Executive Management Committee.