ACCREDITATION SERVICES

SCC Requirements and Guidance for the Accreditation of Laboratories Engaged in Test Method Development and Non-Routine Testing

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Preface

This SCC Requirements and Guidance 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 accreditation@scc.ca.

The general requirements for the competence of testing and calibration laboratories are described in ISO/IEC 17025:2017. These requirements are designed to apply to all types of objective testing and calibration, therefore need to be interpreted with respect to the type of testing and calibration concerned and the techniques involved, SCC Requirements and Guidance documents also apply.

This Program Speciality Area – Test Method Development and Non-routine testing (PSA-TMDNRT) document provides an elaboration, interpretation and additional requirements to those requirements in ISO/IEC 17025:2017 that are required for laboratories involved in performing test method development and non-routine testing. It is expected that where no elaborations, interpretations or additional requirements are stipulated in this document for the elements of the standard, best scientific practices in the area of test method development and non-routine testing will guide the assessment process.

To obtain initial accreditation by SCC under PSA-TMDNRT program, a laboratory shall successfully complete both a proficiency testing regimen and on-site assessment by technical assessors. The assessments will be conducted as outlined in the Accreditation Program Overview.

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

The PSA-TMDNRT program applies to the accreditation of laboratories that are developing test methods and/or conducting Non-routine Testing in one or more testing areas.

NOTE: Routine testing performed infrequently is not under the scope of this PSA. Refer to Accreditation Program Overview, Annex F6 for further details.

SCC recognises that a need exists to provide accreditation to laboratories performing Test Method Development (TMD) and Non-routine Testing (NRT). Laboratories may choose to be accredited to do both TMD and NRT, or just TMD (accreditation to perform only NRT is not available). When a laboratory is accredited to perform NRT within the context of TMDNRT, test reports are the end result. When a laboratory is accredited to perform TMD, test methods are the end result.

Laboratories seeking accreditation of their capability under the program speciality area – TMDNRT shall be required to first demonstrate their conformance to ISO/IEC 17025. Beside demonstrating their conformance to ISO/IEC 17025 the laboratory should meet the following guidelines:

- general procedures about test method development and non-routine testing including method approval;
- authorisation of staff who are responsible for test method development and validation of new and/or modified methods;
- records related to the full development, validation, and/or verification process;
- maintenance of a flexible scope if accredited for TMDNRT such as scope parameters (techniques, technologies and test parameters that apply to this PSA). Refer to SCC *Guidelines for the Presentation of Laboratory Scopes of Accreditation* for further details.

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 doesn't 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.

2. Normative References

- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
- SCC Accreditation Program Overview
- SCC Requirements and Guidance for the Accreditation of Testing Laboratories
- SCC Requirements and Guidance for Method Validation in Testing Laboratories
- SCC Guidance for The Presentation of Laboratory Scopes of Accreditation
- SCC Requirements and Guidance – Proficiency Testing for Testing and Medical Laboratories

- ILAC G18:04/2010 ILAC Guideline for the Formulation of Scopes of Accreditation for Laboratories
- Eurachem/CITAC Guide, Quality Assurance for Research and Development and Non-routine Analysis (first edition, 1998)
- Eurachem Guide, The Fitness for Purpose of Analytical Methods, A Laboratory Guide to Method Validation and Related Topics (second edition, 2014)

3. Terms and Definitions

Test Method Development (TMD): Developing methods and procedures in order to conduct testing or solve an analytical problem. Although this might involve only adaptation of existing, validated test methods, laboratories performing Test Method Development & Evaluation and Non-routine Testing (NRT) are usually involved in more complex projects. TMD may also include validating test methods and/or evaluating test kits.

Routine Analysis: The analytical problem has been encountered before and a suitably validated accredited test method for solving the problem exists and is in regular use. The staff training, calibration and quality control used with the method will depend on the main purpose of sample analysis in order to meet customer's objectives.

Routine Analysis Conducted Infrequently: The analytical requirement has been encountered before. However, the testing is not in regular use or has low or very occasional sample requests (e.g. seasonal). A suitable validated accredited test method for solving the issue exists; however, specific quality assurance and quality control measures are required prior to the commencement (reuse) of the testing on customer samples and need to be defined by the laboratory in a documented procedure.

Non-routine Testing (NRT): Ad-hoc or one-of-a-kind work that is carried out for a specific purpose and may reflect a degree of innovation and limited notice. Typically, it is used in the context of work on out-of-the-ordinary samples where established methods of analysis are unsuitable. These analyses require either significant adaptation of established methods, new method development or the establishment of innovative approaches.

Validation (ISO/IEC 17000): Confirmation of plausibility for a specific intended use or application through the provision of objective evidence that specified requirements (5.1) have been fulfilled.

Verification (ISO/IEC 17000): Confirmation of truthfulness through the provision of objective evidence that specified requirements (5.1) have been fulfilled.

4. General Requirements

No additional requirements.

5. Structural Requirements

ISO/IEC 17025:2017	Additional Requirement	Guidance
5.6 (a)	The laboratory shall maintain a quality system that includes or makes reference to all TMDNRT activities.	In addition to the specific requirements, laboratories performing analyses should also apply the best scientific practices accepted nationally or internationally for each relevant testing field or discipline. Eurachem / CITAC Guide, Quality Assurance for Research and Development and Non-routine Analysis (1998).
5.5 & 5.6	The laboratory shall ensure that a project management system is in place for TMD which includes: • research planning • management/assignment of qualified staff and resources • process monitoring and project management proportionate to size of the project • a project life cycle planning and tracking document or similar electronic project management tracking system (see 8.4.1 below) that may be known as the "**project plan**". For NRT activities, a process to manage non-routine tests is required, and must include items that clearly show the rationale for choosing the test, how the results are reliable, etc.	In case where no pre-established methods are in place, existence of project plans should be applicable for NRT activities.

6. Resource Requirements

ISO/IEC 17025:2017	Additional Requirement	Guidance
6.2 Personnel		
6.2.2	The laboratory shall provide evidence that the personnel performing specific tasks are qualified based on the competence requirements for personnel involved in method development and/or validation. Furthermore, the personnel involved in developing and validating methods in the fields associated with the procedures and techniques that make reference to how TMD and/or NRT is being performed shall demonstrate their competencies	Additional policies and procedures to determine competency requirements necessary for the performance of TMD and/or NRT should also be considered. This competence can be acquired and demonstrated in a variety of ways such as but not limited to: • Formal education and training; • Technical experience; • Research and development projects; • Project management • Participation in standardization committees; • Participation in scientific committees.
6.2.5 (e)	When changes to the competence requirements of TMD and/or NRT are required in response to the needs of the project, the staff concerned shall demonstrate proficiency in the newly identified requirements and be (re)-authorized.	
6.3 Accommodation and Environmental Conditions		
6.3.1	The laboratory shall ensure that facilities are appropriate for TMD and/or NRT. This includes that the facility is adequate for each project and measures are in place to avoid cross-contamination which can vary from project to project, if applicable.	
6.4 Equipment		
6.4.1	If the instrument is novel or modified	This is ideally performed by verifying

	and is operating outside the claims of the manufacturer, appropriate action shall be taken to demonstrate the instrument is operating adequately for its planned use. If an instrument or piece of equipment is used by a different person, for different projects, within a brief time, the laboratory shall assess and implement whether special cleaning or maintenance is required.	the instrument outside of its manufacturer's claimed range, ensuring it is appropriate and fit for purpose.

7. Process Requirements

ISO/IEC 17025:2017	Additional Requirement	Guidance
7.1 Review of Requests, Tenders, and Contracts		
7.1.1 (a) to (d)	The laboratory shall provide evidence that policies and procedures related to review of requests, tenders and contracts are established and the project approval process is linked to these policies and procedures	The extent of method validation, and the consequences in time and cost, may become one of the key issues to be agreed upon between the laboratory and customer.
7.2 Selection, Verification, and Validation of Methods		
7.2.1.6	The laboratory shall provide documented evidence that the development and operation of methods within the flexible scope is maintained by following all the necessary steps. The method verification/validation procedures or plans shall identify any relevant validation guides or standards that are followed and define the terminology used by the laboratory.	The verification should include an initial estimate of the measurement uncertainty. Development plans for TMD and/or NRT should include periodic confirmation that the needs of the customer are being fulfilled.

	The method verification/validation shall be done according to a pre-approved plan. If required by the contract or project, the customer may also approve the validation/verification plan. In TMDNRT, the laboratory makes many decisions as to what needs to be done, such as which performance characteristics will be challenged in a method verification. The rationale and justification for these decisions shall be documented. Refer to the SCC Requirements and Guidance for Method Validation in Testing Laboratories. Refer to SCC Guidance for The Presentation of Laboratory Scopes of Accreditation for more details on how a flexible scope shall be presented.	
7.2.2.1	A TMDNRT laboratory that modifies a standard method to be used outside of its intended scope or otherwise modified shall validate the new method to the extent necessary to meet the requirements of this document.	
7.4 Handling of Test and Calibration Items		
7.4.1	Handling, protection and storage of unfamiliar or novel samples shall be included in the respective procedure.	
7.5 Technical records		
7.5.1	Where standard operating procedures do not already exist or are inappropriate, descriptive notes shall be made to describe the procedures used in the work.	Enough detail should be recorded so that at some later time, the procedures used can be reconstructed. In case where several procedures were attempted before one was found satisfactory, records

		should be kept of the failures so that they can be avoided in future.
7.6 Evaluation of measurement uncertainty		
7.6	The laboratory shall evaluate the measurement uncertainty for new methods and for NRT. The estimate shall ensure all uncertainty components are included.	Data points used to validate the methods for NRT may be limited, therefore periodic re-evaluation of the uncertainty should be performed to include more data when available.
7.7 Ensuring the Validity of Results		
7.7.1	The laboratory shall have quality control procedures to monitor validity of results generated from TMDNRT. When performing NRT, participation in appropriate proficiency testing is required. Where there is no proficiency testing participation, the rationale shall be recorded on the PT plan or by referring to it. Refer to the *SCC Requirements and Guidance - Proficiency Testing for Testing and Medical Laboratories*	
7.8 Reporting of Results		
7.8.1	The results of the project shall be reported to the customer in the agreed upon format.	In the context of this PSA, this may include, for example: • a test report (NRT), • a test method, a project report (technical or otherwise) (TMD), • a report/thesis on research work (TMD).

8. Management System Requirements

ISO/IEC 17025:2017	Additional Requirement	Guidance
8.4 Control of Records (Option A)		

8.4.1	Project life cycle records for TMD activities shall include:
	• Project identification number and title
	• Customer identification (internal & external)
	• Project lead, principal investigator, or project manager
	• Detailed scope and objective(s) of the project
	  ○ Start and completion dates (where applicable)
	  ○ Strategic plan (where applicable)
	  ○ Timelines for planned activities (where applicable)
	  ○ Resources (internal & external) (where applicable)
	  ○ Project approval process (where applicable)
	• Tracking system
	  ○ Review, process as required
	  ○ Progress reports to customer (where applicable)
	  ○ Deviation reports (where applicable)
	  ○ Reports such as validation reports and/or summary reports (where required by the contract/project)
	• Project conclusions/ recommendations
	• Final project report
	• Project/Method Validation completion, approval and date(s)
	Project life cycle records for NRT activities shall include:
	• Customer identification (internal & external)
	• Detailed scope and objective(s) of the work	

	○ Start and completion dates (where applicable) ○ Strategic plan (where applicable) ○ Timelines for planned activities (where applicable) ○ Resources (internal & external) (where applicable) • Conclusion/recommendation to the customer.	
8.5 Actions to address risks and opportunities (Option A)		
8.5.1	The laboratory shall ensure that TMDNRT activities are included when considering risks and opportunities associated with its laboratory activities. For further details, refer to SCC Requirements and Guidance for the Accreditation of Testing Laboratories (RG-LAB).	
8.7 Corrective Actions (Option A)		
8.7.1	In TMD and NRT, it is not uncommon to deviate from procedures. It is important that the quality system supports documentation of these deviations by assessing their level of risk.	When necessary, the deviation should be elevated to a more thorough investigation. This does not preclude from using established corrective actions processes as required already in this section of the standard.
8.8 Internal Audit (Option A)		
8.8.1	Internal audit schedule and procedure shall include projects and activities related to this PSA.	
8.9 Management Reviews (Option A)		
8.9.1	Management review shall include projects and activities related to this PSA.	

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