DIAGNOSTIC ACCREDITATION PROGRAM
College of Physicians and Surgeons of British Columbia

Accreditation Standards 2015

Pulmonary Function

Version 1.2 (Effective May 3, 2017)

Enhancing public safety through excellence in diagnostic medicine accreditation

DIAGNOSTIC ACCREDITATION PROGRAM OF BRITISH COLUMBIA
Pulmonary Function Accreditation Standards 2015

Established in 1971, the Diagnostic Accreditation Program (DAP) has a mandate to assess the quality of diagnostic services in the province of British Columbia through accreditation activities. As a Program of the College of Physicians and Surgeons of British Columbia, the mandate and authority of the DAP is derived from the *Health Professions Act:* Bylaws of the College of Physicians and Surgeons Section B.

The DAP is committed to promoting excellence in diagnostic health care through the following activities:

- Establishing performance standards that are consistent with professional knowledge to ensure the delivery of safe, high quality diagnostic service;
- Evaluating a diagnostic service's level of actual performance to achieving the performance standards;
- Establishing a comparative database of health care organizations, and their performance to selected structure, process, and outcome standards or criteria;
- Monitoring the performance of organizations through the establishment of external proficiency testing programs and other robust quality indicators of performance;
- Providing education and consultation to health care organizations, managers, and health professionals on quality improvement strategies and "best practices" in diagnostic health care;
- Ensuring information learned from accreditation processes is used for system wide improvement;
- Reporting to government, stakeholders and the public on the performance of the diagnostic health care system as assessed through accreditation;
- Strengthening the public's confidence in the quality of diagnostic health care;
- Assisting organizations to reduce risks and increase safety for patients and staff;
- Assisting organizations to reduce health care costs by promoting quality practices that increase efficiency and effectiveness of services; and
- Serving and safeguarding the public.

The Diagnostic Accreditation Program currently has twenty-three (23) accreditation programs covering the following diagnostic services:

Diagnostic Imaging

- Diagnostic Radiology
- Diagnostic Mammography
- Diagnostic Ultrasound
- Diagnostic Echocardiography
- Diagnostic Computed Tomography
- Diagnostic Magnetic Resonance Imaging
- Diagnostic Nuclear Medicine
- Diagnostic Bone Densitometry

Laboratory Medicine

- Sample Collection, Transport, Accessioning and Storage
- Hematology
- Chemistry
- Transfusion Medicine
- Microbiology
- Anatomic Pathology
- Point of Care Testing
- Cytology
- Cytogenetics

Neurodiagnostic Services
- Electroencephalography
- Evoked Potentials
- Electromyography & Nerve Conduction Studies

Pulmonary Function
- Hospital Based Services
- Community Based Services

Polysomnography

Accreditation Standards

The foundation of the accreditation programs are the provincial standards and accompanying criteria and criterion descriptors set by the Diagnostic Accreditation Program. These are evidence based, outcome focused mandatory requirements and best practices that are aligned to the principles of quality. The standards, criteria and criterion descriptors are directive in nature yet allow the diagnostic service flexibility in how they approach and address each element. The accreditation standards are high level directive goal/outcome/deliverable statements that are to be reached. The accompanying criteria and criterion descriptors specify the activities that must be completed to support the standard being achieved.

Standards are:
- Outcome focused
- Directed at the operational level
- Goal statements of best practice
- Directive not prescriptive

Criteria and criterion descriptors:
- Specify activities to be completed
- Roll-up to standard attainment

The Diagnostic Accreditation Program's accreditation standards are developed through a collaborative, consultative and consensus building process that involves health professionals and organizations, academics, experts, consumers, health authorities, colleges and the Ministry of Health Services. The process for standards development and review allows for considerable input from the diagnostic services that will be using the standards.

The DAP accreditation standards consist of three components:

1. **Standard** – a goal statement of achievable levels of performance. An accreditation standard is identified by a first level whole number ending in ".0" such as 1.0, 2.0, 3.0 etc.

2. **Criterion** – activities or components of the standards that once implemented lead to the overall attainment of the standard. A criterion is identified by the first level number indicating the standard that it is associated to, and a second level number such as X.1, X.2, X.3, etc.

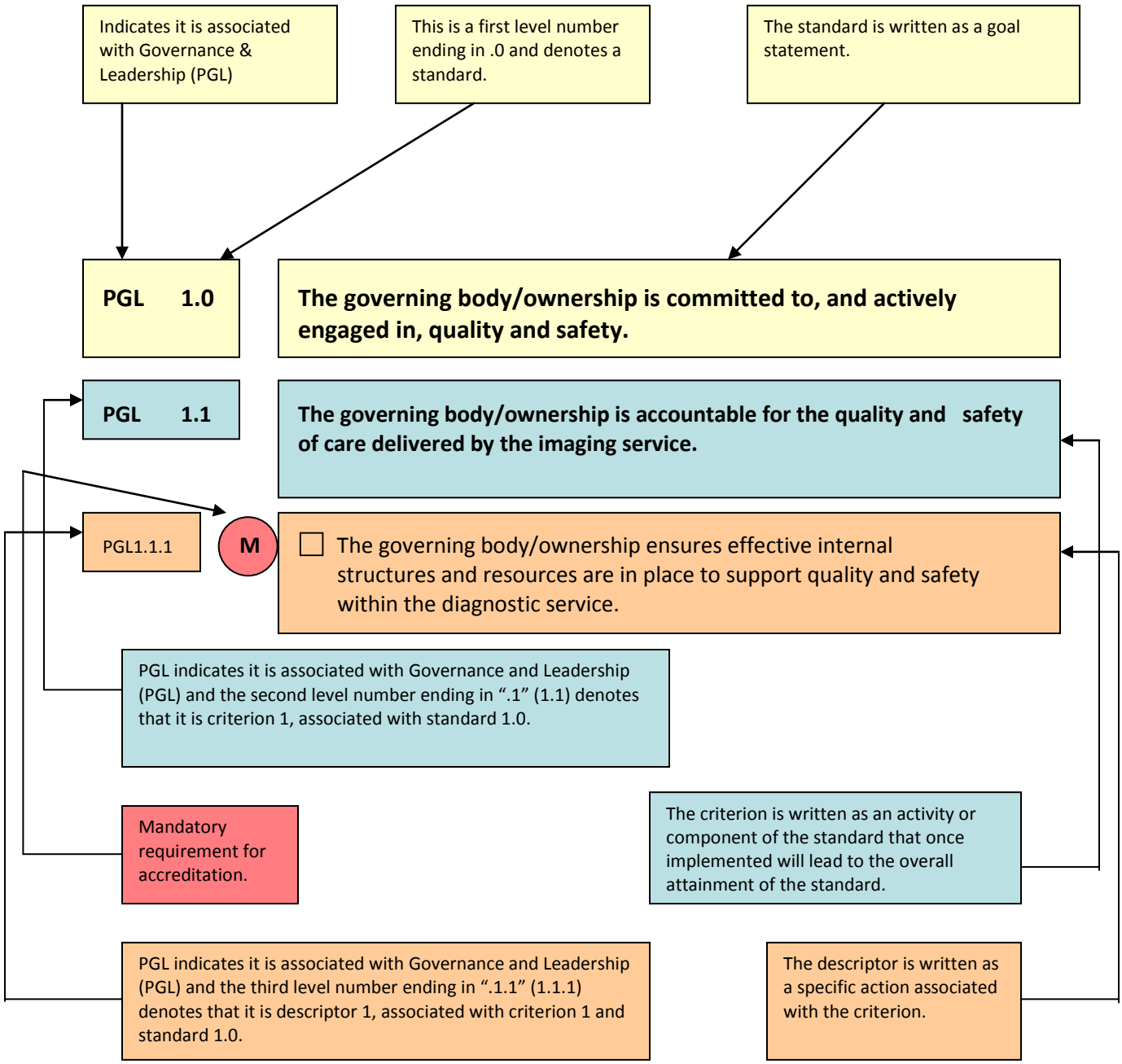
3. **Criterion Descriptors** – specific actions for each criterion. Criterion descriptors are identified by the first level standards number, the second level criterion number and a third level criterion number such as X.Y.1, X.Y.2, etc. A criterion descriptor is either a mandatory requirement for

accreditation, or a best practice. Mandatory criterion descriptors are indicated by a bold type face '**M**'.

Quality Category Codes

Governance and Leadership	PGL
Medical Staff	PMS
Human Resources	PHR
Patient and Client Focus	PPC
General Safety	PSA
Patient Safety	PPS
Infection Prevention and Control	PIPC
Quality Improvement	PQI
Information Management	PIM
Equipment and Supplies	PES
Global Modality	GP
Pulmonary Function	PF

Example of an Accreditation Standard



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ACCREDITATION STANDARDS 2015

GOVERNANCE AND LEADERSHIP

Introduction:
Each organization has a corporate governance structure that is ultimately responsible for the quality and safety of services provided. For large organizations, such as health authorities and some privately owned facilities, this governance structure is the Board of Directors. For other privately owned facilities the governance structure may be a partnership group or an individual as the sole proprietor. The term "governing body/ownership" is used in these standards to refer to those individuals who provide corporate governance to the organization.

Each organization, regardless of its complexity, also has a leadership structure. Many leadership responsibilities directly affect the provision of diagnostic services as well as the day to day operations of the diagnostic department. In some cases, these responsibilities will be shared amongst leaders; in other cases, a particular leader may have primary responsibility. Regardless of the organization's structure, it is important that leaders carry out all of their responsibilities.

The Governance and Leadership section of the accreditation standards addresses:
- Governance
- Leadership
- Service planning
- Ethics

GOVERNANCE

PGL 1.0 The governing body/ownership is committed to, and actively engaged in, quality and safety.

PGL 1.1 The governing body/ownership is accountable for the quality and safety of care delivered by the diagnostic service.
Intent: The governing body/ownership defines their expectations for the diagnostic service management and senior leaders to create and maintain a quality and safety focused culture.

PGL1.1.1 **M** ☐ The governing body/ownership ensures effective internal structures and resources are in place to support quality and safety within the diagnostic service.

PGL1.1.2 **M** ☐ Reports on the quality and safety within the diagnostic service are received by the governing body/ownership at least once per year.

LEADERSHIP

PGL 2.0 The accountability and responsibility for key leadership functions is assigned.
Guidance: Functions may be assigned to an individual, leadership group or committee. An individual may be assigned to more than one key function.

PGL 2.1 Accountability and responsibility is assigned for:

PGL2.1.1 ☐ defining scope of service.
PGL2.1.2 ☐ budget development.
PGL2.1.3 ☐ medical staff.
PGL2.1.4 ☐ human resources.
PGL2.1.5 ☐ satisfaction/complaints management.
PGL2.1.6 ☐ staff safety.
PGL2.1.7 ☐ patient safety.
PGL2.1.8 ☐ infection prevention and control.
PGL2.1.9 ☐ disaster planning.
PGL2.1.10 ☐ quality improvement.
PGL2.1.11 ☐ information management.
PGL2.1.12 ☐ equipment and supplies.
PGL2.1.13 ☐ technical operations.

PGL 2.2 Responsibility for the clinical oversight of diagnostic service quality and safety is assigned and supported by the organization.
Guidance: Clinical oversight describes a system through which an organization continually improves the quality of their services and safeguards high standards of care through an environment that promotes clinical excellence.

PGL2.2.1 **M** ☐ A senior medical leader is appointed with responsibility for the quality and safety of the medical practice within the diagnostic service.

PGL2.2.2 **M** ☐ Medical leaders are actively involved in the monitoring of the clinical caseload.

PGL2.2.3 **M** ☐ Administrative and technical leaders are appointed with responsibility for the quality and safety of operational processes and technical operations within the diagnostic service.
Intent: It is the expectation that the job descriptions of diagnostic service leaders include quality and safety responsibilities.

PGL2.2.4 **M** ☐ There is a defined structure and process through which the medical, administrative and technical leaders are held accountable.

PGL2.2.5 **M** ☐ Medical, administrative and technical leaders work collaboratively to provide effective oversight of diagnostic service quality and safety.
Guidance: Reported safety and quality issues are discussed regularly.

PGL2.2.6 ☐ The organization provides leaders with the necessary training and support to effectively oversee the diagnostic service quality and safety.

PGL 2.3 There is a documented and dated organizational chart.
Guidance: The organizational chart includes medical, technical and administrative staff.

PGL2.3.1 **M** ☐ The management structure of the diagnostic service is clearly delineated.

PGL2.3.2 **M** ☐ Lines of accountability, responsibility and authority, as well as the interrelationships of all staff are clear.

PGL2.3.3 **M** ☐ Relationships to other organizations are identified (e.g. remotely located medical leadership).

SERVICE PLANNING

PGL 3.0 Diagnostic services meet the current and future needs of the patient population it serves.

PGL 3.1 The diagnostic service is in alignment with the mission, vision, values and strategic direction of the organization.
Intent: The governing body/ownership establishes the direction and unity of purpose for the organization.

PGL3.1.1 ☐ The mission, vision, and values of the organization have been communicated to all staff.

PGL3.1.2 ☐ The strategic direction of the organization has been communicated to the diagnostic service leadership.

PGL3.1.3 ☐ The strategic direction of the diagnostic service is in alignment with the mission, vision and values of the organization.

PGL3.1.4 ☐ The medical, administrative and technical leaders of the diagnostic service establish an operational plan that is aligned with the strategic direction of the organization.

PGL 3.2 The diagnostic service defines and documents their scope of services.

PGL3.2.1 ☐ The diagnostic service determines the scope of services using a process that considers relevant factors (e.g. patient population, existing capacity, clinical value of testing, referring physician requirements, etc.).

PGL3.2.2 ☐ The scope of service is documented and communicated to all staff.

PGL3.2.3 ☐ The scope of service is communicated to referring practitioners.

PGL 3.3 Annual operating and capital budgets are developed.

PGL3.3.1 ☐ Resources required to deliver the scope of service are identified.

PGL3.3.2 ☐ New capital equipment required to deliver the scope of service is identified.

PGL3.3.3 ☐ Budgets are developed with input from key leaders.

ETHICS

PGL 4.0 The diagnostic service delivers services and makes decisions in accordance with ethical principles.

PGL 4.1 The diagnostic service promotes an environment that fosters and requires ethical and legal behaviour.

PGL4.1.1 ☐ There is a written code of ethics for professional behaviour.

PGL4.1.2 ☐ There is a process for addressing unethical or illegal behaviour.

ACCREDITATION STANDARDS 2015

MEDICAL STAFF

Introduction:
The medical staff of the organization is comprised of those medical practitioners who hold a valid license to practice medicine in British Columbia, and who have been appointed to the medical staff by the governing body/ownership of the organization. The governing body/ownership has a responsibility to ensure that only qualified and competent medical practitioners are appointed to the medical staff. The medical staff is accountable to the governing body/ownership.

The Medical Staff section of the accreditation standards addresses:
- Medical staff leadership
- Medical staff credentialing and privileging
- Delegation of medical acts
- Medical staff contracts/agreements

MEDICAL STAFF LEADERSHIP

Introduction:
For health authority/hospital based diagnostic services, the medical leader may have the title of Chief, Department Head, Medical Director, or an alternate title. The medical leader and medical staff of health authority/hospital based diagnostic services operate within the provisions set out in the Medical Staff Bylaws, and are accountable to the governing body through the established medical staff structure of the health authority/hospital.

In private diagnostic service facilities, each physician is responsible for ensuring the activities of medical leadership take place, including assuring the competence of all physicians providing medical services within the organization through a peer review process.

If a physician is the owner in solo practice, they are responsible for ensuring the activities of medical leadership take place, inclusive of ensuring that they are qualified and competent themselves to undertake the scope of medical service provided within their organization.

See also Quality Improvement Accreditation Standards PQI 3.1 – PQI 3.2.

PMS 1.0 A medical leader is appointed with assigned responsibilities and accountabilities for the diagnostic service.

PMS 1.1 The medical leader has responsibility for medically related activities.

The medical leader:

PMS1.1.1 **M** ☐ works in collaboration with the governing body/ownership to grant physician privileges within the diagnostic service.

PMS1.1.2 ☐ establishes standardized interpretive comments and report formats.

PMS1.1.3 **M** ☐ is involved in the development and monitoring of performance measures for the diagnostic service.
Guidance: Medical leader involvement is critical to the development of clinical performance measures/indicators for the diagnostic service.

PMS1.1.4 ☐ makes recommendation on the number of qualified competent medical staff necessary to ensure quality and safety of diagnostic service provision.

PMS1.1.5 **M** ☐ establishes and monitors policies and procedures for the delegation of medical acts.

PMS1.1.6 **M** ☐ authorizes the implementation of technical/medical operational policies and procedures related to the diagnostic service.

PMS1.1.7 ☐ coordinates and integrates the diagnostic service with other departments and services.
Intent: If additional testing is recommended for a patient, the facility should have the capacity to perform the recommended tests, or refer the patient to another facility.

PMS1.1.8 **M** ☐ continuously monitors the professional performance of medical staff practicing in the diagnostic service through a peer review process.

PMS1.1.9 **M** ☐ actively participates in quality oversight and improvement activities.

REMOTELY SUPERVISED FACILITIES

Intent: Remotely supervised facilities provide services without medical leadership regularly on site. These facilities are typically small and located in remote communities where test interpretation is performed off-site at a larger facility or hospital.

PMS 1.2 Medical leaders must visit the remotely supervised facility to assess the quality and safety of the service.

PMS1.2.1 **M** ☐ The medical leader visits the facility prior to assuming responsibility for medical leadership for a new service.

PMS1.2.2 **M** ☐ At a minimum, the medical leader visits the facility annually.
Guidance: The annual visit may be undertaken by a delegated physician, or a technical delegate deemed qualified by the medical leader unless delegated medical acts are performed on-site.

PMS1.2.3 **M** ☐ The medical leader or delegate assesses the complexity of services provided and undertakes more frequent visits if warranted.

PMS 1.3 Logs to record the medical leader or delegate visits to remotely supervised facilities are maintained.

PMS1.3.1 **M** ☐ A log is kept to record the visit of the medical leader or delegate to the diagnostic service.

PMS1.3.2 **M** ☐ Recommendations for improvement or required follow-up are recorded in the log.

PMS1.3.3 **M** ☐ In the event that a delegate conducts the visit, the medical leader must receive a copy of the log within two weeks of visit completion.

PMS1.3.4 **M** ☐ The log is signed by the person conducting the visit.

PMS 1.4 Roles of authority, responsibility and accountability are clearly defined and maintained at remotely supervised facilities.

PMS1.4.1 **M** ☐ The medical leader or designated interpreting physician maintains ongoing communication with the technical staff and test requestors.

PMS1.4.2 **M** ☐ Processes are in place to ensure the prompt availability of an interpreting physician for consultation whenever required.

PMS1.4.3 **M** ☐ The medical leader documents those tests that may be performed at remotely supervised facilities.

MEDICAL STAFF CREDENTIALING AND PRIVILEGING

Introduction:
Credentialing is a process that involves the collection, verification and assessment of information regarding the education, training, experience and ability of an individual physician to perform a requested privilege. In British Columbia physicians must have the requisite credentials as outlined in the Provincial Privileging Dictionaries. Refer to http://bcmqi.ca/privileging-dictionaries.

Credentialing for physicians who hold privileges at any Health Authority facility is performed by the Health Authority, and includes assessing eligibility for MSP billings for restricted services. Many medical offices are owner operated solo practices and the physician may not hold privileges with a Health Authority; therefore, the physician would not have proceeded through a credentialing process. In these instances the physician is licensed to their scope of practice through the College of Physicians and Surgeons of BC. For MSP billing purposes for a restricted diagnostic service, the College will review the associated credentials required to be eligible to bill for these services and will notify MSP of the eligibility. For further information please contact credentialing@cpsbc.ca.

For community-based multi-physician facilities the medical director and ownership are responsible to ensure the physicians that practice in their facilities are appropriately credentialed, either through the Health Authority or by reviewing the credentials of the physician and ensuring that the physician has been deemed eligible to bill MSP for the services. There must be a formal process used for credentialing and privileging, and it is the expectation of these accreditation standards that the medical director and ownership can demonstrate these processes.

PMS 2.0 The diagnostic service has qualified and competent medical practitioners.

PMS 2.1 Information for each medical practitioner is collected, verified and assessed relative to the requested scope of practice/procedure.

This information includes:

PMS2.1.1 **M** ☐ current registration and licensure from the College of Physicians and Surgeons of British Columbia in the relevant specialty.

PMS2.1.2 **M** ☐ MSP billing eligibility confirmation from the College of Physicians and Surgeons of British Columbia to bill for restricted services, if not affiliated with a health authority.

PMS2.1.3 **M** ☐ relevant education and training.

PMS2.1.4 **M** ☐ evidence of physical ability to perform the scope of practice/procedure.

PMS2.1.5 **M** ☐ experience and competency to perform the scope of practice/procedure.

PMS 2.2 Medical staff only practice within the scope of their privileges.

PMS2.2.1 **M** ☐ An accurate list of all medical practitioners practicing within the diagnostic service is maintained.

PMS2.2.2 **M** ☐ A record is maintained for each medical practitioner indicating the scope of service/procedures they are permitted to practice within the diagnostic service and this is communicated to the practitioner and the organization.

PMS 2.3 Pulmonary Function (PF) services are provided by qualified and competent physicians.

PMS2.3.1 **M** ☐ Physicians providing adult or pediatric diagnostic pulmonary function services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries.

Guidance: Pulmonary function services are considered core and non-core privileges, depending on the relevant specialty; therefore may require further training, experience and demonstrated skills. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform diagnostic pulmonary function.

DELEGATED MEDICAL ACTS

Refer to the College of Physicians and Surgeons of British Columbia for additional information, accessible at https://www.cpsbc.ca/files/pdf/PSG-Delegation-of-a-Medical-Act.pdf.

PMS 3.0 The delegation of medical acts does not compromise patient safety or quality.

PMS 3.1 Delegated medical acts are clearly defined.

PMS3.1.1 **M** ☐ Each delegated medical act is clearly defined and circumscribed.

PMS3.1.2 **M** ☐ The degree of medical supervision required is identified.

Guidance: Medical supervision may be direct, with the physician in attendance, or through technology (e.g. video link, telephone).

PMS3.1.3 **M** ☐ Competency requirements to perform the delegated medical act are clearly identified.

PMS 3.2 The delegation of medical acts has been approved and accepted.

PMS3.2.1 **M** ☐ Approval from the governing body/ownership of the organization has been obtained prior to the delegated medical act being carried out in the organization.

PMS3.2.2 **M** ☐ The delegation of the medical act has been accepted by the individual(s) who will perform the delegated medical act.

PMS3.2.3 **M** ☐ The diagnostic service maintains a list of approved medical acts and the individuals authorized to conduct each delegated medical act.

PMS 3.3 Delegated medical acts are performed by competent individuals.

PMS3.3.1 **M** ☐ Additional training is provided to individuals performing the delegated medical act.

PMS3.3.2 **M** ☐ Competency assessment to perform a specific delegated medical act is conducted by a physician or technical delegate.
Guidance: Competency assessment of the technical delegate is conducted by a physician with relevant expertise in the medical act.

There is a competency assessment record for each individual performing delegated medical acts. The competency assessment record includes:

PMS3.3.3 **M** ☐ the date of the assessment.

PMS3.3.4 **M** ☐ the specific act(s) being assessed.

PMS3.3.5 **M** ☐ the name of the physician or technical delegate conducting the assessment.

PMS3.3.6 **M** ☐ the signature of the individual attesting to the competence of the individual performing the specific act(s).

PMS3.3.7 **M** ☐ The competency of the individual performing the specific delegated medical act is reassessed annually by a physician or technical delegate.
Guidance: The record of assessment for each individual is updated annually following the reassessment.

MEDICAL STAFF CONTRACTS/AGREEMENTS

Introduction:
Medical practitioners may be employees of an organization or may operate as independent medical practitioners under contract/agreement to a group or to the organization. Having a contract/agreement in place assists both parties to articulate expectations and communicates how disagreements will be resolved.

PMS 4.0 The diagnostic service effectively manages relationships with medical practitioners under contract/agreement.

PMS 4.1 There is a contract/agreement in place between the medical practitioner/group and the diagnostic service that specifies:

PMS4.1.1 ☐ services to be provided.

PMS4.1.2 ☐ names of the medical practitioner(s) providing the services.

PMS4.1.3 ☐ hours of service provision by the medical practitioner(s).

PMS4.1.4 ☐ location of where the medical practitioner(s) will be providing service.

PMS4.1.5 ☐ provision for on-call service during and outside regular operating hours.

PMS4.1.6	**M**	☐	participation in quality improvement activities. [1]
PMS4.1.7		☐	compliance with occupational health and safety regulations.
PMS4.1.8		☐	compliance with organizational and service policies and procedures.

PMS 4.2 There is a designated individual(s) assigned to manage the contract between the medical practitioner/group and the diagnostic service to:

PMS4.2.1	☐	ensure an effective and quality service is provided.
PMS4.2.2	☐	document any changes to the contract.
PMS4.2.3	☐	resolve any concerns brought forward by either party.

SPECIFIC DOCUMENTS REFERENCED

[1] Health Canada Safety Code 33, Section 3.2.3, 2009.

ACCREDITATION STANDARDS 2015

HUMAN RESOURCES

Introduction:
The management of human resources encompasses the policies, procedures and systems that influence the behavior and performance of staff. The diagnostic service must have methods in place to ensure that staff are managed as effectively as possible, since the quality of care and services provided within the diagnostic service will be greatly affected by the quality of the staff working in the department.

There is a strategy to ensure that qualified and competent staff are recruited and retained and that they are motivated and engaged in the work that they perform. This will help ensure that the needs and requirements of the diagnostic service and the population served are effectively met.

The Human Resources section of the accreditation standards addresses:

- Human resources planning
- Staff selection and retention
- Staff roles and records
- Staff orientation and training
- Professional development and continuing education
- Clinical teaching
- Competency assessment
- Performance feedback

Definitions:

Certification: Recognition that an individual has met predetermined standardized criteria (e.g. passed a required exam, or set of required exams).

Registration: Ongoing membership in a professional body that has assessed that an individual has satisfied the defined criteria for membership.

HUMAN RESOURCES PLANNING

PHR 1.0 The diagnostic service identifies current and future human resource requirements.

PHR 1.1 Human resource planning supports the diagnostic service's goals and objectives.

PHR1.1.1 ☐ There is a human resources plan to identify adequate staffing numbers and required competencies to meet the current and future needs of the diagnostic service.

PHR1.1.2 ☐ The human resources planning process involves key staff who are knowledgeable about the required competencies of staff, diagnostic technology and service delivery.

PHR1.1.3 ☐ Clinical teaching requirements are included in the human resources plan.
Intent: Human resource planning including the allocation of resources for both staff and student education.

PHR1.1.4 ☐ The human resources plan is monitored and revised as necessary.

STAFF SELECTION AND RETENTION

PHR 2.0 The diagnostic service has procedures in place to select and retain qualified and competent staff.

PHR 2.1 The diagnostic facility has qualified and competent staff to deliver services.

PHR2.1.1 ☐ The diagnostic facility selects and recruits staff based on qualifications and experience (e.g. certification, academic preparation, knowledge, skills and reference checks).

PHR2.1.2 **M** ☐ Therapists are certified with the Canadian Society of Respiratory Therapists (CSRT); or, are graduates from a recognized training school of respiratory therapy and are eligible to undergo examination from the Canadian Board for Respiratory Care (CBRC).

PHR 2.2 The diagnostic service is able to retain and engage staff.

PHR2.2.1 ☐ The diagnostic service has strategies in place to retain qualified staff.

PHR2.2.2 ☐ There are mechanisms in place to assess and enhance workforce engagement, motivation and morale (e.g. involvement in appropriate decision-making, staff-surveys).

PHR2.2.3 ☐ There are processes for staff to bring forward concerns/complaints, and for the diagnostic service leadership to respond in a fair, objective and timely manner.

PHR2.2.4 ☐ Workloads are monitored and managed.

STAFF ROLES AND RECORDS

PHR 3.0 The staff and leadership of the diagnostic service understand their roles and accountabilities.

PHR 3.1 Job descriptions exist for all staff.

PHR3.1.1 **M** ☐ There are job descriptions for all staff that reflect current practice and evolving responsibilities.

PHR3.1.2 ☐ Job descriptions are regularly reviewed.

PHR3.1.3 ☐ Staff are aware of their responsibilities and understand reporting relationships.

PHR 4.0 Staff records are complete, current and confidential.

PHR 4.1 Individual human resource records are kept for all staff and contain:

PHR4.1.1 ☐ evidence of qualifications including certification or registration.

PHR4.1.2 ☐ evidence of education and training appropriate for the position.

PHR4.1.3 ☐ immunization and health reports as required by the organization's human resources policies.

PHR4.1.4 ☐ orientation, continuing education and in-service training records.

PHR4.1.5 ☐ performance evaluations and feedback.

PHR4.1.6 ☐ competency assessments.

PHR4.1.7 ☐ recruitment information including references.

PHR4.1.8 ☐ evidence of a criminal record check if in contact with children or vulnerable adults.

PHR4.1.9 ☐ evaluations and feedback (e.g. complaints).

PHR 4.2 Human resource information and records are kept confidential.

PHR4.2.1 **M** ☐ Only authorized individuals have access to records.

PHR4.2.2 **M** ☐ Consent is obtained from the employee prior to the release of information contained in their human resources record.
Intent: Consent from the employee is required for the release of human resource records outside of the organization. Internal access to records (e.g. release) is limited to authorized individuals within the organization.

PHR4.2.3 **M** ☐ Records are disposed of appropriately and in accordance with legislation.

STAFF ORIENTATION AND TRAINING

PHR 5.0 Orientation, training and continuing education for the safe provision of quality diagnostic services is provided.

PHR 5.1 New staff receive orientation and training appropriate for their job position.

New staff receive orientation and training that includes:

PHR5.1.1	**M**	☐	patient safety (e.g. definitions and reporting processes for adverse events and critical incidents).
PHR5.1.2	**M**	☐	patient identification.
PHR5.1.3	**M**	☐	management of infectious materials including routine precautions, needle stick, injury protocol and personal protective equipment.
PHR5.1.4	**M**	☐	sharps handling and disposal.
PHR5.1.5	**M**	☐	WHMIS (e.g. appropriate disposal of solutions and supplies).
PHR5.1.6	**M**	☐	staff injury prevention and reporting.
PHR5.1.7	**M**	☐	fire safety.
PHR5.1.8	**M**	☐	management of aggressive behaviour.
PHR5.1.9	**M**	☐	violence and harassment in the workplace.
PHR5.1.10	**M**	☐	emergency responses/codes.
PHR5.1.11	**M**	☐	disaster response.
PHR5.1.12	**M**	☐	information management processes and systems.
PHR5.1.13	**M**	☐	confidentiality of data and information.
PHR5.1.14	**M**	☐	relevant policies and procedures related to performing the duties of the position.
PHR5.1.15	**M**	☐	roles and responsibilities of the individual and key staff.
PHR5.1.16		☐	patient rights and patient consent.
PHR5.1.17		☐	the organization's mission, vision and values.
PHR5.1.18		☐	sensitivity to cultural and religious diversity.

PHR 5.2 Orientation and ongoing training is provided to existing staff to uphold the quality and safety of the diagnostic service.

PHR5.2.1	**M**	☐	Orientation and training is provided to current staff in response to changing roles, technology, competency demands, laws and regulations or after an extended absence. *Intent: The frequency of ongoing training and re-orientation must be defined by the diagnostic service. The interval should be appropriate for the duties and responsibilities of the each staff member.*

Existing staff are provided with ongoing training or orientation in:

PHR5.2.2	**M**	☐	infection prevention and control policies and procedures relevant to their position or job (e.g. blood and body fluid exposure procedures).
PHR5.2.3	**M**	☐	identifying, reporting and disclosing information regarding adverse events and critical incidents.
PHR5.2.4	**M**	☐	instrument and equipment use, maintenance and safety.
PHR5.2.5	**M**	☐	patient identification.

PHR5.2.6 **M** ☐ ensuring the confidentiality of data and information.
Guidance: This includes information on the release of patient information, legal responsibilities regarding confidentiality, the possible consequences of breeching confidentiality, and reporting, documenting and investigating security incidents.

PHR5.2.7 ☐ risk management.
Intent: Risk management involves the identification and management of risks associated with the diagnostic and patient care process. Clinical risks involve those aspects of the diagnostic and patient care process that could cause harm to a patient. At a minimum, staff receive training in identifying risks and determining risk levels.

PHR5.2.8 ☐ quality improvement methods and tools.
Guidance: Training is provided to staff members who conduct internal or clinical audits, perform risk assessments or develop performance indicators.

PROFESSIONAL DEVELOPMENT AND CONTINUING EDUCATION

PHR 5.3 Professional development and continuing education are available for staff.

PHR5.3.1 ☐ Professional development and continuing education is encouraged and supported.

PHR5.3.2 ☐ Staff participate in ongoing education, training and professional development to meet the needs of the diagnostic service.

PHR5.3.3 ☐ The diagnostic service monitors education and training to determine if objectives have been achieved and to identify improvements.

PHR5.3.4 ☐ The diagnostic service ensures that opportunities for reinforcement of knowledge and retraining are made available.

CLINICAL TEACHING

PHR 5.4 Participation in clinical teaching does not compromise patient care.

PHR5.4.1 **M** ☐ Patient care is not compromised during or as a result of clinical teaching.
Intent: The diagnostic service has determined if, when and under what conditions students can work alone or unsupervised, and what safeguards are in place.

PHR5.4.2 ☐ Service standards of the diagnostic service are maintained during clinical teaching.

PHR5.4.3 ☐ Staff assigned to clinical teaching understand their roles and responsibilities and have the appropriate qualifications as specified by the academic institution.

PHR5.4.4 ☐ Students are supervised by experienced and qualified staff.

PHR 6.0 The diagnostic service has a staff performance management system to improve the quality of service.

COMPETENCY ASSESSMENT

PHR 6.1 The competency of individual staff is assessed.
Intent: Competency assessments evaluate the knowledge, skills and abilities of staff to ensure that they are proficient in performing their duties.

PHR6.1.1 **M** ☐ The focus of staff competency assessments is improvement.

PHR6.1.2 **M** ☐ The diagnostic service has defined the knowledge, skills and abilities that are subject to competency assessment.

PHR6.1.3 **M** ☐ Competency assessment of new staff is performed prior to the completion of a probationary or orientation period.

PHR6.1.4 **M** ☐ Competency assessment of existing staff is performed when new technology or new procedures are introduced.

PHR6.1.5 **M** ☐ Existing staff members are assessed on the use of current technology or current procedures prior to performance appraisals.

PHR6.1.6 **M** ☐ Competency assessments are conducted and reviewed by individuals with appropriate education, experience and qualifications.

PHR6.1.7 **M** ☐ Action is taken when a staff member's assessed competence does not meet expectations or when the staff member is not performing satisfactorily.

PERFORMANCE FEEDBACK

PHR 6.2 Individual staff members receive performance feedback.

PHR6.2.1 **M** ☐ A performance appraisal is regularly conducted based on job responsibilities and expectations.
Guidance: The diagnostic service must define the frequency of staff performance appraisals; however, the service is strongly encouraged to conduct appraisals every 1-2 years.

PHR6.2.2 ☐ Development plans are generated, monitored and revised, as necessary.

ACCREDITATION STANDARDS 2015

PATIENT AND CLIENT FOCUS

Introduction:
Engaging and involving patients and clients in their healthcare ensures their needs are met in a safe and effective manner. A patient and client focused culture enables the diagnostic service, to be more responsive and enhances the quality and safety of the care and services provided to patients and clients.

The Patient and Client Focus Standards examine patient and client-centered services including how the diagnostic service determines the requirements, expectations and preferences of patients and clients. Examples of clients may include referring physicians, WorkSafeBC, and insurance companies.

The Patient and Client Focus section of the accreditation standards addresses:
- Management of patient and client relationships
- Measurement of patient and client satisfaction
- Patient rights and consent

MANAGEMENT OF PATIENT AND CLIENT RELATIONSHIPS

PPC 1.0 The diagnostic service seeks to understand and be responsive to the requirements of patients and clients.

PPC 1.1 The diagnostic service identifies its patients and clients and establishes plans to meet their needs.

PPC1.1.1 ☐ The diagnostic service identifies patients and clients and defines their needs.

PPC1.1.2 ☐ The goals and objectives of the diagnostic service are aligned with patient and client needs and expectations.

PPC1.1.3 ☐ Cultural and spiritual sensitivities of patients and clients are acknowledged and respected without compromising quality or safety.

PPC 1.2 Service standards of the diagnostic service are defined and communicated to patients and clients.

PPC1.2.1 ☐ The diagnostic service confirms the receipt of the test request and communicates the approximate appointment wait time to the patient.
PPC1.2.2 **M** ☐ There is a process for patient prioritization.
PPC1.2.3 **M** ☐ Urgent and non-urgent tests are defined and identified.
Guidance: It may not be necessary to define urgent and non-urgent tests in all circumstances (e.g. services that accept drop-in patients).
PPC1.2.4 **M** ☐ Wait time to next available appointment for urgent tests is defined.
PPC1.2.5 **M** ☐ Wait time to next available appointment for non-urgent tests is defined.
PPC1.2.6 **M** ☐ Turnaround times for reports are defined and monitored.
Guidance: Turnaround times are established for all aspects of the reporting process including dictation, transcription and distribution of final report.
PPC1.2.7 ☐ Service standards, including wait-times and turnaround times, are made available to referring practitioners and patients.

PPC 1.3 Interpreting physicians are responsive to patient-related clinician inquiries.

PPC1.3.1 ☐ Interpreting physicians are responsive to case specific or procedural inquiries.
PPC1.3.2 ☐ Interpreting physicians provide education to clinicians in a timely and meaningful manner when needed.

MEASUREMENT OF PATIENT AND CLIENT SATISFACTION

PPC 2.0 Patient and client satisfaction is measured to gain information for improvement.

PPC 2.1 The diagnostic service collects and analyzes patient and client satisfaction data to improve service delivery.

PPC2.1.1 ☐ Data collection methods are appropriate for each patient and client group.
PPC2.1.2 ☐ Data collection methods allow information to be associated to specific processes within the diagnostic service.
PPC2.1.3 ☐ Data collection methods ensure comparable results from one cycle to the next.
PPC2.1.4 ☐ Patient and client satisfaction data is analyzed.
PPC2.1.5 ☐ Goals and priorities for improvement are determined.

PPC 2.2 There is a process in place to gather and follow-up on patient and client complaints.

PPC2.2.1 **M** ☐ There is a process for patients and clients to register complaints and provide feedback.
PPC2.2.2 ☐ There are methods to identify complaints within the patient and client satisfaction data that require specific action.
PPC2.2.3 ☐ There is a procedure for documenting complaints from patients and clients.
PPC2.2.4 **M** ☐ Responses to patient and client inquiries and complaints are addressed promptly.
PPC2.2.5 ☐ The resolution of complaints is documented.

PPC2.2.6 ☐ Information gained from complaints is used to make improvements as necessary.

PATIENT RIGHTS AND CONSENT

PPC 3.0 The diagnostic service respects the rights of patients.
Refer to the Government of Canada's Patient's Bill of Rights for additional information, accessible at http://dsp-psd.pwgsc.gc.ca/Collection-R/LoPBdP/BP/prb0131-e.htm.

PPC 3.1 Patient rights are communicated to patients and staff.

PPC3.1.1 **M** ☐ Staff understand and respect the rights of the patients.

PPC3.1.2 ☐ Patients are informed of their rights.

PPC 3.2 Patients are involved in decision making about their care, procedure(s) and/or service(s). [1]

PPC3.2.1 ☐ Patients are provided with information about their procedures so that they can participate in making informed decisions.

PPC3.2.2 ☐ The patient is made aware of the health care professionals involved in their procedure.

PPC3.2.3 ☐ Patients are provided with information about their right to refuse a procedure or service.

PPC3.2.4 ☐ When patients are unable to make decisions about their care, procedure(s), and/or services, a substitute decision maker(s) is involved in making these decisions in accordance with policy and provincial law and regulation.

PPC3.2.5 **M** ☐ Decisions made by a patient with regard to giving or withholding consent are respected.

PPC 3.3 The diagnostic service ensures that patients are provided with the information necessary to give or withhold informed consent.
Intent: Obtaining informed consent is a process of communication that establishes a mutual understanding between the patient and healthcare provider(s) involved in the diagnostic procedure. It provides patients with the information they need to make informed decisions and ultimately results in the patient's authorization or agreement to undergo the procedure for which informed consent is being obtained. Informed consent is a process that encompasses patient needs and preferences, patient education and compliance with the Health Care (Consent) and Care Facility (Admission) Act – see associated link: www.qp.gov.bc.ca/statreg/stat/H/96181_01.htm.

PPC3.3.1 **M** ☐ The diagnostic service identifies the specific tests or procedures that require informed consent as well as the circumstances that would allow for exceptions to it.

PPC3.3.2 **M** ☐ The diagnostic service clearly identifies the healthcare providers who are authorized and responsible for obtaining informed consent.
Guidance: Refer to the Health Care (Consent) and Care Facility (Admission) Act for the definition of a healthcare provider.

PPC3.3.3 **M** ☐ The informed consent process provides the patient with sufficient information to understand the proposed procedure and make a decision.

PPC3.3.4 **M** ☐ Information given to the patient is provided in a manner they are able to understand.

PPC3.3.5 **M** ☐ The informed consent process includes an opportunity for patients to ask questions about their proposed procedure.

PPC3.3.6 **M** ☐ Informed consent is documented in the patient's record in accordance with hospital or service policy and provincial legislation.
Guidance: Documentation should at a minimum contain the patient's name; the date informed consent is obtained; a description of the procedure, examination or service for which informed consent is being obtained (including the date on which it will be performed); and whether the patient does or does not consent to the procedure, examination or service. Documentation may be recorded in the format of a form, in progress notes, or elsewhere in the patient's record.

SPECIFIC DOCUMENTS REFERENCED

[1] Joint Commission 2009 Hospital Accreditation Standards*. Rights and Responsibilities of the Individual.* Illinois, USA, pp. 321-334.

ACCREDITATION STANDARDS 2015

GENERAL SAFETY

This section of the accreditation standards addresses:

- Management responsibilities
- Safety practices and equipment
- Appropriate physical environment
- Disasters and emergency preparedness

Occupational Health and Safety

The accreditation standards relating to occupational health and safety includes those most critical to staff safety in the diagnostic service; however, they do not encompass all of the requirements under the *Workers Compensation Act of British Columbia*. Leaders are encouraged to review section 115 of this *Act* and the associated *Occupational Health and Safety Regulations* to ensure they are meeting all regulatory requirements in British Columbia. Questions specific to the *Act* and the associated *Occupational Health and Safety Regulations* should be directed to WorkSafeBC for interpretation, advice and direction.

MANAGEMENT RESPONSIBILITIES

PSA 1.0 Potential hazards and risks to staff, patients and visitors are minimized.

PSA 1.1 There is a safety program in place that includes:

PSA1.1.1 ☐ the engagement of staff.
Guidance: All diagnostic service staff are encouraged to become involved in the safety program through the sharing of responsibilities, participation in audits, representation on a safety committee, etc.

PSA1.1.2 **M** ☐ monthly safety audits/inspections of the work area, equipment, and practices to identify and resolve safety hazards.
Guidance: Occupational health and safety regulations require safety audits/inspections to be conducted regularly. The inspection results must be reviewed by the occupational health and safety committee or health and safety representative.

PSA1.1.3 **M** ☐ reviewing health and safety activities and incident trends.
PSA1.1.4 **M** ☐ identifying and implementing the action(s) to resolve health and safety concerns.
PSA1.1.5 **M** ☐ the prompt investigation of staff related safety incidents including near misses to determine action necessary to prevent recurrence.
Intent: A near miss is an incident that did not result in injury, illness or damage but had the potential to do so.
PSA1.1.6 **M** ☐ the retention of records and statistics, including reports of safety inspections and staff incident investigations.

PSA 1.2 A safety manual is readily available to staff that includes:

PSA1.2.1 **M** ☐ how to access first aid services and/or medical assistance for staff related injuries.
Guidance: If the diagnostic service is part of a larger facility (over 50 staff), there must be immediate access to an Occupational First Aid Attendant (OFAA) with a minimum of a level 2 occupational first aid certificate. If the facility is self-contained, a level 1 OFAA is sufficient until the total staff surpasses 50. Detailed tables specifying the first aid requirements are found in the Occupational Health and Safety Regulation at the end of Part 3. It must be noted that medical facilities are NOT exempt from these requirements. Medical facilities may have staff take the appropriate OFA course, but some leeway is provided to allow for existing qualification to be considered equivalent.
PSA1.2.2 **M** ☐ the policy and procedure for investigating and reporting staff safety incidents including near misses.
PSA1.2.3 **M** ☐ exposure control plans, based on existing occupational hazards.
PSA1.2.4 **M** ☐ requirements for the use of personal protective and other safety equipment.
PSA1.2.5 **M** ☐ Workplace Hazardous Materials Information System (WHMIS) program information.
PSA1.2.6 **M** ☐ emergency evacuation plans.
PSA1.2.7 **M** ☐ procedures to protect staff “working alone” or in “isolation”.
Guidance: "Working alone or in isolation" is defined as working in circumstances where assistance would not be readily available to the worker in case of emergency or if the worker is injured or becomes unwell.
PSA1.2.8 **M** ☐ procedures to manage violent and aggressive behaviour.
Guidance: The procedure for dealing with the prevention of, and response to, incidents of violence must distinguish between incidents involving two workers ("improper conduct") and incidents of aggressive behaviour from a patient or member of the public ("violence"). All incidents of improper conduct and violence must be formally investigated, whether any injury occurred or not.

PSA 1.3 Safety issues are discussed and monitored.

PSA1.3.1 **M** ☐ The diagnostic service has a safety committee or health and safety representative.
Guidance: If there are 20 or more employees, a joint occupational health and safety committee (JOHSC) must be functioning. If the diagnostic service is part of a larger facility, a member of the committee must have the responsibility to represent the diagnostic service. If the facility has between 10 and 19 staff, the workers must select a person to be their Health and Safety Representative. This person, in effect, carries out the same functions as the committee in a larger facility. For

organizations with less than 10 employees, the employer is required to hold regular meetings with the staff to discuss matters relating to maintaining a healthy and safe workplace. Records of these meetings must be kept. Sections 125 to 140 of the Workers Compensation Act provide all the details about committee requirements and function.

PSA1.3.2 **M** ☐ Minutes of the last three safety committee meetings are posted.

SAFETY PRACTICES AND EQUIPMENT

PSA 1.4 Chemicals are used, stored and disposed of safely.

PSA1.4.1 **M** ☐ Hazardous liquids such as corrosives are stored below eye level.

DSA1.4.2 **M** ☐ The amount of hazardous liquids in a work area must not exceed the quantity reasonably needed for routine tasks.[1]

PSA1.4.3 **M** ☐ Containers for flammable liquids are kept closed when not in use.

PSA1.4.4 **M** ☐ Flammable liquids are stored in approved cabinets.
Guidance: Refer to the product Material Safety Data Sheets (MSDS) *for handling and storage.*

PSA1.4.5 **M** ☐ MSDS is available and current for controlled substances subject to WHMIS regulations.

PSA1.4.6 **M** ☐ Controlled substances are labeled appropriately.
Guidance: This applies to both the original supplier issued container and any secondary containers that have a workplace label indicating: product name; safe handling procedures; and reference to MSDS.

PSA1.4.7 **M** ☐ Chemicals are disposed of in accordance with WHMIS requirements.

PSA 1.5 Spills are handled effectively and safely.
Guidance: Based upon the chemicals and volumes used, the diagnostic service should consult with WorkSafeBC to determine if spill kits and/or spill control teams are required.

PSA1.5.1 **M** ☐ Spill kits are readily available.

PSA1.5.2 **M** ☐ Procedures to control and clean-up spills are documented and readily available to staff.

PSA 1.6 Fire safety measures are implemented.

PSA1.6.1 **M** ☐ Appropriate fire extinguishing equipment and procedures are in place.

PSA1.6.2 **M** ☐ Fire drills are conducted at least once per year.

PSA 1.7 Electrical safety measures are implemented.

PSA1.7.1 **M** ☐ Equipment and supplies are clearly labelled and comply with electrical safety regulatory requirements (e.g. Canadian Standards Association [CSA] or equivalent).

PSA1.7.2 **M** ☐ Regular inspections are performed to assess electrical safety (e.g. extension cords and surge power bars are assessed for damage and inappropriate use, proper isolation of electrical equipment attached to the patient, etc.).

PSA 1.8 Personal protective equipment is available for staff.

See also Infection Prevention and Control Accreditation Standards.

PSA1.8.1 **M** ☐ Adequate and appropriate personal protective equipment is available to protect staff from chemical or biological hazards.
Guidance: Personal protective equipment may include gloves, lab coats/gowns and masks.

PSA1.8.2 **M** ☐ Latex-free gloves are available to staff with latex sensitivities.

PSA 1.9 There are mechanisms in place to prevent staff from assuming postures that could result in musculo-skeletal injuries.

PSA1.9.1 **M** ☐ There are guidelines for equipment adjustment to ensure optimal ergonomics.

PSA1.9.2 ☐ There are guidelines for proper body mechanics while performing procedures.

PSA1.9.3 ☐ Positioning and immobilizing devices are available to staff.

PSA1.9.4 **M** ☐ Adequate assistance and transfer/lift devices are available when moving or lifting patients.
Guidance: Transfer/lift devices include 'transavers', slider boards and ceiling or mobile patient lifts.

PSA1.9.5 **M** ☐ The weight limit of lifting equipment is clearly marked.

PSA 1.10 Compressed gas is maintained and stored safely.

Guidance: An example of a compressed gas would be oxygen.

PSA1.10.1 **M** ☐ Gas cylinders are clearly labeled with the cylinder's contents.

PSA1.10.2 **M** ☐ A pressure-reducing regulator or device is used for all compressed gas cylinders.

PSA1.10.3 **M** ☐ Any gauge whose pointer (indicator or needle) does not go back to the zero point when pressure is removed is replaced.

PSA1.10.4 **M** ☐ Adapters between cylinders and pressure reducing regulators are NOT used.

PSA1.10.5 **M** ☐ Cylinders not in use are shut off and capped.

PSA1.10.6 **M** ☐ Cylinders are secured to prevent falling during storage, transportation and use (e.g. chaining a cylinder to a secure object).

PSA1.10.7 ☐ Cylinders are kept in an upright position.
Guidance: Larger sized cylinders (e.g. H/K) should be kept in an upright position.

PSA1.10.8 **M** ☐ Cylinder carts are used to move large cylinders and specifically designed cylinder holders are used to carry small cylinders.

PSA1.10.9 **M** ☐ Cylinders that are empty are clearly identified.

APPROPRIATE PHYSICAL ENVIRONMENT

PSA 2.0 The design and layout of the physical space allows service delivery to be safe, efficient and accessible for patients, visitors and staff.

PSA 2.1 The design and layout of the physical space meets laws, regulations and codes.

PSA2.1.1 ☐ Inspections by external authorities (e.g. Fire Marshall, WorkSafeBC, building inspections) are performed and maintained.
Guidance: New facilities should maintain a copy of the occupancy permit as issued by a building inspector.

PSA2.1.2 **M** ☐ Emergency exit routes are marked and provide an unimpeded exit.

PSA 2.2 The location of the diagnostic service is accessible to the patient population it serves.

PSA2.2.1 ☐ Clear signage is in place to direct patients to the diagnostic service.

PSA2.2.2 ☐ Patients with special needs can access the location with ease.

PSA2.2.3 ☐ Patient washrooms are clean, conveniently located and accessible.

PSA 2.3 The physical environment ensures patient safety and privacy.

PSA2.3.1 **M** ☐ Patient areas are safe and clean.

PSA2.3.2 **M** ☐ A secure and private location for changing clothing and for the temporary storage of personal items is available, if needed.
Guidance: This may be relevant for the type of testing performed (e.g. Exercise Testing).

PSA2.3.3 **M** ☐ Furniture is safe for patient use.

PSA2.3.4 ☐ Confidential or sensitive information is collected from and communicated to patients in an area that does not compromise their privacy.
Guidance: This includes telephone consultations that involve the exchange of patient information.

PSA2.3.5 **M** ☐ Patient information cannot be viewed by other patients or visitors.

PSA2.3.6 **M** ☐ Patient privacy is not compromised during the diagnostic procedure.

PSA 2.4 The design and layout of the space supports safe and appropriate service delivery.

PSA2.4.1 ☐ For each activity undertaken within the diagnostic service, there are appropriate furnishings, work surfaces and floor finishes.

PSA2.4.2 ☐ There is sufficient space to allow unobstructed movement and safe working conditions within the diagnostic service and around large pieces of equipment.

PSA2.4.3 **M** ☐ Activity, workspace and equipment is designed or positioned to reduce the risks of ergonomic distress disorders and accidents (e.g. musculoskeletal injuries, repetitive stress injuries, etc.).
Guidance: If workers experience symptoms indicating a musculoskeletal injury, the employer must investigate and make appropriate changes to the work area. This might be ergonomically designed chairs, anti-fatigue mats for staff that must stand for most of the work day. The employer must have conducted a risk assessment for the potential for musculoskeletal injury that will include handling of patients who

are heavy or have restricted ability to move or the use of awkwardly placed controls on equipment. Controls, including equipment and training, must have been put in place to address all the identified moderate or high risk situations. WorkSafe BC has two worksheets ("A" and "B") in the publications section of the website, which provide a template for conducting the risk identification and assessment. These worksheets can be found at http://www2.worksafebc.com/pdfs/ergonomics/MSI_worksheet_A_fillable.pdf?_ga=1.245774660.1138311406.1379014432 and http://www2.worksafebc.com/pdfs/ergonomics/MSI_worksheet_B_fillable.pdf?_ga=1.149796342.1138311406.1379014432 .

DSA2.4.4 **M** ☐ Security measures are in place relative to the threat of theft and tampering with patient samples, drugs, chemicals and confidential information.
Guidance: The threat of theft or tampering is assessed, and based upon that assessment appropriate security measures are implemented.

PSA 2.5 The physical environment meets the needs of staff.

PSA2.5.1 **M** ☐ A secure and private location for changing clothing and for storage of personal belongings is available to staff.

PSA2.5.2 ☐ A separate and comfortable location to rest is available to staff during break times.

PSA2.5.3 ☐ Washrooms are conveniently located and separate from patient washrooms.
Guidance: WorkSafeBC guideline G4.85(1)-1 recommends that separate male and female washrooms are provided when there are more than 9 workers.

PSA2.5.4 **M** ☐ Storage and consumption of food and beverages is permitted in designated areas only.

PSA 2.6 Sinks and eyewashes are available to staff.

PSA2.6.1 **M** ☐ There are clearly labeled hand washing sinks.
Intent: Sinks used for soiled equipment should be deemed "dirty" and not used for hand washing.

PSA2.6.2 **M** ☐ Hand washing sinks have unimpeded drainage (e.g. not stoppers).

PSA2.6.3 ☐ Access to hand washing sinks is unimpeded.
Guidance: If there is only one sink available and that sink may also be used for other than hand washing there is a process to clean the sink prior to using the sink for hand washing; or a sanitizing gel must be made available to staff to use followed by hand washing at the nearest available clean sink. Unimpeded access means that staff would always be able to access the sink (e.g. a sink located in a washroom is not considered as having unimpeded access).

PSA2.6.4 **M** ☐ Eyewash stations are conveniently located and regularly flushed, when appropriate.
Guidance: Consult with WorkSafeBC to determine the type of eyewash station required based upon the chemicals used in the diagnostic service.

PSA 2.7 Lighting, temperature and ventilation is appropriate.

PSA2.7.1 **M** ☐ Lighting provides sufficient illumination for safe working.

PSA2.7.2 **M** ☐ Emergency lighting is available in the event of power failure.
Guidance: Emergency lighting units must be tested regularly.

PSA2.7.3 ☐ Ambient temperature, humidity, lighting, noise level and air quality is controlled to a level compatible with staff and patient comfort and that does not compromise diagnostic procedures.
Guidance: Temperature and humidity concerns are addressed in the "ASHRAE publication Handbook of Fundamentals" or in the WorkSafeBC publication "Indoor Air Quality" that may be accessed from the website www.worksafebc.com/publications/health_and_safety/by_topic/assets/pdf/indoor_air_bk89.pdf.

PSA2.7.4 ☐ Air flow is monitored to ensure adequate ventilation, as required.
Guidance: The monitoring of air flow (e.g. the number of air exchanges per hour) may be a responsibility of the facility management and may not necessarily be conducted by the diagnostic service.

DISASTER AND EMERGENCY PREPAREDNESS

Introduction: Disaster and emergency preparedness examines how the diagnostic service plans to respond to disasters. A disaster may be internal such as a flood, fire, or loss of electrical power; or the disaster may be a community wide disaster such as an earthquake.

PSA 3.0 The diagnostic service is prepared for disasters and emergencies.

PSA 3.1 There is a disaster and emergency preparedness plan that addresses a response to an emergency.

PSA3.1.1 ☐ The role and capability of the diagnostic service during a disaster or emergency is identified.
Guidance: A process is in place to identify which staff will be contacted and what their roles/responsibilities may entail.

The plan for response to disasters and emergencies includes:

PSA3.1.2 ☐ a staff recall system.

PSA3.1.3 ☐ access to first aid equipment.

PSA3.1.4 ☐ alternate service sites if needed.

PSA3.1.5 ☐ alternate sources of supplies, utilities and communication.

PSA 3.2 The disaster and emergency response plan is regularly reviewed to ensure it is valid and updated.

PSA3.2.1 ☐ Disaster and emergency plans are reviewed with all staff and they are aware of their roles and responsibilities in the event the plan is implemented.

PSA3.2.2 ☐ The plan is tested through practice drills. Changes to plans, procedures and training methods are made when necessary.

PSA3.2.3 ☐ Contact names and phone numbers on fan-out lists are current.

SPECIFIC DOCUMENTS REFERENCED

[1] WorkSafe BC, OH&S Regulations, Part 5, Chemical Agents and Biological Agents, 5.20 Containers and Storage. Retrievable from: http://www2.worksafebc.com/Publications/OHSRegulation/Part5.asp#SectionNumber:5.20

ACCREDITATION STANDARDS 2015

PATIENT SAFETY

Introduction:
Patient safety is fundamental to the delivery of quality diagnostic services and optimal patient outcomes. A priority for all diagnostic services is to ensure that procedures are safe and a continuous effort is made to improve patient safety. Appropriate and sufficient resources should be allocated to support the diagnostic service's implementation of the patient safety priorities or goals.

The Patient Safety section of the accreditation standards addresses:

- Creating a culture of patient safety
- Patient identification
- Medication management and administration
- Adverse events and critical incidents
- Medical emergency management

CREATING A CULTURE OF PATIENT SAFETY

PPS 1.0 The diagnostic service creates a culture of patient safety and makes patient safety a priority.

PPS 1.1 The activities of the diagnostic service ensure patient safety.

PPS1.1.1 ☐ Mechanisms are available for staff to identify, provide feedback on, and communicate openly about patient safety issues and concerns.

PPS1.1.2 **M** ☐ There is a process for patients and their advocates to report concerns related to patient safety.

PPS1.1.3 **M** ☐ There are systems in place to ensure patient safety notices, alerts and other information is communicated.

PPS1.1.4 **M** ☐ Mechanisms are in place to address patient sensitivities and allergies.
Guidance: At a minimum, latex-free products are made available for both patients and staff (e.g. gloves, mouthpieces).

PPS1.1.5 **M** ☐ All patient safety issues are documented and investigated.

PPS 1.2 Patient safety is safeguarded through effective continuity of care.
Intent: Continuity of care refers to the provision of seamless patient care and service(s) through effective integration, coordination and information sharing amongst the various healthcare providers involved in the patient's care and/or service(s). Having processes in place to enhance continuity of care helps to protect patients from harm from a lack of communication amongst healthcare providers. It also helps to ensure that patients receive appropriate support to access other services as necessary. [1]

PPS1.2.1 **M** ☐ There are processes in place to ensure effective and timely transfer of patient information between healthcare providers at interface points (e.g. shift changes, patient discharge, movement to other departments, etc.).
Guidance: The information transferred depends on the test/procedures performed and could include test complications, new symptoms, and medications administration.

PATIENT IDENTIFICATION

PPS 2.0 Positive patient identification precedes commencement of the test or procedure.

PPS 2.1 Patient identification is confirmed prior to a patient's test or procedure by the individual(s) performing the test or procedure.

PPS2.1.1 **M** ☐ Patients are involved in the identification process to the fullest extent possible.

PPS2.1.2 **M** ☐ Positive patient identification is confirmed prior to commencing all procedures and tests by the person(s) performing the test or procedure.

PPS2.1.3 **M** ☐ At least two unique patient identifiers are used when verifying patient identification.

PPS2.1.4 **M** ☐ The individual conducting the test verifies the correct procedure with the patient prior to commencing the test.

PPS2.1.5 ☐ The diagnostic service maintains a list of acceptable patient identifiers.
Guidance: Acceptable patient identifiers include the patient's first and last name and date of birth; or patient's first and last name and a unique personal identifier number (e.g. Provincial Health Number).

PPS2.1.6 **M** ☐ In-patients are identified with a wristband or service-approved alternative procedure.

PPS2.1.7 **M** ☐ Staff confirm that information on the wristband is consistent with verbal information provided by the patient.

PPS2.1.8 **M** ☐ Pediatric and other patients who cannot provide identification information are identified by a responsible adult.

PPS2.1.9 **M** ☐ Patient identity information discrepancies are resolved prior to performing the test.

MEDICATION MANAGEMENT & ADMINISTRATION

PPS 3.0 The diagnostic service has methods in place to ensure that medication is managed and administered to patients safely and effectively.

PPS 3.1 Medications are stored and disposed of safely.

PPS3.1.1 **M** ☐ Storage of medications complies with manufacturer's recommendations.

PPS3.1.2 **M** ☐ All stored medications are labeled with the contents, expiration date, and any warnings as applicable.

PPS3.1.3 **M** ☐ The diagnostic service regularly inspects all medication storage areas and medications.

PPS3.1.4 **M** ☐ All medications are disposed of using appropriate facility accepted disposal methods.

PPS 3.2 The diagnostic service ensures that all medications are labeled.

PPS3.2.1 **M** ☐ Medication containers are labeled with the medication name, strength and quantity when medications are prepared but not administered immediately.

PPS3.2.2 **M** ☐ All medications are labeled with the date prepared and the expiration date when prepared but not administered within 24 hours or when the expiration occurs in less than 24 hours.

PPS3.2.3 **M** ☐ Any medication containers found unlabeled are immediately discarded.

PPS 3.3 The appropriateness of all medication orders is reviewed.

PPS3.3.1 **M** ☐ Only authorized staff request medications.
Guidance: There is a facility policy that defines "authorized individual" that includes medical physicians and other designated health professionals as permitted by governing legislation, rules and bylaws.

PPS3.3.2 **M** ☐ Medication orders are reviewed for possible patient allergies or sensitivities.

PPS3.3.3 **M** ☐ Medication orders are reviewed for the appropriateness of the dose, frequency, and route of administration.

PPS3.3.4 **M** ☐ Medication orders are reviewed for potential contraindications and adverse interactions.

PPS3.3.5 **M** ☐ All concerns, issues, or questions related to the appropriateness of a medication order are resolved with the prescriber or staff involved with the patient's care or services prior to administration.

PPS 3.4 Medications are administered safely.

PPS3.4.1 **M** ☐ Only authorized staff obtain and administer medication (e.g. medical practitioners).

PPS3.4.2 **M** ☐ Patient identity is verified prior to medication administration.

PPS3.4.3 **M** ☐ There is a process in place to ensure that the correct medication is selected prior to administration.

PPS3.4.4 **M** ☐ Prior to administration, the medication is visually inspected for color, clarity and expiration date.

PPS3.4.5 **M** ☐ There is a process in place to ensure the individual administering the medication verifies that the medication is administered at the proper time, in the prescribed dose, and by the correct route to the correct patient.

PPS 3.5 Patients are monitored to ensure that medication(s) have been administered safely and effectively.

PPS3.5.1 **M** ☐ Patients are monitored to assess the effectiveness of the medication(s) administered to them.

PPS3.5.2 **M** ☐ Patients are monitored for any potential side effects or adverse reactions resulting from medication administration.

PPS3.5.3 **M** ☐ Staff know how to respond to adverse drug events, significant drug reactions, and medication errors.

PPS3.5.4 **M** ☐ Prior to discharge from the diagnostic service, the patient is monitored for a sufficient amount of time to ensure readiness for discharge.

PPS3.5.5 **M** ☐ Readiness to discharge is documented in the medical record.
Guidance: In the event of potential side effects or adverse reactions resulting from medication administration the readiness to discharge is documented.

RISK & DISCLOSURE

Definitions:

Adverse events can be defined in three ways:

- An unexpected and undesired incident directly associated with the care or services provided to the patient;
- An incident that occurs during the process of providing health care and results in patient injury or death;
- An adverse outcome for a patient, including injury or complication.

Critical incident is defined as an incident resulting in serious harm to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate

investigation and response. The investigation is designed to identify contributing factors and the response includes action to reduce the likelihood of recurrence.

A *near miss* is an incident that did not result in injury, illness or damage but had the potential to do so.

PPS 4.0 Adverse events and critical incidents, including near misses are managed appropriately.

PPS 4.1 There are policies, procedures and practices for managing adverse events and critical incidents.

PPS4.1.1 ☐ Definitions of adverse events, critical incidents and near misses applicable to the diagnostic service are communicated to all staff.

PPS4.1.2 **M** ☐ Policies, procedures and practices for addressing adverse events and critical incidents are documented and available to all staff.

PPS4.1.3 **M** ☐ All adverse events and critical incidents are documented.

PPS4.1.4 **M** ☐ Policies and procedures for reporting, investigating and making recommendations following a near miss are documented and available to staff.

PPS4.1.5 ☐ There is a systematic process to investigate adverse events and critical incidents to determine multiple underlying contributing factors.
Guidance: The investigation process is appropriate for the magnitude of the problem and risk to patient or staff safety.

PPS4.1.6 ☐ There are policies, procedures and practices for disclosing information to patients following an adverse event and/or critical incident.

PPS4.1.7 ☐ Staff know whom to contact for advice or direction and are aware of their role during an adverse event or critical incident.

PPS4.1.8 ☐ There is a defined process for reporting an adverse event or critical incident to the administration of the organization and to outside organizations.

PPS4.1.9 ☐ Support and counseling are available to patients, their families and staff following an adverse event or critical incident.

PPS 4.2 There is a process to determine and manage the medical significance of adverse events and critical incidents.

PPS4.2.1 **M** ☐ All reported adverse events and critical incidents are immediately assessed by appropriate technical and medical staff to determine medical significance.

PPS4.2.2 **M** ☐ The referring practitioner is informed in cases of medical significance.

PPS4.2.3 ☐ Appropriate technical and medical staff assesses indications for halting further tests and authorizing resumption.

PPS4.2.4 ☐ Medical staff assess indications for withholding diagnostic reports and review already released reports for potential recall.

PPS 4.3 Recommendations following an adverse event or critical incident are implemented to decrease the likelihood of recurrence.

PPS4.3.1 ☐ There are mechanisms in place for management to regularly track and trend aggregate data collected through the reporting process.

PPS4.3.2 **M** ☐ Changes made to the diagnostic service's systems and processes to prevent recurrence are documented.
PPS4.3.3 ☐ Recommendations and changes implemented are communicated to relevant staff.
PPS4.3.4 ☐ Changes implemented are continuously monitored and evaluated to ensure effectiveness.

MEDICAL EMERGENCY MANAGEMENT

PPS 5.0 The diagnostic service has procedures in place to handle medical emergencies.

PPS 5.1 There are procedures to handle medical emergencies in a timely and effective manner.

PPS5.1.1 **M** ☐ There is a medical emergency response procedure in place.
PPS5.1.2 **M** ☐ Staff are familiar with the procedure(s) for responding to medical emergencies.
PPS5.1.3 **M** ☐ Emergency call systems are available in patient care areas.
Guidance: Facilities should conduct a risk assessment to determine what emergency call systems are required (e.g. patient washrooms, changing rooms, etc.).

Staff know how to access:
PPS5.1.4 **M** ☐ emergency medical services.
PPS5.1.5 **M** ☐ emergency equipment and supplies.

PPS5.1.6 **M** ☐ The facility identifies staff who respond to medical emergencies and provides training in the use of emergency equipment.

ACCREDITATION STANDARDS 2015

INFECTION PREVENTION AND CONTROL

Introduction:
Facilities establish infection prevention and control activities and precautions to help reduce the possibility of acquiring and transmitting an infection. The type and scope of the activities and precautions are influenced by the size of the facility, the resources available, the services provided, and the patients served.

This section of the Infection and Prevention and Control accreditation standards addresses:
- Planning
- Routine practices
- Additional precautions
- Cleaning of surfaces and ancillary medical equipment
- Disinfection of ancillary medical equipment

PLANNING

PIPC 1.0 Planning for infection prevention and control is effective, integrated and coordinated.

PIPC 1.1 An infection prevention and control plan is developed and implemented.

PIPC1.1.1 **M** ☐ There are documented policies and procedures for infection prevention and control (e.g. an infection control manual).

PIPC1.1.2 **M** ☐ Activities associated with increased risk of infection to staff, patients and visitors are identified and assessed.

PIPC1.1.3 **M** ☐ Precautions used to eliminate or minimize the risk of infection are identified and defined.

PIPC1.1.4 ☐ Responsibility for infection prevention and control activities is assigned.

PIPC1.1.5 ☐ There is access to up-to-date infection prevention and control resources (e.g. infection control practitioners, expert consultant(s) and website(s).

PIPC1.1.6 ☐ Infection prevention and control surveillance or monitoring activities are scheduled and conducted regularly.

PIPC1.1.7 ☐ Infection control data is reviewed and analyzed and actions are taken when issues are identified.

PIPC1.1.8 ☐ Infection control data is reported to an appropriate authority.

PIPC1.1.9 ☐ There is a regular review of the infection prevention and control plan.

ROUTINE PRACTICES

PIPC 2.0 Routine practices for preventing the transmission of infection are implemented.

Guidance: The term "routine practices" (or "standard precautions") is used to describe a system to prevent transmission of infections in health care settings. These practices are to be used at all times, with all patients regardless of diagnosis or infectious status.

PIPC 2.1 Hand hygiene is used to prevent and control the spread of infection.

Intent: Hand hygiene is the single most important activity for preventing the transmission of infections.

PIPC2.1.1 **M** ☐ There are readily-accessible designated hand hygiene sinks or other forms of hand hygiene products.

PIPC2.1.2 **M** ☐ Hand hygiene is performed with soap and warm water or an alcohol based hand rub.

Guidance: Hand hygiene practice requirements may vary depending on the infectious disease status of the patient. Hand hygiene practices are consistent with the facility's policies and procedures for infectious diseases.

PIPC2.1.3 **M** ☐ Hand hygiene is performed before direct contact with a patient.

PIPC2.1.4 **M** ☐ Hand hygiene is performed after direct contact with a patient.

PIPC2.1.5 **M** ☐ Hand hygiene is performed before gloves are put on and immediately after removing gloves.

PIPC2.1.6 **M** ☐ Hand hygiene is performed between clean and dirty procedures on the same patient.

PIPC2.1.7 **M** ☐ Hand hygiene is performed before preparing or handling medications.

PIPC2.1.8 **M** ☐ Soap and warm water is used if hands are visibly soiled.

PIPC 3.0 Personal Protective Equipment (PPE) is worn by staff as a barrier against blood and body fluid exposure.

Guidance: See also General Safety Accreditation Standards.

PIPC 3.1 Personal protective equipment is used appropriately.

PIPC3.1.1 **M** ☐ Personal protective equipment is used when there is potential contact or exposure to blood and body fluids.

PIPC3.1.2 **M** ☐ Personal protective equipment is changed between patients.

PIPC3.1.3 **M** ☐ Personal protective equipment is removed and disposed of properly or reprocessed according to manufacturer's recommendations.

PIPC 3.2 Gloves are worn by staff for protection against infection.
Intent: Gloves are used as an additional measure, not as a substitute for appropriate hand hygiene. Gloves are not required for routine patient care activities.

PIPC3.2.1 **M** ☐ Gloves are worn when there is potential for contact with blood or body fluids.
PIPC3.2.2 **M** ☐ Gloves are worn when the staff member has open skin lesions on their hands.
PIPC3.2.3 **M** ☐ Gloves are changed between patients and procedures and disposed of properly.
PIPC3.2.4 **M** ☐ Gloves are removed immediately after a specific task and before touching clean environmental surfaces.
PIPC3.2.5 **M** ☐ Gloves are worn when handling soiled equipment (e.g. mouthpieces).
PIPC3.2.6 **M** ☐ Sterile gloves are worn for sterile procedures.
PIPC3.2.7 **M** ☐ Single-use disposable gloves are not reused or washed.

PIPC 3.3 The diagnostic service has a process for the assessment and use of a N95 respirator/mask.
See also Information Management (PIM7.3) accreditation standards.

PIPC3.3.1 **M** ☐ A risk assessment is conducted to determine if and when the use of N95 respirators/masks for staff is necessary.
Intent: An N95 respirator/mask helps protect staff from respiratory pathogens that are transmitted via the airborne route. Staff must use N95 respirators/masks if they may be exposed to an airborne infection that is listed in the WorkSafeBC Regulations and a risk assessment has indicated that this infection poses a potential hazard. It is recommended that the diagnostic service consults with Occupational Health and Safety (OH&S) and infection control resources regarding conducting the risk assessment.

PIPC3.3.2 **M** ☐ Fit testing of N95 respirators/masks is performed annually and is documented.
Intent: A respirator/mask will not be effective unless it forms an adequate seal against the staff members face. The only way to be certain a specific respirator/mask forms this seal is to do a fit test.

PIPC 3.4 Gowns are worn by staff as a barrier against infection.

PIPC3.4.1 **M** ☐ Gowns are worn when there is potential for soiling clothing with blood, body or other fluids.
Guidance: Gowns should be fluid resistant.

ADDITIONAL PRECAUTIONS

PIPC 4.0 Patients, staff and visitors are protected from potential or known communicable diseases.

PIPC 4.1 Additional precautions are used for patients with known or suspected communicable diseases.
Intent: Additional infection prevention and control precautions are necessary for specific pathogens or clinical presentations. Professional knowledge, skills and judgment are

used to assess the potential routes of transmission and the appropriate additional precautions to be taken (e.g. contact, droplet or airborne precautions).

PIPC4.1.1 **M** ☐ Patients with known or potential communicable diseases are identified.
Guidance: Known or suspected communicable diseases may be identified in many ways e.g. asking the patient, notation on the requisition, or noted in the information system. It is not necessary to wait for a specific diagnosis or microbiologic confirmation before initiating appropriate precautions when patient assessment clearly indicates a clinical syndrome or risk factors related to a potentially communicable disease. For the patient who has, or is suspected of, having a disease requiring additional precautions it is important to institute these precautions immediately. They may be instituted by any health care provider as soon as the communicable disease, clinical presentation, or risk factors are suspected or identified.

PIPC4.1.2 **M** ☐ For patients with a known or potential communicable disease, appropriate staff are notified of additional precautions required.

PIPC4.1.3 **M** ☐ Patients with a known or potential communicable disease are placed directly into a single room and do not wait in a common waiting room or, if a single room is not available, the patient is placed in an area of the waiting room separated from other patients by at least 2 meters, and time spent in the waiting room is minimized.
Intent: This is if infection is spread by droplet route. If spread by aerosol route, e.g. chicken pox or measles, the 2 meter distance does not apply.

PIPC4.1.4 **M** ☐ The patient wears a procedure mask if they are coughing or sneezing and hand hygiene is offered when appropriate.

PIPC4.1.5 **M** ☐ N95 respirators/masks are available for all staff who enter the procedure room if there is a known, or suspected airborne infection.
Guidance: Airborne transmission refers to transmission of infection by inhaling aerosols e.g. tuberculosis, measles, or chicken pox (varicella). This can occur when a patient coughs, sneezes, or talks. These infectious agents can be acquired by susceptible individuals who may be at some distance away from the source patient.

PIPC4.1.6 **M** ☐ An appointment is scheduled at the end of the day or alternative measures are taken to minimize exposure to other patients.

PIPC 4.2 Mechanisms are in place to ensure staff have current up to date immunizations or are aware of their previous infectious disease medical history.

PIPC4.2.1 **M** ☐ All staff are aware of and have documentation of their vaccination history, medical history, or serologic test results.

PIPC4.2.2 **M** ☐ Staff that have the potential to be exposed to blood and body fluids are offered the Hepatitis B vaccination.
Guidance: WorkSafeBC requires the Hepatitis B vaccination series be offered to employees with "occupational exposure to blood borne pathogens". Occupational exposure is defined as reasonably anticipated contact.

PIPC 5.0 Blood and body fluid exposure precautions are used to safeguard staff.

PIPC 5.1 There is a defined follow-up process that addresses possible or actual blood and body fluid exposure.

PIPC5.1.1 **M** ☐ There are documented policies and procedures for follow-up to blood and body fluid exposure.

PIPC5.1.2 **M** ☐ For blood and body fluid exposure the staff member has local first aid administered, if required, and then is immediately referred for medical assessment (within 2 hours), appropriate therapy and follow up.
Guidance: It is preferable to go to an emergency department as they have the necessary medications on site, rather than a family physician who does not have the medications in his/her office.

PIPC5.1.3 **M** ☐ An incident investigation is completed for all staff who have had a potential or actual blood or body fluid exposure.

PIPC 5.2 Safe and effective practices are followed for the use and disposal of sharps.

PIPC5.2.1 **M** ☐ Safety engineered sharps or devices that have built in safety mechanisms are used.

PIPC5.2.2 **M** ☐ Used needles and other sharp instruments are not recapped.

PIPC5.2.3 **M** ☐ Used sharps are disposed of immediately in designated puncture resistant containers located in the immediate area where the sharp was used.
Guidance: In areas where sharps containers have not been mounted, portable sharps containers are used.

PIPC5.2.4 **M** ☐ Sharps containers are sealed and replaced when they are filled up to the designated line on the container.

PIPC5.2.5 **M** ☐ Sharps containers are appropriately disposed.

CLEANING OF SURFACES AND ANCILLARY MEDICAL EQUIPMENT

PIPC 6.0 The physical environment of the diagnostic service is clean.

PIPC 6.1 Safe and effective cleaning of the physical environment is maintained.

PIPC6.1.1 **M** ☐ Policies and procedures are in place indicating the frequency and method of environmental cleaning and disinfection.

PIPC6.1.2 **M** ☐ Equipment and surfaces in direct contact with a patient or blood and body fluid are cleaned and disinfected before use with another patient.

PIPC6.1.3 **M** ☐ A barrier (sheet or paper) is placed on the procedure table and changed between patients. Alternatively, the table is cleaned between patients.

PIPC6.1.4 **M** ☐ If there is significant environmental contamination (e.g. from stool, urine, wound drainage, or uncontrolled respiratory secretions) all horizontal surfaces and frequently touched surfaces are appropriately cleaned and disinfected before the room and/or equipment is used for another patient.

PIPC6.1.5 **M** ☐ Paper liners, linens, patient gowns, etc. are appropriately disposed of or laundered between patients.

PIPC6.1.6 **M** ☐ The flooring in patient care areas is cleaned regularly.

PIPC 6.2 The diagnostic service reduces the risk of infections associated with ancillary medical equipment.

PIPC6.2.1 ☐ Routinely used patient testing equipment are cleaned or discarded between patients (e.g. blood pressure cuffs, stethoscope, tourniquets).

PIPC6.2.2 **M** ☐ Single use medical devices are not reprocessed.
Intent: The reuse of single-use devices can affect their safety, performance, and effectiveness and expose patients and staff to unnecessary risk.

DISINFECTION OF ANCILLARY MEDICAL EQUIPMENT

Introduction: A risk classification is given to medical devices that present a high risk of infection if contaminated by any microorganism. For purposes of these standards the risk classification of re-usable medical equipment will be addressed and for the diagnostic service this specifically covers mouthpieces, cardiopulmonary exercise equipment and spacers for bronchodilator administration.

PIPC 7.0 There is a safe and effective process for disinfection of medical devices.

PIPC 7.1 Standardized disinfection practices for the decontamination of reusable medical devices are implemented.

PIPC7.1.1 **M** ☐ There is a designated storage area for soiled equipment that is distinct from patient testing area.

PIPC7.1.2 **M** ☐ Cleaning of the medical equipment is performed in a distinctly separate area from where disinfected/sterile medical equipment are handled or stored.[1]

PIPC7.1.3 **M** ☐ Transport of soiled medical equipment is performed in a closed container or bag.

PIPC7.1.4 **M** ☐ Disinfection of medical equipment is performed following manufacturer's recommendation (e.g. reusable mouthpieces are disinfected via pasteurization process).

GLOSSARY

Cleaning means the removal of all foreign material (e.g. soil, organic material) from the surface.

Decontamination is the process of cleaning, followed by the inactivation of pathogenic micro-organisms, in order to render an object safe for handling.

Disinfectant is a chemical agent that kills most disease-producing micro-organisms but not necessarily resistant bacterial spores.

Pasteurization is a high level disinfection process by heating a liquid to a certain temperature and then cooling it down in order to kill process pathogenic (disease-causing) agents.

SPECIFIC DOCUMENTS REFERENCED

[1] Patient Safety Branch – Ministry of Health. Best Practice Guidelines for Cleaning, Disinfection and Sterilization in Health Authorities. March 2007. p.47.

ACCREDITATION STANDARDS 2015

QUALITY IMPROVEMENT

Introduction:
To improve the quality and safety of services provided to patients, the diagnostic service must continuously evaluate its performance and use this information to identify ways that it can improve. This form of self-evaluation must be planned and ongoing, and must focus on systems, processes and the performance of individuals integral to the diagnostic and/or clinical process. Standardizing key processes and documenting best practices allows for the collection and analysis of data concerning the current performance of the key processes. This information can be used to focus improvement activities, and monitor the implementation of changes resulting from a structured continuous quality improvement process.

Every organization and diagnostic service, regardless of size, practices quality improvement to some degree. In some organizations, quality improvement may be highly formalized with comprehensive quality improvement plans and structures. In other organizations, quality improvement may be far less formal.

The Quality Improvement section of the accreditation standards addresses:

- Establishing an integrated and coordinated Quality Improvement Program
- Providing leadership and structure to the Quality Improvement Program
- Evaluating operational processes through internal audit
- Evaluating clinical quality through clinical audit and medical peer review
- Proactively identifying and managing clinical risk
- Using performance measures to monitor clinical and operational quality

QUALITY IMPROVEMENT PROGRAM (QIP)

Introduction: The purpose of a Quality Improvement Program (QIP) is to objectively and systematically monitor and evaluate the quality and appropriateness of services provided, and to pursue opportunities for improvement. For a QIP to be effective, it must be integrated into organization-wide improvement efforts and have assigned leadership and oversight. A QIP consists of the integrated and coordinated activities including operational and clinical audit, clinical risk management and quality assurance and control activities. The size and structure of the organization and the diagnostic service will direct how comprehensive and resourced the QIP is.

PQI 1.0 There is an integrated and coordinated Quality Improvement Program (QIP).

PQI 1.1 The diagnostic service has a quality improvement committee.

PQI1.1.1 ☐ There are terms of reference for the quality improvement committee.
PQI1.1.2 ☐ The committee is chaired by a leader within the diagnostic service.
PQI1.1.3 ☐ The committee is accountable to an organization-wide quality improvement body.
PQI1.1.4 ☐ The membership of the committee includes medical, technical and administrative staff of the diagnostic service, and other non-diagnostic service representatives as appropriate.

PQI 1.2 There is a written description of the Quality Improvement Program.

PQI1.2.1 ☐ The objectives of the QIP are identified and aligned with organization-wide quality improvement structures and initiatives.
PQI1.2.2 ☐ There is an explicit definition of how quality is defined in the diagnostic service.
PQI1.2.3 ☐ The roles, responsibilities and authorities of all individuals and structures of the QIP are defined.
Guidance: The responsibility for the QIP may be assigned to an individual or to the quality improvement committee.
PQI1.2.4 ☐ The QIP is accountable to the governing body/ownership.
PQI1.2.5 ☐ The QIP is evaluated on an ongoing basis.

PQI 1.3 Quality improvement initiatives are planned, implemented and evaluated.

PQI1.3.1 ☐ Performance data is used to identify and prioritize improvement opportunities.
PQI1.3.2 ☐ Appropriate people (staff, stakeholders, clients) are involved in improvement initiatives.
PQI1.3.3 ☐ Clear, measurable statements are developed explaining the goal(s) of each improvement initiative.
PQI1.3.4 ☐ Plans for improvement initiatives are developed, documented and implemented.
PQI1.3.5 ☐ Quality improvement initiatives are evaluated after implementation.
PQI1.3.6 ☐ Action is taken if an initiative does not achieve or sustain planned improvements.
PQI1.3.7 ☐ The results of improvement initiatives are documented and communicated to staff, stakeholders and clients.

KEY OPERATIONAL PROCESSES, CLINICAL PROCESSES AND INTERNAL AUDITS

PQI 2.0 The diagnostic service improves quality by documenting and auditing key operational processes.

PQI 2.1 Key operational processes are defined and documented.
Guidance: Operational processes are those activities that are necessary to support the effective delivery of care and service.

PQI2.1.1 **M** ☐ Key operational processes that can impact the quality of service are identified.
PQI2.1.2 ☐ Identified processes are documented through flowcharting and/or written procedures.

PQI 2.2 Clinical processes and procedures are defined and documented.
Guidance: Clinical processes are specific processes that directly impact the patient's care. Examples of clinical processes may include equipment limitations and test interpretation.

PQI2.2.1 **M** ☐ Clinical processes and procedures that can impact quality of service are identified.
PQI2.2.2 ☐ Identified processes and procedures are documented through flowcharting and/or written procedures or protocols.

PQI 2.3 An internal audit program is established to monitor key operational processes.
Guidance: Internal audits ensure compliance with documented procedures and flowcharts, identify potential risks and opportunities for improvement.

Procedures for conducting internal audits are documented and include:

PQI2.3.1 ☐ name of the key operational process.
PQI2.3.2 ☐ frequency of audit.
PQI2.3.3 ☐ individual appropriate to conduct the audit.
Guidance: It is preferable that individuals do not audit their own activities.
PQI2.3.4 ☐ the training requirements for those involved in the audit.
PQI2.3.5 ☐ methodology to conduct the audit and document the results.
PQI2.3.6 ☐ responsibility for audit review and follow-up activities.

PQI2.3.7 **M** ☐ Internal audits of key operational and clinical processes are performed.

PQI 2.4 Internal audits are performed in the following areas:

PQI2.4.1 ☐ governance and leadership (e.g. the review of quality and safety reports by the governing body/ownership).
PQI2.4.2 ☐ medical staff (e.g. transfer of function).
PQI2.4.3 ☐ human resources (e.g. the process to assess the competence of staff).
PQI2.4.4 ☐ patient and client focus (e.g. the process to assess patient satisfaction).
PQI2.4.5 ☐ safety (e.g. patient identification or processes to conduct safety inspections).
PQI2.4.6 ☐ information management (e.g. privacy and confidentiality processes).
PQI2.4.7 ☐ quality improvement (e.g. medical peer review process).

MEDICAL PEER REVIEW

Introduction:
Medical peer review contributes to improving processes and outcomes by providing performance feedback to individual physicians. It is a proactive tool for identifying, tracking and resolving inappropriate clinical performance, discrepancies and medical errors during all stages of the diagnostic process. Peer review can be an internal process undertaken by peers within the organization, or a process external to the organization utilizing outside peers. Peer review may be performed on a 'case by case' basis in relation to critical incidents, complaints or medical staff reappointment processes. It may also be performed on randomly selected cases as part of a systematic effort to monitor performance of practitioners as a proactive complement to routine performance data collection and review.

PQI 3.0 The diagnostic service improves quality through a medical peer review program.

PQI 3.1 There is an established medical peer review program.

PQI3.1.1 **M** ☐ Medical leadership for the medical peer review program is assigned.

PQI3.1.2 **M** ☐ The medical leader ensures the medical peer review program is developed, implemented and monitored.

PQI3.1.3 **M** ☐ The medical leader ensures the focus of the peer review program is quality improvement.

PQI3.1.5 **M** ☐ individual results of medical peer review are communicated to the medical practitioner.

PQI3.1.6 **M** ☐ aggregate results of medical peer review are communicated to the diagnostic service medical practitioners.

PQI3.1.7 **M** ☐ changes in practice are implemented, as necessary.

PQI3.1.8 ☐ where possible, there is participation in larger peer review databases to enable comparisons, benchmarking and statistical relevance.

PQI 3.2 The medical peer review program includes the following elements.

PQI3.2.1 **M** ☐ A defined number of cases and reports are randomly selected for medical peer review for each interpreting physician on a semi-annual basis.
Guidance: At a minimum, the peer review program includes the retrospective review of 10-12 physician studies per year. The type of examinations reviewed reflects the scope of services provided.

PQI3.2.2 **M** ☐ The completeness and accuracy of reporting is assessed.
Guidance: Medical peer review assessment templates are available on the DAP website http://www.dap.org/Default.aspx?p=57.

PQI3.2.3 **M** ☐ The number of cases reviewed is recorded and reported.
Guidance: Medical peer review annual summary templates are available on the DAP website http://www.dap.org/Default.aspx?p=57.

PQI3.2.4 **M** ☐ Significant discrepancies between primary report and review are recorded and reported.

PERFORMANCE INDICATORS

Introduction: In order to improve the quality and safety of services provided, it is important to measure and analyze the performance of processes and then use that data to make improvements. Most organizations have limited resources and can not collect data to monitor everything. Organizations must choose clinical and operational processes and outcome indicators most important to monitor the quality and safety of the services they provide.

PQI 4.0 Indicators are used to monitor operational and clinical performance.

PQI 4.1 Indicators are developed to monitor and improve performance.

PQI4.1.1	**M**	☐ Indicators are developed to monitor the quality and safety of the diagnostic service.
PQI4.1.2		☐ Indicators are used to identify current status and areas for improvement.
PQI4.1.3		☐ Indicators are rate-based (contain a numerator and denominator).
PQI4.1.4		☐ Indicators have defined reporting periods.
PQI4.1.5		☐ Indicators give direction to quality improvement activities.

PQI 4.2 Indicators are established to monitor performance in the following operational areas:

PQI4.2.1	☐ human resources (e.g. staff turnover rate).
PQI4.2.2	☐ safety (e.g. patient injury rate, adverse drug events).
PQI4.2.3	☐ patient and client focus (e.g. wait time from referral to examination).
PQI4.2.4	☐ quality improvement (e.g. peer review discrepancy rate).
PQI4.2.5	☐ information management (e.g. reported breaches in confidentiality).
PQI4.2.6	☐ high risk clinical processes (e.g. procedure infection rates, medication reactions).

ACCREDITATION STANDARDS 2015

INFORMATION MANAGEMENT

Introduction:
Information management processes may be basic or complex, depending on the information system used Information systems can be paper-based; fully electronic or a combination of the two. Operational and clinical information must be accurately generated by the laboratory to ensure staff and clients have access to necessary and appropriate information.

The Information Management section of the accreditation standards addresses:

- Planning
- Confidentiality
- Medical records
- Document control
- Retention of documents and records

PLANNING

PIM 1.0 Plans for managing clinical and management information are effective, integrated and coordinated.

Intent: Planning is one of the most critical components of information management and requires the collaborative involvement of all levels and areas of the organization. The diagnostic service's plan for information management considers all the information used by the diagnostic service; both clinical and management information. Planning includes the assessment of the system and resources necessary to implement and maintain the current and future information needs of the diagnostic service.

PIM 1.1 There is an information management plan for the diagnostic service.

PIM1.1.1 ☐ The information management plan engages key stakeholders and includes the identification of information requirements.
Intent: Key stakeholders may include respirologists, administrators, therapists, referring physicians and information specialists.

PIM1.1.2 ☐ The information management plan is aligned with organization wide information management processes and establishes the priority of current and future information needs.

PIM1.1.3 ☐ The information management plan includes communication of priorities to the administration of the organization and identifies the resources required for the implementation and sustainability of information management processes.

PIM1.1.4 ☐ The information management planning process considers data organization, collection and storage, communication, display, security and information system performance.

PIM 2.0 Information is available and used to make effective decisions.

PIM 2.1 The diagnostic service has access to the data and information which meets the needs and requirements of users.

PIM2.1.1 **M** ☐ Data can be assessed in a timely fashion.

PIM2.1.2 **M** ☐ Data and information can be collected, linked and combined from multiple sources.

PIM2.1.3 **M** ☐ Historical and current data can be assessed and compared.

PIM2.1.4 ☐ Costs associated with service delivery can be determined.

PIM2.1.5 ☐ Resource utilization can be determined and managed.

PIM2.1.6 **M** ☐ Information can be exchanged with other organizations, as appropriate.

PIM2.1.7 ☐ Clinical and management reports can be routinely obtained.

PIM2.1.8 ☐ Custom reports can be designed if necessary.

PIM 3.0 There are processes to ensure the availability of information.

PIM 3.1 The diagnostic service is prepared for events that could impact the availability of information.

PIM3.1.1 **M** ☐ There is a documented disaster recovery plan and associated risk assessment for recovery and access to data.

PIM3.1.2 ☐ The disaster recovery plan has been tested.

PIM3.1.3 **M** ☐ For computerized information systems, database and diagnostic test data back-up is performed daily and the backup is securely located in a separate physical location.

PIM3.1.4 **M** ☐ Data stored on-site and off-site is accessible, but protected from unauthorized access and safeguarded against harm (e.g. water, fire, etc.).

PIM 3.2 Downtime procedures are available and communicated to staff.

Intent: Downtime procedures are required for both scheduled and unscheduled system downtime.

PIM3.2.1 **M** ☐ Downtime procedures are communicated to staff.

PIM3.2.2 **M** ☐ Users know how to contact support staff in the event of system and/or equipment malfunction.

PIM3.2.3 ☐ The reasons for, and frequency of, information system downtime is documented.

CONFIDENTIALITY

PIM 4.0 Patient confidentiality and information is protected through policies and procedures.

PIM 4.1 Data access is restricted, controlled and monitored.

PIM4.1.1 **M** ☐ Policies are in place that specify the level of access that is permitted for each category of staff, including information recorded in patient files from other service areas in the organization.
Intent: Personal information is accessed only by those who are engaged in the primary purpose for which the information was captured.

PIM4.1.2 **M** ☐ Authorized staff maintain user access and restriction controls.

PIM4.1.3 **M** ☐ User access is monitored.

PIM4.1.4 **M** ☐ There is a policy that addresses how to handle unauthorized access.

PIM4.1.5 **M** ☐ For computer-based systems there is a policy for password confidentiality and use.

PIM4.1.6 **M** ☐ Generic login accounts are not used.

PIM4.1.7 **M** ☐ There is a procedure to remove patient identifiers from test data and reports prior to secondary use (e.g. records used for research or teaching purposes).
Guidance: This procedure includes the removal of embedded or "burned-in" patient demographics.

PIM4.1.8 **M** ☐ Security incidents are reported, documented, investigated and resolved. Actions are taken to prevent recurrence.

PIM 4.2 The service has policies for the release or destruction of data.

PIM4.2.1 **M** ☐ There is a policy for the use and disclosure of personal information.
Intent: The policy must include the release of information to patients, family, other service areas, other organizations, for research or education purposes or legal reasons.

PIM4.2.2 **M** ☐ There is a policy that identifies how personal information is distributed (e.g. email, facsimile, web-based technology).

PIM4.2.3 ☐ Personal information that is subject to restricted access is identified.

PIM4.2.4 **M** ☐ Confidential data is destroyed appropriately.

PIM4.2.5 **M** ☐ Education is provided to users of information systems to ensure the confidentiality of data.
Guidance: The education includes information on the release of patient information, legal responsibilities regarding confidentiality, the possible consequences of breeching confidentiality, and reporting, documenting and investigating security incidents.

MEDICAL RECORDS

PIM 5.0 The diagnostic service maintains complete and accurate medical records.
See also Global Accreditation Standard (GP4.0) and the Pulmonary Function modality-specific accreditation standards.

PIM 5.1 The medical record includes accurate patient identification information.

PIM5.1.1 **M** ☐ The facility uniquely identifies the patient and tests performed.
Guidance: There is a system for uniquely identifying patients and records used from the time the patient presents through all stages of the test. The facility ensures that correct patient identification is maintained on all records, including reports. Every patient has a unique facility-issued patient identifying number and each test is uniquely associated to that patient.

PIM5.1.2 **M** ☐ The patient name, patient identifying number and facility name are clearly identified on the file/patient medical record.

PIM 5.2 Data integrity is monitored and maintained.

PIM5.2.1 **M** ☐ There are policies and procedures for reporting and reconciliation of data entry errors and patient identification issues.

PIM5.2.2 **M** ☐ Reconciliation is performed by authorized individuals.

PIM5.2.3 **M** ☐ Audits are performed to identify the individuals who have viewed incorrect patient information.
Guidance: Follow-up notification should be provided to alert individuals that they have viewed incorrect patient information. This notification should be documented.

PIM5.2.4 **M** ☐ Information that is entered manually is verified for accuracy prior to user access.
Intent: There are risks associated with manual re-entry and whenever possible this should be discouraged.

PIM5.2.5 **M** ☐ Information captured electronically from other organizations is verified for accuracy prior to user access.
Intent: There can be risks with associating external information with internal patient medical records. Procedures should exist to ensure data integrity and also to deal with discrepancies in information provided from external organizations

PIM 5.3 Current and historical clinical data can be accessed by staff and clients when needed.

PIM5.3.1 **M** ☐ Test data is available when the patient moves from one facility to another.

PIM5.3.2 ☐ Digital and hard-copy storage ensures an orderly and legible permanent record that is available without delay.

PIM5.3.3 ☐ Digital storage allows for the availability and electronic linking of multiple studies and diagnostic reports for individual patients.

PIM5.3.4 ☐ Data is retrievable “on-line” for a designated period of time, depending on the needs of the facility.

PIM5.3.5 ☐ “On-line” storage capacity planning is periodically performed to ensure the storage needs of the facility are maintained.

PIM5.3.6 **M** ☐ There is sufficient storage for hardcopy records.

DOCUMENT CONTROL

PIM 6.0 The diagnostic service defines and maintains procedures to control key operational documents.

Guidance: This standard refers to key documents such as operational policies and procedures.

PIM 6.1 The diagnostic service defines and maintains document control procedures.

PIM6.1.1 **M** ☐ There are defined procedures for the maintenance and review of documents.

PIM6.1.2 ☐ There is a list of controlled documents that identifies the current version and distribution.

Guidance: In some organizations and facilities, a document is distributed to one or more other locations or areas.

Documents are well marked and uniquely identified to include:

PIM6.1.3 **M** ☐ a title.

PIM6.1.4 **M** ☐ the current revision date or version.

PIM6.1.5 **M** ☐ identification of the individual responsible for the authorization and release of the document.

PIM6.1.6 **M** ☐ Documents follow a standardized format.

PIM6.1.7 **M** ☐ Only current authorized versions of documents are available for active use and invalid or obsolete documents are promptly removed from all points of use.

PIM6.1.8 **M** ☐ Operational documents are archived for later reference and archival time is defined by the medical leader.

PIM6.1.9 **M** ☐ Where hand written amendments are permitted, the amendments indicate date of entry and identification of the person making the change.

PIM6.1.10 ☐ Hand written amendments are permanently incorporated into procedures, and documents are reissued within 6 months.

PIM6.1.11 ☐ There are established procedures on how to make changes to documents in computerized systems.

PIM6.1.12 ☐ Supplemental information or job aids are dated and associated to the full procedure.

Guidance: Information written on separate pieces of paper, sticky notes and other unauthorized material must be linked to a policy, procedure or process. These job aids are not a substitute for information that should be contained in written procedures.

PIM 6.2 There are mechanisms to communicate changes to procedures and documentation

PIM6.2.1 **M** ☐ New or revised policies, procedures, protocols and/or positioning manuals are communicated and available to staff.

PIM6.2.2 **M** ☐ Communication of new or revised procedures and documentation is recorded.

RETENTION OF DOCUMENTS AND RECORDS

PIM 7.0 The diagnostic service retains documents and records.

PIM 7.1 Retention times for diagnostic reports complies with the service's policy or provincial requirements (e.g. B.C. Limitation Act), whichever is longer.

PIM7.1.1 **M** ☐ Medical records are stored according to British Columbia's revised Limitation Act (2013).
Guidance: The medical record comprises all the clinical data and information related to the patient's diagnostic procedure. The medical record contains all relevant documents for testing including, but not limited to: the request, hard copy or electronic worksheets and reports. Facilities and medical leaders establishing retention times outside of the requirements of the Limitation Act should seek and act according to expert legal advice on this matter.

PIM 7.2 Retention times are established for key operational documents.

Retention times are identified for the following:

PIM7.2.1 ☐ test protocols.
PIM7.2.2 ☐ quality improvement records.
PIM7.2.3 ☐ records of internal and external audits.
PIM7.2.4 ☐ complaints and actions taken.
PIM7.2.5 ☐ adverse event and/or critical incident reporting forms and records of investigation.
PIM7.2.6 ☐ staff training and orientation records.
PIM7.2.7 ☐ staff competency records.

PIM 7.3 Equipment testing records are retained.

See also Equipment and Supplies (PES2.0) accreditation standards.
See also Infection Prevention (PIPC3.3) accreditation standards.

PIM7.3.1 **M** ☐ Acceptance testing records are retained for the lifetime of the equipment.
PIM7.3.2 **M** ☐ Equipment Q.C. records are retained for a minimum of three years.
Intent: As far as practicable, recorded data must be indicated as data points on a control chart when the measurement is made. In this form, trends can be more easily detected. A log book or other easily identifiable method of recording must be used and records must be kept for a minimum of 4 years.
PIM7.3.3 **M** ☐ Preventative maintenance records are retained for the lifetime of the equipment.
PIM7.3.4 **M** ☐ Personal protective equipment records are retained as per facility policy (e.g. N95 mask fit testing).

Definitions

Information systems are defined as an organized combination of hardware, software, communication network and data resources that collects, transforms and disseminates information in an organization.

The *medical record (often referred to as the patient health record)* includes all the clinical data and information related to the patient's diagnostic procedure and treatment.

Patient identifiers: Information directly associated with an individual that reliably identifies the individual as the person for whom the service or treatment is intended. Acceptable identifiers may include the individual's first and last name, an assigned identification number, or other person-specific identifiers.

ACCREDITATION STANDARDS 2015

EQUIPMENT AND SUPPLIES

Introduction:
Manufacturers of equipment will provide installation, verification and maintenance requirements that must be followed to ensure adequate equipment functionality.

The Equipment and Supplies section of the accreditation standards addresses:

- Equipment operation
- Equipment testing and quality assurance
- Calibrations
- Biological Controls
- Biological References
- Solutions and Supplies

Definitions:

Safety testing is a process to verify compliance with the performance specifications of the equipment as written in the purchase contract. It also verifies that the equipment performance meets the manufacturer's specifications and complies with federal and provincial or territorial regulations.

Safety testing is to be performed prior to any clinical use of the equipment and performed by an individual with in-depth knowledge of the particular type of equipment and the relevant regulations. This individual is to be independent of the manufacturer.

Medical Device Regulations encompass all other safety considerations and the question of efficacy for all medical equipment sold in Canada. It is the responsibility of the manufacturer or distributor to ensure that the equipment conforms to the requirements of these regulations. Evidence of compliance includes an active Health Canada medical device licensing number.[1]

See also Information Management Accreditation Standards PIM 7.3.

EQUIPMENT OPERATION

PES 1.0 Equipment is safely operated, maintained and monitored in a manner that ensures performance specifications are met.

PES 1.1 There is a current inventory for all equipment used in the diagnostic chain that includes:

PES1.1.1	**M**	☐	name of item.
PES1.1.2	**M**	☐	manufacturer.
PES1.1.3	**M**	☐	serial number or other identifier.
PES1.1.4	**M**	☐	date of installation.
PES1.1.5		☐	condition of equipment at the time it was acquired (e.g. new, refurbished).
PES1.1.6	**M**	☐	acceptance testing.
PES1.1.7	**M**	☐	quality control records.
PES1.1.8	**M**	☐	preventative maintenance records.
PES1.1.9	**M**	☐	repair records.

PES 1.2 Diagnostic equipment is appropriately operated.

PES1.2.1	**M**	☐	An orientation and training program is provided for all equipment to ensure safe, consistent, and accurate operation.
PES1.2.2	**M**	☐	Specialized equipment and instrumentation is operated by competent staff with the necessary education, knowledge, skills and certification.
PES1.2.3	**M**	☐	Equipment is used only as intended by the manufacturer.
PES1.2.4	**M**	☐	Equipment operators have access to the manufacturer's operator manual for the specific equipment used in the facility.[2]
PES1.2.5	**M**	☐	All equipment is located and stored in a safe and secure location.
PES1.2.6		☐	Equipment is located to maximize efficiency.

PES 1.3 The diagnostic service investigates and resolves problems involving all equipment.

PES1.3.1	**M**	☐	Roles and responsibilities for reporting, investigating and resolving equipment problems are clearly communicated and understood.
PES1.3.2	**M**	☐	There is a list of service staff and their contact information.
PES1.3.3	**M**	☐	Responsible staff members are trained in resolving equipment problems.
PES1.3.4	**M**	☐	Information about problems is collected, documented, monitored and analyzed.
PES1.3.5	**M**	☐	Actions to prevent recurrence are identified.
PES1.3.6	**M**	☐	Manufacturer-issued defects, recalls and safety advisories are acted upon immediately.
PES1.3.7	**M**	☐	There is a process for resolving non-compliance or quality issues with the vendor in a timely manner.
PES1.3.8	**M**	☐	Equipment problems that impact test quality or safety are reported and repaired.
PES1.3.9	**M**	☐	Any equipment that is not functioning as per manufacturer guidelines or poses a safety risk is clearly labeled and removed from service.
PES1.3.10	**M**	☐	Any equipment that exhibits performance limitations, but is deemed safe, is identified to all relevant staff.
PES1.3.11	**M**	☐	Equipment and other instruments that are new, relocated or entering into service after repair are calibrated, validated and verified, as appropriate, before clinical use.

PES 1.4 Activities for monitoring pulmonary function diagnostic equipment are recorded.

PES1.4.1 **M** ☐ Day-to-day activities for pulmonary function testing equipment are recorded in a log book (e.g. equipment calibration logs, trouble shooting, equipment maintenance).

EQUIPMENT TESTING AND QUALITY ASSURANCE

PES 2.0 Equipment testing is performed prior to clinical use.

PES 2.1 Acceptance testing is performed after purchase and prior to clinical use of equipment.

PES2.1.1 **M** ☐ New, replaced, or relocated equipment has acceptance testing performed prior to clinical use.

PES2.1.2 **M** ☐ The tester is independent of the manufacturer.[3]

PES2.1.3 ☐ Results from the acceptance testing are used to establish baseline values of operational performance.

PES2.1.4 **M** ☐ Acceptance testing records are available for review.

Acceptance testing of diagnostic equipment includes:

PES2.1.5 **M** ☐ an initial inspection of the system and any ancillary equipment.

PES2.1.6 **M** ☐ an inspection of documentation.

PES2.1.7 **M** ☐ biological controls have 10 tests performed to ensure accuracy and repeatability.

PES2.1.8 ☐ data analysis to identify a shift or bias from the previous or other testing equipment to the new equipment.

PES2.1.9 **M** ☐ a defined procedure to notify interpreting staff if a systematic bias has been identified.

PES2.1.10 **M** ☐ a review of the test data by the medical leader prior to clinical use.

PES2.1.11 **M** ☐ The DAP is notified of new or replaced equipment prior to clinical use.
Guidance: A notification of significant change in service form must be submitted to the DAP clinical use of the equipment. The notification of significant change in service form is available at http://dap.org/Default.aspx?p=181.

DES2.1.12 **M** ☐ Acceptance testing reports are submitted to the DAP.
Guidance: Acceptance testing reports includes the biological control data for each test performed. Please refer to Pulmonary Function worksheets at http://dap.org/Default.aspx?p=169.

PES 2.2 Repaired or upgraded equipment has the necessary testing performed prior to clinical use.

PES2.2.1 **M** ☐ Testing is performed for damaged/repaired equipment or equipment with major software/hardware upgrades prior to clinical use.
Guidance: This may require acceptance testing or specific QC testing to ensure the equipment meets regulatory standards or manufacturer's specifications.

PES 3.0 Quality Assurance programs are established to ensure the attainment of intended quality.

Intent: A quality assurance program means the planned and organized actions necessary to provide adequate confidence that the equipment and its related components will reliably produce quality test data providing the necessary information for accurate clinical assessment. A quality assurance program includes quality control procedures for the monitoring and testing of medical diagnostic equipment and related components, and administrative methodologies to ensure that monitoring, evaluation and corrective actions are properly performed. Quality Control procedures are an essential component of a quality assurance program which clearly specify the technical procedures necessary for the monitoring and testing of the diagnostic equipment and related components.

PES 3.1 Quality Control procedures are performed by staff knowledgeable in the testing procedures.

PES3.1.1 **M** ☐ There is a designated person(s) responsible for monitoring and reviewing QC on a regular basis.
Intent: The facility determines who is trained and knowledgeable to perform and monitor QC procedures. Some QC procedures may be designated to individuals. For example, technologists may perform some frequently scheduled QC procedures, QC coordinators, equipment service providers, consultants, and biomedical service engineers may perform more specialized.

PES3.1.2 **M** ☐ Staff have the necessary training, reference and education materials available to ensure QC is performed according to manufacturer's recommendations or recognized best practices.

PES 3.2 Quality Control testing equipment is maintained and monitored.[4]

PES3.2.1 **M** ☐ All equipment used for acceptance and quality control testing is evaluated for their functionality and performance on a regular basis according to manufacturer's recommendations (e.g. 3 L calibration syringe has a manufactures' expiration date).

PES3.2.2 **M** ☐ Testing equipment is operated following manufacturer's recommendations.

PES 3.3 Out of range or unacceptable QC values are promptly reviewed and investigated.

PES3.3.1 **M** ☐ When QC problems are identified; procedures are implemented to determine cause(s).

PES3.3.2 **M** ☐ Corrective action is taken and monitored.

PES3.3.3 **M** ☐ QC problems, investigations and corrective actions are documented and retained.

PES 3.4 There is a preventive maintenance program in place for the diagnostic and ancillary equipment.

PES3.4.1 **M** ☐ Documented preventive maintenance is performed at regular intervals by appropriately trained staff according to manufacturer's recommendations.

PES3.4.2 **M** ☐ Maintenance personnel ensure that the record of all repair and maintenance procedures are properly recorded and when required, communicated to relevant staff.[5]

PES3.4.3 ☐ Maintenance personnel review the maintenance procedures periodically and update them to ensure optimum patient an operator safety.

CALIBRATIONS / VERIFICATION

PES 4.0 Calibrations/verifications are used to ensure that Quality Control (QC) testing of pulmonary function equipment is achieved.

PES 4.1 Calibration/verifications is performed on pulmonary function equipment to ensure equipment is ready for patient testing.

PES4.1.1 **M** ☐ The procedures for calibration/verification are documented.
PES4.1.2 **M** ☐ Calibrations/verifications are performed as per manufacturer's recommendations.
PES4.1.3 **M** ☐ Calibrations/verifications are performed daily or prior to patient testing.
PES4.1.4 **M** ☐ Frequency of calibration/verification is defined.
PES4.1.5 **M** ☐ A certified 3 L syringe is used for calibration/verification.
Intent: 3 L syringes are replaced as per manufacturer's recommendation.
PES4.1.6 **M** ☐ A leak test is periodically performed on 3 L syringe(s).
PES4.1.7 **M** ☐ Calibration/verification is performed with a filter in line, if filters are used during patient testing.
PES4.1.8 **M** ☐ Lung volume testing equipment is calibrated if the temperature change is greater than 2 Celsius.
PES4.1.9 **M** ☐ Documentation for calibrations/verifications is available for review.
PES4.1.10 **M** ☐ The flowrate for delivering an aerosol via a nebulizer size has been determined[6].

BIOLOGICAL CONTROLS

PES 5.0 Biological controls are used ensure Quality Control (QC) testing of pulmonary function equipment is achieved.

PES 5.1 Biological controls are used to ensure pulmonary function equipment to ensure equipment is ready for patient testing.

PES5.1.1 **M** ☐ QC policies and procedures for biologic controls are documented and maintained.
PES5.1.2 **M** ☐ Biologic controls are used to asses and maintain equipment function.
PES5.1.3 **M** ☐ Biological controls have normal and repeatable lung function test results (e.g. no asthma or other respiratory problems).
PES5.1.4 ☐ Multiple control subjects are used.
Guidance: The availability for multiple control subjects allows for inter-therapist reliability and having a back-up subject in cases of abnormal results or health issues.
PES5.1.5 **M** ☐ QC testing uses the same procedures as applied to the patient population.
PES5.1.6 **M** ☐ Biological control measurements meet all criteria for acceptability and repeatability.
PES5.1.7 **M** ☐ Lung volume testing equipment is calibrated if the temperature change is greater than 2 Celsius.
PES5.1.8 **M** ☐ Documentation for calibrations is available for review.

PES5.1.9 **M** ☐ Comparability of biologic control data between similar or identical instruments performing the same test is performed and verified at regularly defined intervals.

PES5.1.10 **M** ☐ QC and patient data from all equipment and analyzers performing the same test are compared on a regular basis and inconsistencies are investigated.

PES 5.2 Biological control data is managed to ensure quality control for pulmonary function equipment.

PES5.2.1 **M** ☐ QC is recorded and charted in such a way that allows for review.

PES5.2.2 **M** ☐ QC results and worksheets are reviewed and verified.

PES5.2.3 **M** ☐ Roles and responsibilities for QC are well defined and include the medical leader.

PES5.2.4 **M** ☐ When QC problems are identified, corrective actions are taken to determine cause(s) (e.g. QC results that fall outside acceptable criteria).

PES5.2.5 **M** ☐ Procedures are in place for the appropriate handling of patients while QC problems are investigated.

PES5.2.6 **M** ☐ Biological control measurements meet all criteria for acceptability and repeatability.

PES5.2.7 **M** ☐ QC data is collected and submitted to the Diagnostic Accreditation Program of B.C. as required.
For Spirometry QC program: http://dap.org/Default.aspx?p=170
For PF Laboratory QC program: http://dap.org/Default.aspx?p=169

BIOLOGICAL REFERENCES (NORMALS)

PES 6.0 Biological references are established for the population the diagnostic service serves.

PES 6.1 Biological references are established to ensure accurate test results for interpretation.

PES6.1.1 **M** ☐ A list of biological references used is defined and documented.

PES6.1.2 **M** ☐ The biological references reflect the patient population it serves.

PES6.1.3 **M** ☐ The limitations for the biological references are communicated to all staff.
Guidance: Biological references may include a specific age range, gender and ethnic population.

PES6.1.4 **M** ☐ The list of biological references used is reviewed by the medical leader.
Guidance: Refer to Global Pulmonary Function Accreditation Standards GP 3.1.1

SOLUTIONS & SUPPLIES

PES 7.0 Solutions and supplies are monitored in a way that reduces or eliminates shortages and waste.

PES 7.1 The storage and monitoring of solutions and supplies ensures an effective inventory control system.

PES7.1.1 **M** ☐ Storage complies with manufacturer's recommendations.

PES7.1.2 ☐ Receipt and service entry dates are recorded as necessary.

PES7.1.3	**M**	☐	Expiration dates are monitored.
PES7.1.4		☐	Rejected/expired goods are clearly marked and dealt with appropriately.
PES7.1.5		☐	Inventory control problems and actions taken are documented.
PES7.1.6		☐	There is a process for resolving non-compliance or quality issues with the vendor in a timely manner.
PES7.1.7		☐	Documentation of supply utilization is routinely reviewed.
PES7.1.8		☐	There are policies and procedures for the appropriate disposal of solutions and supplies.

Definitions:

Acceptance testing is a term used referring to the functional testing of equipment and/or software during the implementation phase.

Calibration refers to the relationship between input and output signals that can be used to correct accuracy in spirometers and gas analyzers.

Verification is a term used to indicate that specific requirements and accuracy are fulfilled pertaining to calibration.

SPECIFIC DOCUMENTS REFERENCED

[1] Health Canada. Medical Devices Active License Listing (MDALL). Retrievable from: http://www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic-eng.php

[2] Health Canada Safety Code 35. Radiation Protection in Radiology—Large Facilities. Safety Procedures for the Installation, Use and Control of X-ray Equipment in Large Medical Radiological Facilities, Section A, 1.3.4, p.8

[3] Health Canada Safety Code 35. Radiation Protection in Radiology—Large Facilities. Safety Procedures for the Installation, Use and Control of X-ray Equipment in Large Medical Radiological Facilities, Section B, 2.2.4, p.23

[4] Health Canada Safety Code 35. Radiation Protection in Radiology—Large Facilities. Safety Procedures for the Installation, Use and Control of X-ray Equipment in Large Medical Radiological Facilities, Section B, 4.2.1, p.35

[5] Health Canada Safety Code 35. Radiation Protection in Radiology—Large Facilities. Safety Procedures for the Installation, Use and Control of X-ray Equipment in Large Medical Radiological Facilities, Section A, 1.7.3, p.10

[6] American Journal of Respiratory and Critical Care Medicine. Guidelines for Methacholine and Exercise Challenge Testing. 2000. Vol161, p.315.

ACCREDITATION STANDARDS 2015

GLOBAL PULMONARY FUNCTION

The Global Accreditation Standards are to be used in conjunction with the category specific Accreditation Standards.

The Global section of the accreditation standards addresses:

- Test Requests
- Patient Preparation
- Procedures and Documentation
- Medical Record
- Interpretation and Reports
- Reporting Processes

Definition:

An *addendum report* is sent when additional information that must be reported has become available.

Authorized individual is a term used to describe a physician or other designated health professional defined under relevant legislation as having the ability to request diagnostic tests.

A *corrected report* is sent when an originally reported result or information in the report has been subsequently found to be incorrect such that a new report is issued. Significant differences in preliminary reports and subsequent reports should be treated as corrected reports.

TEST REQUESTS

GP 1.0 Test requests are standardized and ensure that accurate, comprehensive and appropriate information is relayed.

Guidance: Requests are to be completed for all diagnostic tests. Requests may be verbal, written (requisitions) or electronic.

GP 1.1 Processing of the test requests ensures:

GP1.1.1 **M** ☐ tests are only performed when requested by authorized individuals.
Guidance: There is a facility policy that defines "authorized individual" that includes medical physicians and other designated health professionals as permitted by governing legislation, rules and bylaws.

GP1.1.2 **M** ☐ verbal requests are immediately followed with an authorized electronic or written request.

GP1.1.3 **M** ☐ requests that lack the necessary information or contain errors are reconciled prior to the test.

GP1.1.4 **M** ☐ authorized individuals requesting tests are notified when tests are cancelled by the diagnostic service.

GP 1.2 The appropriateness of requested diagnostic services is assessed.

GP1.2.1 ☐ Clinical indications for requesting tests are made available.

GP1.2.2 **M** ☐ Processes are in place to assess test appropriateness.

GP 1.3 Requests contain accurate and appropriate information that includes:

GP1.3.1 **M** ☐ the patient's first and last name.

GP1.3.2 **M** ☐ a unique personal identifier number such as Provincial Health Number (PHN) or facility–issued identifier number.

GP1.3.3 **M** ☐ date of birth.

GP1.3.4 **M** ☐ gender.

GP1.3.5 **M** ☐ name and contact information of authorized individual.
Intent: If an urgent/stat report is required the authorized individual's contact information is provided.

GP1.3.6 **M** ☐ clear indication of the authorized individual.

GP1.3.7 **M** ☐ name(s) of any other individual who is to receive a copy of the report.

GP1.3.8 **M** ☐ test type(s) and any specific instructions.

GP1.3.9 **M** ☐ pertinent clinical information including indications, history, and provisional diagnosis.
Intent: The clinical information is sufficient to ensure the appropriate test is performed. Provisional diagnosis is provided when applicable to assist in determining the most appropriate diagnostic test.

GP1.3.10 **M** ☐ the date the request is received.

GP1.3.11 **M** ☐ indication of urgency.
Intent: There is an effective system in place to ensure patient prioritization. For emergent patient prioritization cases the urgency is indicated on the request either by the authorized individual and/or by the diagnostic physician or designate.

PATIENT PREPARATION

GP 2.0 Patients are appropriately prepared for the test being performed.

GP 2.1 Patient instructions are clearly communicated.

GP2.1.1 **M** ☐ Patients and/or supporting individuals are advised of patient instructions prior to the test, as needed.

GP2.1.2 **M** ☐ Test request guidelines (e.g. patient instructions) are available to patients and referring practitioners.

GP2.1.3 ☐ Patient instructions are available in a variety of languages considering the population served.

GP2.1.4 ☐ There are processes to identify and work with patients who do not speak English.

GP2.1.5 **M** ☐ Staff acknowledge and respect cultural and spiritual sensitivities of patients without compromising test quality and safety.
Guidance: The cultural and spiritual sensitivities of patients may result in differing reactions and behaviors; with the potential to impact the test.

GP2.1.6 ☐ Multi-lingual staff are identified and available where practical and in accordance with the diagnostic service policy.

GP 2.2 Pre-test information is collected and assessed prior to commencing the test.

GP2.2.1 **M** ☐ There are processes in place to ensure that patients have followed the preparation instructions and to address situations where patients are inappropriately prepared.

GP2.2.2 ☐ Any factors that may affect the test are documented and considered.
Guidance: A patient's medical condition may change from the point of referral to testing date.

GP2.2.3 **M** ☐ Processes ensure relevant prior tests are available for comparison.
Guidance: The criteria to obtain relevant prior tests are clearly defined by the medical leader to ensure processes are followed. In some instances relevant prior tests will need to be requested from external organizations.

GP2.2.4 **M** ☐ Patients are assessed for contraindications to the procedure or other exclusion criteria.
Guidance: When required, the technologist should consult with the physician, nursing staff and/or care giver concerning the patient's condition and any limitations.

PROCEDURES AND DOCUMENTATION

GP 3.0 Standardized procedures are used in diagnostic facilities to obtain test results.

GP 3.1 There is a process to ensure that procedural documents are reviewed.

GP3.1.1 **M** ☐ Procedures are reviewed every 1-3 years by qualified individual(s).

GP 3.2 The diagnostic facility ensures documentation is available to ensure consistency of testing.

Guidance: Documentation includes both electronic and paper-based systems.

GP3.2.1 **M** ☐ All procedures are documented, communicated to, and available to staff performing the testing.

GP3.2.2 **M** ☐ Documentation contains all the relevant information necessary to perform the test.

Guidance: Relevant information necessary to perform the test may include: title, purpose, process flowchart, testing instructions, supporting documents, equipment and maintenance, special safety precautions, expected values or results (normative values).

GP3.2.3 **M** ☐ Manufacturer's documentation is only used as a supplement to the diagnostic facilities procedure.

Intent: There should be documentation for all diagnostic procedures performed at the facility. Equipment or product information supplied by the manufacturer may be used to supplement procedural documentation but cannot be used as a substitute.

GP3.2.4 **M** ☐ Manufacturer's changes to procedures are incorporated in a timely manner.

GP 3.3 Testing is performed according to established procedures.

GP3.3.1 **M** ☐ Diagnostic testing is consistent with the procedures in manuals.

GP3.3.2 **M** ☐ Before clinical procedures are used, including those not recognized as standard practice; are validated by the medical leader to confirm they satisfy the intended use.

GP3.3.3 ☐ Validation results for new protocols are retained.

GP 3.4 Procedure manuals are current, accurate and available to staff.

All the information necessary to perform the test is available and includes:

GP3.4.1 **M** ☐ name of test.

GP3.4.2 **M** ☐ purpose or principle.

GP3.4.3 **M** ☐ equipment and supplies.

GP3.4.4 **M** ☐ patient preparation.

GP3.4.5 **M** ☐ testing details.

GP3.4.6 **M** ☐ monitoring and reporting details.

GP3.4.7 **M** ☐ exclusion criteria.

GP3.4.8 **M** ☐ reference values used.

GP3.4.9 **M** ☐ references/guidelines used in the development of the procedures.

GP3.4.10 **M** ☐ reviewed by the medical leader.

MEDICAL RECORD

GP 4.0 The medical record is current, accurate and contains relevant test details.

GP 4.1 Tests are labeled in a standardized way that allows for proper patient identification that include:

GP4.1.1 **M** ☐ patient's first and last name.
GP4.1.2 **M** ☐ second patient identifier (e.g. identifying number or date of birth).
GP4.1.3 **M** ☐ facility name.
GP4.1.4 **M** ☐ date and time of test.

GP 4.2 Comprehensive test details are recorded in the medical record that includes:
Intent: Test details may be recorded electronically or on written requisitions/worksheets. All details are made available to the interpreting physician.

GP4.2.1 **M** ☐ the paper or electronic patient requisition.
GP4.2.2 **M** ☐ technologist performing test.
GP4.2.3 **M** ☐ date and time of test.
GP4.2.4 **M** ☐ relevant medication information (e.g. name, route, and dose).
GP4.2.5 **M** ☐ deviations from the standard procedure are recorded particularly when there are reasons for test limitations.
GP4.2.6 **M** ☐ relevant clinical information provided by the patient or observed complications pertinent for interpretation purposes.

INTERPRETATION AND REPORTS

GP 5.0 Diagnostic reports are in a standardized format that provides comprehensive and necessary information for clinical decision-making.

GP 5.1 Reports are comprehensive and include appropriate patient and relevant clinical information.
Reports include the following information:

GP5.1.1 **M** ☐ the patient's first and last name.
GP5.1.2 **M** ☐ a unique personal identifier number such as MRN, PHN or facility-issued identifier number.
GP5.1.3 **M** ☐ date of birth.
GP5.1.4 **M** ☐ height.
GP5.1.5 **M** ☐ weight (or BMI).
GP5.1.6 **M** ☐ race
GP5.1.7 **M** ☐ reference values
GP5.1.8 **M** ☐ gender.
GP5.1.9 **M** ☐ facility name.
GP5.1.10 **M** ☐ test(s) performed.
GP5.1.11 **M** ☐ clinical indication for the test.
GP5.1.12 **M** ☐ name of authorized individual requesting test.

GP5.1.13 **M** ☐ the individual performing the test (e.g. name or unique identifier).
GP5.1.14 **M** ☐ report recipient(s).
GP5.1.15 **M** ☐ date of the test.
GP5.1.16 ☐ the time of test, if relevant (e.g. patients likely to have more than one test type per day).
GP5.1.17 **M** ☐ date of interpretation (e.g. dictation and/or transcription).
Intent: Having both dates may be useful to some facilities when determining report turnaround times.
GP5.1.18 **M** ☐ report status (e.g. preliminary or final).
GP5.1.19 **M** ☐ multiple page reports include patient identifiers on each sequentially numbered page.

GP 5.2 Reports contain sufficient information to assist in diagnosis.
Intent: When required, previous reports are promptly available for review and comparison with the current test. A request for diagnostic test includes relevant clinical information, a working diagnostic or pertinent clinical signs and symptoms and may include specific clinical questions to be answered in the final report. Such information helps tailor the most appropriate diagnostic test to the clinical scenario, enhances the clinical relevance of the report, and thus promotes optimal patient care.
GP5.2.1 ☐ Standardized report templates are used.

The body of the report includes the following:
GP5.2.2 **M** ☐ procedures performed.
Guidance: The report includes a description of the studies or procedures performed, medications, equipment used, relevant patient preparation and positioning details.
GP5.2.3 **M** ☐ findings.
GP5.2.4 **M** ☐ potential limitations.
GP5.2.5 **M** ☐ clinical issues.
GP5.2.6 **M** ☐ comparison with relevant tests and reports is included in final report.
GP5.2.7 **M** ☐ the impression (e.g. conclusion or diagnosis) section of the report.
Guidance: Unless the report is brief, each report contains an "impression" section.

GP 5.3 A timely and accurate final report is issued for all tests.
Intent: A final report is the definitive means of communicating test results to the authorized individual or other relevant healthcare provider. Additional methods for communication of results are encouraged in certain situations.
GP5.3.1 **M** ☐ Final reports are issued for all tests.
GP5.3.2 **M** ☐ A copy of the final report is archived by the diagnostic service as part of the patient's medical record (paper or electronic) and is retrievable for future reference.
GP5.3.3 ☐ The final report is verified by the reporting physician to minimize typographical errors, accidentally deleted words, and confusing or conflicting statements.
GP5.3.4 **M** ☐ Reports are verified and signed off by a reporting physician. If the content of the report is <u>not</u> verified by the author, there is a process in place to verify the accuracy of the transcription and this is clearly indicated on the report.

GP5.3.5 **M** ☐ Medical staff responsible for the patient is notified of report delays in variance with established turn-around-times and in cases that may compromise patient care.

GP5.3.6 ☐ The use of abbreviations or acronyms is limited to avoid ambiguity.

REPORTING PROCESSES

GP 6.0 Effective communication minimizes the risks of both reporting and patient management errors.

Intent: E*ffective communication is tailored to satisfy the need for timeliness, support the role of a diagnostic physician and minimize the risk of communication errors. The authorized individual or relevant healthcare provider shares in the responsibility for obtaining results of diagnostic tests he or she has requested.*

GP 6.1 Preliminary reports provide information necessary for clinical decision-making.

Intent: Preliminary reports may be communicated in a written, electronic, or verbal format. Preliminary reports may be time sensitive, and are not expected to contain all the reportable findings. A preliminary report may not have the benefit of prior diagnostic studies and/or reports and may be based upon incomplete information due to evolving clinical circumstances. Nevertheless, clinical decision making may be based on this report due to the need for immediate patient management. Situations that may require preliminary reports may include interpretations provided to emergency departments, surgical departments and critical care units.

GP6.1.1 **M** ☐ Preliminary reports are clearly identified.

GP6.1.2 **M** ☐ All preliminary reports are followed by a final report.

GP6.1.3 **M** ☐ Medical staff responsible for the patient are notified as soon as possible when there is a significant discrepancy between a preliminary and the final written report.

GP6.1.4 **M** ☐ Documentation of communication of any discrepancy between a preliminary and final report is incorporated into the final report.

GP 6.2 Urgent and other non-routine test findings are effectively communicated.

Intent: Routine reporting of test findings is communicated through the usual channels established by the hospital or the diagnostic service. However, in urgent or other non-routine clinical situations, the interpreting physician expedites the delivery of a diagnostic report (preliminary or final) in a manner that ensures timely receipt of the findings. Documentation of this communication is extremely important because clinical care errors may relate to flaws in the chain of communication.

GP6.2.1 **M** ☐ There is a written procedure on communication of urgent and other non-routine tests findings (e.g. critical findings/results).

Intent: A diagnostic service's policy on communication can be an effective tool to promote patient care. The policy can provide guidance on the types of communications that are most critical, the individuals responsible for receiving communications and the methods of communication that are most appropriate.

GP6.2.2 **M** ☐ Appropriate medical staff is notified by direct means (e.g. in person or by telephone) according to facility policy for communication of urgent and other non-routine findings (e.g. critical results).

GP6.2.3 **M** ☐ Contingency plans are available in the event that the medical staff cannot be contacted.

Notification and actions taken in response to urgent, unexpected or unusual findings are documented in the patient's medical record. The medical record includes:

GP6.2.4 **M** ☐ the urgent findings.
GP6.2.5 **M** ☐ the name of the person to whom the urgent findings were given.
GP6.2.6 **M** ☐ the date and time the urgent findings were communicated.
GP6.2.7 **M** ☐ how the urgent findings were communicated (e.g. telephone, in person).

GP 6.3 There are policies and procedures in place to deal with corrected and addendum reports.

GP6.3.1 **M** ☐ There are policies and procedures that address corrected and addendum reports.
Guidance: There are clear directions that indicate when a corrected report is required and the steps that are to be taken when issuing a corrected or addendum report.
GP6.3.2 **M** ☐ Corrected and addendum reports are clearly identified.
GP6.3.3 **M** ☐ Both the original and the new results are reported.
GP6.3.4 **M** ☐ The date and time the change or addition was made are recorded.
GP6.3.5 **M** ☐ The identity of the person making the change or addition is recorded.
GP6.3.6 **M** ☐ Notification of clinical staff is recorded when there is a significant discrepancy between the original and the corrected or addendum report.

ACCREDITATION STANDARDS 2015

PULMONARY FUNCTION (PF)

Introduction:
In addition to the Global Accreditation Standards, these specific accreditation standards for Pulmonary Function provide additional mandatory requirements and best practices for accreditation.

The Pulmonary Function section of the accreditation standards addresses additional requirements related to:

- Patient preparation
- Diagnostic procedures
  - Pulmonary Function procedures
  - Equipment
  - Reporting
- Sample collection
  - Arterial Blood Gases

PATIENT PREPARATION

PF 1.0 Patients are prepared for the test being performed.
See also Global Accreditation Standards GP 2.0.

PF 1.1 Pre-testing information is collected and assessed prior to commencing the test.

PF1.1.1 **M** ☐ A current medication list is reviewed and any recent medical change is documented prior to testing.
Intent: The current medical list or recent medical change is discussed with the patient and is also documented.

PF1.1.2 **M** ☐ Current medical and physical history and other patient specific factors are documented and considered prior to patient testing.
Guidance: Processes are in place to identify and assist patients that are wheelchair bound or limited to a stretcher.

PF1.1.3 **M** ☐ Processes are in place to ensure that patients have followed preparatory instructions.

PF1.1.4 **M** ☐ Procedures are in place for patients that are on supplemental oxygen.
Guidance: Patients on supplemental oxygen have access to an alternative source of supplemental oxygen in order to conserve their tank.

PF1.1.5 **M** ☐ Testing procedures are explained and demonstrated to the patient.

PF1.1.6 **M** ☐ Patient height and weight is taken without shoes.
Guidance: For individuals that have repeat testing height and weight is taken if the last time of test exceeds 6 months or when clinically relevant. Height measurement is taken at normal tidal respiration/breathing.

PF1.1.7 **M** ☐ Patient height correction factors are applied for patients with spinal deformities and limitations (e.g. kyphoscoliosis or wheelchair bound).

Patients are orientated to the testing equipment and includes:

PF1.1.8 **M** ☐ a stationary chair with no wheels.

PF1.1.9 **M** ☐ nose clips.

PF1.1.10 **M** ☐ filter/mouthpiece.

SPIROMETRY

PF 2.0 Spirometry tests are standardized and recorded in a manner to ensure accurate results for interpretation.

PF 2.1 Procedures for spirometry testing follow current standards and best practices.

PF2.1.1 **M** ☐ The therapist appropriately coaches the patient throughout the entire maneuver.

PF2.1.2 **M** ☐ The patient is observed during the test.
Guidance: Ensure that the patient is maintaining an airtight seal throughout the maneuver and is aware for signs of distress (e.g. syncope).

PF2.1.3 **M** ☐ Procedures are in place for patients on supplemental oxygen.
Guidance: If oxygen is removed for testing then saturation is continuously monitored.

PF2.1.4 **M** ☐ Exclusion criteria for spirometry testing is established and includes but is not limited to patients with cardiac instability.
Guidance: For more information on exclusion criteria refer to Global Pulmonary Function Accreditation Standards GP 2.2.4 and GP 3.4.7.

PF 2.2 Equipment requirements for spirometry follow current standards and best practices.

Spirometry equipment is capable of:

PF2.2.1 **M** ☐ Graphical displays for flow versus volume data.

PF2.2.2 **M** ☐ Graphical displays for volume versus time data.

PF 2.3 Acceptability and repeatability for spirometry follow current standards and best practices.

PF2.3.1 **M** ☐ A minimum of three acceptable maneuvers are recorded.

PF2.3.2 **M** ☐ The two largest values (FEV1, FVC) agree within 150 mL.

PF2.3.3 **M** ☐ If FVC or FEV1 is less than 1 L, then they agree within 100 mL.

PF2.3.4 **M** ☐ The start of the FVC maneuver is fast and unhesitating, with back extrapolation of less than 5% of the FVC or 0.15 L, whichever is greater.

PF2.3.5 **M** ☐ The PEF for the two largest acceptable trials agree within 10%.
Guidance: The peak on the flow – volume curve is sharp and pointed and not rounded.

PF2.3.6 **M** ☐ Coughing during the first second of exhalation is not acceptable.

PF2.3.7 **M** ☐ For EOT (end of test) criteria a plateau of one second is achieved with no change in volume.
Guidance: Refer to the Volume – Time curve for a one second plateau.

PF2.3.8 **M** ☐ For adults, EOT criteria for exhalation is for a minimum of 6 seconds.

PF2.3.9 **M** ☐ Glottic closure is ruled out.
Guidance: The use of a flow-time curve may be used as an aid to visualize a premature plateau.

PF2.3.10 **M** ☐ Inspiratory and expiratory efforts are full and rapid, without hesitation.

PF2.3.11 **M** ☐ Graphical data (Flow – Volume curve or Volume – Time curve) for the maneuvers with the two largest values are similar.

PF2.3.12 ☐ A maximum of eight maneuvers are performed.

PF 2.4 Reporting of spirometry follows current standards and best practices.

PF2.4.1 **M** ☐ All volumes and flows are reported at body temperature and pressure saturated with water vapor (BTPS) conditions.

PF2.4.2 **M** ☐ The largest FVC from at least two acceptable maneuvers is reported.
Guidance: The FVC can be used for lung volumes if it is equal to or greater than the SVC. However, the SVC should be greater than the FVC.

PF2.4.3 **M** ☐ The largest FVC and largest FEV_1 from acceptable maneuvers are reported, if appropriate.

PF2.4.4 **M** ☐ The largest PEF obtained is reported.

PF2.4.5 ☐ All other flows (e.g., FEF_{25-75}%, FEF_{50}%) are reported from the "best" test. The "best" test is defined as the maneuver with the largest sum of FVC and FEV_1.

PF2.4.6 ☐ All inspiratory measurements (e.g., FIVC, PIF, and FIF_{50}%) are the largest values obtained.

PF2.4.7 **M** ☐ Graphical data for a flow-volume curve is included in the final report.

PF2.4.8 **M** ☐ If a single volume-time tracing or flow-volume curve is included in the final report, it is the spirogram from the effort with the largest sum of FVC and FEV_1.

PF2.4.9 ☐ If reporting, the highest acceptable MVV (L/min) and MVV rate (breaths/min) are used.

PF2.4.10 **M** ☐ Therapist's comments on patient effort and cooperation, difficulties, medication history or other factors that impacted the test are reported.

PF 2.5 Procedures for Flow Volume Loops (FVL) follow current standards and best practices.

PF2.5.1 **M** ☐ Inspiratory and expiratory efforts are full and rapid, without hesitation.
Intent: FVL aid in ruling out intrathoracic/extrathoracic obstruction and provide graphical data for obstructive versus restrictive disorders.

PF2.5.2 **M** ☐ Graphical data for a flow-volume curve is included in the final report.

PF2.5.3 ☐ A single volume-time tracing or flow-volume curve is included in the final report; it is the spirogram from the effort with the largest sum of FVC and FEV_1.

PF2.5.4 ☐ Expiratory and inspiratory flow-volume curves from different acceptable efforts may be combined to produce a flow-volume loop.

PF2.5.5 **M** ☐ The two largest acceptable maneuvers have reproducible curves.

PF 2.6 Procedures for bronchodilator administration follow current standards and best practices.

See also Patient Safety Accreditation Standards PPS3.0: Medication Management & Administration.

There is a defined procedure to administer bronchodilators that includes:

PF2.6.1 **M** ☐ dosage.

PF2.6.2 **M** ☐ means of delivery (MDI or nebulizer – including flowrate).

PF2.6.3 **M** ☐ repeat administration.

PF2.6.4 **M** ☐ time period for post bronchodilator testing.
Intent: Spirometry testing is not performed until 15 minutes after bronchodilator administration.

PF2.6.5 **M** ☐ A spacer is used in conjunction with a MDI (meter dose inhaler).

PF2.6.6 **M** ☐ The medication type and dosage are reported in the final report.

PF2.6.7 **M** ☐ There is a defined procedure to track total dosages used /remaining.
Intent: To ensure that an effective dose is administered each time and that the medication is not empty (e.g. puffers).

PF 2.7 Procedures for upright/supine spirometry follow current standards and best practices.

PF2.7.1 **M** ☐ Clear indication of upright and supine in documented in the report.

PF2.7.2 ☐ The degree of supine is documented in the report.
Guidance: Most often stretchers are used for testing but sometimes patients that are wheelchair bound have limitations on the degree of recline.

PF 2.8 Procedures for pediatric spirometry follow current standards and best practices.

Testing in a pediatric population can present many challenges, from lack of cooperation or simply not being able to perform the test, but with good coaching there still can have success performing pulmonary function tests. Therefore, the environment and technologist in the pulmonary function setting should be non-threatening and positive.

PF2.8.1 ☐ Testing is performed in a standardized position and is indicated on the report.
Guidance: The standardized position could either be standing or seated.

PF2.8.2 **M** ☐ The highest acceptable FVC and FEV1 (or FEV0.5) is reported.

PF2.8.3 ☐ Two repeatable maneuvers within 10% of each other are obtained.
Guidance: For pediatric testing, obtaining repeatable results can be difficult to achieve therefore even reporting a single acceptable trial may provide some essential information.

PF2.8.4 **M** ☐ Back extrapolated volume is less than 80 mL or 12.5% whichever is greater.

PF2.8.5 ☐ For pediatrics, EOT criteria for exhalation is for a minimum of 3 seconds.

PF2.8.6 ☐ For FVC < 1.0L, repeatability of the next largest FVC is within 100 mL.

PF2.8.7 ☐ For FVC > 1.0L, repeatability of the next largest FVC is within 150 mL.

PF2.8.8 ☐ All other flows (e.g., FEF_{25-75}%, FEF_{50}%) are reported from the "best" test.
Guidance: All other flows should be interpreted with caution due to high variability in the pediatric population.

LUNG VOLUMES

Accreditation standards for Lung Volume testing are applicable to both adult and pediatric population.

PF 3.0 Tests for lung volumes are standardized and recorded in a manner to ensure accurate results for interpretation.

PF 3.1 Equipment preparation for determining lung volumes follows current standards and best practices.

PF3.1.1 **M** ☐ Volume calibration (verification) is performed daily or prior to patient testing.

PF3.1.2 **M** ☐ Pulmonary function equipment is given adequate time to warm-up prior to patient testing, as per manufacturer's recommendation.

PF3.1.3 **M** ☐ The system is checked daily to ensure it is leak-free.
Guidance: The door seal is adequate and physically inspected.

For Plethysmography:

PF3.1.4 **M** ☐ The mouth occlusion shutter has minimal resistance to opening and closing.
Guidance: The shutter should not be "sticky".

PF3.1.5 **M** ☐ An isothermal lung simulator is periodically used to verify volume accuracy for plethysmography methods.

PF3.1.6 **M** ☐ Calibration of mouth pressure and box pressure transducers is performed daily or prior to patient testing.

PF 3.2 Procedures for Plethysmography method for determining lung volumes follow current standards and best practices.

PF3.2.1 **M** ☐ There are processes to address factors that limit the patient's access into the bodybox (e.g. claustrophobia, wheelchair, other factors).

PF3.2.2 **M** ☐ The bodybox door is closed for a minimum of 30 seconds prior to testing.
Intent: Enough time is allowed for temperature stabilization to minimize thermal drift.

PF3.2.3	**M**	☐	The patient's mouthpiece is a at a comfortable height to ensure minimal flexion/extension of the neck.
PF3.2.4	**M**	☐	A baseline of 3 to 4 tidal breaths are established prior to FRC maneuver. *Guidance: The shutter is closed at end of expiration for 2 to 3 seconds.*
PF3.2.5	**M**	☐	The panting maneuver occurs at baseline against a closed shutter.
PF3.2.6	**M**	☐	Plethsmography uses panting maneuvers for determining lung volumes. *Guidance: Hands should support the patient's cheeks during the TGV measurement.*
PF3.2.7	**M**	☐	Panting maneuver frequency is between 0.5 and 1.0 Hz (30-60 breaths/minute).
PF3.2.8	**M**	☐	The point at which a slow vital capacity (SVC) maneuver is performed is well defined.
PF3.2.9		☐	SVC maneuvers are performed directly after or linked with the FRC_{pleth} maneuver.
PF3.2.10	**M**	☐	The difference between FRC and TGV is accounted for, when reporting FRC_{pleth} *(also referred to as switch-in-volume).* *Intent: Not all patients are at FRC when the shutter is closed. Therefore the difference between the baseline and the point at which the shutter is closed should be less than 200 mL.*
PF3.2.11	**M**	☐	Pressure-volume graphs display a series of closed superimposed straight lines.
PF3.2.12	**M**	☐	TGV (Thoracic Gas Volume) slopes are edited as per lab procedure.

PF 3.3 Procedures for Nitrogen washout method for determining lung volumes follow current standards and best practices.

PF3.3.1	**M**	☐	A 100% O_2 gas source is available for a minimum of 10 minutes.
PF3.3.2	**M**	☐	The demand valve allows adequate flow with minimal resistance.
PF3.3.3	**M**	☐	A three point calibration is performed prior to each procedure on systems using a nitrogen washout method.
PF3.3.4	**M**	☐	Supplemental O_2 is removed from the patient for a minimum of 15 minutes.
PF3.3.5	**M**	☐	There are processes to deal with patients with very severe lung disease or hypoxemia.
PF3.3.6	**M**	☐	Test end point is identified when the nitrogen concentration of less than 1.5% for three successive breaths.
PF3.3.7	**M**	☐	There is a 15 minute interval between tests for repeat testing.

PF 3.4 Procedures for Inert Gas Dilution method for determining lung volumes follow current standards and best practices.

PF3.4.1	**M**	☐	There is a 5 minute interval between tests for repeat testing.
PF3.4.2	**M**	☐	Test end point is identified when helium concentration is within 0.02% for 30 seconds (helium dilution).
PF3.4.3	**M**	☐	CO_2 and water (H_2O) absorbers are fresh (replace according to manufacturer's recommendations) and placed in the proper order.
PF3.4.4	**M**	☐	The fan to mix and circulate gases is operational.
PF3.4.5	**M**	☐	Two-point (zero to full scale) calibration of the Helium analyzer is performed at prior to patient testing and as per manufacturer's recommendation.
PF3.4.6	**M**	☐	When appropriate earplugs are worn (e.g. patients that have perforated ear drums).

PF 3.5 Reporting of lung volumes follows current standards and best practices.

PF3.5.1 **M** ☐ The mean Functional Residual Capacity (FRC).

PF3.5.2 **M** ☐ In adults, three technically acceptable FRC_{pleth} maneuvers agree within 5%.

PF3.5.3 ☐ In pediatrics, three technically acceptable FRC_{pleth} maneuvers agree within 5%.
Intent: The pediatric population may have some variability, but should be able to obtain repeatable results.

PF3.5.4 **M** ☐ The method for reporting IC, ERV, RV and TLC is defined.

PF3.5.5 **M** ☐ The largest VC is reported.
Guidance: The SVC should be greater than the FVC.

DIFFUSING CAPACITY

Accreditation standards for Diffusing Capacity are applicable to both adult and pediatric populations.

PF 4.0 Diffusing Capacity tests (DLCO) are standardized and recorded in a manner to ensure accurate results for interpretation.

PF 4.1 Procedures for DLCO testing follow current standards and best practices.

PF4.1.1 **M** ☐ Patient is rested in a seated position for a minimum of 5 minutes prior to the first trial and test.
Guidance: Heavy exercise is avoided prior to testing.

PF4.1.2 **M** ☐ There is a minimum of 4 minutes between test intervals.

PF4.1.3 **M** ☐ A maximum of 5 trials is performed.

PF4.1.4 **M** ☐ Time of last cigarette is documented, if applicable.

PF4.1.5 **M** ☐ During the maneuver, exhalation is relaxed down to RV.

PF4.1.6 **M** ☐ During the maneuver, inspiration to TLC is maximum.

PF4.1.7 **M** ☐ Valsalva or Mueller maneuvers are avoided during the breath hold time (BHT).

Procedures are documented for patients that are on supplemental oxygen that includes:

PF4.1.8 **M** ☐ duration of time oxygen is removed prior to testing.

PF4.1.9 **M** ☐ guidelines for monitoring saturation.

PF4.1.10 **M** ☐ defined minimum saturation for tests being stopped.

PF 4.2 Equipment preparation for determining diffusing capacity follow current standards and best practices.

PF4.2.1 **M** ☐ Volume calibration is performed daily or prior to patient testing.

PF4.2.2 **M** ☐ A two-point (zero and full scale) calibration of the gas analyzer(s) is done daily or prior to patient testing and as manufacturer's recommendation.

PF4.2.3 **M** ☐ The content for gas cylinder mixtures follow manufacturer's recommendations.

PF4.2.4 **M** ☐ Discard volumes include anatomical and mechanical deadspace.

PF4.2.5 **M** ☐ The system dead space includes the mouth filter.

PF4.2.6 **M** ☐ Prior to the alveolar sample collection, the washout volume for anatomical and mechanical dead space is 0.75 to 1.0 L.

PF4.2.7 **M** ☐ For volumes less than 2 L a discard volume of 0.5 L is used and is documented.

PF4.2.8 **M** ☐ Graphical display of volume time curve is available for review.

PF4.2.9 **M** ☐ Procedures are in place for manual adjustments of discarded and sample gas volumes.

PF 4.2.10 **M** ☐ After a tank change for the lung diffusion mixture, results are validated with a biological control.
Intent: A biological control is used to verify the contents of the lung diffusion mixture are accurate.

PF 4.3 Acceptability and repeatability for diffusing capacity follow current standards and best practices.

PF4.3.1 **M** ☐ Procedures are in place for manual adjustments of discarded and sample gas volumes.

PF4.3.2 **M** ☐ The inspired volume of test gas is at least 85% of the largest VC.

PF4.3.3 **M** ☐ The target volume of inspired gas occurs in less than 3 seconds.

PF4.3.4 **M** ☐ The breath time hold is 8-12 seconds and any deviations are documented.

PF4.3.5 **M** ☐ During the breath hold, Valsalva or Müller maneuvers are avoided.

PF4.3.6 **M** ☐ During the breath hold, leaks are monitored.

PF4.3.7 **M** ☐ Expiration after breath hold is less than 4 seconds with appropriate clearance of dead space before sampling the alveolar gas.

PF4.3.8 **M** ☐ Graphical display of volume time curve is available for review.

PF4.3.9 **M** ☐ There are two acceptable maneuvers that agree within 3 mL CO/min/mmHg or within 10% of the highest value.

PF 4.4 Reporting of diffusing capacity tests follow current standards and best practices.

PF4.4.1 **M** ☐ The average of at least two acceptable maneuvers.

PF4.4.2 **M** ☐ Established normals for Hb (male and female) are defined and communicated to staff.

PF4.4.3 **M** ☐ Adjustments (e.g., Hb, COHb, PO_2) are documented and reported separately along with the data used to make the adjustment.

The report includes:

PF4.4.4 **M** ☐ measured, uncorrected DLCO.

PF4.4.5 **M** ☐ predicted DLCO.

PF4.4.6 **M** ☐ percent predicted DLCO.

PF4.4.7 **M** ☐ DLCO/VA (also known as KCO).

PF4.4.8 **M** ☐ VA.

PF4.4.9 **M** ☐ IVC.

RESPIRATORY MUSCLE FUNCTION

Accreditation standards for Respiratory Muscle Function are applicable to both adult and pediatric populations.

PF 5.0 Respiratory muscle function tests are standardized and recorded in a manner to ensure accurate results for interpretation.

PF 5.1 Procedures and reporting for MIP (Maximum inspiratory pressure) / PImax testing follow current standards and best practices.

PF5.1.1	**M**	☐	PImax is measured near residual volume (RV).
PF5.1.2		☐	The number of efforts, degree of repeatability, percent of predicted, and lower limit of normal are reported.
PF5.1.3		☐	Pressures are reported as percent of predicted TLC.
PF5.1.4	**M**	☐	The most negative PImax in cmH_20 that can be sustained for a minimum of 1.0 second is reported.
PF5.1.5		☐	During the maneuver, exhalation is relaxed down to RV.
PF5.1.6	**M**	☐	During the maneuver, inspiration effort is maximum.
PF5.1.7		☐	Valsalva or Müller maneuvers are avoided during the breath hold time (BHT).

PF 5.2 Procedures and reporting for MEP (Maximum expiratory pressure) / PEmax testing follow current standards and best practices.

PF5.2.1	**M**	☐	PEmax is measured near total lung capacity (TLC).
PF5.2.2		☐	The number of efforts, degree of repeatability, percent of predicted, and lower limit of normal are reported.
PF5.2.3		☐	Pressures are reported as percent of predicted TLC.
PF5.2.4	**M**	☐	The most positive PEmax in cmH_20 that can be sustained for minimum of 1.0 second is reported.
PF5.2.5		☐	Hands are placed on cheeks during the maneuver. *Intent: Valsalva maneuvers against a closed valve will cause volume loss in expanded cheeks.*
PF5.2.6		☐	A tight seal around the mouth piece is emphasized. *Intent: Valsalva maneuvers against a closed valve with cause volume loss in around the lips and mouth piece.*

CONDUCTANCE/RESISTANCE

Accreditation standards for Conductance and Resistance and are applicable to both adult and pediatric populations.

PF 6.0 Conductance/Resistance tests are standardized and recorded in a manner to ensure accurate results for interpretation.

PF 6.1 Procedures and reporting for conductance/resistance testing follow current standards and best practices.

PF6.1.1 **M** ☐ Bronchodilators are avoided prior to testing.

PF6.1.2 ☐ Patient is instructed to perform small uniform pants between 1.5 – 2.0 breaths per second.

PF6.1.3 **M** ☐ The bodybox door is closed for a minimum of 30 seconds prior to testing.
Intent: Enough time is allowed for temperature stabilization to minimize thermal drift.

PF6.1.4 ☐ Open shutter loops are closed and linear.

PF6.1.5 **M** ☐ Tracings are available for review and within the calibrated pressure range.
Guidance: The open shutter tangent measurements are between (-) 0.5 to (+) 0.5 L/s.

PF6.1.6 ☐ During the closed shutter, data is collected for at least 2 to 3 breaths.

PF6.1.7 ☐ At a minimum, an average of 3 acceptable trials are reported.

PF6.1.8 **M** ☐ Report includes therapist's comment about test quality, patients' understanding of testing process, and, if appropriate, which criteria were not achieved.

REACTIVE AIRWAYS

PF 7.0 Methacholine Challenge tests are standardized and recorded in a manner to ensure accurate results for interpretation.

Accreditation standards for Methacholine Challenge Tests are applicable to both adult and pediatric populations.

PF 7.1 Procedures for Methacholine Challenge testing follow current standards and best practices.

PF7.1.1 **M** ☐ Methacholine is stored as per manufacturer's recommendations.

PF7.1.2 **M** ☐ Methocholine solution is at room temperature for testing.

PF7.1.3 **M** ☐ There are defined documented procedures for dealing with acute bronchospasm.

PF7.1.4 **M** ☐ A medical doctor experienced in acute bronchospasm reversibility is on-site.

PF7.1.5 **M** ☐ Processes are in place to ensure the patient has withheld the appropriate medications prior to testing.

PF7.1.6 **M** ☐ Prior to testing a pre and post bronchodilator screening spirometry results are reviewed.

PF7.1.7 **M** ☐ The delivery method for methacholine has been established (e.g. Dosimeter or nebulizer).

PF7.1.8 **M** ☐ Dosing protocol is defined (e.g. Two- minute tidal breathing or five-breath dosimeter protocol).

PF7.1.9 **M** ☐ Staff are aware of how to calculate PC_{20}.
Guidance: In cases where on the first dose the patient's FEV1 decreased by greater than 20% the actual dose where the PC_{20} would have occurred would need to be calculated.

PF7.1.10 **M** ☐ End of test criteria are defined.

PF7.1.11 **M** ☐ Noseclips are worn during methacholine administration.

PF7.1.12 **M** ☐ Reversing protocol is defined and documented.

PF7.1.13 **M** ☐ Spirometry is performed and FEV_1 is at least 90% of baseline after the last dose of diluent or post bronchodilator administration.

PF7.1.14 **M** ☐ Therapist's comments on patient effort and cooperation, difficulties, medication history or other factors that impacted the test are reported.

Procedure for MCT is defined and includes:

PF7.1.15 **M** ☐ the frequency and duration of tidal breathing, if applicable.

PF7.1.16 **M** ☐ flowrate for the nebulizer, if applicable.
Guidance: Refer to Equipment and Supplies Accreditation Standards PES 4.1.10.

PF7.1.17 **M** ☐ baseline spirometry is from highest acceptable trial post diluent.

PF7.1.18 **M** ☐ measurements are taken at 30 and 90 seconds post diluent.

PF7.1.19 **M** ☐ at each dose, the highest FEV1 is selected from the acceptable trials.

PF7.1.20 **M** ☐ subsequent dosages are administered at 5 minute intervals.

PF7.1.21 ☐ When shortening the test procedure, a two-fold increase in methacholine dose is NOT used for:

PF7.1.22 ☐ a child.

PF7.1.23 ☐ a patient known to have moderate to severe asthma.

PF7.1.24 ☐ a patient with airflow obstruction on baseline spirometry.

PF7.1.25 ☐ patients where the FEV_1 fell by more than 10% after the previous methacholine dose.

PF 7.2 Equipment preparation for Methacholine Challenge testing follow current standards and best practices.

PF7.2.1 **M** ☐ The testing room has adequate ventilation.
Intent: A minimum of two air exchanges per hour.

PF7.2.2 **M** ☐ Exhalation filters are used on nebulizers to minimize the chance that the therapist will be exposed to the methacholine aerosol.

PF7.2.3 **M** ☐ Mechanisms are in place to ensure that the delivery method is working appropriately *(refer to Equipment & Supplies Accreditation Standards PES4.1.10)*.

PF 7.3 Acceptability and repeatability for methacholine challenge testing follows current standards and best practices.

PF7.3.1 ☐ An acceptable and repeatable baseline spirometry is obtained prior to testing (*refer to Spirometry standards).*

PF7.3.2 **M** ☐ Baseline spirometry is defined and established.

PF7.3.3 **M** ☐ Baseline spirometry is selected from the highest acceptable FEV1.
Intent: The highest FEV1 post diluent (e.g. Saline solution) from acceptable trials.

PF7.3.4 **M** ☐ A minimum of two acceptable spirometry trials are performed at each dose / concentration.
PF7.3.5 **M** ☐ A decrease of FEV1 by ≥ 20% is confirmed with an acceptable trial(s).
PF7.3.6 ☐ A maximum of four FEV1 maneuvers are performed at each dose/concentration.

PF 7.4 Reporting of Methacholine Challenge testing follows current standards and best practices.

PF7.4.1 **M** ☐ Signs and symptoms of acute bronchospasm are recorded.
PF7.4.2 **M** ☐ Deviations from protocols are documented.
PF7.4.3 **M** ☐ Data is available for each step in the protocol, including bronchodilator reversal.
PF7.4.4 **M** ☐ Data is expressed as a percent of baseline or the post-diluent value.
PF7.4.5 **M** ☐ The dose is expressed as mg/mL concentration of inhaled methacholine.
PF7.4.6 **M** ☐ Therapist comments include evaluations of patient effort and cooperation, whether coughing occurs, and patient response to specific queries concerning the presence of shortness of breath, wheezing, and other symptoms that can be used to confirm the response.
PF7.4.7 **M** ☐ The concentration that caused a 20% fall in FEV_1 (PC_{20}) is reported in mg/mL.
PF7.4.8 **M** ☐ The dose that caused a 20% fall in FEV_1 (PD20) is reported in mg.
PF7.4.9 ☐ If applicable, FVC, FEV_1, and FEV_1/FVC ratio (if complete FVC maneuvers were performed) are reported for spirometry.
PF7.4.10 ☐ If applicable, specific conductance (sGaw) or specific resistance (sRaw) is reported for plethysmography measurements.
PF7.4.11 ☐ If applicable, sGaw or sRaw is measured, the concentration that causes a 40% fall in sGaw or a 40% rise in sRaw is reported.

EXERCISE – INDUCED ASTHMA (EIA)

PF 8.0 Exercise-induced asthma (EIA) tests are standardized and recorded in a manner to ensure accurate results for interpretation.

EIA testing should be performed under the supervision of a physician appropriately trained to conduct clinical exercise tests. The degree of supervision will be determined by the clinical condition of the patient being tested.
Patients are advised to wear is loose-fitting, comfortable clothing and shoes suitable for exercise.
Accreditation standards for Exercise Induced Asthma testing are applicable to both adult and pediatric populations.

PF 8.1 Procedures for EIA tests follows current standards and best practices.

PF8.1.1 **M** ☐ Pre and post spirometry results are reviewed prior to testing.
PF8.1.2 ☐ Methacholine challenge results are reviewed prior to testing.
PF8.1.3 **M** ☐ The patient is orientated to the testing equipment (treadmill or cycle ergometer).

PF8.1.4 **M** ☐ End-points are explained to the patient (attainment of maximal heart rate, development of limiting symptoms, or blood pressure, ECG or O_2 saturation out of range) and the patient is reassured about safety.

PF8.1.5 **M** ☐ The manner of which symptoms (breathlessness, leg fatigue, chest tightness etc.) will be rated (Borg scale) is communicated to the patient.

PF8.1.6 **M** ☐ Indications and risks have been discussed with patient prior to testing.

PF8.1.7 **M** ☐ A physician is present during testing.
Intent: A medical doctor experienced in acute bronchospasm reversibility is on-site.

The testing protocol is defined and includes:

PF8.1.8 **M** ☐ establishing a baseline spirometry.

PF8.1.9 **M** ☐ workload.
Guidance: A warmup time of at least one minute is given prior to testing.

PF8.1.10 **M** ☐ recording of baseline heart rate and blood pressure.

PF8.1.11 **M** ☐ monitoring ECG.

PF8.1.12 **M** ☐ calculating maximum heart rates to be reached.
Guidance: The target for the patient's maximum heart rate to be achieved should be for 85% of maximum heart rate.

PF8.1.13 **M** ☐ intervals for spirometry (or FVL) (e.g. 5, 10, 15, 20 minutes).

PF8.1.14 **M** ☐ criteria for reversing patient's spirometry back to baseline.

PF 8.2 Reporting of EIA tests follows current standards and best practices.

The report includes:

PF8.2.1 **M** ☐ baseline spirometry.

PF8.2.2 **M** ☐ spirometry at all intervals.

PF8.2.3 **M** ☐ maximum heart rate achieved.

PF8.2.4 **M** ☐ workload.

PF8.2.5 **M** ☐ duration of exercise.

PF8.2.6 **M** ☐ detailed therapist comments for of events or complications that occurred.

PULSE OXIMETRY

PF 9.0 Pulse oximetry testing is conducted in a way that ensures the collection of accurate data for interpretation.

PF 9.1 Pulse oximeter tests are conducted and recorded in a manner that ensures accurate results.

PF9.1.1 **M** ☐ An appropriate probe (e.g. finger, ear, nose or forehead) is selected based on the clinical requirements of the patient.
Guidance: Staff should be aware of the limitations of the different devices.

PF9.1.2 **M** ☐ A good signal waveform is achieved that correlates with the pulse.
Guidance: Nail polish or artificial acrylic nails are assessed prior to finger probe placement.

PF9.1.3 **M** ☐ The accuracy of capture is evaluated by comparing the palpated pulse to the reported heart rate on the device.

PF9.1.4 ☐ Good blood flow is encouraged for a peripheral site probe.
Guidance: Actual physical rubbing may be required to stimulate blood flow.

PF9.1.5 ☐ Disparity between SpO_2 and SaO_2 readings, or the SpO_2 and the clinical presentation of the patient, is investigated prior to reporting results.

PF9.1.6 ☐ Situations that may affect pulse oximetry results are defined (e.g. abnormal hemoglobin, intramuscular dyes, external sources of motion, ambient light, electrical interferences).

PF9.1.7 ☐ Oximeter types throughout the testing continuum are standardized.
Intent: Since there are differences in accuracy among various oximeter brands and types, the same type of device should be used for serial measurements on a patient.

PF9.1.8 **M** ☐ The probe is cleaned between patient applications according to manufacturer recommendations.

PF 9.2 Overnight oximetry tests are conducted and recorded in a manner that ensures accurate results.

The patient receives instructions on the pulse oximeter that includes:

PF9.2.1 **M** ☐ turning the oximeter on and off.

PF9.2.2 **M** ☐ placing and securing the probe.

PF9.2.3 **M** ☐ ensuring that a good signal is achieved.

PF9.2.4 **M** ☐ maintenance of a diary.

PF9.2.5 **M** ☐ There is a process to ensure the battery will last for the duration of the test.
Intent: This is done to ensure that oximetry testing is not compromised by dead batteries.

PF9.2.6 **M** ☐ The date and time settings of the oximeter are verified prior to testing.

PF9.2.7 **M** ☐ Pulse rate and oxygen saturation data are collected for at least four hours.
Guidance: Six hours of data is preferable.

PF9.2.8 **M** ☐ Unedited data is available to the interpreting physician.

The overnight oximetry data includes:

PF9.2.9 **M** ☐ SpO_2% mean.

PF9.2.10 **M** ☐ SpO_2% minimum.

PF9.2.11 **M** ☐ total time the SpO_2 is below 88%, 85%, and 80%.

PF9.2.12 **M** ☐ the desaturation index (the number of 4% desaturations/hour).

PF9.2.13 **M** ☐ heart rate (mean, minimum and maximum).

PF9.2.14 **M** ☐ graphic data of SpO_2 and cardiac rate for the duration of the test.

PF9.2.15 **M** ☐ indication of PAP settings (e.g. CPAP or Bilevel).

PF9.2.16 **M** ☐ indication of oxygen conditions (e.g. flow rate).

PF9.2.17 **M** ☐ the type of probe used to monitor saturation (e.g. finger, ear or forehead probe).

Six Minute Walk Test (6MWT)

PF 10.0 Six minute walk tests (6MWT) are conducted in a way that ensures the collection of accurate data for interpretation.

A 6MW test is different than a walking oximetry test (refer to Pulmonary Function Accreditation Standards PF11.0). The function of a 6MW test may be to assess exercise tolerance and therapy in chronic conditions (e.g. pulmonary hypertension). The goal of this test is to measure the total distance that an individual is able to walk in a six minute period of time.

PF 10.1 6MWT are conducted in a manner that ensures accurate results.

PF10.1.1 **M** ☐ Testing follows standardized protocols.

PF10.1.2 **M** ☐ The patient's effort is self-paced and is allowed to rest as frequently as possible but if they sit down to rest the test is terminated.
Intent: The patient is allowed to rest by stopping or leaning against the wall but as soon as they require to sit down the test is terminated.

PF10.1.3 **M** ☐ Signs and symptoms are assessed throughout the test (e.g. chest pain, unstable balance, diaphoresis).

PF10.1.4 ☐ The test is performed indoors, along a flat, long, straight, 30 meter, unobstructed corridor with a hard surface.
Guidance: The patient should have an unobstructed path in an area that has little to no traffic to interfere with their path.

PF10.1.5 ☐ The course is marked with visible markers (e.g. traffic cones) and Incremental distance markers are used (e.g., every 10 meters) to help measure the distance walked.
Guidance: A starting line, which marks the beginning and end of each 30 meter lap, is marked on the floor.

PF10.1.6 ☐ Recommended that patients wear loose-fitting, comfortable clothing and shoes suitable for exercise.

PF10.1.7 ☐ Patients use their usual walking aids during the test (cane, walker etc.).

PF10.1.8 ☐ Patients are unassisted in carrying their oxygen cylinders.

PF10.1.9 **M** ☐ A stopwatch is used to time the test.
Intent: Timer is not stopped until 6 minutes has lapsed or test is terminated.

PF10.1.10 ☐ A mechanical counter is used to count laps.

PF 10.2 Reporting 6MWT follows current standards and best practices.

The 6MW test data includes:

PF10.2.1 **M** ☐ Pre and Post Borg scale rating.

PF10.2.2 **M** ☐ Pre and Post blood pressure.

PF10.2.3 **M** ☐ Pre and Post oximetry.

PF10.2.4 **M** ☐ heart rate.

PF10.2.5 **M** ☐ total distance walked.

PF10.2.6 **M** ☐ pace of walk.
Guidance: Comments should include subjects pace of walk during testing (e.g slow, moderate, fast).

PF10.2.7 **M** ☐ indication of oxygen conditions (e.g. flow rate, delivery device, mode of transport).
PF10.2.8 **M** ☐ reason for early termination, if applicable.

Exercise Testing for the Assessment of Desaturation

Exercise testing for the assessment of desaturation is also known as walking oximetry. Although the timing of the test often extends to six minutes and it may be performed in a corridor; it is different from a "Six Minute Walk Test". See accreditation standards PF10.0 for specific details on the Six Minute Walk Test.

PF 11.0 Exercise testing for the assessment of desaturation is safe and conducted in a way that ensures the collection of accurate data for interpretation.

PF 11.1 Preparations and procedures for exercise tests are follow current standards and best practices.

PF11.1.1 ☐ Patients wear loose-fitting, comfortable clothing and shoes suitable for exercise.
PF11.1.2 ☐ Patients use their usual walking aids during the test (cane, walker etc.).
PF11.1.3 **M** ☐ Patients are resting for a defined period of time prior to testing.
PF11.1.4 **M** ☐ Patients are orientated to the equipment and testing instructions are explained or demonstrated.

PF 11.2 Exercise tests are conducted and recorded in a manner that ensures accurate results for interpretation.

For corridor testing:

PF11.2.1 ☐ the patient walks (without running) at a pace that they can maintain for 5-10 minutes.
Guidance: Precautions should be taken to ensure the therapist supervising the testing does not set the pace. In order to do this the therapist should walk behind the patient as opposed to in front of or beside the patient. When walking behind the patient care must be taken to ensure the patient does not feel rushed during testing.

PF11.2.2 ☐ a minimum of 30 meters of flat, unobstructed corridor is available to conduct the test.

For cycle ergometer testing:

PF11.2.3 ☐ handlebars and saddle heights are adjusted to the appropriate level.
PF11.2.4 ☐ cycling rate (RPM) and workload (watts) are established.
Guidance: This cycling rate and workload are determined by the therapist based on the activity tolerance of the patient.

For treadmill testing:

PF11.2.5 **M** ☐ treadmill-walking techniques are explained or demonstrated.
PF11.2.6 ☐ a brief trial walk is used to familiarize the patient with the equipment.
PF11.2.7 ☐ a spotter is positioned at the rear of the treadmill.

PF11.2.8 ☐ the treadmill speed and grade are determined by the therapist based on the activity level that elicits dyspnea in a given patient.
Guidance: Typically this is 1MPH, but it varies from patient to patient.

PF11.2.9 **M** ☐ a minimum of three minutes of exercise is achieved.

PF11.2.10 ☐ the workload is increased or decreased as tolerated by the patient.

Exercise parameters are recorded during testing at 30 second intervals:

PF11.2.11 **M** ☐ SpO_2.
Guidance: The type of probe used (finger, ear, forehead) is appropriate for the patient. For example, patients with poor perfusion (e.g. Scleroderma) to the extremities may require an ear or forehead probe.

PF11.2.12 **M** ☐ heart rate.
Guidance: Precautions should be taken to prevent error in recording these parameters. A stop-watch or other dedicated timer should be used and staff must be vigilant to recognize subtle changes during testing.

PF11.2.13 **M** ☐ Signs and symptoms are assessed throughout the test (e.g. chest pain, unstable balance, diaphoresis).

PF11.2.14 **M** ☐ Criteria for stopping the exercise test are defined.

Exercise parameters are recorded includes:

PF11.2.15 **M** ☐ total exercise time.

PF11.2.16 **M** ☐ end of exercise SpO_2.

PF11.2.17 **M** ☐ end of exercise heart rate.

PF11.2.18 ☐ blood pressure.

PF11.2.19 ☐ Borg scale or visual analog scale results.

PF11.2.20 **M** ☐ any symptoms such as shortness of breath and/or leg fatigue.

PF11.2.21 **M** ☐ workload in watts (for ergometer cycle testing).

PF11.2.22 ☐ pace of exercise and if any stops were required.

PSG 11.3 Procedures for the use of supplemental oxygen for exercise tests follow current standards and best practices.

PF11.3.1 **M** ☐ A resting baseline saturation is recorded prior to testing.
Guidance: The resting baseline saturation maybe on room air or on the level of FIO_2 indicated by the ordering physician.

PF11.3.2 **M** ☐ The approach to determine the lowest oxygen flow rate required is established.

PF11.3.3 **M** ☐ Oxygen saturation is measured during exercise.
Guidance: Measuring oxygen saturation immediately after exercise is not appropriate. In hypoxemic patients, oxygen saturation generally increases rapidly after cessation of exercise.

PF11.3.4 **M** ☐ The period of time the patient is rested for during each level of oxygen increase is defined.
Intent: During the titration the patient's oxygen requirements may increase and therefore the level of FIO_2 being administered may increase respectively. As a result, the time period the patient is rested for at each level of FIO_2 is established.

PF11.3.5 **M** ☐ The patient is observed for SpO_2 stability.
Intent: At any specific FIO_2 enough time has been given for saturation to equilibrate.

PF11.3.6 **M** ☐ Post testing the therapist ensures that the saturation recovers to an acceptable baseline.
Intent: The therapist ensures that the saturation post exercise recovers to a safe level as per laboratory protocol.

PF 11.4 The reporting of exercise testing for the assessment of desaturation assists in the interpretation of patient's oxygen requirements.

PF11.4.1 ☐ The patient's position and activity level is reported.

PF11.4.2 **M** ☐ If used, supplemental oxygen flow rate, delivery device and details of how the oxygen tank was carried are reported.

PF11.4.3 ☐ If oxygen is used, baseline saturation levels are documented.

PF11.4.4 **M** ☐ The oximeter type, probe type and placement is reported.

PF11.4.5 ☐ If performed, arterial blood gas results and directly measured saturations of O_2Hb, COHb and MetHb are reported.

PF11.4.6 ☐ The stability and range of fluctuation of readings is reported as well as the length of observation of readings.

PF11.4.7 ☐ The clinical appearance of the patient is included if significant, including peripheral perfusion, skin temperature, cyanosis and other signs and symptoms.

PF11.4.8 ☐ Correlation of the heart rate readout on the oximeter with the actual palpated heart rate is reported.

PF11.4.9 **M** ☐ $Sp0_2$ and HR are reported at 30 second intervals.

Cardiopulmonary Exercise Testing

PF 12.0 Cardiopulmonary exercise testing is safe and conducted in a way that ensures meaningful, relevant data is reported.

Cardiopulmonary exercise testing should be performed under the supervision of a physician appropriately trained to conduct clinical exercise tests. The degree of supervision will be determined by the clinical condition of the patient being tested.
Patients are advised to wear loose-fitting, comfortable clothing and shoes suitable for exercise.

PF 12.1 Preparations and procedures for cardiopulmonary exercise tests follow current standards and best practices.

PF12.1.1 ☐ Explain that the test is a maximum stress test, and that the mouthpiece or mask must be in place for the duration of the test.

PF12.1.2 ☐ The patient is orientated to the testing equipment (treadmill or cycle ergometer).

PF12.1.3 ☐ The patient is instructed to breathe quietly for 2 to 3 minutes. Feedback may be needed to avoid inappropriate breathing patterns (e.g. hyperventilation).

PF12.1.4 ☐ End-points are explained to the patient (e.g. attainment of maximal heart rate, development of limiting symptoms, or blood pressure, ECG or O_2 saturation out of range) and the patient is reassured about safety.

PF12.1.5 ☐ The manner of which symptoms (e.g. breathlessness, leg fatigue, chest tightness, etc.) will be rated (e.g. Borg scale).

PF12.1.6 ☐ Resting pulse oximetry is obtained prior to testing.

Procedures for cardiopulmonary exercise tests includes:

PF12.1.7 ☐ Exercise protocols designed to determine VO_2 max as one end point typically lasts about 10 minutes.
Guidance: Protocols can be modified with total expected exercise time in mind.

PF12.1.8 ☐ Criteria for stopping the exercise test (other than the patient's fatigue and inability to continue) are defined.

PF12.1.9 ☐ When exercise is terminated because of the above criteria, the patient is observed until stable and physiologic variables have returned to baseline conditions.

PF 12.2 Methodology and equipment used for cardiopulmonary exercise testing is safe and standardized.

For treadmill testing:

PF12.2.1 **M** ☐ the patient is instructed about the use of the treadmill.

PF12.2.2 ☐ a brief trial walk is used to familiarize the patient with the equipment and check the ECG signal for motion artifact.

PF12.2.3 ☐ a spotter is positioned at the rear of the treadmill.

PF12.2.4 ☐ the patient is instructed not to use their hands and arms for support during testing.
Guidance: If railings are used, the back of the hands or a light touch can be used for balance but the patient should avoid weight support which has an effect on VO_2max and exercise time. In addition, the use of upper extremities increases the muscle artifact in the ECG tracing.

PF12.2.5 ☐ incremental protocols are established.
Guidance: The treadmill protocol should be appropriate for the patient and clinical questions to be answered.

PF12.2.6 ☐ any modification to the treadmill protocol is documented.
Guidance: Modification to treadmill protocols can be used to accommodate exercise limitations of the patient.

For cycle ergometer testing:

PF12.2.7 **M** ☐ the patient is instructed about the use of the cycle ergometer.

PF12.2.8 ☐ the handlebar and saddle height are adjusted appropriately.
Guidance: When the pedal is at bottom center, knee flexion should be about 20°.

PF12.2.9 ☐ the patient is instructed on pedal speed (appropriate to ergometer) with a typical target of 60 rpm.

PF12.2.10 ☐ a brief trial with little or no power output is performed to familiarize the patient with the equipment and to check the ECG signal for motion artifact.

PF12.2.11 ☐ incremental protocols are established.
Guidance: The cycle ergometer protocol should be appropriate for the patient and clinical questions to be answered.

PF12.2.12 ☐ the protocol includes 3 minutes of unloaded pedaling.

PF12.2.13 ☐ the work rate is increased in 5 to 25 Watt increments every minute until the patient reaches volitional exhaustion, or test is terminated by the medical monitor.

PF12.2.14 ☐ the incremental exercise period is approximately 8-12 minutes in duration. Guidance: *The work rate is decreased for patients suspected of having reduced exercise tolerance and the work rate is increased for very fit patients.*

PF 12.3 Cardiopulmonary exercise tests are monitored and recorded in a way that ensures the collection of accurate data for interpretation.

Electrocardiograms (ECG)

PF12.3.1 **M** ☐ ECG electrodes are placed according to a simulated 12 – lead exercise placement configuration[1].

PF12.3.2 ☐ Chest hair is removed when required.

PF12.3.3 ☐ Cable stabilization is used to reduce motion artifact.

PF12.3.4 ☐ There is a job aide that demonstrates the correct placement of ECG.

PF12.3.5 **M** ☐ A baseline ECG is obtained prior to testing.

PF12.3.6 **M** ☐ ECG data is collected at 1 to 2 minute intervals.

PF12.3.7 **M** ☐ ECG data is monitored continuously during exercise and for at least 3 minutes post exercise or until clinically stable.

PF12.3.8 **M** ☐ Changes on the ECG that require urgent medical attention are identified and advice is sought from the medical leader or other appropriate clinician.

PF12.3.9 **M** ☐ ECG data that requires medical attention is available for review.

Blood Pressure (BP)

PF12.3.10 **M** ☐ A baseline BP is obtained prior to testing.

PF12.3.11 ☐ Blood pressure is measured at a minimum every 2 minutes and at peak exercise.

Pulse Oximetry (HR & SpO_2)

PF12.3.12 **M** ☐ A baseline pulse oximetry is obtained prior to testing.

PF12.3.13 ☐ Pulse oximetry is monitored continuously during exercise and during the recovery phase.

Subjective measurements

PF12.3.14 **M** ☐ Subjective measurements are measured at rest, during exercise and immediately post exercise (e.g. Borg scale for shortness of breath or leg fatigue).

Recovery Phase

PF12.3.15 ☐ Recovery includes a cool-down phase at a reduced work rate (e.g., unloaded pedaling) for 2 to 4 minutes followed by 2 to 6 minutes of rest with ECG and symptom monitoring.

PF12.3.16 **M** ☐ Recovery values are stable before discontinuation of monitoring.
Intent: Recovery values do not have to reach pretest levels but should be stable.

PF 12.4 The reporting of cardiopulmonary exercise testing results provides meaningful cardiac and pulmonary function data to clinicians.

PF12.4.1 **M** ☐ At the termination of exercise the reason for stopping the test is defined and recorded (e.g., legs hurt, shortness of breath, or fatigue).
Intent: This may assist in the determination of maximal effort and help the clinician understand the patient's exercise limitations.

Data is reported at a minimum:

PF12.4.2 **M** ☐ from rest.

PF12.4.3 **M** ☐ near or at the anaerobic threshold (AT) if identifiable.

PF12.4.4 **M** ☐ for the maximal workload achieved.

PF12.4.5 **M** ☐ for VO_2 max and VCO_2 at STPD conditions in L/min.
Guidance: VO_2max may also be normalized for body weight (mL/min/kg). However, this may be misleading in obese individuals.

PF12.4.6 **M** ☐ for V_E is reported at BTPS conditions in L/min.

PF12.4.7 **M** ☐ for PaO_2, $PaCO_2$ (if obtained) and $P_{ET}CO_2$ in mmHg.

PF12.4.8 **M** ☐ for SpO_2 and SaO_2 (from CO-oximetry and reported as a percent).

PF12.4.9 **M** ☐ for Pre exercise spirometry.

SAMPLE COLLECTION

PF 13.0 Sample collection processes ensure that high quality samples are obtained and patient needs are met.

PF 13.1 Laboratories provide guidance and instruction for staff that collect samples for testing and to users of the service.

A current and comprehensive sample collection manual is available that includes:

PF13.1.1 ☐ ordering instructions including Information System entry.

PF13.1.2 ☐ patient preparation information including information provided to patients and/or caregivers.

PF13.1.3 **M** ☐ collection information including sample type, volume and timing, if applicable.
Guidance: Sample volume requirements should be periodically reviewed to ensure appropriate amounts of sample are collected.

PF13.1.4 **M** ☐ sample labeling.

PF13.1.5 **M** ☐ sample handling.

PF13.1.6 **M** ☐ sample storage.

PF13.1.7 **M** ☐ sample transport.
Intent: Transport of sampling must include mode of transport and packaging for transportation (e.g. room air versus ice).

PF13.1.8 **M** ☐ sample processing.

PF13.1.9 **M** ☐ timeline from collection to sample analysis.

PF13.1.10 ☐ laboratory testing that can be ordered STAT.

PF13.1.11 ☐ There are mechanisms to provide feedback to sample collectors and to refer them to procedures on issues related to sample quality.

PF13.1.12 **M** ☐ Staff are aware of what measures to take for patients who experience adverse reactions from phlebotomy such as fainting, seizures and injuries.

PF13.1.13 **M** ☐ There is a policy that defines the qualifications, training and competency assessment for staff collecting arterial punctures.

PF 13.2 Sample collection equipment ensures high quality samples are obtained for testing.

PF13.2.1 **M** ☐ A selection of needles and other equipment is available to serve the typical patients having samples collected.

PF13.2.2 **M** ☐ Sample collection carts and trays are clean, without clutter and have sharps discard containers.

PF13.2.3 **M** ☐ Needles and blood collection holders are not preassembled in blood collection trays.
Guidance: This does not apply to pre-packaged one piece needle-holder devices that are in compliance with WorkSafeBC requirements.

PF13.2.4 ☐ Collection equipment including phlebotomy chairs are used to reduce safety risks to patients and staff.

PF13.2.5 **M** ☐ Sample collection equipment is disposed of in an appropriate and safe manner.

PF13.2.6 **M** ☐ Pillows are not used during phlebotomy.

PF 13.3 Arterial blood sample collection ensures high quality samples are obtained for testing with minimal discomfort for the patient.

PF13.3.1 **M** ☐ Sample collection sites are appropriately selected.

PF13.3.2 **M** ☐ The patient is examined for the presence of a radial artery occlusion prior to arterial puncture using a Modified Allen's test.

PF13.3.3 ☐ Samples are collected away from a hematoma of any size.
Intent: Collecting a sample through a bruised site can affect some test results.

PF13.3.4 **M** ☐ Phlebotomy sites are properly decontaminated.

PF13.3.5 **M** ☐ There is a system in place to prevent ambient air contamination of arterial blood gases prior to analysis.

The sample collection site is disinfected:

PF13.3.6 **M** ☐ by initially cleansing the site with 70% isopropyl alcohol and allowing the site to air dry.

PF13.3.7 **M** ☐ by ensuring the antiseptic remains in contact with the skin for at least 30 seconds.

Appropriate precautions are taken to prevent bruising that includes:

PF13.3.8 **M** ☐ adhesive bandages, (preferably hypoallergenic) and/or gauze pads and hypoallergenic tape are available for post-phlebotomy care.

PF13.3.9 ☐ small prepackaged gauze pads are preferably used over cotton balls for post-arterial-puncture care[2].
Intent: Cotton balls are not recommended because of the possibility of dislodging the platelet plug at the arterial-puncture *site.*

PF13.3.10 **M** ☐ the gauze is placed over the site and mild pressure is applied.

PF13.3.11 **M** ☐ the therapist observes the patient for excessive bleeding and the development of a hematoma.
Intent: Pressure should be applied for as long as necessary to stop the bleeding.

PF13.3.12 **M** ☐ a process to address instances when sample collection is difficult.

PF 13.4 Labeling provides information necessary to link samples to patients and distinguish samples.

PF13.4.1 **M** ☐ Samples are only labeled immediately after the collection process in the presence of the patient by staff collecting the sample[3].

PF13.4.2 **M** ☐ Sample labeling is written on, or attached to, sample containers (not lids).

PF13.4.3 **M** ☐ All samples are indelibly labeled.

PF13.4.4 **M** ☐ When printed labels are affixed to the sample containers after handwritten labeling of the primary sample, the printed label does not obscure the original handwriting.
Guidance: The standards recognize that on occasion printed labels are too large for the labeled sample. If possible the printed label should not obscure the original patient identifiers.

PF13.4.5 **M** ☐ Multiple samples collected from one patient at the same time (e.g. right versus left arterial sampling) are uniquely identified.
Guidance: Multiple samples collected from one patient should be distinguished from one another. Typically this is done by noting the site or providing a number on the sample label that corresponds to a site or number on the request. This does not apply to multiple tubes of blood collected by routine phlebotomy.

PF13.4.6 **M** ☐ Similar samples collected at different times are uniquely distinguished.

PF13.4.7 **M** ☐ There is a written policy regarding correction of information on sample labels.

Guidance: The policy may be as simple as "There is to be no correction of information on sample labels". The laboratory defines circumstances under which correction of the information on sample labels is permitted. A record of all such corrections should be maintained. The laboratory should investigate errors in sample labeling and develop corrective/preventive action as appropriate including education of staff that collect samples.

Definitions:

Back extrapolated volume refers to the volume that occurs as a result of hesitation prior to an forced expiratory maneuver.

Müller *maneuver* refers to the production of negative intrathoracic pressure by closing the glottis and making a forced inspiratory effort.

Switch-in-volume refers to the volume difference between TGV and FRC when the shutter is closed.

Valsalva maneuver refers to the high intrathoracic pressure caused by closing the glottis and constricting the abdominal and chest muscles.

PC_{20} (provocative concentration) refers to the methacholine concentration interpolated at which a 20% decrease occurs (usually in reference to FEV1).

PD_{20} (provocative dose) refers *to the* methacholine dose which cause the FEV1 $\geq$ 20% to occur.

SPECIFIC DOCUMENTS REFERENCED

[1] Reconstruction of Standard 12-Lead ECGs from 12-Lead ECGs Recorded with the Mason-Likar Electrode Configuration. Computers in Cardiology 2007; 34:701-704.

[2] Clinical Laboratory Standards Institute. *H03-A6: Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture.* 2007. Standard 7.9, p 4.

[3] Clinical Laboratory Standards Institute. *H03-A6: Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture.* 2007. Standard 8.15, p 18-19.

REFERENCES AND RESOURECES

American Thoracic Society/European Respiratory Society (ATS/ERS) Standards. 2005.

ATS Pulmonary Function Laboratory Management and Procedural Manual. 2005. 2nd Edition.

Canadian Respiratory Journal. *Spirometry in Primary Care.* 2013. Vol. 20 No. 1.

Ruppel's Manual of Pulmonary Function Testing. Carl D. Mottram. 2013. Tenth Edition.

ACCREDITATION STANDARDS 2015

GLOSSARY

Preamble

This glossary has been adapted from one provide by the International Society for Quality in Health Care (ISQua). Some of ISQua's definitions have been altered to better reflect the needs of diagnostic facilities in British Columbia. Some definitions have been imported from the Institute of Medicine and the Clinical Laboratory Standards Institute.

Accreditation

A recognition of the achievement of accreditation standards by a diagnostic facility or organization, demonstrated through an independent external peer assessment of that organization's level of performance in relation to the Diagnostic Accreditation Program's standards, criteria and criterion descriptors.

Accreditation body

The organization responsible for the accreditation program and the granting of accreditation status.

Access

Ability of clients or potential clients to obtain required or available services when needed within an appropriate time.

Accountability

Responsibility and requirement to answer for tasks or activities. This responsibility may not be delegated and must be transparent.

Appropriateness

The degree to which service is consistent with requirements and current best practice.

Assessment

Process by which the characteristics and needs of clients, groups or situations are evaluated or determined so that they can be addressed. The assessment forms the basis of a plan for service or action.

Audit

A systematic examination and review to determine whether actual activities and results comply with planned arrangements.

Best practice

An approach that has been shown to produce superior results, selected by a systematic process, and judged as exemplary, or demonstrated as successful. It is then adapted to fit a particular organization.

Clients

A group or an individual who access the services of, or information from the diagnostic facility. Client groups may include referring health care professionals, the patient's family, community, insurers and other third party payers, employers, and patient advocacy groups.

Community

Collectivity of individuals, families, groups and organizations that interact with one another, cooperate in common activities and solve mutual concerns, usually in a geographic locality or environment.

Competence

Guarantee that an individual's knowledge and skills are appropriate to the service provided and assurance that the knowledge and skill levels are regularly evaluated.

Complaint

Expression of a problem, an issue, or dissatisfaction with services that may be verbal or in writing.

Complementary

Services or components that fit with each other, or supplement one another, to form more complete services.

Confidentiality

Guaranteed limits on the use and distribution of information collected from individuals or organizations.

Consent

Voluntary agreement or approval given by a client.

Continuity

The provision of coordinated services within and across programs and organizations, and over time.

Contract

Formal agreement that stipulates the terms and conditions for services that are obtained from, or provided to, another organization. The contract and the contracted services are monitored and coordinated by the organization and comply with the standards of the government and the organization.

Contracted Service Provider

Contracted service providers include any vendor, contractor, or supplier that provides services. Examples of contracted service providers could include housekeeping services, preventative maintenance providers, referred out diagnostic services and consultants.

Coordination

The process of working together effectively with collaboration among providers, organizations and services in and outside the organization to avoid duplication, gaps, or breaks.

Credentialing

The process of assessing and attesting to an individual's knowledge, skills, and competence and their compliance with specific requirements.

Criterion

Specific step to be taken, or activity to be done, to fulfill a standard. In the DAP document, criterion are indicated by a number such as x.1, x.2, x.3…)

Criterion Descriptor

A specific activity used to rate a criterion. In the DAP Standards, descriptors are indicated by checkboxes.

Culture

A shared system of values, beliefs and behaviors.

Customers

The patients/clients of a client organization. Internal customers/staff of the organization.

Data

Facts from which information can be generated.

Document control system

A planned system for controlling the release, change, and use of important documents within the organization, particularly policies and procedures. The system requires each document to have a unique identification, to show dates of issue and updates and authorization. Issue of documents in the organization is controlled and all copies of all documents are readily traceable and obtainable.

Education

Systematic instructions and learning activities to develop or bring about change in knowledge, attitudes, values or skills.

Effectiveness

The degree to which services, interventions or actions are provided in accordance with current best practice in order to meet goals and achieve optimal results.

Efficiency

The degree to which resources are brought together to achieve results with minimal waste, re-work and effort.

Ethics

Standards of conduct that are morally correct.

Evaluation

Assessment of the degree of success in meeting the goals and expected results (outcomes) of the organization, services, programs or clients.

Evidence

Data and information used to make decisions. Evidence can be derived from research, experiential learning, indicator data and evaluations. Evidence is used in a systematic way to evaluate options and make decisions.

Follow-up

Processes and actions taken after a service has been completed.

Form

A paper or electronic document which requests services or captures information.

Goals

Broad statements that describe the outcomes an organization is seeking and provide direction for day-to-day decisions and activities. The goals support the mission of the organization.

Governance

The function of determining the organization's direction, setting objectives and developing policy to guide the organization in achieving its mission, and monitoring the achievement of those objectives and the implementation of policy.

Governing body

Individuals, group or agency with ultimate authority and accountability for the overall strategies directions and modes of operation of the organization. Also known as the council, board, board of commissioners, etc.

Guidelines

Principles guiding or directing action.

Health professionals

Medical, nursing or allied health professional staff who provide clinical treatment and care to clients, having membership of the appropriate professional body and, where required, having completed and maintained registration or certification from a statutory authority.

Human resources

The personnel requirements of the organization

Human resources file

The collection of information about a staff member covering personnel issues such as leave, references, performance appraisals, qualifications, registration and employment terms.

Incidents

Events that are unusual, unexpected, may have an element of risk, or that may have a negative effect on clients, groups, staff, or the organization.

Indicator

Performance measurement tool, screen or flag that is used as a guide to monitor, evaluate and improve the quality of services. Indicators relate to structure, process and outcomes.

Information

Data that is organized, interpreted and used. Information may be in written, audio, video or photograph form.

Information systems

Systems for planning, organizing, analyzing and controlling data and information, including both computer-based and manual systems.

Leadership

Ability to provide direction and cope with change. It involves establishing a vision, developing strategies for producing the changes needed to implement the vision; aligning people; and motivating and inspiring people to overcome obstacles.

Licensure

Process by which a government authority grants permission to an individual practitioner or healthcare organization to operate or to engage in an occupation or profession.

Management

The group or individual responsible for, or the activity of, setting targets or goals for the future through planning and budgeting, establishing processes for achieving those targets and allocating resources to accomplish those plans. Ensuring daily operation of the diagnostic setting. Ensuring that plans are achieved by organizing, staffing, controlling and problem-solving. Management could include: directors, managers and department heads as well as charge and chief technical staff.

Mandatory

A compulsory descriptor identified in the DAP standards. Unfulfilled mandatory descriptors will result in immediate recommendations with specified time frames for follow-up.

Method Validation

The process of proving that an analytical method is acceptable for its intended purposes.

Mission

A broad written statement in which the organization states what it does and why it exists. The mission sets apart one organization from another.

Need

Physical, mental, emotional, social or spiritual requirement for well-being. Needs may or may not be perceived or expressed by those in need. They must be distinguished from demands, which are expressed desires, not necessarily needs.

Objective

A target that must be reached if the organization is to achieve its goals. It is the translation of the goals into specific, concrete terms against which results can be measured.

Organization

Comprises all sites/locations under the governance of, and accountable to, the governing body/owner(s).

Operational plan

The design of strategies, which includes the processes, actions and resources to achieve the goals and objectives of the organization.

Orientation

The process by which staff become familiar with all aspects of the work environment and their responsibilities.

Partners

The organizations that the organization works and collaborates with to provide complementary services.

Partnerships

Formal or informal working relationships between organizations where services may be developed and proved jointly, or shared.

Peer review

A process whereby the performance of an organization, individuals or groups are evaluated by members of similar organizations or the same profession or discipline and status as those delivering the services.

Performance appraisal

The continuous process by which a manager appraisal and a staff member review the staff member's performance, set performance goals, and evaluate progress towards these goals.

Philosophy

A statement of principles and beliefs made by the organization by which it is managed and delivers services.

Policy

A documented statement of overall intent and direction by those in the organization, endorsed by management.

Procedures

Written specified instructions conveying the approved and recommended steps for a particular act or series of acts.

Processes

Series of interrelated activities that involve multiple steps or engage multiple people.

Qualified

Having the credentials for, being professionally and legally prepared and authorized to perform specific acts.

Qualitative

Data and information expressed with descriptions and narratives, a method that investigates the experience of users through observation and interviews.

Quality

The degree to which health service for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.[1]

Quality Control

The monitoring of output to check if it conforms to specifications or requirements and action taken to rectify the output. Quality Control helps to ensure the accuracy and reproducibility of procedures.

Quality improvement

A process that seeks to meet client's needs and expectations by using a structured approach to selectively identify areas to improve, and that improves all aspect of the services, including outcomes of service to patients and clients.

Quality plan

The current action plan for meeting service quality requirements.

Quantitative

Data and information that is expressed in numbers and statistics, a method that investigates phenomena with measures.

Recruitment and selection

Processes used to attract, choose and appoint qualified staff and surveyors.

Research

A non-diagnostic process which contributes to an existing body of knowledge through investigation, aimed at the discovery and interpretation of facts.

Results (Outcomes)

The outputs, values, reports and interpretations of tests, procedures or examinations.

Rights

Something that can be claimed as justly, fairly, legally or morally one's own. A formal description of the services that clients can expect and demand from an organization.

[1] Institute of Medicine

Risk

Chance or possibility of danger, loss or injury. This can relate to the health and well-being of staff and the public, property, reputation, environment, organizational functioning, financial stability, market share and other things of value.

Risk management

A systematic process of identifying, assessing and taking action to prevent or manage clinical, administrative, property and occupational health and safety risks in the organization.

Safety

The degree to which the potential risk and unintended results are avoided or minimized.

Scope

The range and type of services offered by the organization and any conditions or limits to service coverage.

Services

Products of the organization delivered to clients, or units of the organization that deliver products to clients.

Staff

Individuals who contribute to the delivery of the diagnostic service. This includes both employees of the organization as well as independent contractors.

Stakeholder

Individuals, organizations or groups that have an interest or share in services.

Standard

An achievable level of performance against which actual performance is compared. In DAP documents standards are identified as whole numbers (i.e. 1.0, 2.0, 3.0…).

Strategic plan

A formalized plan that establishes the organization's overall goals and that seeks to position the organization in terms of its environment.

Supplier

Suppliers include any vendors that provide goods. Goods are any items purchased such as supplies, equipment, devices or reagents.

Survey

External peer assessment which measures the performance of the diagnostic service against an agreed set of standards, criteria and criterion descriptors.

Surveyor

External peer reviewer, assessor of diagnostic service performance against agreed standards.

Values

Principles, beliefs or statements of philosophy that guide behavior and that may involve social or ethical issues.

Vision

Description of what the organization would like to be.

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