Medical Laboratory Accreditation Program (MLAP)

Program Overview

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Standards Council of Canada

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Medical Laboratory Accreditation (MLAP): Program Overview

SCC accreditation helps medical testing laboratories deliver services with confidence and attract new customers. SCC accreditation proves a medical testing laboratory's ability to manage and perform activities defined by its specific program scope of accreditation.

For laboratories based in Quebec, the program is offered in collaboration with the Bureau de normalisation du Québec (BNQ). Under this program, medical testing laboratories are assessed by BNQ and based on BNQ's recommendation, are accredited by SCC.

1. Accreditation Program Requirements

ACCREDITATION REQUIREMENTS ***(SCC is a signatory to ILAC and APAC for this accreditation program)***	**PARTNER**	**REGULATOR/ SCHEME OWNER**
• ISO 15189:2012 Medical laboratories — Requirements for quality and competence (until December 2025) • ISO 15189:2022 Medical laboratories — Requirements for quality and competence • ISO 15190:2020 - Medical laboratories — Requirements for Safety • CAN/CSA-Z902-20 Blood and blood components • SCC Requirements & Guidance – Proficiency Testing for Testing and Medical Laboratories • SCC Guidance for the Presentation of Laboratory Scopes of Accreditation • ILAC P8:11/2023 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status • ILAC P9:01/2024 ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing • ILAC P10:07/2020 ILAC Policy on Traceability of Measurement Results	Bureau de normalisation du Québec (BNQ)	Medical laboratories are required to be accredited in the provinces of Quebec, Ontario, New Brunswick, and Newfoundland and Labrador.

2. Accreditation Cycle

As per Program Overview LAP.

3. Partner Organization

As per Program Overview LAP.

4. Group Accreditation

As per Program Overview LAP.

5. Scope Retention for Routine Tests Conducted Infrequently

As per Program Overview LAP.

6. Policy for the Selection of Sample Collection Facilities and of Establishments where POCT is offered to be Evaluated

6.1 Introduction

This document is intended for the assessment of medical laboratories which have multiple sample collection facilities and/or establishments or sector where POCT is performed or offered (sites) to ensure that the evaluation provides adequate confidence in the conformity of the management system to the applicable standard across all facilities (sites), all POCT on the scope and that the evaluation is both practical and feasible in economic and operative terms.

Normally initial assessments and subsequent reassessments should take place at every site of the organization included in the scope of accreditation. However, where an organization's activity is carried out in a similar manner at different sites, all under the organization's authority and control, the accreditation body may put into operation appropriate procedures for sampling the sites at the initial assessment and subsequent reassessments. This document addresses the calculation of sample size.

6.2 Requirements for the organization

The organization's management system shall be under a centrally controlled and administered plan and be subject to central management review.

For the external establishments where is perform POCT or perform sample collection facilities, all the relevant sites (including the central administration function) shall be subject to the internal audit program of the organization, and all shall have been audited in accordance with that program prior to the accreditation body starting its evaluation.

For facilities that participate in sample collection activities, the laboratory must demonstrate that it conducts assessments to ensure compliance with pre-analytical requirements.

It shall be demonstrated that the central laboratory of the organization has established a management system in accordance with the relevant management system standard and that the whole organization meets the requirements of the standard.

6.3 Sampling

Methodology

The sample should be selected based on the factors set out below and should result in a representative range of different sites being selected, without excluding the random element of sampling within a certain geographical region.

The sample should be selected so that the differences among the sites selected over the period of validity of the certificate are as large as possible.

The site selection may include, among others, the following aspects:

- Results of internal site audits and management reviews or previous accreditation assessments;
- Records of complaints and other relevant aspects of corrective and preventive action;
- Significant variations in the size of the sites;
- Variations in shift patterns and work procedures;
- Type of establishments or sector;
- Number of POCT operators in the same site;
- Different type of POCT;
- Complexity of the management system and processes conducted at the sites;
- Maturity of the management system and knowledge of the organization; and
- Geographical dispersion.

This selection is to be done at the start of the assessment process. The laboratory shall be informed of the sites to be included in the sample. This can be on relatively short notice but should allow adequate time for preparation for the assessment activity.

Size of Sample

The following calculation is applied:

Guiding the number of sites or site category to be visited is as follows:
Initial assessment and subsequent reassessments: the size of the sample should be the square root of the number of sites, rounded up to the next whole number.

In the case of the samples collection sites, the main sample collection site (usually the one attached to the laboratory) shall be assessed during every initial accreditation and subsequent reaccreditations.

The size or frequency of the sample should be increased where the accreditation body's risk analysis of the activity covered by the management system subject to accreditation indicates special circumstances in respect of factors such as:

- Variations in working practices (e.g., shift working);
- Variations in activities undertaken;
- Records of complaints and other relevant aspects of corrective and preventive action;

- Results of internal audits and management review; and
- Results of the accreditation body's previous assessment activities.

Example:
One laboratory with one central sample collection site and 27 sample collection sites

Initial assessment: central sample collection site and 6 (sq. root of 27 rounded up to the next whole number) sample collection sites are visited (total of 7).

Reassessment: central sample collection site and 6 (sq. root of 27 rounded up to the next whole number) sample collection sites are visited (total of 7).

The same calculation applies for the external site with POCT.

Additional Sites

On the application of a new group of sites to join an already accredited laboratory, the new group of sites is considered as an independent set for the determination of the sample set for the scheduled reassessment. After the inclusion of the new group, the new sites will be added to the existing ones for determining the sample size for future reassessment visits.

Example:
For the previous example, the laboratory decides to include 5 new sites.
For the reassessment, central sample collection site, 6 (sq. root of 27 rounded up to the next whole number) sample collection sites among the ones previously accredited and 3 sites among the new ones (sq. root of 5 rounded up to the next whole number) are visited, total sites visited being 9.
For the future reassessments, 7 (sq. root of 32 rounded up to the next whole number) sites are visited.

6.4 Outcome of the assessment of sample collection facilities and of the establishments where POCT is offered or performed

For an organization to obtain and maintain accreditation, all the visited sites shall meet the appropriate requirements of the standard.

Revision History

VERSION	DESCRIPTION OF CHANGE(S)	APPROVED DATE
1	• Initial Release • Separating program-specific content out of the ASB Program Overview • International recognition • Made reference to LAP POV in applicable sections • ISO 15189 is now listed • Added applicable ILAC accreditation requirement	2024-04-01