# CLAS 1510E Assessment Guide

**FOR USE WITH**

**ISO/IEC 17025:2005**
**(CAN-P-4E)**
***"GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES"***

## for the Assessment of Calibration Laboratories

National Research Council Canada
Institute for National Measurement Standards
Calibration Laboratory Assessment Service (CLAS)
Ottawa, Ontario, Canada K1A 0R6
tel. (613) 993-5976
fax. (613) 952-1394

**This document is based upon Standards Council of Canada (SCC) PALCAN Document CAN-P-1510E (Feb. 2006) and is issued with the consent of the SCC PALCAN Program. CLAS is the PALCAN Partner that is responsible for assessment of calibration laboratories for certification by CLAS and accreditation by the SCC to CAN-P-4E (i.e., ISO/IEC 17025:2005).**

## INSTRUCTIONS ON THE USE OF THE CLAS 1510E ASSESSMENT GUIDE

**IMPORTANT NOTICE**
**This assessment guide is an abridged version of the text in ISO/IEC 17025: 2005 and is tailored for calibration laboratories. In case of disagreement between this document and ISO/IEC 17025: 2005, the standard will prevail.**

### 1. Instructions to laboratories

Laboratories are requested to complete the Comments column only. Do not fill in the check boxes. Simply provide a reference to the specific paragraph(s) of the laboratory's management system documentation (policy, procedures, instruction, etc) that addresses the ISO/IEC 17025:2005 requirement. If more space is required, a separate page can be attached as an Appendix referenced to this assessment guide. Where an item does not apply, it should be indicated as not applicable, together with a brief explanation of why it does not apply.

### 2. Instructions to CLAS assessors

CLAS Assessors are requested to complete the entire assessment guide while assessing both the technical and non-technical elements of ISO/IEC 17025:2005 (CAN-P-4E). Fill the checkboxes ☐ in the first column as follows:

☑ = meets requirements

☒ = doesn't meet requirements, or a suggestion for improvement is proposed

⁄ = not applicable (N/A)

The boxes may be toggled by double-clicking on them while in MS Word 2002 or compatible software.

Column widths of all tables can be adjusted in batch using the macro AdjustAllTables. It can be executed by double-clicking on the green square here or at the top of Section 4.1. The macro also updates the Table of Contents.

### SUMMARY OF CHANGES FROM ISO/IEC 17025:1999 TO ISO/IEC 17025:2005

The changes to from ISO/IEC 17025:1999 (CAN-P-4D) to ISO/IEC 17025: 2005 (CAN-P-4E) that affect CLAS 1510E are shown in ***bold underlined italic and highlighted in yellow*** throughout this document. The summary of changes in substance from CLAS 1510D to CLAS 1510E are as follows:

a) Client is replaced by Customer
b) Quality System or Quality Management System is replaced by Management System (MS)
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

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|---|---|---|---|

## 4 Management requirements

### 4.1 Organization

**[Double-click here to adjust columns for ALL 23 tables & to update table of contents]**

| Clause & Requirement | Comments |
|---|---|
| **4.1.1 Laboratory Registration**<br><br>The laboratory shall be an entity that can be held legally responsible. **See CAN-P-1630[4.1.1]** | |
| **4.1.2 Laboratory Requirements**<br><br>The laboratory is responsible for carrying out its calibration activities in a manner that meets the requirement of ***CAN-P-4E (ISO/IEC 17025: 2005)***, and the needs of the ***customer***, regulatory authorities or recognition organizations.<br><br>**See CAN-P-1630[4.1.2] and CAN-P-1570** | |
| **4.1.3 Scope of Management System**<br><br>The management system shall cover activities in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary/mobile facilities. | |
| **4.1.4 Organization Conflict of Interest**<br><br>When lab is part of an organization with activities other than calibration, responsibilities shall be defined for key **organization** personnel that have an involvement/influence on the calibration activities to identify potential conflicts of interest.<br><br>**See CAN-P-1630[4.1.4]** | |
| **4.1.5a Management and Technical Personnel**<br><br>The laboratory shall have managerial and technical personnel, ***who, irrespective of other responsibilities, have*** the authority and resources needed to ***implement, maintain and improve the MS***.<br><br>**See CAN-P-1630[4.1.5a]** | |
| **4.1.5b Undue Pressure**<br><br>The laboratory shall have arrangements to ensure that management and personnel are free from internal and external commercial, financial and other pressures that may adversely affect the quality of their work.<br><br>**See CAN-P-1630[4.1.5b]** | |
| **4.1.5c *Customer* Confidentiality**<br><br>The laboratory shall have **policies** and **procedures** related to ***customer*** confidentiality, including **procedures** for protecting electronic storage and transmission of results.<br><br>**See CAN-P-1630[4.1.5c]** | |

| Clause & Requirement | Comments |
|---|---|
| **4.1.5d Operational Integrity**<br><br>The laboratory shall have **policies** and **procedures** to avoid involvement in activities that would diminish the confidence in its competence, impartiality, judgement or operational integrity. | |
| **4.1.5e Organisation Chart(s)**<br><br>The laboratory shall define the organization and management structure of the laboratory including the relationships between quality management, technical operations, and support services and, if applicable, the position of the laboratory within the parent organization. **See CAN-P-1630[4.1.5e]** | |
| **4.1.5f Responsibility And Authority**<br><br>The laboratory shall define the responsibility and authority of all personnel who manage, perform or verify work affecting the quality of calibrations. | |
| **4.1.5g Laboratory Supervision**<br><br>The laboratory shall provide adequate supervision of personnel for calibration activities. | |
| **4.1.5h Technical Management**<br><br>The laboratory shall identify technical management that has overall responsibility for technical operations and resources.<br><br>**See CAN-P-1630[4.1.5h]** | |
| **4.1.5i Quality Manager**<br><br>The laboratory shall appoint a member of staff as quality manager who shall have defined authority and responsibility for ensuring that ***the management*** system ***related to quality i***s implemented and followed at all times, and who shall have direct access to the highest level of management at which decisions are made.<br><br>**See CAN-P-1630[4.1.5i]** | |
| **4.1.5j Managerial Substitution**<br><br>The laboratory shall appoint deputies for key managerial personnel, where practical. **See CAN-P-1630[4.1.5j]** | |
| ***4.1.5k Personnel Awareness***<br><br>***The laboratory shall ensure that personnel are aware of how they contribute to the achievement of the objectives of the management system.*** | |
| ***4.1.6 Communication of MS***<br><br>***Top management shall ensure that appropriate processes exist which communicate the effectiveness of the management system.*** **See CAN-P-1630[4.1.6]** | |

## 4.2 *Management system*

| Clause & Requirement | Comments |
|---|---|
| ☐ **4.2.1 *Management* system documentation**<br><br>The laboratory shall establish, implement and maintain a ***management system*** appropriate to the scope of its activities. The laboratory shall document to the extent necessary: policies, systems, programmes, procedures, instructions. The system's documentation shall be communicated, understood and implemented by the appropriate personnel. (**See CAN-P-1630[4.2.1]**) | |
| ☐ **4.2.2 Quality Manual**<br><br>The lab shall maintain a quality manual that shall include ***management system*** **policies** ***related to quality, including a quality policy statement.*** | |
| ☐ **4.2.2 Quality Policy Statement**<br><br>The **quality policy** statement shall be issued under the authority of ***top management*** and shall document the overall objectives. ***The quality policy statement shall be reviewed during management review***. **See CAN-P-1630[4.2.2].** The quality policy statement shall include:<br><br>**a)** the laboratory management's commitment to good professional practice and quality of ***customer*** service;<br><br>**b)** the management's statement of the laboratory's standard of service (**See CAN-P-1630[4.2.2b]);**<br><br>**c)** the ***purpose*** of the ***management s***ystem ***related to quality;***<br><br>**d)** a requirement for personnel to be familiar with the quality documentation and implement the policies and procedures;<br><br>**e)**<br>**-** the laboratory management's commitment to comply with ***CAN-P-4E (ISO/IEC 17025: 2005) and***<br>***- to continually improve the MS and its effectiveness.*** | |
| ☐ ***4.2.3 Commitment to the MS***<br><br>***Top management shall provide evidence of commitment to:***<br>▪ ***develop and implement the MS;***<br>▪ ***continually improve the effectiveness of the MS.***<br><br>☐ ***4.2.4 Customer Focus***<br><br>***Top management shall communicate to the organization the importance of meeting customer requirements.***<br><br>☐ ***4.2.7 MS Integrity***<br><br>***Top management shall ensure the integrity of the MS when changes are planned and implemented.***<br><br>**See CAN-P-1630[4.2.3,4&7]** | |

| Clause & Requirement | Comments |
|---|---|
| ☐ ***4.2.5*** **Quality Manual**<br><br>The lab shall maintain a quality manual that:<br><br>▪ shall include or make reference to supporting procedures including technical procedures;<br><br>▪ shall outline the structure of the documentation used in the ***management system.***<br><br>**See CAN-P-1630[4.2.5]** | |
| ☐ ***4.2.6*** **Quality Manual**<br><br>The lab shall maintain a quality manual that:<br><br>▪ shall define the roles and responsibilities of technical management and the quality manager, including their responsibilities for ensuring compliance with ***CAN-P 4E (ISO/IEC 17025: 2005)***; | |

**4.3 Document control**
**See CAN-P-1630 and CAN-P-1628 generally applicable to this section**

| Clause & Requirement | Comments |
|---|---|
| ☐ **4.3.1 Procedures**<br><br>The lab shall establish and maintain **procedures** to control all ***management system*** documentation (internal and external documentation) are established and maintained. **See CAN-P-1630[4.3.1]** | |
| ☐ **4.3.2.1 Approval and Issue**<br><br>Documents issued to personnel as part of the ***management system*** shall be reviewed and approved by authorised personnel prior to issue. | |
| ☐ **4.3.2.1 Master List**<br><br>The laboratory shall maintain a readily available master list (or equivalent document control **procedure**) of all ***management system*** documentation, which ***shows*** documents current revisions and distribution. **See CAN-P-1630[4.3.2.1].** | |
| ☐ **4.3.2.2a Availability**<br><br>The **procedure**(s) adopted shall ensure authorized editions of appropriate documents are ***readily*** available where required. | |
| ☐ **4.3.2.2b Periodic revision**<br><br>The **procedure**(s) adopted shall ensure documents are periodically reviewed and, where necessary, revised to ensure continuing suitability. | |

| Clause & Requirement | Comments |
|---|---|
| ☐ **Obsolete Documents**<br><br>**4.3.2.2c)** The **procedure**(s) shall ensure invalid or obsolete documents are promptly removed, and<br><br>**4.3.2.2d)** those retained for either legal or knowledge preservation purposes are suitably marked. | |
| ☐ **4.3.2.3 Identification**<br><br>***The management system*** documentation ***shall be*** uniquely identified by:<br><br>▪ date of issue and/or revision number;<br>▪ page numbering;<br>▪ total number of pages or a mark to signify the end of the document;<br>▪ the issuing authority(ies).<br><br>**See CAN-P-1630**[4.3.2.3] | |
| ☐ **4.3.3.1 Document Changes**<br><br>Changes to documents shall be reviewed and approved by the same function that performed the original review, or a designate.<br><br>The designated personnel shall have access to pertinent background information upon which to base their review and approval. | |
| ☐ **4.3.3.2 Altered or New Text**<br><br>The altered or new text shall be identified in the document or the appropriate attachments, where **practicable**. **See CAN-P-1630**[4.3.3.2] | |
| ☐ **4.3.3.3 Hand-written Amendments**<br><br>**Procedures** and authorities for hand-written amendments to documents shall be defined.<br><br>Amendments shall be clearly marked, initialled and dated. A revised document shall be formally re-issued. | |
| ☐ **4.3.3.4 Computerised Amendments**<br><br>**Procedures** shall be established for changes to and control of computerised documents.<br><br>**See CAN-P-1628**[4.3.3.4] | |

## 4.4 Review of requests, tenders and contracts

| Clause & Requirement | Comments |
|---|---|
| ☐ **4.4.1 Policies and Procedures**<br><br>The **policies** and **procedures** related to review of requests, tenders and contracts shall be established and maintained. The **procedures** shall ensure:<br><br>**a)** requirements, including methods to be used, are defined, documented and understood;<br><br>**b)** laboratory capability and resources meet requirements;<br><br>**c)** appropriate method is selected and capable of meeting ***customers'*** requirements.<br><br>***Differences between the request/tender and contract shall be resolved before work begins and acceptable to laboratory and customer***.<br><br>**See CAN-P-1630[4.4.1]** | |
| ☐ **Records of Review**<br><br>The laboratory shall maintain records of reviews, that include:<br><br>**4.4.2)** pertinent discussions with ***customer; and*** significant changes.<br><br>**4.4.3)** subcontracted work. | |
| ☐ **4.4.4 Notification of *Customer***<br><br>***Customer*** shall be informed of any deviations from the contract. | |
| ☐ **4.4.5 Contract Amendments**<br><br>If contract needs to be amended after work has commenced, the same contract review process shall be repeated, and any amendments shall be communicated to all affected personnel. | |

## 4.5 Subcontracting of calibrations

| Clause & Requirement | Comments |
|---|---|
| ☐ **4.5.1, 4.5.4 Competency**<br><br>The lab shall ensure that subcontractors are competent (e.g., comply with ***CAN-P-4E (ISO/IEC 17025: 2005)***) and shall maintain a register of subcontractors used and a record of the evidence of compliance with ***CAN-P-4E (ISO/IEC 17025: 2005)*** for the work in question. **See CAN-P-1630[4.5.1&4]** | |
| ☐ **4.5.2, 4.5.*3 Customer* Approval**<br><br>***Customer s***hall be advised in writing before work is sub-contracted and where appropriate gain approval. Lab is responsible to ***customer*** for sub except when sub is specified by the ***customer*** or regulatory authority. **See CAN-P-1630[4.5.2-3]** | |

## 4.6 Purchasing services and supplies

| Clause & Requirement | Comments |
|---|---|
| ☐ **4.6.1 Policies and Procedures**<br><br>The laboratory shall have a **policy** and **procedure**(s) related to:<br>▪ selection and purchasing of supplies and services ***that affect the quality of calibrations;***<br>▪ purchase, reception and storage of supplies.<br><br>**See CAN-P-1630 [4.6] and CLAS Document 9** | |
| ☐ **4.6.2 Verification**<br><br>The laboratory shall ensure that purchased supplies that affect the quality are:<br>▪ not used until verified compliant with specifications or requirements defined in the methods,<br>▪ and shall maintain records of actions taken to check compliance. | |
| ☐ **4.6.3 Purchasing Documents**<br><br>Purchasing documents shall contain:<br>▪ data describing the services and supplies ordered, and<br>▪ be reviewed and approved for technical content prior to release. | |
| ☐ **4.6.4 Approved Suppliers**<br><br>The laboratory shall :<br>▪ evaluate suppliers of critical consumables, supplies and services which affect the quality, and<br>▪ shall maintain records of investigation of suppliers and a list of all approved suppliers. | |

### 4.7 *Customer* Service

| Clause & Requirement | Comments |
|---|---|
| ☐ ***4.7.1*** **Cooperation and confidentiality**<br><br>The laboratory shall ***be willing to cooperate with customers to:***<br>▪ clarify the ***customer*** requests;<br>▪ monitor the laboratory's performance.<br><br>***In so doing, the*** laboratory ***must*** ensure confidentiality to other ***customers.***<br><br>**See CAN-P-1630[4.7.1]** | |
| ☐ ***4.7.2 Customer Feedback***<br><br>***The laboratory shall seek customer feedback, both positive and negative (e.g. client surveys).***<br><br>***The feedback shall be used and analysed to improve:***<br>▪ ***The management system;***<br>▪ ***The calibration activities;***<br>▪ ***Customer service.***<br><br>**See CAN-P-1630[4.7.2]** | |

### 4.8 Complaints

| Clause & Requirement | Comments |
|---|---|
| ☐ **4.8 Policies and Procedures**<br><br>The laboratory shall document a **policy** and **procedure** for the resolution of complaints from ***customers*** or other parties. **See CAN-P-1630[4.8]** | |
| ☐ **4.8 Records**<br><br>The laboratory shall maintain records of complaints, investigations and corrective actions taken. | |

### 4.9 Control of nonconforming calibration work

| Clause & Requirement | Comments |
|---|---|
| ☐ **4.9.1 Policies and Procedures**<br><br>The laboratory shall have and implement a **policy** and **procedures** related to work or results that do not conform to procedures or agreed ***customer*** requirements. **See CAN-P-1630[4.9.1].** The **policy** and **procedures** shall ensure:<br><br>**a)** responsibilities and authorities are designated and actions are defined and taken;<br><br>**b)** evaluation of the significance of the nonconforming work is made;<br><br>**c)** ***correction is*** taken immediately, together with any decision about the acceptability of the nonconforming work; **see CAN-P-1630[4.9.1c]**<br><br>**d)** ***customer*** is notified and work recalled, where necessary; **see CAN-P-1630[4.9.1d]**;<br><br>**e)** responsibility for authorising the resumption of work is defined. | |
| ☐ **4.9.2**<br><br>When the evaluation (4.9.1.b) indicates that the non-conformance could recur or be related to the system the corrective action procedures given in ***4.11*** shall be promptly followed. | |

### *4.10 Improvements*

| Clause & Requirement | Comments |
|---|---|
| ☐ **4.10** Continual Improvement<br><br>The laboratory shall continually improve the effectiveness of its management system using:<br>• quality policy and quality objectives,<br>• audit results,<br>• analysis of data,<br>• corrective and preventive actions,<br>• management review.<br><br>**See CAN-P-1630[4.10]** | |

## ***4.11*** Corrective action

| Clause & Requirement | Comments |
|---|---|
| ☐ ***4.11.1*** **Policies and Procedures**<br><br>The laboratory shall:<br><br>▪ document a **policy** and **procedures** and<br>▪ designate appropriate authorities for implementing corrective actions.<br><br>**See CAN-P-1630[4.11]** | |
| ☐ ***4.11.2*** **Cause Analysis**<br><br>The **procedures** shall start with an investigation and cause analysis. **See CAN-P-1630[4.11]** | |
| ☐ ***4.11.3*** **Select Implement**<br><br>The laboratory shall:<br><br>▪ identify, select and implement the action(s) most likely to eliminate the problem and to prevent recurrence;<br>▪ document and implement any required changes. | |
| ☐ ***4.11.4*** **Monitor**<br><br>The laboratory shall monitor and document actions ***for effectiveness***. | |
| ☐ ***4.11.5*** **Additional Audits**<br><br>The laboratory shall implement additional internal audits of appropriate areas, when necessary or when non-***conformities*** cast doubt on the laboratory's ***compliance with own*** policies and procedures. | |

## ***4.12*** Preventive action

| Clause & Requirement | Comments |
|---|---|
| ☐ ***4.12.1*** **Action Identification**<br><br>Needed improvements and potential sources of non-***conformities (either technical or MS)*** shall be identified. **See CAN-P-1630[4.12]** | |
| ☐ ***4.12.1*** **Action Plans**<br><br>***Once identified,*** preventive action plans shall be developed, implemented and monitored ***to reduce likely hood of occurrence.*** | |
| ☐ ***4.12.2*** **Procedure**<br><br>**Procedures** for preventive actions shall include:<br>▪ initiation of such actions and<br>▪ application of controls to ensure they are effective. | |

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## ***4.13*** Control of records
**See CAN-P-1630 and CAN-P-1628 generally applicable to this section**

| Clause & Requirement | Comments |
|---|---|
| ☐ **Procedures**<br><br>***4.13.1.1)*** The laboratory shall establish and maintain **procedures** related to control of quality and technical records for: identification; collection; indexing; access; filing; storage; maintenance; disposal. **See CAN-P-1630**[4.13.1.1]<br><br>***4.13.1.4)*** The laboratory shall have **procedures** for the protection, backup and access of electronic records. **See CAN-P-1628.** | |
| ☐ **Record Integrity**<br><br>All records shall be:<br>***4.13.1.2)*** legible; readily available; maintained in a suitable environment, **see CAN-P-1630**[4.13.1.2]**;**<br><br>***4.13.1.3)*** held secure and in confidence. | |
| ☐ ***4.13.1.2*** **Retention Times**<br><br>Retention times shall be established. **see CAN-P-1630**[4.13.1.2] | |
| ☐ ***4.13.2.1*** **Technical Records**<br><br>The laboratory shall retain technical records of:<br>▪ all original observations;<br>▪ derived data;<br>▪ sufficient information to establish an audit trail;<br>▪ calibration records of its standards and measurement equipment;<br>▪ staff records;<br>▪ copies of each calibration **certificate** issued;<br>▪ personnel responsible for calibration;<br>▪ personnel responsible for checking results. | |
| ☐ ***4.13.2.1*** **Record Information**<br><br>Records maintained shall contain sufficient information to:<br>▪ identify factors affecting uncertainty;<br>▪ enable the original method conditions to be repeated. | |
| ☐ ***4.13.2.2*** **Recording**<br><br>Observations, data and calculations shall be recorded at the time they are made and be identifiable to the specific task. | |

| Clause & Requirement | Comments |
|---|---|
| ☐ ***4.13.2.3*** **Corrections to Records**<br><br>Any changes to the original records shall be made so that:<br>▪ original record is not obscured;<br>▪ correct value entered alongside;<br>▪ alterations signed or authorised by initial by the person making the correction. | |
| ☐ ***4.13.2.3*** **Corrections to Electronic Records**<br><br>When mistakes occur in electronic records, equivalent measures (see above) shall be taken to avoid loss or change of original data stored electronically. **See CAN-P-1628** | |

***4.14*** **Internal audits**

| Clause & Requirement | Comments |
|---|---|
| ☐ ***4.14.1*** **Requirements**<br><br>Internal audits shall be periodically conducted to verify operations comply with:<br>▪ all elements of the ***management system*** and<br>▪ requirements of ***CAN-P-4E (ISO/IEC 17025: 2005)***.<br><br>**See CAN-P-1630**[4.14] | |
| ☐ ***4.14.1*** **Procedure**<br><br>The laboratory shall ensure that audits follow a predetermined:<br>▪ **schedule** and<br>▪ **procedure.**<br><br>**See CAN-P-1630**[4.14.1] | |
| ☐ ***4.14.1*** **Requirements**<br><br>The laboratory shall ensure that:<br>▪ The internal audit programme shall address all the elements of the ***management system*** including the calibration activities;<br>▪ audits are **planned** and organised by the Quality Manager;<br>▪ audits are conducted by trained and qualified personnel, independent of the activity to be audited where resources permit. | |
| ☐ ***4.14.2*** **Corrective Action**<br><br>The laboratory shall ensure that corrective actions are implemented; the ***customer*** is notified in writing of compromised results. | |
| ☐ ***4.14.3*** **Records**<br><br>The laboratory shall ensure that records of audits and corrective actions are maintained. | |

| Clause & Requirement | Comments |
|---|---|
| ☐ ***4.14.4*** **Requirement**<br><br>The laboratory shall ensure that follow-up audit activities verify and record the implementation and effectiveness of corrective actions. | |

## ***4.15.*** Management reviews

| Clause & Requirement | Comments |
|---|---|
| ☐ ***4.15.1*** **Objectives**<br><br>The laboratory's ***top*** management shall periodically carry out a review of the ***management system*** and calibration activities, based on predetermined **schedule** and **procedure**, to ensure continuing suitability and effectiveness and to introduce necessary changes or improvements. **See CAN-P-1630**[4.15] | |
| ☐ ***4.15.1*** **Contents**<br><br>The management review shall take account of:<br><br>▪ suitability of policies and procedures;<br>▪ reports from managerial and supervisory personnel;<br>▪ outcome of recent internal audits;<br>▪ corrective and preventive actions;<br>▪ assessments by external bodies;<br>▪ results of interlaboratory comparisons or proficiency tests;<br>▪ changes in the volume and type of the work;<br>▪ ***customer*** feedback;<br>▪ complaints;<br>▪ ***recommendations for improvement***<br>▪ other relevant factors (e.g., quality control activities, resources and staff training). | |
| ☐ ***4.15.2*** **Actions Taken**<br><br>The management shall ensure that actions are carried out within an appropriate and agreed timescale. | |
| ☐ ***4.15.2*** **Records**<br><br>The laboratory shall maintain records of findings from management reviews and actions taken. | |

## 5 Technical requirements
**See CAN-P-1630[5] Generally applicable to section 5**

### 5.1 General
This section does not contain any requirements

### 5.2 Personnel

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.2.1 Qualifications**<br><br>Personnel performing specific tasks shall be qualified on the basis of education, training, experience and/or demonstrated skills, as required. **See CAN-P-1630[5.2&5.2.1]** | |
| ☐ **5.2.1 Trainees**<br><br>Staff being trained shall have adequate supervision. **See CAN-P-1630** | |
| ☐ **5.2.2 Training Program**<br><br>The laboratory management shall formulate the goals with respect to the education, training and skills of the laboratory personnel. | |
| ☐ **5.2.2 Procedures**<br><br>The laboratories shall have a **policy** and **procedures** for:<br>▪ identifying training needs and<br>▪ provision of training.<br><br>The training programme shall be relevant to the present and anticipated tasks of the laboratory.<br><br>***The effectiveness of the training actions taken shall be evaluated***.<br><br>**See CAN-P-1630[5.2.2]** | |
| ☐ **5.2.3 Employees**<br><br>Personnel shall be employed or contracted by the laboratory. Contracted personnel and additional technical and key support personnel shall be supervised, competent and work in accordance with the ***management system***. | |
| ☐ **5.2.4 Job Description**<br><br>The laboratory shall maintain current job descriptions for managerial, technical and key support staff. **See CAN-P-1630[5.2.4]** | |
| ☐ **5.2.5 Authorised Personnel**<br><br>Management shall authorize specific personnel to:<br>▪ perform specific calibration activities;<br>▪ issue calibration certificates;<br>▪ give opinions and interpretations; | |

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.2.5 Records**<br><br>The laboratory shall maintain records for all technical personnel (including contracted personnel) for:<br>▪ relevant authorisation(s), and date confirmed;<br>▪ competence, and date confirmed;<br>▪ educational and professional qualifications;<br>▪ training, skills and experience.<br><br>This information shall be readily available. | |

**5.3 Accommodation and environmental conditions**

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.3.1 Technical Requirements**<br><br>The technical requirements for accommodation and environmental conditions that can affect the results shall be documented. | |
| ☐ **5.3.1 Facility**<br><br>The laboratory shall ensure that:<br>▪ accommodation be such as to facilitate correct calibration;<br>▪ environmental conditions do not invalidate the results or adversely affect the required quality of results.<br><br>Particular care shall be taken when calibrations are undertaken on-site. | |
| ☐ **5.3.2 Monitoring**<br><br>The laboratory shall monitor, control and record environmental conditions, where applicable. | |
| ☐ **5.3.2 Termination**<br><br>Calibrations shall be terminated when results are jeopardised by the environmental conditions. | |
| ☐ **5.3.3 Incompatible Activities**<br><br>There shall be effective separation between areas of incompatibility activity. | |
| ☐ **5.3.4 Access**<br><br>Access to and use of areas affecting the quality of calibrations shall be controlled by the laboratory. | |
| ☐ **5.3.5 Housekeeping**<br><br>▪ Housekeeping measures shall be adequate.<br>▪ Special **procedures** shall be prepared where necessary.<br><br>**See CAN-P-1630[5.3.5]** | |

## 5.4 Calibration methods and method validation

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.4.1 Methods and Procedures**<br><br>The laboratory shall use appropriate methods and procedures for calibrations within its scope, including handling, transport, storage and preparation of items to be calibrated and, where appropriate, an estimation of uncertainty and statistical techniques for analysis of data. **See CAN-P-1630**[5.4.1] | |
| ☐ **5.4.1 Equipment Instructions**<br><br>The laboratory shall have instructions for the use and operation of equipment, where the absence of the instructions could jeopardize the results.<br><br>All instructions, standards, manuals, and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel. | |
| ☐ **5.4.1 Method Deviations**<br><br>Deviations from calibration methods shall be:<br>▪ documented;<br>▪ technically justified;<br>▪ authorised and,<br>▪ accepted by ***customer***.<br><br>**See CAN-P-1630**[5.4.1#2] | |
| ☐ **5.4.2 Method Selection**<br><br>The laboratory shall use calibration methods that:<br><br>▪ meet the needs of the ***customer***;<br>▪ and are appropriate for the calibration;<br>▪ where appropriate, are published in or based on the latest international, regional or national standards.<br>▪ when necessary, are supplemented with additional details to ensure consistent application. | |
| ☐ **5.4.2 Non-*Customer* Specified Method Selection**<br><br>For non-***customer*** specified methods, the laboratory shall inform the ***customer*** of the method chosen, and select methods that are either:<br>▪ published reference methods;<br>▪ or laboratory developed methods validated and appropriate for the intended use;<br>▪ or methods adopted by the laboratory validated and appropriate for the intended use.<br><br>**See CAN-P-1630**[5.4.2] | |

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.4.2 Confirmation**<br><br>The laboratory shall confirm that it can properly operate standard methods before introducing the calibrations and shall repeat the confirmation, if the standard method changes. **See CAN-P-1630**[5.4.2#2] | |
| ☐ **5.4.2 Inappropriate Methods**<br><br>The laboratory shall inform the ***customer*** if the method proposed by the ***customer*** is inappropriate or out of date. **See CAN-P-1630** | |
| ☐ **5.4.3 Laboratory Developed Methods**<br><br>The laboratory-developed methods shall be **planned**, and shall be assigned to qualified personnel equipped with adequate resources. Plans shall be updated and effective communications amongst all personnel involved shall be ensured. **See CAN-P-1630**[5.4.3] | |
| ☐ **5.4.4 Non-standard Methods**<br><br>When methods are used that are not covered by standard methods, these methods shall:<br>▪ be subject to the ***customer's*** agreement;<br>▪ include clear specifications of the ***customer's*** requirements;<br>▪ include the purpose of the calibration;<br>▪ be validated appropriately before use. | |
| ☐ **5.4.5.2 Requirement Method Validation**<br><br>The laboratory shall validate:<br>▪ non-standard methods,<br>▪ lab-developed methods<br>▪ standard method used outside their intended use,<br>▪ amplifications and modifications of standard methods.<br><br>The method validation shall include:<br>▪ records of results obtained;<br>▪ **procedure** used;<br>▪ a statement that the method is fit for the intended use.<br><br>**See CAN-P-1630**[5.4.5.2] | |
| ☐ **5.4.5.3 Range and Accuracy**<br><br>The laboratory shall ensure the range and accuracy of the values obtained from validated methods are relevant to the ***customers'*** needs. | |
| ☐ **5.4.6.1 Uncertainty of Measurement**<br><br>Laboratory shall have a **procedure** to estimate the uncertainty of measurement for all calibrations and types of calibrations. **See CLAS Requirements Documents 3 and 5**[5.4.6.1] | |

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.4.6.2 & 5.4.6.3 Requirement Uncertainty of Measurement**<br><br>Laboratory **shall:**<br>▪ attempt to identify all important components of uncertainty and make a reasonable estimation;<br>▪ ensure that the form of reporting of the result does not give a wrong impression of the uncertainty;<br>▪ utilize appropriate methods of analysis.<br><br>**See CAN-P-1630[5.4.6.2] and CLAS Requirements Document 5** | |
| ☐ **5.4.7.1 Calculations and Data Transfers**<br><br>Calculations and data transfers shall be checked in a systematic manner | |
| ☐ 5.4.7.2 **Computers or Automated Equipment**<br><br>When computers or automated equipment are used, the laboratory shall ensure that:<br><br>**a)**<br>▪ user-developed software is sufficiently documented and suitably validated;<br>▪ computers and automated equipment are maintained to ensure proper functioning;<br><br>**c)** appropriate environmental and operating conditions are provided.<br><br>**See CAN-P-1628 and CAN-P-1630[5.4.7]** | |
| ☐ **5.4.7.2 b) & 5.10.7 Procedures Protection of Data**<br><br>When computers or automated equipment are used **Procedures** for protection of data shall be established and include:<br>▪ integrity and confidentiality of data entry or collection;<br>▪ storage;<br>▪ transmission;<br>▪ processing.<br><br>**See CAN-P-1628[5.4.7]** | |

## 5.5 Equipment

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.5.1 to 5.5.4 Operation**<br><br>All equipment (including that outside the laboratory's permanent control) required for the calibration shall be:<br><br>**5.5.1)** available and functioning properly; capable of achieving required accuracy; compliant with specifications;<br><br>**5.5.2)** checked and calibrated before being placed into service and before use;<br><br>**5.5.3)** operated by authorised personnel; operated using readily available current instructions on use and maintenance of equipment;<br><br>**5.5.4)** uniquely identified, where practicable. **See CLAS Requirements Document 4[5.5.4].**<br><br>**See CAN-P-1630[5.5.1]** | |
| ☐ **5.5.5 Records**<br><br>Records of equipment shall be maintained and include:<br><br>**a)** identity of the equipment and its software;<br><br>**b)** manufacturer's name, model, and serial number or other unique identification;<br><br>**c)** checks that the equipment complies with the laboratory requirement and standard specification;<br><br>**d)** current location, where appropriate;<br><br>**e)** the manufacturer's instructions, if available, or reference to their location;<br><br>**f)** calibration history and due date of next calibration;<br><br>**g)** the maintenance **plan**, where appropriate, and maintenance carried out to date;<br><br>**h)** any damage, malfunction, modification or repair to the equipment. | |
| ☐ **Procedures**<br><br>**Procedures** for the management of measuring equipment shall be established and shall include:<br><br>**5.5.6)** safe handling; transport; storage; use; **planned** maintenance;<br><br>**5.5.10)** intermediate calibration checks to ensure that equipment continues to perform satisfactorily;<br><br>**5.5.11)** Updating of copies (e.g. in computer software) where calibrations give rise to correction factors. | |

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.5.7 Out-of-Service**<br><br>Equipment subjected to overloading or mishandling, giving suspect results, or shown to be defective or outside of specified limits shall be taken out-of-service, and shall be:<br><br>▪ isolated or clearly labelled or marked as being out-of-service;<br>▪ examined for the effect of the defect or departure from specified limits on previous calibrations;<br>▪ addressed under the "Control of nonconforming work" procedure (see 4.9).<br><br>**See CAN-P-1630[5.5.7]** | |
| ☐ **5.5.8 Calibration Status**<br><br>Where **practicable** equipment requiring calibration shall be identified to indicate the status of calibration including date of last calibration and date or expiration criteria. | |
| ☐ **5.5.9 Return to Service**<br>If equipment goes outside the direct control of the laboratory, it shall ensure that the function and calibration status are checked and shown to be satisfactory before being returned to service. **See CAN-P-1630[5.5.9]** | |
| ☐ **5.5.12 Adjustments**<br><br>Calibration equipment, including both hardware and software, shall be safeguarded from adjustments that would invalidate results. | |

**5.6 Measurement traceability**

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.6.1 & 5.6.2 & 5.6.3 Calibration Program**<br><br>The laboratory shall have a calibration **programme** and **procedure** for all its measurement equipment and reference standards having significant effect on the accuracy or validity of the result. **CLAS Requirements Document 9[5.6.1].** | |
| ☐ **5.6.2.1**<br><br>The calibration **programme** shall ensure the measurements from the laboratory meet the traceability requirements of **CLAS Requirements Document 9**. | |

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.6.2.1.1 & 5.6.2.2.1 Traceability**<br><br>When using external calibration services, the laboratory shall ensure:<br>▪ certificates contain the measurement results;<br>▪ certificates include the measurement uncertainty and/or compliance statement.<br><br>**See CLAS Requirements Document 9** | |
| ☐ **5.6.3.1 Requirement Reference Standards**<br><br>Reference standards **shall:**<br>▪ be used for calibration only and for no other purpose<br>▪ be calibrated before and after any adjustment.<br><br>**See CAN-P-1630[5.6.3.1]** | |
| ☐ **5.6.3.3 Intermediary Checks**<br><br>The laboratory shall have defined **procedures** and **schedules** to conduct intermediary checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards; reference materials.<br>**See CLAS Requirements Document 3[5.6.3.3].** | |
| ☐ **5.6.3.4 Transport & Storage**<br><br>The laboratory shall have procedures for safe handling, transport, storage, and use of reference standards to prevent contamination or deterioration and protect their integrity. | |

**5.7 Sampling**

This section is not applicable to calibration laboratories that calibrate every item received. **See CAN-P-1630[5.7]**

**5.8 Handling of calibration items**

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.8.1 Procedures**<br><br>The laboratory shall have **procedures** for calibration item management. Procedures shall address: transportation; receipt; handling; protection; storage; retention and/or disposal; and other provisions necessary to protect the integrity of the item and the interests of the laboratory and the ***customer***. | |
| ☐ **5.8.2 Sample Identification**<br><br>The laboratory **shall**: have a system for identifying calibration items; ensure the retention of the identification throughout the life of the item.<br><br>The system **shall** be designed and operated so as to ensure that: items cannot be confused physically or when referred to in records or other documents; if appropriate, it can accommodate a sub-division of groups of items and the transfer of items within and from the laboratory. | |

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.8.3 Deficiencies**<br><br>Any abnormalities and deficiencies upon item receipt shall be recorded; if in doubt about suitability of item, ***customer*** shall be consulted for further instructions; This discussion shall be recorded. | |
| ☐ **5.8.4 Procedures Handling and Preparation**<br><br>The laboratory shall have **procedures** for: storage, handling, and preparation of the calibration items. | |
| ☐ **5.8.4 Facilities & Environmental Conditions**<br><br>The laboratory shall:<br>▪ have appropriate facilities to avoid deterioration, loss or damage to the calibration items;<br>▪ follow handling instructions provided with the item;<br>▪ have arrangements for storage and security of secured items or portions of items concerned.<br><br>When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded, as appropriate. | |

**5.9 Assuring the quality of results**
**See CAN-P-1630 Generally applicable to section 5.9**

| Clause & Requirement | Comments |
|---|---|
| ☐ ***5.9.1*** **Quality Control**<br><br>The laboratory shall have quality control **procedures** for monitoring the validity of calibrations undertaken. ***See CLAS Requirements Document 3 and CAN-P-1630***[5.9.1]<br><br>This monitoring shall be **planned** and reviewed. The planned quality control data shall be reviewed, recorded to detect trends, and, where practicable, statistical techniques shall be applied to the reviewing.<br><br>The quality control activities may include, but not be limited to:<br>***a)*** regular use of CRM and/or internal quality control using secondary RM;<br>***b)*** participation in ILC or PT programmes (***See CLAS Requirements Document 7***[5.9.1#2]);<br>***c)*** replicate calibrations using the same or different methods;<br>***d)*** recalibration of retained items;<br>***e)*** correlation of results for different characteristics of an item. | |
| ☐ ***5.9.2 Analysis***<br><br>***Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. See CAN-P-1630***[5.9.2] | |

| Clause & Requirement | Comments |
|---|---|
| ☐ ***5.9.1*** **Additional Requirements from CAN-P-1630**<br><br>Assessors to verify that the laboratory:<br>▪ is aware that SCC recognizes PT providers<br>▪ is aware of any calibration PT providers listed in the CAN-P-1630 section 5.9;<br>▪ participates in one such activity every four years per field of calibration or more frequently where readily available.<br>▪ has records of searches for PT providers where none were found;<br>▪ has initiated corrective action for reported outliers or marginal results.<br><br>Review all PT/ILC or Round-robins in support of section ***5.9.1***. Outliers have been investigated. | |

**5.10 Reporting the results**
***See CAN-P-1630[5.10] Generally applicable to section 5 and 5.10 as well as CAN-P-1628 and CAN-P-1570 and CLAS Requirements Document 6***

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.10.1 General Reporting Requirements**<br><br>All results shall be: reported accurately, clearly, unambiguously and objectively in accordance with any specific instructions in the calibration methods. | |
| ☐ **5.10.1 Reported Information**<br><br>The results **shall** include:<br><br>▪ all the information requested by the customer;<br>▪ all the information necessary for the interpretation of the test or calibration results;<br>▪ all information required by the method used. | |
| ☐ **5.10.1 Simplified Reporting**<br><br>Any excluded information (i.e. for internal customers or in the case of a written agreement with the customers) **shall** be readily available in the laboratory records. | |

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.10.2 & 5.10.4 Calibration Certificates**<br><br>**5.10.2** Calibration certificates shall contain (**See CAN-P-1630[5.10.2])**:<br>a) a title;<br>b) name and address of laboratory (**See CAN-P-1630[5.10.2b]**); and location where tests or calibrations carried out, if different;<br>c) the unique report I.D. on each page (**See CAN-P-1630[5.10.2c]**);<br>d) name and address of customer (**See CAN-P-1630[5.10.2d]**);<br>e) identification of method used;<br>f) unambiguous item identification, description and condition;<br>g) date of item receipt, where critical to validity; and date calibration carried out.<br>h) reference to sampling plan and procedures used, where relevant;<br>i) test and/or calibration result, with units;<br>j) name(s), function(s) and signature(s) or equivalent identification of person(s) authorising the report or certificate (**See CAN-P-1630[5.10.2j]**);<br>k) statement to the effect that the results relate only to the items tested or calibrated, where relevant;<br><br>**5.10.4** and where necessary for the interpretation of results:<br>a) calibration conditions;<br>b) uncertainty of measurement and/or statement of compliance with an identified metrological specification or clause;<br>c) measurement traceability evidence.<br><br>**See CAN-P-1630[5.10.4]** | |
| ☐ **5.10.6 Results obtained from subcontractors**<br><br>The subcontractor shall report the results in writing or electronically. Subcontracted results shall be clearly identified (in the report). **See CAN-P-1630[5.10.6]** | |
| ☐ **5.10.8 Format of reports and certificates**<br><br>The format shall be designed to accommodate each type of calibration carried out and to minimize the possibility of misunderstanding or misuse. | |
| ☐ **5.10.4.2 Calibration certificate and compliance Data Records**<br><br>The calibration certificate shall relate only to quantities and results of functional tests.<br><br>The laboratory shall maintain records of measurement results and associated uncertainties, when these items are omitted from the reported statement of compliance. | |

| Clause & Requirement | Comments |
|---|---|
| ☐ **5.10.4.2 Statement of Compliance**<br><br>When statement of compliance with a specification is made, this shall identify clauses met or not met.<br><br>Uncertainty of measurement shall be accounted for (e.g., by guardbanding) when statements of compliance are made.<br><br>**See CAN-P-1630[5.10.4.2]** | |
| ☐ **5.10.4.3 Repairs and Adjustments**<br><br>Calibration results before and after adjustments/repairs shall be reported, if available. | |
| ☐ **5.10.4.4 Calibration Intervals**<br><br>Calibration certificates or labels shall not contain any recommendation on calibration intervals unless requested by the ***customer*** or legally regulated. **See CAN-P-1630[5.10.4.4]** | |
| ☐ **5.10.5 Opinions and Interpretations**<br><br>When opinions and interpretations are included, the laboratory shall document the basis upon which opinions and interpretations have been made. **See CAN-P-1630[5.10.5]** | |
| ☐ **5.10.7 Electronic transmission of results**<br><br>The requirements of ***CAN-P4E (ISO/IEC 17025: 2005)*** shall be met (see 5.4.7). | |
| ☐ **5.10.9 Amendments**<br><br>Issue, as necessary, amendments to calibration certificates that:<br>▪ reference the original;<br>▪ are identified as supplemental;<br>▪ meet calibration certificate requirements of ***CAN-P-4E (ISO/IEC 17025: 2005).***<br><br>When it is necessary to issue a complete new certificate, this shall be uniquely identified and shall contain a reference to the original. | |

| Date: | Lab: | Assessor: | 330007-9108- SCC File# |
|---|---|---|---|

## REFERENCES

CLAS Requirements Document 3 *Minimum Requirements for Measurement Standards for Laboratory Certification*

CLAS Requirements Document 4 *Requirements for Identifying Measurement Equipment and its Calibration Status*

CLAS Requirements Document 5 *General Requirements for Evaluating and Expressing the Uncertainty of Measurement Results*

CLAS Requirements Document 6 *Requirements for Calibration Certificates Issued by CLAS Laboratories*

CLAS Requirements Document 7 *CLAS Requirements for Proficiency Testing*

CLAS Requirements Document 9 *Requirements for Measurement Traceability*

CAN-P-1570 *PALCAN Handbook*

CAN-P-1628 *PALCAN Policy on the Use of Information Technology in Accredited Laboratories*

CAN-P-1630 *PALCAN Interpretations for Conducting Assessments of Testing and Calibration Laboratories*

## INTERPRETATIVE NOTES

**These are abridged notes taken from the applicable *CLAS Requirements Documents* and from PALCAN guidance documents. Please see the complete referenced documents for details. In case of disagreement between this document and the complete ones, the latter will prevail.**

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4.1.1 The assessor can request documentation on laboratory incorporation, registration as a company, or designation as part of a public entity. "Legally identifiable" = "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." The apparent intent is to ensure control over the status of accreditation. There must be clear boundaries of personnel and floor space. A suggested test for the assessment team is to determine whether or not the corporate boundaries of the proposed accreditation are clear and distinguishable. See CAN-P-1630[ 4.1.1 and Annex C] for full details.

4.1.2 CAN-P-1631 gives requirements for the use of accreditation body logos and claims of accreditation status. It's taken verbatim from ILAC G14:2004. Laboratories also must abide by the conditions of the CLAS Trademark License Agreement and also CAN-P-1570 Section 13 and Appendix E for the SCC trademark license agreement.

4.1.4 This applies only to laboratories that are part of a larger organization. Real, apparent, and "potential" conflicts must be considered. See CAN-P-1630 for full details.

4.1.5a Mobile laboratories and "one man shows" are eligible for CLAS certification and SCC accreditation but their management systems must be clear that services aren't provided in the absence of a designated person or position. See CAN-P-1630 for full details.

4.1.5b There should be signed conflict of interest statements that address BOTH internal and external conflicts. If not, or if only external conflicts are addressed, then the lab must demonstrate how it ensures that these requirements are met; e.g., by a separate laboratory policy, code of ethics, employment contract, and arrangements and authorities for relieving undue internal pressure from, for example, excessive workloads. See CAN-P-1630 for full details.

4.1.5c These may include confidentiality agreements and employment contracts. Refer to CAN-P-1628 re. use of information technology in accredited labs.

4.1.5e Org chart(s) with the reporting relationship to any parent organization or ownership should normally be sufficient presentation of the organization and management structure of the lab.

4.1.5h This should address the provision of necessary recources 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. CLAS requires the identity of the Quality Manager and the Technical Management.

4.1.5i This should address the provision of necessary recources 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. CLAS requires the identity of the Quality Manager and the Technical Management.

4.1.5j At least one deputy for each key role must be pre-designated to accommodate unforeseen emergencies.

4.1.6 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.

4.2.1 CLAS does not retain controlled copies of the laboratory Quality Manual (QM). However, CLAS is to be kept informed of significant changes to a laboratory's MS. The laboratory will need a procedure that ensures CLAS is promptly advised of any change that could affect its accredited status.

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) must be documented, preferably in the QM, and if not, the QM must include a reference to the appropriate document.

4.2.2b 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&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 or calibration activities are usually referred to as methods or more specifically as test methods or calibration procedures.

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 calibrations. When different procedures or techniques are used for non-accredited calibrations, the laboratory must also document and demonstrate how the staff conducting the calibrations can differentiate between accredited and non-accredited calibrations in the laboratory. This is especially important when using the SCC and/or CLAS trademarks or an accreditation statement on calibration certificates and when subcontracting calibrations that are accredited or when the report also contains non- accredited calibration results.

4.3.2.1 The document master lists are considered documents and are therefore subject to the ISO/IEC 17025 requirements for document control. The document master list must be readily available. Calibration procedures and any other technical documents used to provide the accredited service must also be controlled and covered on an appropriate document master list.

4.3.2.3 All documents in the management system (including Quality Manual, policy, process, procedures, instructions, and forms) must have 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
4.4.1 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, instructions 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.

4.5.1&4 When a laboratory never performs a test/calibration, it cannot be granted accreditation for that test/measurement [TG LABS 11/89.3]. 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. 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” calibrations are outside the scope of the accreditation. 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 onsite 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.

4.5.2-3 SCC and CLAS have 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. 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 subcontracting 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. Examples of activities and work that are not considered sub-contracting: 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 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. 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. When a laboratory is "subcontracting" an accredited test/calibration (for what ever reason) to another laboratory that is part of the same legal entity and is accredited SCC or an SCC recognized body for the specific test 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.

4.6 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. Accredited calibration laboratories must in addition comply with the requirements of CLAS Document 9 - Requirements for Measurement Traceability (available at http://inms-ienm.nrccnrc. gc.ca/clas/refrence_documents_e.html). 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.

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 or other active means of inquiry. The requirement for analysis will provide a critical element of management review. The surveys or inquiries should be meaningful in covering the activities of the laboratory. This requirement properly implemented will provide a source for continual improvements of the MS.

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.

4.9.1 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: 1)- stop using the balance : define who is responsible for the monitoring of the calibration schedule; 2) check other balances to determine calibration status; isolate any other past due balances; 3) calibrate any balances past due; it is recommended to perform calibration as received and after adjustment (if adjustments are needed); 4) review results of calibration; 5) if balances were within calibration, there is no need to recall work; 6) 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; 7) evaluate the significance to determine if this is potentially repetitive or related to a potential problem with own procedures; 8) 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. The following would fall under corrective actions, 4.11: 1) 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); 2) determine the most likely cause or causes; 3) decide if any actions are needed to eliminate the causes; 4) undertake any action necessary to eliminate these causes and to prevent such a mistake from reoccurring again; 5) do the necessary follow-up; 6) monitor for effectiveness; 7) close out the corrective action. 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.

4.9.1c 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).

4.9.1d It is necessary to inform the customer only if non-conforming work has a "significant influence" and affected the test/measurement result.

4.10 A new requirement for ISO/IEC 17025: 2005. Laboratories will need to demonstrate continual improvement.

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.

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4.12 This refers to identification of "needed" improvements and the prevention of "potential" nonconformities. 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 nonconformities 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). 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). Items that can be considered to assess this point include: 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. 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 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 that 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.

4.13.1.1 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: MS files (CAR, PAR, IA and MR); Calibration/equipment files; Personnel training/qualification files; Customer files (reports and raw data). Where the identification, collection, indexing…is done differently this generally (but not always) requires multiple procedures.

4.13.1.2 SCC & CLAS do not state a minimum retention time. Raw data must be in a permanent medium (no pencil). When forms are used to records raw data, the lab must have a procedure to prevent the loss or alteration of the data and ensure that all necessary measurements in a series are conducted (e.g., bound forms, sequentially numbered, folders containing all the materials related to one project)

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4.14 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. 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 .
4.14.1 Assessment 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. 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.

4.15 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. 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. 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. 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.

5 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: http://www.scc.ca/en/programs/lab/index.shtml. For the PSA of calibration, the program-specific requirements are found on the CLAS website. They are called CLAS Requirements Documents.

5.2&5.2.1 For one man shows or mobile laboratories, see note under 4.1.5. (APLAC Common Assessor Training Course 2000-04-10 to 14). Section 5.2 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. As part of the assessment process, laboratories are required to demonstrate their competence and the assessment team is required to evaluate the competence. 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. 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. ILAC guidance to clause 5.2.1 (G.5.2.1): 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.

5.2.2 All training should be documented, including in-house training provided by the laboratory. The new requirement of ISO/IEC 17025: 2005 requires an evaluation of the effectiveness. There must be evidence of post training follow up evaluation.

5.2.4 Job descriptions must be dated and preferably signed, to demonstrate that each incumbent has read it and is in agreement.

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).

5.4.1 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. 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.

5.4.1#2 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.
5.4.2 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 are accepted by the assessors. Additional deviations/modifications may require an application for scope extension.

5.4.2#2 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.

5.4.3 In-house procedures must be formally documented and submitted for review by the assessment team. It is important to note that by accrediting such procedures, SCC and CLAS are not validating them.

5.4.5.2 Repeatability data can be used to support validation of a calibration procedure but cannot, on its own, be considered a complete validation of the procedure. Such data demonstrates only the ability to produce consistent results, whether correct or not. In addition, the laboratory requires data that demonstrates the ability to provide correct results.

5.4.6.1 For calibrations, refer to CLAS Requirements Document 5 - Evaluating and Expressing Uncertainty of Measurements. 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.nrccnrc. gc.ca/clas/refrence_documents_e.html

5.4.6.2 This applies to measurements done by outside suppliers and also measurements done in-house by the laboratory itself. Refer to CLAS Requirements Document 5 and also EA-4/02 guidance document published by the European Cooperation for Accreditation.

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. 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. 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). The validation test plan should also include robustness to ensure that the software responds as expected when invalid inputs are provided.

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.

5.5.4 For calibration laboratories, see CLAS Requirements Document 4 - Requirements for Identifying Measurement Equipment and its Calibration Status available at http://inms-ienm.nrccnrc. gc.ca/clas/refrence_documents_e.html for identifying calibration equipment and standards.

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: 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. 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. 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. 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. 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.

5.5.7 It is not mandatory that defective equipment be stored in a specific place if it is well marked and there is no danger of inadvertent use.

5.5.9 The "function and calibration status" implies the verification that the device is operating within stated 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).

5.6.1 For additional guidance refer to ILAC P10 – ILAC Policy on Traceability of Measurement Results and ILAC G2 – Traceability of Measurements both available at http://www.ilac.org/

5.6.3.1 Reference standards shall be calibrated before and after any adjustments in order to be able to provide the lab with the necessary data to evaluate any potential effect on items calibrated with this reference.

5.6.3.3 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.nrccnrc. gc.ca/clas/refrence_documents_e.html .

5.7 Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing of a representative sample of the whole.

5.9.1 Assessment teams 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. 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) 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). For calibration laboratories, CLAS Requirements Document 7 - CLAS Requirements for Proficiency Testing applies. Quality control of the measurement processes is an important requirement for calibration laboratories. See CLAS Requirements Document 3 - Minimum Requirements for Measurement Standards for Laboratory Certification for minimum quality control requirements for different types of calibration services. Document 3 is available at http://inms-ienm.nrccnrc. gc.ca/clas/refrence_documents_e.html . See CAN-P-1630 for additional information on proficiency testing and interlaboratory comparison and PT providers.

5.9.1#2 Proficiency testing to satisfy the requirements of CAN-P-4 (ISO/IEC 17025) is carried out by the Calibration Laboratory Assessment Service (CLAS) using a formal proficiency testing process. The process is designed to verify the measurement capabilities of applicant and CLAS-certified laboratories. Each quantity in the laboratory's scope is subject to one or more of the following proficiency testing techniques, unless decided otherwise by the CLAS program; e.g., the required resources are not available, or the proficiency test would not be conclusive. Verification of each quantity is normally performed when a laboratory is first assessed and subsequently once per assessment cycle. If the performance of the laboratory is called into question, additional proficiency testing may be performed using these techniques. This is consistent with the frequency requirements published in APLAC MR001 "Procedures for Establishing and Maintaining Mutual Recognition Arrangements amongst Accreditation Bodies". This document is available at http://www.aplac.org . CLAS requirements for proficiency testing follow the general guidelines published in ILAC G22 "Use of Proficiency Testing as a Tool for Accreditation in Testing". This publication is available at www.ilac.org . In addition to the proficiency activities organised by CLAS, laboratories are encouraged to seek out and to participate in proficiency testing programs offered by recognised proficiency testing providers. It remains the responsibility of applicant and CLAS-certified laboratories to verify their calibration capabilities on an on-going basis through proficiency testing to meet the requirements of CLAS and CAN-P-4 (ISO/IEC 17025). See CLAS Requirements Document 7 for more details.

5.9.2 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 reinforced. 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.

5.10 CAN-P-1628 PALCAN Policy on the Use of Information Technology in Accredited Laboratories applies when electronic mediums are used in this section. 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 . ILAC guidance to clause 5.10 (G.5.10.1): 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: "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)." 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/calibration reports/certificates.

5.10.2 The lab need not provide all this information 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.

5.10.2b The address referred to here is the laboratory's address and where applicable that of the site where the calibration was conducted when done away from the laboratory.

5.10.2c A certificate number is strongly suggested. See CLAS Document 6 regarding pagination.

5.10.2d If the calibration is done for internal purposes, it is not necessary to state the name and address of the customer.

5.10.2j 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). 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). Persons signing reports/certificates are referred to as signatories by certain Accreditation Bodies. SCC and CLAS do not keep a list of approved signatories as this is the responsibility of the laboratory to control its signatories.

5.10.4 Calibration certificates issued by CLAS laboratories must identify the measurement standards used where practicable. 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 .

5.10.6 It is necessary to identify the results that were sub-contracted; however, it is not necessary to identify the sub-contractor. This does not supercede the ISO/IEC 17025 [5.10.1] requirement for calibration certificates to include all the information requested by the customer.

5.10.4.2 Based upon ILAC guidance to clause 5.10.4.2 (G.5.10.4.2.1) 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/. This requirement is especially important when the result of the measurement is indeterminate (i.e., when the measurement result, extended by the measurement uncertainty, crosses the specification limits (see CAN-P-1630 or ILAC G-8 for a graphic illustration of what's meant here). In these cases, it is impossible to determine within the stated level of confidence, whether the measurement is within the specification limits or not. 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.nrccnrc. gc.ca/clas/refrence_documents_e.html (under the discussion of guardbanding) for a description and examples of various acceptable methods for taking uncertainty into account. 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).

5.10.4.4 See CAN-P-1630[4.4.1] in regards to determining customers' needs for reporting of calibration intervals.

5.10.5 Laboratories shall not normally be accredited for the provision of interpretations and opinions except when required by regulations. When this is done, these interpretations should be clearly identified as such and separated from the results in the final report submitted to the customer.