ACCREDITATION SERVICES

SCC Requirements and Guidance for the Accreditation of Testing Laboratories (RG-Lab)

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Standards Council of Canada

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Table of Contents

Preface

Accreditation of a testing laboratory by Standards Council of Canada (SCC) is the formal recognition of the competence of a laboratory to perform specific tests or types of tests recognized and listed by SCC.

To become accredited, laboratories must meet the general requirements in the international standard, ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. This will be verified by the Standards Council's accreditation process. Laboratories must demonstrate competence to perform the specific test or types of tests for which they wish to become accredited. In addition, there are a number of Program Specialty Areas (PSA) addressing specific requirements for specialties such as Environmental, Agriculture and Food Products, Forensic, Mineral Analysis, etc.

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

The accreditation procedures of SCC conform to the requirements of the International Laboratory Accreditation Cooperation (ILAC) and others detailed in the Accreditation Services Program Overview Annex F.

Supplementary information regarding the program is available on the SCC website, www.scc.ca.

1. Scope

This document contains normative and informative guidance for laboratories accredited to ISO/IEC 17025:2017 by the Standards Council of Canada. Laboratories and assessment teams alike must use this document to assure compliance.

This document covers all accredited testing laboratories. Program Specialty Areas (PSAs) often have additional Requirements and Guidance, such as:

- Forensics – *SCC Requirements and Guidance for the Accreditation for Forensic Testing Laboratories*
- Mineral Analysis – *SCC Requirements and Guidance for the Accreditation of Mineral Analysis Testing Laboratories*
- ITSET – *SCC Requirements and Guidance for the Accreditation of Information Technology Security - Evaluation and Testing Facilities*
- TMDNRT – *SCC Requirements and Guidance for Accreditation of Laboratories Engaged in Test Method Development and Non-Routine Testing*

In creating this document, SCC did not restate or clarify requirements of the Standard that are deemed sufficiently clear. In cases where the intent of clauses was deemed less than obvious, guidance was provided to explain SCC's approach to interpreting the clause.

As a general guidance, laboratories should interpret each requirement in the Standard ("shall" statement) in such a way that the evidence of meeting that requirement is required. In most cases the guidance column provides examples of such evidence. That does not mean other evidence would not be considered.

Laboratories are encouraged to carefully consider the guidance section in conjunction with the corresponding clauses of the Standard. This will help in better understanding and ensure conformance against the requirements of the standard.

Note that this document does apply to calibration laboratories. For supplemental requirements and guidance on calibration labs, please contact the National Research Council – Calibration Laboratory Assessment Service (NRC-CLAS) at nrc.canada.ca.

2. Normative References

- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17000 Conformity assessment - Vocabulary and general principles
- ISO 9000 Quality Management Systems – Fundamentals and Vocabulary
- SCC Requirements and Guidance for Method Validation in Testing Laboratories
- SCC Guidance for The Presentation of Laboratory Scopes of Accreditation
- SCC Requirements & Guidance – Proficiency Testing for Laboratories (Testing and Medical)
- SCC Accreditation Services Program Overview
- SCC Requirements and Guidance for the Accreditation of Information Technology Security - Evaluation and Testing Facilities
- ILAC P10 ILAC Policy on Metrological Traceability of Measurement Results
- ILAC P14 ILAC Policy on Uncertainty in Calibration
- ILAC G8 Guidelines on Decision Rules and Statement of Conformity
- ILAC G24 Guidelines for the determination of calibration intervals of measuring instruments
- ILAC R7, Rules for the use of ILAC MRA Mark
- NCSL RP-1, Establishment & Adjustment of Calibration Intervals, 2010 edition, 2010.
- Guide to the Expression of Uncertainty in Measurement (GUM), Joint Committee for Guides in Metrology (JCGM), 2008

- Eurachem/CITAC Guide, Use of uncertainty information in compliance assessment, 1st edition, 2007
- International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM) (3rd edition; JCGM 200:2012)
- ISO Guide 35:2017, Reference materials – Guidance for characterization and assessment of homogeneity and stability.

3. Terms and Definitions

The following definitions apply to the interpretation of ISO/IEC 17025 and are based on ISO 9000. The definitions of VIM also apply.

Policy: A policy is an operational pillar of an organization from which actions and procedures follow. As such, it must state the overall direction of the organization regarding the subject activity and it must be clearly identified as a policy.

Procedure: A procedure must specify a way to perform an activity and must usually contain the purpose and scope of the activity, what shall be done and by whom, when, where and how it shall be done. The procedure must also address what materials, equipment and documents shall be used and how it shall be controlled and recorded. Where this Standard requires a procedure, SCC expects such procedure to be documented.

Process: A set of interrelated or interacting activities that use inputs to deliver an intended result.

Conformity: Fulfillment of a specified requirement.

International vocabulary of basic and general terms in metrology (VIM): In general, a vocabulary is a “terminological dictionary which contains designations and definitions from one or more specific subject fields” (ISO 1087-1:2019 3.7.5). The present Vocabulary pertains to metrology, the “science of measurement and its application”. It also covers the basic principles governing quantities and units.

Nonconformity: Non-fulfillment of a specified requirement (ISO 9000)

Verification: A provision of objective evidence that a given item fulfils specified requirements. (VIM JCGM 200:2012)

Validation: A verification, where the specified requirements are adequate for an intended use. Refer to the SCC Requirements and Guidance for Method Validation in Testing Laboratories. (VIM JCGM 200:2012)

Objective evidence: Information that can be proved true based on facts obtained through observation, measurement, testing or other means.

Quality Assurance: All the planned and systematic activities that are used to fulfill the requirements for quality.

Management review: A process that requires top management to review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

Record: A document stating results achieved or providing evidence of activities performed.

Corrective Action: An action taken to eliminate the causes of an existing nonconformity, defect or undesirable situation in order to prevent recurrence.

Mutual Recognition Agreement (MRA): An international agreement by which two or more countries agree to recognize one another's conformity assessments.

National Conference of Standards Laboratories (NCSLI): A Professional Trade Organization who provides the best opportunities for the world's measurement science professionals to network and exchange information, to promote measurement education and skill development and to develop a means to resolve measurement challenges.

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 two years (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).

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

Mobile laboratory: A 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 according to the normal SCC assessment procedure.

Permanent Laboratory: A calibration or testing laboratory erected on a fixed location. This is the laboratory location (address) denoted on the scope of accreditation.

Critical equipment: Equipment used by testing and calibration laboratories that are critical only if they affect the results of a test or calibration from the scope of accreditation and they are on the metrological traceability path established as part of the uncertainty of measurement.

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.

4. General Requirements

ISO/IEC 17025	Additional Requirement	Guidance
4.1 Impartiality		
4.1.2		Examples of commitment to impartiality include but are not limited to: developing policies mentioned in clause 8.2.2 of the ISO/IEC 17025 standard, identification of risks associated with impartiality, addressing those risks as well as including them in the Management Review.
4.1.4	The evidence of on-going identification, and analysis of risks to impartiality is required.	Examples of risks to impartiality may include but are not limited to: • Part of a bigger organization; • Reporting lines; • Relationships: individuals and as a group; • Roles and responsibilities with potential conflict of interest; • Work schedules that are too tight; • Performance targets based on number of tests completed; • Prospect of losing revenue from major clients; • Self-interest, emotional, financial, or other personal interests; and • Self-review.
4.1.5	Evidence of mitigation, elimination or acceptance of identified risks is required In cases where no feasible mitigation can be found, the justification shall be documented.	
4.2 Confidentiality		
4.2.1	Regardless of the means the lab chooses to meet this requirement,	Confidentiality is extensively covered, expanding the requirements for

	there shall be evidence to demonstrate commitments towards confidentiality and that these are made known to its customers. The evidence shall also be available for informing and obtaining consent in advance from the customers for the information the laboratory intends to make public, with the exception of information already made public by the customer.	confidentiality from section 4.2 of ISO/IEC 17025:2017. The commitment to confidentiality may be demonstrated through direct or indirect means. Direct means include incorporating confidentiality clauses in contractual agreements, making a statement regarding confidentiality in the test reports/certificates, and a public statement in the official website. Alternatively, the lab can establish and effectively implement policies, procedures, and practices backed by necessary infrastructure for collection, storage, transmission, transfer and disposal of information, thereby demonstrating its commitment and responsibility towards safeguarding confidentiality of information. Any breaches should be actionable and where necessary through legal means as well.
4.2.2		Examples of information the lab may be required or authorised to share include but may not be limited to: test results required by their regulators, or information an accreditation body like SCC needs during the lab's assessments as part of the accreditation program. The laboratory can choose the appropriate way of advising their customers, e.g. incorporating this provision into the contract with the client or notifying them ad hoc.
4.2.3		Two points are important when the laboratory receives information about its customers from a source other than the customer: 1. The information shall be kept confidential between the lab and the customer. 2. The source of the information must not be disclosed to the customer. Example: If a complaint is filed to the

		laboratory by a third party (complainant) against the customer of the laboratory, the laboratory can tell its customer about the contents of the complaint, however, it must keep that information confidential with its customer, and the laboratory cannot disclose the source's identity to the customer unless agreed by the source of the information.
4.2.4		Typical implementation is a signed confidentiality agreement or equivalent arrangement that is legally enforceable and executed prior to granting access to such information.

5. Structural Requirements

ISO/IEC 17025	Additional Requirement	Guidance
5.1		"Legal Entity" – the laboratory exists either as an individual entity in jurisdiction(s) within which it operates, or as a **defined part** of another legal entity. Either way, within the context of this Standard and the accreditation requirements, it is essential that the boundaries be clearly defined in terms of the physical space, documentation, staff, equipment etc., all the elements that are required to be assessed towards accreditation.
5.2		Formerly required in the RG-Lab for the 2005 version of the Standard, it was for the lab to document how it separated the functions of quality and lab management when assigned to the same person; With the risk-based approach used throughout this Standard, it is left to the laboratory to assess such risks, especially risks to impartiality, and to

		implement mitigation plans/strategies.
5.4	Accredited laboratories shall comply with the requirements for the use of the SCC accreditation symbol detailed in the Accreditation Agreement.	Refer to the *Accreditation Program Overview* for the use of accreditation symbols and for claims of accreditation status.
5.5 a-c		An organisational chart is recommended but not required, if the lab can produce documentary evidence demonstrating the required elements of its organization and its relationships within the larger entity, as applicable. Documenting its procedures to the "extent necessary": It is left to the laboratory to determine such extent, keeping in mind the purpose of ensuring the consistency of laboratory activities and the validity of test results. For example, as part of improvement efforts, the laboratory should identify areas where there is inconsistent interpretation on how the activity should be performed that is not documented as a procedure or work instruction and determine whether documentation is necessary.
5.6 a-e		There is no longer a requirement for the distinct role of quality manager, however the requirements on implementation and maintenance of the management system implies that the same responsibilities be maintained. It is up to the lab to determine how these responsibilities will be assigned but should make sure the management system is properly implemented and maintained. The responsibilities can be distributed among a group of employees or held with the single person as done in the previous standard. There is no longer a requirement on deputies for key management positions, but there is a requirement on ensuring effectiveness of laboratory activities. It is then left to the lab to

		figure out how this effectiveness will be ensured. This is another area where a risk-based approach would be appropriate.
5.7 a-b		The evidence of communication regarding the effectiveness of the management system would include records of disseminating the relevant results of the management review, additional staff meetings addressing the subject, bulletin boards, etc. Interviews with staff should reveal whether communication is taking place and is effective. The laboratory should be able to demonstrate with documented evidence that when the changes are introduced, risk to the integrity of the management system is considered, and adequate measures were taken to maintain the integrity of the system. This can be part of the process under 8.5 (Actions to address risks and opportunities).

6. Resource Requirements

ISO/IEC 17025	Additional Requirement	Guidance
6.2 Personnel		
6.2.5 a-f		There is no longer a requirement to assess the effectiveness of training, however monitoring is now required. Emphasis should be put on monitoring competence on an ongoing basis.
6.2.6	The other activities where authorization is required include, but are not limited to: Investigating complaints, verification on the action taken on non-conformities, resumption of work after being halted due to non-conformities,	

	approving deviations, and conducting internal audits.	
6.3 Facilities and environmental conditions		
6.3.1		The terminology changed from Accommodation to Facilities which has broader coverage. This encompasses the lab activities that are performed within the permanent facilities, on-site facilities, customer facilities, 3rd party facilities and other locations where the lab activities could take place such as sampling and calibration as applicable.
6.3.4		The controls should take into account the following as required: • Access controls; • Temperature; • Humidity; • Lighting; • Electromagnetic interferences; • Vibration; • Air and water quality; • Contamination; and • Separation of incompatible activities and materials. It is a best practice to give consideration to health and safety measures.
6.3.5		Examples include, but may not be limited to: Sampling locations if included in the lab activity, mobile lab facilities, customer facilities, 3rd party and contractor facilities, where applicable.
6.4 Equipment		
6.4.1		This section applies to electronic media also associated with the equipment whenever used, including: equipment software and data acquisition equipment. The term “equipment” was expanded to also include software, reagents, and reference materials.

6.4.2	It is essential that laboratories have access to equipment to perform the accredited tests SCC does not normally consider granting accreditation when the laboratory does not have access to the equipment that performs the test. When a laboratory is using equipment/facilities that are not part of the laboratory furnishings, 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, fixtures, and environmental conditions) and allow SCC assessors to evaluate compliance of the equipment. Equipment and/or facilities that are outside the laboratory's permanent control that are critical to the test shall have records supporting that the conditions of Sections 6.3 and 6.4 have been met. Accreditation can be granted for tests conducted on-site. For additional requirements refer to Annex A of this document.	When the laboratory can present reasonable justification for not having the necessary equipment under its permanent control, SCC should consider granting accreditation in such cases, provided that the equipment and its use meet all the requirements from this standard and the test in question.
6.4.6		Calibration should provide metrological traceability while verification ensures that the metrological traceability is still valid.
6.4.7	The laboratory can make use of the risk-based approach to decide on the calibration intervals if not defined by a regulatory authority; however, the chosen intervals shall be justified and duly documented.	

6.5 Metrological Traceability		
6.5.1	The key requirements to establish metrological traceability shall include: - an unbroken chain of calibration / references; - measurement uncertainty evaluated appropriately at each link of the chain; - validation/verification of methods and documented results; - demonstrated competence at each link. Laboratories shall retain all relevant records/certificates for reference materials or reagents used in preparing reference materials to demonstrate conformance to measurement traceability requirements including evidence of its verification to meet established criteria.	In Annex A of the ISO/IEC 17025 Standard, a detailed guidance is included on how to establish and demonstrate metrological traceability: the term has been changed from Measurement Traceability to Metrological Traceability with the emphasis given to a documented unbroken chain to establish traceability. Guidance on calibration intervals can be found at: • *ILAC G24-Guidelines for the determination of calibration intervals of measuring instruments;* • *NCSLI RP-1 Establishment & Adjustment of Calibration Intervals*; • *International vocabulary of metrology — Basic and general concepts and associated terms*. For additional requirements refer to: *ILAC P10 – ILAC Policy on Metrological Traceability of Measurement Results* available at ilac.org.
6.5.2	Testing laboratories shall use calibration providers and suppliers of reference materials accredited by an accreditation body signatory to ILAC MRA. Other recognized calibration providers may be used provided that they demonstrate metrological traceability according to A3 - Appendix A of ISO/IEC 17025:2017 in that there is a path that includes an appropriate regional or international MRA or signatory agreement. This shall include the capabilities for specific measurands, ranges and uncertainties that are recognized. When a testing laboratory performs in-house calibration, it shall meet all requirements of a calibration laboratory including the following:	Calibration laboratories under the SCC Laboratory Accreditation Program accredited in cooperation with the NRC-CLAS. These laboratories are also be subject to the policies and procedures of NRC-CLAS.

	- demonstrated competence; - validity of calibration procedures; - suitability and control of equipment; - evaluation of MU; - application of an appropriate decision rule when deciding whether the calibrated item is fit for service. SCC will evaluate these testing laboratories on a case-by-case depending on the specifics of in-house calibration program.	
6.5.3	When testing laboratories use calibration/reference material providers that are not accredited or accredited by an Accreditation Body that is not an ILAC MRA Signatory or by an NMIs that is not a signatory to the CIPM MRA, please refer to: Appendix A of ISO/IEC 17025:2017 - ILAC P10 – *ILAC Policy on Metrological Traceability of Measurement Results.* These providers' capabilities shall be assessed in order to demonstrate their competence and traceability. The testing laboratory shall be able to demonstrate the provider's competence, as there is no metrological traceability without it.	When a recognized calibration/ reference material provider is not available, a non-recognized provider may be allowed providing that the lab due diligence based on a risk assessment of the impact of using this route
6.6 Externally Provided Products and Services		
6.6.1	When a laboratory subcontracts a test for which they are accredited, it shall preferably be subcontracted to a laboratory that is accredited to ISO/IEC 17025 by a signatory to the ILAC MRA for that specific test. If this is not possible, the laboratory may choose a non-accredited laboratory provided they can demonstrate that the sub-contracted laboratory meets the requirements of the appropriate clauses of ISO/IEC 17025.	
6.6.2 c	Laboratories shall evaluate calibration certificates to ensure predetermined acceptance criteria of the testing	Note: examples of verifying calibration certificates include, a website

	laboratory and maintain a record of this evaluation.	database, documenting accreditation and scope of the calibration laboratory.
6.6.3	SCC-accredited testing laboratories shall specify their requirements on purchasing orders or equivalent to ensure specifications are understood so that all purchased supplies and services will ensure the quality of the test result(s). Laboratories shall ensure that a record of the specifications for goods and services affecting quality of test results as well as acknowledgement from the supplier of these specifications is maintained.	Example: Range of calibration, uncertainty of measurement, statement of conformity, choice of decision rule for this purpose, supplier's accreditation/certification status. Suppliers may maintain the products/service specifications in their online portals or in the form of catalogues with clear reference to the particular products and services. Such records are also acceptable.

7. Process Requirements

ISO/IEC 17025	Additional Requirement	Guidance
7.1 Review of Requests, Tenders, and Contracts		
7.1.1		The examples of requirements include, but are not limited to: • The methods to be used; • Outsourced activities; • Decision rules as applicable; • Turnaround time; • Measurement Uncertainty; • Chain of Custody; • Type of reports and extent of details; • Information management including confidentiality; • Contractual obligations and amendment criteria; and • Report/ results transmission protocols.
7.1.1c	The laboratory shall inform their customers of their intent to sub-contract prior to having such work sub-contracted and obtain the customer's approval in writing or equivalent.	When a laboratory is subcontracting an accredited test to another laboratory that is part of the same legal entity and is accredited for the same test by SCC or an SCC-recognized accreditation

		body for the specific test being subcontracted, SCC does not consider the movement of this test item between such facilities as subcontracting unless it is restricted by the contractual arrangements. The test report produced shall however identify the facility that conducted the test. The requirements of ISO/IEC 17025 Section 7.4 Handling of Test or Calibration Items shall apply. Unless there is any contractual, legal or similar obligation, it is not required that a laboratory identify to their customer the identity of the subcontractor.
7.1.2	The laboratory shall maintain the records of pertinent communication with the customer.	
7.1.3		Refer to ILAC G8 Guidelines on Decision Rules and Statement of Conformity for further guidance into Decision Rules.
7.1.4	The laboratory shall maintain evidence to demonstrate that the deviations are assessed by competent and authorized persons, deemed reasonable and approval granted and subsequently accepted by both parties.	
7.1.8		The records of reviews, including significant changes, should be sufficient to establish a full audit trail.
7.2 Selection, Verification, and Validation of Methods		
7.2.1	Refer to *SCC Requirements and Guidance for Method Validation in Testing Laboratories*.	Refer to the *SCC Guidelines for the Presentation of Laboratory Scopes of Accreditation* for acceptable tests for accreditation. This document also describes guidelines for in-house methods.
7.2.1.5		Instead of the “laboratory shall confirm”, the term “verify” is used, and references “methods” instead of “standard methods”, thus expanding

		the admissible range to methods other than standard ones, that can be considered validated, e.g., the ones developed by subsidiaries (labs) under the same parent company, equipment manufacturer, test kit developer. For further details, refer to *SCC Requirements and Guidance for Method Validation in Testing Laboratories*.
7.2.2.4 a-e		The laboratory may decide to have a formal procedure of the type explicitly required elsewhere in this Standard, e.g., Nonconforming Work (7.10) or Handling of Test or Calibration Items (7.4). As far as the requirements of this clause, however, the term “procedure” may be understood to mean a record of the steps used in the validation with the necessary degree of detail for a proper audit trail.
7.3 Sampling		
7.3.1		Sampling is now included as a laboratory activity in addition to testing and calibration. This clause also applies to laboratories that perform sub-sampling, e.g. testing non-homogeneous samples. Sampling methods may be accredited by SCC based on the same applicable requirements for testing and calibration methods. When the lab is responsible for sampling, the contribution from the sampling activity should be considered when evaluating the uncertainty of measurement.
7.4 Handling of test or calibration items		
No additional Requirements or Guidance.		

7.5 Technical records		
7.5.1	A laboratory shall ensure they retain all relevant records and maintain their integrity to establish a full audit trail.	Examples of relevant records may include, but are not limited to: • Sampling records; • Sample shipping and storage; • Testing and analysis; • Equipment including reagents and standards; • Calibration and verification; • Measurement Uncertainty (MU) calculation; • Verification of software related to lab activities; • QA/QC results; • Records verification/validation; • Records of approval; • Customer communication regarding requests for testing, changes and transmission of results; and • Test reports and amendments.
7.5.2	It is essential the lab adopts an appropriate version tracking mechanism or equivalent when using software applications to ensure the traceability and integrity of the data. Handwritten records shall be dated, initialed and traceable to whomever is making the amendment	
7.6 Evaluation of measurement uncertainty		
7.6	A critical element of the concept of measurement traceability is measurement uncertainty. All laboratories shall estimate measurement uncertainty associated with all accredited tests and calibrations. This can be achieved by following adequate procedures consistent with: • "*Guide to the Expression of Uncertainty in Measurement*" *(GUM)* • *ILAC P14, ILAC Policy on Uncertainty in Calibration*	Throughout 7.6.1 - 7.6.3 the term "evaluating" has replaced "estimating" as stated in the 2005 version concerning MU. Although the MU may always be an estimate, the change is meant to emphasize that calculating the MU estimates involves thorough assessment (evaluation) of all contributing factors.

	• *ISO Guide 35 Reference materials – General and statistical principles for certification*, where applicable. 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 (u), combined standard uncertainty (u_c) and expanded uncertainty (U) (normally at a coverage factor of k=2). The definitions for standard uncertainty (μ), combined standard uncertainty (μc) and expanded uncertainty (U) shall be those defined in VIM 3rd Ed. Calibration laboratories shall report the uncertainty of measurement in compliance with *ILAC P14 ILAC Policy on Uncertainty in Calibration.* This includes testing laboratories that perform in-house calibrations. The numerical value of the expanded uncertainty shall be given to, at most, two significant digits and the numerical value of the measurement results shall round to a consistent number of significant digits. 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.	
7.7 Ensuring the Validity of Results		
7.7.1	The records of the resulting data and actions taken shall be maintained to establish a clear audit trail. Refer to the *SCC Requirements & Guidance – Proficiency Testing for Laboratories (Testing and Medical)*. Note that SCC PSA requirements have specific requirements for Proficiency Testing. These are defined in the individual PSA documentation and must be adhered to.	The outcome of the risk analysis may be used to develop the strategy whereby the type, frequency and extent of quality control measures necessary are determined for ensuring the validity and reliability of results on a sustainable basis.
7.8 Reporting of Results		
7.8.1	Refer to the *Accreditation Services Program Overview* and the SCC's customers' Master Accreditation-Licence Agreement for guidance and requirements on publicizing accreditation status on test reports.	Accredited laboratories may also use the ILAC MRA logo on their test reports by signing a Licence Agreement available from SCC. ILAC R7 Rules for the use of ILAC MRA Mark: The use of the ILAC MRA Mark by ILAC MRA signatories and their accredited assessment conformity assessment bodies (CAB's) is voluntary, however ILAC strongly encourages its use. Laboratories that are accredited by an Accreditation Body that is a signatory of the ILAC or regional Multilateral Agreement in the field of testing, may state on certificates and reports, in the appropriate language: "SCC is a signatory to the ILAC, IAAC, and APAC Multilateral Agreement / Arrangement for mutual recognition of accreditation status of testing and calibration laboratories."
7.8.2	When reporting an accredited test, the method listed in the report shall be identical to the method listed on the	This requirement is only applicable when relating the report to an accredited test or method.

	laboratory's SCC scope of accreditation. The test report must include the unique identifier or exact title of the method, as specified on the scope of accreditation. The subcontracted test shall be clearly identified, and this is also applicable for the tests that are performed at locations within the same legal entity.	This also applies to the methods in the scope of accreditation that are sub-contracted. Examples of method designation: • AOAC 990.03 • ASTM D2513 • MFHPB 20
7.8.3	It is acceptable for certain laboratories not to issue a final report. This applies to cases where the vast numbers of samples make it impractical for each report to be signed, or the data for the final report to be transmitted electronically to the proper authority. However, in these cases, the results must remain traceable to the person authorizing the result. A person signing reports does not need formal technical expertise in the area of testing being reported. If the person signing the reports does not have the technical expertise, the laboratory shall be able to demonstrate that the results have been reviewed and accepted by a technically qualified person.	Examples where the test reports should carry qualifying statements: • reporting results below the detection limit; • reporting results with method deviation • reporting results where the integrity of the sample received is questionable; • when any nonconformities/deviations occurred during the storage of the sample or performance of the tests; • insufficient sample to produce results with high confidence; and • when sub sampling occurred after receiving the sample information These qualifiers should become an integral part of the report when they are necessary for proper interpretation of the results; as such they should not be removed at the request of the customers.
7.8.6	A laboratory is considered to be making a statement of conformity when any result is somehow identified as meeting or exceeding a specification or limit, including a Maximum Allowable Concentration (MAC). In this case, the requirements regarding statements of conformity and decision rules applied by the laboratory must be documented and agreed upon with the customer. Whenever a statement of conformity is	Guidance on decision rules can be found at: • ILAC G8 – Guidelines on the Reporting of Compliance with Specification • Eurachem/CITAC Guide – Use of uncertainty information in compliance assessment.

	made in the test report, that statement must be interpreted relative to a decision rule that must be documented and shown or referenced in the report. The risks of falsely accepting or falsely rejecting a result must also be documented only when the decision rule is not prescribed by the customer, regulations or normative documents	
7.8.7	For opinions and interpretations in Forensic testing laboratories, please refer to: *SCC Requirements and Guidance for the Accreditation for Forensic Testing Laboratories*.	
7.9 Complaints		
7.9.1		Of note here is that the requirement is on a documented “process”, and not a “procedure” (refer to Terms and Definitions). Examples of expected documentation would include, but are not limited to: a process map, CRM (Customer Relationship Management) module or equivalent, outlining steps in complaint handling and resolution with responsibilities and preferably timelines identified.
7.9.2		The laboratory needs to show evidence that the details of its complaint-handling process are readily available to any interested party. It implies that the lab should put in place a mechanism to make this information readily available to the client.
7.9.6		If the laboratory cannot find an independent individual within the lab, this requirement could be met through externally provided services. As such, the confidentiality and other requirements for externally provided services should be met.
7.9.7		Expected evidence is the

		communication to the complainant about the closure. In cases where the complainant does not respond to the outcome of resolution that was communicated, and thus leaves ambiguity as to whether or not to close the complaint, it is acceptable to include a disclaimer within the communication with the client, of the type “if no response is received from the complainant with respect to the outcome within n days, the complaint is considered closed.”
7.10 Nonconforming work		
7.10.1 a-f		The requirements in a) to f) remain essentially the same as in the 2005 version, except for b) where the risk-based approach is required when deciding the actions to be taken, including halting or repeating of work and withholding reports. Both ad-hoc risk analysis and application of risk mitigation strategies established in the plan (8.5) are acceptable, if there is evidence of risk assessment preceding the actions taken.
7.11 Control of data and information management		
7.11.1		This includes access to the information required to perform the support functions.
7.11.2	The records from the validation testing shall provide objective evidence that the software functions as expected and details its fitness for the intended use.	
7.11.3	The laboratory shall manage and update the user directory as required to ensure the access and privilege levels are current and appropriate. The information system used by the lab shall be protected and backed up in such a manner that it will be available	

	to users whenever required to perform their tasks.	
7.11.4	This shall be part of the internal audit process or part of the regular evaluation of externally provided services.	When 3rd party services are obtained, all the requirements of externally provided services should be met.
7.11.6	Evidence of checking calculations and data transfers shall be retained.	

8. Management System Requirements

ISO/IEC 17025	Additional Requirement	Guidance
8.1 Options		
8.1.3 Option B	The laboratory must advise SCC during the assessment planning stage that it had elected Option B for implementing management system requirements. Certification to ISO 9001 is not required. A laboratory that is certified to ISO 9001 cannot claim exemption from being assessed against the applicable clauses of ISO 9001. The scope of such assessment shall include at a minimum all the management system requirements assessed in labs choosing Option A (Internal audits, management review etc.). Additionally, the laboratory will be assessed on how well does their 9001-based system support and demonstrate "the consistent fulfilment of the requirements of Clauses 4 to 7". For example, if the laboratory has implemented "8.4 Control of externally provided processes, products and	

	services" under ISO 9001, it will have to demonstrate how it aligns with the requirements from "6.6 Externally provided products and services" in this Standard, as well as in applicable SCC RG documents.	
8.2 Management system documentation (Option A)		
8.2.1		Notably, the standard does not require a quality policy or a quality manual. It has given the flexibility to the laboratories to decide on this as well as determine the extent of documentation. Besides the procedures that are required, the outcome of the risk assessment may be used to decide on the extent of additional documentation (examples of inputs for risk assessment include nonconformities, observations complaints, feedback from customers and personnel, internal audits, external audits). As implied by the clause, the policies and objectives must be documented to the extent necessary to fulfill the purpose of the Standard. That extent is left for the laboratory to determine. The objectives should be aligned with the strategic direction as well as the quality standards set by the lab. It is a best practice to develop objectives that are Specific, Measurable, Achievable, Relevant and Time Bound (SMART).
8.3 Control of Management System Documents (Option A)		
	Management system documentation (Option A)	
8.3.2a	The identity of the approver shall be specified as being a position/title in the organization. Using only the name of the organization or department does not meet requirements for the approver as it does not clearly specify the identity of the approver in the organization.	

	When a laboratory decides to maintain a system where the controlled documents available to personnel need not be signed by the approver, there shall be evidence that the documents have been approved prior to release. 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. In those cases, the authority to approve documents shall also be defined in the document control procedure. There shall be a specified level of access to electronic documents corresponding to that authority.	
8.3.2b	When significant changes are made to a document, evidence of additional training for personnel shall be provided and records maintained. When changes or updates are made to externally controlled documents, evidence of a technical review and the corresponding required actions (if applicable) shall be also maintained.	
8.4 Control of Records (Option A)		
8.4.1	This section applies to both paper and electronic records used as the primary medium for record retention in this section.	
8.4.2	The retention period shall be reasonable to establish an audit trail when SCC conducts the assessments. It shall also meet the contractual requirements. Raw data shall be recorded using an indelible medium with sufficient longevity to support the established retention time.	When records are maintained in electronic format, the laboratory should determine the frequency of backups to prevent any detrimental impact on laboratory activities. It is a best practice to store back up data at a remote location with sufficient distance to escape any damage from a disaster at the main site. The backup media should be regularly tested to ensure that they can be relied upon for emergency use when necessary.

8.5 Actions to address risks and opportunities (Option A)		
8.5.1	Both risks and opportunities shall be considered.	This is a new requirement. The laboratory is expected to move away from a reactive mode of operation to proactively consider risks and opportunities, and plan actions accordingly. Preventive actions from the previous revision of the Standard is one example of actions resulting from addressing the risks; the procedure is not required, but 8.5.2 requires it to be a planned activity, with corresponding evidence Requirements on identifying risks to impartiality (4.1.4), actions resulting from nonconformity analysis (7.10.1), as well as risks of falsely accepting or rejecting the result (7.8.6.1) would, among others, be examples of such activity. The following are some of the additional risks that should be identified: • Vendors; • Customers; • Personnel; • Technology; • Information security; • Equipment; • Results/ reporting; • Business risk; and • Documentation. Opportunities, in the context of Section 8.5, can be thought of as risks that have a favorable outcome. They always have an element of uncertainty and are usually not in the laboratory's control. For these reasons, Opportunities in the context of Section 8.5 are not the same as Opportunities for Improvement in the context of Section 8.6.
8.5.2		The laboratory should retain records to substantiate that the actions to address

		the risks and opportunities are implemented and their effectiveness evaluated.
8.6 Improvement (Option A)		
8.6.1		There is no longer a requirement for a procedure on preventive actions. These can be taken as part of improvement or as action taken to address risks and opportunities (8.5). The note under this clause provides multiple examples of ways in which these opportunities can be identified. Except for “laboratory activities” replacing “testing and “calibration”, the clause is identical to 4.7.2 in the previous edition.
8.6.2	Evidence is required of proactively seeking feedback and analysing it for the purpose of improving the quality of laboratory activities.	
8.7 Corrective Actions (Option A)		
8.7.1		Following from 7.10.3, when the analysis indicates the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, corrective action is necessary to eliminate the cause and recurrence. Although the term “root cause” is no longer used, it can be reasonably concluded that a thorough cause analysis is expected in order for corrective action to be able to eliminate that cause, so the nonconformity “…does not recur or occur elsewhere…”. It would be a best practice to document the timelines and responsibility for implementing the planned actions. 8.7.1e is the new element, requiring the laboratory to update the planned actions for addressing the risks with the

		results of corrective actions (8.5). A well-established risk assessment framework will likely facilitate managing the corrective action process more effectively.
8.7.3		The laboratory should retain all the evidence necessary to establish the audit trail from identifying the nonconformity to verifying the effectiveness of corrective actions and implementing changes in the management system.
8.8 Internal Audit (Option A)		
8.8.1	SCC requires that such audits be conducted on an annual basis.	
8.8.2	When the internal audit is performed by personnel not independent of the activity being audited, the laboratory shall demonstrate the effectiveness and the impartiality of the internal audit. Every part of the management system supporting accredited laboratory activities, including provisions from RG documents shall be audited annually. The annual audit shall include tests and techniques that are representative of at least the methods on the scope of accreditation. The laboratory's internal audit plan and programme shall be developed to ensure that all the accredited tests are audited over a reasonable specified time frame not more than 4 years. The laboratory shall keep records to demonstrate the competency of the internal auditors. For the audits that include technical areas, the laboratory shall demonstrate that at least one of the internal audit members has the appropriate capabilities, experience, and/or knowledge.	It is not necessary to audit each person or each testing/measurement procedure, or to audit every aspect at one time. The outcome of the risk assessment may be taken as an input to decide the frequency of auditing the methods covered under the scope of accreditation.

8.9 Management Reviews (Option A)		
8.9.1	SCC requires that such reviews be conducted annually at a minimum. However extended timeframes are acceptable based on a justified risk-based approach.	Where the laboratory stages their management review as a series of meetings, there should be one meeting review that summarizes the year's activities and looks forward to the coming year. Although the standard does not require a documented approach for risk identification as part of either risks and opportunities (8.5) or risks to impartiality (4.1), there should be a process to obtain an appropriate output from these activities, to be used as input for the management review.
8.9.3		It is a best practice to document the action items with responsibilities and time targets identified.

Annex A – Additional requirements for testing and calibration laboratories performing on-site activities.

Application

For applicant laboratories:

Application for accreditation is explained in the SCC Accreditation Program Overview. At the time of application, the laboratory shall identify clearly on the proposed scope sampling (where applicable) and tests/calibrations activities that are planned to be performed on-site within the proposed scope of accreditation. Sampling is not an activity that can be performed on its own, but as part of a test method, and therefore cannot be accredited by itself. It shall be identified, but not as an accredited test method. Sampling is not applicable for calibration activities. In addition, 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 clause 5.5 (b) shall also be submitted at the time of application. If the laboratory decides to perform Test Method Development (TMD) and Non-routing Testing (NRT) at on-site locations, these shall be clearly indicated as well. All on-site laboratories must be identified on the application form, be assessed as part of the permanent laboratory assessment, and be confirmed on the laboratory's scope of accreditation.

For accredited laboratories:

The process is the same as scope extensions explained in Accreditation Services Program Overview. Laboratories shall identify clearly on the proposed scope, which activities such as sampling, tests/calibrations activities are going to be performed on-site and for which the scope extension requested. Same additional requirements regarding the list of equipment, personnel and authorities of personnel performing on-site testing/calibration shall apply.

SCC Initial Assessment and Subsequent Reassessment

The laboratory shall ensure that personnel who are authorized to perform on-site testing (and associated sampling) activities 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 its discretion, choose one of its 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, will be conducted by SCC or its partner where a test/calibration and sampling (as applicable) are 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.

Presentation of On-Site Activities on Scope of Accreditation

Scopes for laboratories accredited for some on-site testing and associated sampling activities including TMDNRT (where applicable) will include a clear mark or references to indicate which sampling/tests/calibrations are also accredited when 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.

All the requirements of ISO/IEC 17025 and all other relevant SCC Requirements and Guidance documents apply to all accredited laboratories and they extend to their on-site facilities. This section presents requirements to be used in conjunction with the requirements of ISO/IEC 17025. The intent of this section is to elaborate and provide additional requirements and guidance to some of the clauses of ISO/IEC 17025 which are specifically applicable to on-site testing and calibrations.

5. Structural Requirements

ISO/IEC 17025	Additional Requirement	Guidance
5.4	The testing/calibration activities performed on-site shall be covered by the management system. A laboratory performing on-site testing/calibration at temporary facilities, mobile laboratories or at customer's sites shall be permanently identified. When 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.	

5.5 (a)	The laboratory shall define its organization and management structure including its on-site sampling, testing and/or calibration capabilities as applicable**.**	
5.5 (b)	The laboratory shall specify the additional responsibilities, authorities and interrelationships of all personnel who manage, perform or verify work affecting the quality of the on-site tests/calibrations. Sampling activities according to section 7.3 maybe applicable.	

6. Resource Requirements

ISO/IEC 17025	Additional Requirement	Guidance
6.2 Personnel		
6.2.1	On-site testing/calibration shall be performed by personnel who are employed by, or under contract to the laboratory and authorized in a formal way. Personnel that are neither employed nor contracted by the laboratory shall not perform any activities.	In exceptional cases, where personnel are neither employed nor contracted by the laboratory to perform part or all of the test/calibration, they shall be supervised at all times by the laboratory's trained, competent and authorized personnel to perform this specific test/calibration. The supervisor should be employed by, or under contract to the laboratory.
6.2.5 (d)	Any testing conducted away from the permanent laboratory (such as in on-site laboratories, in a mobile testing laboratory or in the field) shall also be under adequate technical control from the permanent laboratory. Authorized personnel, preferably in a management capacity shall be involved in the setting up of an on-site laboratory.	
6.3 Facilities and environmental conditions		
6.3.3	Records shall demonstrate that accommodation and environmental	The technical requirements for 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.	conditions that can affect the results of tests and calibrations performed on-site should be documented and available to staff performing the on-site testing/calibration.
6.3.4 (a)	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.	
6.3.4 (b)	When necessary, the laboratory shall maintain sufficient records to demonstrate effective separation between neighbouring areas (including shared facilities with the customer) in which there are incompatible activities while being on-site. Those records could be floor plans, photographs, etc.	
6.4 Equipment		
6.4.1	It is the on-site laboratory's responsibility to ensure that borrowed or rented equipment shall be treated the same as the permanent equipment. This type of equipment shall receive the same checks/calibrations and other controls as laboratory-owned equipment, prior to and during use. 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.	The provider of borrowed or rented equipment is considered to be an external provider and the requirements of ISO/IEC 17025:2017 section 6.6 therefore apply.
6.4.3	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 environmental changes or other relevant parameters shall be known	The impact of the changing environment when equipment or instruments move between sites should be addressed and fully documented.

	and documented.	
6.4.13	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 visits and at any time upon request.	
6.5 Metrological Traceability		
6.5.1	For accredited calibration laboratories, all the requirements contained in the CLAS Requirements Documents available on the NCR/CLAS website are also applicable to on-site calibrations. For testing laboratories, the requirements for critical equipment also apply to rented or borrowed critical equipment.	
6.5.2 (b)	The status of reference standards or certified reference materials for on-site activities shall be maintained following the same procedures established at the permanent laboratory.	The response of these materials to the environmental changes or other relevant parameters should be known and documented.
6.6 Externally Provided Products and Services		
6.6.1 (c)	Externally provided products and services used for on-site testing/calibration that affect the quality of testing/calibration shall meet the same requirements as for the permanent laboratory.	

7. Process Requirements

ISO/IEC 17025	Additional Requirement	Guidance
7.1 Review of requests, tenders and contracts		
7.1.4	Procedures for the review of requests, tenders and contracts shall cover the	The level of authorization of the personnel involved in requests, tenders

	review of requests for on-site testing/calibrations.	and contracts associated with on-site testing/calibrations should be included.
7.1.5	When deviations from the contract occur during on-site testing/calibration, records that customers have been advised shall be maintained.	
7.1.6	Records of the review of requests, tenders and contracts shall identify the details of the on-site activities such as the location where testing/calibration will be performed, and the personnel who will be performing the testing/calibration on-site. When applicable, for testing laboratories, the records shall include the requirements for equipment needed for the testing when it is borrowed equipment that belongs to the customer	
7.3 Sampling		
7.3.3	When sampling is part of the on-site testing, records shall be maintained at the respective site.	
7.6 Evaluation of measurement uncertainty		
7.6	Adequate procedures for estimation of measurement uncertainty associated with all accredited tests performed on-site shall be considered.	An estimate of the measurement uncertainty of calibrations performed on-site should not be larger than the stated uncertainty at the permanent laboratory. An estimate of the measurement uncertainty of testing performed on-site would normally be larger than the stated uncertainty at the permanent laboratory.
7.7 Ensuring the Validity of Results		
7.7.1	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 always under control.	On-site and mobile laboratories should be subject to the same quality control measures as permanent facilities; however more extensive measures may be required. This should be evaluated on a case-by-case basis and be consistent with the applicable PSA requirements.

7.7.2	If the on-site facility is semi-permanent (> 1 month) then the requirements for proficiency testing or interlaboratory comparisons shall apply. Refer to *SCC Requirements and Guidance – Proficiency Testing for Laboratories (Testing and Medical)* for more details.	
7.8 Reporting of Results		
7.8.1.2	Transmission of interim results shall be allowed only under documented procedures.	The level of authorization of the personnel involved in the acceptance and transmission of test/calibration results during on-site testing/calibration activities should be included.
7.8.2.1.(b)	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.	
7.10 Nonconforming work		
7.10.1	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 upon requirements of the customer.	
7.10.1 (a)	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 be also clearly documented in the procedure(s).	

8. Management System Requirements

ISO/IEC 17025	Additional Requirement	Guidance
8.3 Control of Management System Documents (Option A)		
8.3.2.(a)	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.	A specific control list for all documents necessary to properly perform on-site testing/calibration activities should be kept up to date by the laboratory's permanent location.
8.6 Improvement (Option A)		
8.6.1	The laboratory shall continually improve the effectiveness of its management system using customers comments obtained on-site.	
8.6.2	Customers' comments, both positive and negative obtained on-site shall be part of the customer feedback.	
8.8 Internal Audit (Option A)		
8.8.1	Test/calibration methods applied to the on-site activities shall be audited annually. The internal audit programme shall, include the testing and/or calibration activities performed on-site, including mobile laboratories where applicable to assess whether the on-site tests and/or calibrations continue to comply with the requirements of the management system.	It is recommended that the designated internal auditor visit on-site and mobile laboratories as part of the internal audit process.
8.9 Management Reviews (Option A)		
8.9.1	Management reviews shall include a review of on-site testing/calibration activities.	

-End of Document-