cpsa
COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

Accreditation Program Guide

Diagnostic Laboratory -
4 year accreditation

June 2023 V37

1.0 Purpose of Accreditation

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

The College of Physicians & Surgeons of Alberta (CPSA) diagnostic accreditation programs:

- assist facilities with a process of ensuring accuracy and reliability of examination/services
- provide standards of practice and assess compliance to these standards
- identify deficiencies that affect the quality of examination/services, and impact patient and/or staff safety
- evaluate a facility's quality system's ability to identify and mitigate risk and variability in system processes
- gives formal recognition of a facility's provision of quality diagnostic services
- encourage and facilitate peer review
- provide educational opportunities for both the facility being accredited and the Assessment Team
- promote uniformity in practice provincially, where variations in practice are counter-productive for the province
- maintain a comprehensive data repository for scope of service/levels of laboratory and resources
- promote standardization and educational initiatives across Canada through inter-provincial collaboration
- promote and encourage dialogue amongst stakeholders on best practices and best ways to incorporate them into the workflow
- ensure effective medical direction over medical practices so that business interests do not determine the standards of care

2.0 College of Physicians & Surgeons of Alberta (CPSA) Accreditation Program

2.1 CPSA LINES OF BUSINESS

CPSA is mandated by legislation to regulate the practice of medicine in Alberta and is responsible for licensing physicians, administering standards of practice and conduct, and resolving physician-related complaints.

It also provides leadership and direction on issues of importance to the health care system such as access to services, quality improvement, patient safety and privacy.

CPSA regulates the practices of medicine in Alberta including:

- registering physicians
- accrediting health facilities
- supporting continuing competence
- investigating and resolving physician-related complaints
- contributing to public policy affecting health care delivery
- guiding professional conduct and ethical behavior

2.2 CPSA MISSION, VISION, VALUES

Our Vision
Professional, ethical and competent regulated members, providing the highest quality care for all Albertans.

Our Mission
To serve and protect all Albertans, contributing to their health and wellness by supporting and guiding regulated members to proudly provide safe, high-quality care, together with healthcare partners and patients.

Our values

We do the right thing.
We act responsibly, respectfully and with integrity, aspiring to be fair and responsible. We acknowledge our mistakes as well as our successes, and strive to do what's right in the service to the public.

We make informed decisions.
Our decisions are based on evidence, knowledge, experience and best practice. We plan, measure outcomes and apply what we learn.

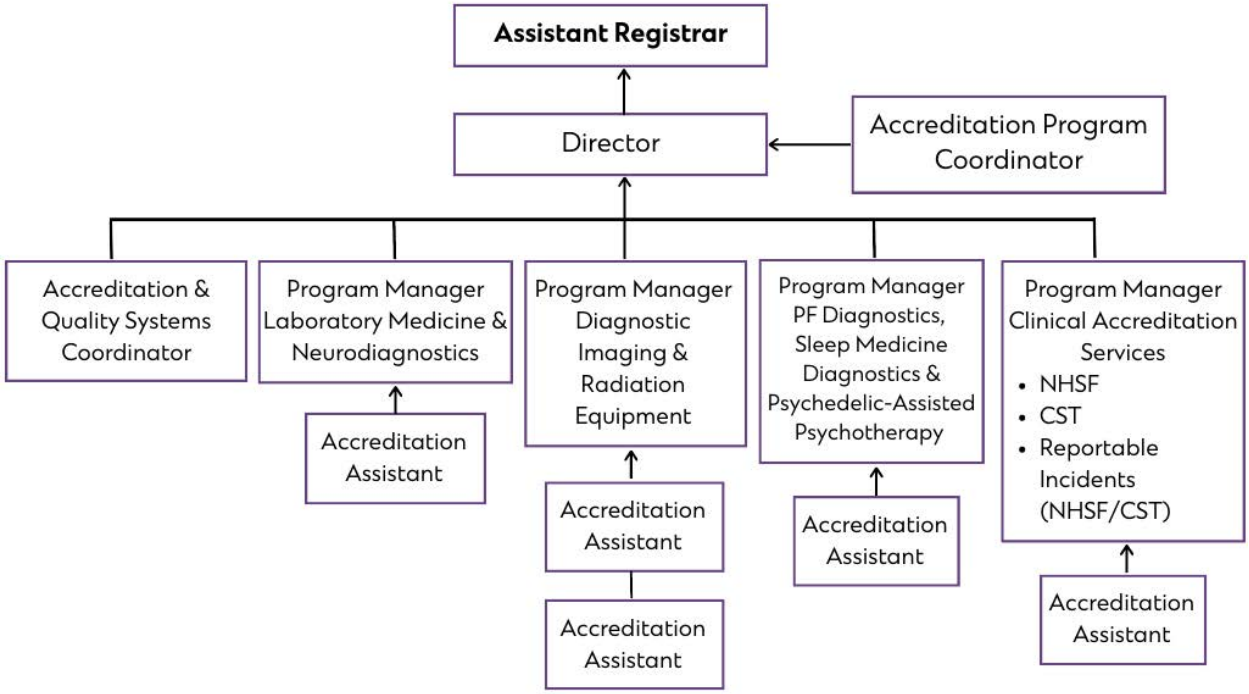
We empower people.
We believe people perform best when they see the Vision, set their own goals, have the resources they need and aspire to excellence and personal growth.

We collaborate.
We invite others to contribute to achieving our goals and value their time and expertise. We share what we know generously within our legislated limits, and seek opportunities to collaborate externally in areas of mutual interest.

We are innovators.
We think ahead to create opportunity. We set the bar high and value creativity in exploring new and better ways of doing our work.

We enjoy and find meaning in our work.
We care about what we do and give our best. While our work is serious, we enjoy camaraderie with our coworkers and take time to celebrate each other's milestones and achievements.

2.3 CPSA ORGANIZATIONAL STRUCTURE (ACCREDITATION DEPARTMENT) - FIGURE 1



CPSA: Feb. 2023

2.4 ACCREDITATION PROGRAM HISTORY

In 1965, CPSA, upon recommendation from the Alberta Society of Pathologists, took steps to set up a program for accreditation for diagnostic medical laboratories. The Advisory Committee on Laboratory Medicine, which then reported to Council of CPSA, was formed. The mandate of the Committee was to monitor and improve the quality of clinical laboratory services in Alberta. In order to meet this mandate, the Committee developed a process for accreditation that included requirements for on-site assessments of medical laboratories and a proposal for a proficiency-testing program to monitor testing performed.

The first assessments for accreditation took place in 1968 and included only non-hospital based laboratories. In 1970 the Alberta Department of Health entered into a contract with CPSA to accredit hospital-based laboratories on their behalf and to make recommendations to them pertaining to accreditation.

The CPSA Accreditation scope includes:

- Diagnostic Imaging (DI)
- Diagnostic Laboratory (LAB)
- Neurodiagnostics (NEURO)
- Cardiac Stress Testing (CST)
- Sleep Medicine Diagnostics (SMD)
- Hyperbaric Oxygen Therapy (HBOT)
- Pulmonary Function Diagnostics (PFD)
- Non-Hospital Surgical Facility (NHSF)

2.5 AUTHORITY AND OVERSIGHT

The College of Physicians & Surgeons of Alberta is constituted under the *Health Professions Act* (Schedule 21) with a mandate to regulate medical practitioners and medical practice in the best interests of the public of Alberta. Authority to accredit specified medical services and facilities is one aspect of that mandate.

Pursuant to section 8.4 of Schedule 21 of the Health Professions Act, and the Bylaws of CPSA, facility staff are required to cooperate fully with any assessment, which shall include:

a) permitting the assessment team to enter the laboratory facility and assess the premises and all diagnostic equipment located therein;
b) permitting the assessment team to assess all records pertaining to the provision of diagnostic laboratory services, and providing copies of the same if so requested;
c) providing to the assessment team, information requested by them in respect of the provision of diagnostic laboratory services, in the facility;
d) providing the information described in clause (c) in the form requested by the assessment team;

e) providing requested samples or copies of any material, specimen, or product originating from the diagnostic laboratory services, provided by the facility;
f) answering questions posed by the assessment team as to procedures or standards of performance and if requested, providing copies of records relating to procedures followed and standards of performance applied in the diagnostic laboratory facility;
g) providing requested copies of all documents and information relating to business arrangements involving the practice conducted in the diagnostic laboratory facility.

Although CPSA's statutory authority does not extend to health services in approved hospitals or healthcare facilities operated by the Government of Canada or the Government of Alberta (*Health Professions Act* Schedule 21 - 8.1(1)), the value of practice uniformity between the private and public sectors and the credibility of CPSA's programs have long been acknowledged by practitioners and government. Consequently, five of CPSA's accreditation programs (laboratory medicine, diagnostic imaging, pulmonary function, sleep medicine, and neurophysiology) are under contract with government agencies (AHS) to provide accreditation of public sector facilities.

CPSA's accreditation programs are overseen by a standing committee, the Medical Facility Accreditation Committee (MFAC), with members appointed by the Council from diverse disciplines in clinical and diagnostic medicine. MFAC conducts a secondary review of practice standards developed by the accreditation advisory committees, hears argument on all changes to accreditation standards and reviews all facility accreditation and physician approval statuses.

The 6 standing advisory committees are composed of peer professionals (both physician/technical) who identify the needs and realities of Alberta stakeholders based on local practice.

2.6 OVERVIEW OF LABORATORY ACCREDITATION PROGRAM

CPSA administers accreditation programs for those services that Council determines deserve explicit standards and verification of compliance with those standards, whether pertaining to the qualifications of physicians who provide them or the safety of those services to the public.

Accreditation looks at compliance, emphasizing continuous quality improvement and promoting optimum performance. More specifically, CPSA's accreditation program looks closely at policies, processes and procedures to assess the safety and reliability of the service being provided, as well as the performance of the people involved and the product produced.

The Laboratory Accreditation Program examines all aspects of laboratory quality and operations including:

- organization, management and personnel
- quality management systems
- physical facilities
- equipment, reagent and supplies
- laboratory information systems
- pre-examination, examination and post-examination activities
- quality assurance activities
- safety
- point-of-care testing

The Laboratory Accreditation Program is a peer review process with a goal to improve laboratory performance through objective evaluation. Assessors evaluate a laboratory's compliance with the specific requirements of a standard based on objective observation and assessment.

Benefits of CPSA laboratory accreditation program

- Assists facilities with the process of ensuring accuracy and reliability of testing/services
- Provides standards of practice and assesses compliance to the standards
- Identifies deficiencies that affect the quality of testing/services, as well as patient and staff safety
- Provides educational opportunities for both the facility being accredited and the inspection team
- Promotes uniformity in practice provincially – where variations in practice are counter-productive for the province.
- Promotes standardization and educational initiatives across Canada through interprovincial collaboration
- Maintains a comprehensive data repository for scope of service/modalities/levels of testing and resources within the province
- Promotes and ensures dialogue amongst providers and administrators on best practices and best ways to incorporate them into the workflow.
- Encourages and facilitates peer review.
- Ensures effective medical direction over medical practices so that business interests do not determine the standards of care.

Confidentiality

All assessment findings are confidential and are only disclosed to parties explicitly associated with an assessment. Documented consent must be obtained from the assessed facility for release of assessment findings or accreditation certificates to other parties.

Frequency and selection of laboratories to be assessed

Diagnostic laboratories are assessed initially when opened, subsequently on a four year rotation and if they relocate their laboratory to a different physical facility. This does not preclude an interim assessment that may be required as a result of expansion of services.

Assessments are conducted by geographical Sector areas ensuring that all laboratories within the designated Sector are assessed in the same calendar year. At the beginning of the year, all facilities in the area due to be assessed are identified and the Assessment Coordinator(s) and Team Leader(s) are assigned. All facilities, both public and private, performing laboratory examination for patient management, with the exception of physicians doing basic testing, are required to undergo an assessment. CPSA does not register or accredit Physician Office Laboratories.

After a new facility is registered and initially accredited, it will then be added in to the regular Sector geographical 4-year cycle. If the timing of this next 4-year cycle is very close to when the new facility was accredited, CPSA may choose not to re-assess the facility.

Facilities who are not reporting results for patient management and only testing as part of a screening process do not require CPSA Accreditation.

On-going self-assessment

CPSA laboratory accreditation General Standards requires facilities to conduct formal internal audits of all system elements, both managerial and technical, at a frequency defined in their quality management system. Facilities are not required to submit audit findings to CPSA.

CPSA accreditation standard tools are a significant resource for self-audits as they promote a constant state-of-readiness. Laboratories are able to customize the standards tools by:

- tailoring to scope of testing
- documenting/embedding links to policies, processes, procedures, records, forms and labels beside the relevant standard
- utilizing the tool for the performance of comprehensive or targeted audits in between the 4-year CPSA assessments

2.7 LABORATORY CLASSIFICATION

*Annual Fee Classifications For Diagnostic Laboratories	
A	High Complexity
B	Moderate Complexity
C	Basic Complexity
D	Specialized Complexity

*Categories apply to Annual General Administration Fees

Basic complexity
Perform test examinations limited to urinalysis, POCT pregnancy tests, glucose (glucose meters)

Moderate complexity
Perform routine chemistry, hematology/coagulation, transfusion medicine (type/screen/crossmatch or dispensary-only) (e.g. rural hospital laboratories)

High complexity
Perform moderate complexity scope of examinations plus any of the following (e.g. urban tertiary care laboratories etc.):

- Anatomic Pathology
- Microbiology (comprehensive organism identification and susceptibility testing)
- Molecular diagnostics
- Specialized chemistry and hematology
- Transfusion Medicine serological investigations

Specialized complexity
Perform only limited scope of examinations or very esoteric scope

2.8 PERSONNEL

2.8.1 CPSA laboratory accreditation personnel and roles

The Assistant Registrar for Accreditation has overall responsibility for the diagnostic accreditation programs and is supported by the Director of Accreditation, the Program Manager for Laboratory Accreditation Services and the Accreditation Program Coordinator.

2.8.2 Advisory Committee on Laboratory Medicine

The Advisory Committee on Laboratory Medicine (ACLM) oversees CPSA's accreditation program for medical diagnostic laboratories. Through the development of evidence based standards and monitoring facility compliance with those standards, the Committee promotes high standards of medical practice in diagnostic facilities.

Roles and responsibilities of the ACLM

- Develop and maintain evidence based standards for laboratory practice;
- Provide advice to the Medical Facility Accreditation Committee (MFAC) on pending decisions relating to the provision of laboratory medicine services;
- Monitor compliance with CPSA approved standards through on-site assessments for accreditation;
- Facilitate the introduction of new technologies;
- Provide advice to others in the health care system on the use of off-site/point-of-care laboratory testing by non-laboratorians;
- Provide education to promote safety and quality improvement initiatives;
- Respond to the needs of stakeholders for improved laboratory services in Alberta

Membership

Membership considers expertise, geographic location, urban versus rural and public versus private representation. Members who serve by virtue of their position, serve as long as they fill that position.

All voting members are registered health professionals responsible to their respective professional regulatory body for their competence, their standards of practice and their conduct.

The Chair is selected from the membership and appointed by the Medical Facility Accreditation Committee. In the absence of the Chair, an alternate will be selected from the members present.

It is the responsibility of the Chair to represent the Committee (either in person or virtually) for any appeals of Committee decisions that are made to MFAC.

Membership is comprised of 10 voting members.

For voting members, representation includes but is not limited to the following:

- Laboratory Physicians
- Laboratory Technologists

Tenure

Committee members are appointed by MFAC for the following terms:
Chair – Three year term with the option of a one year extension
Voting members – Five year term with the option of a one year extension

2.9 ASSESSMENT TEAMS

2.9.1 Assessment coordinator

Each assessment team will include an Assessment Coordinator who is a consultant of CPSA. Their primary role is to coordinate, organize, and facilitate the assessment process.

2.9.2 Team selection

CPSA selects the members of the team which may include experienced laboratory technologists, clinical laboratory doctoral scientists, and laboratory physicians. All team members are provided with the training, information and material necessary to conduct a fair and thorough assessment.

Selection of the assessment team is based on:

- scope and complexity of laboratory services
- number/geographic location of facilities
- experience of team members

The Assessment Coordinator(s) are present at each on-site assessment to promote consistency and continuity and to ensure an un-biased process.

2.9.4 Assessment team training

All assessment team members are required to participate in a CPSA Assessor Training module, within 6 weeks prior to performing an on-site assessment. Following completion of the training module, assessment team members must demonstrate competency by successful performance of an on-line examination.

Upon successful completion of the training module and exam, all assessors receive a continuing professional development certificate.

2.9.5 Conflict of interest / confidentiality agreements / liability

All members of CPSA accreditation committees and assessment teams sign a Confidentiality Agreement with CPSA on an annual basis. Committee members and assessors are also required to confidentially destroy all confidential assessment materials or return to CPSA for confidential disposal.

Assessment team members are also required to sign a Conflict of Interest for each assessment cycle to ensure there are no potential conflicts specific to that assessment.

While performing assessments for CPSA, assessors are advised not to display conduct that can be reasonably construed as a solicitation or offer consultant services that may compromise the objectivity of the assessment.

2.10 WESTERN CANADA ACCREDITATION ALLIANCE (WCAA)

In 2013, the medical regulatory bodies of the four western Canadian provinces embarked on a journey to consider opportunities for diagnostic laboratory accreditation resource sharing and collaboration. It is a well-recognized fact that standards and accreditation process development is a resource intensive initiative. The ultimate goal of sharing resources would also culminate in the enhanced standardization of accreditation processes across the member provinces.

To this end, the Western Canada Accreditation Alliance was formed. The initial and primary focus of the group was to join forces in the development of a common set of laboratory accreditation standards. The 4 member provinces in a fair and collaborative process, determined the key elements that were felt to be essential in a diagnostic accreditation standard. One of these critical elements was the certification of the standards by the International Society for Quality in Health Care External Evaluation Association (IEEA) as the value of achieving international recognition and validation of the standards was universally recognized and supported by all members.

Provincial representatives from each of the 4 member provinces utilized these elements to compare and evaluate each one of the provincial base documents. The unanimous group consensus was to use the newly minted Alberta standards as the foundation documents based on this evaluation process.

The Alliance members developed the framework for a formal “Memorandum of Agreement” (MOA). This agreement outlines the operating parameters for the use of the common standards by those jurisdictions choosing to accept them as the standards used by their accreditation program. Specifically, the MOA outlines strict guidelines for standards revision management, control, protection and distribution of standards. In addition, the MOA also requests that each WCAA member province actively commit to promoting the WCAA to its

provincial stakeholders to encourage participation of assessors in cross-jurisdictional assessments.

To date, three of the four western provinces (Alberta, Saskatchewan and Manitoba) have committed to the WCAA initiative by signing the MOA.

The WCAA logo has been developed which is tailored for each provincial jurisdiction. The standards in each province incorporate both the WCAA logo and the provincial regulatory body logo.

On-going revision of the standards incorporates stakeholder feedback from all WCAA member organizations and facilities.

3.0 Standards Document

3.1 STANDARDS OVERVIEW

The Standards are the basis for accreditation decisions and are compiled by CPSA and stakeholder experts and are reviewed and approved by the Advisory Committee on Laboratory Medicine, with final vetting and approval by the 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, and other recognized provincial, national and international standards (e.g. College of American Pathologists, CLSI, CSTM, Canadian Standards Association). Each accreditation standard has 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 (Medical laboratories – Requirements for quality and competence).

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

CPSA Laboratory Accreditation program currently maintains the following standards documents for the assessment of diagnostic laboratory facilities:

- General (also includes LIS, Safety and POCT)
- Anatomic Pathology
- Chemistry (also includes Urinalysis and Toxicology)
- Fertility Assessment – Semen Analysis

- Flow Cytometry
- Hematology
- Microbiology
- Molecular Diagnostics and Genetics
- Transfusion Medicine

For Histocompatibility (HC) Testing, CPSA accepts certification/accreditation by American Society for Histocompatibility & Immunogenetics (ASHI) or the College of American Pathologists (CAP). CPSA accreditation standards apply to the general sections of the TT/HC laboratory (Physical Facility, Safety LIS etc.).

There is only one customizable standard set for ALL facility types regardless of scope (High, Moderate Complexity, Basic Complexity, Specialized Complexity).

All accredited Alberta facilities receive a complete standards document set. CPSA accredited laboratories and other approved users may access, print or make a copy of the standards for their non-commercial personal use. Any other reproduction in whole or in part requires written permission from CPSA and the material must be credited to CPSA.

Prior to each assessment **customized standards** documents, **tailored to the scope of testing** of a facility, will be made available to:

- facilities for self-assessment and/or to prepare for an on-site CPSA assessment.
- CPSA assessors in preparation for on-site assessments and to record objective evidence/ observations while performing on-site assessments.

IEEA accreditation

On April 19, 2022 at a meeting of the Board Accreditation Committee of the International Society for Quality in Health Care External Evaluation Association (IEEA) the CPSA Standards for Diagnostic Laboratory Accreditation received IEEA reaccreditation (effective May 2022 through to May 2026).

For more information on IEEA international accreditation see: www.isqua.org

3.2 FORMAT OF STANDARDS

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.

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

- Organization, Management & Personnel
- Quality Management System
- Physical Facilities
- Equipment, Reagents & 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 specific standard.

Figure 2 - 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 □ N/A □ Observation:

Each standard consists of the following components:

- **CPSA 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 a 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) linked to reference listing 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 of objective evidence** (field is expandable in electronic document)

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, interviews 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.

Assessment of Compliance Categories – the CPSA "PEN" or CPEN

Compliance Assessment Category:	
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/A	not applicable to scope of service or testing

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 direct 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 the assessor and/or the Advisory Committee. 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 occurences is to promote and focus on quality initiatives.

3.4 TERMS AND DEFINITIONS

A listing of applicable 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 this document. Specific reference citation details can be accessed by clicking on individual link(s) included beside each standard. 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 CPSA 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 by CPSA 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 by CPSA if clarification of submission is required

4.0 Accreditation Process – 4-year Re-accreditation

4.1 INITIATION

	Responsibility	Task	Additional Information
1	CPSA	• identifies Sector/laboratories to be assessed • notifies Laboratory Director(s)	• Laboratories revert to Provisional accreditation status throughout the accreditation process • Entire Sector is assessed within the same calendar year • Sector assessments for larger Sectors are split into multiple assessment initiations (typically Spring/Fall) • Sector/facilities are given their specific assessment initiation timelines at the beginning of the assessment calendar year (e.g. June / September).
2	CPSA	Selects proposed Assessment Coordinators (AC)	Assigned Assessment Coordinators are selected.
3	CPSA	Provides **Sector area** to be assessed with the *Assessment Logistics Form*	The Sector area or facility laboratory director is requested to complete and sign the *Assessment Logistics Form* which includes: • provision of key Sector assessment contacts • request for aggregate Sector summation conference • approval of proposed Assessment Coordinator(s)
4	Facility/Sector CPSA	Completes Assessment Logistics Form	Completed form is submitted with signatures to CPSA within the specified timeline CPSA sets-up secure SharePoint access for the key Sector assessment contacts and communicates this information
5	CPSA/AC	Determines specific assessment dates and prepares draft schedule	CPSA in collaboration with the ACs determine the specific assessment dates. Sector area assessment cycles encompassing multiple facilities are kept to 5 business days to minimize the required assessor time commitment. CPSA prepares and distributes draft assessment schedules to Sector/facility • Ensures that the Sector/facility has reviewed and has no concerns with the schedule
6	CPSA	Provides pre-recorded training sessions for Sector/facility personnel	Facility Training focuses on: • overview of assessment process steps • use of the standards tool • assessment logistics & timelines

4.2 PRE-ASSESSMENT

	Responsibility	Task	Additional Information
7	CPSA	Provides **each laboratory** to be assessed with a "*Pre-assessment Data Verification*" (PADV) Form	The PADV requests submission of the following for each individual facility undergoing assessment: • general facility information • hours of operation • scope of testing / test menu • Sector managed programs / processes • organizational structure • examples of examination request forms and patient reports • analyzer/instrument list by laboratory section • list of examinations and analyzers implemented since the last 4 year assessment • complete list of examination procedures • Summarized External Quality Assurance/Proficiency Testing programs by discipline • List of POCT analyzer/equipment/kits • List of POCT procedures performed
8	Facility	Completes PADV form and submits along with required documentation and signature to CPSA within the specified timeline	CPSA follows up directly with the facility regarding any missing documentation or documentation requiring further clarification.
9	CPSA	Selects assessment team members based on Sector/facility scope of testing, availability & experience	CPSA reviews the scope of testing for each facility based on the submitted PADV documentation. Selection of the assessment team is based on: • scope and complexity of laboratory services • requirement for out-of-province assessors • number/geographic location of facilities • experience of team members CPSA ensures separate assessors (i.e. not the AC) are assigned for the assessment of ALL components of the General Standards (QMS, Safety, LIS, POCT).

4.2 PRE-ASSESSMENT - CONTINUED

	Responsibility	Task	Additional Information
10	CPSA	Advises Laboratory Director(s) of proposed assessment team members and requests formal written approval using the Proposed Team Member Form	For each facility/Sector area assessment, the Laboratory Director receives a listing of the proposed team members including their: • name • scope of assessment activities • location of employment/employer
11	Facility	Submits written approval of assessment team members to CPSA	If any original members are not approved by the facility/Sector due to an identified conflict of interest, CPSA will solicit alternate assessment team members and request approval.
12	CPSA	Sends confirmation of team approval and assessment dates to assessors	CPSA sets up assessor access to SharePoint and sends notification
13	CPSA	Distributes customized assessment tools (Standards documents) to Sectors/facilities	Customization is based on information provided on the completed PADV form. Sections not pertaining to the facility are removed. There still may be individual standards within sections that are not applicable to each facility. Assessors will not be assessing these specific requirements.
14	CPSA	Conducts internal laboratory and external stakeholder surveys	CPSA sends a link to internal / external client stakeholders to complete a brief on-line survey regarding the laboratory service. The surveys encompass stakeholder satisfaction with: • physical facility • pathologist services • general on-site laboratory services including test menu and turn-around time • referral testing services • communication • workload • training and competency Survey findings are reviewed by CPSA staff. Any significant findings are summarized and provided to the assessment team for corroboration. These are also upload to the facility SharePoint site for its information.

4.2 PRE-ASSESSMENT - CONTINUED

	Responsibility	Task	Additional Information
15	CPSA	Prepares customized assessment supporting documents for provision to Assessors	CPSA prepares customized tools/supporting documentation for assessors: • summary of previous citations and responses referenced to current standards • PADV scope of testing crosswalk for all facilities • further customized facility-specific standard sets (reflecting assessor focus of assessment) • facility and discipline specific assessor guides
16	CPSA / AC	Distributes final summary and detailed facility schedules	Final summary assessment schedule is uploaded to the Facility and Assessor SharePoint sites Detailed facility schedules are uploaded to the Facility SharePoint sites
17	CPSA	Coordinates Sector/facility logistics with the facility/Sector area assessment contact	CPSA requests the following for the Sector area and each facility by requesting completion of the *On-site Assessment Logistics – Sector* forms: o meeting room for Sector summation conference (if required) o meeting room for each facility o provision of lunches as required by schedule o access to any laboratory records located outside the laboratory o facility to communicate with appropriate clinical/administrative contacts with notification that a clinical transfusion medicine, POCT, Respiratory (where applicable) and IT assessment will occur in conjunction with the laboratory assessment.
18	Sector/facility	Sends completed On-site Assessment Logistics – Sector & Facilities forms	Completed forms are submitted within the specified timelines. CPSA confirms receipt of all information regarding the above arrangements and follows-up with facilities regarding any missing or conflicting information.
19	CPSA	Distributes assessment documentation to each assessment team member to facilitate adequate preparation	CPSA provides each team member the appropriate information for the assessment, including: • the customized assessor facility-specific standard sets • completed PADV/PADV scope of testing crosswalk • summary of previous citations and responses • discipline specific assessor guides for each facility • copy of the General Standards All assessment information is provided to team members via their secure SharePoint site.

4.2 PRE-ASSESSMENT - CONTINUED

	Responsibility	Task	Additional Information
20	CPSA	Assessment team training session(s)	CPSA assessment team training: • Mandatory for all assessment team members to participate in • Following completion of the training session, assessors and team leaders must demonstrate competency by successful performance on an examination • Continuing education certificates are provided upon successful demonstration of competency • If there have been no changes to the processes and if it has been less than six months since an assessor previously took the training and exam, if they feel comfortable enough in the process they are not required to take it again for the upcoming Assessments. Training sessions encompass: • Overview of CPSA's assessment process and standards documents • General assessment guidance and techniques • CPSA assessor policies (e.g. confidentiality, conflict of interest, honoraria, expenses, etc.) • Specific assessment logistics • Specific roles and responsibilities
21	Assessment Team	Reviews assessment documentation and materials in preparation for the on-site assessment.	Each member is expected to review the assessment documentation relevant to their scope of assessment activities to ensure that they are adequately prepared to perform a thorough and efficient assessment. The primary purpose is to: • become familiar with the General and applicable discipline-specific standards • become familiar with the scope of activity (test menu, workload, master document list for P/P/P, analyzer/instrument list) including which programs/processes are Sector managed • identify areas of concern for further follow-up during the assessment (previous citations) Standards tools can be further customized by each assessor to meet their personal preferences for recording of observations and assessment categories on-site (e.g. add personal comments/directives, add additional space for recording, etc.) Assessors are expected to bring their own customized tools, either paper or electronic tablet version, to use during the assessment.

4.3 ON-SITE ASSESSMENT

	Responsibility	Task	Additional Information
22	AC/TL	Conduct an opening meeting with Sector/facility personnel	At the beginning of the on-site assessment at each facility, the AC conducts an opening meeting for Sector/facility personnel that encompasses: • introductions • assessment logistics and timelines • assessment process outline
23	Facility	Conducts facility tours for assessment team members	An initial tour of the entire laboratory will give a general overview of the laboratory operation and key personnel.
24	Assessment team members	Conduct on-site assessments in areas of expertise	**The Assessment Process – General:** The accreditation assessment process involves: • verifying **compliance** with the intent of accreditation standards • follow-up of previously identified areas of concern • interaction with laboratory staff at all levels • interaction with non-laboratory physicians and other health care providers (via surveys) • review of Sector managed areas (e.g., POCT, LIS) **Assessor Behaviour:** • engage in clear and concise dialogue with facility staff • explain the assessment process to facility staff, as required • exhibit positive body language • assess according to the standards (unbiased approach) o there are many ways to meet the intent of a standard • adopt an educational rather than a consultative OR punitive approach o the goal of the assessment is laboratory improvement • do not act as a consultant • be conscious of timelines and assessment schedules and obligations

			The CPSA Assessment Tool: The on-site assessment is performed using the facility specific standards document tools. Each assessor must utilize both the General Standards tool **and the** discipline-specific Standards tool(s). 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 specific standard. **Assessment of Compliance** • 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 standard. • Where AOCs state “all of the following”, compliance with all elements is expected (e.g. test request form) • 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, interviews or a combination of these techniques.

4.3 ON-SITE ASSESSMENT - CONTINUED

	Responsibility	Task	Additional Information
25	Assessment team members	Conduct on-site assessments in areas of expertise CPSA Assessor Guides: • Anatomic Pathology • Chemistry • Flow Cytometry • General/LIS/System Host • General/Pre-Post Examination • General/QMS • General/QMS/Safety • General/QMS/Safety/LIS • General/Safety • Hematology • LIS Facility • Microbiology • Molecular Diagnostics and Genetics • POCT • Semen Analysis • Team Leader • Transfusion Medicine	**Guidance for Assessors:** **When assessing laboratory sections:** • **It is not possible to review the entire scope of laboratory operations** o focus on areas of highest and lowest test volumes, likely problem areas and test results with highest impact on patient care o directly assess ALL standards with either a PS or SS designation o verify that all non-conformances cited on the previous assessment have been corrected o utilize **CPSA Assessor Guides** to focus / direct assessment • **Review Sector managed programs / processes** • **Review documents (policies, processes and procedures - PPPs) and records** o the assessor should choose a random, representative selection of documents and records to review o assessors should not rely solely on documents/records chosen or selected by the facility for review. • **Observe activities:** o engage in meaningful dialogue with laboratory and non-laboratory staff (ask open ended questions such as: (what, when, where, why, who, how) o compare observed activities to the facility policies, processes and procedures o use techniques, such as: ▪ tracer method: follow a sample through pre-examination, examination & 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**

4.3 ON-SITE ASSESSMENT - CONTINUED

	Responsibility	Task	Additional Information
26	Assessment team members	Conduct on-site assessments in areas of expertise	• **Record objective evidence:** o as immediately as possible after encountering citation o using the customized assessment tool (paper or electronic) o do not rely on memory o be factual and thorough o provide ample background detail for interpretation and determination by CPSA of the requirement/EOC • **Photographic evidence for the Advisory Committee:** o for safety related citations, consult with AC for necessity to corroborate observation with photographic evidence o AC will be responsible for notifying the facility contact and taking required photographs o AC will ensure that no individuals or confidential information are identifiable in the photographs **Compliance Assessment Categories:** • **Non-conformances (N)** o failure to meet the intent and/or requirement of the standard o The standards are process based and a single non-compliance may encompass one or more observations. • **In-progress citations (P)** o working towards meeting intent and requirements of standard; assessor notes evidence of timely progress towards full compliance o require submission of future evidence of compliance based on direction from the assessor and/or the Advisory Committee. o 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 o are not meant to address partial or incomplete compliance (e.g. incomplete manuals) • **Exceeds requirement citations (E)** o recognize those situations where a facility exceeds the intent of the standard and employs commendable practice. o the intent of capturing these occurrences is to promote and focus on quality initiatives.
27	Assessment team members	Notify AC/CPSA immediately of any serious deficiencies that may have immediate impact on staff or patient safety	Assessors encountering any situation that in their judgment, represents potential for significant immediate harm to staff or patients are directed to bring it to the attention of: #1 - the laboratory personnel for immediate action as deemed appropriate #2 - AC who will consult with the CPSA and determine the necessity and urgency
28	Assessment team members	Communicate PEN findings (assessors) to AC while on-site	**PEN Findings:** The AC will determine and communicate the timelines and frequency for debriefing assessors to obtain assessment PEN findings. At larger facility assessments this could be multiple times per day. AC will ask assessors to provide the following for each citation and record the details in the citation recording template: • Standard number (if known) • Compliance assessment category (PEN) • Detailed observation/objective evidence • Comments (where applicable) The AC ensures all citations include sufficient and clear detail in the objective evidence to facilitate CPSA determination of the requirement, EOC and timeline for EOC. If the assessor and/or AC is unable to determine the appropriate standard number to reference the citation, ACs are advised to record the other

			citation details and CPSA will make the determination.

4.3 ON-SITE ASSESSMENT - CONTINUED

	Responsibility	Task	Additional Information
29	AC/TL	Conduct pre-summation conference team meeting	The AC de-brief with the entire assessment team prior to the facility summation conference to determine and summarize key findings for presentation at the summation conference. The AC will make particular note of systemic/Sector issues (e.g. document control in multiple lab sections).
30	AC/TL	Conduct a summation conference for the Sector/facility management and personnel	The primary purpose of the summation conference is to highlight the key findings and outline the next steps in the assessment process. The AC serves as the primary spokespersons during the summation meeting in order to bring consistency of format and detail to the process. In person summation conferences are conducted at each facility at the end of the facility assessment. Due to the size and complexity of the various health Sectors, the option of also conducting a Sector area summation conference is also made available. A request for a Sector area conference is indicated on the Assessment Logistics Form. The Sector/area summation conferences address significant findings noted in multiple facilities in the Sector area. Summation conference agenda: • Short review of the objectives of the accreditation process • Review of commendable findings and practices including any 'E' citations • Review of significant non-conformances. (The purpose of this is to ensure that there are no "significant surprises" in the report when received by the facility/Sector.)

			• Overview of the next steps in CPSA accreditation process including timelines for: o compilation and distribution of final report o facility responses and submission of EOC • Acknowledgement of laboratory personnel for their cooperation and support of the accreditation process. • Facility questions

4.4 POST-ASSESSMENT

	Responsibility	Task	Additional Information
31	CPSA	Formats and finalizes draft facility reports	Based on the citation recording summaries provided by the AC/CPSA, CPSA completes/finalizes the following for each facility report: • Facility demographics and key personnel • Assessment information and team details • Accreditation process dates • Facility Overview • Citations: o Standard number o Safety Risk category o Compliance assessment category (PEN) o Detailed observation/objective evidence o Requirement o Evidence of Compliance (where applicable) o Timeline for submission of EOC Guidelines for requirement of 30 day EOCs: • Significant safety issue All other requests for 90 day EOCs are based on the judgment of the assessors/CPSA and include but are not limited to the following: • All 'P' – 'In Progress' citations • Issues cited on previous assessment reports • All requirements categorized as PS/SS • Systemic/multi-facility issues CPSA ensures consistent/uniform: • application of the standards based on similar observations • wording of requirements and EOC • timelines for submission of EOC

4.4 POST-ASSESSMENT - CONTINUED

	Responsibility	Task	Additional Information
32	CPSA	Prepares Sector aggregate report and citation cross-reference	Based on the Citation Recording Summary provided by the AC, CPSA compiles a Sector aggregate report that includes: • aggregate assessment information (facilities / assessment dates) • assessment team details • aggregate assessment statistics and graphs • link to a detailed citation document that lists each separate standard citation by number and cross-references which facilities are cited for each standard
33	CPSA	Sends any themes to ACLM for advice	• presents any themes or items that require ACLM advice, these are presented in an anonymized fashion
38	CPSA	Prepares and distributes final facility reports to Laboratory Director(s)	• format reports to include a section for a facility response to each individual non-conformance/ in-progress citations (put this row in blue). • posts the finalized individual facility reports on the secure CPSA SharePoint site after meeting if any issues were presented to Committee or before meeting if no issues • notifies the Laboratory Director of the facility and designated distribution contact that the final reports are available electronically

4.4 POST- ASSESSMENT - CONTINUED

	Responsibility	Task	Additional Information
35	CPSA	Provides accreditation evaluation forms to facilities and assessors	To evaluate the effectiveness of the assessment process and customer satisfaction, facilities and the assessment team are asked to provide feedback on the Accreditation Evaluation Forms. Stakeholders are afforded the opportunity for anonymous comment. Results are compiled and reviewed annually by CPSA. Changes to process are implemented as appropriate based on feedback.
36	Sector/facility	Submits a response to requirements and requested evidence of compliance	Facilities are required to input their response directly into the report and embed any requested supporting documentation/EOC as applicable. Responses are uploaded to secure facility SharePoint site. **For requirements with requests for EOC:** Facilities must provide a response and required EOC based on timelines specified in the report (30 or 90 days from the date of the report). **Responses to requirements without requests for EOC:** Facilities must provide a response within 90 days from the date of the report.
37	CPSA	Reviews Sector/facility responses to requirements and requested evidence of compliance	• reviews responses to requirements and requested evidence of compliance and presents to ACLM, in an anonymized fashion, if any advice is required or responds to facility if no advice from ACLM is required
38	CPSA	Communicates to assessors	• once first responses are received sends communication to assessors to confidentially destroy documents and delete electronic files

4.4 POST- ASSESSMENT - CONTINUED

	Responsibility	Task	Additional Information
39	CPSA	Responses back to facility	• moves “Response Acceptable” rows to end of report with a heading of Acceptable Responses, adds to list as further responses are deemed acceptable
40	CPSA	Grants Full accreditation status	CPSA determines if any outstanding non-conformances (either due to volume or type of non-conformances) would substantiate a reversion to “Provisional” status. If this decision is made, a “Provisional” certificate is issued and the laboratory is advised to replace their “Full” certificate with the “Provisional” certificate. Once the identified “provisional” non-conformance(s) are satisfactorily addressed, the laboratory is granted “Full Accreditation” status. A certificate is issued once approval has been given by the Medical Facility Accreditation Committee. If a laboratory is denied accreditation, the laboratory may access CPSA’s formal appeal process.

5.0 Honoraria and Expense Reimbursement

For assessors - Refer to the current Honoraria and Expense Policy (on the CPSA Assessor SharePoint site) for guidance and information.

6.0 Annual / Assessment Fees

Annual Fees
Facilities will be invoiced annually in January/February for the upcoming fiscal period of April 1 – March 31 for the Annual Fee.

Assessment Fees
An assessment fee will be invoiced at the same time as the report is distributed to the facility.