

ACCREDITATION SERVICES

SCC Requirements and Guidance for the Presentation of Laboratory Scopes of Accreditation

Version 4

Standards Council of Canada



Standards Council of Canada 55 Metcalfe Street, Suite 600 Ottawa, ON K1P 6L5

Telephone: + 1 613 238 3222

Fax: + 1 613 569 7808 accreditation@scc.ca www.scc.ca

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1. Introduction

This document provides guidance in the preparation of the scope of accreditation (Scope) to be presented for submission to the Standards Council of Canada (SCC) laboratory accreditation and proficiency testing provider accreditation programs along with an application for accreditation.

The purpose of this document is to help organizations prepare proposed testing, calibration or proficiency testing provider scopes in applications for accreditation to avoid delays caused by revisions to the proposed scope during the assessment process. These criteria also apply to maintaining accredited scopes.

The Scope of Accreditation demonstrates that the laboratory possesses the competence and necessary infrastructure to provide reliable and sustainable services within the defined scope.

2. References

Note: Unless stated otherwise, the latest revision of the reference document applies.

- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17011 Conformity assessment Requirements for accreditation bodies accrediting conformity assessment bodies.
- ISO 15189 Medical laboratories Requirements for quality and competence
- ISO/IEC 17043 Conformity assessment General requirements for proficiency testing
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- ILAC G18 Guideline for the Formulation of Scopes of Accreditation for Laboratories
- EA-4: Guidance on the level and frequency for Participation in Proficiency Testing Activities
- SCC Accreditation Services: Accreditation Program Overview
- SCC Requirements and Guidance for the Accreditation of Mineral Analysis Testing Laboratories
- SCC Requirements and Guidance for the Accreditation of Information Technology Security Evaluation and Testing Facilities
- SCC Requirements and Guidance for the Accreditation for Forensic Testing Laboratories
- SCC Requirements & Guidance Proficiency Testing for Laboratories (Testing and Medical)
- SCC Requirements and Guidance for Accreditation of Laboratories Engaged in Test Method Development and Non-Routine Testing
- SCC Requirements and Guidance for Method Verification and Validation in Testing Laboratories
- SCC and Partner Scope Templates

3. Definitions

Analytical principle: general principle that describes the method performed by the medical laboratory to detect, identify, characterize and/or determine the concentration of an analyte (parameter), including, if necessary, the pre-treatment or the detection method.

Conformity Assessment Body: body that performs conformity assessment activities and that can be the object of accreditation (ISO/IEC 17011)

Fixed Scope: The scope that captures a complete description of a pre-determined accredited activity. It is a combination of information concerning the field of activity (e.g., testing, calibration, medical, provision of proficiency testing provider -), the product/object/ matrices tested/calibrated, discipline or service provided)

Flexible Scope of Accreditation: scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body as confirmed by the accreditation body. (ISO/IEC 17011)

Laboratory: Body that performs one or more of the following activities:

- testing
- calibration
- sampling associated with subsequent testing or calibration

(ISO/IEC 17025)

Measurement Technique: The process of testing/calibrating/identifying the property, including any pre-treatment required to present the sample, as received by the laboratory to the measuring device. (e.g., ICP-MS, Rockwell Hardness, PCR, Microscopy, force Measurement) [EA-4]

Non-Routine Testing: 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 required either significant adaptation of established methods, new method development or the establishment of innovative approaches.

Note 1: Non-routine test methods may only be accredited under the requirements of the SCC Requirements and Guidance for Accreditation of Laboratories Engaged in Test Method Development and Non-Routine Testing.

Principal Discipline: major divisions or departments within medical laboratory scope.

Product: The item to which measurement technique is being applied. (e.g., soil, vegetables, serum, polystyrene, concrete) (EA-4).

Property/Analytical parameter: The quantity being measured. (e.g., arsenic, fat, creatinine, Escherichia coli, length, hardness, force) (EA-4).

Scope Listing: A specific laboratory activity listed on the scope of accreditation.

Sub-discipline: specific sub-categories of the principal discipline within medical laboratory's scope.

4. Purpose and Application

The scope of accreditation is a publicly available document maintained by SCC in cooperation with accredited laboratories. The scope forms part of the accreditation information and is intended to list specific testing clearly and unambiguously and/or calibration capabilities, or schemes for PT providers for which an organization is accredited.

SCC collaborates with its partner organizations to offer Laboratory Accreditation Programs and in such cases the scope will be finalized in consultation with the partners.

- a. National Research Council Canada Calibration Laboratory Assessment Service (NRC-CLAS): Scopes for calibration laboratories will be finalized by discussions between NRC-CLAS and the laboratory. Similarly, when a laboratory performs both calibration and testing and wants scopes for both calibration and testing activities, SCC will also discuss it with NRC-CLAS for the calibration part. Calibration laboratories wanting to become accredited shall meet the NRC-CLAS published requirements in addition to the SCC accreditation requirements and the requirements of ISO/IEC 17025. For more information, please refer to: nrc.canada.ca.
- b. Bureau de normalisation de Quebec-Évaluation des laboratoires (BNQ-EL): Scopes for testing laboratories will be finalized by discussions between BNQ and the laboratory. For organizations located in the province of Quebec, laboratory accreditation program is offered in partnership with the Bureau de normalisation du Quebec (BNQ). Under this program, organizations are assessed by the BNQ against the requirements of ISO/IEC 17025 for testing/calibration and ISO 15189 for medical laboratories. For more information about the medical laboratory accreditation, please refer to SCC Program Overview, Annex G and www.bng.qc.ca.

The scope of accreditation is assessed at each stage of the accreditation cycle. Requests for revisions to the scope may be made at anytime during the accreditation cycle. Revisions to the scope may include extension, reduction or editorial changes. All scope revisions are assessed by SCC to ensure all requirements of this document are being met and those of SCC partners when involved in the assessment activities.

The accreditation and the scope are site specific. The accredited site must be identified on the scope even when part of a larger organization. The laboratories that perform onsite testing or calibration shall identify clearly on the proposed scope, which tests and calibrations are to be performed onsite for which the laboratory seeks accreditation. Where a laboratory is part of a group accreditation, all locations in the group accreditation shall be identified on each Scope of Accreditation.

For testing laboratories and PT providers, the accredited capabilities of the organization will be identified under each Product/Service Class category. For calibration providers, the accredited capabilities of the organization will be identified under measurement parameter(s).

The scope may contain one or more of the following:

- A single or multiple test method(s)
- Calibration capabilities in a range of fields of testing or calibration
- Schemes/Parameters (in the case of a PT provider)
- Medical disciplines/subdiscipline (in the case of a medical laboratory)

For testing laboratories, the scope may be defined as a fixed scope and/or a flexible scope. Flexible scopes are offered to testing laboratories that have obtained accreditation under the program specialty area of Test Method Development and Non-Routine Testing (TMDNRT) and/or Forensics under ISO/IEC 17025 Accreditation. SCC also offers flexible scopes for Medical Laboratories that come under ISO 15189 Accreditation and other industry applicable standards.

Other laboratories may be eligible and shall be considered on a case-by-case basis, the decision will be made at the sole discretion and professional judgement of the SCC. Such decision will be based on several factors including, expertise of the laboratory in the area requested for the flexible scope, nature of the laboratory operation, expertise required from the assessment team and time needed to assess such scopes. The exact nature and breadth of the flexible scope and applicable annual fees for flexible scopes will be determined at that time.

Note 2: SCC recognizes that it may not be practicable in some cases, to specify precise details for every test for which accreditation is sought. In such cases, the scope will be adapted to the situation.

5. Fixed Scopes and Flexible Scopes

5.1 Fixed Scope

Fixed scopes capture a more complete description of pre-determined accredited activities of a Laboratory. A Fixed scope does not allow additional or modified activities to be added without further assessment.

According to ISO/IEC 17011, a fixed scope of accreditation shall, at least, identify the following:

- Testing laboratories (including medical laboratories):
 - o materials / products/objects / matrix tested
 - o component, parameter or characteristic tested
 - tests or types of tests performed and, where appropriate, the techniques, methods and/or equipment used.

In case of multianalyte method(s), best efforts shall be taken to list most of the analytes that are being analyzed by the test(s) performed to ensure the full capabilities of the methods are captured. If the list of the analytes is exhaustive and too big in nature, grouping based on similarities may be applicable.

- Calibration laboratories:
 - o the calibration and measurement capability (CMC) expressed in terms of:
 - measurand or reference material.
 - calibration or measurement method or procedure and type of instrument or material to be calibrated or measured.
 - measurement range and additional parameters where applicable (e.g. frequency of applied voltage).
 - o measurement uncertainty.
- Proficiency testing providers:
 - o schemes that the proficiency testing provider is competent to provide.
 - type of proficiency testing items.
 - the measurand(s) or characteristic(s) or where appropriate the type of measurand(s) or characteristic(s) that are to be identified, measured or tested.

5.2 Flexible Scope

SCC allows flexible scopes only for testing laboratories based on the eligibility criteria outlined in section 6.2. Testing laboratories may request a flexible scope within SCC's Laboratory Accreditation Program. When a flexible scope is chosen under ISO/IEC 17025 accreditation, the provisions in SCC Requirements and Guidance for Accreditation of Laboratories Engaged in Test Method Development and Non-Routine Testing apply, unless the laboratory is accredited with the Forensic Program Specialty Area, in which SCC Requirements and Guidance for the Accreditation for Forensic Testing Laboratories apply. In addition, SCC offers flexible scopes to laboratories accredited to ISO 15189

A flexible scope of accreditation allows laboratories to make changes in methodology and other parameters that fall within the competence of the laboratory as confirmed by the accreditation body. However, such modifications to methodology cannot be applied to new competencies that have not previously been assessed and accredited by SCC or its partners or are in different PSAs; and hence not covered by the flexible scope of accreditation.

A flexible scope for labs can be established based on degrees of freedom for flexibility such as:

- Flexibility concerning products/objects/matrix/sample that draw similarity among them (Flexibility in this regard is not applicable for Medical Laboratories)
- Flexibility concerning parameters/components/analytes/properties
- Flexibility concerning the performance of the method
- Flexibility concerning the method

Note 3: When an organization operates a flexible scope, refer to ILAC G18 for further information.

6. Acceptable Scope Content

Accreditation means recognition of the competence of a laboratory to carry out and report tests in accordance with specified requirements in the methods. In general, SCC does not accredit activities of a subjective or interpretative nature.

SCC grants accreditation to a laboratory for those activities that the laboratory itself is competent to carry out. Laboratories are required to be capable of demonstrating that they themselves perform the test or measurement for which accreditation is sought or granted. Accreditation can only be granted for tests or measurements that a laboratory can demonstrate, by objective evidence, that they have conducted themselves.

The scope of accreditation may be defined as a fixed scope or a flexible scope. An organization may choose, in agreement with SCC, a fixed or a flexible scope. SCC recognizes that it may be impractical, in some cases, to specify precise details for every test for which accreditation is sought. Therefore, applicant and accredited laboratories are allowed to opt for a flexible scope.

The scope must be sufficiently detailed to identify the test methods to be accredited. Test methods occasionally refer to other test methods to conduct portions of the test procedure. These are referred to as nested methods. When a laboratory needs to specifically refer to a nested method on a report, or when a laboratory needs to be considered accredited specifically for the nested method, the nested method must also be listed on the scope in addition to the principal method. Presentation of the scope shall be clear as to which activities the lab is granted accreditation.

The scope may be revised following an assessment or reassessment visit or through SCC's scope extension/reduction process. This can consist of either a suitable reduction or could, when acceptable to both parties, result in added capabilities.

6.1 Fixed Scope

Fixed scopes of accreditation must be as detailed as possible and give the specific identification of all testing methods to be accredited for both standardized methods and in-house developed methods. Please refer to the appendix for examples as to how scopes should be presented. Additionally, SCC has created scope templates for each program that can be obtained upon request.

6.2 Flexible Scope

Flexible scopes allow the scope to be presented in a more generic way and allows for changes and extension of the specific activities within the boundaries described in the scope of accreditation and to the extent competency is assessed and accredited by SCC.

A flexible scope allows for:

flexibility concerning parameters/analytes/properties which allows for changes with

- respect to parameters that are analyzed using a method.
- flexibility to introduce a new or modified product/matrix/sample that draws similarity to the product/matrix/sample included in an accredited method or analysis (this is not permissible for medical labs).
- flexibility concerning the performance of the method which allows for changes in the
 performance of the method for a given product/matrix/specimen type and a given
 parameter (e.g. modification of measuring range and uncertainty for a specific
 parameter).
- flexibility concerning the method which allows adoption of methods that are equivalent to methods already covered by accreditation.

A flexible scope does not allow the laboratory to make the following changes without informing the SCC (via an approved request for scope extension):

- introducing a new method or new equipment using a measurement technique, or technology different than the ones already evaluated during the assessment.
- Introduce a new or modified product/matrix/sample that does not have similarity to matrix/sample/product included in an accredited method or analysis.
- changing the measurement techniques or technology of an existing accredited method for a method that has not been evaluated during the assessment.
- claiming accreditation for a different Program Specialty Area than the one evaluated during the assessment.

The following information shall be presented for each flexible scope.

- Program Specialty Area and Field of Testing.
- Description of activities: brief description on type of analysis is being conducted including type of matrix/samples to be analyzed.
- Description of measurement techniques: outlining the techniques involved in the measuring the products/matrix/sample mentioned before (type of equipment and/or measurement technique).

The laboratory shall maintain a current list of methods (with matrices) covered by the accreditation including newly modified, introduced or developed methods. This list shall be a controlled document and shall be part of the management system documentation / records. This list shall be readily and publicly available upon request. The flexible scope shall refer to said controlled document or shall give information on how to obtain the list.

In addition, the lab shall maintain a documented procedure to manage the changes without compromising the quality and the integrity of the test results.

Once the lab starts performing the tests on a routine basis, the methods performed within a flexible scope may be transferred to the fixed scope section. This could take place during a reassessment at the laboratory's request.

6.3 Modified Published Methods

A laboratory shall refer to the identification of a published method in its scope only if applied without modification. If a published method is modified, regardless of the extent of modification, the word modified shall be used in the scope listing. Since modified published test methods are treated as in-house methods, the laboratory is required to produce validation information in support of the modification. Please refer to SCC Requirements and Guidance for Method Verification and Validation in Testing Laboratories for further guidance.

Please refer to the Appendix for examples of scope presentation.

When a laboratory only performs some parts of the test method, the exclusions shall be clearly identified within brackets, if the lab chooses to preserve the title of the published method. In rare cases, these requirements may be waived at the sole discretion and professional judgement of the assessment team, the onus is on the laboratory to justify its position with supporting evidence to the satisfaction of the assessment team as well as the SCC independent reviewers. (Note 6).

The accreditation, when granted, will relate solely to tests listed in the approved scope of accreditation. The tests listed on the scope must be performed by the laboratory and the laboratory must possess in-house capabilities (Note 4) and competence to do so.

Acceptable tests for accreditation may include any of the following:

- Test methods contained in standards published nationally or internationally by accredited or recognized standards-development organizations.
- Manufacturer-published documents containing pertinent information on the use of major test equipment, which essentially constitute an element of the test method, such as a set of analytical instrument instructions or an equipment operating manual.
- Methods published in recognized journals and research papers in the relevant fields.
 However, these will be treated as in-house methods, especially in terms of validation data.
- Test methods, procedures or supplementary instructions developed internally, or derived from other test methods, provided they are properly documented, maintained, and supported by validation data.

Note 4: Definition: In-house capabilities: when the applicant or accredited laboratory possesses at the accredited location, the equipment, qualified personnel, and records of actual tests conducted using that equipment and personnel.

Note 5: Where standards, such as product standards, are listed, the laboratory is only considered accredited for the testing elements in those standards for which capabilities reside. Laboratories listing compendiums, standards or other published methods containing multiple tests or techniques for which they do not have in-house testing capabilities for all, must specifically either identify chapters, sections, clauses or appendices for which they do not have "in-house capabilities" using either:

- a. "Except for:" and listing specific tests within the standard or compendium for which the laboratory does not have capabilities by reference to chapter/section or clause number and complete title: or
- b. "Only for:" and listing specifically those tests within the standard or compendium for which the laboratory has capabilities by reference to chapter/section or clause number and complete title.

7. Restriction for the Content of a Scope

Only activities for which a laboratory can demonstrate competence in compliance with the SCC requirements and the requirements of the applicable conformity standard (for testing, calibration, or provision of PT) will be listed on the scope.

In general, SCC does not accredit activities of a subjective or interpretative nature. SCC grants accreditation to a laboratory for those activities that the laboratory itself demonstrates competency to carry out such activities through objective evidence.

Under normal circumstances, preparatory (sampling), and test methods that do not generate test results shall not be listed on the scope of accreditation unless such methods serve for the other accredited methods in the scope. Please refer to section 6 for information regarding nested methods.

8. Preparation of the Proposed Scope

The laboratories and the PT providers shall use designated scope templates provided by SCC and/or its partners.

Note 6: Section 8 pertains to the laboratories that are directly assessed by SCC. The laboratories being serviced by SCC through its partners (NRC-CLAS or BNQ-EL) shall consult with the respective partner for specific information when preparing the scope.

8.1 List of Test Methods - Fixed Scopes

The list of tests for which accreditation is sought should contain the exact designation or the reference number followed by the exact published title of the method or standard, or follow the format provided in the Appendix whichever is deemed more descriptive. However, all in-house methods should follow the format and descriptions provided in the Appendix.

The year designator for a standard or method is to be included only if a superseded method is still being used for a specific application. All other standards or methods are to be listed without year, as it is understood that the laboratory always uses the most recent revision of each listed method unless otherwise specified by date.

Review and consider the restrictions listed in section 7 of this document.

For microbiology test methods, the name of the organism shall be written in full and in italics in the title of the method included in the scope.

8.2 The SCC Classification System for the Test Methods – Fixed Scopes for Testing Laboratories

This section only applies to fixed scopes of accreditation.

The classification for testing scopes is based on the Harmonized Commodity Description and Coding System (HS Convention) of the World Customs Organization (WCO). An ideal system would try to follow as closely as possible to the HS Convention terminology and codification.

The HS Convention enables grouping of tests by categories and sub-categories, which in turn enables a standard classification for all testing scopes. This system is also used to classify assessor areas of expertise, thus facilitating the matching of suitably qualified assessors with the scope of any specific laboratory. This section is to introduce the approach that will facilitate the use of the classification system. Section 11 of this document contains a partial list of the PSC classification system that includes sub-categories as well. For additional details please refer to: http://www.wcoomd.org/en/topics/nomenclature/instrument-and-tools/hs-nomenclature-2017-edition/hs-nomenclature-2017-edition.aspx

There are 14 principal categories that classify all tests. These are named Product Service Class (PSC) Codes and they appear in the Scope as:

UPPER CASE BOLD UNDERLINE

Each PSC is divided into sub-categories named Major Sub-Headings and they appear as:

Title Case Bold Underline

The Major Sub-Headings are further subdivided into Minor Sub-Headings and they appear as:

Title Case Bold

Where any Major or Minor heading does not suit, the laboratory may create a Miscellaneous Heading that should appear in brackets as:

(Title Case Bold)

8.3 Instruction for Building the Scope

- a. Refer to the list of tests developed in section 8.1 as the working document to produce the proposed scope.
- b. Review Section 11 of this document and identify the relevant PSCs that apply to the tests of the proposed scope. When a minor heading is selected, verify the PSC and

- applicable Major Heading since some minor headings appear in more than one PSC.
- c. There are two ways of proceeding from this point: either move the tests from the list under the correct headings or import the appropriate PSC under which the tests will be listed.

Laboratories that are presenting a flexible scope (see section 5.2) shall include a description that is unambiguous and clearly defines the laboratory competence and capabilities as it refers to the flexibility granted.

Other Considerations:

- d. Tests are listed under the appropriate Minor Sub-Headings. When all or most of the Minor Sub-Headings apply, the tests should be listed under the Major Heading, without the use of a Minor Sub-Heading.
- e. A Minor Sub-Heading must be listed with its corresponding Major and PSC as a cascading system. Minor Sub-Headings are specific and cannot be exchanged between Major Sub- Headings or PSCs, similarly for Major Sub-Headings.
- f. Each PSC, Major or Minor Sub-Heading may be followed by a description. This is a free- form text that may be used to describe that section. The description must not be misleading regarding the testing capabilities or constitute publicity in any manner. SCC reserves the right to edit these descriptions as appropriate. A description may be appropriate when multiple Minor or Major Sub-Headings apply to a group of tests.
- g. It is recommended that a test not be listed more than once even if multiple categories apply. The test is to be listed under the most common heading. The other applicable headings should contain a reference to the heading where the test is listed.
- h. Counting the number of listings: The test methods and the techniques if listed separately, should be counted separately and noted a at the bottom of the scope document. If the same test methods/standards are listed, or referred under different sections of the scope, they should be counted separately.

Fields of Testing and Description- Testing Laboratories

Fields of Testing are defined as recognized spheres of science, engineering or technology that describe a general area of related testing activities for classification purposes. These are different from the PSCs and are a more general classification. The defined Fields of Testing are as follows:

Acoustics and Vibration: Measurement of noise, sound and vibratory motions; tests on acoustic and vibration measuring equipment; measurement of acoustic and vibration effects on, and properties of,

materials, assemblies and structures; testing of insulating materials, and devices intended to protect against noise and vibrations.

Biological: Biological, microbiological, biochemical, molecular biological testing and measurement for the examination of foods, drugs and pharmaceutical products, including testing for environmental, medical and veterinary purposes.

Chemical/Physical: All methods of chemical analysis and detection, including instrumental and automated tests, associated physical tests such as viscosity and surface tension determinations, and calibration of the testing equipment involved by means of standard reference materials.

Electrical/Electronic: Measurement of electrical quantities and parameters, including tests on all types of electronic equipment and components, electrical machinery, appliances and devices such as luminaries.

Forensic: Specialized services for objective examination of evidence gathered to determine compliance with or contravention of laws, or otherwise to be presented in court or a regulatory capacity when necessary, and always conducted under enhanced levels of security and with demonstrable and unequivocal continuity of sample handling.

lonizing Radiation: Detection and measurement of all types of ionizing radiation and radioactivity, including X-rays, gamma rays, other products of nuclear fission and fusion, and all related dosimetry testing.

Mechanical/Physical: Measurement of strength of materials and assemblies and related properties such as surface hardness, pressure and metallographic parameters, and including determination of aerodynamic, hydraulic and pneumatic parameters.

Non-Destructive Examination: Direct examination of materials, components, assemblies and structures by such specialized techniques as radiography, ultrasonics, penetrants, magnetic particles and eddy currents, to detect and locate discontinuities without affecting the fitness for use of the examined article.

Optics & Optical Radiation: Testing of optical and photometric properties and parameters; measurements made with and on optical and photometric equipment and instruments; measurement of colour and surface smoothness (reflectance, gloss); measurements involving visible (light) and near-visible (infrared, ultraviolet) wavelengths of radiation.

Thermal & Fire Resistance: Measurement and detection of heat energy, temperature, thermal conductivity/resistivity and heat capacity of materials and objects; flammability, fire resistance and burn rate testing of materials and assemblies; testing of heat actuated devices and thermally protective products including fire prevention, fire protection, firefighting equipment and clothing, and the specific materials used.

SCC Program Specialty Areas (PSAs) and other Accreditation Programs

Program Specialty Areas (PSAs) are specific technical fields of measurement or testing, or disciplines within which several fields of testing combine to allow the articulation of requirements specific to that PSA for the accreditation of laboratories seeking recognition of competence within the PSA. To be considered a PSA within the SCC program, a need must be identified by a stakeholder group for specific technical interpretations of the requirements to ISO/IEC 17025. Other accreditation programs such as Proficiency Testing Program and Medical Laboratory

programs are also covered under this document. Descriptions about these programs are provided in this section.

All SCC Requirements and Guidance are available without charge from the SCC website at https://www.scc.ca/en/about-scc/publications/criteria-and-procedures.

The following PSAs form part of the SCC program. A brief description follows, but more specific details are available in the program's Requirements and Guidance document or obtained from SCC via accreditation@scc.ca.

10.1 Agriculture Inputs, Food, Animal Health and Plant Protection (AFAP)

For laboratories that perform testing of agriculture inputs such as seeds, feed and fertilizer, food, animals and plants for:

- · Chemical analysis ranging from percent levels to trace levels, and
- Qualitative and quantitative microbiological analysis.
- Federally regulated animal diseases
- Federally regulated plant quarantine pests
- Seed testing for regulatory purposes

Accreditation for this PSA is the formal recognition by SCC of the competence of a food, feed, fertilizer, animal health and plant pest-testing laboratory to perform and control this type of testing.

The Canadian Food Inspection Agency (CFIA) may require accreditation to ISO/IEC 17025 by a CFIA-recognized accreditation body such as SCC for laboratories performing testing in this PSA to support specific regulatory requirements in the CFIA Framework for Quality Management Oversight of Laboratories Conducting Testing in Areas Under the CFIA Mandate.

10.2 Calibration (in partnership with NRC-CLAS)

The Calibration PSA is for laboratories offering calibration services in specific measurement parameters. Laboratories accredited for this PSA may list their calibration and measurement capabilities (CMC) for which the laboratory is accredited. Laboratories seeking accreditation for this PSA are to apply to NRC-CLAS.

Calibration and measurement capabilities for accredited laboratories are listed on the CLAS web page:

https://nrc.canada.ca/en/certifications-evaluations-standards/calibration-laboratory-assessment-service/directory-accredited-calibration-laboratories

The guidelines and requirements for calibration laboratories are available at: https://nrc.canada.ca/en/certifications-evaluations-standards/calibration-laboratory-assessment-service.

10.3 Environmental Testing

The program is designed to ensure testing laboratories meet minimum quality and reliability standards and to ensure a demonstrated uniform level of proficiency among these testing laboratories. This includes, but is not limited to, the measurement of biological, chemical, physical, or toxicological characteristics of either the receiving environment or discharges to the receiving environment and includes as appropriate, biological, chemical and physical fields of testing on the environmental surroundings (air, water, soil, flora and fauna) and waste samples (gaseous, liquid and solid). Laboratories must successfully participate in the proficiency testing programs identified in the PSA document.

10.4 Fasteners

Applies to laboratories that conduct tests and measurements on threaded fasteners, providing services supporting fastener production, such as plating, producing material destined for fastener manufacture and commercial laboratories offering testing services.

10.5 Forensic

For the accreditation of laboratories that provide analytical results of documented quality to the Canadian Courts of Law in both criminal and civil proceedings or regulatory appeal panels_as applicable. Accredited laboratories demonstrate adherence to recognized practices and standards in the forensic sciences. Accreditation for this PSA is the formal recognition by SCC of the competence of a forensic testing laboratory to manage and perform the following types (disciplines) of forensic testing:

- DNA Testing for Immigration Purposes
- Toxicology
- Forensic Biology / DNA
- Forensic Chemistry / Trace Evidence
- Forensic Drug Chemistry
- Forensic Equine Drug Testing
- Forensic Toxicology
- Questioned Documents Examination
- DNA Databasing

Note 7: laboratories that are performing relationship testing come under the PSA Forensic.

Please refer to SCC Requirements and Guidance for the Accreditation for Forensic Testing Laboratories for additional details.

10.6 Information Technology Security Evaluation and Testing (ITSET)

Defines the additional requirements for accreditation of laboratories seeking recognition for testing in the areas of:

- Common Criteria product and system evaluations.
- ITS product reviews.
- Secure electronic commerce application evaluations.
- Biometric device testing.
- Vulnerability and tiger team testing; and
- Specialized commercial security device testing.

Please refer to the SCC Requirements and Guidance for the Accreditation of Information Technology Security Evaluation and Testing Facilities for additional details.

This PSA is structured into specific ITS Approval Domains, each recognized by an ITS Competent Authority, such as the Communications Security Establishment (CSE) of the Government of Canada.

10.7 Mineral Analysis

This PSA for mineral analysis testing laboratories applies to tests associated with the measurement of all media used in mining exploration and processing. This includes, but is not limited to, sediments, rocks, ores, metal products, tailings, other mineral samples, water and vegetation. However, it cannot cover all aspects of mineral analysis testing and shall be regarded as being representative of this area of activity.

Please refer to the SCC Requirements and Guidance for the Accreditation of Mineral Analysis Testing Laboratories for additional details.

10.8 Test Method Development & Evaluation and Nonroutine Testing

This program specialty area applies to the accreditation of laboratories that perform 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, test reports are the product. When a laboratory is accredited to perform TMD, test methods are the product.

Laboratories seeking accreditation of their TMD, evaluation and/or NRT capability under this document shall be required to demonstrate their conformance to ISO/IEC 17025. These labs are eligible to seek a flexible scope.

Please refer to the SCC Requirements and Guidance for Accreditation of Laboratories Engaged in Test Method Development and Non-routine Testing for additional details.

10.9 Medical

In the case of a fixed scope, the scope of accreditation must be as detailed as possible and give the specific identification of all testing methods to be accredited. The scope must list the principal disciplines, the sub-disciplines, analytical principle, analytical parameter(s), matrices and the reference to a standardized method, if applicable.

There are 13 principal disciplines considered for medical laboratory accreditation. Flexibility is allowed to add a principal discipline / sub-discipline which is not listed under section 11 'Medical Testing". As a general rule, tests are listed under the appropriate Principal Disciplines. A sub-discipline must be listed with its corresponding Principal Discipline.

A test may not be listed more than once even if it applies to multiple disciplines. For these cases the test is to be listed under the first listed applicable Principal Discipline. Additional listings are referenced to the first Principal Discipline where the test is listed.

In addition, Point of Care Testing (POCT) may be included in the scope of accreditation. This will be covered under the requirement of ISO 15189 Medical laboratories — Requirements for quality and competence .. For laboratories based in Quebec, the program is offered in collaboration with the Bureau de normalisation du Québec (BNQ). For this program, medical testing laboratories are assessed by BNQ and based on the recommendation from BNQ, SCC accredits the medical laboratories. Please refer to the medical laboratory scope template for further details. Requirements for Medical Laboratory Accreditation Program are defined in SCC Accreditation Program Overview, Annex G.

10.10 Proficiency Testing Providers (PTP)

Proficiency Testing Providers that serve laboratories and groups of laboratories may seek formal accreditation of their competence in the provision of these services. Such formal recognition of competence from SCC is provided under this PSA and/or program. Applicant organizations will normally be involved in the development and delivery of PT samples, and/or the analysis of PT results from client laboratories. Accreditation includes examination of the competence of the organizations involved in proficiency testing sample production. Please refer to the Proficiency Testing Provider laboratory scope template for further details. Accreditation requirements are contained in ISO/IEC 17043 and defined in SCC Accreditation Program Overview, Annex H.

List of Products and Services by Class (PSC) Codes

Please note that this is an example of the List of Products and Services by Class (PSC) Codes, please refer to the LAP Scope Template for an up-to-date list.

ANIMAL AND PLANTS (AGRICULTURE)

Agricultural Products: (except food and chemicals)

Cannabis

Cotton

Linen

Tobacco

Animal and Fishery Products: (except food)

Feathers

Furs

Leathers

Foods and Edible Products: (Human and Animal Consumption)

Animal or Vegetable Fats and Oils and Their Cleavage Products; prepared edible fats;

animal or vegetable waxes

Beverages, Spirits and Vinegar

Cannabis and Cannabis Products

Cereals and Products of the Milling Industry

Coffee, Tea, Mate, and Spices

Dairy Products

Edible Fruits and Nuts

Edible Vegetables and Certain Roots and Tubers

Eggs and Fish

Feeds

Meat and Edible Meat Offal

Nutrition Labelling

Preparation of Vegetables, Fruits, Nuts and Parts of Plants

Preparation of Cereals, Flour, Starch; Pastry Cook's Products

Sugars and Sugar Confectionery

Unprocessed Milk:

Chemical Tests

Microbiological Tests

Forestry Products:

Seeds:

Soils:

Constituents and Nutrients

Physical Parameters

Other (Specify):

Veterinary

CHEMICALS and CHEMICAL PRODUCTS

<u>Chemical Compounds:</u> (not elsewhere specified)

Inorganic

Liquid

Organic

<u>Chemicals for Agricultural Industry:</u>

Biocides

Fertilizers

Herbicides

Insecticides

Pesticides

Chemicals for Food Industry:

Additives

Minerals

Preservatives

Vitamins

Cleaning Agents:

Disinfectants

Floor Polish

Soaps & Detergents

Wax Remover

Water Treatments

Explosives:

Ammunition

Blasting

Fireworks

Powders

<u>Petrochemical Products:</u> (not elsewhere specified)

Liquids

Pharmaceuticals and Cosmetics:

Capsule

Cream

Drugs

Injection

Liquid

Sterile Dressings

Tablet

Polymers: (not elsewhere specified)

Other (Specify):

CONSTRUCTION

Building Constructions and Prefabricated Buildings:

Airports

Buildings

Commercial

Dwellings

Industrial Buildings

Construction Materials: (Excluding textile products)

Caulking, Sealing and Glazing Compounds

Ceiling Coverings

Fasteners and Hardware (See also METALLIC and TEXTILES Sections)

Fire Resistant

Flammability

Floor Coverings (See also WOOD Section)

Insulating Materials

Miscellaneous Construction Materials

Panels (See also ELECTRICAL Section)

Plumbing Products

Roof Coverings

Vapour Barriers,

Water Proofing Membranes

Wall Coverings

Windows and Doors

Pipelines:

Prefabricated Assemblies and Kitchen, Office Sections:

Cabinets

Counters

Frames

Metallic Structures

Trusses

Ventilation Equipment

Road and Railway & Civil Constructions:

Bridges

Crossing

Dams

Embankments

Pavement

Overpasses/Trestles

Rails

Subways/Tunnels

Other (Specify):

ELASTOMERS AND PROTECTIVE AND COATINGS

Adhesives (Organic Resins) and Glues: Adhesives

Binders

Cement

Glues

Miscellaneous Materials

Putty

Sealant

Paints; Varnishes; Inks; Coatings; and Allied Products:

Inks

Lacquers

Miscellaneous Products

Paints and Protective Coatings

Application and Working Properties

Applied Coatings Performance

Colour and Appearance

Constituents

Printing inks Turpentine

Varnishes

Plastics; Resins and Rubbers:

Plastics

Resins and Rubbers

Other (Specify):

ELECTRICAL PRODUCTS AND ELECTRONIC PRODUCTS

Communications Equipment and Systems:

Broadcasting

Components and Assemblies

Power and Signal Distribution Equipment

Radio Telecommunication

Radio, Television and Electronic Apparatus

Telecommunications Equipment

Wiring and Related Products

Components and Assemblies:

Circuit Breakers and Fuses

Conductors

Insulators

Rectifiers

Switches and Controls

Transformers

Wiring and Related Products

Electrical Appliances:

Cooking and Liquid Heating

Heating, Refrigerating and Air Conditioning

Lighting and Fixtures

Miscellaneous Electrical Appliances (Specify)

Motor Operated Electrical Appliances

Washing Equipment

Equipment, Miscellaneous:

Automotive Components

Conductors

Enclosures

Grounding

Hazardous Location Equipment

Insulators

Panels

Shielded Rooms

Welding

Information Processing and Business Equipment:

Computers

Data Processing Equipment

Office Machines

Photocopying and Related Equipment

Power Supplies

Typewriter

Medical Devices:

Breathing Apparatus and Equipment

Diagnostic Instruments

Health Care and Health Hazard Technologies

Limbs (Prostheses)

Pacemakers

Resuscitators

Surgical Instruments (See MEDICAL Section)

Treatment Equipment

Materials:

Plastics

Motors, Generators, and Machines:

Complete Unit

<u>Scientific Instruments: (For biological, chemical electrical, mechanical optical and physical examination)</u>

Circuit Breakers and Fuses

Components and Assemblies

Laboratory Equipment

Recorders

Rectifiers

Switches and Controls

Timers

Transformers Other (Specify):

ENVIRONMENTAL AND OCCUPATIONAL HEALTH AND SAFETY

Air Quality: (Outdoor Stack Emission)

Biological Materials Quality:

Environmental:

Air

Air (Occupational Health)

Air Cartridge

Air Emission Filter/RC

Air Filter

Air Impingers

Air-Tedlar Bag

Ambient Air

Animal Tissue

Ash, Sludge and Soil/Sediment

Biological

Biological Oils

Biological Tissues

Biologicals

Biomaterials

Biosolids

Biota

Charcoal Tube

Compost

Diesel Particulate Matter

Dust fall

Effluent

Effluent/Liquids

Environmental Products

Fish

Fish Feed/Fish Meal/Fish Tissue

Fish Feed/Fish Meal/Fish Tissue/Fish Oil

Fish Tissue

Fluoride Candles

Food Stuffs

Hydrocarbon

Industrial Waste

Leachate

Leachates

Liquid

Liquid Waste

Liquids

Manure

Oil

Paint

Particulates

Petroleum Products

Plant Tissue

PSD

Pulp

Pulp and Paper

Radio Chemistry

Rainwater

Raw Sewage

Seawater

Sediment (Toxicology)

Sediment/Sludge

Sewage

Sewage/Effluent

Sewage/Effluent/Soil

Slides/wedge

Sludge

Sludges

Soil

Soil (Radiochemistry)

Soil (Toxicology)

Soil/Sediment

Soil/Sediment (Toxicology)

Soil/Sludge

Soil/Sludge/Compost/Sediment

Soil/Sludge/Sediment

Soil/Solid

Soil/Solid Industrial Waste

Solids/Waste

Soils/Sludge/Compost/Sediment

Solid Waste

Solids

Solids/Sludge

Solids/Sludge/Sediment

Surface Water

Tailings & Waste Rock

Tailings, Waste Rock, Soil & Ore

Tissue

Vegetation

Vehicle Exhaust

Waste

Wastewater

Wastewater (Microbiology)

Water (Inorganic)

Water (Microbiology)

Water (Organic)

Water (Radiochemistry)

Water (Toxicology)

Water/Effluents

Water/Effluents/Sewage

Water/Wastes

Water/Wastewater

Environmental Conditioning:

Temperature

Vibration and Shock

Environmental Conditions and Systems:

Marine Conditions

Meteorological Conditions

Liquid Wastes:

Occupational Health and Safety:

Air Monitoring

Asbestos

Building Components

Biohazard Cabinets

Clean Air Devices

Clothing

Detection Instruments

Diving

Emitting Equipment

Fire Protection

Health Hazard Technologies

Noise

Personal Protection

Security Equipment

Warning Devices

Sediments, Soils:

Solid Waste; Nuclear:

Water Quality:

Drinking Waters

Ground Waters

Industrial Chemicals and Wastes

Industrial Effluent

Precipitation

Process Waters

Recycled Waters

Saline Waters

Surface Waters

Other (Specify):

FORENSICS

Counterfeits

Firearms / Tool Marks Forensic Biology / DNA

Forensic Chemistry / Trace Analysis Forensic Drug Chemistry

Forensic Equine Drug Testing Forensic Toxicology

Questioned Documents Examination Other (Specify):

MACHINERY

Boilers, Pressure Vessels and Piping:

Portable Utility Engines

Pumps and Related Equipment

Munitions and Arms: (Ballistics)

Bombs

Cartridge

Civilian Small Arms

Grenades

Military Heavy Arms

Military Small Arms

Military Warheads

Shotgun

Stationary Equipment:

Engines

Hoists

Turbines

Winches

<u>Transportation</u>, <u>Agricultural and Construction Vehicles and Components:</u>

Automobiles, Light Trucks, Vans & Trailers

Boats and Ships

Recreational, All-Terrain

Trucks, Heavy Duty, Commercial, Buses & Trailers

Other (Specify):

MARKETPLACE PRODUCTS-CONSUMER AND BUSINESS

Books:

Educational

Materials

Magazines and Journals

Newspapers

Equipment, Miscellaneous:

Burglary Protection Equipment

Mechanical Equipment

Motors, Generators and Machines

Furniture and Consumer Articles:

Furniture

Hazardous Products

Household Products

Musical Instruments

Sports Equipment

Tools

Toys

Marine Products:

Flotation Aids, Components

Lighting Fixtures, Marine Products

Trade and Commercial Goods:

Business Materials

Containers and Packaging

Other (Specify):

MEDICAL

Medical Products:

Devices (Non-Electrical)

Limbs

Surgical Instruments

Sterile Dressings (See also CHEM Pharmaceuticals)

Treatment Equipment

Medical Testing:

- 1) Bacteriology
- 2) Biochemistry
- 3) Cytology
- 4) Genetics / Cytogenetics
- 5) Hematology
- 6) Immunology
- 7) Microbiology
- 8) Molecular Biology
- 9) Mycology
- 10) Parasitology
- 11) Pathology
- 12) Transfusion medicine
- 13) Virology

Other (Specify):

Veterinary:

METALLIC ORES AND PRODUCTS

Articles of Metal:

- All Forms, Articles of Metal
- Welded
- Components, Articles of Metal
- · Cast, Forged, Welded or Pressed Metal Components

Basic Metal Products: (Ingots, pigs, bar, sheets)

Concentrates, Metallic Liquors and Other Process Products:

Metallic Ores:

- Formulations
- Metal Powders
- Precious Metals
- Rocks and Ores
- Sediments

Mineral Analysis Testing

- Assay, Umpire Assay Work
- Contract Settlement Assaying
- Geotechnical Testing
- Mineral Assaying

Semi-Fabricated Products: (Extrusion, rolled sections)

Tools, Fasteners and Hardware:

Other (Specify):

NONDESTRUCTIVE EXAMINATION

Acoustic Emission:

Eddy Current:

<u>Industrial Ultrasonics:</u>

Industrial Radiography:

Infra-Red Thermography:

Leak Testing:

Liquid Penetrant:

Magnetic Particle:

Ultrasonic:

Vibration Analysis:

Visual, Welding:

Other (Specify):

NON-METALLIC MINERALS AND PRODUCTS

Bituminous and Other Organic Materials, Coal and Tar:

Bitumen

Cement and Cement Based Products:

- Accessories
- Composites and Types (Concrete, Mortar, etc.)
- Gypsum
- Lime
- Products (Blocks, etc.)

Ceramics; Clay and Clay Products:

- Bricks and Structural Tile
- Ceramics
- Clays
- Porcelain Enamels
- Refractory and Firebrick

Energy Equipment: (Appliances)

- Handling of Liquid Fuels
- Kerosene Fired
- Appliances
- Miscellaneous, Energy Equipment
- Natural Gas Fired Appliances
- Oil Fired Appliances
- Propane Fired Appliances
- Safety Devices and Supplies
- Solid Fuel Fired Appliances
- Venting Equipment for Products of Combustion

Glass and Glass Products:

- Constituents and Formulations
- Glassware

Oil Shale and Tar Sands:

Petroleum Crudes and Natural Gas:

- Petroleum Refinery Products: (Including asphalt materials; petrochemicals; fuels and lubricants)
- Asphalt
- Fuels and Lubricants
- Petrochemicals
- Solvents

Soil; Aggregates; Stone; Sand:

- Aggregates (See Geotechnical Surveys, this section
- Geotechnical Surveys
- Constituents
- Hydrogeology
- Methods
- Soils
- Stone
- Sand

Solid Fuels and By-Products:

- Coke
- Peat

Other (Specify):

TEXTILES AND FIBROUS MATERIALS

Apparel and Other Finished Textile Products:

- Carpets
- Clothing
- Flags and Decorations
- Furniture Coverings
- Mattresses
- Tents
- Window Coverings

Textile Mill Products: (Including synthetic and natural fibres)

- Aircraft Materials
- Fabrics
- Fibres
- Yarns

Other (Specify):

WOOD PRODUCTS

Construction Materials: (Including for Furniture)

- Finished Wood
- Floor covering
- Logs
- Lumber
- Panel Products (Except Plywood)
- Plywood
- Poles
- Prefabricated Components
- Timers

- Wood Preservatives
- Wood Products, General

Fasteners and Hardware: (See Construction)

Paper and Allied Articles

- Containers and Packaging (See Marketplace Products)
- Packaging Components and Materials
- Paper and Paperboard
- Paper Products
- Pulp

Physical Properties of Wood Products

- Density, Wood Products
- Moisture Content, Wood Products

Structures and Components of Wood Products

Other (Specify)

Note 8: The above is a partial list and if any product is not captured in the list, the Team Lead and Lab will consult with each other and identify a suitable class code based on the Harmonized Commodity Description and Coding System (HS Convention) of the World Customs Organization (WCO). Please refer to: http://www.wcoomd.org/en/topics/nomenclature/instrument-and-tools/hs-nomenclature-2022-edition.aspx

12. Appendix – Examples for the presentation of scope

The examples provided below capture only the minimum information required.

12.1 Testing Laboratories – Fixed Scope

SOP Name/Identifier could be under the	1. Title / Description
following three options: 1. reference method	2. Title/Description (modified reference method)
2.modified reference method	3. Title / Description (in-house)
3. internal method identifier	Technique / Equipment
	Tooliiniquo / Equipmont
	Matrices / Component /
	parameter / Characteristic
	Analytes/ Material / Product

Following are some specific examples considering different scenarios.

 Where a reference method is followed exactly as written and the lab does not rewrite the method in their own format:

Reference Method Unique ID	Title/Description
	Technique / Equipment
	Matrices / Component /
	Matrices / Component /
	parameter / Characteristic
	A 14 (M 4 : 1/B 1 4
	Analytes/ Material / Product

Where a reference method is followed exactly as written and the lab re-writes the

method in their own format, there are **two** options:

Reference Method Unique ID	Title/Description (internal method unique ID and Title)
	Technique / Equipment
	Matrices / Component /
	parameter / Characteristic
	Analytes/ Material / Product

OR

Title/Description (internal method unique ID and Title)	Reference Method Unique ID
	Technique / Equipment
	Matrices / Component /
	parameter / Characteristic
	Analytes/ Material / Product

• Where a reference method is modified, in any way, there are **two** options:

Internal Method Unique ID	Title/Description (modified + reference method unique ID)
	Technique / Equipment
	Matrices / Component /
	parameter / Characteristic
	Analytes/ Material / Product

OR

Title/Description (modified + reference	Internal Method Unique ID
method unique ID)	Technique / Equipment
	Matrices / Component /

parameter / Characteristic
Analytes/ Material / Product

• Where a method is developed in-house, there is **one** option:

Internal Method Unique ID	Title/Description
	Technique / Equipment
	Matrices / Component /
	parameter / Characteristic
	Analytes/ Material / Product

12.2 Testing Laboratories – Flexible scope for TMDNRT Laboratories

Program specialty Area
Field of Testing
Description of Activities
Description of Measurement Techniques
Procedures used for Test Method Development & Evaluation and Non-routine Testing

12.3 Testing Laboratories – Flexible scope for Forensics Laboratories

Program specialty Area
Field of Testing
Description of Activities
Description of Measurement Techniques

12.4 PT Providers

Title / Description / Scheme

Type of activity / parameter

Measurand(s) or characteristic(s) or where appropriate the type of measurand(s) or characteristic(s)

Measurement range, target concentration and additional parameters where applicable

12.5 Calibration Laboratories

SOP Name/Identifier	Title / Description
	calibration or measurement method or procedure and type of instrument or material to be calibrated or measured
	Measurand or reference material
	Measurement range and additional parameters where applicable
	measurement uncertainty

Note 9: For further guidance, please contact NRC-CLAS for information on presentation of scopes of accreditation for calibration laboratories. https://nrc.canada.ca/en/certifications-evaluations-standards/calibration-laboratory-assessment-service

12.6 Medical Laboratories

Principal Discipline
Sub-discipline
Analytical parameters
Analytical Principle
Matrices /Component/Characteristic

A laboratory having POCT accreditation according to ISO 15189 lists POCT on the scope of accreditation in the annexes of the scope created for this purpose. Under the discipline to which the POCT belongs, an indication is included to link the discipline to the corresponding POCT. Please refer to the medical laboratory scope template to find out how sites within/under the same establishment of the accredited laboratory are presented.

Note 10: Please contact the Bureau de normalisation du Québec - Évaluation des laboratoires (BNQ-EL) for information on presentation of scopes of accreditation for medical laboratories for further guidance at bnq.qc.ca.

- End of Document -