cpsa

COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

Accreditation Program Guide

Diagnostic Laboratory Facilities: New & Relocating Facilities

Version: December 2021 v21

cpsa

COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

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 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 & Surgeons of Alberta (CPSA) Accreditation Program

3.1 CPSA LINES OF BUSINESS

The 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.

The Council of the CPSA is composed of physicians elected by members of the profession in Alberta, the two Deans of Medicine in Alberta and four members of the public appointed by the Minister of Health and Wellness.

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 Vision

The highest quality medical care for Albertans through regulatory excellence.

Our Mission

Serving the public by guiding the medical profession.

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.

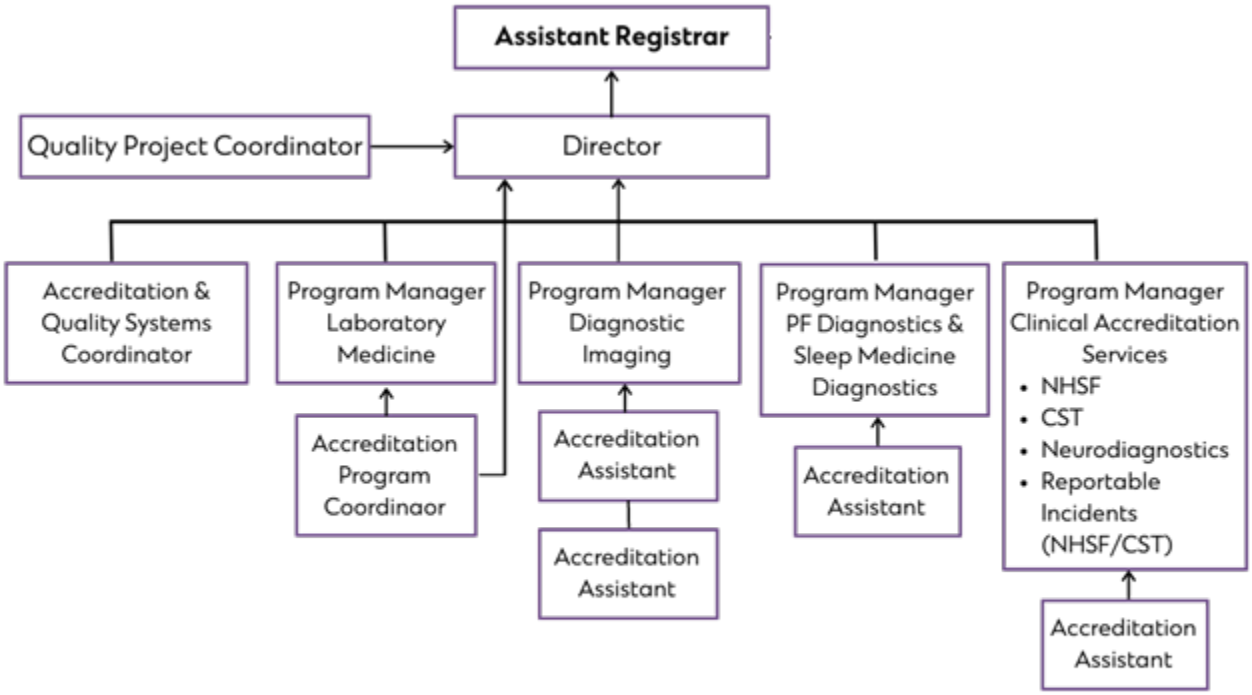
We empower people.
We believe people perform best when they see the Vision, set their own goals, have the resources they need and aspire to excellence and personal growth.

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 (ACCREDITATION DEPARTMENT) - FIGURE 1



3.4 ACCREDITATION PROGRAM HISTORY

In 1965, the 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 the 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 the 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)
- Vestibular Testing
- Hyperbaric Oxygen Therapy (HBOT)
- Pulmonary Function Diagnostics (PFD)
- Non-Hospital Surgical Facility (NHSF)

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 LABORTORY ACCREDITATION PROGRAM

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.

Assessment Model

The CPSA hybrid model consists of a comprehensive desk audit of submitted materials and an on-site assessment focusing on high risk, patient/staff/safety elements and those activities that require direct observation/validation.

Desk audit assessment includes but is not limited to:

- Policies / processes / procedures
- Formal, controlled templates/documents/forms
- Completed records / logs
- Audit reports
- Site –visit reports
- Training and competency documentation

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. 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
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

3.8 PERSONNEL

3.8.1 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.

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;

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 a minimum of 10 voting members and 5 non-voting members.

For voting members, representation includes but is not limited to the following:
- Laboratory Physicians
- Laboratory Technologists

Non-Voting Members:
- Assessment Coordinators

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

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 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.

3.9.5 Conflict of Interest / Vaccination Status / 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 and Vaccination Status Attestation 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, 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 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.

IEEA 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/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)

4.3 ASSESSMENT OF COMPLIANCE (AOC)

- Although the AOC questions address the key evidence required to meet the intent of each standard, they **<u>are not meant to be all encompassing</u>**.
- 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 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/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.

4.4 TERMS AND DEFINITIONS

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

4.5 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.

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 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 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/RELOCATION

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 (ALF)	• 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	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)

6.2 PRE-ASSESSMENT

	Responsibility	Task	Additional Information
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	CPSA	Seeks approval of assessment team members	• uploads the completed form to the Facility SharePoint site for review and approval
9	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
10	CPSA	Organize assessment team training session	• sets up assessment team training session or other appropriate arrangements (review of presentation / teleconference etc.)
11	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

6.3 ON-SITE ASSESSMENT

	Responsibility	Task	Additional Information
12	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
13	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.
14	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

15	AC	Records assessment citations	• records the following for each citation in the citation recording template:
			  • standard number (if known)
			  • compliance assessment category (PEN)
			  • detailed observation/objective evidence
			  • comments (where applicable)

16	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)
17	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

6.4 POST-ASSESSMENT

	Responsibility	Task	Additional Information
18	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

19	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:
			  • approval for commencement of testing
			  OR
			  • 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

20	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)
21	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 • notifies the Laboratory Director of the facility and any designated distribution contacts that the final reports are available electronically
22	CPSA	Provides accreditation evaluation forms to all relevant stakeholders	• sends links to assessors and facility stakeholders for the on-line Accreditation Evaluation surveys
23	CPSA	Reviews facility responses to requirements and requested evidence of compliance	• reviews responses to requirements and requested evidence of compliance • consults with individual assessment team members for clarification where required

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:
  ○ AC Citation Recording Form
  ○ Previous citations regarding renovations (nothing for moves)
  ○ Expense Claim form
• Provisional letter is not required as facility will not have stopped testing
• 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 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 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 on a quarterly basis for those facilities who were assessed in that quarter. For Annual Fees, these are thereafter invoiced in December prior to the next fiscal year of April 1 – March 31.

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

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

Appendix A

Accreditation Standards – Standards Development Policy and Processes

1.0 Standards Development Policy

1.1	Principles
1.1.1	Standards are: 1) evidence based 2) process based, wherever possible 3) in alignment with ISO principles 4) inclusive of a quality management system 5) in compliance with ISQua principles for standards development 6) comprehensive and practical 7) include provincial specific directives, where necessary 8) consistent across CPSA programs, wherever possible 9) individually referenced
1.1.2	The format of the standards: 1) facilitates standardized reporting and improved report turnaround time 2) facilitates improved data management capabilities 3) includes a compliance assessment scale 4) includes a risk assessment scale
1.1.3	The development process includes: 1) extensive review of relevant reference documents 2) input from experts 3) feedback from a broad stakeholder review
1.1.4	New sets of standards, or substantial revisions, are approved by the appropriate Advisory Committee, Medical Facilities Accreditation Committee (MFAC), and Council through the MFAC Report.

2.0 Standards Development Processes

2.1 Project Plan

2.1.1 The Accreditation & Quality Systems Coordinator (AQSC) develops a plan for the project, including specific deliverables and timelines, using the *Standards Development Project Timeline template*.

2.1.2 The Program Manager (PM) and Accreditation Director (AD) review, edit and approve the project plan.

2.2 Draft Standard(s)

2.2.1 The AQSC:

1) develops a framework for the document(s), based on the *Accreditation Standards Template*
2) drafts the common non-program specific elements of the standards, in alignment with the existing accreditation program standards (e.g., Quality Management System, Safety, Infection Prevention & Control, Medical Device Reprocessing, etc.)
3) confers with the PM regarding the pertinent program specific reference sources
4) performs an environmental scan and obtains relevant references. (See Appendix B- Referencing)

2.2.2 The PM:

1) reviews the references provided by the AQSC for relevancy.
2) researches and obtains additional relevant references.

2.2.3 The AQSC & PM develop the draft standards document(s):

1) review the cross-program common standards for alignment with the program and edit as required
2) draft the program specific standard content, associated Assessment of Compliance (AOC) questions and cited references
3) ensure that each standard is supported by more than one reference, wherever possible
4) determine if guidance is required for interpretation of any standard or AOC
5) draft detailed Appendix for any province specific requirements.

2.2.4 The program-specific Accreditation Assistant (AA) formats the draft document(s), in alignment with the existing accreditation program standards.

2.2.5 The Accreditation Program Coordinator (ACP) reviews the draft document(s) for formatting.

2.3	Expert Focus Groups
2.3.1	The PM establishes specific expert focus groups (limited to 4-5 specific experts) to perform a high-level of the draft standards, including but not limited to: 1) inclusion of all relevant technical sections 2) removal of inapplicable or irrelevant standards 3) relevancy and comprehensives of the reference documents.
2.3.2	The PM & AQSC hold teleconferences with the focus groups to outline the: 1) project and process 2) expectations and timelines for review of the draft standards.
2.3.3	The AA distributes the draft document(s) for focus group review (see Appendix A – Versioning), including directions for submission of feedback, with required evidence. Alternatively, a face-to-face meeting may be held to perform a group review.
2.3.4	The focus group reviews the draft document(s) for a specified period (generally 2 weeks) and submits feedback.
2.3.5	The AA collates the submitted feedback.
2.3.6	The PM & AQSC review the feedback and revise the document(s) as required.
2.3.7	The AA reformats the draft document(s) (see Appendix A – Versioning).
2.4	**Stakeholder Review**
2.4.1	The PM & AQSC determine the timeline for Stakeholder Review (generally 4 – 6 weeks).
2.4.2	The PM & AQSC prepare, based on available templates, the *Standards Review Guidance Document*, the *Stakeholder Standards Review Form* and the *Email* to accompany the release of the draft standards for broad stakeholder review.
2.4.3	The AA prepares the stakeholder distribution list.
2.4.4	The AA sends the draft revised standards (password protected .pdf with draft watermark), *Standards Review Guidance Document* and the *Stakeholder Standards Review Form* to relevant stakeholders. **Note:** Depending on the number of stakeholders, the Program may choose to post the draft standards to a secure SharePoint site and provide site access to stakeholders.
2.4.6	Stakeholders review the draft document(s) for the specified period) and submit feedback.
2.4.7	The AA collates the submitted feedback in the *Stakeholder Consultation Summary* form.
2.4.8	The PM & AQSC review the feedback and revise the document(s) as required.
2.4.9	The AA reformats the draft document(s).

2.5	Standards Piloting
2.5.1	A pilot of the standards is conducted by the Assessment Coordinators, in consultation with the AQSC and PM, to ensure that each standard is relevant, understandable, measurable, beneficial and achievable.
2.5.2	Feedback is provided to the CPSA on the following: 1) relevance of standards to scope of stakeholder practice 2) measurability of the standard 3) rating scale 4) wording of the standards (clear and unambiguous).
2.5.3	The AQSC and PM review the pilot feedback and incorporate validated revisions.
2.5.4	The AA reformats the draft document(s) (see Appendix A – Versioning).

2.6	Approval
2.6.1	The PM and AQSC determine questions / issues arising from stakeholder feedback requiring Committee consultation.
2.6.2	The PM and AA prepare the dossier for the Advisory Committee meeting, including the draft standards and highlighting any questions / issues.
2.6.3	The PM presents the draft standards to the Advisory Committee for review and approval.
2.6.4	The PM and AQSC incorporate any changes resulting from the Advisory Committee review and approval.
2.6.5	The AA reformats the document(s) (see Appendix A – Versioning).
2.6.6	The PM presents the standards to the MFAC for review and approval.
2.6.7	The PM and AQSC incorporate any changes resulting from the MFAC review and approval.

2.7	Implementation
2.7.1	The AA prepares the final version of the standards, including final confirmation of formatting, and document name and date to reflect the version number (see Appendix A – Versioning). The copyright is also incremented to the year of distribution of the new version. This is known as the current version.
2.7.2	The APC reviews the draft document(s) formatting.
2.7.3	The AA prepares current version Word and PDF documents.
2.7.4	The AA prepares a working copy of the standards from the current version Word document.
2.7.5	The AA posts the standards (Word and PDF current versions) on the secure SharePoint site.
2.7.5	The PM develops a memo for standards distribution, based on the *Standards Initial Distribution Memo Template*.
2.7.6	The AA sends the memo for standards distribution to appropriate facility contacts (Medical Directors and/or alternate contacts as per Program processes) notifying that the standards are available on the SharePoint site for a 3-month period.

2.7.7 The PM and AQSC develop appropriate educational presentations / tools related to the new standards for stakeholders (e.g., webinars, Program Guides, website, etc.).

2.7.8 The AD, PM and AQSC pursue ISQua accreditation of the new standards.

2.8 Distribution to Stakeholders other than accredited facilities

2.8.1 Distribution of copies of the standards to stakeholders other than accredited facilities (e.g., regulatory bodies, etc.) required approval by the AD.

2.8.2 If approved The CPSA provides a PDF version (watermarked "not for distribution").

2.8.3 For other external stakeholders (e.g. instrument vendors etc.):

1) approval is considered on an ad hoc basis by the Assistant Registrar
2) if approved, the CPSA provides a PDF version for sale at a cost of $ 900.00 CDN per set.

2.9 Standards Copyright / Reference Permission Request

2.9.1 CPSA accredited facilities and other approved users may download, print or make a copy of any part of the standards documents for their noncommercial personal use.

2.9.2 Any other reproduction in whole or part requires written permission for the CPSA and the material must be credited to the CPSA.

2.9.3 To receive permission to reproduce/reference all or part of the Accreditation Standards, the facility must submit the *Standards Copyright/Reference Permission Request* form.

2.9.4 The AA who receives the request submits the form, upon receipt, to the appropriate PM for approval.

2.9.5 If the requestor is not previously approved, the PM reviews the request with the AD for approval.

2.9.6 The PM signs the authorization section of the form and directs the AA to return the form to the requestor indicating approval.

2.9.7 If approval is not granted, the PM communicates with the requestor outlining why the request was denied.

Appendix A-1: Versioning Guidelines for Standards Documents:

Version #	Action
Draft d1	To focus group
Draft d2	For public comment
Month, YYYY – Draft d3	Advisory Committee
Month, YYYY – Draft d4	MFAC
Month, YYYY – Draft d5	Council
Month, YYYY – v1	For Final Distribution
Month, YYYY – v1.1*	Upon annual / ad-hoc revision
Month, YYYY – v.2**	Upon 4-year revision

***** Sub-versions: version sub# (e.g., .1) continually increments with the release of revisions (annual or ad-hoc) of a version

****** Version # continually increments with the release of a new 4-year version of the standards

Appendix A-2: Reference Bibliography Guidelines for Standards Documents

Reference	Format
Book, single author	Resource directory acronym. Last name, First initial. *Book Title: Subtitle.* Edition or Version (if other than first). Place: Publisher. Year.
Book, two authors	Resource directory acronym. Last name, First initial. Last name, First initial. *Book Title: Subtitle.* Edition or Version (if other than first). Place: Publisher. Year.
Book, multiple authors	Resource directory acronym. Last name, First initial. Last name, First initial and Last name, First initial. *Book Title: Subtitle.* Edition or Version (if other than first). Place: Publisher. Year.
Chapter in edited book	Resource directory acronym. Chapter author's Last name, First initial. *Chapter Title.* Editor's First initial, Last name. Edition or Version (if other than first). *Book Title* (pp # - #) Place: Publisher. Year.
Guideline e.g. CLSI	Resource directory acronym. *Guideline Title: Subtitle.* Edition or Version (if other than first). Place: Publisher. Year.
Article	Resource directory acronym. Last name, First initial. *Title of article.* Title of Journal (or Periodical). Volume #. pp #-#. Year.
Website	Resource directory acronym. Last name, First initial. *Title of document.* Retrieved from http:// (URL)

References:

1. APA. *APA Format Citation Guide*. Retrieved from https://www.mendeley.com/guides/apa-citation-guide
2. AHS. *Guide to Writing Laboratory Documents.* Laboratory Quality Manual. Version 1.5,9. Alberta Health Services. 2018.

COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Appendix B

Accreditation Standards Revision Process

1.0 Revision Policy

1.1	Annual Revision
1.1.1	Stakeholder requests for revision and post-assessment feedback surveys are reviewed upon receipt.
1.1.2	Any required revisions received throughout the year are recorded in the standards revision tracking spreadsheet for follow-up in the annual revision process. 1) Accreditation Quality Systems Coordinator (AQSC) will contact WCDAA signatories annually (Sept.) to request and review out of province revision requests.
1.1.3	All required revisions are incorporated and tracked.
1.1.4	Standard revisions are recommended for approval by the Advisory Committee (AC) and approved by the Medical Facility Accreditation Committee (MFAC).
1.1.5	Following the approval process: 1) a new sub-version of the standards is issued. 2) the Stakeholder Implementation Process is initiated.
1.1.6	If a revision requires an extraordinary standards release prior to the annual review, this would follow the same process as the annual revision.
1.2	**4-year Stakeholder Review**
1.2.1	Every four years, a comprehensive stakeholder consultation process is performed.
1.2.2	The current standards are distributed to stakeholders for review and comment.
1.2.4	CPSA reviews the findings from the stakeholder review and incorporates any revisions as indicated.
1.2.5	Standard revisions are recommended for approval by the Advisory Committee (AC) and are approved by the Medical Facility Accreditation Committee (MFAC).
1.2.6	Following the approval process: 1) a new version of the standards is issued. 2) the Stakeholder Distribution Process in initiated.
1.3	**Standards to External Stakeholders**
1.3.1	For other external stakeholders (e.g. instrument vendors etc.) requesting copies of CPSA accreditation standards: 1) approval is considered on an ad hoc basis by the Assistant Registrar 2) if approved, the CPSA provides a PDF version for sale at a cost of $ 900.00 CDN per set.

2.0 Revision Processes

2.1 Standards Resource Management

2.1.1 The Accreditation & Quality Systems Coordinator (AQSC) is responsible for maintaining the Standards Resource directory including:

1) acquiring new versions of cited reference documents when available
2) filing new versions in the electronic directory
3) archiving old versions of resources
4) informing appropriate Program Managers of available material
5) performing an environmental scan for any potential new reference sources

See also *Accreditation Reference Management Process*

2.2 Revision Management

2.2.1 The Program Manager (PM) is responsible for:

1) an environmental scan of relevant reference materials (new, updated, obsolete) on a consistent, on-going basis
2) notifying the AQSC in writing (either by email or by entering into the standards revision management spreadsheet) of any new, updated or deleted reference materials and any stakeholder revision requests
3) notifying stakeholder in writing acknowledging receipt of request and if submitted revision has been accepted or declined with rationale as appropriate

2.2.2 The AQSC reviews:

1) requests from stakeholders to determine validity of the request and the submitted references
2) feedback from stakeholder post-assessment satisfaction surveys
3) changed, new or obsolete reference materials received from the PM, stakeholders or other sources
4) all cited references
5) feedback from stakeholder review annually and from stakeholder consultation every 4 years

2.2.3 Reference review determines:

1) currency of the reference material
2) any changes to content and implication on the standards/AOC
3) any new content and necessity for new standards/AOC
4) any deleted content and implication on the standards/AOC
5) any changes in reference numbers

Proposed changes must be determined with consideration of other relevant references.

2.2 Revision Management continued

2.2.4 For updated versions of documents, the AQSC:

1) retrieves the electronic or hard copies of the new and previous versions
2) opens the standards in which the document is referenced
3) searches for the individual standards where the document is referenced
4) compares the new version to the previous version of the document to determine if changes to the standards are required based on:
    a. change in the content
    b. additional new content
    c. deleted content
5) archives the previous version of the document

Note:

1) For CAP checklist standards that are deleted, check to see if:
    a. merged into another revised standard
    b. moved to another checklist (most commonly GEN or COM)

Accreditation CAP Standards Revisions_v1_10102019 - Copy.docx

2.2.5 The AQSC consults with the PM on any proposed changes.

2.2.6 The AQSC enters all proposed revisions to standards, AOC, guidance and reference materials into the *Standards Revision Management* spreadsheet with green highlighting.

2.2.7 The AQSC:

1) incorporates validated changes to standards into the current working copy of the relevant standards document
2) updates the bibliography in the standards document

2.2.8 Deleted standards are archived and the numbers are retired never to be used again to ensure there is an intact audit trail for each standard.

If a substantive revision of a document or document section is done, consideration may be given to renumbering of the standards in that document/section. A crosswalk of the numbering changes will be prepared and this information will be provided to stakeholders with the distribution of the new standards.

2.2.9 The AQSC updates the *Standards Revision Management* spreadsheet detailing:

1) the standards number
2) source of the change
3) the type of change (standard/AOC /references/guidance, etc.) and details of the change
4) requirement for vetting by the Advisory Committee (changes to Standard only – new, deleted or revised)
5) for deleted standards, indication that the standard number is archived
6) date of change and version # being edited

2.2.10 The AQSC highlights the completed revision in the *Standards Revision Management* spreadsheet in yellow.

2.2	Revision Management continued
2.2.11	The AQSC enters all reference changes on a separate worksheet in the *Standards Revision Management* spreadsheet; where it is a change only to the reference(s), this change is not recorded on the worksheet that details changes to standard, AOC, etc. Only those changes where the reference # changes are recorded, not if only document version changes
2.3	**Stakeholder Review and Standards Consultation (4 year revision)**
2.3.1	The program specific Accreditation Assistant (AA) posts the current standards (pdf of working copy) and *Stakeholder Standards Review form* to secure SharePoint site for stakeholder review and comment.
2.3.2	The AA notifies the applicable stakeholders of the review period (determined by each PM for their programs).
2.3.3	The AQSC, in consultation with the PM, reviews the stakeholder feedback and incorporates validated revisions.
2.3.5	The AQSC, in consultation with the PM, reviews the feedback and incorporates validated revisions.
2.4	**Approval**
2.4.1	The AA creates the *Standard Review & Revisions – for Committee* document listing changes to standards only that are highlighted in yellow in the *Standards Revision Management* spreadsheet. Committee discussion/recommendation for approval is only required for revisions to the actual standards and not to the assessment of compliance (AOC) questions, guidance or references.
2.4.2	The PM presents the *Standard Review & Revisions – for Committee* document to the Advisory Committee for review and recommendation for approval.
2.4.3	Once added to document, the "Yes" in the "To Committee" cell is changed to the date of the Committee Meeting.
2.4.4	The PM and AQSC incorporate any changes resulting from the Advisory Committee review into the working copy of the standards and track the changes in the *Standards Revision Management* spreadsheet.
2.4.5	After Advisory Committee recommendation for approval and required editing, the AA prepares the *Standard Review & Revisions – for MFAC* document, using the *Standard Review & Revisions – for Committee* document, with any required edits.
2.4.6	The PM presents the *Standard Review & Revisions – for MFAC* document, to MFAC for review and approval.
2.4.7	The PM and AQSC incorporate any changes resulting from the MFAC review into the working copy of the standards and track the changes in the *Standards Revision Management* spreadsheet.

2.5	Implementation
2.5.1	The AQSC changes the dates and version to reflect the new version number (see Appendix B – Versioning).The AA reviews the formatting of the working copy.
2.5.2	Once the AA is satisfied that the formatting is correct, the AA provides the Accreditation Program Coordinator (APC) with a link to the new version of the standards for review and final acceptance.
2.5.3	The AA prepares a current document (Word and .pdf) from the working copy.
2.5.4	The AA prepares the comprehensive *Standards Revision Summary* document(s) for each standards document (e.g., general/discipline/modality), which lists the numbers of all standards that have had any revision (standard, AOC, guidance, references).
2.5.5	The AQSC / PM compare the revision summary to *the Standards Revision Management* spreadsheet for accuracy.
2.5.6	After the *Standards Revision Summary* document(s) is confirmed, the PM removes all yellow highlighting of all revisions in the *Standards Revision Management* spreadsheet.
2.5.7	The PM archives the reference change worksheet and creates a new one for the subsequent year.
2.5.8	The AA compiles the *Standards Revision Statistics* document that tallies the total number of revisions.
2.5.9	The AA ensures that the facility contact lists (MD and/alternates) are current and correct (request current IT excel list as appropriate).
2.5.9	The AA posts the new version of all standards (Word and pdf versions) on the secure SharePoint site, as well as the *Standards Revision Summary* document(s) and the *Standards Revision Statistics* document.
2.5.10	The AA notifies appropriate facility contacts (Medical Directors and/or alternate contacts as per Program processes) that the standards are available on the SharePoint site for a 1-month period.

Appendix B-1: Stakeholder Feedback on Standards

There is a formal process for the submission of stakeholder requests for revisions to current standards.
Revision requests from stakeholders are accepted at any time for consideration if they meet the following conditions: ○ they are submitted using the *Stakeholder Standard Revision Request* form. ○ there is identification of specific standard or section if applicable to multiple standards. ○ they are supported by verifiable references; link or attachment (justification) included. ○ they are applicable to all accredited facilities and not limited to organization specific practice. ○ contact information is included for use by the CPSA if clarification of submission is required.
Stakeholder (assessor and facility) satisfaction surveys are distributed after each assessment.
Stakeholder surveys include the following question: *Please rate the following aspects of the CPSA Standards:* *(Strongly Agree / Agree/Disagree/Strongly Disagree/NA)* ○ *The content of the standards is relevant to accredited facilities.* ○ *The framework / format of the standards is understandable and user friendly.* ○ *The wording of the standards is clear and unambiguous.* ○ *There is a transparent system for measuring / rating compliance with each standard.* ○ *The process for requesting a revision to the standards is clear and easy to follow.* ○ *The information provided to users on approved standards revisions is clear and concise.*

Appendix B-2: Versioning Guidelines for Standards Documents: Annual

Version #	Action
Version: Month, YYYY – Draft v#-d1	Advisory Committee
Version: Month, YYYY – Draft v#-d2	MFAC
Month, YYYY – v#	For Final Distribution

Ad-hoc Revision

Version #	Action
Version: Month, YYYY – Draft v#.1-d1	Advisory Committee
Version: Month, YYYY – Draft v#.d2	MFAC
Month, YYYY – v#.1	For Final Distribution

***** Sub-versions: version sub# (e.g., .1) continually increments with the release of revisions (annual or ad-hoc) of a version

4-year Revision

Version #	Action
Version: Month, YYYY – Draft v#-d1	For public comment
Version: Month, YYYY – Draft v#-d2	Advisory Committee
Version: Month, YYYY – Draft v#-d3	MFAC
Month, YYYY – v#	For Final Distribution

***** Version # continually increments with the release of a new 4-year version of the standards

Appendix B-3: Timelines for Annual Standards Revision

Program	Standards Review Period	Advisory Committee Meeting*	MFAC Meeting	Council Meeting	Release Date
Diagnostic Imaging	April - May	May / June	June	September	October
NHSF	April - May	May / June	June	September	October
CST	July - August	N/A	September	December	January
Pulmonary Function	July - August	September	September	December	January
Sleep Medicine	July - August	September	September	December	January
Neurodiagnostics	September - October	Early November	November	December	January
Laboratory	November - December	January	February	February	March

*Advisory Committee standards approval meetings to be scheduled to facilitate progression to MFAC and subsequently Council meeting dates

Appendix B-4: Timelines for 4-year Stakeholder Consultation

Program	Standards Review Period	Stakeholder Review Period	Standards Pilot	Advisory Committee Meeting*	MFAC Meeting	Council	Release Date
Diagnostic Imaging	January – February	March	April	May / June	June	September	October
NHSF	January – February	March	April	May / June	June	September	October
Pulmonary Function	May - June	July	August	September	September	December	January
Sleep Medicine	May - June	July	August	September	September	December	January
Neurodiagnostics	July – August	September	October	November	November	December	January
CST	May - June	July	August	N/A	September	December	January
Laboratory	August - September	October	November	January	February	February	March

*Advisory Committee standards approval meetings to be scheduled to facilitate progression to MFAC and subsequently Council meeting dates

Appendix B-5: Cycle for 4-year Standards Stakeholder Consultation

Program	Initial 4-year review	Month
Laboratory	2022	October
Diagnostic Imaging	2023	March
Pulmonary Function	2024	June
Sleep Medicine	2024	June
Neurodiagnostics	2025	August
NHSF	2025	March
CST	2025	June