Accreditation Program Guide

Sleep Medicine Diagnostics Accreditation: Management of Changes to an Accredited Facility

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College of Physicians & Surgeons of Alberta

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1 Scope

This document addresses the process to be followed when changes to a currently accredited Sleep Medicine diagnostic laboratory occur. This includes:

- Addition of new services/tests
- Relocations
- Renovations
- Amalgamations
- Changes in ownership
- Changes in Medical Director
- Closure of a lab

2 Purpose of Accreditation

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

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

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

3 Determination of Requirement for Sleep Medicine Diagnostics Accreditation

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

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

4.1 CPSA Lines of Business

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

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

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

The lines of business for the CPSA are as follows:

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

4.2 CPSA Mission, Vision and Values

4.2.1 Our Mission

Serving the public by guiding the medical profession

4.2.2 Our Vision

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

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

4.2.3 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, and have the resources they need to 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.

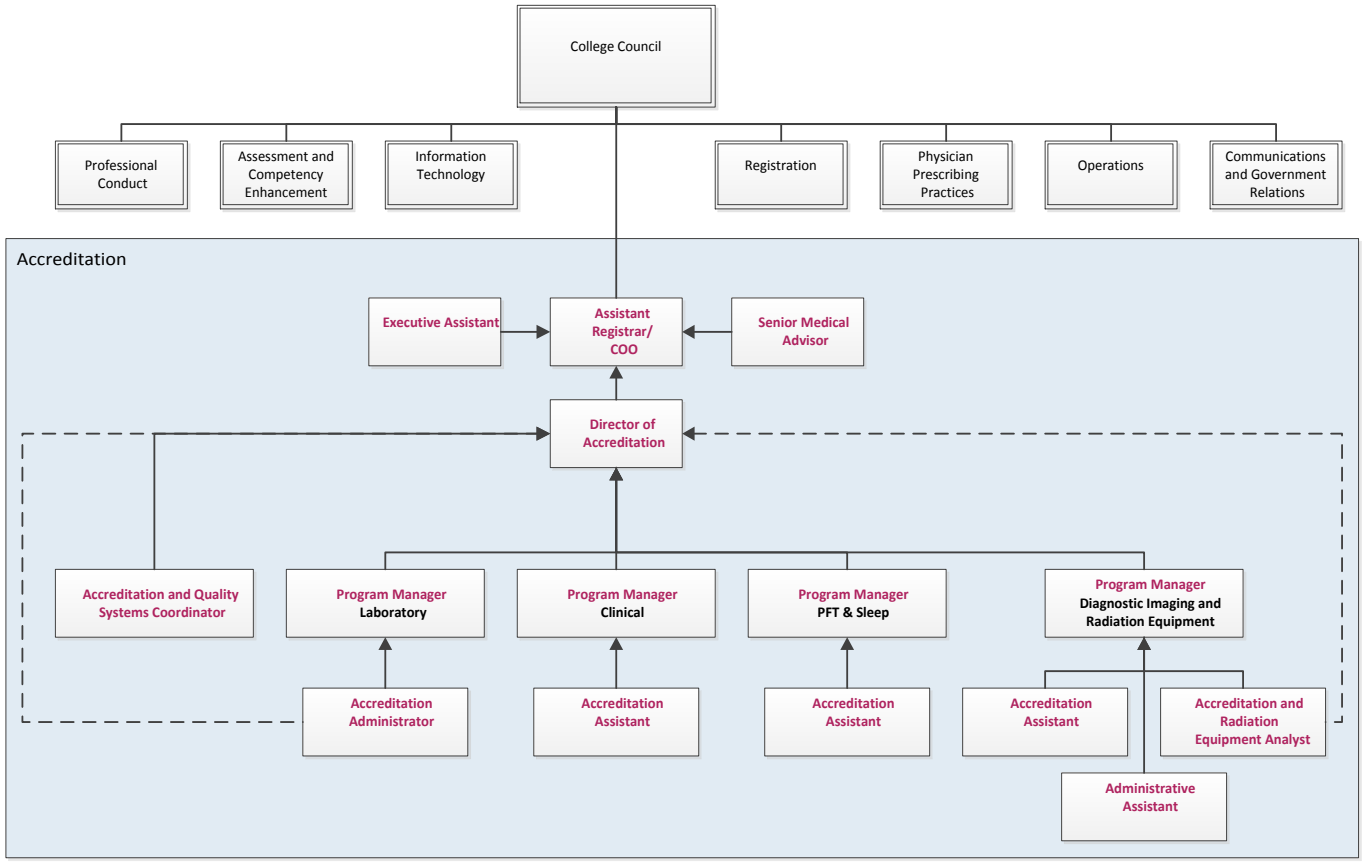
We think ahead to create opportunity. We set the bar high and value creativity in exploring new and better ways of doing our work.

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.

4.3 CPSA Organizational Structure

CPSA Organizational Chart - Figure 1



4.4 Accreditation Program History

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

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

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

- Cardiac Exercise Stress Testing (CEST)
- Hyperbaric Oxygen Therapy (HBOT)
- Non-Hospital Surgical Facilities (NHSF)
- Pulmonary Function Diagnostics (PFD)
- Sleep Medicine Diagnostics (SMD)
- Vestibular Testing

4.5 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 is 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 Sleep Medicine Diagnostics 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 Sleep Medicine Diagnostics 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 Sleep Medicine Diagnostics 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 Sleep Medicine Diagnostics facility;
g) providing requested copies of all documents and information relating to business arrangements involving the practice conducted in the Sleep Medicine Diagnostics facility.

Although the CPSA's statutory authority does not extend to health services in approved hospitals or 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 the CPSA's programs have long been acknowledged by practitioners and government. Consequently, four of the CPSA's accreditation programs (Laboratory Medicine, Pulmonary Function Diagnostics, Sleep Medicine Diagnostics and Neurophysiology) are under contract with government agencies to provide accreditation of public sector diagnostic 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 and audits minutes of all other meetings to report on the diligence and objectivity of the work conducted.

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

4.6 Overview of Sleep Medicine Diagnostics (SMD) 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 Accreditation Program examines all aspects of Sleep Medicine Diagnostics (SMD) 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 storage
- 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 service provision and performance through objective evaluation. Assessors evaluate facility compliance with the specific requirements of a standard based on objective observation and assessment. All accreditation assessment findings are vetted by the Advisory Committee on Sleep Medicine Diagnostics to eliminate any potential personal assessor bias, ensure a consistent and thorough approach for all facilities, and to review standards for applicability to current best practice.

4.7 Benefits of the CPSA 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

4.8 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.

4.9 Frequency and Selection of Laboratories to be Assessed

Sleep Medicine 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.

At the beginning of the year, all facilities in the area due to be assessed are identified and the Assessment Coordinator is assigned. All facilities performing laboratory examination for patient management are required to undergo an assessment.

After a new facility is registered and initially accredited, it will then be added in to the regular 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.

4.10 On-going Self-Assessment

The CPSA Sleep Medicine Diagnostics 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

4.11 Laboratory Classifications

4.11.1 Polysomnography (Level 1)

Labs providing attended sleep diagnostic tests (multi-parametric tests) to assess for sleep disorders which includes the determination of sleep stage.

These labs also provide:

- EEG montages for seizure detection
- Multiple Sleep Latency Tests (MSLT)
- Maintenance of Wakefulness Tests (MWT)
- Esophageal pressure monitoring
- Actigraphy
- End-tidal CO2 monitoring
- Transcutaneous CO2 monitoring

Level 1 labs are further classified as providing either services to adult or pediatric patients or both and a distinction is also made between standard or comprehensive polysomnography and polysomnography for complex respiratory patients.

4.11.2 Unattended Polysomnography Testing (Level 2)

Lab provides unattended sleep diagnostic tests to assess for sleep disorders which includes the determination of sleep stage.

4.11.3 Home Sleep Apnea Testing (Level 3)

A lab providing unattended sleep diagnostic tests to assess for obstructive sleep apnea without the determination of sleep stage. This term aligns with that used by AASM and more clearly aligns with the intent of this testing than any other term. It is otherwise known by many names, including Portable Monitoring (PM) or Level III or LIII or L3 or Ambulatory Testing (AT). At a minimum, devices used in HSAT must record airflow, respiratory effort, and blood oxygenation. The HSAT is **NOT** the same as Unattended Polysomnography Testing (UPSGT).

4.12 Personnel

4.12.1 CPSA Sleep Medicine Diagnostics Accreditation Personnel and Roles

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

4.12.2 Advisory Committee on Sleep Medicine Diagnostics (ACSMD)

The Advisory Committee on Sleep Medicine Diagnostics oversees the CPSA's accreditation program for medical Sleep Medicine Diagnostics facilities; for private facilities as defined in CPSA by-laws and for public facilities through contract with Alberta Health Services. Through the development of evidence based standards and monitoring facility compliance with those standards, the Committee promotes high standards of medical practice in Sleep Medicine Diagnostics facilities.

Roles and Responsibilities of the ACSMD

- Develop and maintain evidence based standards for Sleep Medicine Diagnostics practice;
- Provide advice/recommendations to the Medical Facility Accreditation Committee (MFAC) on pending decisions relating to the provision of Sleep Medicine Diagnostics services;
- Monitor compliance with CPSA approved standards through reviewing on-site assessment accreditation reports;
- Provide education to promote safety and quality improvement initiatives;
- Respond to the needs of stakeholders for improved services in Alberta
- Review and audit of the business practices of the facility to ensure compliance with relevant CPSA by-laws and standards.

Membership and Tenure

Committee members are appointed by MFAC. 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
- College and Association of Respiratory Therapist representatives

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.

4.13 Assessment Teams

4.13.1 Composition

4.13.1.1 Assessment Coordinator

Each assessment team will include an Assessment Coordinator who is a consultant of the 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 Diagnostics Accreditation is a process-based audit model; it is not possible to directly assess every individual standard for the entire scope of service provision.

While performing assessments for the 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.

4.13.1.1.1 Assessment Coordinator Training

All Assessment Coordinators are required to participate in CPSA training sessions before being allowed to perform any on-site assessments. Following completion of the training sessions, they must demonstrate competency by successful completion of an on-line examination.

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

4.13.1.2 Physician Reviewer

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

4.13.2 Conflict of Interest

Assessment team members are required to declare any conflicts of interest for each assessment. The names of the assess team are provided to the facility in advance to ensure that the lab has the opportunity to confirm that no conflict of interest exists.

4.13.3 Confidentiality Agreements

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

4.13.4 Liability

The CPSA's liability insurance specifically extends to cover Assessment Coordinators who are contracted or act as agents. As well, HPA section 126(1) extends liability protection to all CPSA staff, contractors and agents.

5 Standards Document

5.1 Standards Overview

The Standards are the basis for accreditation decisions and are compiled by CPSA and stakeholder experts, they are reviewed and approved by the Advisory Committee on Sleep Medicine Diagnostics, with vetting and approval by the Medical Facility Accreditation Committee, with final vetting and approval by the Council of the College.

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 Medical Directors receive a complete standards document set. CPSA accredited 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 the CPSA and the material must be credited to the CPSA.

Prior to each assessment, standards documents applicable to the scope of the Sleep Medicine Diagnostics services 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.

5.2 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 document is organized in the following order:

- Leadership
    - Entity
    - Ethics and Conflict of Interest
    - Mission, Vision and Values
    - Goals and Objectives
    - Legislation and Due Diligence
- Planning
    - Quality Management
    - Management of Change
    - Safety
    - Infection Prevention and Control
- Resources
    - Personnel
    - Infrastructure
    - Equipment, Consumables and Supplies
    - Information Systems
- Competence
- Communication and Reporting

- Documented Information
- Operations
    - Pre-examination Policies, Processes and Procedures
    - Examination Policies, Processes and Procedures
    - Post-examination Policies, Processes and Procedures
- Evaluation
- Improvement
- Terms and Definitions
- References
- Appendices:
    - Requirements for Alberta Diagnostic Sleep Medicine Facilities and Services
    - Authorized requesters of Sleep Medicine Diagnostic Tests

Standards Document Format Example - 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 SMD facility or service to obtain the required information prior to conducting the SMD 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 SMD 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)

5.2.1 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 Compliance 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

C - "Meets intent" all policies and procedures are in place with accompanying documentation.

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 completed.

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

N - "Does not meet intent" upon objective assessment of the evidence, a failure to meet the intent and/or requirement of the standard will result in a citation of non-compliance recorded during the assessment.

The standards are process based and 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.

Receipt of "FULL" accreditation status is contingent upon satisfactory resolution of all non-compliances. This is completed when the CPSA receives evidence from the facility of compliance (N and P).

5.3 Terms and Definitions

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

5.4 Reference Listing

A detailed reference citation listing is provided at the end of this document. Specific references can be accessed by clicking on individual link(s) included beside each standard. The references support the content and intent of each standard. It should be noted that all components of the cited references may not always be relevant and/or applicable. Compliance is expected with CPSA Standards.

5.5 Review and Revision of Standards

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

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

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

- Submitted using the Stakeholder Standards Review Form.
- Identification of specific standard or section if applicable to multiple standards
- Supported by detailed rationale/justification AND verifiable references (link or attachment must be included)
- Applicable to all Sleep Medicine Diagnostics 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

6 Accreditation Process – Management of Changes to Previously Accredited Facilities

6.1 Added Tests or Services

Notification of the CPSA is required before a new test or service may be implemented, e.g. the addition of non-specific inhalation challenges, addition of arterial blood gas sampling and analysis, or the changing of the scope of the lab from Level II to Level III.

- Notification must be in writing and should be made either by letter or email to the Program Manager as soon as possible to facilitate assessment resource planning.
- Notification must occur a minimum of 6 weeks in advance of the planned implementation of the new service.
- 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

6.2 Change in Testing Equipment

Notification of the CPSA is required.

On-site assessment 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.

6.3 Relocations

Notification of the CPSA is required in advance of the relocation.

- Notification must be in writing and should be made either by letter or 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.

An onsite assessment will be scheduled

- 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.

6.4 Renovations

6.4.1 Minor Renovations

Notification of the CPSA is required in advance of the renovation.

- Notification must be in writing and should be made either by letter or email to the Program Manager.

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 Advisory Committee on Sleep Medicine Diagnostics.
- 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.

6.4.2 Major Renovations

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

Notification of the CPSA is required in advance of the renovation.

- Notification must be in writing and should be made either by letter or 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

6.4.2.1 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.

6.4.2.2 Return to current location post-renovation

An on-site 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.

6.4.2.3 Operations continuing during renovation (no temporary facility)

An on-site 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.

6.5 Amalgamation of SMD Labs

Notification of the CPSA is required.

- Notification must be in writing and should be made either by letter or email to the Program Manager
- 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

6.6 Change in Ownership of SMD Lab

Notification of the CPSA is required.

- Notification must be in writing and should be made either by letter or email to the Program Manager
- 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

6.7 Change in Medical Director

Notification of the CPSA is required.

- Notification must be in writing and should be made either by letter or email to the Program Manager
- Notification must include the effective date of the change

6.8 Closing an Existing Accredited SMD Lab

Notification of the CPSA is required.

- Notification must be in writing and should be made either by letter or email to the Program Manager
- Notification must include the effective date of the closure.

6.9 Assessment Timeline

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	Notify CPSA intent to move/renovate/add new services to facility	At least 6 weeks before changes implemented
2.	CPSA	CPSA reviews the notification 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) Adds AC to the ALF the lab submitted
5.	Facility/Zone 4-6 weeks before assessment	Completes Assessment Logistics Form (ALF)	Completed form is submitted with signatures to CPSA within the specified timeline
6.	CPSA 4-6 weeks before assessment	SharePoint access	The CPSA sets up secure SharePoint access for the key zone assessment contacts identified in the ALF and communicates this information.

6.10 Pre-Assessment

	Responsibility	Task	Additional Information
7.	CPSA 4-6 weeks before assessment	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 requests submission of the following for each individual facility undergoing assessment: • general facility information • hours of operation • key facility personnel (including those that the CPSA will interview via teleconference ~ 1 week prior to the assessment) • scope of modalities (services) • zone managed programs / processes • organizational structure • blank examples of facility examination request (requisitions/consultation) forms and blank screening form/questionnaires)
8.	SMD facility 4-6 weeks before assessment	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 4-6 weeks before assessment	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.	AC 4-6 weeks before assessment	Determines assessment date in consultation with the facility	Assessments are not scheduled until all assessment documentation is received. CPSA sets up assessment team access to SharePoint and sends notification AC notifies CPSA of dates.
11.	Assessment team 2-4w prior to assessment	Reviews assessment documentation and materials in preparation for the on-site assessment.	Each assessment team member is expected to review the assessment documentation to ensure that they are adequately prepared to perform a thorough and efficient assessment. The primary purpose is to: • become familiar with the standards • become familiar with the scope of service including which programs/processes are zone managed • identify areas of concern for further follow-up during the assessment (previous citations)

6.11 On-site assessment

	Responsibility	Task	Additional Information
12.	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 • assessment logistics and timelines • assessment process outline
13.	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.
14.	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 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.

	Responsibility	Task	Additional Information
	AC On-site	(cont'd)	Compliance with the standard may be assessed by review of documents and records, observation, interviews or a combination of these techniques. It is not possible to review the entire scope of operations • focus on areas of highest and lowest Sleep Medicine diagnostics volumes, likely problem areas and Sleep Medicine diagnostics results with highest impact on patient care • directly assess ALL standards with either a PS or SS designation • verify that all non-conformances cited on the previous assessment have been corrected • Review Zone managed programs/processes • 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 for review. Record objective evidence: • as immediately as possible after encountering citation • using the assessment standards tool (paper or electronic) • do not rely on memory • be factual and thorough • provide ample background detail for interpretation and determination by the CPSA of the requirement/EOC Photographic evidence for the Advisory Committee: • 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

	Responsibility	Task	Additional Information
	AC On-site	(cont'd)	Compliance Assessment Categories: Non-conformances (N) • failure to meet the intent and/or requirement of the standard • The standards are process based and a single non-compliance may encompass one or more observations. In-progress citations (P) • working towards meeting intent and requirements of standard; assessor notes evidence of timely progress towards full compliance • require submission of future evidence of compliance based on direction from the AC 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 • are not meant to address partial or incomplete compliance (e.g. incomplete manuals) Exceeds requirement citations (E) • recognize those situations where a SMD facility exceeds the intent of the standard and employs commendable practice • the intent of capturing these occurrences is to promote and focus on quality initiatives
15.	AC On-site	Notify AC/CPSA immediately of any serious deficiencies that may have immediate impact on staff or patient safety	ACs 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 the Sleep Medicine diagnostics personnel for immediate action as deemed appropriate AC will consult with the Program Manager at CPSA immediately via telephone
16.	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

	Responsibility	Task	Additional Information
			• 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.) • 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
17.	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
18.	CPSA (Physician reviewer)	Physician reviewer reviews reports to ensure ATS criteria for interpretation are being met	If a report review is required the PR will have one business week to review the reports and associated paperwork and submit findings back to the CPSA via SharePoint
19.	CPSA	Prepares report	
20.	CPSA (ACSMD)	Vets and approves final facility report.	ACSMD reviews/revises/ approves the facility assessment citations to: • eliminate any personal bias • ensure consistent application of the standards from one assessor/assessment to another • endorse EOC requirement • ensure standards/requirements reflect current best practice In addition to providing a report summarizing facility compliance with accreditation standards, the ACSMD also provides an educational service to physicians through feedback with respect to interpretations of the studies reviewed.
21.	CPSA	Loads the final report into the facility's folder on SharePoint, Notifies the facility the report is available	

	Responsibility	Task	Additional Information
22.	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.
23.	CPSA	Reviews facility responses to requirements, recommendations and requested evidence of compliance.	The CPSA reviews the facility responses to the requirements, recommendations and requested evidence of compliance and provides recommendations to the ACSMD as to the appropriateness of the response. The CPSA reviews the assessment team feedback for consistency prior to ACSMD review.
24.	CPSA (ACSMD)	Reviews/approves facility responses. Recommends full accreditation status.	At the next meeting following the receipt of 30 day responses, the ACSMD reviews/revises/ approves the recommendations of the assessment team on the facility responses, regarding: • acceptability of response/corrective action • any further action/clarification required
25.	CPSA (MFAC)	Grants full accreditation status.	Accreditation decisions of the ACSMD are reviewed and approved by MFAC. If a facility is denied accreditation, the facility may access the CPSA formal appeal process.
26.	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.

7 Honoraria and Expense Reimbursement

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

8 Assessment Fees

A list of current Sleep Medicine Diagnostics Fees can be found on the CPSA website.

An invoice is issued after the AC has reviewed the report. Payment to the CPSA is due upon receipt of the invoice.

9 List of Accredited Laboratories

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