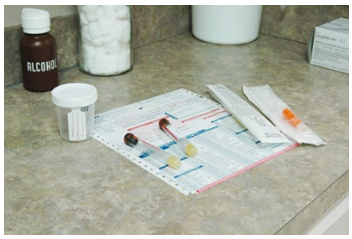
College of Physicians and Surgeons of Saskatchewan

Laboratory Quality Assurance Program



ACCREDITATION PROGRAM GUIDE

Medical Laboratory Facilities – 4-Year Accreditation

Contents

1.0 Purpose of Accreditation

The purpose of assessing and accrediting laboratories is to evaluate and ensure compliance with established standards, identify areas of excellence and to provide recommendations for improvement.

Accreditation is defined as the public recognition of quality achievement by a health care organization, as demonstrated through an independent external peer comparison of the organization's performance against current best practices.

2.0 Authority and Oversight

The CPSS is contracted by the Ministry of Health (MOH) to operate the Laboratory Quality Assurance Program (LQAP). As designated in the Medical Laboratory Licensing Act and Regulations, the LQAP is responsible for the requirements and standards of Medical Laboratories in the Province.

The LQAP Committees consist of the Program Management Committee (PMC) and discipline specific Quality Assurance (QA) Committees for Anatomic Pathology, Chemistry, Hematology, Microbiology, and Transfusion Medicine. Committees are comprised of medical and technical experts in these disciplines. The QA Committees review facility assessment reports and proficiency testing deficiencies. The PMC is the oversight body for operations and decision making for the program. It is comprised of the chairs of the discipline specific committees along with representation from the Saskatchewan Association of Combined Laboratory and X-ray Technologists, Saskatchewan Society of Medical Laboratory Technologists and a representative from the MOH.

Those facilities holding a Medical Laboratory License are subject to assessment. All Assessment findings are shared with the MOH. The MOH receives bi-annual updates of accreditation status.

2.1 Overview

Facilities are assessed on a four-year rotation. Assessment may occur prior to four-year rotation if PMC determines that evidence of compliance was not adequate.

The LQAP uses a peer review process with a goal to improve laboratory performance through objective education. Assessors evaluate a laboratory's compliance with the specific requirement of a standard based on objective observation and assessment.

Accreditation looks at compliance, emphasizing continuous quality improvement and promoting optimum performance. The program looks at policies, processes, and procedures to assess the safety and reliability of the service provided as well as the performance of the people involved, and the product produced.

The LQAP examines all aspects of laboratory quality and operations including:

- Organization, management, and personnel

- Quality management systems
- Physical facilities
- Equipment, reagents, and supplies
- Laboratory information systems
- Pre-examination, examination and post-examination activities
- Quality assurance activities
- Safety
- Point-of-care testing

All assessment findings are reviewed by discipline specific Quality Assurance Committees and the Program Management Committee to ensure consistency for all facilities.

Responses for non-conformance are due within 30 or 60 days of final report; this includes evidence of compliance.

PMC determines if acceptable evidence of compliance has been received. PMC determines if any outstanding non-conformances would substantiate a reversion to "provisional" accreditation status. If this decision is made a "provisional" certificate is issued and the laboratory must replace their previous certificate. Once the "provisional" non-conformances are satisfactorily addressed, the laboratory is granted "full accreditation" and a new certificate is issued.

Program Management Committee grants accreditation upon receiving acceptable evidence of compliance.

2.2 Assessment Teams

Peer review is conducted by the assessment team. Trained team leaders conduct opening and summation conferences and assist in report and response review. Team members have subject matter expertise and are selected based on scope of service.

2.2.1 Assessment Team Training

All assessment team members are required to participate in Assessor Training, within 6 weeks prior to performing an on-site assessment. Upon successful completion of the training assessors receive a continuing education certificate if requested.

2.2.2 Confidentiality

All assessment team members must sign a confidentiality agreement. All confidential assessment materials must be destroyed or returned to LQAP for confidential disposal.

2.2.3 Conflict of Interest

All assessment team members are required to sign a conflict-of-interest agreement.

3.0 Standards Document

3.1 Standards Overview

The standards are the basis for accreditation decisions and are compiled by CPSA, WCDAA members and other relevant stakeholder experts. They are reviewed and approved by WCDAA member organizations with final approvals by the CPSA Advisory Committee on Laboratory Medicine and Medical Facility Accreditation Committee.

The standards are evidence based and reference accepted best practices, Provincial and Canadian legislation, relevant International Organization for Standardization (ISO) standards (e.g. College of American Pathologists, CLSI, CSTM, Canadian Standards Association). Each accreditation standard has an accompanying reference citation(s).

All standards included in the documents are mandatory requirements for accreditation.

The Standards are process-based and incorporate a quality management system approach. The language, terms, and organization of the documents are consistent with ISO 15189.

A review of accreditation standards occurs on an ongoing basis, considering and incorporating stakeholder feedback. Comprehensive formal review occurs on an annual basis.

The CPSA/WCDAA currently maintains the following standards documents for the assessment of medical laboratory facilities:

- General
- Anatomic Pathology
- Chemistry
- Fertility Assessment – Semen Analysis
- Flow Cytometry
- Hematology
- Microbiology
- Molecular Diagnostics & Genetics
- Transfusion Medicine

For Histocompatibility (HC) Testing the LQAP accepts certification/accreditation by American Society for Histocompatibility & Immunogenetics (ASHI) or the College of American Pathologists (CAP).

Prior to each assessment, customized standards documents, tailored to the scope of testing of a facility, and are made available to:

- Facilities for self-assessment and/or prepare for an on-site accreditation assessment
- Assessors for on-site assessments

3.2 Format of Standards

All standards documents are consistently organized in the following order (as applicable in each document):

- Organization, Management and Personnel
- Quality Management System
- Physical Facilities
- Equipment, Reagents, and Supplies
- LIS
- Pre-examination policies, processes, and procedures
- Examination policies, processes, and procedures
- Quality Assurance of examination procedures
- Post-examination policies, processes, and procedures
- Safety
- POCT

The 'General Standards' document includes ALL standards common to ALL disciplines. To eliminate redundancy, the discipline-specific standards include ONLY those standards specific and relevant to each discipline. For example, general quality control, proficiency testing, calibration, validation, and procedure manual standards are not repeated in each discipline standard.

Standard Document Format Example

#	Standard	Reference	Assessment of Compliance
G.10.2 Safety – Physical Facility continued			
G.10.2.2 **SS**	Laboratory design ensures containment of hazards, appropriate to the level of assessed risks in technical work and associated areas.	CSA[3] 15190 – 6.2, 6.3.6 NCCLS[8] GP17-A2 – 4.2.6 Guidance: Laboratories working with viable biological agents shall have design characteristics appropriate to the containment of microorganisms of moderate to high risk to the individual. Laboratories designed to work with organisms of Risk Group III or above shall include design characteristics for greater containment.	Does the laboratory design ensure containment of the following hazards: - Microbiological? - Chemical? - Radiological? - Physical? Does the laboratory design provide a safe working environment in associated office areas and adjoining public space? Does the laboratory have a process to minimize and respond to environmentally related risks to the health and safety of employees, patients, and visitors?

			C ☐ P☐ E ☐ N ☐
			Observation:

Each standard consists of the following components:

- Standard number
- Patient or staff safety risk category (where applicable):
    - Each standard has been reviewed to determine if it represents a direct and/or immediate patient or staff safety risk.
    - Those with either patient safety (PS) or staff safety (SS) designation indicate that any non-compliance may have direct and/or immediate impact on safety.
    - PS/SS standards are 'shaded' for ease of detection.
    - Assessors must ensure that ALL standards with either a PS or SS designation are directly assessed at the time of the on-site assessment.
- Description of standard requirement.
- Specific reference(s) (e.g. CLSI, ISO, AABB, College of American Pathologists) are listed at the end of the document.
- Interpretation guidance where relevant regarding the application of requirements.
- Assessment of compliance questions (AOC) that provide specific guidance and practical direction for evaluation of compliance with the standard.
- Compliance assessment category checkboxes.
- Observation field for recording objective evidence.

3.3 Assessment of Compliance (AOC)

- Although the AOC questions address the key evidence required to meet the intent of each standard, they are not meant to be all encompassing.
- There may be other evidence that demonstrates compliance with the intent of the standard. Individual assessors apply their own expertise in determining compliance with each standard.
- Compliance with the standard may be assessed by review of documents and records, observation or a combination of these techniques.
- Where AOCs state "All of the following", compliance with all elements is expected to achieve compliance with the standard.

Compliance Assessment Categories:	
C	Meets intent and requirements of standard
P	In progress (working towards meeting intent and requirements of standard; assessor notes evidence of progress towards full compliance)
E	Exceeds requirements of standard
N	Does not meet intent and/or requirements of standard

N – Upon assessment of the objective evidence, failure to meet the intent and/or requirement of the standard will result in an assessment of non-compliance.

The standards are process based and a single non-compliance may encompass one or more observations. In assessing compliance with the standard, assessors will record specific objective evidence, which will be included in the report for each non-compliance.

P – "In Progress" citations require submission of future evidence of compliance based on direction from PMC. Examples where this assessment may be applied include situations such as: equipment purchased but not on-site and/or implemented; renovations in progress but not complete.

Receipt of "FULL" accreditation status is contingent upon satisfactory resolution of all non-compliances (N and P).

E – "Exceeds Requirement" recognizes those situations where a facility exceeds the intent of the standard and employs commendable practice. The intent of capturing these occurrences is to promote and focus on quality initiatives.

3.4 Terms and Definitions

A list of application terms and definitions is provided at the end of each standards document.

3.5 Reference Listing

A detailed reference listing is provided at the end of each document. The references support the content and intent of each standard. It should be noted that all components of the cited references may not always be relevant and/or applicable. Compliance is expected with CPSS standards.

3.6 Review and Revision of Standards

A comprehensive review of references occurs annually to ensure they are compliant with current standard references and best practices. Supporting references and any new references are reviewed, updated and their impact (if any) on the wording of the requirement is assessed.

Any stakeholder may offer suggestions for standards revision at any time.

Revision submissions are considered ONLY if they meet the following conditions:

- Submitted using the Stakeholder Standards Review Form.
- Identification of specific standard or section if applicable to multiple standards.
- Supported by detailed rationale/justification AND verifiable references (link or attachment must be included).
- Applicable to all diagnostic laboratory facilities across the province and are not limited to organization specific practice.
- Contact information included for use if clarification of submission is required.

3.7 Copyright

The WCDAA Standards are copyright College of Physicians and Surgeons of Alberta. College of Physicians and Surgeons of Alberta (CPSA) accredited laboratories and other approved users may download, print or make a copy of this material for their noncommercial personal use. Any other reproduction in whole or in part requires written permission from the CPSA and the material must be credited to the CPSA.

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4.0 Accreditation Process

4.1 Initiation

LQAP notifies facility of their assessment.

4.2 Pre-assessment

LQAP in collaboration with the laboratory supervisor determines specific assessment dates.

LQAP sends a letter to the region that includes:

- Notification of dates and times
- Request of test menu
- Provision of lunch
- Room for assessment team

LQAP selects a team leader and assessment team. Potential conflicts of interest are considered when selecting the assessment team. Selection of assessment team is based on:

- Scope and competency of laboratory service
- Experience and availability of team members
- Out of province assessor requirements

The LQAP distributes customized standards to facilities. Customization is based on information provided from the facility. Sections not pertaining to the facility are removed.

LQAP prepares and distributes customized assessment supporting documents for each assessor:

- Previous inspection report
- 4-year summary of EQA performance
- Facility test menu
- Customized facility specific standards (reflecting assessor focus)

- Discipline specific assessor guides
- Expense form
- Copy of General standards

The LQAP organizes accommodation and travel for assessment teams. This information is distributed to the individual team members and to the team leader.

Assessment team training is conducted by LQAP. Assessment team training:

- Mandatory for assessment team members to participate in prior to the assessment
- Continuing education certificates are when requested

Training sessions encompass:

- Overview of LQAP assessment process and standards
- General guidance
- Overview of confidentiality, honoraria, expenses

Assessment team members are expected to review the assessment documentation relevant to their scope of assessment activities to ensure they are prepared. The purpose of the review is to become familiar with the General and the discipline specific standards and to identify areas of concern for further follow-up. (Previous citations, EQA exceptions)

Prior to the assessment, the team leader conducts a meeting for the team members. This meeting is usually the evening prior to the assessment and includes:

- Introductions
- Schedule
- Discussion of areas of concern/focus
- Questions
- Confirmation of each assessor's discipline

Assessment team members conduct on-site assessments in areas of expertise.

Assessment process – General:

- Verifying compliance with the intent of accreditation standards
- Follow up previous non-conformances
- Interact with staff at all levels
- Each assessor must use both the General standards and their discipline specific standards

Assessor Behavior:

- Engage in clear and concise dialogue with facility staff
- Assess according to the standards
- Use an educational approach

- Do not act as a consultant
- Be conscious of assessment timeline
- Closed toed shoes

Assessment of Compliance (AOC)

- The AOC questions address key evidence required to meet the intent of each standard, they are not meant to be all encompassing
- There may be other evidence that demonstrates compliance with the standard
- Where the AOC state “all of the following”, compliance with all elements is expected
- Assessors apply their own expertise in determining compliance or may consult with the team leader.
- Compliance with the standard may be assessed by review of documents

Guidance for assessors

When assessing laboratory sections:

- It is not possible to review the entire scope of laboratory operations
    - Focus on areas of highest and lowest test volumes, likely problem areas and test results with highest impact on patient care
    - Directly assess ALL standards with either a PS or SS designation
    - Verify that all non-conformances cited on the previous assessment have been corrected
    - Utilize the Assessor Guides to focus/direct assessment
- Review regional managed programs/processes (LIS, POCT)
- Review documents (policies, processes, and procedures – PPP’s) and records
    - The assessor should choose a random representative selection of documents and records to review
    - Assessors should not rely solely on documents/records chosen or selected by the facility for review
- Observe activities
    - Engage in meaningful dialogue with laboratory and non-laboratory staff (ask open ended questions such as what, when, where, why, who, how)
    - Compare observed activities to the facility policies, processes, and procedures
    - Use techniques such as:
        - Tracer method: follow a sample through pre-examination, examination and post-examination
        - Drill-down: further investigate areas of concern
        - Show/teach me: staff members describe a procedure as they perform it
- Gather information
    - Always seek corroboration/validation/verification of findings
    - Evaluate for significance
- Determine the scope and nature of potential citations

    - Is there a P/P/ or P?
    - Is the P/P/ or P in compliance with the standards?
    - Is the P/P/ or P being followed as written?
    - Is there evidence of training/competency assessment for the activity?
    - Is there acceptable documentation of the activity?
    - Is the required review of the activity performed and documented?
- Discuss/confirm potential deficiencies with facility representatives
- Record objective evidence
    - As immediately as possible after encountering citation
    - Paper or electronic may be used to document
    - Do not rely on memory
    - Be factual and thorough
    - Provide ample background detail for interpretation and determination
- Photographic evidence for the QA Committees
    - For safety related citations, consult with team leader for necessity to corroborate observation with photographic evidence
    - Team leader will be responsible for notifying the facility contact and taking required photographs
    - Team leader will ensure that no individuals or confidential information are identifiable in the photographs

Compliance Assessment Categories:

- Non-conformances (N)
    - Failure to meet the intent and/or requirement of the standard
    - The standards are process based and a single non-compliance may encompass one or more observations
- In-progress citations (P)
    - Working towards meeting intent and requirements of standard; assessor notes evidence of timely progress towards full compliance
    - Examples where this assessment may be applied include situations such as: equipment purchased but not on-site and/or implemented; renovations in progress but not complete
    - Are not meant to address partial or incomplete compliance (e.g. incomplete manuals)
- Exceeds requirement citations (E)
    - Recognize those situations where a facility exceeds the intent of the standard and employs commendable practice
    - The intent of capturing these occurrences is to promote and focus on quality initiatives

4.3 On-Site Assessment

At the beginning of the on-site assessment at each facility, the team leader conducts an opening meeting for facility personnel to include:

- Introductions
- Assessment timeline
- Process outline

A tour of the laboratory follows which gives a general overview of the laboratory operation and key personnel.

The assessment team members must notify the team leader immediately of any serious deficiencies that may have immediate impact on staff or patient safety. The team leader will bring it to the attention of the appropriate laboratory personnel for prompt action. The team leader will determine the necessity and urgency of possibly contacting the LQAP.

The assessment team members must communicate the non-conformance to the individual recording results multiple times throughout the day. The assessors must provide:

- Standard number
- Compliance assessment category
- Detailed observation/evidence

All citations must include sufficient and clear detail in the evidence.

The team leader will conduct a pre-summation conference team meeting. This meeting will summarize the assessment findings.

A summation conference will be conducted by the team leader. In person summation conferences are conducted at each facility at the end of the assessment.

Summation conference will include:

- Citations
- Commendable findings
- Acknowledgement of laboratory personnel for their co-operation

4.4 Post-Assessment

The final report is completed by LQAP and is based on the citation recorded summaries. LQAP ensures consistent:

- Application of the standards based on observations
- Wording of requirements

Evidence of compliance (EOC) is required either 30 or 60 days after receiving the final report. A significant safety issue would require a 30-day response. All other EOC is due in 60 days.

Discipline specific and Program Management Committee review the reports. This review/revision/approval of reports is to:

- Eliminate bias
- Ensure consistent application of standards
- Ensure standards reflect best practice

The final report is distributed by LQAP to laboratory supervisor and Director Clinical Quality Safety Logistics. The final reports are formatted to include a section for the facility response to each non-conformance.

Accreditation evaluation forms are sent to facilities and assessors. This is to evaluate the effectiveness of the assessment process and customer satisfaction. Results are compiled and reviewed by LQAP.

EOC responses are reviewed by LQAP, discipline specific QA committees and PMC and team leader. The responses are reviewed for acceptability. Accreditation decisions of the LQAP are approved by PMC.

5.0 Honoraria and Expense Reimbursement

All assessors will be given an expense form. LQAP requires receipts for all expenses. The LQAP provides honoraria for:

- The assessors training session
- Travel time
- Assessment day
- Meals

All forms are submitted to LQAP.

6.0 Assessment Invoice

An invoice is issued to the facility after the assessment report is complete. Payment is due upon receipt of the invoice.