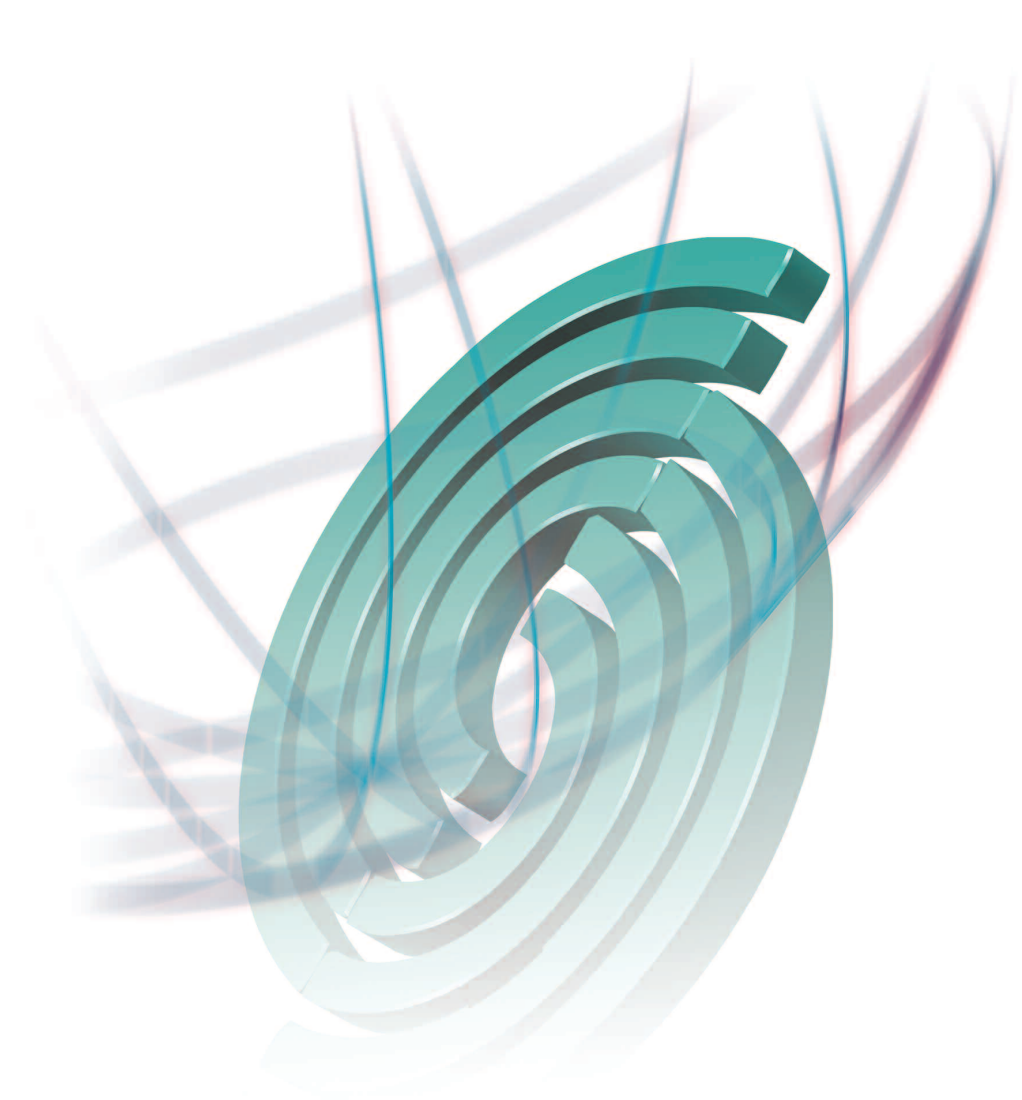

Standards Council of Canada
Conseil canadien des normes

# Requirements for the Accreditation of Testing and Calibrations Laboratories Performing On-Site Testing and Calibrations

**CAN-P-1632**
July 2010

Canada

# REQUIREMENTS FOR THE ACCREDITATION OF TESTING AND CALIBRATIONS LABORATORIES PERFORMING ON-SITE TESTING AND CALIBRATIONS

# EXIGENCES RELATIVES À L'ACCRÉDITATION DES LABORATOIRES D'ESSAIS ET D'ÉTALONNAGE PROCÉDANT À DES ESSAIS ET DES ÉTALONNAGES SUR SITE

# CAN-P-1632




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## FOREWORD

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

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

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

In addition, the Council serves as the government’s focal point for voluntary standardization and represents Canada in international standardization activities, sets out policies and procedures for the development of National Standards of Canada, and for the accreditation of standards development organizations, product and services certification bodies, testing and calibration laboratories, proficiency testing providers, management systems certification bodies, personnel certification bodies and inspection bodies. In addition SCC administers the OECD Good Laboratory Practice (GLP) initiative on behalf of Health Canada and Environment Canada. SCC promotes and supports the principle of recognition of accreditation or equivalent systems as a means of decreasing the number of multiple assessments and audits, both in Canada and with Canada’s trading partners.

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

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

## PREFACE

The Task Group Laboratories (TG Labs) is constituted by and reports to the Advisory Committee on Conformity Assessment (ACCA). The TG Labs is responsible for applications for accreditation from laboratories, assessments of applicant laboratories and reassessments of accredited laboratories and making recommendations, as required, to the ACCA and the Council.

The specific requirements for on-site testing and calibrations in the present document were developed by the TG Labs.

This document was designed to meet International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Standard 17025:2005 requirements. Rather than serving as a "stand alone" document, it was designed to harmonize with and complement the SCC document CAN-P-4E (ISO/IEC 17025:2005), "General Requirements for the Accreditation of Calibration and Testing Laboratories", which is ISO/IEC 17025:2005 verbatim, and to follow the standard SCC assessment protocol.

Accreditation by SCC requires an on-site assessment of the laboratory to demonstrate competence and conformance with the requirements of CAN-P-4E.

The scope of these requirements will be evaluated periodically to respond to customer, laboratory and accreditation requirements as well as improvements in the available science and technology or regulatory changes.

This Preface is not an integral part of this document.

## INTRODUCTION

The general requirements for the competence of testing and calibration laboratories are described in CAN-P-4E (ISO/IEC 17025:2005). These requirements are designed to apply to all types of calibration and objective testing and therefore need to be interpreted with respect to the type of calibration and testing concerned and the techniques involved. F0410E (Assessment Rating Guide) is the tool used to assess conformance to requirements in CAN-P-4E. The SCC policy documents (CAN-P-1630, CAN-P-1570, etc.) also apply.

Although ISO/IEC 17025:2005 is applicable to on-site testing or calibrations as per requirement of Section 4.1.3 of CAN-P-4E, it is recognized that additional interpretations and guidance for assessment teams are necessary to assess such capabilities.

This document provides an elaboration, interpretation and additional requirements to those requirements in CAN-P-4E that are required for laboratories involved in performing on-site testing or calibrations. It is expected that where no elaborations, interpretations or additional requirements are stipulated in this document for the elements of the standard, that the SCC PALCAN Policy documents (CAN-P-1630, CAN-P-1570, etc.) and best scientific practices in the area will guide the assessment process.

This document identifies the minimum requirements for accreditation of laboratories supplying on-site testing or calibration services.

This document does not re-state all the provisions of CAN-P-4E and laboratories are reminded of the need to comply with all of the relevant criteria detailed in CAN-P-4E and the current edition of the CAN-P-1570 “PALCAN Handbook”. The main clause numbers in this document generally follow those of CAN-P-4E, but since not all clauses require interpretation, the numbering of clauses may not be continuous. Clause 6 is unique to this document and explains how on-site accredited tests and calibrations are specifically mentioned in the laboratory’s scope of accreditation as well as the application process and the surveillance process (including reassessment activities) for these specific tests or calibrations.

Accreditation under this policy is the formal recognition by SCC of the competence of a testing or calibration laboratory to manage and perform specific on-site testing or calibrations. It is not a guarantee that test results will conform to standards or agreements between a testing laboratory and its customers. Business transactions between an accredited testing laboratory and its customers are legal matters between the two parties.

This document has been approved by the Task Group Laboratories (TG Labs) and the Advisory Committee on Conformity Assessment (ACCA) of SCC.

## GENERAL AND ADDITIONAL REQUIREMENTS

Laboratories accredited through PALCAN shall meet all requirements in the international standard CAN-P-4E (ISO/IEC 17025:2005) "General Requirements for the Competence of Testing and Calibration Laboratories" and the requirements that are defined in CAN-P-1570, "PALCAN HANDBOOK Program Requirements for Applicant and Accredited Laboratories". Conditions outlined in the PALCAN Handbook as well as the additional CAN-Ps listed in section 5.1 of CAN-P-1570 apply to all accredited laboratories. The CAN-Ps referenced in section 5.2 of CAN-P-1570 applies to the laboratories recognized for a specific Program Specialty Area (PSA).

The checklist that is used to assess the management and technical requirements of CAN-P-4E is the latest version of F0410E, "Assessment Rating Guide".

The requirements of CAN-P-15CA ("Accreditation Programs: Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings") also apply to all SCC accredited laboratories.

## 1 SCOPE

This policy applies to testing/calibrations performed outside the laboratory permanent premises, for example at a client's premises or in the field. It does not apply to other permanent facilities that a laboratory or organization may possess such as those outline in the SCC Policy on Group Accreditation (CAN-P-1570, Appendix B). When the other facility holds its own legal affiliation, it shall hold a separate accreditation with SCC.

## 2 NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CAN-P-4E (ISO/IEC 17025:2005), General Requirements for the Competence of Testing and Calibration Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-15CA, SCC Conformity Assessment Accreditation Program Requirements and Procedures for the Suspension and Withdrawal of Accreditations and the Resolution of Complaints, Disputes and Appeals. Standards Council of Canada, Ottawa, Ontario, Canada.

F0410E, Assessment Rating Guide. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1570 PALCAN Handbook, Program Requirements for Applicant and Accredited Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1623, PALCAN Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing (APLAC TC 005). Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1624, PALCAN Policy on the Use of Proficiency Testing as a Tool for Accreditation in Testing (ILAC G22:2004). Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1625, Policy on Guidelines and Procedures for Laboratories with Serious and Critical Non-Conformities. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1626, PALCAN Policy on Calibration and Measurement Traceability. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1626 Appendix A, Required Definitions for SCC Accredited Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1628, PALCAN Policy on the Use of Information Technology in Accredited Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1629, PALCAN Guidance for the Validation of Test Methods. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1630, PALCAN Interpretations for Conducting Assessments of Testing and Calibration Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1631, PALCAN Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status (ILAC G14:2000). Standards Council of Canada, Ottawa, Ontario, Canada.

CLAS Requirements Documents – refer to the CLAS website:
http://www.nrc-cnrc.gc.ca/eng/services/inms/calibration-laboratory/requirement-documents.html

(VIM) 3rd ed.:2007, International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM) (JCGM 200:2008) available on the BIPM's website (www.bipm.org/en/home/). Also issued as ISO/IEC Guide 99, First edition 2007

## 3 TERMS and DEFINITIONS

All definitions in CAN-P-4E and VIM 3rd ed. [e.g. laboratory, testing laboratory, calibration laboratory, calibration, test, calibration method, test method, verification, quality system, quality manual, reference standard, reference material, certified reference material, traceability, proficiency testing, (accreditation) requirements] and those applicable from ISO 9000 [e.g. quality assurance, quality control] apply.

The definitions below are to ensure clarity and consistency. All required definitions are reproduced

for convenience in the document CAN-P-1626 Appendix A (*"Required Definitions for SCC Accredited Laboratories"*). **Those definitions shall be employed by all testing and calibration laboratories accredited by SCC**.

**Note:** there are new or revised definitions for many terms in VIM 3rd Ed.:2007. Laboratories shall update all their Quality System documents to reflect the definitions as defined below as well as the required definitions in CAN-P-1626 Appendix A ("*Required Definitions for SCC Accredited Laboratories"*).

**On-site testing/calibration**
Testing/calibration performed by staff of an accredited testing/calibration laboratory outside of the premises or grounds on which the permanent laboratory/permanent base is located. On-site testing may include sampling when sampling is part of the documented test method.

**Mobile laboratory**
Fully equipped, self-contained, transportable testing or calibration laboratory capable of performing tests or calibrations under controlled environmental conditions and under the direct control of the accredited laboratory

**Temporary facilities**
Temporary facilities for special events (e.g. Olympic Games, world championships, etc.) are not subjected to this document and should be processed as described in SCC procedure TP92.22.

**Permanent Laboratory**
A calibration or testing laboratory erected on a fixed location. This is the laboratory location (address) denoted on the scope of accreditation. Laboratories may be accredited for on-site testing or calibration.

**On-site laboratory**
A testing or calibration laboratory facility set up in a dedicated location or at a customer's premises, outside of the organization's permanent base or headquarters for the duration of the testing or calibration activities but not for periods expected to exceed one year (e.g. a Construction Materials laboratory set up at an airport construction site, a calibration laboratory under contract set up in support of a customer's manufacturing process). All on-site laboratories must be identified on the application paperwork, be assessed as part of the permanent laboratory assessment, and may be identified on the laboratory's scope of accreditation.

## 4 MANAGEMENT REQUIREMENTS

All the requirements in section 4 of CAN-P-4E and all other relevant CAN-P series documents apply to all accredited laboratories and it extends to their on-site facilities. This section of these requirements is to be used in conjunction with the CAN-P-4E document. The intent of this section is to provide elaboration, interpretation and additional requirements to some of the clauses of CAN-P-4E which are specifically applicable to on-site testing and calibrations . Some

sub clause numbering will be unique to this section. The following section numbers correspond directly to the clauses in CAN-P-4E.

## 4.1 Organization

4.1.3 The testing/calibration activities performed on-site shall be covered by the management system. A laboratory performing on-site testing/calibration shall be permanently identified; in situations where an organization requests an accreditation for a group of laboratories performing on-site testing/calibration, each of the latter shall bear a unique permanent identification.

4.1.5

c) The laboratory shall define its organization and management structure including its on-site testing capabilities (e.g. organizational chart).

f) The laboratory shall specify the responsibilities, authorities and interrelationships of all personnel who manage, perform or verify work affecting the quality of the on-site tests/calibrations. In particular, the laboratory must clearly indicate to the SCC or its partners the level of authorization of the personnel performing on-site tests/calibrations in terms of contract review (4.4), non-conforming work (4.9) and acceptance and transmission of tests/calibration results (5.10).

The laboratory shall identify signatories, criteria for signatory approval and limits of signatory authority. These criteria should include an assessment of the following attributes:

- qualifications and experience,
- position in the overall staff structure,
- demonstrated experience with the test/calibration procedures or methods,
- demonstrated familiarity and awareness of the requirements of CAN-P-4 and SCC policies, especially requirements for control of equipment, environmental conditions, and technical records as well as requirements for results checking and reporting.

g) Any testing conducted away from the permanent laboratory (such as in on-site laboratories, in a mobile testing laboratory or in the field) must also be under adequate technical control from the permanent laboratory. An approved signatory must be involved in the setting up of an on-site laboratory.

Note: This would normally require either the location of an approved signatory at each on-site location or having an approved signatory visit each on-site location at least once each week, and the maintenance of a diary recording the dates and relevant activities of each visit.

## 4.2 Quality Manual

4.2.1 The management of a laboratory performing on-site activities shall be documented in its

quality manual or shall reference other quality documentation within the quality manual.

4.2.6 The responsibilities and authorities of the technical management and the quality manager in relation to on-site testing or calibration activities shall be defined in the quality manual.

## 4.3 Document control

4.3.1.1 The laboratory shall have procedures to describe how and when all instructions, standards, manuals and reference data relevant to the work of on-site testing/calibration activities are kept up to date and made readily available to personnel performing on-site work.

4.3.2.1.1 A specific control list for all documents necessary to properly perform on-site testing/calibration activities shall be kept up-to-date by the laboratory's permanent location.

4.3.2.2e The procedure(s) adopted shall ensure that authorized editions of appropriate documents are available to staff where on-site testing/calibration is performed, including management system documents, test/calibration procedures, forms, etc.

Note: see also CAN-P-1630 interpretative note.

## 4.4 Review of Requests, Tenders and Contracts

4.4.1 Procedures for review of Requests, Tenders and Contracts shall cover review of request for on-site testing/calibrations. Records of review of requests, tenders and contracts shall identify the details on the on-site activities such as the location where testing/calibration will be performed, the personnel who will be performing the testing/calibration on-site. When applicable, for testing laboratories, the records shall include requirements on equipment needed for the testing when it is borrowed equipment that belongs to the client (see 5.5.1).

4.4.1.1 The permanent laboratory shall receive written consent for performing on-site tests from the owner of the test site before commencing any work at that site.

4.4.2 Records of pertinent discussions with the clients while on-site shall be maintained.

4.4.4 When deviations from the contract occur during on-site testing/calibration, records that customers have been advised shall be maintained. (see 5.4.1)

4.4.5 If a contract needs to be amended after work has commenced on-site, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

## 4.6 Purchasing services and supplies

4.6.1 Supplies and reagents and consumables materials used for on-site testing/calibration that affect the quality of tests/calibration shall be selected and purchased by the laboratory performing on-site testing/calibration activities.

If supplies that affect the quality of the tests are received in a permanent laboratory and transported to the field, measures need to be in place to ensure these supplies are not compromised by transit to the on-site or storage under various environmental conditions.

## 4.7 Customer service

4.7.1 In situations where the customer needs to have access to the site where testing/calibration activities are performed, the laboratory staff shall ensure that all applicable regulatory requirements are complied with as well as any specific customer site safety requirements.

4.7.2 Customers both positive and negative comments obtained on-site shall be part of customer feedback.

## 4.9 Control of Non-conforming testing and/or calibration work

4.9.1 The laboratory shall document and apply a policy and procedures when any aspects of the on-site testing/calibration, or the results of the work, do not conform to its own procedures or the agreed requirements of the customer.

4.9.1.1 The responsibilities and authorities of the personnel performing on-site testing/calibration shall be clearly documented in the laboratory procedures when non-conforming work is identified. The authority for authorizing resumption of work shall also be clearly documented in the procedure.

## 4.10 Improvement

The laboratory shall continually improve the effectiveness of its management system using customers comments obtained on-site.

## 4.13 Control of Records

4.13.1.1 The procedures for control of on-site records shall cover the identification, collection, indexing, access, filing, storage, maintenance, disposal, security and transportation of all technical records, especially original observations, generated on-site.

4.13.1.5 When records obtained on-site are kept electronically, the laboratory shall have procedures to protect and back-up those records and to prevent unauthorized access to or amendment of these records until they are stored at the permanent laboratory.

4.13.1.6 Laboratory on-site generated records shall be paginated using a page numbering system

which indicates the total number of pages.

4.13.2.1 The laboratory shall have documented procedures to ensure that it maintains a coordinated record keeping system for all its records generated on-site and the integration of those records into the laboratories permanent records. The records required to support the technical data shall be such that in the absence of the personnel who performed the on-site testing/calibration, another competent personnel could competently evaluate what had been performed and interpret the data. Records shall include the identity of the personnel responsible for sampling, and carrying out test/calibration on-site and checking the results.

The records for each on-site test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. Environmental conditions, such as temperature, humidity and other environmental factors shall be recorded appropriately (see 5.3).

The results obtained from the on-site test(s)/calibration(s) shall be subject to review as indicated in the accredited testing laboratories policies and procedures.

4.13.2.2 Procedures shall exist for recording and reporting all results obtained at the on-site location at the time they are made.

4.13.2.4 All records shall be traceable to the personnel performing the on-site testing/calibration and where appropriate, to the uniquely identified laboratory number (see 4.1.3). It shall be clear from the record who has performed all steps of the test/calibration and when each step of the test/calibration was performed.

4.13.2.5 All observations or test/calibration results obtained on-site shall be preserved. Records shall be made in a permanent manner and maintained so that they are not obliterated by rain, humidity, spills, leaks or other environmental factors that may affect the immediate or future readability of the records. Electronic records, photocopies, tracings or hand-drawn facsimiles shall also be preserved (e.g. tape or CD/DVD backup of electronic files).

### 4.14 Internal Audits

4.14.1 Every part of the laboratory's quality system shall be audited annually including a representative sampling of test/calibration methods applied on-site.

4.14.1.1 The designated internal auditor shall visit on-site and mobile laboratories as part of the internal audit process.

4.14.1.1 The internal audit programme shall address all elements of the management system, including the testing and/or calibration activities performed on-site, including in mobile

laboratory to assess whether the on-site tests and/or calibrations continue to comply with the requirements of the management system.

### 4.15 Management Reviews

4.15.1 Management reviews shall be conducted at least annually and shall include a review of on-site testing/calibration activities and customer's comments obtained on-site.

## 5 TECHNICAL REQUIREMENTS

All the requirements in section 5 of CAN-P-4E and all other relevant CAN-P series documents apply to all accredited laboratories. This section of these requirements is to be used in conjunction with the CAN-P-4E document. The intent of this section is to provide elaboration, interpretation and additional requirements to some clauses of CAN-P-4E for which procedures are specifically applicable to on-site testing/calibration. The following section numbers correspond directly to the clauses in CAN-P-4E. Some sub clause numbering will be unique to this section.

### 5.2 Personnel

5.2.1 The laboratory shall ensure that all staff performing on-site testing/calibration are competent to perform the work required. The term 'competent' implies demonstrating the requisite knowledge, skills and abilities to perform the specific on-site tests/calibrations at a specific on-site location. Records of competence of staff performing on-site testing/calibration shall be maintained by the laboratory and may include training records, analysis of Proficiency Testing (PT) samples, Inter Laboratory Comparisons (ILC) performed by this person or other demonstration of proficiency such as similar tests/calibrations performed in the laboratory premises.

5.2.2 The laboratory shall have policy and procedures for documenting training, retraining and maintenance of skills, expertise and demonstrated on-going competence for personnel performing on-site testing/calibration. Records shall be sufficiently detailed to provide evidence that staff performing particular tasks have been properly trained and that their subsequent ability to perform these tests/calibrations has been formally assessed. The management of the laboratory shall formulate acceptance criteria used to confirm that staff is competent to perform on-site testing/calibration.

5.2.3 On-site testing/calibration shall be performed by personnel who are employed by, or under contract to, the laboratory. Personnel that are not employed nor contracted by the laboratory shall not normally assist in the performance of the test/calibration performed on-site. In exceptional cases where personnel that are not employed nor contracted by the laboratory perform part or all of the test/calibration, they shall be supervised at all time by laboratory's trained, competent and authorized personnel to perform this specific test/calibration. The supervisor shall be employed by, or under contract to, the laboratory. Personnel that are not employed nor contracted by the laboratory shall not perform

accredited tests/calibrations, unassisted, under any circumstances.

5.2.5 A laboratory shall have clear records of the authorizations and competencies of personnel, including contracted personnel, to perform tests/calibrations performed on-site testing specific to a specific location/set up and to operate particular types of equipment at that specific on-site location. All records shall be maintained and shall include the date on which authorization and competence is confirmed.

## 5.3 Accommodation and environmental conditions

5.3.2 When on-site environmental conditions may affect the results of the test/calibration, the laboratory shall keep records of these conditions during the performance of the entire on-site test/calibration. Records shall demonstrate that accommodation and environmental conditions during the on-site testing/calibration did not invalidate the results by affecting instrument/equipment function or the test/calibration item. Records to demonstrate that the requirements of the test/calibration method were met shall be available. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations performed on-site shall be documented and available to staff performing the on-site testing/calibration.

5.3.2 Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.

5.3.3 When necessary, the laboratory shall maintain sufficient records to demonstrate effective separation between neighbouring areas (including shared facilities) in which there are incompatible activities while being on-site. Those records could be floor plans, photographs, etc.

5.3.4 Access to the operational area where on-site testing/calibration is performed shall be limited when unrestricted access could invalidate the test/calibration results and/or create risks to the health and safety of personnel or other persons.

5.3.5 Procedures shall be in place to ensure good maintenance of the on-site facility in order not to invalidate tests/calibration results, as appropriate to the technical activities concerned.

## 5.4 Test and calibration methods and method validation

5.4.6 Estimation of uncertainty of measurement

5.4.6.1 For calibration laboratories, the best measurement uncertainty of calibrations performed on-site will not be larger than the stated uncertainly at the permanent laboratory.

5.4.6.2 For testing laboratories, the best measurement uncertainty of calibrations performed on-

site will normally be larger than the stated uncertainly at the permanent laboratory.

5.4.6.2 Testing laboratories shall demonstrate implemented use of adequate procedures for estimation of the uncertainty of measurement associated with all accredited tests performed on-site. Such procedures must take into account the environmental conditions, when appropriate. When it is not possible to determine the measurement uncertainty, i.e. for qualitative tests, the laboratory shall demonstrate that the testing/calibration were performed within the defined limits of the reference test/calibration methods.

## 5.5 Equipment

5.5.1 CAN-P-1630 section 5.5.1 indicates that SCC does not normally consider granting accreditation when the laboratory is not equipped to perform the test/calibration. However, CAN-P-1630 recognizes that in specific cases where some specialized test/calibrations use equipment that is either rare or prohibitively expensive or when a specialized facility and operator are required, SCC may consider providing accreditation under specific conditions. TG Labs will review each such occurrence on a case by case basis. In those cases where the laboratory needs to use equipment other than owned by the laboratory, such as customer's borrowed equipment or rented equipment, the laboratory shall ensure that the requirements of CAN-P-4E and CAN-P-1630 are met for this equipment. The provider of borrowed or rented equipment is considered to be a supplier and the requirements of CAN-P-4E section 4.6 therefore apply.

5.5.1.1 If the laboratory has to borrow equipment it shall document that its specific personnel have the competency to operate that specific equipment. If it is critical equipment this includes the adherence to the SCC traceability policy requirements in CAN-P-1626.

5.5.1.2 The laboratory shall have its own documented procedures for the operation and calibration of all borrowed equipment.

5.5.2 Equipment and its software used for testing/calibration and sampling shall be checked and/or calibrated on-site before each use. Records of such checks and calibrations shall be kept by the laboratory, including records for borrowed and rented equipment. The laboratory must have procedures for the checking of equipment before and after on-site testing/calibration. For critical equipment, the laboratory shall maintain records supporting that the conditions of 4.13.2, all section 5.3, all sections 5.5 and 5.6.1 of CAN-P-4E, CAN-P-1626 and CLAS Requirements Documents (for accredited calibration laboratories) have been met.

5.5.4 Test/calibration records shall contain unique identification of all equipment including borrowed and rented equipment used during on-site tests/calibrations.

5.5.5 Records for all equipment, including borrowed or rented equipment, used for testing/calibrations performed on-site shall be available for SCC or its partners to review at the time of SCC or its partners visits and at any time upon request.

5.5.6 The laboratory shall have procedures for the safe handling, transport, storage, use and planned maintenance of measuring equipment owned, borrowed or rented by the laboratory and that are used for on-site testing/calibration.

The movement of equipment or instruments between sites and the impact of the changing environment upon such equipment as defined in 5.6.3.4 is a major concern that shall be addressed by the laboratory and fully documented.

5.5.6.1 A list of all equipment used during each on-site testing/calibration shall be maintained by the laboratory. This list shall indicate unique identification of equipment used and shall list the equipment that have been transported on-site, and the ones that have been borrowed or rented.

5.5.7 The laboratory must have specific procedures to ensure that the requirement of this section is also met for equipment that are not owned by the laboratory. Procedures shall ensure that the laboratory is promptly advised by the owner of the borrowed or rented equipment when such equipment has been shown to be defective or outside specified limits for example at the next calibration. The effect of the defect and departure from specified limits on previous tests/calibrations shall be examined by the laboratory and the "Control of Non-Conforming work" procedure shall be instituted (CAN-P-4E clause 4.9).

5.5.9 Requirements of CAN-P-1630 section 5.5.9 concerning equipment going outside the direct control of the laboratory applies for all equipment used for on-site testing/calibration. The laboratory shall check the function and the calibration status of all equipment used for the on-site test/calibration before the performance of the testing/calibration. Records of such checks shall be maintained. These checks shall be performed on-site before the test/calibration for equipment that is sensitive to transportation or at the permanent laboratory before and after the test/calibration when such equipment is not sensitive to transportation.

5.5.9.1 Reference materials shall be supplied by the accredited laboratory.

5.5.11 The laboratory shall ensure and provide evidence that the requirement of section 5.5.11 of CAN-P-4E is met for borrowed and rented equipment, when applicable.

## 5.6 Measurement Traceability

5.6.1 For accredited calibration laboratories, all the requirements contained in the CLAS Requirements Documents are also applicable to on-site calibrations. CLAS Requirements Documents are available on the NRC/CLAS website.

For accredited testing laboratories, SCC requirements for traceability of critical equipment used for accredited on-site testing shall be met as defined in CAN-P-1626. These requirements also apply to rented or borrowed critical equipment.

When critical equipment belongs to a third party, the laboratory shall have procedures to

ensure that it is informed when equipment used in prior tests is found to be received out-of-tolerance during the next calibration. See also 5.5.7.

5.6.3.4 When it is necessary to use reference standards for on-site activities, adequate procedures shall be implemented to ensure that the calibration status is maintained and not invalidated during the transportation, handling and storage during the on-site activities. The response of such reference standards to environmental changes or other relevant parameters shall be known and documented.

## 5.7 Sampling

5.7.3 When sampling is part of the on-site testing, records shall be maintained to demonstrate that requirements of CAN-P-4E section 5.7.3 are met.

## 5.8 Handling of Test and Calibration Items

5.8.2 The laboratory shall have a system for identifying on-site test/calibration items. The system shall ensure that items cannot be confused physically or when referred to in records or other documents.

5.8.3 The requirements of this section of CAN-P-4E apply also for on-site test/calibration items. Before the test/calibration begins, the laboratory shall record abnormalities, or departures from normal or specified conditions, as described in the test or calibration method.

5.8.4 When the items have to be stored or conditioned under specified environmental conditions, the laboratory shall provide evidence that these conditions were maintained, monitored and recorded.

## 5.9 Assuring the quality of test and calibration results

5.9.1 When quality controls, including reference materials, are needed before or during the on-site testing before the test begins, records shall be maintained that the test was under control at all times (see 5.5.9.1). Special Quality Control (QC) measures or materials, including PT requirements need to be addressed on a case by case basis and have to be consistent with any specific PSA requirements.

5.9.1b If the on-site facility is semi permanent (> 1 month) then the requirements for proficiency testing or interlaboratory comparisons apply.

## 5.10 Reporting the results

5.10.1 Transmission of interim results shall be allowed only under documented procedures.

5.10.2b The test/calibration report or certificate shall include the name and address or the

identification (see 4.1.3) of the laboratory and the location where the on-site tests/calibrations were carried out as well as any applicable environmental conditions.

# 6 APPLICATION, ASSESSMENT ACTIVITIES, SCOPE PRESENTATIONS

## 6.1 Application

For applicant laboratories

Application for accreditation is explained in the PALCAN Handbook CAN-P-1570. At the time of application, the laboratory shall identify clearly on the proposed scope which tests/calibrations are proposed to be performed on-site and for which the laboratory applies for accreditation. Also a list of equipment and personnel involved in these on-site activities needs to be submitted at the time of the application. The authorities of personnel performing on-site testing/calibration as per 4.1.5.f shall also be submitted at the time of application.

For accredited laboratories

The process is the same as scope extensions. Refer to CAN-P-1570 on how to apply for scope extensions. In their request laboratories shall identify clearly on the proposed scope which tests/calibrations are proposed to be performed on-site and for which the laboratory applies for accreditation. Also a list of equipment and personnel involved in these on-site activities needs to be submitted at the time of the application. The authorities of personnel performing on-site testing/calibration as per 4.1.5.f shall also be submitted at the time of application.

## 6.2 SCC initial assessment and subsequent reassessment

The laboratory shall ensure that personnel who are authorized to perform on-site testing/calibrations are present at some point during the SCC or its partners assessment/reassessment activities so that SCC or its partners can evaluate staff competence to perform such tests/calibrations. Also all records for equipment shall be available for review by the SCC or its partner's assessors, including records for borrowed or rented equipment, when applicable. For calibration laboratories, NRC CLAS will, at their discretion, choose one of their calibration laboratories for an on-site visit so that NRC CLAS personnel may witness a full calibration in front of their technical experts.

The assessment of the on-site activities, including the examination of the implementation of the management system on-site, will be conducted by the SCC or its partners where a test/calibration is being performed, when the examination of records and interview of personnel is not sufficient for the SCC or its partners to be confident in the laboratory competence to perform such on-site tests/calibrations.

## 6.3 Presentation of on-site activities on scope of accreditation

Scopes for laboratories accredited for some on-site testing/calibration will include a clear mark

or references to indicate which tests/calibrations are also accredited when performed on-site.

In addition, scopes of accreditation will include in the first page in the Clients served field a statement that “some tests are available on-site” or “some calibrations are performed on-site”.

For calibration laboratories, the capabilities that are also available on-site will be clearly mentioned on the NRC/CLAS certificate for example in the Notes section or in the Remarks column.

For testing laboratories, the tests that are also available on-site will be clearly identified with a special note referring to the present policy at the end of the scope of accreditation.

Note: In cases where the best on-site and the best in-laboratory uncertainties are different, both uncertainties shall be given on the scope.

### 6.4 Group accreditation

Where more than one mobile laboratory for a given organization is seeking accreditation, requirements of Appendix B of CAN-P-1570 will apply when a Group Accreditation is requested by this Organization.