Accreditation Program Guide

Diagnostic Laboratory:
New & Relocating Facilities

January 2019 – v14

College of Physicians & Surgeons of Alberta

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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 and 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 that 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 testing 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 Determination of Requirement for Diagnostic Laboratory Accreditation

Laboratories are required to be accredited by the CPSAs diagnostic laboratory accreditation program if they perform and report diagnostic testing for patient management. Facilities such as physician office settings where screening testing (eg. urine dipstick) may be performed to inform/guide clinical treatment or practice but is not reported do not require accreditation.

3.0 College of Physicians and Surgeons of Alberta (CPSA) Accreditation Program

3.1 CPSA Lines of Business

The College of Physicians & Surgeons of Alberta 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.

The Council of the College of Physicians and Surgeons of Alberta sets direction and policy for the College, while daily operations are managed by the College Registrar and leadership team. College Council includes Physician members elected by their medical colleagues and public members appointed by Alberta's Lieutenant-Governor in Council. Alberta's medical school deans also hold a Council seat, and medical learners are represented as observers.

The lines of business for the CPSA are as follows:

- Register physicians
- Investigate and resolve physician-related complaints
- Provide clinical review
- Accredit health facilities
- Guide professional conduct and ethical behavior
- Contribute to public policy affecting health care delivery

3.2 CPSA Mission, Vision and Values

Our Mission
Serving the public by guiding the medical profession

Our Vision
Albertans are healthier because the College of Physicians & Surgeons of Alberta:

- ensures that physicians are competent throughout their careers;
- supports physicians in providing compassionate, caring and ethical services to the people of Alberta;
- fosters quality health care for all Albertans through innovation, collaboration and cooperation with other key stakeholders; and
- advocates for public policy that contributes to the health of Albertans.

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.

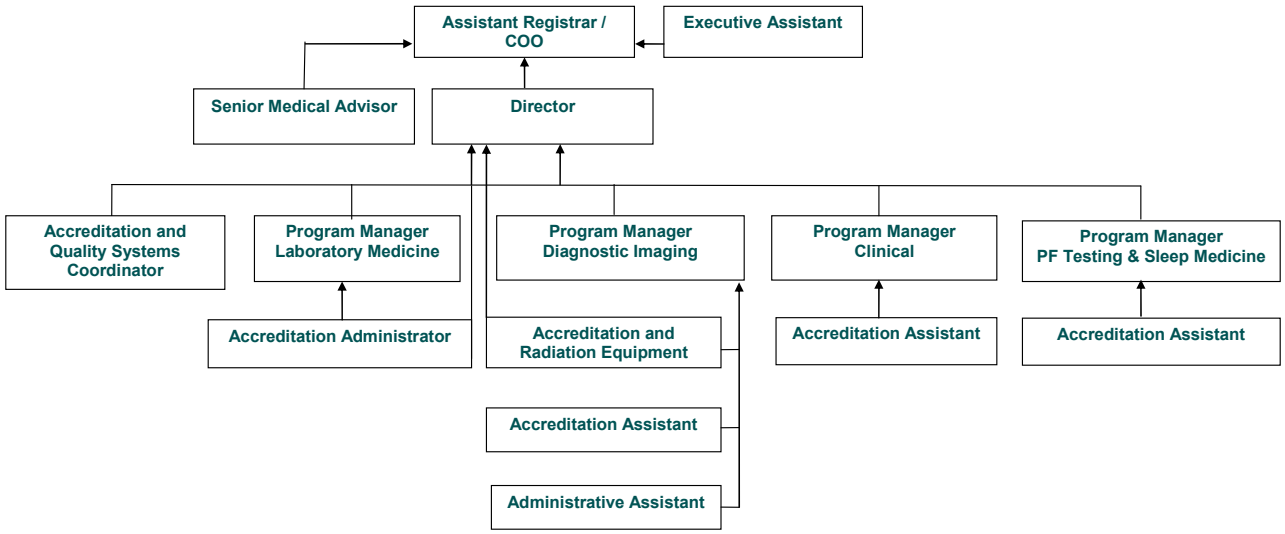
We empower people.
We believe people perform best when they see the Vision, set their own goals, have the resources they need and aspire to excellence and personal growth.

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.

3.3 CPSA Organizational Structure - Figure 1



3.4 Accreditation Program History

In 1965, the College of Physicians and Surgeons of Alberta, 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 the College of Physicians and Surgeons of Alberta, 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 the CPSA to accredit hospital-based laboratories on their behalf and to make recommendations to them pertaining to accreditation.

Since that time, the CPSA has remained the accreditor of all public and private diagnostic laboratories in the province of Alberta.

3.5 Authority and Oversight

The College of Physicians and 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 the College, 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 the 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, the value of practice uniformity between the private and public sectors and the credibility of the CPSA's programs have long been acknowledged by practitioners and government. Consequently, four of the CPSA's accreditation programs (laboratory medicine, diagnostic imaging, pulmonary function and neurophysiology) are under contract with government agencies (AHS) to provide accreditation of public sector facilities.

The 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. A member of the MFAC also attends a full meeting of the individual accreditation advisory committees each year to report on the diligence and objectivity of the work conducted.

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. The Advisory Committee on Laboratory Medicine includes participation by an external pathologist consultant expert. The consultant expert's role is to observe and report to AHS on the objectivity of the CPSA's accreditation decisions in regard to AHS medical laboratories.

3.6 Overview of Laboratory Accreditation Program - General

The 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, the 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. All accreditation assessment findings are vetted by the Advisory Committee on Laboratory Medicine to eliminate any potential personal assessor bias, ensure consistent and thorough approach for all facilities, and to review standards for applicability to current best practice.

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 and Team Leader 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. The 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, the 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
The 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 the CPSA.

The 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

3.7 Laboratory Classifications

*Annual Fee Classifications for Diagnostic Laboratories	
A	High Complexity – High Volume
B	High Complexity – Medium Volume
C	Moderate Complexity – Medium Volume
D	Moderate Complexity – Low Volume
E	Basic Complexity – Low Volume
F	Specialized Complexity – High Volume
G	Specialized Complexity – Low-Medium Volume

*Categories apply to Annual General Administration and Annual ALQEP 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 (e.g. Provincial Laboratory, Canadian Blood Services, Regional Fertility Clinic, Genetics Laboratory Services etc.)

***Volume based on Total Annual Testing Volume:**
High: > 500, 000
Medium: 50, 000 – 499, 999
Low: < 50,000

*Volume is based from actual volumes provided by facilities/Sectors on submission of their Pre-Assessment Data Verification Forms; volumes will verified on an annual basis with Sectors/facilities

3.8 Personnel

3.8.1 CPSA Laboratory Accreditation Personnel and Roles

The Advisory Committee on Laboratory Medicine (ACLM) oversees the 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.

3.8.2 Advisory Committee on Laboratory Medicine

The Advisory Committee on Laboratory Medicine (ACLM) oversees the 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;
- Review and audit of the business practices of the facility to ensure compliance with relevant CPSA By-laws and Standards.

Membership and Tenure
Committee members are appointed by MFAC for an undefined term. 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.

Membership includes:
- Laboratory Physicians
- Clinical Laboratory Doctoral Scientists
- Laboratory Technologist(s)

Non-Voting Members:
- 5 Assessment Coordinators

All voting members are professionals responsible to professional regulatory Colleges for their competence, their standards of practice and their conduct.

The Advisory Committee on Laboratory Medicine also includes participation by an external pathologist consultant expert. The consultant expert's role is to observe and report to AHS on the objectivity of the CPSA's accreditation decisions in regard to AHS medical laboratories.

3.9 Assessment Teams

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

3.9.2 Team Leader
The assessment Team Leader is assigned by the CPSA with care being taken to avoid any potential conflicts of interest. The primary role of the Team Leader, in addition to representing the CPSA/assessment team with the laboratory's management, is to serve as a spokesperson, to conduct assessments in their area of expertise and to perform a high level review of organization, management and personnel standards. Where the need arises, the Team Leader is responsible for mitigating and resolving conflict and providing guidance to the assessment team.

3.9.3 Team Selection
The Assessment Coordinator(s) in collaboration with the CPSA, select 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 materials necessary to conduct a fair and thorough assessment.

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

3.9.4 Assessment Team Training
All assessment team members are required to participate in the CPSA Assessor Training and Exam, within 6 weeks prior to performing an on-site assessment. Assessment team members must demonstrate competency by successful performance of an on-line examination.

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

3.9.5 Conflict of Interest / Confidentiality Agreements /Liability

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

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

The CPSA's liability insurance specifically extends to cover assessors who are employed, contracted or act as agents. As well, the HPA extends liability protection to all CPSA staff, contractors and agents. While performing assessments for the 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.

3.10 Western Canada Diagnostic Accreditation Alliance

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 Canadian Diagnostic Accreditation Alliance (WCDAA) 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 WCDAA member province actively commit to promoting the WCDAA 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 WCDAA initiative by signing the MOA.

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

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

4.0 Standards Document

4.1 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.

The 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 the 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 Complexity – High Volume, High Complexity – Medium Volume, Moderate Complexity – Medium Volume, Moderate Complexity – Low Volume, Basic Complexity – Low Volume, Specialized Complexity – High Volume, Specialized Complexity – Low-Medium Volume).

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 the CPSA and the material must be credited to the 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.

ISQua Accreditation:
On May 15, 2018 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 2018 through to May 2022).

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

4.2 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 □ 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.
- **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)

4.3 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 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.

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

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 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.

4.4 Terms and Definitions

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

4.5 Reference Listing

A detailed reference citation listing is provided at the end of this document. Specific references 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.

4.6 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 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 the 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 the CPSA if clarification of submission is required

5.0 CPSA Laboratory Facility Assessment Requirements – Relocations, Renovations & Amalgamations

Type of assessment	CPSA Notification Required[#]	On-site Assessment Required	Requirement to submit validation data for equipment to CPSA prior to assessment	Comments
New Facility; never accredited	Yes	Yes	No	Equipment validations to be reviewed at on-site assessment
4-year accreditation	No	Yes	No	Equipment validations to be reviewed at on-site assessment; CPSA will ask sites to specify new tests/equipment implemented since previous 4-year assessment
Previously Accredited Labs – Addition of New Testing Discipline (e.g. Microbiology)	Yes	Yes	No	Assessment limited to new discipline Equipment validations to be reviewed on site
Previously Accredited Labs – [&]Major Renovation				
Temporary Facility	Yes	No	No	
Post-renovation Facility	Yes	*Yes	No	Return to current location post-renovation
Post-renovation Facility (no temporary facility)	Yes	*Yes	No	Remained operational in current facility during renovations
Previously Accredited Labs – Permanent Laboratory Move				
Move within existing facility	Yes	*Yes	No	Equipment validations to be reviewed at on-site assessment
Move to new building/hospital	Yes	*Yes	No	Equipment validations to be reviewed at on-site assessment
Previously Accredited Labs – Amalgamation of Laboratories	Yes	At CPSA discretion	At CPSA discretion	Request notification of amalgamation specifying which site is being closed etc.
Ad hoc Assessment	N/A	At CPSA discretion	At CPSA discretion	Assessments for cause (e.g. stakeholder complaint; natural disaster; EQA performance etc.)

Notes:

*- Assessment limited to review of physical space and relevant safety – related standards; timing of assessment is flexible and not contingent upon resumption of testing

[&]- Major renovations include structural changes to facilities that result in significant changes to physical layout and workflow processes

[#] - Notification to CPSA should be made by email to the Program Manager as soon as possible to facilitate assessment resource planning; additional information regarding costs and timelines will be provided after notification

Exceptions to on-site assessment requirement include:

- reconfiguration of laboratory spaces without structural changes (this includes moveable wall systems)
- minor laboratory space repairs (e.g. counter top/bench replacement; floor repair, utility changes/upgrades
- relocation/consolidation of testing from one accredited location to another (e.g., moving Influenza PCR testing from a centralized location to a rapid response lab); as with the implementation of a new examination, it would be assessed at the next 4 year assessment

The final determination of whether an on-site assessment is required is at the discretion of the CPSA Advisory Committee on Laboratory Medicine.

6.0 Accreditation Process – New Facility Accreditation

6.1 Initiation:

	Responsibility	Task	Additional Information
1	CPSA	Assessment Initiation	• CPSA receives notification of intent to open a new facility • CPSA verbally provides facility with general overview of the registration and assessment processes • Directs facility to registration documents on the CPSA website and advises to complete and return
2	CPSA	Receives completed Registration Form and reviews submitted PADV form and prepares assessment documentation	• accesses completed PADV form and submitted documentation • follows up directly with the facility regarding any missing documentation or documentation requiring further clarification • reviews oversight of blood gas testing (i.e. ? covered under Pulmonary accreditation)
3	CPSA/AC	Determines specific assessment dates in consultation with facility management	• CPSA liaises with the facility administration to determine specific or approximate assessment date(s) to facilitate the assessment prior to opening and the performance of patient testing • selects Assessment Coordinator (AC) and Team Leader (where required)
4	CPSA	Provides facility to be assessed with the Assessment Logistics Form	• pre-populates the ALF for the site and emails to the Laboratory Director for completion
5	CPSA	CPSA sets up facility SharePoint site and contacts	CPSA upon receipt of the completed ALF: • set up facility SharePoint folder • requests facility SharePoint site access for designated individuals • uploads completed ALF to Facility folder • provides facility contacts with SharePoint access direction • sets up customized “Assessment Citation Recording Form” and posts to AC SharePoint site • prepares and uploads customized Standards documents for the facility to the Facility SharePoint site • advises AC of availability of completed ALFs on facility SharePoint site

6.2 Pre-assessment:

	Responsibility	Task	Additional Information
6	AC	AC liaises with key facility contact	• communicates with key facility contact, introducing self as primary contact for assessment logistics using AC-facility-AC Introduction – email script (using single site section)
7	CPSA/AC	Determines assessment team requirements based on scope of testing, availability, and experience	• discuss with AC assessor needs specific to facility type
8	AC/CPSA	Recruits assessment team members based on known facility scope of testing, availability & experience	• send recruitment invitations (using *appropriate Assessor Invitation* email script) • send confirmation to confirmed assessors (using *Assessor Initial Confirmation* email script)
9	CPSA	Seeks approval of assessment team members	• prepares "Assessment Team Approval" form • uploads the completed form to the Facility SharePoint site for review and approval
10	CPSA	Receive approval of assessment team members	• access and review signed "Assessment Team Approval" form • if any original members are not approved by the facility due to an identified conflict of interest, solicits alternate assessment team members and requests approval
11	CPSA	Sends recruited assessors the Assessor Demographic Form to complete	• sends *Assessor Demographic Forms* to assessors who confirmed participation in the assessment
12	CPSA	Complies ADF	• compiles ADFs and updates assessor database
13	AC	Distributes draft summary assessment schedule	• uploads draft summary assessment schedule to the Facility SharePoint site • notifies the facility contact to review the schedule and ensure there are no concerns
14	CPSA	Set up assessor contact list	• prepares detailed assessor contact list and uploads to the assessor SharePoint site
15	CPSA	Uploads assessor documentation to General and Specific Assessor Folders	• Uploads the following documentation to General and Specific Assessor Folders: o Expense and Honoraria Policy o pre-populated expense and honoraria forms o New-Relocated Facility Program Guide o Pre-populated Confidentiality and Conflict of Interest agreements o assessor contact list

6.2 Pre-assessment - continued:

	Responsibility	Task	Additional Information
16	AC	Assessment team confirmation communication	• sends assessment confirmation email to all team members (using the *Assessor Confirmation* email script) indicating that the following information will be accessible on the Assessor SharePoint site: • summary schedule • assessor contact list • Expense and Honoraria Policy • pre-populated expense and honoraria forms • Program Guide • Confidentiality and Conflict of Interest agreements
17	CPSA	Sets up assessor SharePoint access and uploads documentation	• sets up assessor access to SharePoint • sends notification to assessors with access details
18	AC	Prepare and upload finalized facility assessment schedule	• uploads finalized summary assessment schedule to the Facility SharePoint site • notifies the facility contact to review the schedule and ensure there are no concerns
19	CPSA	Prepare customized standards and assessor guides	• Prepares *Assessor Customized Standards & Guides* spreadsheet for use in preparing the further customized standards and assessor guides to be distributed to each assessor • Customize standards for each assessor based on the spreadsheet
20	AC	Coordinates team accommodation logistics	• determines hotel requirements (locations, dates, numbers of rooms) • secures appropriate number of rooms for the team members • provides the hotel with a detailed rooming list (name, check-in date/ check-out date etc) to finalize the individual reservations • ask hotel to provide confirmation numbers for each individual assessor and advises hotel that each individual is responsible for their own incidentals • communicates accommodation arrangements with the CPSA • uploads Rooming List, with confirmation numbers, to the General Assessment Documentation folder on the Assessor SharePoint site
21	AC	Prepare and upload finalized assessor assessment schedule	• prepares the detailed *Assessor Schedule* for the assessment • uploads to the Assessor SharePoint site in .pdf format
22	AC	Coordinates team transportation logistics	• determines detailed travel requirements including mode of transportation and delegation of drivers where applicable • makes arrangements for rental vehicle • where required, develops a detailed travel schedule including modes of transportation, times and hotels • uploads detailed travel schedule to the Assessor SharePoint site
23	CPSA	Organize assessment team training session	• sets up assessment team training session or other appropriate arrangements (review of presentation / teleconference etc.)

6.2 Pre-assessment - continued:

	Responsibility	Task	Additional Information
24	AC	Communicate assessment logistics to Assessment Team	• AC sends detailed email (using the *Team Logistics* email script) to the assessment team providing details on: o accommodations o travel (to and from assessment) o transportation during the on-site assessments o pre-assessment team meeting o availability of detailed travel and detailed assessor schedules on the Assessor SharePoint site o assessor training o expense and honoraria claims
25	CPSA	Distributes assessor specific documentation to each assessment team member	• uploads to each assessor's secure SharePoint folder on the Assessor SharePoint site: o the customized assessor standard sets o assessor specific guides
26	CPSA	Distributes assessment documentation to all assessors for assessment preparation	• uploads to subject specific folders under the facility folder on the Assessor SharePoint site: o completed PADV o copy of the General standards • notifies the AC that the Assessor documentation has been uploaded
27	AC	Notification of availability of pre-assessment documentation	• notifies assessors that pre-assessment documentation has been uploaded to the Assessor SharePoint site (using the *Pre-Assessment Documentation* email script)
28	CPSA	Assessment team and team leader 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 Training sessions encompass: • Overview of the CPSA 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 • Team Leader specific roles and responsibilities
29	AC	Final pre-assessment reminder	• sends communication to all assessors (using the *Final Assessment Reminders* email script) confirming/reminding regarding: o pre-assessment preparation activities o team logistics o team meeting if scheduled o required documentation to bring on-site o AC contact information

6.3 On-site Assessment:

	Responsibility	Task	Additional Information
30	AC	Conducts pre-assessment team briefing meeting	• conducts a briefing meeting for assessment team members ensuring that when assessing laboratory sections in new facilities assessors focus on: o a review of policies, processes and procedures o pre-examination activities o validation/ verification of equipment and procedures o physical facility o training and competency o safety o LIS o post-examination activities including report formats • ensures all assessment team members have required documentation for the assessment • follows-up with/debriefs any team members unable to attend the team meeting
31	ACL	Conduct an opening meeting with facility personnel	• conducts the opening meeting for facility stakeholders at the beginning of the on-site assessment • follows the Opening Meeting agenda/script • ensures all key points are addressed
32	AC	Logistics reminders	• ensures all team members are aware of on-site logistics including location of meeting room and lab areas, washrooms, lunch arrangements, reporting expectations etc.
33	AC	Regular communication and interaction with assessment team	• monitors assessor timelines closely to ensure that all areas are being adequately assessed and resources are being managed as required • follows up with CPSA for any significant safety issues • obtains photographic evidence for any significant safety related citations
34	AC	Tracks travel and on-site assessment time and meal provision	• provides CPSA with details on travel and on-site assessment time and meal provision
35	AC	Records assessment citations	• records the following for each citation in the citation recording template: o standard number (if known) o compliance assessment category (PEN) o detailed observation/objective evidence o comments (where applicable)
36	AC	Conduct pre-summation conference team meeting	• de-briefs with the entire assessment team prior to the facility summation conference to determine and summarize key findings • notes systemic issues (e.g. document control in multiple lab sections)
37	AC	Conduct a summation conference for facility management and personnel	• conducts the summation conference for all facility stakeholders at the end of the on-site assessment (highlight key findings, give kudos, and outline next steps) • follows the Summation Conference agenda/script • ensures all key points are addressed

6.3 On-site Assessment - continued:

	Responsibility	Task	Additional Information
38	AC	Submits facility citation summary to CPSA	• uploads the completed facility citation summary to the AC SharePoint site

6.4 Post-Assessment:

	Responsibility	Task	Additional Information
39	AC	Verbally communicates overall findings from the on-site assessment to CPSA	• immediately following the facility's on-site assessment, the AC provides the CPSA with an overview of the findings from the assessment including any significant findings that would impact the facility receiving approval to commence testing and reporting of patient results
40	CPSA	Communicates decision on commencement of testing to facility	• based on the communication received from the AC, the CPSA determines whether the facility can commence testing and reporting of patient results • the facility receives an immediate, formal electronic communication indicating: o approval for commencement of testing (Provisional accreditation status pending ACLM review) OR o the requirement for resolution of identified significant non-conformances • upon resolution of the identified significant non-conformances, the CPSA communicates the approval for commencement of testing and reporting of patient results (Provisional accreditation status pending ACLM review)
41	AC	Complete post-assessment communication and send final forms	• sends email to all assessors (using the *Post Assessment* email script) • send the completed *Assessor Time Tracking* forms to CPSA
42	CPSA	Reviews Assessor Honoraria/Expense forms	• receives honoraria and expense forms from assessors and fills in travel/on-site time and meal information • processes claim forms for reimbursement • uploads copy of final claim forms to each assessors secure SharePoint folder for their records
43	CPSA	Prepares draft reports	• prepares report based on citation recording form • performs a second review of report (objective evidence in conjunction with standard, requirement and EOC for accuracy)
44	CPSA/AC	Provides report to AC	• sends report to ACs for review prior to meeting • ACs do a details review of the objective evidence in conjunction with the requirements and EOCs for accuracy
45	AC	Presents report to ACLM	• presents the report to the ACLM and represents the assessment team in responding to questions or clarification requests
46	CPSA	Prepares and distributes final facility report to Laboratory Director(s)	• formats report to include a section for a facility response to each individual non-conformance/ in-progress citations • posts the finalized individual facility report on the secure CPSA SharePoint site within 10 days of the ACLM meeting • notifies the Laboratory Director of the facility and any designated distribution contacts that the final reports are available electronically

6.4 Post-Assessment - continued:

	Responsibility	Task	Additional Information
47	CPSA	Provides accreditation evaluation forms to all relevant stakeholders	• sends links to assessors and facility stakeholders for the on-line Accreditation Evaluation surveys
48	CPSA	Reviews facility responses to requirements and requested evidence of compliance	• reviews responses to requirements and requested evidence of compliance and provides recommendations to the ACLM as to the appropriateness of the response • consults with individual assessment team members for clarification where required
49	CPSA	Prepares responses for ACLM review	• reviews the AC/TL feedback for consistency • provides a section in each report to facilitate the Committee responses
50	CPSA	Communicates to assessors	• once first responses are received sends communication to assessors to confidentially destroy documents and delete electronic files

7.0 Accreditation Process – Renovated/Moved Facility Accreditation

Steps for Renovated Facility Assessment
• CPSA receives notification of intent to move/renovate facility • CPSA verbally provides facility with general overview of the assessment processes • If temporary facility no on-site assessment required • If post-renovated or move facility, on-site limited to review of physical space and relevant safety related standards, timing is flexible and not contingent upon resumption of testing
• CPSA advises assessment coordinator to work with facility contact to determine date of assessment
• CPSA provides AC (on AC SharePoint site) with: o AC Citation Recording Form o Previous citations regarding renovations (nothing for moves) o Expense Claim form • Provisional letter is not required as facility will not have stopped testing • Report to be provided to Committee at its next Committee meeting • If previous outstanding citation regarding renovations, add to report: CPSA advised that facility will be moving back to renovated area and an on-site assessment was conducted on DATE, this outstanding citation will be carried forward to a Renovated Facility Report. No further response required to this report

8.0 Honoraria and Expense Reimbursement

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

9.0 Assessment Fees for New/Moved Facilities

New facilities are invoiced for:

- a Registration Fee which is invoiced upon receipt of the New Facility Registration Form by the CPSA
- an Annual Admin Fee, approximately one week after receipt of the Assessment Report
- a New Facility Assessment Fee which covers the cost of the on-site assessment, approximately one week after receipt of the Assessment Report

Thereafter, an assessment fee will be invoiced following each 4 year on-site assessment (for private facilities) and (for public facilities) Alberta Health Services is invoiced at the beginning of the year that the Sector area is undergoing an assessment.

Payment to the CPSA is due upon receipt of these invoices.

A list of current Laboratory Fees can be found on the CPSA website.

10.0 List of Accredited Laboratories

A list of CPSA accredited laboratories is available on the CPSA website.