Standards Council of Canada
Conseil canadien des normes

Laboratory Accreditation Program (PALCAN)

Policy on Calibration and Measurement Traceability

CAN-P-1626: 2011

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Canada

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Standards Council of Canada
270 Albert Street, Suite 200
Ottawa, ON K1P 6N7

Telephone: + 1 613 238 3222
Fax: + 1 613 569 7808
Email: info@scc.ca
Website: www.scc.ca

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Foreword

The Standards Council of Canada (SCC) is a crown corporation established by an Act of Parliament in 1970 to foster and promote efficient and effective voluntary standardization in Canada. Although financed in part by Parliamentary appropriation, SCC policies and operations are managed independently of Government. The SCC is overseen by a Board of Directors whose membership includes government and private sector representation.

With the goal of enhancing Canada's economic competitiveness and social well-being, SCC leads the efforts of Canadians in the development and use of national and international standards and offers a range of standardization-related programs and accreditation services to both standards development bodies and conformity assessment organizations.

SCC accreditation programs are accessible to all applicants from World Trade Organization (WTO) member economies, as defined by an Order in Council to the *Standards Council of Canada Act*. In accepting applications from outside Canada, SCC respects the International Accreditation Forum's (IAF) Cross Frontier Policy. Additionally, under formal agreements, SCC works in cooperation with foreign accreditation bodies to ensure the effective surveillance of accredited client activities.

SCC program policies and procedures are designed to meet the impartiality, non-discriminatory and conflict of interest requirements of ISO/IEC 17011, *Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*. Clients who believe the SCC has failed to comply with these requirements should submit an official complaint in accordance with the most recent version of CAN-P-15, available at www.scc.ca.

For more information, visit www.scc.ca.

Introduction

This Canadian Procedural (CAN-P) Document is part of series of publications issued by the Standards Council of Canada (SCC) that define the policy and operational requirements for core programs established in support of its mandate. Requests for clarification, amendments, or additional copies should be addressed to info@scc.ca.

SCC accreditation or recognition is a formal attestation of an organization's competence to manage and perform activities defined by its specific program scope. Accreditation or recognition does not function as a guarantee that the services provided by the accredited or recognized organization will satisfy the demands of its clients. Business transactions between these organizations and their clients remain legal matters between the two parties.

Please be aware of the following directives used within this document: "shall" is used to express a requirement that the user *must* satisfy in order to be in compliance with the CAN-P; "should" is used to express a recommendation, or that which is advised but not required; and "may" is used to express an optional, permissible, action that the user may undertake within the limits of this CAN-P.

A list of all SCC programs and accredited bodies, along with their scopes of accreditation, is publicly available at www.scc.ca.

1. Policy

This Policy applies to calibration and measurement traceability of critical measurement equipment as defined in ISO/IEC 17025:2005 (CAN-P-4E) *General Requirements for the competence of testing and calibration laboratories* section 5.6.1 and in section 4.6 of this document**.**

It is Standards Council of Canada Policy that:

1. the calibration of critical equipment used in the performance of the tests and capabilities listed on the Scope of Accreditation under the requirements of ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories,* section 5.6 shall be conducted by a calibration provider that is accredited for suitably small uncertainties or that can otherwise demonstrate its competence.

   The definition of critical equipment adopted by SCC is: *"equipment used by testing and calibration laboratories that is necessary to perform a test or calibration from the scope of accreditation and which has a significant effect on the uncertainty of measurement of test or calibration results"*.

2. laboratories shall maintain records of the calibration providers used for all critical equipment.

3. laboratories shall take a proactive approach towards complying with these requirements.

4. SCC recognizes the competence of calibration providers for the specific calibration and measurement capabilities listed in the Scope of Accreditation issued by SCC or an Accreditation Body recognized by SCC. Further SCC recognizes the specific calibration and measurement capabilities of National Metrology Institutes (NMI) that are signatory to the Comité International des Poids et Mesures Mutual Recognition Arrangement (CIPM MRA) as listed in the following link: http://www1.bipm.org/utils/en/pdf/signatories.pdf.

5. SCC will allow the use of non-recognized calibration providers only under special circumstances, with additional requirements to be met during the assessment to demonstrate the calibration provider's competence.

6. calibration and measurement capabilities that are not recognized shall be competently assessed to demonstrate competence of the calibration provider and traceability as required in the ISO/IEC 17025 Standard.

7. the laboratory shall demonstrate the competence of the calibration provider

8. SCC may include qualified members on the assessment team to evaluate these competences and the records that support them.

9. where it can be established that the associated contribution from calibration yields less than 1/3rd to the uncertainty of the final test result the equipment can be considered non-critical and hence this traceability policy as it relates to critical equipment does not apply.

10. all the terms and definitions in section 4 as well as the determination of measurement uncertainty on test results and its statement on calibration certificates or test reports outlined in section 5.4 applies to all SCC applicant and accredited testing and calibration laboratories.

2. Objectives

The Standards Council of Canada (SCC), as a Member of International Laboratory Accreditation Cooperation (ILAC), adheres to the general ILAC Policy on Traceability of Measurement Results as outlined in section 2 of ILAC P10:2002. This state's *"Laboratories accredited by ILAC Member Bodies shall be able to demonstrate that calibration of critical equipment, and hence the measurement results generated by that equipment, relevant to their scopes of accreditation, are traceable to the International System of Units (SI units). This generally means traceability to the SI units, where possible, to a relevant primary standard through a demonstrated and competent unbroken chain of comparisons Where such traceability is not technically possible or reasonable, the laboratory and the client and other interested parties may agree to using certified reference materials provided by a competent supplier or using specified methods and/or consensus standards that are clearly described and agreed by all parties concerned; (See: Notes 1and 2)."*

Measurements shall meet the requirements of metrological traceability as defined in the *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM 3rd Ed).

Hence, the objectives of this SCC policy on calibration and measurement traceability are as follows:

2.1 To identify and provide means to identify acceptable calibration providers for critical equipment for Applicant and Accredited laboratories seeking or maintaining accreditation in accordance with CAN-P-4 (ISO/IEC 17025) General requirements for the competence of testing and calibration laboratories.

2.2 To provide requirements where a recognized calibration provider does not exist for the required calibrations for critical equipment.

2.3 To specify how laboratories shall document and demonstrate the competence of calibration and measurement capabilities.

2.4 To provide laboratories, Team Leaders and Technical Assessors with guidance to assess the selection of calibration providers for critical equipment and to highlight the documentation requirements.

2.5 To:

a) highlight, for all testing and calibration laboratories accredited by SCC, the required definitions of Metrological Traceability (VIM 3rd Ed.), and other important related definitions for critical equipment, calibration provider and in-house calibration (refer section 4),

b) highlight, for all testing and calibration laboratories accredited by SCC, the requirements for the determination of measurement uncertainty and its statement on calibration certificates or test reports,

c) facilitate the identification of recognized calibration providers, such as calibration laboratories assessed by the National Research Council of Canada's Calibration Laboratory Assessment Service (NRC-CLAS) and accredited by the SCC and those accredited by Accreditation Bodies signatory to mutual recognition arrangements, to which the SCC is a signatory and NMIs that are signatory to the CIPM MRA,

d) facilitate the selection of a calibration provider and the documentation requirements to meet this SCC policy,

e) ensure alignment with the ILAC Policy on Traceability of Measurement Results (ILAC P 10).

NOTE 1: The ILAC Policy on Traceability of Measurement Results from ILAC P 10:2002, section 2 (e) states: "Laboratories holding only management systems certification will be deemed to have not demonstrated the necessary technical competence". In the context of this policy and North American terminology, Quality Systems Registration to the ISO 9000 series will be deemed to not have demonstrated the necessary technical competence.

NOTE 2: The ILAC P10 document uses a definition of traceability that comes from ILAC G2:1994 and VIM2:1994. ILAC is currently reviewing ILAC P10 and it is expected that the revised document will be aligned with definitions from VIM 3rd Ed.

NOTE 3: Citation of a NIST Test Number by the calibration service provider is not acceptable evidence of verification of traceability of measurement results (National Conference of Standards Laboratories-International Position Statement 96-1).

3. Scope

3.1 This policy applies to all SCC ISO/IEC 17025 applicants and accredited laboratories. Laboratories accredited for calibration are also subject to the Policies of NRC-CLAS.

3.2 This policy document establishes acceptable means of demonstrating the competence of calibration providers.

3.3 This policy applies to initial calibration and recalibration of all critical equipment.

3.4 Due to the nature of some tests, it is not possible, realistic or relevant to expect traceability of measurement results to be demonstrated. The ILAC Policy on Traceability of Measurement Results (ILAC P10:2002, section 2 (a) Note 1) states: it is recognized by ILAC that, due to the nature of some tests, it is not possible, realistic or relevant to expect traceability of measurement results to be demonstrated.

4. Terms and Definitions

All definitions in ISO/IEC 17000 and VIM 3rd Ed. shall apply.

Note:
There are new or revised definitions for many terms in VIM 3rd Ed. Laboratories should update all their Quality System documents to reflect these revised definitions.

4.1 Critical equipment

As referenced in ISO/IEC 17025:2005 section 5.6.1, the definition for "critical" equipment in ILAC-P10:2002 *ILAC Policy on Traceability of Measurement Results* is: “Critical equipment used by testing and calibration laboratories is considered by ILAC to be those items of equipment necessary to perform a test or calibration from the scope of accreditation **AND** which have a significant effect on the uncertainty of measurement of test or calibration results.”

Hence the definition of critical equipment adopted by SCC is:

Critical equipment

equipment used by testing and calibration laboratories that is necessary to perform a test or calibration from the scope of accreditation and which has a significant effect on the uncertainty of measurement of test or calibration results.

4.2 Calibration Providers

Recognized Calibration Provider

laboratory that is ISO/IEC 17025 accredited by an Accreditation Body Signatory to the ILAC/APLAC Mutual Recognition Arrangements (MRA) or IAAC Multilateral Recognition Arrangement (MLA) or a NMI signatory to the CIPM MRA Refer to CAN-P-1570 – Laboratory Accreditation Program (PALCAN) Handbook, section 1.5.

Non-Recognized Calibration Provider

all providers other than those identified above.

4.3 In-House Calibration

In-House Calibration

calibration of critical equipment conducted by a laboratory

- for its own use within the laboratory itself, or;
- for other accredited elements within its own organization

Note:
"In-house calibration" should not be defined in Quality System documents as to be confused with:

- verification of calibrated critical equipment prior to use, such as calibrated balances
- routine calibration of equipment prior to use as defined in ISO/IEC 17025:2005 section 5.6 for the calibration of gas chromatographs and other such analytical instrumentation. This is generally defined as calibration or internal calibration.

5. Calibration and Measurement Traceability

5.1 Requirements for recognized calibration providers

Calibration laboratories that are accredited by an Accreditation Body, signatory to a regional or international recognition arrangement or National Metrology Institutes that are signatories to the CIPM Mutual Recognition Arrangement are recognized calibration providers. The capabilities are for specific measurands, ranges and uncertainties that are recognized.

The section that follows describes in detail those recognition arrangements to which SCC is a signatory and how to locate the NMIs that are signatories to the CIPM MRA.

5.2 Recognized calibration providers for critical equipment

5.1.1 Calibration laboratories accredited under the SCC LAP (PALCAN) program in cooperation with the NRC-CLAS for listed measurement capabilities. These laboratories form the Canadian Calibration Network (CCN), a directory can be found on both the SCC and NRC web-sites;

5.1.2 Calibration laboratories accredited by accreditation body's signatory to a regional or international arrangement (MRA or MLA) to which SCC is also a signatory. Under these arrangements between laboratory accreditation organizations, each organization recognizes the equivalence of accreditations performed by the signatories and promotes the acceptance of the calibration results within its own economy. Hence, SCC recognizes the following:

a) The International Laboratory Accreditation Cooperation (ILAC) http://www.ilac.org/ilacarrangement.html - Select "ILAC Arrangement Signatories"

NOTE 1: The foregoing evaluate Regional Cooperation Bodies and Accreditation Bodies (ABs) against the requirements of ISO/IEC 17011 Conformity Assessment - General requirements for accreditation bodies accrediting conformity assessment bodies

b) The Asia Pacific Laboratory Accreditation Cooperation (APLAC) http://www.aplac.org/membership_by_category.html

NOTE 1: The foregoing evaluate Accreditation Bodies (ABs) against the requirements of ISO/IEC 17011 Conformity Assessment - General requirements for accreditation bodies accrediting conformity assessment bodies

c) The Inter-American Accreditation Cooperation (IAAC) http://www.iaac.org.mx

NOTE 1: The foregoing evaluate Accreditation Bodies (ABs) against the requirements of ISO/IEC 17011 Conformity Assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.

5.1.3 National metrology institutes signatory to the Comité international des poids et mesures (CIPM) Mutual Recognition Arrangement with calibration services listed in the following link: http://www.bipm.org/ Select "MRA, JCRB and key comparison data base", "BIPM key comparison database (KCDB), "Appendix C", "Select parameter(s)", "Select country"

NOTE 1: the Comité international des poids et mesures (CIPM) operates a Consultative Committee on Amount of Substance. This group is very active in the realisation and implementation of a structured international chemical measurement system. Canada is represented on this Committee by NRC, as is the case with the physical measurement Consultative Committees.

NOTE 2: the three North American National Metrology Institutes, signatory to the CIPM MRA, are:

- Canada - The Institute for National Measurement Standards/National Research Council of Canada (NRC); http://inms-ienm.nrc-cnrc.gc.ca
- United States of America - National Institute for Standards and Technology (NIST) http://www.nist.gov
- Republic of Mexico - Centro Nacional de Metrología (CENAM) http://www.cenam.mx/

5.3 General information concerning non critical equipment

According to clause 2.3 of APLAC TC005 in CAN-P-1623 *PALCAN Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing*, "The laboratory should identify all significant components of uncertainty for each test. One component with an uncertainty of less than 1/5 to 1/3 of the total test

uncertainty will not usually have much impact on the total measurement uncertainty." However, several of these may be significant and cannot be ignored.

It is Standard Council of Canada Policy that, for testing laboratories, where it can be established that the associated contribution from calibration yields less than 1/3rd to the uncertainty of the final test result the equipment can be considered non-critical and hence this traceability policy as it relates to critical equipment need not be applied. This can be demonstrated by calculating the Measurement Uncertainty (MU) for the calibration and comparing it with the overall MU for the test result or with the relevant specification for accuracy for the instrument as defined in the test method, whichever is applicable.

5.4 Determination and Statement of Measurement Uncertainty

A critical element of the concept of measurement traceability is measurement uncertainty.

It is SCC policy that laboratories calculate measurement uncertainty using adequate procedures consistent with the “Guide to the Expression of Uncertainty in Measurement” (GUM) and its’ supplemental documents and/or ISO Guide 35, where applicable, for estimation of the uncertainty of measurement associated with all accredited calibrations and where measurement uncertainty analysis is applicable, for accredited tests.

Irrespective of the type of testing, testing laboratories shall identify and control the significant components of measurement uncertainty.

For quantitative tests, numerical estimates are expected for those tests which produce numerical results. At a minimum, this shall include the calculations for standard uncertainty (μ), combined standard uncertainty (μ_c) and expanded uncertainty (U) (normally at a coverage factor of k=2).

The definitions for standard uncertainty (μ), combined standard uncertainty (μ_c) and expanded uncertainty (U) shall be those defined in VIM 3rd Ed.

Accredited calibration laboratories shall report the uncertainty of measurement in compliance with sections 6.2 to 6.5 of the ILAC Policy for the Uncertainty in Calibration (ILAC P14:2010)

The measurement result and the associated uncertainty shall be reported and the uncertainty statement must be accompanied by an explanation of the meaning of the uncertainty statement. An example of such an explanation might be the statement “*The measured result for [name of measurand] is xxx “units” ± yyy “units”. The reported uncertainty is expanded using a coverage factor k=2 for a level of confidence of approximately 95%, assuming a normal distribution”.* Statements of uncertainty which do not specify at least the coverage factor and the confidence level are incomplete and they are inadequate for the purpose of demonstrating that measurement traceability has been achieved.

The numerical value of the expanded uncertainty shall be given to, at most, two significant figures and the numerical value of the measurement results shall

rounded to a consistent number of significant figures. Rounding rules used shall be in compliance with the guidance provided in the GUM section 7.

Reported uncertainties shall be estimated in the same manner as the laboratories Calibration Measurement Capability (CMC), except that the characteristics of the "best" device are replaced with those of the device under test.

Accredited calibration laboratories shall not report a smaller uncertainty than the CMC listed on their scope of accreditation.

6. Selection of a Calibration Provider and Documentation Requirements

The process of selecting a calibration provider or for conducting in-house calibrations for critical equipment is outlined in the sections below.

The specific minimum documentation requirements a laboratory shall maintain for all providers of calibration used are detailed in the sections that follow.

6.1 Requirements for using a Recognized Calibration Provider

Recognized calibration providers are defined in section 4 and section 5:

6.1.1 Laboratory shall specify the service required in accordance with ISO/IEC 17025:2005 section 4.6 which includes measurand(s), range(s) and associated uncertainty values.

6.1.2 Laboratory shall verify the calibration certificate complies with ISO/IEC 17025:2005 section 5.10.

Note: examples of verifying calibration certificates include, a website database, documenting accreditation and scope of the calibration laboratory.

6.2 Requirements for using an Non-Recognized Calibration Provider where a Recognized Calibration Provider does not exist

Where a recognized calibration provider does not exist, the requirements of this section apply. The laboratory shall not have to assess the competence of the non-recognized calibration provider; however, the laboratory shall document and retain documentation on the capabilities of the non-recognized calibration provider. The non-recognized calibration provider shall meet the competence requirements outlined in Annex A.

6.2.1 Laboratory shall specify service required in accordance with ISO/IEC 17025:2005 section 4.6, to include measure(s), range(s) and associated uncertainty values.

6.2.2 Laboratory shall specify content of calibration certificate in accordance with ISO/IEC 17025:2005 section 5.10.

6.2.3 Laboratory shall retain the following additional records:

- records of search for recognized calibration providers at the time the calibration took place;
- calibration capability of external non-recognized calibration provider, documented using the checklist format in Annex A;
- traceability of standards used by the external non-recognized calibration provider;
- calibration procedures used by the external non-recognized calibration provider: published methods or in-house procedure;
- validation for in-house procedures where published methods exist.

6.3 Requirements for performing Non-Recognized In-House Calibrations

Where a laboratory performs its own non-recognized in-house calibrations on its critical equipment, the laboratory shall demonstrate a level of competence equivalent to the competence of available recognized calibration providers for the calibration required. The laboratory shall meet the competence requirements outlined in Annex A.

The laboratory records shall support and demonstrate the full extent of the competence of the in-house non-recognized calibration provider and the assessment of that provider.

6.3.1 Laboratory shall be assessed and required to meet the applicable requirements of ISO/IEC 17025 for the calibrations conducted;

6.3.2 Abridged reporting of calibration results is acceptable as long as the conditions of ISO/IEC 17025:2005 sections 5.10.1 and 4.13.2.1 are maintained;

Note: A full report shall be produced if the calibration results are to be used in another laboratory, such as in another site (e.g. calibration laboratory/laboratories which perform calibrations within the organization).

6.3.3 Laboratory conducting in-house calibrations shall retain the following additional records for proof of:

- In-House capability, using the checklist format in Annex A;
- measurand(s), range(s) and associated uncertainty values;
- adequacy of environment conditions for calibration;
- demonstrated technical competence of laboratory personnel conducting the calibration;
- demonstrated metrological traceability of all standards;
- demonstrated metrological traceability for measurand(s), range(s) and reported uncertainties;
- calibration procedures used by the laboratory: published methods or non-standard/modified procedure;
- procedures for evaluating measurement uncertainty;

- validation of uncertainty provided;
- validation for non-standard/modified procedures where published methods exist;
- Proficiency Testing participation records to support reported result(s) and uncertainty.

6.3.4 SCC shall assess the competence of the laboratory to conduct in-house calibrations including, but not limited to:

- competence of personnel conducting the calibrations;
- traceability of standards;
- records of measurements and environmental conditions;
- procedures for evaluating measurement uncertainty.

6.3.5 SCC may include, as needed, additional team member(s) to verify competence of the laboratory to conduct in-house calibrations. This can include both on-site and offsite assessments or a combination thereof. Additional costs may apply. Specialist calibration assessors will only be used when either calibration is outside the area of expertise of the technical assessors who would normally conduct the assessment or reassessment or if it will be more time or cost effective.

7. References and Bibliography

This policy considered the following in its development:

a) CAN-P-4E (ISO/IEC 17025:2005), *General requirements for the competence of testing and calibration laboratories.*
b) 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
c) CAN-P-1570, *Laboratory Accreditation Program (PALCAN) Handbook*
d) CAN-P-1623, *PALCAN Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing (APLAC TC005)*
e) ISO/IEC Guide 98-3, *Uncertainty of Measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*
f) ISO Guide 35, *Reference materials — General and statistical principles for certification*
g) ILAC P10:2002, *ILAC Policy on Traceability of Measurement Results*
h) ISO/IEC 17000:2004, *Conformity Assessment – Vocabulary and General Principles*
i) ILAC P14:2010, *ILAC Policy on Uncertainty in Calibration*

8. Contact for Calibration and Measurement Traceability

Applicant or accredited laboratories with questions or concerns on matters regarding calibration or measurement traceability should contact the SCC Client Manager responsible for their file.

Standards Council of Canada
200-270 Albert Street,
OTTAWA, ON K1P 6N7

Tel: +1 613 238 3222
Fax: +1 613 569 7808
E-mail: info@scc.ca, or the Internet address of the Client Manager responsible for the applicant or accredited laboratory file.

Annex A: Checklist for the Assessment of the Calibration and Traceability of Critical Equipment

(NORMATIVE)

Checklist for the Assessment of the Calibration and Traceability of Critical Equipment

(Cautionary note: only positive answers may not be sufficient to demonstrate compliance with this policy).

1 General Remarks

All the requirements outlined in sections 6.1 to 6.4 above apply, whether they are identified in this list or not.

The assessor (either laboratory or SCC technical assessor) for measuring equipment shall have sufficient knowledge and expertise in the fields of metrology and calibration.

Determine if the equipment is critical before proceeding.

2 Appropriate Calibration of Measuring Equipment

2.1 Is an appropriate calibration prescribed for all measuring instruments:

- appropriate with respect to the measurement uncertainty of the measuring equipment?
- appropriate with respect to the influence of the measured quantity on the test result?

2.2 Is an appropriate functional test determined for such measuring instruments which are based on natural constants (e.g. defined wave lengths)?

3 Calibration Provider

3.1 Is the calibration carried out by a recognized external body generally responsible for calibrations or by a body accredited for that purpose?

3.1.1 By a National Metrology Institute?

3.1.2 By a recognized accredited calibration provider?

If the answer is yes, then all the requirements of CAN-P-1626 section 6.1 apply and no further action is required.

3.2 Is the calibration carried out internally or externally by a laboratory not falling into the categories mentioned in 3.1.1 or 3.1.2:

3.2.1 By a competent external non-recognized calibration provider?

3.2.2 By a competent internal body of the institute or company operating the test laboratory?

3.2.3 By a technically competent staff group or single person in the test laboratory?

3.2.4 By the user of the measuring equipment himself?

If the answer is yes, then all the requirements of section 6.2 or 6.3 or 6.4 and the sections below apply.

The sections below only applicable if the answer is yes for one of the questions of 3.2

4 Calibration Facilities

4.1 Are internal certified reference standards, reference standards and, if appropriate, working standards, available for all measuring and test instruments and measurand(s) and range(s) which are relevant for the measurement and test results?

4.2 Are the standards, directly or indirectly, in any case by an unbroken chain and documented by certificates, linked to national standards and labelled accordingly for each measurand and range by a calibration label?

4.3 Are all instruments being part of the calibration equipment properly identified?

4.4 Is each calibration described in a calibration method or procedure, (e.g. by switching diagrams or flow charts)?

4.5 Is the calibration procedure described step by step?

4.6 Are defined environmental conditions ensured during calibrations?

4.7 Are there adequate environmental conditions for the calibrations?

4.8 Are relevant environmental conditions recorded during calibrations?

4.9 Are procedures for the calculation of the measurement uncertainty of the calibration equipment specified and are they followed?

4.10 Are recalibration intervals fixed in accordance with the intended use and the properties of the equipment and are there programmes for regular recalibrations?

5 Specified Calibration Procedures

5.1 Is the measuring equipment of a “self-calibration” type?

5.1.1 Is the internal reference calibrated?

5.1.2 Is the process of “self-calibration” checked?

5.2 Does the measuring equipment include an internal calibration of a less stable component by means of an internal reference?

5.2.1 Is the internal reference calibrated?

5.2.2 Is the procedure of internal calibration checked?

5.2.3 Is the internal calibration performed regularly, (e.g. before each use of the measuring equipment)?

5.3 Is the complete measuring system calibrated as a whole?

5.3.1 Are the single components of the measuring system adjusted, especially with respect to zero setting?

5.3.2 How the labelling is performed for a complete measuring system?

5.4 Is each single component of a measuring system calibrated?

5.4.1 Are the calibration parameters for the complete measuring system determined from the values of the single components?

5.5 What is done in the case of disposable measuring devices which cannot be calibrated individually (e.g. strain gauge transducers)?

5.5.1 Are samples calibrated? Is continuous sample testing practiced?

5.5.2 Which body is performing sample testing?

5.5.3 Does the body according to 5.5.2 fulfill the requirements of ISO/IEC 17025 respectively?

5.5.4 Is the body accredited according to ISO/IEC 17025?

5.6 Are certified reference materials or reference materials used for the calibration?

5.6.1 Are the reference materials certified?

5.6.2 Are the measurement uncertainties stated on the certificates?

5.7 Are the calibrations computer-aided?

5.7.1 Is the software validated?

5.7.2 By which method?

6 Responsibilities for the Administrative Aspects of Calibration of Measuring Equipment

6.1 Is each user of measuring equipment aware that he/she is himself/herself responsible for the calibration status of the measuring equipment?

6.2 Can each user demonstrate their technical competency to calibrate the specific equipment?

6.3 Is each new measuring equipment calibrated before use?

6.4 Are those measuring instruments of which the validity period is expired brought to recalibration by a confirmation system?

6.5 Are there regulations concerning the responsibility for the internal reference standards, for their traceable calibration and for the working standards?

6.6 Are there regulations concerning the responsibility for the reliability of calibration software?

7 Documentation

7.1 Are there records of the search for recognized and non-recognized calibration providers at the time the calibration took place?

7.2 Are the technical competencies of laboratory personnel conducting the assessment of the external non-recognized calibration provider documented? Are they appropriate?

7.3 Are the demonstrated technical competencies of laboratory personnel conducting in-house calibrations documented? Are they appropriate?

7.4 Are the calibration methods documented? Are they appropriate?

7.5 Are non-standard/modified calibration methods documented and validated? Are they appropriate?

7.6 Is there documentation for the adequacy of the environmental conditions? Are they appropriate?

7.7 Is there documentation for the traceability of all standards? Is the stated traceability appropriate?

7.8 Is there documentation for metrological traceability for the measurand(s) and range(s)?

7.9 Is the observance of fixed recalibration intervals supervised?

7.10 In the case where calibrations have to be performed before each measurement, are these cases clearly identified? Are the measuring instruments labeled accordingly?

7.11 Are the results of calibrations - including environmental conditions, if applicable – documented and filed? Are they available to the user of the measuring instrument?

7.12 Is a calibration label used as a visible indication of an established confirmation system for the measuring equipment?

7.13 Are controls for calibration and adjustment sealed which should not be affected by the user?

7.14 Are there procedures for the evaluation and determination of measurement uncertainty? Does it meet the requirements required in section 5.4?

7.15 Is there documentation for the validation of the measurement uncertainty values obtained? Are the stated measurement uncertainty values appropriate?

7.16 Are the calibration results and the associated measurement uncertainties documented?

7.17 Are there proficiency testing participation records, where applicable, to support the uncertainty provided?

- End of Annex A -

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270 Albert Street, Suite 200, Ottawa, ON K1P 6N7 Canada
Tel: + 1 613 238 3222 Fax: + 1 613 569 7808 info@scc.ca www.scc.ca