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Conseil canadien des normes



PALCAN Interpretations for Conducting
Assessments of Testing
and Calibration Laboratories

CAN-P-1630
January 2008

**PROGRAM FOR THE
ACCREDITATION OF LABORATORIES – CANADA
(PALCAN)**

**PALCAN INTERPRETATIONS FOR CONDUCTING
ASSESSMENTS OF TESTING AND CALIBRATION
LABORATORIES**

***PROGRAMME D'ACCREDITATION
DES LABORATOIRES – CANADA (PALCAN)***

***INTERPRÉTATION PALCAN DES EXIGENCES RELATIVES À
L'ÉVALUATION DES LABORATOIRES D'ESSAIS ET D'ÉTALONNAGES***

**CAN-P-1630
January 2008**

This document supersedes and replaces CAN-P-1630 February 2006. This document also includes all of the decisions contained in D92.3 “Task Group-Laboratories (TG LABS) PALCAN Policies and Procedures” related to the technical aspects of laboratory accreditation.

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FOREWORD

The Standards Council of Canada (“SCC” or “the Council”) is a crown corporation established by an Act of Parliament in 1970, amended in 1996, to foster and promote efficient and effective voluntary standardization in Canada. It is independent of government in its policies and operations, although it is financed partially by Parliamentary appropriation. The Council consists of members from government and the private sectors.

The mandate of the Council is to promote the participation of Canadians in voluntary standards activities, promote public-private sector cooperation in relation to voluntary standardization in Canada, coordinate and oversee the efforts of the persons and organizations involved in the National Standards System, foster quality, performance and technological innovation in Canadian goods and services through standards-related activities, and develop standards-related strategies and long-term objectives.

In essence, the Council promotes efficient and effective voluntary standardization in Canada in order to advance the national economy, support sustainable development, benefit the health, safety and welfare of workers and the public, assist and protect consumers, facilitate domestic and international trade and further international cooperation in relation to standardization.

In addition, the Council serves as the government’s focal point for voluntary standardization and represents Canada in international standardization activities. It sets out policies and procedures for the development of National Standards of Canada, and for the accreditation of Standards Development Organizations, of Product Certification Bodies, of Inspection Bodies, of Testing and Calibration laboratories, of Proficiency Testing Providers, of Management Systems Certification/Registration Bodies, of Personnel Certification Bodies and of Auditor Training Course Providers. It also promotes and supports the principle of recognition of accreditation or equivalent systems as a means of decreasing the number of multiple assessments and audits, both in Canada and with Canada’s trading partners.

This document is one of several issued by the Standards Council of Canada to define the policies, plans, and procedures established by the Council to help achieve its mandate.

Requests for clarification and recommendations for amendment of this document, or requests for additional copies should be addressed to the publisher directly at info.palcan@scc.ca.

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PREFACE

This document forms part of a series of Standards Council of Canada (SCC) CAN-P documents dealing with the voluntary accreditation of organizations involved in standards development, product certification, inspection, calibration and testing, proficiency testing, management systems certification/registration, personnel certification and auditor training course providers.

Accreditation by the SCC is the formal recognition of the competence of a laboratory to manage and perform specific tests or types of tests recognized and listed by the SCC. It is not a guarantee that test results will conform to standards or agreements between a calibration or testing laboratory and its customers or that test results are acceptable to certification organizations. Business transactions between an accredited calibration or testing laboratory and its customers are legal matters between the two parties.

Accreditation is available for all types of tests, measurements and observations and is currently offered in the following fields of testing: Acoustics & Vibration, Biological, Calibration, Chemical, Electrical/Electronic, Ionizing Radiation, Mechanical, Non-destructive Evaluation, Optics & Optical Radiation, and Thermal & Fire.

A listing of each accredited laboratory, with a summary of its accredited testing capabilities by classes of products and services along with a list of detailed scope of testing is published on the SCC website, www.scc.ca.

To become accredited, laboratories must meet the general requirements outlined in this document, which are those in the international standard, ISO/IEC 17025-2005, *General requirements for the competence of testing and calibration laboratories*. This will be verified by the Standards Council's accreditation process. In addition, laboratories must demonstrate competence to perform the specific tests or types of test for which they wish to become accredited. Applicants must also agree to abide by the SCC conditions for accreditation found in associated documents used by the SCC's Program for the Accreditation of Laboratories – Canada (PALCAN). The documents are identified in the CAN-P-1570 PALCAN Handbook and appendices, which details other program processes. In addition, there are a number of Program Specialty Areas (PSA) addressing specific requirements for specialty areas such as Environmental, Agriculture and Food Products, Forensic, Mineral Analysis, etc.

The accreditation procedures of the SCC conform to the recommendations of the International Laboratory Accreditation Conference (ILAC) and others detailed in the Bibliographical section of this document.

Supplementary information regarding the program is available on the SCC website and from the PALCAN Secretariat.

This Preface is not an integral part of this document

GENERALLY APPLICABLE INTERPRETATIONS:

1. Summary of changes from CAN-P_4D to CAN-P-4E

➤ The changes to from CAN-P-4D (ISO/IEC 17025: 1999) to CAN-P-4E (ISO/IEC 17025: 2005) that affect CAN-P-1630 are highlighted in yellow throughout this document. The summary of changes in substance from CAN-P-4D to CAN-P-4E are as follows:

- a) Client is replaced by Customer
- b) Quality System or Quality Management System is replaced by Management System
- c) New or Additional requirements:
 - New requirement section 4.1.5k with emphasis on personnel involvement in MS and quality objectives
 - New requirement sections 4.1.6, 4.2.3, 4.2.4 and 4.2.7 with emphasis on top management involvement
 - New requirement section 4.7.2 with emphasis on Customer Focus
 - Added requirement for section 5.2.2 to evaluate effectiveness of training
 - New requirement section 5.9.2 requiring analysis of monitoring activities and correction when out-of-tolerance is encountered

➤ There are also miscellaneous re-numbering of ISO 17025: 1999 clauses in ISO/IEC 17025: 2005 to accommodate new requirements listed above:

- a) Section 4.10, 4.11, 4.12, 4.13 and 4.14 from ISO/IEC 17025: 1999 are now Section 4.11, 4.12, 4.13, 4.14 and 4.15 respectively in ISO/IEC 17025: 2005
- b) Section 4.2.3 renumbered to section 4.2.5
- c) Section 4.2.4 renumbered to section 4.2.6

➤ There are no changes to the technical requirements from CAN-P-4D to CAN-P-4E (except 5.2.2 and 5.9.2 as noted above)

2. A list of SCC CAN-P interpretive documents for PSA's (CAN-P-PSA), such as CAN-P-1587 Guidelines for the Accreditation of Agricultural and Food Products Testing Laboratories, is available from the SCC Web site at <http://www.scc.ca/en/programs/lab/index.shtml> (select applicable program specialty area on right side of page).

3. In case of differences between the interpretations for a specific clause of ISO/IEC 17025 in this document (CAN-P-1630) and any CAN-P-PSA document, the interpretation in the PSA document shall prevail.

4. All laboratories must meet the conditions specified in CAN-P-1570 PALCAN Handbook and appendices, CAN-P-15 Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings, as well as any applicable PSA requirements.

5. Comment on the Scope of International Laboratory Accreditation Cooperation (ILAC) Guidance

Where SCC has provided an interpretation or guidance is established for specific requirement/applications, additional general requirements are not to be added. Guidance is expressed by use of the word “should”. If guidance to a requirement is given, then by following it the laboratory will meet that requirement. Alternative ways may be used if they are shown to give an equivalent outcome.

6. Acronyms have been used in this document to alleviate the text. A complete list of Acronyms with their definitions is appended to this document.

1 Scope

The following SCC Interpretative Notes are intended as guidance for the assessment of each requirement of CAN-P-4E (ISO/IEC 17025: 2005). Items designated as such are extracted from the SCC Task Group-Laboratories (TG LABS) minutes or internationally recognized documents and interpretations. Laboratories and Assessment Teams must use this interpretive guide.

CAN-P-4E (ISO/IEC 17025: 2005) Section No.	<u>SCC Interpretative Note</u>
1.5	It is strongly suggested that the laboratory have a safety committee, or if the laboratory is small, an employee with responsibility for overall safety; this can be a suggestion or a requirement depending on the type of testing activities. If an assessor observes a danger for laboratory personnel it should be stated as a required action. (APLAC Common Assessor Training Course 2000-04-10 to 14)

2 Normative References

3 Terms and definitions

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
3	<p><u>Terms and definitions</u> The following definitions apply to the interpretation of ISO/IEC 17025: 2005 (CAN-P-4E) and are based on ISO 8402. These apply regardless of the superseded status of ISO 8402.</p> <p><u>Policy:</u> must state the overall direction of the organization with regard to the subject activity. This definition applies to the requirements of Sections 4.1.5 c), 4.1.5 d), 4.2.2, 4.4.1, 4.6.1, 4.8, 4.9.1, 4.11.1 and 5.2.2.</p> <p><u>Procedure:</u> must specify a way to perform an activity and must usually contain the purpose and scope of the activity, what shall be done and by whom, when, where and how it shall be done. The procedure must also address what materials, equipment and documents shall be used and how it shall be controlled and recorded. This definition applies to the requirements of Sections 4.1.5 c), 4.1.5 d), 4.3.1, 4.3.2.2, 4.3.3.3, 4.3.3.4, 4.4.1, 4.6.1, 4.8, 4.9.1, 4.11.1, 4.13.1.1, 4.13.1.4, 4.14.1, 4.15.1, 5.2.2, 5.3.5, 5.4.5.2, 5.4.6.1, 5.4.6.2, 5.4.7.2, 5.5.6, 5.5.10, 5.5.11, 5.6.1, 5.6.3.1, 5.6.3.3, 5.6.3.4, 5.7.1, 5.7.3, 5.8.1, 5.8.4 and 5.9.1.</p> <p><u>Conformity:</u> fulfillment of a specified requirement.</p>
3 (cont'd)	<p><u>Non-conformity:</u> non-fulfillment of a specified requirement.</p> <p><u>Verification:</u> confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.</p> <p><u>Validation:</u> confirmation by examination and provision of objective evidence that particular</p>

	<p>requirements for a specific intended use are fulfilled. Refer to CAN-P-1629 PALCAN Policy for the Validation of Test Methods.</p> <p>Objective evidence: information which can be proved true based on facts obtained through observation, measurement, test or other means.</p> <p>Quality Assurance: all the planned and systematic activities that are used to fulfill the requirements for quality.</p> <p>Management review: formal evaluation by top management of the status and adequacy of the management system in relation to the quality policy and objectives.</p> <p>Record: document which furnishes objective evidence of activities performed or results achieved.</p> <p>Traceability: <i>For a product or activity:</i> ability to trace the history, application or location of a product or activity related to the origin of the material and parts, the product processing history or the distribution and location of the product after delivery. <i>For calibration:</i> refer to ILAC P10 Section 1.4 and CLAS Requirements Document 9 published on the CLAS website at http://inms-ienm.nrc-cnrc.gc.ca/clas/refrence_documents_e.html <i>For Testing:</i> refer to CAN-P-1626 PALCAN Policy on Traceability Requirements for Calibration Sources Used by Accredited Testing Laboratories and CAN-P-1627 PALCAN Policy on Selection of Physical Calibration Sources for Testing Laboratories. <i>For data collection:</i> ability to trace the history, application or location as it relates to the calculations and data generated.</p> <p>Preventive actions: action taken to eliminate the causes of a POTENTIAL non-conformity, defect or undesirable situation in order to prevent OCCURRENCE.</p> <p>Corrective Action: action taken to eliminate the causes of an EXISTING non-conformity, defect or undesirable situation in order to prevent RECURRENCE.</p>
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4 Management requirements

4.1 Organization

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.1.1	Annex C gives the definition prepared by SCC Legal Counsel. An assessor can request such information as documentation on the laboratory incorporation, the registration as a company, or designation as part of a public entity.
4.1.2	Refer to CAN-P-1631 PALCAN Guidelines For The Use Of Accreditation Body Logos And For Claims Of Accreditation Status (a verbatim adoption of ILAC G14:2004 Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status). Refer to CAN-P-1570 PALCAN Handbook Section 13 and CAN-P-1570 Appendix E Trademark Licensing Agreement.

4.1.4	<p>The statement should refer to both real and apparent conflicts of interest. It is to be noted that this clause applies only to laboratories that are part of a larger organization. According to an ILAC presentation “potential” conflicts of interest is new to ISO/IEC 17025.</p> <p>A third party laboratory is one that is not part of the organization for which the testing is being conducted; a second party laboratory could be doing testing from its suppliers and a first party laboratory is doing testing of its own products (e.g. an in-house manufacturing laboratory). These designations are not specifically used by SCC for formal classification of laboratory types; however, they are important to some international bodies.</p>
4.1.5 a)	<p>Mobile laboratories and “one man shows”, as with many applicants under QS 9000 can be covered by ISO/IEC 17025: 2005 if their MS indicates that “No services shall be provided during the absence of a designated person” (the person could be designated by title if part of a larger organization as in the case of mobile labs or even the Owner for a one man show) or words to that effect. This note also applies to 5.2 (APLAC Common Assessor Training Course 2000-04-10 to 14).</p>
4.1.5 b)	<p>The laboratory personnel should sign a conflict of interest statement that addresses both internal and external conflicts. If this is not the practice or if only external conflicts are addressed in the conflict of interest statement, the laboratory must demonstrate how it ensures this requirement is met, e.g. by a separate laboratory policy, code of ethics, employment contract, and arrangements and authorities for relieving undue internal pressures from, for example, excessive workloads, etc.</p>
4.1.5 c)	<p>These may include confidentiality agreements and employment contracts. Refer to CAN-P-1628 PALCAN Policy on the Use of Information Technology in Accredited Laboratories.</p>
4.1.5 e)	<p>An organisation chart or charts with the reporting relationship to any parent organisation or ownership should normally be a sufficient presentation of the organisation and management structure of the laboratory.</p>
4.1.5 h) 4.1.5 i)	<p>New to ISO/IEC 17025: 2005 is the requirement for technical management (not necessarily one technical manager). This should address the provision of necessary resources to the laboratory, how technical management is achieved (appointing a Technical Manager, or other); and Quality Manager (there must be a person in the laboratory with the role of quality manager). It is not acceptable to provide only an organization chart; there must be a description, especially for any relationships without direct reporting to each other. It is preferable that the roles of Technical Management and Quality Manager be appointed to separate persons. If this is not possible, the laboratory will have to document how the person separates both functions.</p> <p>SCC requires the identity of the Quality Manager and the Technical Management and does not require the identity of any other indispensable staff.</p>
4.1.5 j)	<p>It is important that at least one deputy for each key role be pre-designated to accommodate unforeseen emergencies.</p>
4.1.6	<p>This requirement along with the requirements of 4.2.3, 4.2.4 and 4.2.7 make up a series of new requirements with Top Management emphasis designed to foster Management Commitment and involvement in the MS.</p>

4.2 Management system

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.2.1	The SCC does not retain controlled copies of the laboratory Quality Manual (QM). However, SCC is to be kept informed of changes to a laboratory's MS. The laboratory will need a procedure that ensures SCC is promptly advised of any change that could affect its accredited status. Technical Assessors should leave their copies of the laboratory documentation at the laboratory at the conclusion of the on-site visit. The Team Leader retains and provides the management system documentation to the Senior Program Officer responsible for the file. SCC will keep the most recent copy on file until the next on-site visit. Previous visit uncontrolled copies of the management system documentation will not be returned but will be shredded by SCC.
4.2.2	The Quality policy statement must be signed by top management, having the highest authority in the laboratory with the responsibility and authority for the budgeting of all necessary laboratory resources. If it cannot be signed (e.g. electronic systems) there must be a means of ensuring top management endorsement and control (document control) of the policy (password protection, directory rights, etc.). The management system objectives stated in the Policy must be measurable and must be reviewed during management review. (Refer to the interpretative note Section 4.15.) All requirements specified in 4.2.2 (a) to (e) <u>must</u> be documented, preferably in the QM, and if not, the QM must include a reference to the appropriate document.
4.2.2 b)	The Policy statement could refer to such things as service standards; meeting customer specifications within a certain number of days, etc.
4.2.3, 4.2.4 and 4.2.7	This requirement along with the requirements of 4.1.6 make up a series of new requirements with Top Management emphasis designed to foster Management Commitment and involvement in the MS.
4.2.5	Supporting procedures including technical procedures in this context implies the management system procedures. Procedures for conducting testing activities are usually referred to as methods (test methods).

4.3 Document control

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.3	CAN-P-1628 PALCAN Policy on the Use of Information Technology in Accredited Laboratories applies when electronic mediums are used in this Section.
4.3.1	It is important that these procedures address both internal and external (e.g. regulations, SCC scope of accreditation, SCC CAN-P Program Documents) documents used or distributed in the laboratory. Procedures must address the monitoring of the originating authority (particularly when the documents are external) and describe how updates are acquired and how the laboratory determines if any action is needed as a result of any changes to such documents / regulations. The use of how also implies what is done by whom when and where (refer to definition of Procedure (Section 3). Laboratories are encouraged to maintain a management system that applies to all their activities and

	not only the accredited tests. Where laboratories apply different techniques or procedures in the conduct of activities that are not accredited, the laboratory personnel must be able to distinguish between accredited and non-accredited tests and calibrations. When different procedures or techniques are used for non-accredited tests/calibrations, the laboratory must also document and demonstrate how the staff conducting the tests/calibrations can differentiate between accredited and non-accredited tests/calibrations in the laboratory. This is especially important when using the SCC mark or an accreditation statement on test reports or calibration certificates and when subcontracting tests or calibrations that are accredited or when the report also contains non- accredited test/calibration results.
4.3.1 (cont'd)	The document master lists are considered documents and are subject to the requirements of this procedure.
4.3.2.1	The document master list must be readily available.
4.3.2.3	All documents in the management system (Quality Manual, policy, process, procedures, instructions and forms) must have a unique identification. It is not necessary for documents to be signed by the approvers to indicate that they are approved. Some electronic systems control the approval of documents without signatures. A laboratory could also have a paper based system without signatures; however, in this case, signatures should be a suggestion.
4.3.3.2	The requirement states practicable not practical. Cases where this would not be practicable would be where extensive changes were made. The purpose of identifying change is to make it simple to identify by all concerned. When extensive changes are made the document needs to be considered as a whole and more comprehensive training / direction on the changes needs to be provided.
4.3.3.4	CAN-P-1628 PALCAN Policy on the Use of Information Technology in Accredited Laboratories applies when electronic mediums are used as the primary medium for document control.

4.4 Review of requests, tenders and contracts

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.4.1	Such requirements could also include statements on the timeliness of testing, disposal or return of customer items. For calibration laboratories: sufficient information should be solicited to determine the customers' needs and to ensure that the service will be fit for the customers' purpose (see ISO/IEC 17025: 2005 Section 5.4.2). This includes determining whether or not an accredited service is required (see CAN-P-1630 Section 4.3.1), any specific needs for range and uncertainty of measurement (see ISO/IEC 17025: 2005 Section 5.4.5.3), any specific needs for reporting measurement uncertainty and/or compliance to an identified specification (see ISO/IEC 17025: 2005 Section 5.10.4.1 b), taking uncertainty into account when reporting such compliance (see ISO/IEC 17025: 2005 Section 5.10.4.2), criteria for adjusting the equipment, and confirming any customer requests for reporting of any calibration interval (see ISO/IEC 17025: 2005 Section 5.10.4.4). The calibration laboratory must include in the policy on how such issues are to be taken into account when the customer does not to state a preference. This policy would need to be available to such customers.

4.5 Subcontracting of tests and calibrations

<p>CAN-P-4E (ISO/IEC 17025: 2005 Section No.)</p>	<p><u>SCC Interpretative Note</u></p>
<p>4.5.1</p> <p>4.5.1 (cont'd)</p>	<p>When a laboratory never performs a test/calibration, it cannot be granted accreditation for that test/measurement [TG LABS 11/89.3].</p> <p>When a laboratory sub-contracts a test or calibration for which they are accredited, such as to meet peak demands, preference shall be given to ISO/IEC 17025: 2005 laboratories that are accredited for the specific test or calibration by an Accreditation Body that is a signatory to the APLAC/ILAC MRA. The requirements for sub-contracting in section 4.5 of ISO/IEC 17025: 2005 must be applied. Refer to interpretative note Section 4.5.4. Records of review of the scope of accreditation of the service provider must be available.</p> <p>When a testing laboratory “sub-contracts” calibrations for which they are not accredited, this is not considered “sub-contracting” and requirements of sections 4.6 and 5.6 of ISO/IEC 17025: 2005 must be applied to these purchases for purposes of accreditation.</p> <p>When a testing laboratory “sub-contracts” tests for which they are not accredited OR when a calibration laboratory “sub-contracts” calibrations for which they are not accredited then the requirements of section 4.5 of ISO/IEC 17025: 2005 may be applied at the laboratory’s discretion; however, these “sub-contracted” tests or calibrations are outside the scope of the accreditation.</p>
<p>4.5.2</p> <p>4.5.2 (cont'd)</p>	<p>SCC has never required that a laboratory identify to whom they had subcontracted a test and the name of the sub-contractor is also not required here. Under the requirement of this section, the laboratory must however inform their customers of their intent to sub-contract “prior” to having the work sub-contracted. Records of customer consent must be retained.</p> <p>An ISO/IEC 17025: 2005 accreditation from the SCC is for a specific scope of capabilities and for a specific site (physical location of the accredited unit). The requirements for sub-contracting actually apply, in principle, only to the subcontracting of an accredited test/calibration. The subcontracting of accredited tests/calibrations should not be confused with “subcontracting” of other tests and work. Organizations routinely “subcontract” work for a variety of reasons and when this work is not an accredited test/calibration, the conditions of ISO/IEC 17025: 2005 Section 4.5.1 do not actually apply as far as accreditation requirements are concerned.</p> <p>Examples of activities and work that are not considered sub-contracting:</p> <ol style="list-style-type: none"> 1. Calibration of measurement or test equipment when the laboratory is not accredited for calibrations; 2. Outsourcing part of a test/calibration for which the laboratory is not accredited <p>These examples would essentially be considered purchasing and in the case of item 2 the SCC would not be reviewing the activity. Item 1 would be reviewed under the requirements of 4.6 Purchasing and 5.6 Traceability.</p> <p>ISO/IEC 17025: 2005 views subcontracting much more formally than what most organizations normally practice. When an organization has different subcontracting practices than those required by ISO/IEC 17025, then different procedures are required with a clear distinction within the procedures as to when the ISO/IEC 17025: 2005 procedures apply.</p> <p>When a laboratory is “subcontracting” an accredited test/calibration (for what ever reason) to</p>

	another laboratory that is <u>part of the same legal entity and is accredited SCC</u> or an SCC recognized body <u>for the specific test</u> being subcontracted, SCC does not consider the movement of this test/calibration item between such facilities as “subcontracting”. The test/calibration report produced will however need to be identified to the facility that conducted the test/calibration. The requirements of ISO/IEC 17025: 2005 Section 5.8 Handling of Test and Calibration Items applies.
4.5.4	If a sub-contractor is not accredited for the specific service (refer to description in the interpretative note Section 4.5.1), the laboratory must ensure that qualified and trained personnel conduct an on-site assessment of the sub-contractor's facilities and must conduct regular reassessments, or otherwise ensure to SCC satisfaction the adequate competence of the sub-contractor. The laboratory must retain records of training and qualifications of the personnel that conduct such assessments. Such an on-site assessment must cover at least all the elements of ISO/IEC 17025. Interpretations published in CAN-P-1630 shall apply. Evidence of this assessment (checklists, notes and reports) as well as any findings and their resolution, must be available for review. Evidence of compliance to ISO/IEC 17025: 2005 is not applicable in the case of a customer or regulator specified sub-contractor.

4.6 Purchasing services and supplies

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.6	<p>CAN-P-1627 PALCAN Policy on the Selection of Physical Measurement Calibration Sources for Testing Laboratories outlines specific requirements to be met by applicant and accredited testing laboratories in the purchase of calibration services. Laboratories must develop and implement procedures that meet this policy and make available for review the required records. Test and calibration laboratories must clearly specify their technical requirements to outside providers of traceability. The examples of technical requirements mentioned in CAN-P-1630 Section 4.4.1 and in CAN-P-1630 Section 5.10.4.2 apply equally here.</p> <p>Accredited calibration laboratories must in addition comply with the requirements of CLAS Document 9 - Requirements for Measurement Traceability (available at http://inms-ienm.nrc-cnrc.gc.ca/clas/refrence_documents_e.html).</p> <p>Accredited test laboratories must have policies for specifying the details of their calibration needs (refer to CAN-P-1630 Section 4.4.1) to their suppliers of calibration services.</p>

4.7 Service to the Customer

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.7.1	Careful consideration of potential implications must be addressed prior to providing customer access to the laboratory to address such items as protection of the confidentiality of all the laboratory's customers, including protecting the confidentiality of test/calibration items that could belong to competing customers or protected by legal implications.
4.7.2	A new requirement for ISO/IEC 17025: 2005 specifying customer feedback. This is generally accomplished with surveys. The requirement for analysis will provide a critical element of

	management review. The surveys should be meaningful in covering the activities of the laboratory. This requirement properly implemented will provide a source for continual improvements of the MS.
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4.8 Complaints

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<i>SCC Interpretative Note</i>
4.8	ISO/IEC 17025 does not provide many definitive requirements for complaints other than producing records of their investigation and resolution. It is not necessary for complaints to produce corrective actions (4.11). A complaint can begin by being founded or not. When it is founded, it usually implies that there is at least a non-conformity: something needs to be done to correct a problem identified by a customer. Whether this problem is potentially repetitive or related to a systemic defect will lead to the need to initiate a corrective action (4.11). Also, complaints that are not founded can lead to identifying needs for improvements or initiating preventive action (4.12). The need to provide feedback to the customer on the outcome of the investigation should form an intrinsic element of a complaint handling procedure.

4.9 Control of nonconforming testing and/or calibration work

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.9	<p>This section deals with remedial action and Section 4.11 deals with corrective action. If we consider the example of a balance found to have a past due calibration status, the following items would fall under control of non-conforming work, 4.9:</p> <ul style="list-style-type: none"> - stop using the balance : define who is responsible for the monitoring of the calibration schedule; - check other balances to determine calibration status; isolate any other past due balances; - calibrate any balances past due; it is recommended to perform calibration as received and after adjustment (if adjustments are needed); - review results of calibration; - if balances were within calibration, there is no need to recall work; - if balances were out of calibration check if the deviance had an impact on the final test results and as needed, recall work and notify the customers affected; - evaluate the significance to determine if this is potentially repetitive or related to a potential problem with own procedures; - when the evaluation has confirmed that this is potentially repetitive or related to a system problem then initiate corrective action (a system change beyond the remedial action of calibrating them). When there is no reason to suspect that the occurrence will be either repetitive or related to a system problem then close the non conformance and there is no need for a corrective action. <p>The following would fall under corrective actions, 4.11:</p> <ul style="list-style-type: none"> - investigate all the direct and indirect processes related to the maintenance of the balance calibration status: causes and potential causes of the problem (what were all the possible contributions that lead to these balances being past due calibration); - determine the most likely cause or causes; - decide if any actions are needed to eliminate the causes; - undertake any action necessary to eliminate these causes and to prevent such a mistake from reoccurring again; - do the necessary follow-up; - monitor for effectiveness; - close out the corrective action. <p>The underlying principle that the “correction” or “remedial action” (correcting the non-conformity) is related directly to the activity as opposed to the “corrective action” which involves investigating related processes or systems to determine the root cause. Once the true cause is eliminated, the problem will not reoccur.</p>
4.9.1 c)	<p>The term “corrective action” means “remedial action” and does not mean the same as the “corrective action” of Section 4.11. It is thought that this term in this item was inadvertently not corrected by the ISO/IEC 17025 drafting committee. The final draft standard that was submitted for voting had the term remedial action in this clause. (APLAC Common Assessor Training Course 2000-04-10 to 14).</p>
4.9.1 d)	<p>It is necessary to inform the customer only if non-conforming work has a “significant influence” and affected the test/measurement result.</p>

4.10 Improvement

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.10	A new requirement for ISO/IEC 17025: 2005. Laboratories will need to demonstrate continual improvement.

4.11 Corrective action

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.11	This section deals with correcting a problem that has been evaluated to be either potentially repetitive or that there is a doubt on the procedures. 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 reoccurrence. The correction (remedial action) of Section 4.9.1.c is the correction of the immediate problem, where the corrective action of Section 4.11 and the ensuing root cause analysis extends beyond the immediate problem corrected and considers related systems and processes.

4.12 Preventive action

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.12	<p>This refers to identification of “needed” improvements and the prevention of “potential” non-conformities. It highlights the need to look out for potential problems and opportunities for improvement before problems occur, i.e. a more proactive approach rather than waiting for non-conformities to occur. For example, the approach to internal auditing could be more forward looking and oriented towards identifying areas of risk and not simply be “compliance” auditing (UKAS Newsletter Spring 2000).</p> <p>Methods of identification of potential preventive actions may include such things as Total Quality Management (TQM) Tools. (APLAC Common Assessor Training Course 2000-04-10 to 14).</p> <p>Items that can be considered to assess this point include:</p> <ul style="list-style-type: none"> ▪ opportunities identified in management review minutes; ▪ quality committee minutes; ▪ customer feedback in item 4.7.2. ▪ Statistical analysis of trends to detect unfavourable tendencies before they become problems. <p>The difficulty with the preventative action procedure is defining and determining how such actions will be initiated: how and what prompts a preventive action is the key. This involves identifying the potential sources and then monitoring and analysing them to identify the opportunities for improvements. Once a need for improvement is identified, initiating such actions (for example, investigating what will be affected by the change, what to change and how, monitoring the change</p>

	for effectiveness including the processes directly changed and the processes related that may be affected and/or even additional audits of the affected area) is not substantially different from the initiation of a corrective action other than it is fixing a potential problem rather than an actual problem. Identifying needs for improvement generally involves at least the analysis of the management system outputs (all the management review subjects) as well as customer feedback and feedback from the users of the management system. Example: unfounded complaints can easily lead to identifying improvements.
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4.13 Control of records

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.13	CAN-P-1628 PALCAN Policy on the Use of Information Technology in Accredited Laboratories applies when electronic mediums are used as the primary medium for record retention in this section.
4.13.1.1	<p>This requirement for a procedure requires a laboratory to address all the technical and management system (MS) records. The requirement goes on to stipulate the specific MS records. The technical records are specified in 4.13.2 and the procedure must cover at least the records in support of the auditable trail, which include (but are not limited to) staff training records, equipment calibration records, original observations (raw data) and the report (data manipulations). In principle, while not specifically addressed, this should also include the validation records for in-house developed or modified methods as this is core to the traceability. It is suggested to begin by defining “identification”, “collection”, “indexing”, etc. and review laboratory practices for each required element of the procedure(s) (refer to Section 3 – Definition of procedure) (identification, collection, indexing...) for each of the critical records discussed previously. Most laboratories have at least four (4) distinct sets of records:</p> <ul style="list-style-type: none"> ▪ MS files (CAR, PAR, IA and MR); ▪ Calibration/equipment files; ▪ Personnel training/qualification files; ▪ Customer files (reports and raw data). <p>Where the identification, collection, indexing... is done differently this generally (but not always) requires multiple procedures.</p>
4.13.1.2	<p>SCC does not state a minimum amount of time for the retention of records; however, some PSA’s such as Fastener testing do state a minimum retention time.</p> <p>Raw data must be recorded using a permanent medium (no pencil). When forms are used to record raw data, the laboratory must have a procedure to prevent the loss or alteration of the data and ensure that all necessary tests in a series are conducted (e.g. bound forms, sequentially numbered, folders containing all the material related to one project, so on).</p>
4.13.1.4	Refer to CAN-P-1628 PALCAN Policy on the Use of Information Technology in Accredited Laboratories for electronic mediums.

4.14 Internal audits

CAN-P-4E	
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(ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.14	<p>SCC requires that such audits be conducted on an annual basis except for such laboratories that can demonstrate that their systems are mature and stable.</p> <p>For additional guidance, refer to APLAC TC-002 – APLAC Internal Audits for Laboratories and Inspection Bodies available at http://www.aplac.org/documents/published/htm .</p>
4.14.1	<p><u>A</u>ssessment teams should pay particular attention to check the effectiveness of the internal audits when they could not be done by personnel independent of the activity being audited.</p> <p>Every part of the system must be audited annually; however, it is not necessary to audit each person or each testing/measurement procedure, or to audit every aspect at one time. The annual audit must include tests/calibrations and techniques that are representative of at least the methods on the scope of accreditation and also include an audit of the management system and its implementation to demonstrate compliance with ISO/IEC 17025. The laboratory’s internal audit plan and programme should be developed to ensure that all the accredited tests are audited over a specified time frame.</p>

4.15 Management reviews

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
4.15	<p>SCC requires that such reviews be conducted annually even though the wording of the standard might appear to allow for a longer periodicity. Management reviews are often a series of events / meetings that percolate up through the management structure. In such cases, there should be one review that summarizes the year’s activities and looks forward to the coming year.</p> <p>Refer to the interpretative note Section 4.2.2. The management review must include the review of the Quality Policy and quality objectives. Refer to the definition of management review in Section 3 of this document.</p> <p>For additional guidance refer to APLAC TC-003 – APLAC Management Review for Laboratories and Inspection Bodies available at http://www.aplac.org/documents/published/htm.</p> <p>A general policy on frequency of management reviews (e.g., “Management reviews are conducted at least annually”) does not suffice as meeting the requirements for a predefined schedule. The laboratory must implement a means of ensuring that the time period for the next management review is known to all affected personnel.</p>

5 Technical requirements

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>

5	<p>There are additional interpretive documents that apply to specific programs. These additional interpretations only apply to laboratories that are recognized for these program specific activities. These programs are called Program Specialty Areas (PSA) and a complete list of these programs with the supporting CAN-P documents containing relevant interpretations can be found in CAN-P-1570 PALCAN Handbook and on the SCC web site at:</p> <p>http://www.scc.ca/en/programs/lab/index.shtml</p>
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5.1 General
5.2 Personnel

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
5.2	<p>For one man shows or mobile laboratories, see note under 4.1.5. (APLAC Common Assessor Training Course 2000-04-10 to 14).</p> <p>This section focuses on technical competence. Assessment of competence of personnel is a major factor in the ability of the laboratory to produce competent results. Laboratory personnel should be able to demonstrate they have the knowledge, the skills and the ability to produce competent results for the tests/calibrations they seek to include on their scope of accreditation. The demonstration of the knowledge, skill and ability forms the basis for demonstrated competence.</p> <p>As part of the assessment process, laboratories are required to demonstrate their competence and the assessment team is required to evaluate the competence.</p>
5.2.1	<p>Except for the Forensics PSA: Laboratories shall not normally be accredited for the provision of interpretations and opinions outside the bounds of some pro-forma test reports, which may include pass-fail statements as required by regulations or certain product standards. The SCC will normally accredit organizations for the provision of such professional judgement under CAN-P-3 (ISO/IEC Guide 65) for the accreditation of Certification Bodies or a similar program for inspection bodies under ISO/IEC 17020. Refer also to CAN-P-1630 Section 5.10.5.</p> <p>Appropriate supervision is required for all personnel, not only for personnel undergoing training. When electronic mediums are used by specific personnel, refer to CAN-P-1628 PALCAN Policy on the Use of Information Technology in Accredited Laboratories.</p>
5.2.1 (cont'd)	<p><u>ILAC guidance to clause 5.2.1 (G.5.2.1)</u> G.5.2.1 When the scope of accreditation includes standards or in-house procedures that require the reporting of interpretations of test or calibration results, the Accreditation Body (assessment team) and laboratory should pay particular attention to ensure that the additional aspects of competence given in NOTE 2 of clause 5.2.1 of ISO/IEC 17025 are met for the areas for which the laboratory provides opinions and interpretations. This should involve establishing that the laboratory has effective procedures to ensure that the relevant expert personnel have sufficient understanding of the relevant subject(s) and a realistic appreciation of the limits to their own knowledge in the context of the opinions and interpretations reported.</p>
5.2.2	<p>All training should be documented, including in-house training provided by the laboratory.</p> <p>The new requirement of ISO/IEC 17025: 2005 requires an evaluation of the effectiveness. There must be evidence of post training follow up evaluation.</p>

5.2.4	Job descriptions must be dated and preferably signed, to demonstrate that each incumbent has read it and is in agreement. They must be maintained current.
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5.3 Accommodation and environmental conditions

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<i><u>SCC Interpretative Note</u></i>
5.3.5	It is strongly suggested that the laboratory have a safety committee, or if the laboratory is small, an employee with responsibility for overall safety; this can be a suggestion or a requirement depending on the type of testing/calibration activities. If an assessor observes a danger for laboratory personnel it should be stated as a required action. (APLAC Common Assessor Training Course 2000-04-10 to 14).

5.4 Test and calibration methods and method validation

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
5.4.1	<p>CAN-P-1570 PALCAN Handbook states: The accreditation, when granted, will relate solely to calibrations and tests included in the approved scope of testing or calibration. These must be performed by, or under the direct control of, the applicant laboratory. Acceptable tests for accreditation are described in CAN-P-1570 Appendix B Scope Guidelines.</p>
5.4.1	<p>It is the policy of PALCAN (CAN-P-1570 Appendix B) that the method listed on the scope of accreditation is the latest published edition of a standard or test/calibration method being used unless otherwise specified under regulation or contract. A laboratory is not required to use a new method if this will require new equipment or new skills. However, in such a case, the publication date of the standard or test/calibration method used must be indicated in the scope of accreditation and on test reports, TG LABS 30/91.3.</p> <p>In general, if international or national methods are not followed exactly as written and when they are even “slightly modified” (i.e. addition of new or different QC material, completely different instruments, etc) then these methods become “in-house” or “in-house based on standard method” and are subject to the requirements of Sections 5.4.3 and 5.4.5.2. Refer to CAN-P-1630 Interpretation 5.4.3 and 5.4.5.2.</p>
5.4.2	<p>Laboratories should carefully consider the implications of accepting to perform a method outside its intended/validated/recognized use and consider adding a disclaimer to any ensuing test/calibration reports. The laboratory is only accredited for the methods listed on the current scope of accreditation and includes ONLY the deviations that accepted by the assessors. Additional deviations/modifications may require an application for scope extension.</p> <p>The stated requirement of “The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.” is termed confirmation or verification. The manner in which this confirmation is conducted varies from one discipline to the next. Where PSA CAN-P documents exist, refer to the PSA CAN-P. This requirement is often misunderstood or misquoted to be “validation” of the standard method. While often the confirmation or verification parameters are also parameters that are found in validation (for example, in analytical chemistry the verification requirement can be detection limit and repeatability), the use of the word validation in ISO/IEC 17025 should be restricted to the requirement of 5.4.5 which is applicable for non-standard or laboratory developed methods.</p>
5.4.3	<p>To be accredited, in-house procedures must be formally documented and the applicant must submit with the application 1 or 2 representative test procedures from the list of tests for which accreditation is sought. It is important to note that by accrediting such methods, SCC is not validating in-house methods [TG LABS 10/89.4].</p> <p>TG LABS approved a minimum requirement for documenting and validating such methods (refer to the interpretative note CAN-P-1630 Section 5.4.1 and 5.4.5). Judgment is always called upon from the assessor when evaluating a test method and this policy is intended to help provide more consistency amongst assessments [TG LABS 13/93.3]. That resolution has been supplemented by CAN-P-1629 PALCAN Policy for the Validation of Test Methods.</p>
5.4.5	<p>Refer to PALCAN Policy for the Validation of Test Methods. The following is provided as general guidance for use and validation of method. In case of disagreement between the text below and CAN-P-1629, CAN-P-1629 shall prevail.</p>

For PSA's, refer to the CAN-P-PSA document as there are generally PSA specific interpretations for this requirement. In case of disagreement in the interpretation between the CAN-P-PSA requirements and either the text below or CAN-P-1629, CAN-P-PSA shall prevail.

TG LABS 13/93

METHODS USED AND METHOD VALIDATION

Chemical Laboratories

The SCC encourages and promotes the use of test methods and procedures used in accredited laboratories that are based on nationally or internationally accepted standards. Testing organizations which are not using formally recognized test methods but only "In House Test Methods", will be required to present documented evidence that these methods are producing reliable results and that their customers are well aware of the fact that these methods are not standard methods.

An IN HOUSE TEST METHOD refers to test method procedures which are based on recognized validated procedures but altered by the user to meet their own particular operational necessities.

The testing organization to be accredited, or those already accredited, which are using in house test methods, must be able to clearly demonstrate, by documented evidence, that any and each test procedure modification produces reliable results. On request, all documented results of the validation procedure must be available to the customer and other recipients of the relevant reports.

The design, verification of the method and documentation procedures for validation must be planned and conducted by qualified personnel, equipped with adequate resources. It is desirable that the validation of an in house test method be carried out by personnel independent of those having direct responsibility for the testing work being performed.

This document in the paragraphs that follow lists a few acceptable validation procedures. The choice of the procedure will depend on the extent of the deviation from the published method.

Validation of methodology is a value judgment in which the performance parameters of the method are compared with the requirements for the analytical data. A prerequisite for a valid method is that data produced by the method must attain a state of statistical control. Such a state is obtained when the mean value of a large number of individual values tends to approach a limiting value called the limiting mean.

Methods may be validated by one or more alternative procedures some of which are described below. Apparent differences can be analyzed statistically to confirm their significance. In all cases, the reasons for choosing one or more alternatives must be documented.

- i) Analysis of standard reference materials (SRM) that are identical or almost identical to the test samples.
- ii) In the absence of suitable SRM's, analysis of reference materials that are similar in all respect to the test samples; the use and validity of this reference material must be documented.
- iii) Alternate Method: Using an alternative method to measure the same parameter provides a very high level of confidence if results are confirmed.
- iv) Recovery Studies (Standard Addition): The addition of a know concentration of the parameter of interest to some of the replicates being measured.

	<p>Parameters that should be determined are:</p> <ul style="list-style-type: none"> i) The scope of the method and any known interference. ii) Detection limit. iii) The range of concentration where the method is valid. iv) Precision and bias. v) Intra-laboratory variations. vi) Interlaboratory variations. <p>Judgment is required to determine if some or all of the above is required. Requirements will depend largely on the extent of deviation from the original method.</p>
5.4.5.3	<p>CLAS Interpretation: For calibration laboratories, data demonstrating long term stability of a method can be used to <u>support</u> validation of that procedure, but cannot, on its own, be considered a complete validation of the procedure. Such data demonstrates only the ability to provide consistent results, whether correct or not. In addition, the laboratory requires data that demonstrates the ability to provide the correct or reproducible results.</p>
5.4.6.1	<p>For calibrations, refer to <u>CLAS Requirements Document 5 - Evaluating and Expressing Uncertainty of Measurements</u>. See also CLAS Requirements Document 3 - Minimum Requirements for Measurement Standards for Laboratory Certification, in regards to the uncertainty of measurement standards. Both documents are available at http://inms-ienm.nrc-cnrc.gc.ca/clas/reference_documents_e.html</p>
5.4.6.2	<p><i>For testing</i>, refer to CAN-P-1623 PALCAN Interpretation and Guidance on Estimation of Uncertainty of Measuring in Testing (SCC adoption of APLAC TC-005 verbatim). CAN-P-1623 is available on the SCC web site and APLAC TC-005 is available at http://www.aplac.org/documents/published/htm.</p> <p>For additional guidance refer to ILAC G17 – Introducing the Concept of Measurement Uncertainty (MU) in Testing available at http://www.ilac.org/.</p> <p><i>For laboratories with PSA recognition</i>, there are some PSA’s with specific interpretations on testing MU.</p> <p>Measurement uncertainty, as defined by the GUM, is the only pertinent product of calibration activities. It is important to address both calibrations that are done in-house by the laboratory itself (refer to CAN-P-1627 PALCAN Policy on the Selection of Physical Measurement Calibration Sources for Testing Laboratories) and those that are conducted by outside suppliers. Testing laboratories are to ensure that they also receive appropriate uncertainties of measurement from outside sources of calibration. See also CAN-P-1630 Section 4.6.1 in regards to specifying requirements when procuring calibration services.</p> <p><u>ILAC guidance to clause 5.4.6.2 (G.5.4.6.2)</u> G.5.4.6.2 The complexity involved in estimation of uncertainty of measurement in the case of testing varies considerably from one testing field to another and even within one field itself. It is also often achieved by a less metrologically rigorous process than that which can be followed for calibration. Clause 5.4.6.2 of ISO/IEC 17025 allows for these factors and Accreditation Bodies (assessment teams) should take them into account during assessments.</p>
5.4.6.3	<p>For additional guidance on estimating the uncertainty of measurement in calibration, see CLAS Requirements Document 5 - Evaluating and Expressing Uncertainty of Measurements, together with various tools and presentations available at http://inms-ienm.nrc-cnrc.gc.ca/en/clas/reference_documents_e.php</p> <p>Refer also to Expression of the Uncertainty of Measurement in Calibration, <u>EA-4/02</u>, 1999, European Co-operation for Accreditation.</p>

5.4.7	CAN-P-1628 PALCAN Policy on the Use of Information Technology in Accredited Laboratories applies when electronic mediums are used in this section.
5.4.7.2	For in-house developed/modified software, requirements in ISO 17025 are complex in that software is considered a document that needs to be controlled (4.3.1) and validated (5.4.7.2). In addition it is considered part of the equipment (5.5.2, 5.5.4, 5.5.5, 5.5.11) that needs to be safeguarded against adjustment (5.5.12). In acquisition/manipulation processes, software generally produce critical records (4.12.1) that need to have procedures to identify, collect... and protect/back up (4.12.1.4) when maintained electronically and when electronic records are critical (such as original observations, derivations, calculations), and, as a result are part of the audit trail, the requirements of 4.12.2 also apply. This requirement applies to commercial software that is modified/developed by the user, including user developed equations in EXCEL spread sheets/workbooks that conduct manipulations/calculations.
5.4.7.2 (a)	<p>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 (4.3.1 Document Control procedures for the software).</p> <p>The validation test plan should also include robustness to ensure that the software responds as expected when invalid inputs are provided.</p>

5.5 Equipment

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
5.5	CAN-P-1628 PALCAN Policy on the Use of Information Technology in Accredited Laboratories applies when electronic mediums are used in this Section. This includes equipment software and data acquisition equipment.
5.5.1	It is essential that laboratories have their own equipment and SCC does not normally consider granting accreditation when the laboratory is not equipped to perform the test/calibration. However, where some specialized test/calibrations use equipment that is either rare or prohibitively expensive or when a specialized facility and operators are required, SCC may consider providing accreditation under specific conditions. TG LABS will need to review each such occurrence on a case by case basis and consider the following:

<p>5.5.1 (cont'd)</p>	<p>1. In all cases the interpretative note Section 4.5.1 still applies: a laboratory can not be accredited for a test/calibration it never performs. When a test/calibration is being only witnessed, this is considered purchasing by SCC to satisfy customer needs outside the scope of the laboratory's activities (not subcontracting for the purpose of accreditation) and the laboratory can not be considered for accreditation.</p> <p>2 The laboratory must normally be furnished with the equipment (or possess the facility) to be considered for accreditation. When a laboratory is using equipment/facilities that are not part of the laboratory furnishings, and such equipment/facility is key or critical test/calibration equipment (or facility), then laboratories should not normally be considered for accreditation of these tests. Critical equipment/facilities are defined as equipment/facilities that contribute significantly to the test/calibration uncertainty.</p> <p>3. When the equipment from another facility (or other facilities) is not key or critical equipment/facility, then the laboratory is required to maintain records in sufficient detail to reflect relevant information (for instance relevant requirements prescribed in the method for set-ups and fixtures and environmental conditions) and allow SCC assessor to be capable of evaluating compliance of the equipment.</p> <p>4. Equipment and/or facilities that are outside the laboratory's permanent control that are critical to the test/calibration must have records supporting that the conditions of 4.13.2, all of Section 5.3, all of Section 5.5 and 5.6.1 have been met.</p> <p>Regardless of the aforementioned or of any specific situation, all test/calibrations for which the laboratory is seeking accreditation that require outside equipment or facilities of any kind (critical or not) that are not owned by the laboratory must be presented to the TG LABS for individual consideration (TG LABS). When deemed acceptable by TG LABS, the scope of accreditation will need to clearly describe the specific condition(s) under which accreditation was granted and which equipment/facilities outside the laboratory's control have been approved for use in an SCC accredited test/calibration.</p>
<p>5.5.4</p>	<p>For calibration laboratories, see CLAS Requirements Document 4 - Requirements for Identifying Measurement Equipment and its Calibration Status available at http://inms-ienm.nrc-cnrc.gc.ca/clas/reference_documents_e.html for identifying calibration equipment and standards.</p>
<p>5.5.7</p>	<p>It is not mandatory that defective equipment be stored in a specific place if it is well marked and there is no danger of inadvertently using the defective equipment.</p>
<p>5.5.9</p>	<p>The "function and calibration status" implies the verification that the device is operating within tolerance. Some devices have self checks, others are not subject to effects of transportation and require only conditioning and yet others will require use of some sort of reference material that validates the calibration and function status are shown to be satisfactory (requirements ISO/IEC 17025 Section 5.5.10 refers to "calibration status"). Visual inspection and turn on-off is generally not sufficient but is part of the process. This activity should not require extensive records where self checks and only conditioning are needed but will require some detail in the records where verification with reference material needs to be done (requirements ISO/IEC 17025 Section 5.5.10 refers to defined procedures). This activity must be conducted by staff with the recognized competence to operate and verify the equipment (ISO/IEC 17025 Section 5.2.5).</p>

5.6 Measurement traceability

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<i><u>SCC Interpretative Note</u></i>
5.6.1	<p>Refer to CAN-P-1626 PALCAN Policy on Traceability Requirements for Calibration Sources used by Accredited Testing Laboratories for determining the acceptability of calibration sources.</p> <p>For additional guidance refer to <u>ILAC P10 – ILAC Policy on Traceability of Measurement Results</u> and <u>ILAC G2 – Traceability of Measurements</u> both available at http://www.ilac.org/</p>
5.6.2	<p>SCC accredited test and calibration laboratories may obtain traceability through calibration laboratories that are accredited, for the specific calibrations within the required best uncertainties, by an Accreditation Body that is signatory to the APLAC/ILAC MRA for the scope of calibration. The calibration services must be delivered under the scope of the calibration laboratory’s scope of accreditation.</p> <p>Testing & calibration laboratories need to retain records of verifications of calibration providers according to CAN-P-1627 PALCAN Policy on the Selection of Physical Measurement Calibration Sources for Testing Laboratories. When testing laboratories use calibration laboratories that are not accredited or accredited by an Accreditation Body that is not an ILAC/APLAC MRA Signatory, refer to CAN-P-1627 for additional requirements. These supplemental requirements enforcing a rigorous application of the ILAC P-10 definition of traceability is a requirement that SCC must meet as a signatory the APLAC/ILAC MRA.</p> <p>For calibration laboratories, CLAS Requirements Document 9 - Requirements for Measurement Traceability applies. This document is available at http://inms-ienm.nrc-cnrc.gc.ca/clas/refrence_documents_e.html.</p>
5.6.3.1	<p>Reference standards shall be calibrated before and after any adjustments in order to be able to provide the laboratory with the necessary data to evaluate any potential effect on items calibrated with this reference.</p>
5.6.3.3	<p>See CLAS Requirements Document 3 - Minimum Requirements for Measurement Standards for Laboratory Certification for minimum requirements for checking measurement standards used for different types of calibration services available at http://inms-ienm.nrc-cnrc.gc.ca/clas/refrence_documents_e.html.</p>

5.7 Sampling

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<i><u>SCC Interpretative Note</u></i>
5.7	<p>This clause applies only when the sampling is occurring under the direct control of the laboratory. This includes sub-sampling unless the associated contribution (from sub-sampling) to the overall accuracy of the result contributes little to the total uncertainty of the test result.</p> <p>Sampling is generally not applicable to calibration laboratories.</p>
5.7.1 5.7.1 (cont’d)	<p>PALCAN accredits laboratories for specific sampling procedures that relate <u>only</u> to their accredited testing/calibration activities. Sampling is a crucial element in providing quality test</p>

	results. A laboratory may be accredited for sampling for its testing purposes and such sample can be provided to another laboratory for further testing in an area in which the original laboratory was not accredited. Sampling is excluded from a scope of accreditation if the laboratory staff does not conduct the sampling. Sub-contracting requirements (ISO/IEC 17025 Section 4.5) apply if an outside person does the sampling for the laboratory (TG LABS 9/96.2).
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5.8 Handling of test and calibration items

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
5.8.1	Legal samples could have specific requirements such as chain of custody. For legal purposes, laboratories should be able to demonstrate that the items/samples examined and reported on were those submitted to the laboratory. A ‘chain of custody’ record should be maintained from the receipt of items/samples, which details each person who takes possession of an item, or alternatively the location of that item (e.g. if in storage). It may be useful to have documented procedures that describe the measures taken to secure samples in the process of being examined which must be left unattended.

5.9 Assuring the quality of test and calibration results

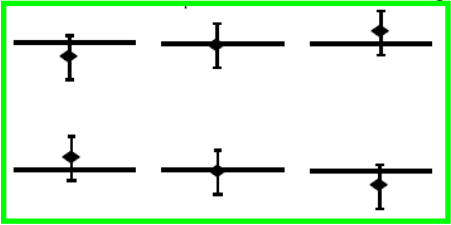
CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
5.9.1	<p><u>General Interpretations:</u></p> <p><u>Assessment teams</u> should encourage laboratories to participate in proficiency testing and when justified and appropriate may make this a requirement of accreditation in certain fields of testing and calibration. Participation in proficiency testing should be considered as part of the surveillance activities.</p> <p><u>Refer to CAN-P-1624 PALCAN Policy on the Use of Proficiency Testing as a Tool for Accreditation in Testing.</u> SCC verbatim adoption of ILAC G22. Under the conditions of SCC’s APLAC/ILAC MRA, SCC must require that laboratories participate in one PT activity major testing field at least every four (4) years. SCC PSA requirements (including calibration laboratories) have specific requirements for PT that exceed the minimum requirement of the MRA. These are defined in the individual PSA documentation and must be adhered to.</p> <p>Technical Assessors should continue to encourage participation in specific PT programs. Where there are no established PT programs, Technical Assessors could encourage the laboratory to require that one be set up. Laboratories must be informed of the value of such participation (TG LABS 6/95.6)</p> <p>Technical Assessors are required to review laboratory participation in proficiency testing or ILC or round robin, and where outliers or poor performance have been reported, ensure the laboratory has initiated and documented suitable Corrective Actions (ISO/IEC 17025 Section 4.11).</p>
5.9.1 (cont’d)	<u>For calibration laboratories</u> , CLAS Requirements Document 7 - CLAS Requirements for Proficiency Testing applies. Quality control of the measurement processes is an important requirement for

	<p>A list of A2LA recognized PT providers can be found at: www.a2la.org/index.cfm</p> <p>EPTIS Proficiency Provider EPTIS has a database of hundreds of PT schemes operated in Europe and the United States. To access the database go to: http://www.eptis.bam.de/</p> <p>APLAC Proficiency Provider List A listing of international proficiency testing providers is found in the document APLAC PT003 (APLAC Proficiency Testing Directory) which is available on the APLAC website at the following location: http://www.aplac.org/documents/published.htm</p>
5.9.2	<p>The analysis of the data resulting from the monitoring activities of section 5.9.1 and determining if a correction or corrective action is required was an implied requirement now reinforces. An isolated process should not exist and when out-of-tolerance is found the requirements of the procedure of section 4.9 (control of non-conforming) is required to be implemented.</p>

5.10 Reporting the results

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<u>SCC Interpretative Note</u>
5.10	<p>CAN-P-1628 PALCAN Policy on the Use of Information Technology in Accredited Laboratories applies when electronic mediums are used in this section.</p> <p>For calibration laboratories, CLAS Requirements Document 6 - Requirements for Calibration Certificates is available at http://inms-ienm.nrc-cnrc.gc.ca/clas/refrence_documents_e.html.</p>
5.10	<p><u>ILAC guidance to clause 5.10 (G.5.10.1)</u> G.5.10.1 Laboratories that are accredited by an Accreditation Body which is a signatory of the ILAC or regional Multilateral Agreement in the field of testing or calibration, may state on certificates and reports, in the appropriate language:</p> <p>“SCC is a signatory to both the ILAC and APLAC Multilateral Agreement/Arrangement for the mutual recognition of test reports and/or calibration certificates (whichever is relevant).”</p>
5.10	<p>Refer to CAN-P-1570 PALCAN Handbook, Section 13 Publicity Guidelines and Appendix E Trademark Licensing Agreement for guidance on publicizing accreditation status on test reports.</p>
5.10.2	<p>It is important to note that the laboratory need not provide all the information required by Section 5.10.2 when the customer specifically requires not to have this information, and that this could not be a cause of potential misinterpretation of the result. Such a requirement by a customer could be documented in the review of tenders and contracts.</p>
5.10.2 b)	<p>The address referred to in this case is the laboratory's address and where applicable that of the site where the test or calibration was conducted when testing or calibration is conducted away from the laboratory.</p>
5.10.2 c)	<p>A serial number is strongly suggested. It may be acceptable to state the total number of pages</p>

	differently than by "Page # of #", e.g. stated at the beginning of the report.
5.10.2 d)	If the testing is conducted for internal purposes, it is not necessary to state the name and address of the customer.
5.10.2 j)	<p>The signature of the person who performed the testing or calibration must be retained in the file but need not appear on the final report. Some laboratories do not even issue a final report, such as certain Dairy laboratories for which the vast numbers of samples make it impractical for each report to be signed, or the data for the final report is transmitted electronically to the proper authority. However, the results must remain traceable to the operator. Some regulatory agencies, dealing with possible legal action, require 2 signatures on a final report. TG LABS members agreed that a flexible approach was necessary and that the statement now appearing in paragraph 5.10.2 of CAN-P-4E (ISO/IEC 17025: 2005) satisfies all concerns (TG LABS 8/92.4).</p> <p>A person signing reports does not need formal technical expertise in the area of testing being reported. If the person is ultimately responsible for the testing and if the person doing the testing is technically qualified and can be identified from the data, then it can be accepted that a supervisor sign the reports (TG LABS 10/94.4). This is a minimum requirement and does not preclude additional requirements for certain needs such as those of regulatory authorities (TG LABS 10/94.2).</p> <p>Some PSA's and some provinces have specific requirements as to the qualifications of the person signing the reports/certificates.</p> <p>Persons signing reports/certificates are referred to as signatories by certain Accreditation Bodies. SCC does not keep a list of approved signatories as this is the responsibility of the laboratory to control its signatories.</p>
5.10.2 k)	<p>There are very few cases where it is not relevant to include such a statement, to ensure against interpretation as part of a certification program. These could include:</p> <ul style="list-style-type: none"> - for internal Quality Control laboratories; if the laboratory is conducting the sampling, testing, and the analysis of the results; - unique tests, where only one sample exists and the product is destroyed in the testing, e.g. some forensic testing.
5.10.2 Notes 1&2	This was a requirement under CAN-P-4C and was relegated to a Note by the ISO/IEC 17025 Working Group because it is an accreditation requirement and not a requirement for technical competence. The SCC normally requires that the laboratory, as a condition of accreditation, adopts the contents of Note 2.
5.10.3	The checklist might lead to the interpretation that opinions and interpretations are accepted by SCC. See the note in 5.10.5 on this subject.
5.10.4.1	Calibration certificates issued by CLAS laboratories must identify the measurement standards used. They must also include a statement of traceability that meets the intent of requirements published in CLAS Requirements Document 6 - Requirements for Calibration Certificates available at http://inms-ienm.nrc-cnrc.gc.ca/clas/refrence_documents_e.html .
5.10.4.2 5.10.4.2 (cont'd)	<p>Based upon ILAC guidance to clause 5.10.4.2 (G.5.10.4.2.1)</p> <p>G.5.10.4.2.1 Accreditation Bodies should provide rules for the way in which measurement uncertainty has to be taken into account when statements of compliance are made. Such rules may follow ILAC G8 available at http://www.ilac.org/.</p> <p>This requirement is especially important when the result of the measurement is indeterminate, as illustrated below. In these cases, where the diamonds represent the measurement result, and the vertical lines represent measurement uncertainty and the horizontal lines represent the upper and</p>

	<p>lower specification limits, it is impossible to determine within the stated level of confidence, whether the measurement is within the specification limits or not.</p>  <p>The issue is one of agreed sharing of risk, between the laboratory and the customer. Specifically, these are: 1) the risk of incorrectly accepting equipment that is actually out of specification (customer risk), versus 2) the risk of incorrectly rejecting (and hence adjusting and recalibrating) equipment that is actually within specification (laboratory's risk). ILAC G-8 proposes that the customers' preferences be determined and respected. When the customer does not state a preference, ILAC G-8 recommends that the measurement result be reported as either "indeterminate" or "out of specification" in all indeterminate cases such as those illustrated here. SCC accredited calibration laboratories must attempt to determine their customers' preferences for sharing this risk (see also CAN-P-1630 Section 4.4.1). These laboratories must have a documented policy and procedure for how the uncertainty is to be taken into account when the customer declines to state a preference. The customer must be informed of this policy before the work is accepted. See CLAS Requirements Document 3 - Minimum Requirements for Measurement Standards for Laboratory Certification available at http://inms-ienm.nrc-cnrc.gc.ca/clas/reference_documents_e.html (under the discussion of guardbanding) for a description and examples of various acceptable methods for taking uncertainty into account.</p> <p>SCC accredited test and calibration laboratories must specify their requirements on purchasing documents for how uncertainty is to be taken into account when calibration services are sought which are to include a reporting of conformance to an identified specification (see also CAN-P-1630 Section 4.6).</p>
<p>5.10.4.4</p>	<p>This applies to calibration laboratories. See also CAN-P-1630 Section 4.4.1 in regards to determining the customers' needs for reporting of calibration intervals.</p> <p>Testing laboratories are reminded that they can set the calibration interval themselves based on their usage and data demonstrating stability, or they can ask the calibration laboratory to recommend an interval.</p>
<p>5.10.5</p>	<p>Except for the Forensics PSA, laboratories shall not normally be accredited for the provision of interpretations and opinions outside the bounds of some pro-forma test reports, which may include pass-fail statements as required by regulations or certain product standards. The SCC will normally accredit organizations for the provision of such professional judgement under CAN-P-3 (ISO/IEC Guide 65) for the accreditation of Certification Bodies or a similar program for inspection bodies under ISO/IEC 17020 (APLAC Common Assessor Training Course 2000-04-10 to 14).</p> <p>Some laboratories could be required to provide such interpretations under regulatory obligations and, if this is the case, these interpretations should be clearly separated from the accredited test results in the final report that is submitted to the customer.</p>
<p>5.10.6</p>	<p><u>ILAC guidance to clause 5.10.6 (G.5.10.6.1)</u> G.5.10.6.1 Accreditation Bodies (assessment teams) should ensure that when the laboratory does not take responsibility for the subcontracted work, as provided for in ISO/IEC 17025 Clause 4.5.3, this fact is clearly stated in the report.</p>
<p>5.10.6</p>	<p>It is necessary to identify the tests or calibrations that were sub-contracted; however, it is not necessary to give the identity of the sub-contractor.</p>
<p>5.10.7</p>	<p>This required element is identified in the CAN-P-1510D checklist with the requirements of Section 5.4.7.</p>

Annex A - Nominal cross-references to ISO 9001:2000

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<i><u>SCC Interpretative Note</u></i>
Annex A	<i>There are no interpretations for this Section</i>

Annex B - Guidelines for establishing applications for specific fields

CAN-P-4E (ISO/IEC 17025: 2005 Section No.)	<i>SCC Interpretative Note</i>
B5	SCC provides such interpretations for PSA's and these are listed on the SCC web site at http://www.scc.ca/en/programs/lab/index.shtml .

Annex C - Features of a Legally Identifiable Laboratory

As determined by the former SCC General Counsel and stated in a memo dated 1992-12-02, these are as follows:

1. While the phrase “legally identifiable” has not been “judicially considered” in our law it likely means “identifiable under law”, without necessarily “having [the] legal capacity to sue and to be sued”, as this would require “each applicant [to] have [a] separate corporate identity under company law.”
2. “Legally identifiable” is therefore taken to mean that a laboratory be “severable, unique or distinguishable from any corporate or organizational parent and from all other operational installations of an applicant [organization that] operate in close proximity with the specific laboratory unit for which accreditation is ... sought.”
3. “The apparent intent ... is to ensure control over the status of accreditation. The accreditation [covers] a distinct ‘corporate’ entity and [is] limited to that entity.”
4. There must be clear “boundaries of personnel and floor space. Where there is overlap, extension, spread or sharing of facilities or personnel”, this must “not call into question the extent of the accreditation” of “the identifiable [(severable, unique, distinguishable)] applicant ... laboratory.
5. “A suggested test” is for the assessment team to determine “whether [or not] the corporate boundaries of the proposed accreditation are clear and distinguishable. If not, the laboratory [is not] ‘legally identifiable’ ”.

Bibliography

<p>CAN-P-4E (ISO/IEC 17025: 2005 Section No.)</p>	<p><u>SCC Interpretative Note</u></p>
<p>Additional SCC Bibliography References</p>	<p><u>ILAC guidance to Bibliography (G.bib.1)</u> G.bib.1 As well as the ISO/IEC publications referenced in the standard, there are documents produced by ILAC and regional cooperations of Accreditation Bodies (e.g. EA, APLAC), and also by professional associations (e.g. Eurochem/CITAC Guide on evaluation of uncertainty of measurement). Accreditation Bodies should encourage laboratories to consult these for guidance for demonstrating competence in specific aspects of laboratory operation for the purpose of accreditation.</p> <p>ILAC publishes an extensive range of information documents and guides to assist Accreditation Bodies, laboratories, trade and regulatory bodies and other interested parties. The guides cover accreditation practices, and subjects such as traceability, legal liability, trade issues related to testing and international agreements.</p> <p><u>Information Series (I series):</u></p> <p>ILAC I1:1994 Legal Liability in Testing (105kb) This document provides information to technically-trained persons working in the testing area about the general approaches to legal liability issues and how they may apply to testing laboratories, Accreditation Bodies and Certification Bodies.</p> <p>ILAC I2:1994 Testing, Quality Assurance, Certification and Accreditation (61kb) This paper explains to those who use results of conformity assessment procedures, something of the features and limitations of those procedures. It is also intended that this information should help in understanding the complexity of the subject and describe the way in which various countries manage their infrastructures in this area.</p> <p>ILAC I3:1996 The Role of Testing and Accreditation in International Trade (111kb) A background document for officials and others dealing with trade policy matters and for technical personnel interested in how test results can impact on trade.</p> <p>ILAC I4:1996 Guidance Documents for the Preparation of Laboratory Quality Manuals (26kb) A reference list of guidance documents available from Accreditation Bodies to assist laboratories in developing their quality manual.</p> <p><u>Guidance Series (G series):</u></p> <p>ILAC G1: 1994 Guidelines for the Establishment and Review of Mutual Recognition Agreements (385kb) These guidelines deal with the major steps involved in preparing for an evaluation for a mutual recognition agreement; for conduct of evaluations; for documentation of agreements; and for maintaining agreements.</p> <p>ILAC G2 has been superseded</p>

ILAC G3:1994 Guidelines for Training Courses for Assessors (52kb)

These guidelines have been prepared to assist laboratory Accreditation Bodies to set up training courses that are in line with international practice and which will enable them to generate the lead assessors and technical assessors that they need.

ILAC G4:1994 Guidelines on Scopes of Accreditation (42kb)

These guidelines have been prepared to assist laboratory Accreditation Bodies to harmonise their practices for expressions of scopes of accreditation. Such harmonisation would be of considerable benefit to international users of test, measurement and calibration data. It would also facilitate the process of establishing mutual recognition agreements between laboratory Accreditation Bodies.

ILAC G5:1994 Calibration and Maintenance of Test and Measuring Equipment (71kb)

This guidance document is written to help calibration and test laboratories operating a management system in accordance with ISO/IEC Guide 25 to implement a system to ensure that measuring and test equipment (including reference materials) used for calibration or testing, in the laboratory premises or on site, comply with the requirements defined.

ILAC G6:1994 Guidance under ISO/IEC Guide 25 for Laboratories Performing Sampling (40kb)

These guidelines set out the general requirements that a laboratory should follow if it is to be recognised as competent to carry out specific sampling activities for the substances, matrices, materials or products which it tests. The guidelines are for use by testing laboratories in the development and implementation of their management systems for sampling. They may also be used by Accreditation Bodies, Certification Bodies and others concerned with the competence of laboratories involved in sampling.

ILAC G7:1996 Accreditation Requirements and Operating Criteria for Horseracing Laboratories (58kb)

The purpose of this document is to provide:

Part A: A compilation of test-method-related requirements for horseracing laboratories that Accreditation Bodies have submitted.

Part B: Recommendations for establishing the presence of prohibited substances that have been agreed within the horseracing industry.

Part C: The performance specification for horseracing laboratories that has been adopted by the International Federation of Horseracing Authorities.

ILAC G8:1996 Guidelines on Assessment and Reporting of Compliance with Specification (46kb)

The guidelines give rules for supplier and customer concerning the assessment and reporting of compliance or non-compliance for a single unit of product using an agreed test method. Legal requirements supersede any agreement.

ILAC G9:1996 Guidelines for the Selection and Use of Certified Reference Materials (29kb)

These guidelines aim at establishing the framework by which laboratories seeking accreditation, and technical assessors, will be able to propose and evaluate the CRM's relevant to their specific needs.

ILAC G10:1996 Harmonised Procedures for Surveillance & Reassessment of Accredited Laboratories (33kb)

These guidelines provide a procedure for a harmonised approach to conducting surveillance and reassessment of accredited laboratories.

ILAC G11:1998 ILAC Guidelines on Assessor Qualifications & Competence (258kb)

This document interprets and amplifies ISO/IEC Guide 58 requirements for an “adequate procedure” for qualifying and monitoring the performance of assessors and describes criteria for lead assessors and technical assessors.

ILAC G12:2000 Guidelines for the Requirements for the Competence of Reference Materials Producers (781kb)

These Guidelines have been developed for evaluation of the competence of reference materials producers with a view to the eventual establishment of internationally accepted criteria.

ILAC G13:2000 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes (726kb)

This document is for providers of proficiency testing schemes who wish to demonstrate their competence by formal compliance with a set of internationally acceptable requirements for the planning and implementation of proficiency testing schemes.

ILAC G17:2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025

This document describes how the concept of uncertainty of measurement should be introduced taking into account present state of the art understanding. It is realized that during the course of the implementation of ISO/IEC 17025, suitable sector-specific guidance will be needed. However, the harmonization of the application of the principles of uncertainty of measurement in testing between different disciplines, industry sectors and economies should remain the main goal.

ILAC G22 2004 Use of Proficiency Testing as a Tool for Accreditation in Testing

The objective of this document is to ensure a consistent good practice for Accreditation Bodies and laboratories in the cost-effective use of proficiency testing in accreditation.

Procedure Series (P series):

ILAC P10-2002 ILAC Policy on Traceability of Measurement Results

This document provides a policy on traceability of measurement results which is intended to be implemented by ILAC members and to encourage the development of supporting bodies such as CIPM/BIPM. Unless otherwise noted in the text for some clauses, this policy is effective as of 1 January 2003.

APLAC Documents:

APLAC publishes an extensive range of information documents and guides to assist Accreditation Bodies, laboratories, trade and regulatory bodies and other interested parties.

The following documents are applicable to SCC laboratory assessments:

APLAC TC-002 APLAC Internal Audits for Laboratories and Inspection Bodies

APLAC TC-003 APLAC Management Review for Laboratories and Inspection Bodies

APLAC TC005 Interpretation & Guidance on Estimation of Uncertainty of Measurement in Testing

APLAC TR001 Guidelines on Training course for Assessors

These documents are available without cost at <http://www.aplac.org/documents/published.htm> .

SCC-CLAS Calibration Programme Documents available at:

	http://inms-ienm.nrc-cnrc.gc.ca/clas/refrence_documents_e.html	
	CLAS Document 3	Requirements for Measurement Standards
	CLAS Document 4	Identification of Measurement Equipment and Calibration
	Status	
	CLAS Document 5	Evaluating and Expressing Uncertainty of Measurements
	CLAS Document 6	Requirement for Calibration Certificates
	CLAS Document 7	CLAS Requirements for Proficiency Testing
	CLAS Document 9	Requirements for Measurement Traceability

Acronym Definition List

Abbreviation	Name	Definition
A2LA	American Association for Laboratory Accreditation	Accreditation Body accrediting laboratories without regard to the territorial limits of the U.S.A.
AB	Accreditation Body	Organization providing accreditation services
AFP	Agriculture and Food Products	PSA related to the regulatory requirements for food testing laboratories
Assessor	Technical Assessor	Person who is part of an assessment team with a recognized expertise in a testing field and recognized knowledge of ISO/IEC 17025
CAN-P	Canadian Procedural Document	SCC published document containing interpretations and SCC policies for specific purposes
CAN-P-4E	SCC-PALCAN Verbatim Adoption of ISO/IEC 17025: 2005	The standard to which the laboratories are assessed
APLAC	Asia Pacific Laboratory Accreditation Cooperation	Asia Pacific Laboratory Accreditation Cooperation (APLAC) groups accreditation bodies in the Asia Pacific region responsible for accrediting calibration, testing and inspection facilities. APLAC's principal objectives are to foster the development of competent laboratories and inspection bodies in member economies, to harmonize accreditation practices in the region and with other regions, and to facilitate mutual recognition of accredited test, measurement and inspection results through the APLAC multilateral Mutual Recognition Arrangement (MRA). For more information: http://www.aplac.org/
CFIA	Canadian Food Inspection Agency	SCC-PALCAN Partner Organization for technical assessment of AFP PSA labs to ISO/IEC 17025

Abbreviation	Name	Definition
CIPM/BIPM	CIPM – International Committee for Weights and Measures BIPM – Bureau internationale des poids et mesures	Its principal task is to ensure world-wide uniformity in units of measurement and it does this by direct action or by submitting proposals to the General Conference (CGPM).
CLAS	Calibration Laboratory Assessment Service	SCC-PALCAN Partner Organization for assessment of calibration PSA labs to ISO/IEC 17025
EA	European co-operation for Accreditation	The international body pledged to play a key part in eliminating technical barriers to trade by achieving a uniform approach to accreditation throughout Europe
EPTIS	European Proficiency Testing Information System	EPTIS has a database of hundreds of PT schemes operated in Europe and the United States. To access the database go to: http://www.eptis.bam.de/
Eurachem/CITAC	Eurachem/Co-Operation on International Traceability in Analytical Chemistry	This guide gives detailed guidance for the evaluation and expression of uncertainty in quantitative chemical analysis, based on the approach taken in the ISO “Guide to the Expression of Uncertainty in Measurement” (GYM).
GUM	ISO Guide to the Expressions of Uncertainty in Measurements	This guide establishes general rules for evaluating and expressing uncertainty in measurement that can be followed at various levels of accuracy and in many fields.
ILAC	International Laboratory Accreditation Cooperation	ILAC is the world's principal forum for the development of laboratory accreditation practices, the promotion of laboratory accreditation, the assistance of developing accreditation systems, and the recognition of competent test facilities. For more information: http://www.ilac.org/
ILC	Interlaboratory Comparisons	The organization, performance and evaluation of tests on the same or similar test items by two or more laboratories in accordance with predetermined conditions.

Abbreviation	Name	Definition
MRA	APLAC-ILAC Mutual Recognition Arrangement	Agreement detailing the conditions of SCC recognition by the international bodies. Details of the MRA are in: http://www.aplac.org/documents/web_docs/mr_001.pdf http://www.aplac.org/documents/web_docs/mr_002.pdf
NRC	National Research Council of Canada	Canadian National Metrology Institute
PALCAN	Program for Accreditation of Laboratories of CANADA	SCC acronym for the branch that delivers accreditation services
PSA	Program Specialty Area	Specifically defined interpretations of ISO/IEC 17025 applicable to specific programs within the ISO/IEC 17025 accreditation activities
PT	Proficiency Testing	Activity in support of ISO/IEC 17025 requirements section 5.9.1
SCC	Standards Council of Canada	National Canadian Body responsible for the National Standards System
TG LABS	Task Group Laboratories	SCC Sub-Committee of the Advisory Committee on Conformity Assessment (ACCA) responsible for recommending changes in SCC PALCAN Policy and performing an independent technical review of assessment reports.