cpsa
COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Accreditation Program Guide

Sleep Medicine Diagnostics - Management of Changes to an Accredited Facility

November 2020 V4

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 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 imaging 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

Laboratories are required to be accredited by the CPSAs Sleep Medicine Diagnostics Accreditation Program if they perform and report diagnostic testing for patient management.

2.0 CPSA Accreditation Program

2.1 CPSA LINES OF BUSINESS

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

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

The Council of 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.

CPSA Regulates the Practices of Medicine in Alberta including:

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

2.2 CPSA MISSION, VISION, VALUES

Our Mission

Serving the public by guiding the medical profession.

Our Vision

The highest quality medical care for Albertans through regulatory excellence.

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 is right in the service to the public.

We make informed decisions.

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

We empower people.

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

We collaborate.

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

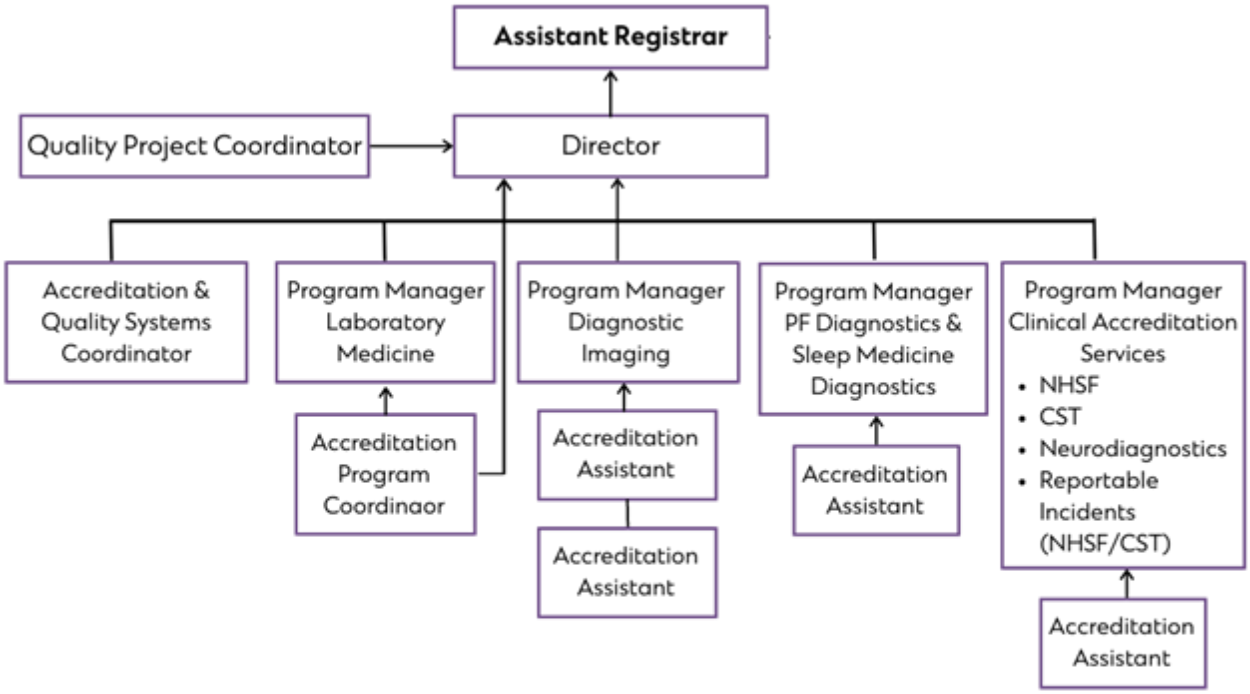
We are innovators.

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

We enjoy and find meaning in our work.

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

2.3 CPSA ORGANIZATIONAL STRUCTURE (ACCREDITATION) - FIGURE 1



2.4 ACCREDITATION PROGRAM HISTORY

In 1965, CPSA, upon recommendation from the Alberta Society of Pathologists, took steps to set up a program for accreditation for diagnostic medical laboratories. The Advisory Committee on Laboratory Medicine, which then reported to Council of 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 CPSA to accredit hospital-based laboratories on their behalf and to make recommendations to them pertaining to accreditation.

The CPSA Accreditation scope has increased since then to include other public and/or private diagnostic programs in Alberta such as:

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

2.5 AUTHORITY AND OVERSIGHT

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

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

a) permitting the Assessment Team to enter the 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 sleep medicine testing providing copies of the same if requested;
c) provide the information described in clause (c) in the form requested by the Assessment Team;
d) provide requested samples or copies of any material or product originating from sleep testing for the facility;

e) answer 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 facility;

f) providing requested copies of all documents and information relating to business arrangements involving the practice conducted in the sleep medicine diagnostics facility.

Although CPSA's statutory authority does not extend to health services in approved hospitals or healthcare facilities operated by the Government of Canada or the Government of Alberta (*Health Professions Act* Schedule 21 - 8.1(1)), the value of practice uniformity between the private and public sectors and the credibility of CPSA's programs have long been acknowledged by practitioners and government. Consequently, four of 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.

A standing committee, the Medical Facility Accreditation Committee (MFAC), oversees CPSA's accreditation programs with members appointed by 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 six standing advisory committees are composed of peer professionals (both physician/technical) who identify the needs and realities of Alberta stakeholders based on local practice.

2.6 OVERVIEW OF SLEEP MEDICINE DIAGNOSTICS PROGRAM

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

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

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

- organization, management and personnel
- quality management systems including policy, process and procedure
- physical facilities
- equipment, supplies, consumables
- information systems and archival
- pre-examination, examination and post-examination activities
- quality assurance activities
- safety
- infection, prevention and control

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

Benefits of CPSA Sleep Medicine Diagnostic 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 facilities to be assessed

Facilities are assessed initially when opened, subsequently on a four-year rotation or if they relocate their facility to a different physical location. This does not preclude an interim assessment that may be required as a result of expansion of testing services or an unsatisfactory performance complaint.

All facilities performing diagnostic laboratory examinations for patient management with the exception of physicians doing basic testing are required to undergo an assessment.

On-going self-assessment

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

CPSA accreditation standard tools are a significant resource for self-audits as they promote a constant state-of-readiness. Facilities 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 assessments

2.7 LABORATORY CLASSIFICATION

2.7.1 Comprehensive Polysomnography (Level 1)

Comprehensive polysomnography is a sleep diagnostic test where the patient comes in and spends the night in a bed hooked to several data gathering systems (EEG [brain wave], EMG [muscle movement], ECG [heart monitoring], OMG [eye movement] etc.) in addition to physiologic parameters, e.g. airflow, respiratory effort, and blood oxygenation level to assess for sleep disorders which includes the determination of sleep stage.

Comprehensive polysomnography labs are further broken down into adult and pediatric labs, and into those that provide other services to the general population and those that also service patients with complex respiratory needs.

2.7.2 Unattended Polysomnography (Level 2)

Unattended polysomnography is a sleep diagnostic test where the patient takes the testing equipment home or is hooked up at a location and then left alone for the night, to assess for sleep disorders which include the determination of sleep stage via some EEG (brain wave) monitoring in addition to physiologic parameters, e.g. airflow, respiratory effort, and blood oxygenation.

2.7.3 Home Sleep Apnea Testing (Level 3)

Home sleep apnea testing (HSAT) is an unattended sleep diagnostic test to assess for only obstructive sleep apnea without the determination of sleep stage. It is otherwise known by many names, including Portable Monitoring (PM) or Ambulatory Testing (AT). At a minimum, devices used in HAST must record airflow, respiratory effort, and blood oxygenation levels.

2.8 PERSONNEL

2.8.1 CPSA Accreditation Personnel and Roles

The Assistant Registrar of Accreditation has overall responsibility for the accreditation programs and is supported by the Director of Accreditation, the Program Manager for Sleep Medicine Diagnostics and the Accreditation Assistant for the program.

2.8.2 Advisory Committee on Sleep Medicine Diagnostics (ACSMD)

The Advisory Committee on Sleep Medicine Diagnostics (ACSMD) advises CPSA's accreditation programs for facilities in the community as defined in CPSA by-laws. Through the development of evidence based standards and monitoring facility compliance with those standards the Committee promotes high standards of medical practice in SMD facilities.

Roles and responsibilities of the ACSMD

- Assist with the developing and maintaining evidence based standards for SMD practice;
- Provide advice/recommendations to the Sleep Medicine Accreditation Program
- Respond to the needs of Albertans for improved services in Alberta

Membership and Tenure

Committee members are appointed by MFAC. 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:

- Respirologists
- Physiologists
- Psychiatrists
- College and Association of Respiratory Therapists of Alberta (CARTA) representative
- Dentists
- Representative from the Alberta Dental Association & College (ADA&C)

Non-Voting Members:

- CPSA Staff
- Assessment Coordinators

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

2.9 ASSESSMENT TEAMS

2.9.1 Assessment Coordinator

Assessment Coordinators are consultants of CPSA. During the assessment, they look at the facility's policies, processes, and procedures and will examine the records and evidence of implementation of the facility's policies, processes, and procedures.

Sleep Medicine Accreditation is a process-based audit model; it is not possible to directly access every individual standard for the entire scope of service provision.

While performing assessments for CPSA, Assessment Coordinators 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.

Assessment Coordinator Training

Assessment Coordinators are required to participate in CPSA training before being allowed to perform any on-site assessments.

Following training, new ACs will shadow at least one assessment being performed by an existing AC and be shadowed on one assessment by an existing AC before performing assessments on their own.

Upon successful completion of the training sessions and exam, all Assessment Coordinators receive a continuing professional development certificate.

2.9.2 Physician Reviewer

A Physician Reviewer will be assigned to an assessment to perform an examination report/interpretation review.

2.9.3 Conflict Of Interest/Confidentiality Agreements/Liability

All members of CPSA accreditation committees, Assessment Coordinators and Physician Reviewers sign a Confidentiality Agreement with CPSA annually. Committee members, Assessment Coordinators and Physician Reviewers are also required to confidentially destroy all confidential assessment materials or return to CPSA for confidential disposal.

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

CPSA's liability insurance specifically extends to cover Assessment Coordinators and Physician Reviewers who are contracted or act as agents. As well, section 126(1) of the Health Professions Act (HPA) extends liability protection to all CPSA staff, contractors and agents. While performing assessments for CPSA, Assessment Coordinators 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.

3.0 Standards Document

3.1 STANDARDS OVERVIEW

The Standards are the basis for accreditation decisions and are compiled by CPSA and stakeholder experts, reviewed and approved by the ACSMD, with vetting and approval by MFAC and final approval by the Council of CPSA.

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. Each accreditation standard has an accompanying reference citation(s).

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

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

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

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

Prior to each assessment, standards documents applicable to the scope of the testing of a SMD 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.

3.2 FORMAT OF STANDARDS

The standards are process-based and incorporate a quality management system approach. The language, terms and organization of the documents are consistent (where relevant) with ISO 15189 and ISO 9001 (2015).

The standards documents are consistently organized in the following order:

- Leadership
- Planning
- Resources
- Competence
- Communication and Reporting
- Documented Information
- Operations
- Evaluation
- Improvement
- Terms and Definitions
- References
- Appendix A: Requirements for Alberta Sleep Medicine Facilities
- Requirements for Alberta Sleep Medicine Facilities
- Laboratory Classification
- Personnel Qualifications
- Authorized Requestors of sleep testing

Example: Standards Document Format - Figure 2

#	Standard	Reference	Assessment of Compliance
SM.7.1.1	**Pre-Examination - Examination Request**		
SM.7.1.1.2 PS	The consultation request form (requisition) includes information sufficient to uniquely identify the patient and the authorized requestor, as well as providing pertinent clinical information necessary for performance and interpretation of the requested examination.	CLSI[4] QMS07 – 5.1.1.2 ISO[1] 15189 – 4.7, 5.4.3 Refer to Appendix A.3 for province specific directives for authorized requestors	Does the consultation request form (requisition) include all of the following elements, if applicable: • patient's first and last name? • a second unique patient identifier (e.g., personal health number)? • date of birth? • gender? • legible full name of authorized requestor? • location/address of requesting physician/healthcare practitioner? • full name, location/address of "copy to" physician/ healthcare practitioner? • type of DSM test requested • any special instructions? • pertinent clinical information including indications, history and provisional diagnosis? • potential contraindications? • indication for a 'STAT' report? • date and time of patient referral by requester if applicable? • clinical information where appropriate to the examination requested? If information on the form is incomplete, is there a process for the DSM facility or service to obtain the required information prior to conducting the DSM test? Is there evidence that the facility maintains a written or electronic record of all requests Are consultation request forms reviewed on a regular basis to ensure they reflect current DSM information and criteria? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

Each standard consists of the following components:

Column 1

- 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.

Column 2

- Description of **standard requirement**

Column 3

- **Specific reference(s)** linked to reference listing at the end of the document
- **Interpretation guidance** where relevant regarding the application of requirements

Column 4

- **Assessment of compliance questions (AOC)** that provide specific guidance and practical direction for evaluation of compliance with the standard
- Compliance assessment category checkboxes
- Observation field for recording of objective evidence (field is expandable in electronic document)

3.3 ASSESSMENT OF COMPLIANCE

- Although the Assessment of Compliance (AOC) questions address the key evidence required to meet the intent of each standard, they **are not meant to be all encompassing**.
- There may be other evidence that demonstrates compliance with the intent of the standard. Individual assessors apply their own expertise in determining compliance with each standard.
- Compliance with the standard may be assessed by review of documents and records, observation, interviews or a combination of these techniques.
- Where AOCs state "All of the following", compliance with all elements is expected to achieve compliance with the standard.
- A single non-compliance may encompass one or more observations. In assessing compliance within the standards, assessors objectively record specific evidence of non-compliance in a detailed itemized report.
- 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.

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

Compliance Assessment Category:	
C	meets intent and requirements of standard
P	in progress (working towards meeting intent and requirements of standard; assessor notes evidence of progress towards full compliance)
E	exceeds requirements of standard
N	does not meet intent and/or requirements of standard
N/A	not applicable to scope of service or testing

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

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

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.

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

3.4 TERMS AND DEFINITIONS

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

3.5 REFRENCE 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 not with the cited references.

3.6 REVIEW AND REVISION OF STANDARDS

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

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

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

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

4.0 Accreditation Process - Management of Changes to an Accredited Facility

4.1 ADDED TESTS OR SERVICES

An assessment is required before a new test or service may be implemented, e.g. the addition of Level 2 testing to an existing Level 3 facility.

- A CPSA Notification – Change to Facility form must be completed and submitted to the CPSA as soon as possible to facilitate assessment resource planning.
- Notification must occur a minimum of 4-6 weeks in advance of the planned implementation of the new service.
- Notification must include the effective date of any changes
- Additional information regarding costs and timelines will be provided after notification
- An onsite assessment is required.
- This assessment will be limited to equipment, policies, processes, and procedures related to the new service.
- Qualification and site acceptance testing of any associated new equipment will be reviewed on site.
- A review of test reports will be done focused on patients who have undergone the new test.

4.2 CHANGE IN TESTING EQUIPMENT

An on-site assessment is scheduled at CPSA discretion; factors considered will be:

- Whether equipment is replacement in kind or not.
- Changes to procedures as a result of the change in equipment
    - Installation qualification/ acceptance testing of any new equipment will be reviewed onsite.
    - A review of test reports may be done focused on patients who have undergone testing with the new equipment.
- A CPSA Notification – Change to Facility form must be completed and submitted to the CPSA as soon as possible to facilitate any assessment resource planning.
    - Notification must occur a minimum of 4-6 weeks in advance of the planned implementation of the new service.
    - Notification must include the effective date of any changes

4.3 RELOCATIONS

A Facility Move assessment will be placed on the accreditation schedule:

- an onsite assessment is required before any testing at the new location may occur
- qualification and site acceptance testing of relocated and any new equipment will be reviewed on site
- A review of test reports may be done focused on patients who have undergone testing with the new equipment.
- a CPSA Notification – Change to Facility form must be completed and submitted to the CPSA as soon as possible to facilitate assessment resource planning
    - additional information regarding costs and timelines will be provided after notification
    - Notification must include the effective date of the relocation

4.4 RENOVATIONS

4.4.1 Minor Renovations

An on-site assessment may be scheduled at CPSA discretion.

A CPSA Notification – Change to Facility form must be completed and submitted to the CPSA in advance of the renovation.

- Notification must include the effective date of any changes

The determination of whether an on-site assessment is required will be determined based on the information provide to the CPSA.

- Exceptions to on-site assessment requirement include:
  - Reconfiguration of facility spaces without structural changes (this includes moveable wall systems)
  - Minor space repairs (e.g. counter top/bench replacement; floor repair, utility changes/upgrades)
- The final determination of whether an on-site assessment is required is at the discretion of the CPSA.
- If it is determined that an onsite assessment is not required, completion and impact of minor renovations will be assessed at the next 4-year accreditation assessment.

4.4.2 Major Renovations

Major renovations include structural changes to facilities that result in significant changes to physical layout and workflow processes.

An on-site assessment may be scheduled at CPSA discretion.

A CPSA Notification – Change to Facility form must be completed and submitted to the CPSA in advance of the renovation.

- notification must be made as soon as possible to facilitate assessment resource planning
- additional information regarding costs and timelines will be provided after notification
- notification must include the effective date of any changes

4.4.3 Temporary Space

If the lab is moving to a temporary, space while renovations are occurring the temporary space will be subject to an assessment.

- The assessment will be limited to review of physical space and relevant safety-related standards.
- Qualification and site acceptance testing of relocated equipment will be reviewed on site.

A CPSA Notification – Change to Facility form must be completed and submitted to the CPSA in advance of the move to the temporary space.

- Notification must be made as soon as possible to facilitate assessment resource planning
- Additional information regarding costs and timelines will be provided after notification
- Notification must include the effective date of the relocation

4.4.4 Return to current location post-renovation

An on-site facility move assessment is required.

- The assessment will be limited to review of physical space and relevant safety-related standards.
- Qualification and site acceptance testing of relocated equipment will be reviewed on site.

4.4.5 Operations continuing during renovation (no temporary facility)

An on-site facility move assessment is required post-renovation.

- The assessment will be limited to review of physical space and relevant safety-related standards.
- Qualification and site acceptance testing of relocated equipment will be reviewed on site.

4.4.6 Amalgamation of SMD Labs

A CPSA Notification – Change to Facility form must be completed and submitted to the CPSA.

- Notification must include the effective date of any changes
- Changes to any operations, locations, etc. must be specified, e.g. if a site is being closed, equipment is being moved, specific tests are being consolidated, etc.

On-site assessment at CPSA discretion

Factors considered will be:

- Changes to procedures as a result of the change
- Consolidation of testing activities
- Moves of equipment between labs
- Staff changes: technical or supervisory staff

4.4.7 Change in Ownership of SMD Lab

A CPSA Notification – Change to Facility form must be completed and submitted to the CPSA.

- Notification must include the effective date of any changes

On-site assessment at CPSA discretion

Factors considered will be:

- Changes to procedures as a result of the change, e.g. if purchased by a larger lab group that results in adopting new group testing procedures
- Staff changes: technical or supervisory staff

4.4.8 Change in Medical Director

A CPSA Notification – Change to Facility form must be completed and submitted to the CPSA.

- Notification must include the effective date of the change

4.4.9 Closing an Existing Accredited SMD Lab

A CPSA Notification – Change to Facility form must be completed and submitted to the CPSA.

- Notification must include the effective date of the closure.

4.5 INITATION

Note: Time frames are approximations and may vary depending on the scope, scheduling of the individual assessments, and unforeseen circumstances. Such as facility renovations or staff resource issues.

	Responsibility	Task	Additional Information
1.	Facility	A Notification of Change Form must be completed and submitted to CPSA disclosing the intent to move/renovate/ add new services to facility	At least 6 weeks before changes are implemented
2.	CPSA	CPSA reviews the Notification of Change Form and determines if an onsite assessment is required.	If it is determined that no onsite assessment is required, the completion of the proposed changes and their impact will be assessed at the next 4-year accreditation assessment.

If it is determined that an onsite assessment is required the process will be as follows:

	Responsibility	Task	Additional Information
3.	CPSA 4-6 weeks before assessment	Provides facility to be assessed with the *Assessment Logistics Form*	The facility Medical Director is requested to complete and sign the *Assessment Logistics Form* which includes: • provision of key assessment/accreditation contacts • approval of proposed Assessment Coordinator
4.	CPSA 4-6 weeks before assessment	Selects Assessment Coordinators (AC)	Potential conflicts of interest are considered when selecting proposed AC(s)
5.	Facility 4-6 weeks before assessment	Completes Assessment Logistics Form (ALF)	Completed form is submitted with signature to CPSA within the specific timeline.
6.	CPSA 4-6 weeks before assessment	SharePoint access	CPSA sets up secure SharePoint access for the key assessment contacts identified in the ALF and communicates this information.

4.6 PRE-ASSESSMENT

	Responsibility	Task	Additional Information
7.	CPSA	Provides the SMD facility to be assessed via SharePoint with a "*Pre-assessment Data Verification" (PADV) Form*	• CPSA initially pre-populates the form with information in the current CPSA database and facilities are directed to carefully review pre-populated data prior to resubmission to the CPSA. The PADV will be tailored to the specific proposed change
8.	SMD facility	Completes *PADV form* and uploads to SharePoint with required signature within the specified timeline	CPSA follows up directly with the Facility regarding any missing documentation or documentation requiring further clarification.
9.	SMD facility	Uploads assessment materials to SharePoint site	All materials required to complete the assessment, (e.g. manuals, sample forms) are uploaded or links provided for the AC to review.
10.	CPSA	Reviews submitted PADV form and prepares assessment documentation	• accesses completed PADV forms and submitted documentation (embedded and uploaded on SharePoint) • AA downloads all desk audit documents submitted via SharePoint into the CPSA facility folders/directories • AA follows up directly with the facility regarding any missing documentation or documentation requiring further clarification • AA notifies the AC that that the material is ready to be reviewed
11.	AC	Desk Audit	The AC reviews the completed PADV forms, submitted documentation (embedded and uploaded on SharePoint) and prepares an initial citation report noting identify areas of concern for further follow-up during the assessment.
12.	AC	Determines assessment date in consultation with the facility	Assessments are not scheduled until the desk audit is completed. CPSA sets up assessment team access to SharePoint and sends notification. AC notifies CPSA of assessment date.

4.7 ON-SITE ASSESSMENT

	Responsibility	Task	Additional Information
13.	AC	Assessor daily self-assessment	AC has the contact-tracking app downloaded and active. AC completes the daily COVID self-assessment without incident • if an illness is noted, AC contacts PM immediately and follows designated protocols CPSA-AA checks daily to ensure that all ACs have completed survey and let PMs know if they have not
14.	AC On-site	Conduct an opening meeting with zone/facility personnel	At the beginning of the on-site assessment at each facility, the AC conducts an opening meeting for zone/group/facility personnel that encompasses: • introductions • the scope of the assessment • assessment logistics and timelines • assessment process outline
15.	SMD facility	Conducts facility tours for assessment team members	An initial tour of the entire facility will give a general overview of the operation and key personnel.

	Responsibility	Task	Additional Information
16.	AC On-site	Conduct on-site assessments	**The Assessment Process – General** The accreditation assessment process involves: • verifying compliance with the intent of accreditation standards • follow-up of previously identified areas of concern • interaction with staff at all levels • review of zone managed areas (as identified by the facility) **The CPSA Assessment Tool:** The on-site assessment is performed using the facility specific standards document tools. **Assessment of Compliance** • Although the Assessment of Compliance (AOC) questions address the key evidence required to meet the intent of each standard, they are not meant to be all-encompassing. • There may be other evidence that demonstrates compliance with the standard. Where AOCs state "all of the following", compliance with all elements is expected (e.g. test request form). Individual assessors apply their own expertise in determining compliance with each standard. Compliance with the applicable standard may be assessed by review of documents and records, observation, interviews or a combination of these techniques. Focus on those standards applicable to the scope of the submitted changes • directly assess ALL applicable standards with either a PS or SS designation • verify that all non-conformances cited on the previous assessment have been corrected • Review documents (policies, processes and procedures - PPPs) and records • the AC should choose a random, representative selection of documents, records and reports to review • ACs should not rely solely on documents, records and reports chosen or selected by the facility to review

	Responsibility	Task	Additional Information
	AC On-site	Conduct on-site assessments	Record objective evidence: • as immediately as possible after encountering citation • using the assessment standards tool (paper or electronic) • do not reply on memory • be factual and thorough • provide ample background detail for interpretation and determination by the CPSA of the requirement/evidence of compliance (EOC) Photographic evidence for Quality Assurance: • for safety related citations, corroborate observation with photographic evidence • AC will be responsible for notifying the SMD facility contact and taking required photographs • AC will ensure that no individuals or confidential information are identifiable in the photographs
17.	AC On-site	Initiate CPSA Critical Findings process if necessary	Assessment Coordinators encountering any situation that in their judgment, represents potential for significant immediate harm to staff or patients are directed to bring it to the attention of: **1.** the SMD testing personnel for immediate action as deemed appropriate **2.** AC will consult with CPSA immediately via telephone CPSA Critical Findings policy, process, and procedure will be followed, if necessary.
18.	AC On-site	Conduct a summation conference for the SMD facility management and personnel	The primary purpose of the summation conference is to highlight the key findings and outline the next steps in the assessment process. The AC serves as the primary spokespersons during the summation meeting in order to bring consistency of format and detail to the process. In person summation, conferences are conducted at each facility at the end of the facility assessment. Summation conference agenda: • Short review of the objectives of the accreditation process • Review of commendable findings and practices including any 'E' citations • Review of significant non-conformances. (The purpose of this is to ensure that there are no "significant surprises" in the report when received by the facility/zone.)

	Responsibility	Task	Additional Information
			• Review of purpose and inclusion of interview findings in final reports • Overview of the next steps in the CPSA accreditation process including timelines for: • meeting of the ACSMD to review the draft final report • distribution of final report • SMD facility responses and submission of EOC • Acknowledgement of SMD facility personnel for their cooperation and support of the accreditation process • facility questions

4.8 POST ASSESSMENT

	Responsibility	Task	Additional Information
19.	AC	Informs CPSA assessment is complete	Contacts the PM, advises them the assessment is complete, and provides their recommendation for provisional accreditation status.
20.	CPSA	Grants provisional accreditation to facility	Once the assessment is complete and barring any significant safety issues, the facility will be granted provisional accreditation.
21.	AC	Uploads findings to SharePoint	ASAP following the assessment the AC will upload their audit findings along with any photographs, sample documents, etc. to the SharePoint site. As soon as possible following each SMD facility's on-site assessment, the AC submits via SharePoint: Citation Recording Summaries including: • standard number (if known) • compliance assessment category (PEN) • detailed observation / objective evidence • comments (where applicable) AC should include any additional information or direction regarding on-site findings that would assist CPSA in finalizing the requirements and requested EOC.

	Responsibility	Task	Additional Information
22.	CPSA	Prepares report	Based on the citation recording summaries provided by the AC, CPSA completes / finalizes the following for each SMD facility report: • SMD facility demographics and key personnel • assessment information and team details • accreditation process dates • SMD facility overview Citations: • standard number • safety Risk category • compliance assessment category (PEN) • detailed observation / objective evidence • requirement • evidence of compliance (where applicable) • timeline for submission of EOC Guidelines for requirement of 30 day EOCs: • significant safety issue All other requests for 90 day EOCs are based on the judgment of the Assessors / CPSA included, but are not limited to, the following: • all 'P' – 'In Progress' citations • issues cited on previous assessment reports • all requirements categorized as PS / SS CPSA ensures consistent / uniform: • application of the standards based on similar observations • wording of requirements and EOC • timelines for submission of EOC
23.	ACSMD	Issues management	If there are issues or concerns based from report non-conformances that require the ACSMD's expertise, CPSA will bring anonymized / redacted issues / themes forward for discussion. The AC will be available at the ACSMD meeting to respond to additional questions or clarification requests (anonymized discussion; the facility will not be named – no identifiers used, e.g. name).

	Responsibility	Task	Additional Information
24.	CPSA (Quality System Coordinator)	Reviews report	Reviews / revises the SMD facility assessment report to: • eliminate any personal bias • ensure consistent application of the standards from one assessor/assessment to another • endorse EOC requirement and timeline for EOC submission based on risk assessment • ensure standards/requirements reflect current best practice
25.	CPSA	Loads the final report into the facility's folder on SharePoint, Notifies the facility the report is available	Within 15-20 business days of the Quality System review CPSA posts the finalized individual facility report on the SharePoint site. CPSA notifies the facility Medical Director and facility Accreditation contact that the final report is available on SharePoint. The final report is formatted to include a section for a facility response to each individual non-conformance/in-progress citations.
26.	Facility	If applicable, the facility submits a response to requirements and/or recommendations requested with evidence of compliance	Facilities are required to electronically input their response directly into the report and embed any requested supporting documentation/EOC as applicable. Responses are uploaded to the secure facility SharePoint site. For requirements with requests for EOC, facilities must provide a response and any required EOC based on timelines specified in the report (30 or 90 days from the date of the report). Responses to requirements without requests for EOC, facilities must provide a response within 90 days from the date of the report.

	Responsibility	Task	Additional Information
27.	CPSA	Reviews facility responses to requirements, recommendations and requested evidence of compliance.	Following the receipt of 30 and 90 day responses, CPSA reviews and either approves the SMD facility responses or revises the requested evidence of compliance, with a view to: • acceptability of response / corrective action • further action / clarification required EOC may be required for any response based on submitted response, regardless of whether EOC was requested in the initial report. If there are issues or concerns based from responses that require the ACSMD's expertise, CPSA will bring anonymized and redacted issues / themes forward for discussion. The AC will be available at the ACSMD meeting to responding to additional questions or clarification requests (anonymized discussion; the facility will not be named – no identifiers used, e.g. name or facility number. CPSA provides a section in each report to facilitate CPSA responses.
28.	CPSA (Quality System Coordinator)	Reviews/approves facility responses.	Reviews the responses to EOC and the CPSA evaluation to: • eliminate any personal bias • ensure consistent application of the standards • endorse any further EOC requirement and timeline for submission based on risk assessment
29.	CPSA	Identifies charts for review (if required by the scope of the change)	6-8 weeks following the implemented change, a random sampling of 10 charts from the testing done at the facility following the change will be requested. The charts should represent the case mix of the population served by the lab and the various interpreters. The SMD facility will be asked to upload the chosen examinations into the chart review section of their response folder on SharePoint. Same day upload is optimal. The SMD facility will have 5 business days from the date of the on-site assessment to provide the documentation. The SMD facility will notify the CPSA when the reports are ready for review.

	Responsibility	Task	Additional Information
30.	CPSA (Physician reviewer)	Physician reviewer reviews reports to ensure criteria for interpretation are being met	If a report review is required, the PR will have one business week to review the reports, associated paperwork, and submit findings back to the CPSA via SharePoint. The chart review is not meant to assess individual specialist competency; it is rather a benchmark of quality testing and processes.
31.	CPSA	Prepares any additional citations based on the physician reviewer report	Based on the physician reviewer report, CPSA creates any additional citations and adds them to the facility report: Citations: • standard number • safety Risk category • compliance assessment category (PEN) • detailed observation / objective evidence • requirement • evidence of compliance (where applicable) • timeline for submission of EOC CPSA ensures consistent / uniform: • application of the standards based on similar observations • wording of requirements and EOC • timelines for submission of EOC
32.	CPSA (Quality System Coordinator)	Reviews updated report	Reviews / revises the added citations from the chart review to: • eliminate any personal bias • ensure consistent application of the standards from one assessor/assessment to another • endorse EOC requirement and timeline for EOC submission based on risk assessment • ensure standards/requirements reflect current best practice
33.	CPSA	Loads the updated report into the facility's folder on SharePoint, Notifies the facility the report is available	Within 15-20 business days of the Quality System review CPSA posts the finalized individual facility report on the SharePoint site. CPSA notifies the facility Medical Director and facility Accreditation contact that the updated report is available on SharePoint.

	Responsibility	Task	Additional Information
34.	Facility	If applicable, the facility submits a response to requirements and/or recommendations requested with evidence of compliance	Facilities are required to electronically input their response directly into the report and embed any requested supporting documentation/EOC as applicable. Responses are uploaded to the secure facility SharePoint site. For requirements with requests for EOC, facilities must provide a response and any required EOC within 30 days from the date of the updated report.
35.	CPSA	Reviews facility responses to requirements, recommendations and requested evidence of compliance.	Following the receipt of the responses, CPSA reviews and either approves the SMD facility responses or revises the requested evidence of compliance, with a view to: • acceptability of response / corrective action • further action / clarification required EOC may be required for any response based on submitted response, regardless of whether EOC was requested in the initial report. If there are issues or concerns based from responses that require the ACSMD's expertise, CPSA will bring anonymized and redacted issues / themes forward for discussion. The AC will be available at the ACSMD meeting to responding to additional questions or clarification requests (anonymized discussion; the facility will not be named – no identifiers used, e.g. name or facility number. CPSA provides a section in each report to facilitate CPSA responses.
36.	CPSA (Quality System Coordinator)	Reviews/approves facility responses.	Reviews the responses to EOC and the CPSA evaluation to: • eliminate any personal bias • ensure consistent application of the standards • endorse any further EOC requirement and timeline for submission based on risk assessment
37.	CPSA	Recommends Full accreditation status	CPSA determines recommendation for Full accreditation status to MFAC which is reviewed at the next meeting for approval. If CPSA recommends that a facility is denied accreditation, the facility may access the formal appeal process.

	Responsibility	Task	Additional Information
38.	CPSA (MFAC)	Grants full accreditation status.	Accreditation recommendations are reviewed and approved by MFAC. If a facility is denied accreditation, the facility may access the CPSA formal appeal process.
39.	CPSA	Provides Certificate of Accreditation and Window Vinyl to display at facility	
40.	CPSA	Provides accreditation evaluation forms to all relevant stakeholders	To evaluate the effectiveness of the assessment process and customer satisfaction, facilities and the assessment team are asked to provide feedback on the Accreditation Evaluation Survey. Stakeholders are afforded the opportunity for anonymous comment. Results are compiled and reviewed annually by the CPSA. Changes to process are implemented as appropriate based on feedback.

5.0 Honoraria and Expense Reimbursement

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

6.0 Annual/Assessment Fees

Annual Fees

Facilities will be invoiced annually in December for the upcoming fiscal period of April 1 – March 31 for the Annual Admin Fee.

Assessment Fees

An assessment fee will be invoiced on a quarterly basis for facilities assessed in that quarter.