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REFERENCES AND RESOURCES

GLOSSARY
1. The Diagnostic Accreditation Program would like to acknowledge the following organizations, groups and individuals for their significant contributions to the development of the accreditation programs’ organization and content.

Diagnostic Accreditation Program Divisions:
Contributions from past division members over the last 35 years have provided the foundation for the quality framework and content of the discipline specific standards.

Diagnostic Accreditation Program Divisions:
- Clinical Pathology
- Anatomic Pathology
- Medical Imaging
- Nuclear Medicine
- Neuroelectrodiagnostics
- Pulmonary Function and Polysomnography

American Society for Quality
Australian Council on Healthcare Standards
Canadian Council on Health Services Accreditation – AIM Accreditation Program
Clinical Laboratory Standards Institute – Quality System Essentials
Health Quality Service (UK)
International Society for Quality in Health Care
International Organization for Standardization – ISO 9001 and 15189
Joint Commission on the Accreditation of Healthcare Organizations

2. The Diagnostic Accreditation Program would also like to acknowledge the following organizations for their significant contributions to the content of the standards.

American Association of Blood Banks
American College of Radiology
American Society of Nuclear Cardiology
American Thoracic Society
Canadian Association of Radiologists
Canadian Association of Radiologists Mammography Accreditation Program
Canadian Electrical Code
Canadian Nuclear Safety Commission
Canadian Society for Transfusion Medicine
Canadian Standards Association
Center for Disease Control
College of American Pathologists
Clinical Laboratory Standards Institute
Government of Canada -Health Canada Safety Codes
Government of Canada - Personal Information Protection and Electronic Documents Act
International Society of Clinical Densitometry
Institute for Magnetic Resonance Safety Education and Research
ACKNOWLEDGEMENTS

Intersocietal Commission for the Accreditation of Echocardiography Laboratories
Osteoporosis Society of Canada
Province of British Columbia - Health Care (Consent) and Care Facility (Admission) Act
Province of British Columbia - Provincial Blood Coordinating Office Directives
Society of Nuclear Medicine
Work Safe BC

3. The Diagnostic Accreditation Program would also like to acknowledge the significant contributions of the organizations who participated in field testing of the draft standards, and the many individuals who participated as surveyors, content experts, targeted reviewers, focus group participants, and advisory committee members.
Diagnostic Accreditation Program of British Columbia

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 of British Columbia.

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

**Laboratory Medicine**
- Sample Collection, Transport, Accessioning & 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 Testing**
- Hospital Based Services
- Community Based Services

**Polysomnography**
Services and Core Functions

The DAP services are delivered in a manner that captures the benefits of peer review, knowledge sharing and professional support. The DAP operates on a continuous quality improvement model, and remains highly committed to supportive, peer-based approaches to accreditation that foster the development of CQI cultures within the diagnostic services.

Core Functions

Establishing accreditation programs targeted at specific diagnostic services:
- Establishing optimal goals, standards, criteria and requirements

Establishing programs for surveyor training and development:
- Selecting skilled and appropriate surveyors
- Providing orientation and training to surveyors
- Evaluating and developing surveyor performance
- Ensuring inter-rater reliability/calibration of surveyors

Establishing processes of accreditation:
- Survey management - survey planning, self assessment and on-site peer review
- Setting the criteria for awarding levels of accreditation
- Timely determination of accreditation decisions
- Establishing the duration and maintenance of accreditation
- Establishing a process for appeal of accreditation decisions
- Reporting accreditation status of organizations to the public

Establishing research and development, and education programs:
- Generating and transferring new knowledge gained through the accreditation process
- Evaluating existing accreditation programs for relevancy and effectiveness
- Identifying the need and requirement for new accreditation programs, standards and/or criteria
- Collecting, analyzing, comparing, and publishing data
- Providing feedback on the performance of diagnostic services
- Acting as a resource centre for quality improvement standards, methods and experience, and as a focal point for the collection of local information, as well as for comparisons with other provinces and countries.

Monitoring performance of organizations:
- Selecting and mandating external proficiency testing programs;
- Establishing new external proficiency testing programs or approaches to monitoring process performance when there is no existing program available;
- Developing and monitoring robust quality indicators of performance
What is Accreditation?

Accreditation is a process that assists diagnostic organizations/facilities/services evaluate and improve the quality of the services they provide to their patients and clients. It is a process that allows for the identification of improvement opportunities leading to an improved quality of service. Accreditation also provides recognition that the organization/facility/service is meeting provincial standards of quality.

The founding principle of the Diagnostic Accreditation Program’s model for accreditation is:

Enabling health care organizations to review and improve systems that support the delivery of safe, high quality diagnostic care

The Purpose of Accreditation

The purpose of accreditation is to provide the diagnostic service with a framework for continuous quality improvement:

- Provides the diagnostic service with an opportunity to effectively evaluate itself against provincially set standards.
- Provides an external objective assessment of performance and comparison with similar diagnostic services through peer-review on-site surveying.
- Identifies significant risk management issues.
- Assists diagnostic services to focus on key improvement opportunities.
- Provides an educational opportunity to all stakeholders throughout the process of accreditation.
- Disseminates the most effective practices amongst organizations through the peer review process.
- Promotes communication, collaboration and teamwork throughout the diagnostic service.
Accreditation Assessment Activities

DAP accreditation involves continuous assessment activities that take place during a 4 year cycle. For new facilities and services, or services that have implemented significant change, an Initial Assessment Process has been developed that requires completion of specific documentation and an initial on-site visit by the DAP prior to services being provided to patients. Previously accredited facilities and services participate continuously in assessment activities throughout the 4 year accreditation cycle.

New Facility/Service or Significant Change in Service Initial Assessment

- Orientation and Education
- Self Assessment (once every 4 years)
- Quality Control (continuous monitoring)
- On-site Assessment (once every 4 years)

4 Year Re-Accreditation Cycle

New Facility or New Diagnostic Service Initial Assessment

A new facility, new services provided by an accredited facility, or services that have implemented significant change proceed through the Initial Assessment process PRIOR to service delivery to patients that includes:

- Completion of documentation outlining facility service profile, equipment, individuals and related qualifications, etc.
- Review of documentation and on-site visit by a DAP Accreditation and Research Development Officer. In certain circumstances the Accreditation and Research Development Officer may be accompanied by other external peer experts.
Accreditation Process

- If the facility/service is granted Provisional Accreditation, they are permitted to commence service delivery to patients subject to satisfactory performance in fulfilling continuous accreditation requirements. If the facility/service is not granted Provisional Accreditation, they are not permitted to commence service delivery to patients.

Orientation and Education

All diagnostic services undergoing accreditation are provided with orientation and education by the DAP. This general orientation session covers topics such as:

- Principles of quality improvement, accreditation, and the quality framework
- Accreditation assessment activities
- On-site Survey
- Standards organization
- Rating Scale
- Working through examples

Self Assessment

The Self Assessment is completed once in the 4 year cycle and precedes the On-site Assessment. Conducting a Self Assessment enables the diagnostic service to evaluate their performance relative to stated standards and best practice. Assessing the diagnostic service’s practices provides a profile of the strengths, risks, and opportunities for improvement. This is both a valuable process and tool to enable the management to focus continuous quality improvement efforts toward specific activities and take action with the creation of a quality improvement plan. The Self Assessment also prepares the diagnostic service for the On-site Assessment.

On-site Assessment

The On-site Assessment is completed once in the 4 year cycle and is conducted by a team of external peers comprised of medical, technical and management surveyors. During the On-site Assessment, the surveyors will assess the performance of the diagnostic service using a patient tracer methodology. This enables the surveyors to assess the performance of the diagnostic service as staff is conducting patient examinations, studies and/or analysis. Detailed survey protocols provide direction to the surveyors outlining what to ask, observe, and assess. The use of protocols also assists with increasing the objectivity and consistency amongst surveyors. The tracer methodology has been used successfully by the The Joint Commission (formerly Joint Commission on Accreditation of Healthcare Organizations) and the DAP approach is based upon their experiences.
Quality Control
Participation in DAP mandated Quality Control programs remains a requirement for accreditation. Throughout the 4 year cycle, the DAP will continue to monitor Quality Control performance of facilities. Quality control performance over the 4 year cycle is factored into the accreditation award decision.

The Accreditation Award
The Diagnostic Accreditation Program of BC is the only regulatory body that can grant the accreditation award on behalf of its governing authority.

Accreditation awards possible are:

1. **Full accreditation** for a period of four years.

2. **Accreditation with report**. This award will be granted to an organization that delivers clinically safe and reliable services but has some anomalies to correct in its organization before it can be granted full accreditation status. The timeframe in which the report must be provided to the DAP will form part of the award requirements.

3. **Non-accreditation**. This status will be given to an organization that does not meet the basic requirement of a clinically safe and reliable service. Non-accreditation status means that no physician in BC may practice in, nor refer patients to, a non-accredited facility. Under current government policy, the Medical Services Plan will also withdraw billing approvals.

As a condition of accreditation, facilities must prominently display the original certificate of accreditation as issued by the DAP. This indicates to the public and patients attending the facility that clinically safe and reliable services are provided by the facility.
All accreditation programs of the Diagnostic Accreditation Program are based upon a quality framework and continuous quality improvement principles. For the purposes of its accreditation programs, the following definitions for quality and quality improvement have been adopted by the Diagnostic Accreditation Program.

**Quality**

The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge\(^1\).

**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.

**The Quality Framework**

The Diagnostic Accreditation Program has adopted a Quality Framework that consists of quality actions and quality categories. The quality actions are those activities related to the Shewart Cycle (Plan-Do-Check-Act) and to supporting processes of education and communication. The quality categories are groups of specific activities that define mandatory requirements and best practices. This framework is used as the basis for establishing standards and criteria that define the conditions for quality.

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1. Institute of Medicine

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- Standards and criteria are used to define the conditions for quality
- All standards and criteria are linked to a quality action and category
Quality Actions

The quality actions are based upon the Shewart cycle that provides an evidence-based approach to continuous improvement. The Shewart cycle is most commonly referred to as the Plan-Do-Check-Act (PDCA) cycle of activities. Augmenting this cycle are the activities of education and communication.

- **Plan** involves those activities related to assessing, identifying, analyzing, problem solving, prioritizing and defining.
- **Do** involves those activities related to implementation or putting into effect. In some instances, standards and criteria identified with “DO” may not be the implementation of planning activities, and are simply a requirement that should be performed.
- **Check** involves those activities that evaluate, monitor, control or check.
- **Act** involves those activities related to taking corrective action when an unanticipated outcome becomes apparent through the “CHECK” activities.
- **Education** involves those activities related to providing and developing knowledge in others.
- **Communication** involves those activities related to imparting information and obtaining information from others.
Quality Categories
Defining Performance Excellence

Performance Excellence

Leadership & Management
Pulmonary Function Testing
Patient & Client Focus
Quality Improvement
Suppliers & Partners

Human Resources
Safety
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 standards 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”.


Example of an Accreditation Standard

1.0 The pulmonary function laboratory has a defined management structure in place to enable the pulmonary function laboratory to achieve its objectives including high quality patient care.

1.2 The pulmonary function laboratory is managed by competent individuals appointed to key functions:

1.2.3 Medical leaders are actively involved in the reporting of the clinical caseload to ensure quality.

- The second level number ending in ".2" (1.2) denotes that it is criterion 2, associated with standard 1.0.
- The criterion is written as an activity or component of the standard that once implemented will lead to the overall attainment of the standard.

- The third level number ending in ".2.3" (1.2.3) denotes that it is descriptor 3, associated with criterion 2 and standard 1.0.
- The descriptor is written as a specific action associated with the criterion.

- This is a first level number ending in .0 and denotes a standard.
- The standard is written as a goal statement.

Mandatory requirement for accreditation.
Management Standards

The management standards are a collection of internationally recognized best practice management activities that apply to all diagnostic services. The majority of these standards have been adopted or adapted from benchmark organizations and programs including:

- Existing guidelines and documentation from the Diagnostic Accreditation Program
- Baldrige National Quality Program: Health Care Criteria for Performance Excellence
- International Society for Quality in Healthcare (ISQua)
- International Organization for Standardization (ISO)
- Institute of Medicine
- National Quality Institute: Canadian Quality Criteria for the Public Sector
Organization and Content Areas of the Management Standards

LEADERSHIP & MANAGEMENT
- Diagnostic service planning
- Resource planning and availability
- Utilization management
- Values and ethics
- Staff participation and well-being
- Risk and disclosure
- Assessing and planning for information needs
- Organizing and controlling data and information
- Data security

HUMAN RESOURCES
- Human resources planning
- Recruitment, retention, credentialing
- Roles and accountabilities
- Enhancing performance in a learning environment

SAFETY
- General safety requirements - minimizing hazards, risks, infection control
- Appropriate physical environment
- Disaster and emergency preparedness

PATIENT & CLIENT FOCUS
- Management of patient and client relationships
- Measurement of patient and client satisfaction

SUPPLIERS & PARTNERS
- Purchasing practices
- Supplier management

QUALITY IMPROVEMENT
- Quality management systems
- Quality assessments and initiatives
- Performance measurement
Pulmonary Function Testing Modality Specific Standards

The modality specific standards are collections of accreditation standards that are specific to a specialty and/or sub-specialty. These standards, criteria and criterion descriptors focus on process management best practices. The standards have been adopted or adapted from organizations and programs including:

- Existing guidelines and documentation from the Diagnostic Accreditation Program
- American Thoracic Society (ATS)
- European Respiratory Society (ERS)
- Canadian Standards Association (CSA)
- Center for Disease Control
- Clinical Laboratory Standards Institute (CLSI)
- Freedom of Information and Protection of Privacy Act
- Health Canada Safety Codes
- Health Care (Consent) and Care Facility (Admission) Act
- International Organization for Standardization (ISO)
- Personal Information Protection and Electronic Documents Act
- Work Safe BC

Organization and Content Areas of the Modality Specific Standards

Pulmonary Function Testing – Hospital Based Services

- Procedure Requests
- Procedure Manuals
- Equipment
- Biologic Controls
- Solutions, Medications and Supplies
- Patient Preparation and Testing
- Spirometry
- Lung Volumes
- Diffusing Capacity
- Maximum Respiratory Pressure
- Six Minute Walk
- Methacholine Bronchoprovocation
- Exercise Induced Bronchospasm
- Conductance/Resistance by Body Plethysmography
- Arterial Blood Gases
- Reporting
- Pulse Oximetry
- Overnight Oximetry
- Exercise Testing for the Assessment of Desaturation
- Cardiopulmonary Exercise Testing
Self Assessment & On-site Assessment

Information

Conducting a Self Assessment enables the diagnostic service to take a snapshot of how they currently measure-up relative to stated accreditation standards. Assessing the diagnostic service’s practices provides a profile of the strengths, risks and opportunities for improvement. This is both a valuable process and tool to enable the management to focus continuous quality improvement efforts toward specific activities and take action with the creation of a quality improvement plan.

**Self Assessment**

During the Self Assessment process, the diagnostic service assesses itself relative to stated standards, criteria and criterion descriptors by using a rating scale. Ideally, the individuals who are involved in this process are those who are able to comment on practices that happen on a day-to-day basis and those who have operational responsibility. In most diagnostic services, this process will involve: directors, managers, department heads, chief technologists, supervisors, technologists, and physicians. The Self Assessment may be completed by a team, or by an individual who consults or meets with others. It is at the discretion of the diagnostic service to determine who will be involved in conducting the Self Assessment and completing the Self Assessment documentation.
The Rating Scale

A rating scale has been developed to allow diagnostic services to assess how well accreditation criteria are fulfilled. The scale points represent five performance categories and a “not applicable” option. The following rating scale guide allows for performance to be assessed relative to the accreditation criteria.

<table>
<thead>
<tr>
<th>5</th>
<th>Exceptional Performance</th>
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<tbody>
<tr>
<td></td>
<td>All criterion descriptors have been fulfilled</td>
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<tr>
<td></td>
<td><strong>AND</strong></td>
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<tr>
<td></td>
<td>There is/are</td>
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<td></td>
<td>Awareness by all relevant staff</td>
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<td></td>
<td>Processes to ensure intended outcomes are achieved [checking/evaluating/auditing/monitoring]</td>
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<tr>
<td></td>
<td>Corrective actions undertaken as needed</td>
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<td></td>
<td>Continuous improvement efforts</td>
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<td></td>
<td>Evidence* to support the above</td>
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<table>
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<tr>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>All criterion descriptors have been fulfilled</td>
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<tr>
<td>There is evidence* to support the above</td>
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<tr>
<th>3</th>
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<tr>
<td>Partial or full implementation of criterion descriptors</td>
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<tr>
<th>2</th>
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<tbody>
<tr>
<td>There is</td>
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<tr>
<td>Recognition of need to implement criterion</td>
</tr>
<tr>
<td>Engagement in planning activities to address criterion</td>
</tr>
<tr>
<td><strong>OR</strong></td>
</tr>
<tr>
<td>Partial or full implementation, with concerns identified by surveyors</td>
</tr>
<tr>
<td>Examples</td>
</tr>
<tr>
<td>a) issues related to safety</td>
</tr>
<tr>
<td>b) less than desirable results may be achieved</td>
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<tr>
<td>c) staff are not aware of critical practices and procedures</td>
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</tbody>
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<table>
<thead>
<tr>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion applicable but no action undertaken</td>
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</table>

*Evidence may take many possible forms*
On-site Assessment

The on-site assessment is conducted by a team of external peers comprised of physician(s), therapist(s) and manager(s). During the on-site assessment, the surveyor will assess the performance of the diagnostic service relative to each standard and criteria. Collection of assessment data by the surveyors will be through discussions with the diagnostic service management and staff, reviewing documentation and observing the diagnostic processes. The on-site assessment also permits the exchange of knowledge and best practices between the diagnostic service and the survey team.

Each surveyor follows specific assessment protocols that directs their assessment activities and allows for comments, observations and recommendations to be recorded. Surveyors assess and use the same rating scale as the diagnostic service to determine how well accreditation criteria have been fulfilled.
PULMONARY FUNCTION LABORATORY MANAGEMENT

1.0 The pulmonary function laboratory has a defined management structure in place to enable the pulmonary function laboratory to achieve its objectives including high quality patient care.

1.1 There is a documented and dated organizational chart that defines:

1.1.1 The management structure of the pulmonary function laboratory.
1.1.2 Lines of accountability.
1.1.3 Responsibility, authority and interrelationships of all staff.
1.1.4 Relationship to any other organization that the pulmonary function laboratory is associated with (e.g. medical leadership located remotely, etc.).

1.2 The pulmonary function laboratory is managed by competent individuals appointed to key functions:

1.2.1 A senior medical leader is appointed with responsibility for the quality of clinical practice within the pulmonary function laboratory.
1.2.2 Medical leaders have certification from the Royal College of Physicians and Surgeons of Canada in the area of specialty they have been appointed.
1.2.3 Medical leaders are actively involved in the reporting of the clinical caseload to ensure quality.
1.2.4 The medical leader or delegated qualified physician is present at the facility to assure the maintenance of a quality management program. The percentage of time or frequency of visits per year is defined and documented and considers the complexity and volume of the studies performed.
1.2.5 Administrative leadership is appointed with responsibility for the administration and operation of the pulmonary function laboratory.
1.2.6 Technical leaders are appointed with responsibility for the technical operations and quality of studies.
1.2.7 Individuals appointed to leadership positions:
1.2.7.1 Have the appropriate qualifications and experience to perform the duties of the position.
1.2.7.2 Receive continuous feedback through annual performance reviews.
1.2.8 There are documented position descriptions for leadership roles that detail:
1.2.8.1 Nature and scope of the position
1.2.8.2 Responsibilities and accountabilities
1.2.8.3 Qualifications required
1.2.8.4 Scope of authority
1.2.8.5 Reporting relationships
1.3 The medical leadership and medical professionals within the pulmonary function laboratory have responsibility for:

1.3.1 Setting standards for clinical quality.
1.3.2 Design and validation of indicators to monitor performance and quality improvement.
1.3.3 Reporting criteria, standardization of interpretive comments and report formats.
1.3.4 Providing educational programs for the medical and pulmonary function laboratory staff and participating in educational programs of the facility.
1.3.5 Operational policies and procedures.
1.3.6 Establishing and monitoring medical quality through a peer review process.

1.4 The pulmonary function laboratory management has responsibility for:

1.4.1 Selecting and validating equipment.
1.4.2 Ensuring that there is sufficient qualified staff with adequate documented training and experience to meet the needs of the pulmonary function laboratory.
1.4.3 Working collaboratively with accrediting and regulatory bodies, administration of the organization, health care providers and patient population served.
1.4.4 Developing and implementing a quality management program.
1.4.5 Implementing a safe working environment for staff that meets applicable regulations.
1.4.6 Implementing processes to address complaints, requests and/or suggestions from patients and clients.
PULMONARY FUNCTION LABORATORY PLANNING

2.0 The pulmonary function laboratory plans services to meet the current and future needs of the patient population it serves.

2.1 The pulmonary function laboratory determines the scope of service utilizing a planning process that takes into account:

2.1.1 The organization’s strategic plan.
2.1.2 Requirements of the patient population served.
2.1.3 Requirements of referring health care professionals.
2.1.4 Existing capacity of the pulmonary function laboratory.
2.1.5 Clinical value of all procedures.
2.1.6 Capital, technology and operational requirements to implement.

2.2 The pulmonary function laboratory has a defined scope of service:

2.2.1 The scope of service the pulmonary function laboratory intends to provide is documented.
2.2.2 The scope of service has been communicated to the administration of the organization and referring health care professionals.

2.3 The pulmonary function laboratory has a documented annual operating plan to guide day-to-day activities:

2.3.1 The plan is developed with input from key staff.
2.3.2 The implementation of the plan is monitored and revised by pulmonary function laboratory management as necessary.
RESOURCE PLANNING & AVAILABILITY

3.0 Resources (human, physical, financial) are appropriately planned for and available to meet the requirements of the patient population served.

3.1 The pulmonary function laboratory identifies, documents and communicates the resources required to deliver services:

3.1.1 Knowledgeable staff from the pulmonary function laboratory are involved in resource identification and documentation processes.

3.1.2 Appropriate information is used to determine resource needs.

3.1.3 Documentation identifying resource requirements is provided to the administration of the organization on an annual basis.

3.2 The administration of the organization has demonstrated commitment to supporting the activities of the pulmonary function laboratory:

3.2.1 The organization has processes for planning and resource allocation that are inclusive of the pulmonary function laboratory management.

3.2.2 Administration provides feedback to the pulmonary function laboratory indicating activities that are supported (approved) and not supported (non-approved).

3.2.3 The pulmonary function laboratory is provided with resources necessary to provide the scope of services approved.

3.2.4 There is demonstrated commitment to acquire technology necessary to implement approved pulmonary function laboratory plans.

3.2.5 Administration communicates and responds appropriately to changing needs and priorities.

3.2.6 Administration communicates and consults with the pulmonary function laboratory when new and/or expanded clinical services are planned to fully understand the impact to pulmonary function laboratory service provision.

3.3 The pulmonary function laboratory distributes and monitors resources:

3.3.1 Resources are distributed in alignment with operational plans and priorities.

3.3.2 Financial and/or statistical reports are available in a timely manner to monitor operating and capital budgets.

3.3.3 Action is taken to address variances.
UTILIZATION MANAGEMENT

4.0 The pulmonary function laboratory participates in utilization management activities.

4.1 The pulmonary function laboratory acts as a resource to facilitate the appropriate use of pulmonary function laboratory services:

4.1.1 ☐ Clinical indications for requesting studies are made available.

4.1.2 ☐ Medical staff provides advice on choice of study including follow-up examinations.

4.2 The pulmonary function laboratory medical staff provides consultation on scientific matters to the clinical staff:

4.2.1 ☐ Pulmonary function laboratory medical staff participates in clinical rounds enabling advice on effectiveness in general as well as in individual patient cases.

4.3 The pulmonary function laboratory service monitors and evaluates wait times:

4.3.1 ☐ There are processes to assess resource allocation and relationship to wait time.

4.3.2 ☐ There are processes to assess equipment utilization and relationship to wait time.
VALUES & ETHICS

5.0 The pulmonary function laboratory delivers services and makes decisions in accordance with its values and ethical principles.

5.1 The pulmonary function laboratory promotes an environment that fosters and requires ethical and legal behaviour:

5.1.1 There is a written code of ethics for business and professional behaviour.
5.1.2 Staff is aware of ethical issues related to services.
5.1.3 There is a process for investigating and addressing unethical or illegal behaviour.

5.2 Staff is aware of ethical and legal issues related to the use of clinical information, reports and tracings for research purposes:

5.2.1 There are clear and explicit policies for the use of patient data, reports and/or tracings.
5.2.2.0 Patient data, reports and/or tracings are only used when:
5.2.2.1 Patient consent has been obtained
5.2.2.2 Ethics Review Board approval has been received
5.2.3 There are policies and procedures in place to ensure the confidentiality of patient and research subject information when research is conducted in clinical space.
5.2.4 Research activities do not interfere with clinical care.
5.2.5 Policies and procedures related to patient and research subject information comply with privacy laws.
6.0 The pulmonary function laboratory maintains a work environment that contributes to the well-being, satisfaction and motivation of all staff.

6.1 Staff is involved in identifying and addressing issues related to well-being (health, safety and environmental concerns):
   6.1.1 Staff suggestions and ideas are encouraged and considered.
   6.1.2 Staff is involved in improvement initiatives.

6.2 There is a process for staff to bring forward concerns and complaints:
   6.2.1 Staff is aware of how to bring forward issues.
   6.2.2 The pulmonary function laboratory management responds to issues in a fair, objective and timely manner.

6.3 The pulmonary function laboratory assesses staff well-being, satisfaction and motivation:
   6.3.1 Assessment methods allow for anonymous participation by staff.
   6.3.2 Information is used for future improvement opportunities.

6.4 There are appropriate mechanisms in place to manage the impact of change:
   6.4.1.0 Change management processes include:
   6.4.1.1 Ensuring appropriate mechanisms for two-way communication are in place
   6.4.1.2 A system to support staff
   6.4.1.3 Involving staff in the implementation of changes, as appropriate
   6.4.2.0 Monitoring the impact of changes on service delivery:
   6.4.2.1 Measuring impact through pre and post indicator tracking
   6.4.3 Mitigating any loss to service level or quality.
RISK & DISCLOSURE

Definitions\(^1\):

*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.

*Disclosure* is understood as the imparting, by health-care workers to patients or their significant others, of information pertaining to any health-care event affecting (or liable to affect) the patient’s interests. The obligation to disclose is proportional to the degree of actual harm to the patient (or realistic threat of such) arising from an untoward event.

7.0 The pulmonary function laboratory manages adverse events and critical incidents.

7.1 The pulmonary function laboratory and/or organization has policies, procedures and practices for identifying and reporting adverse events and critical incidents:

7.1.1 Definitions of adverse event and critical incident applicable to pulmonary function are communicated throughout the pulmonary function laboratory.

7.1.2 Policies, procedures and practices for reporting adverse events and critical incidents are documented and available to all staff.

7.1.3 Staff knows whom to contact for advice or direction.

7.1.4 There is a defined process for reporting an adverse event or critical incident to the administration of the organization and to outside organizations, as applicable.

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

7.2 There is a process to determine and manage the medical significance of adverse events and critical incidents:

7.2.1 All reported adverse events and critical incidents are immediately assessed by appropriate technical and medical staff to determine medical significance.

7.2.2 The referring physician is informed in cases of medical significance.

7.2.3 Appropriate technical and medical staff assesses indications for halting further studies and withholding reports.

7.2.4 Appropriate technical and medical staff assesses indications for recalling already released reports.

7.2.5 There are procedures for reviewing already released reports.

7.3 The pulmonary function laboratory has a systematic process to investigate adverse events and critical incidents to determine multiple underlying contributing factors:

7.3.1 All adverse events and critical incidents are investigated appropriate to the magnitude of the problem and risk to patient and/or staff safety.
7.3.2 Processes for investigation are documented and available to all staff.
7.3.3 Staff is aware of their role during an investigation.
7.3.4 Staff knows whom to contact for advice or direction.

7.4 Recommendations resulting from investigations are implemented to decrease the likelihood of recurrence:

7.4.1 Changes made to the pulmonary function laboratory’s systems and processes to prevent recurrence are documented.
7.4.2 Recommendations and changes implemented are communicated to staff.

7.5 The pulmonary function laboratory management monitors changes implemented to ensure effectiveness:

7.5.1 Recommendations implemented are evaluated to ensure they are producing the intended effect.
7.5.2 The responsibility for authorization of the resumption of studies is defined.
7.5.3 Continuous evaluation and/or audit occurs if there is doubt related to compliance with policies and/or procedures being performed as documented.

7.6 The pulmonary function laboratory and/or organization has policies, procedures and practices for disclosing information to patients when an adverse event and/or critical incident has occurred:

7.6.1 Policies, procedures and practices are documented and available to all staff.
7.6.2 Staff is knowledgeable about disclosure practices and knows where to locate appropriate policy and procedure documentation.
7.6.3 Staff knows whom to contact for advice or direction.

7.7 Staff receive appropriate orientation and training related to risk management practices that includes:

7.7.1 Definitions of adverse events and critical incidents.
7.7.2 Reporting processes.
7.7.3 A process for determining medical significance.
7.7.4 Training to prevent or contain the effects of adverse events and critical incidents.
7.7.5 A process for disclosing information to patients.
INFORMATION MANAGEMENT

8.0 The pulmonary function laboratory uses information to make effective decisions.

8.1 The pulmonary function laboratory prioritizes and plans for its information needs by:

8.1.1 Identifying the clinical and management information required.
8.1.2 Identifying priority of current and future information needs.
8.1.3 Consulting with users.
8.1.4 Ensuring alignment with organization wide information management plans.
8.1.5 Communicating plans and priorities to the administration of the organization.
8.1.6 Securing adequate resources for implementation and sustainability.

8.2 The information management system used to support management decisions allows the pulmonary function laboratory service to:

8.2.1 Gather, link and combine data and information from multiple sources.
8.2.2 Assess and compare current data to historical data.
8.2.3 Determine costs associated with service delivery.
8.2.4 Manage resource utilization.
8.2.5 Exchange appropriate information with other organizations, as appropriate.
8.2.6 Monitor the collection of data and information to ensure data integrity.

8.3 Current and historical management data can be accessed by staff when needed:

8.3.1 Data can be accessed in a timely fashion.
8.3.2 Management reports are routinely generated.
8.3.3 Management can obtain custom designed management reports if necessary.

9.0 The pulmonary function laboratory protects the confidentiality, security and integrity of data and information.

9.1 Patient confidentiality and information is protected through policies and procedures:

9.1.1 Policies and procedures address protecting the confidentiality, security and integrity of patient data and information.
9.1.2 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.
9.1.3 Management regularly reviews policies and procedures with management, medical and technical staff.
9.1.4 Management routinely monitors compliance to policies and procedures.
9.2 The pulmonary function laboratory continually educates information users about:

9.2.1 Processes to ensure the confidentiality, security and integrity of data.
8.2.2 The release of patient information.
9.2.3 Legal responsibilities regarding confidentiality.
9.2.4 The possible consequences of breaching confidentiality.
9.2.5 The reporting, documentation and investigation of security incidents.

10.0 The pulmonary function laboratory has policies and procedures for storage, retention and disposal of clinical and management information.

10.1 The pulmonary function laboratory implements procedures for the appropriate handling of information that includes:

10.1.1 Identification
10.1.2 Collection
10.1.3 Indexing
10.1.4 Storage
10.1.5 Maintenance
10.1.6 Safe disposal

10.2 All documents and records are stored:

10.2.1 To ensure they are readily retrievable.
10.2.2 On an appropriate medium.
10.2.3 In a suitable environment that prevents damage, deterioration, loss or unauthorized access.

10.3 The pulmonary function laboratory has a retention policy that defines the length of time documents and records are to be retained. Retention times are identified for the following documents and records:

10.3.1 Request forms
10.3.2 Patient results and reports
10.3.3 Procedure protocols
10.3.4 Operational policies and procedures
10.3.5 Quality improvement records
10.3.6 Records of internal and external audits
10.3.7 Complaints and actions taken
10.3.8 Adverse event and/or critical incident reporting forms and records of investigation
10.3.9 Staff training and orientation records
10.3.10 Staff performance appraisals
10.3.11 Staff competency records
HUMAN RESOURCES PLANNING

11.0 The pulmonary function laboratory identifies current and future human resource requirements.

11.1 Human resource planning supports the pulmonary function laboratory’s goals and objectives and includes:

- Identifying age demographics of staff.
- Identifying adequate staffing numbers and required competencies.
- Anticipating and responding to changes in the environment.
- Anticipating and assessing the impact of technological change.
- Reviewing plans and revising as necessary.
- Ensuring resources are available to implement the plan.

11.2 The human resources planning process involves key staff and other health professionals who:

- Are knowledgeable about advances in service delivery and technology.
- Are able to determine the required competencies of staff.

11.3 An implemented human resources plan:

- Ensures adequate staff resources for the scope of services provided.
- Is monitored to determine if expected results have been achieved.
- Is revised as necessary.

11.4 Clinical training placements are:

- Included in the human resources plan.
- Resourced to ensure appropriate space, equipment and funding is available.
- Supported by the organization.
RECRUITMENT AND RETENTION OF QUALIFIED PEOPLE

12.0 The pulmonary function laboratory has qualified and competent staff to deliver services.

12.1 The pulmonary function laboratory selects and recruits staff based on:

12.1.1 Qualifications including active licensure and registration or certification with the appropriate provincial or nationally recognized regulatory and/or certification body.

12.1.2 Academic preparation.

12.1.3 Knowledge, skills and experience.

12.1.4 Reference checks.

12.2 Physicians interpreting routine spirometry:

12.2.1 M Have a medical license from the College of Physicians and Surgeons of BC

12.2.2 M Have been credentialed by the Diagnostic Accreditation Program of BC

12.3 Physicians interpreting Category III test:

12.3.1 M Have a medical license from the College of Physicians and Surgeons of BC

12.3.2 M Have specialty certification in respiratory medicine

12.3.3 M Have been credentialed by the Diagnostic Accreditation Program of BC

12.4 Respiratory therapists providing pulmonary function services:

12.4.1 M Are registered with the Canadian Society of Respiratory Therapists and the BC Society of Respiratory Therapists

12.4.2 M Have documented experience in pulmonary function testing and advanced certification as required.

12.4.3 M Have advanced training from a recognized school or a minimum of three (3) months in an accredited Category III pulmonary function laboratory if testing other than routine spirometry is undertaken by the pulmonary function laboratory.

12.4.4 M Have special age-specific training when pediatric testing is undertaken.

12.5 Nurses and other health care providers performing spirometry:

12.5.1 M Have documented experience satisfactory to the senior medical leader.

12.6 Staff work assignments are based upon:

12.6.1 M Accepted standards of practice.

12.6.2 M Qualifications including knowledge, skills and experience.

12.6.3 M Demonstrated competence.

12.6.4 M Volume and complexity of the workload.
12.7 The pulmonary function laboratory assigns non-licensed/non-registered/non-certified staff to appropriate work assignments:

12.7.1 There is a process to determine where non-licensed/non-registered/non-certified staff can work and the type of work they can perform.

12.7.2 The required demonstrated competencies for the work assignment have been documented.

12.7.3 Non-licensed/non-registered/non-certified staff are routinely monitored for competency and development plans are in place to ensure maintenance of competency.

12.8 The pulmonary function laboratory has strategies in place to retain qualified staff:

12.8.1 Contributions by staff are recognized.

12.8.2 Professional development is encouraged and supported.

12.8.3 Well being is promoted and enabled in the workplace.

12.8.4 Information gained through exit interviews is used to enhance retention strategies.

12.9 The pulmonary function laboratory management takes an active role in career progression and succession planning:

12.9.1 Career progression planning for interested staff is available.

12.9.2 Succession planning for leadership and management positions within the pulmonary function laboratory is effective.

12.9.3 Financial and/or other support is provided to encourage and allow continuing education where appropriate.
ROLES AND ACCOUNTABILITIES

13.0 The staff and management of the pulmonary function laboratory understand their roles and accountabilities.

13.1 Position and/or job descriptions exist for all staff and include:
13.1.1 ☐ Position and/or job summary.
13.1.2 ☐ Nature and scope of work.
13.1.3 ☐ Qualifications required.
13.1.4 ☐ Reporting relationships.

13.2 Position and/or job descriptions are regularly reviewed and revised to reflect:
13.2.1 ☐ Current practice.
13.2.2 ☐ Changing performance requirements, duties or qualifications.

13.3 Reporting relationships are clear and understood by staff:
13.3.1 ☐ There is an organizational chart.
13.3.2 ☐ Reporting relationships have been communicated to individual staff.

14.0 Staff records are complete, current and kept confidential.

14.1 Individual human resource records are kept for all staff and contain:
14.1.1 ☐ Evidence of qualifications including current licensure and certification or registration, if applicable.
14.1.2 ☐ Evidence of credentialing and granting of privileges, if applicable.
14.1.3 ☐ Evidence of education and training appropriate for the position.
14.1.4 ☐ Position and/or job description.
14.1.5 ☐ Immunization status at time employment commences.
14.1.6 ☐ Health reports as may be required by the organization's human resources policies.
14.1.7 ☐ Orientation, continuing education and in-service training records.
14.1.8 ☐ Performance evaluations.
14.1.9 ☐ Competency assessments.
14.1.10 ☐ Recruitment information including references.
14.1.11 ☐ Evidence of professional liability insurance coverage, if applicable.
14.1.12 ☐ Evidence of criminal records check if in contact with children.

14.2 Human resource records are maintained in a confidential manner:
14.2.1 ☐ Policy identifies who has access to the records and for what purpose.
14.2.2 ☐ Consent is obtained from the individual prior to release of information.
14.2.3 ☐ Records are disposed of appropriately and in accordance with legislation.
ENHANCING PERFORMANCE IN A LEARNING ENVIRONMENT

15.0 The pulmonary function laboratory provides orientation, training and continuing education for the safe provision of quality care.

15.1 Orientation is provided to all new staff that:

15.1.1.0 ✗ Provides initial training and information about the organization, pulmonary function laboratory and their position that includes:
   15.1.1.1 Mission, vision, values, goals and objectives
   15.1.1.2 Programs and services
   15.1.1.3 Roles and responsibilities of the individual and key staff
   15.1.1.4 Policies of the organization and pulmonary function laboratory and the responsibility for staff to comply
   15.1.1.5 Relevant policies and procedures related to performing the duties of the position
   15.1.1.6 Protecting patient confidentiality
   15.1.1.7 Quality improvement and risk management practices
   15.1.2.0 ✗ Provides training and information about safety that includes:
   15.1.2.1 Management of aggressive behaviour
   15.1.2.2 Violence and harassment in the workplace
   15.1.2.3 Sharps handling and disposal
   15.1.2.4 Fire safety
   15.1.2.5 Blood and body fluids management (standard precautions) including needle stick injury protocol and staff personal protective equipment
   15.1.2.6 Management of cardiac and respiratory arrest
   15.1.2.7 Musculo-skeletal injury prevention
   15.1.2.8 WHMIS and other local, provincial and federal requirements
   15.1.2.9 Emergency response codes
   15.1.2.10 Disaster response
   15.1.2.11 Transport of dangerous goods
   15.1.2.12 Fit testing

15.2 Orientation is provided to existing staff in response to:

15.2.1 ✗ Changing roles.
15.2.2 ✗ New technology.
15.2.3 ✗ New methods.
15.2.4 ✗ Competency demands.
15.2.5 ✗ New laws and regulations.

15.3 The pulmonary function laboratory encourages, supports and provides ongoing education, training and professional development to:

15.3.1 ✗ Maintain and upgrade knowledge and skills as required to meet the needs of the pulmonary function laboratory.
15.3.2 ✗ Encourage working as an integrated team.
15.3.3 ✗ Carry out quality improvement activities.
15.3.4 ✗ Provide services that are patient focused.
15.4 The pulmonary function laboratory monitors education and training to:
15.4.1 Determine if objectives have been achieved.
15.4.2 Determine the degree of application of knowledge.
15.4.3 Ensure sharing and dispersion of knowledge.
15.4.4 Identify improvement opportunities.

15.5 The pulmonary function laboratory has the staff to fulfill clinical teaching obligations:
15.5.1 Staff involved in clinical teaching understand their role and responsibilities.
15.5.2 Staff assigned to clinical teaching have the appropriate qualifications, as specified by the academic institution.

15.6 Participation in clinical teaching does not compromise patient care:
15.6.1 Students are supervised by experienced and qualified staff.
15.6.2 Service standards of the pulmonary function laboratory are maintained.

16.0 The pulmonary function laboratory has a staff performance management system to improve quality of service.

16.1 Individual staff members receive performance feedback:
16.1.1 There are opportunities to provide continuous feedback.
16.1.2 An annual performance appraisal is conducted:
16.1.2.0 Feedback is objective and interactive
16.1.2.2 Feedback results in the generation of a development plan
16.1.2.3 Development plans are monitored and revised as necessary

16.2 The competency of individual staff members is assessed:
16.2.1 New staff is assessed at the completion of a probationary and/or orientation period.
16.2.2 Existing staff are assessed when new methods and/or procedures are introduced.
16.2.3 Existing staff are assessed on current methods and/or procedures prior to performance appraisals.
17.0 The pulmonary function laboratory effectively manages relationships with pulmonary function laboratory medical professionals under contract.

17.1 The pulmonary function laboratory management maintains current and accurate records of the medical professionals providing services:

17.1.1 □ An accurate current list of all medical professionals associated with the pulmonary function laboratory is maintained.

17.1.2 □ There is evidence of current licensure of all medical professionals with the College of Physicians and Surgeons of British Columbia and the Diagnostic Accreditation Program of British Columbia.

17.2 There is a contract in place between the medical professional/group and the pulmonary function laboratory that specifies:

17.2.1 □ Services to be provided to the pulmonary function laboratory.

17.2.2 □ Names of the medical professional(s) providing the services.

17.2.3 □ Hours of service provision by the medical professional(s).

17.2.4 □ Location of where the medical professional(s) will be providing service.

17.2.5 □ Provision for on-call service during and outside regular operating hours.

17.2.6 □ Undertaking of continuing medical education on a yearly basis.

17.3 There is a designated individual(s) assigned to manage the contract between the medical professional/group and the pulmonary function laboratory:

17.3.1 □ To ensure an effective and quality service is provided.

17.3.2 □ To document any changes to the contract.

17.3.3 □ To resolve any concerns brought forward by either party.
18.0 The pulmonary function laboratory minimizes potential hazards and risks.

18.1 The pulmonary function laboratory has a safety program in place that includes documentation and staff education:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.1.1</td>
<td>A safety committee is in place, where appropriate (See Occupational Health and Safety [OH&amp;S] Regulations).</td>
</tr>
<tr>
<td>18.1.2</td>
<td>There is a mechanism to identify and resolve safety hazards.</td>
</tr>
<tr>
<td>18.1.3</td>
<td>Safety policies and procedures are readily available to staff.</td>
</tr>
<tr>
<td>18.1.4</td>
<td>Staff members are aware of and follow safety policies and procedures.</td>
</tr>
<tr>
<td>18.1.5</td>
<td>There are policies and procedures for reporting incidents and accidents.</td>
</tr>
<tr>
<td>18.1.6</td>
<td>There is a policy that protects staff working alone.</td>
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<tr>
<td>18.1.7</td>
<td>There are policies and procedures for the Management of Aggressive Behavior (MOAB).</td>
</tr>
<tr>
<td>18.1.8.0</td>
<td>There is compliance with Workplace Hazardous Materials Information System (WHMIS) regulations:</td>
</tr>
<tr>
<td>18.1.8.1</td>
<td>WHMIS information is readily available</td>
</tr>
<tr>
<td>18.1.8.2</td>
<td>Toxic and corrosive agents are labeled and stored in accordance with WHMIS regulations</td>
</tr>
<tr>
<td>18.1.8.3</td>
<td>Ongoing staff training of regulations is provided</td>
</tr>
<tr>
<td>18.1.9</td>
<td>An action plan for emergency evacuation has been developed and communicated to staff.</td>
</tr>
<tr>
<td>18.1.10</td>
<td>Staff members are familiar with the procedures to take in the event of a fire.</td>
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<tr>
<td>18.1.11</td>
<td>Appropriate fire extinguishing equipment is in place.</td>
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<tr>
<td>18.1.12</td>
<td>Fire drills are regularly conducted.</td>
</tr>
<tr>
<td>18.1.13</td>
<td>First aid resources are available for minor injuries and accidents.</td>
</tr>
<tr>
<td>18.1.14</td>
<td>Internal audits and safety inspections are regularly performed according to pulmonary function laboratory policies and provincial regulations (e.g. safety committees, biomedical engineers, etc.).</td>
</tr>
<tr>
<td>18.1.15</td>
<td>Records of internal audits and any corrective actions taken in response to findings are retained for three years.</td>
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<tr>
<td>18.1.16</td>
<td>Eyewash stations are conveniently located, where appropriate (See OH&amp;S regulations for the provision and location of eyewash stations).</td>
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<tr>
<td>18.1.17</td>
<td>Emergency lighting is available, where necessary.</td>
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<tr>
<td>18.1.18</td>
<td>Emergency call systems are available in patient areas.</td>
</tr>
<tr>
<td>18.1.19</td>
<td>Policies and alternative procedures are in place for patients and staff who have allergies or sensitivities.</td>
</tr>
<tr>
<td>18.1.20</td>
<td>Alternate, latex-free products are available, where appropriate.</td>
</tr>
<tr>
<td>18.1.21.0</td>
<td>Compressed gas cylinders are:</td>
</tr>
<tr>
<td>18.1.21.1</td>
<td>Stabilized appropriately</td>
</tr>
<tr>
<td>18.1.21.2</td>
<td>Stored appropriately</td>
</tr>
<tr>
<td>18.1.21.3</td>
<td>Clearly marked with contents</td>
</tr>
<tr>
<td>18.1.21.4</td>
<td>Moved according to transport guidelines</td>
</tr>
<tr>
<td>18.1.21.5</td>
<td>WHMIS information is readily available</td>
</tr>
<tr>
<td>18.1.21.6</td>
<td>Specialized gas contents are verified prior to use</td>
</tr>
<tr>
<td>18.1.22</td>
<td>Gas cylinder valves are closed when not in use</td>
</tr>
</tbody>
</table>
18.2  The pulmonary function laboratory has procedures in place and provides ongoing staff education to prevent and control infections:

18.2.0  □ There is access to resources and support systems to prevent and control infections including, but not limited to:

18.2.1  □ Adequate housekeeping services
18.2.2  □ Infection control practitioners
18.2.3  □ Standard precautions are practiced with every patient and staff members are protected from contact with blood and body fluids.
18.2.4  □ Appropriate infection control procedures are followed when dealing with patients with communicable diseases.
18.2.5  □ Sufficient, well-marked “clean” sinks and hand-cleansing materials are available.
18.2.6  □ Eating and drinking are not permitted in the pulmonary function laboratory.
18.2.7  □ Information on hand washing procedures and the appropriate use of gloves is provided.
18.2.8  □ Gloves are worn whenever there is a risk of contact to blood or body fluids.
18.2.9  □ There are policies and procedures for the prevention and follow-up of blood and body fluid exposure.
18.2.10  □ Personal protective equipment and supplies are available and used, as needed.
18.2.11  □ Safe and effective cleaning and disinfection of surfaces and other equipment takes place as needed.
18.2.12  □ Cleaning and disinfection of equipment considers best practices, manufacturer’s instructions and facility protocol.
18.2.13  □ There are policies and procedures for glassware and sharps control that includes:

18.2.14  □ Glassware and sharps are discarded in clearly marked puncture-resistant containers
18.2.15  □ Procedures are in place for sharps containers to be disposed of safely
18.2.16  □ Procedures are in place to handle puncture wound accidents
18.2.17  □ There is a policy in place that addresses the reuse of single-use devices (Intent: The reuse of single-use devices can affect their safety, performance and effectiveness and expose patients and staff to unnecessary risk.).
18.2.18  □ Vaccinations, TB skin testing and other preventative measures are available as needed.
18.2.19  □ Fit testing of N95 respirators is performed annually for appropriate staff (See OH&S Regulations).
18.2.20  □ Internal audits and safety inspections are performed according to departmental and facility policies.
18.3 Policies and procedures are in place to deal with patients diagnosed with, or suspected of, having serious infectious diseases such as TB, SARS, MRSA, etc.
18.3.1 Protocols are in place to help identify patient with or at risk of serious infections.
18.3.2 Patients are tested at the end of the day when possible to allow time for decontamination.
18.3.3 Patients are placed in a separate area if possible.
18.3.4 Patients are provided with surgical masks.
18.3.5 Patients are provided with tissues and instructions on coverage when coughing or sneezing.
18.3.6 There is an isolation protocol and reduced transportation.
18.3.7 Disposable flow sensors or in-line N99 filters are used when appropriate.
18.3.8 Test rooms have adequate ventilation.

18.4 Staff exposure to toxic substances such as methocholine are minimized:
18.4.1 Test room has adequate ventilation (at least 2 changes per hour).
18.4.2 Appropriate exhalation filters are used.
18.4.3 Fume hoods or other measures to reduce exposure are available.
18.4.4 The use of dosimeters is encouraged.
18.4.5 Therapists with known active asthma do not perform methacholine challenge testing unless appropriate measures are taken.
18.4.6 Repeated staff exposure to sensitizing agents is minimized.

18.5 The pulmonary function laboratory has policies and procedures in place to handle medical emergencies.
18.5.1 M Staff knows how to access medical services in the case of an emergency
18.5.2 M There are written policies in place for dealing with emergency procedures such as cardiopulmonary arrests.
18.5.3 M Medical and technical staff members are on-site and have appropriate training to deal with medical emergencies.
18.5.4 M Medical and technical staff members have current CPR certification to deal with medical emergencies.
18.5.5 Medical emergency equipment and supplies are readily available and include but are not limited to:
18.5.5.1 Stethoscope and Blood pressure cuffs
18.5.5.2 Oral airways (adult and pediatric)
18.5.5.3 Pocket mask
18.5.5.4 Appropriate syringes, tape and needles
18.5.5.5 Lorazepam
18.5.6 Medical and emergency equipment and supplies are monitored for availability, safety and security on a regular basis
18.5.6.1 Oxygen and suction equipment with the appropriate delivery devices and attachments are readily available.
APPROPRIATE PHYSICAL ENVIRONMENT

19.0 The design and layout of the pulmonary function laboratory’s physical space allows service delivery to be safe, efficient and accessible for patients, visitors and staff.

19.1 The design and layout of the pulmonary function laboratory’s physical space meets laws, regulations and codes:

19.1.1 Inspections by external authorities (e.g. Fire Marshall, WorkSafe BC, and Building Inspections) are performed.

19.1.2 M Records of inspections and any corrective actions taken in response to findings are retained for three years.

19.2 The location of the pulmonary function laboratory is accessible and appropriate to the patient population it serves:

19.2.1 Clear signage is in place to direct patients to the pulmonary function laboratory.

19.2.2 M Areas of restricted access are clearly indicated.

19.2.3 M Patients with special needs can access the location with ease.

19.3 The physical environment of the pulmonary function laboratory meets patient needs:

19.3.1 M Patient areas of the pulmonary function laboratory are safe, clean and private.

19.3.2 M There is space for family and other individuals supporting the patient.

19.3.3 M A secure and private location for changing clothing and for the temporary storage of personal items is available.

19.3.4 M Temperature, humidity, lighting, noise level and air quality are sufficient for patient comfort.

19.3.5 M Washrooms are clean, conveniently located and accessible.

19.3.6 M Wheelchair accessible washrooms are available.

19.3.7 M Furniture and equipment are adequate, consider ergonomics and are safe.

19.4 The design and layout of the space allows for patient privacy and confidentiality:

19.4.1 M Confidential or sensitive information is collected from and communicated to patients in an area that does not compromise their privacy.

19.4.2 M Patient information cannot be viewed by other patients or visitors.

19.4.3 M Telephone consultations involving the exchange of patient information are conducted in a private location so other patients and staff cannot overhear the discussions.

19.4.4 M Patient privacy is not compromised during the diagnostic study.
19.5 The physical environment of the pulmonary function laboratory meets the needs of staff and supports efficient workflow:

19.5.1 Work areas within the pulmonary function laboratory are clean, safe and ergonomically designed.

19.5.2 The design and layout are appropriate for the work performed.

19.5.3 A secure and private location for changing clothing and storage is available.

19.5.4 A separate and comfortable location to rest is available to staff during break times.

19.5.5 Temperature, humidity, lighting, noise levels and air quality are comfortable and appropriate for the work undertaken by staff.

19.5.6 Washrooms are conveniently located and separate from patient washrooms.

19.5.7 Communication systems within the pulmonary function laboratory are appropriate to the size and complexity of the facility and the efficient transfer of messages.
DISASTER AND EMERGENCY PREPAREDNESS

Disasters and emergencies include hazardous situations that may occur directly within the pulmonary function laboratory (internal), or situations that have occurred outside the pulmonary function laboratory (external). In the case of situations occurring outside the pulmonary function laboratory, the standards address the role the pulmonary function laboratory may have to assist other organizations or the community. Examples of hazardous situations may include fires, natural disasters, biochemical and bomb threats, chemical spills, radiation exposure and threats of personal violence.

20.0  The pulmonary function laboratory is prepared for internal and external disasters and emergencies.

20.1  The pulmonary function laboratory has a disaster and emergency preparedness plan that addresses a response to an INTERNAL emergency:

20.1.1  The role and capability of the pulmonary function laboratory during a disaster or emergency is identified.

20.1.2  The pulmonary function laboratory reviews disaster and emergency plans with all staff and they are aware of their roles and responsibilities in the event the plan is implemented.

20.1.3.0  The plan for response to disasters and emergencies includes, but is not limited to:

20.1.3.1  Access to first aid equipment
20.1.3.2  Alternate service sites, if needed
20.1.3.3  Alternate sources of supplies, utilities and communication
20.1.4  The pulmonary function laboratory has a disaster recovery plan.

20.2  The pulmonary function laboratory regularly reviews INTERNAL disaster and emergency response plans to ensure they are valid and updated:

20.2.1  The pulmonary function laboratory has tested its plan by monitoring the effectiveness of the practice drills of the department and/or the organization.

20.2.2  Changes to the plans, procedures and training methods are made, as necessary.

20.3  The pulmonary function laboratory has processes to prevent or minimize the impact of INTERNAL disaster due to non-biohazardous agents such as:

20.3.1  Fire
20.3.2  Flood
20.3.3  Loss of electrical power
20.3.4  Earthquakes
20.4 The pulmonary function laboratory is aware of and participates in organizational emergency preparedness planning that addresses responses to EXTERNAL community emergencies:

20.4.1 The organization has identified the potential risks of a disaster or emergency.
20.4.2 The role and capability of the pulmonary function laboratory during a disaster or emergency is identified.
20.4.3 The pulmonary function laboratory participates in organization-wide disaster and emergency preparedness planning.
20.4.4 The pulmonary function laboratory service plan addresses how to meet the diagnostic needs of mass casualties in the event of a community disaster.
20.4.5 The pulmonary function laboratory reviews disaster and emergency plans with all staff and they are aware of their roles and responsibilities in the event the plan is implemented.

20.4.6.0 The plan for response to disasters and emergencies includes, but is not limited to:

20.4.6.1 A staff recall system
20.4.6.2 Access to first aid equipment
20.4.6.3 Alternate service sites if needed
20.4.6.4 Alternate sources of supplies, utilities and communication

20.5 The pulmonary function laboratory regularly reviews disaster and emergency response plans that are in place for EXTERNAL community emergencies:

20.5.1 The pulmonary function laboratory has tested its plan by monitoring the effectiveness of the department and the organization’s practice drills and makes changes to plans, procedures and training methods if necessary.
20.5.2 Contact names and phone numbers on fan-out lists are current.
21.0 The pulmonary function laboratory seeks to understand and be responsive to the requirements of patients and clients.

21.1 The pulmonary function laboratory seeks to understand the requirements of patients and clients:

21.1.1 Patient and client groups are clearly identified and defined.
21.1.2 The pulmonary function laboratory identifies and defines patient and client requirements.
21.1.3 Information is obtained, analyzed and evaluated.

21.2 Planning takes patient and client requirements, expectations and preferences into consideration:

21.2.1 The goals and objectives of the pulmonary function laboratory are aligned with patient and client needs and expectations.
21.2.2 Future services are planned taking into consideration the requirements, expectations and preferences of patients and clients.

21.3 The pulmonary function laboratory is committed to the importance of meeting service standards and achieving patient and client satisfaction:

21.3.1 Service standards of the pulmonary function laboratory are defined and documented.
21.3.2 Service standards and expectations are communicated to pulmonary function laboratory staff and clients.
21.3.3 Processes are in place to manage planned and unplanned interruptions to service delivery.
21.3.4 Reports are provided in a manner that meets the needs of the clients.
21.3.5 Where appropriate, patients have access to the pulmonary function laboratory outside of regular hours of operation.
21.3.6 The pulmonary function laboratory has defined and established acceptable turnaround times for non-emergent and emergent results that meet client needs.
21.3.7 The pulmonary function laboratory monitors wait times.
21.3.8 There is a process for patient prioritization.
21.3.9 Achievement of service standards are routinely measured and monitored for improvement purposes.

21.4 There are methods and processes in place to enable patients and clients to seek information and obtain services:

21.4.1 Processes are in place for patients and clients to seek information about pulmonary function studies.
21.4.2 Information is readily available that informs patients and clients how to access the pulmonary function laboratory.
21.4.3 Knowledgeable staff is available to provide advice and consultation to patients and clients.
21.4.4 Processes are in place to allow patients to inform the pulmonary function laboratory of specific needs they may have (e.g. patient with physical disability, translator required, etc.).
22.0 The pulmonary function laboratory measures patient and client satisfaction to gain information for improvement.

22.1 The pulmonary function laboratory measures patient and client satisfaction using an approach that:

22.1.1 □ Is appropriate for the collection of feedback from each patient and client group.

22.1.2 □ Enables regular comparable measurement from one measurement cycle to the next.

22.1.3 □ Enables the collection of actionable information linked to specific processes within the pulmonary function laboratory.

22.2 The pulmonary function laboratory uses patient and client satisfaction results to improve service delivery:

22.2.1 □ Patient and client satisfaction data is analyzed.

22.2.2 □ Goals and priorities for improvement are set.

22.2.3 □ There is a process to identify significant feedback that requires specific action.

22.3 There is a process in place to gather and follow-up on patient and client complaints:

22.3.1 □ A receptive environment is provided for patients and clients to provide feedback.

22.3.2 □ Responses to patient and client enquiries and complaints are addressed promptly and effectively.

22.3.3 □ Resolution of complaints is documented.
23.0 The pulmonary function laboratory selects or actively participates in the selection of equipment and capital items through a fair, transparent and accountable process.

23.1 There is a defined process for the selection of equipment and other capital items that includes:

23.1.1 Identifying and documenting performance requirements and specifications.
23.1.2 Communicating performance requirements and specifications to those individuals involved in the purchasing/contracting process.
23.1.3 Active participation by the pulmonary function laboratory in decision-making when the equipment and/or item is critical to the operation of the pulmonary function laboratory.
23.1.4 Use of criteria to guide selection decisions.
23.1.5 Access to resources to ensure an appropriate selection process is implemented and maintained.
23.1.6 Disclosure of potential or real conflict of interest by individuals involved in the selection process.
23.1.7 Controlling and protecting documents and information related to the selection process and awarding of the contract.

23.2 Selection decisions for equipment and/or capital items are based upon criteria that consider:

23.2.1 The level and type of service provided by the pulmonary function laboratory.
23.2.2 Performance records of the equipment and/or capital item and vendor.
23.2.3 The knowledge and skills required by staff to use the equipment and/or capital item.
23.2.4 Well-being and best interest of the patient.
23.2.5 Potential risks or impacts to infection control, occupational health and safety and waste creation and disposal.
23.2.6 An analysis of cost and benefit.
23.2.7 Physical space limitations.
23.2.8 Ability to protect the privacy and security of patient information during equipment servicing.

23.3 The pulmonary function laboratory has processes to ensure equipment and/or capital items that could affect the quality of the studies are verified prior to use:

23.3.1 Equipment and/or capital items are inspected upon receipt by the pulmonary function laboratory.
23.3.2 The pulmonary function laboratory has procedures and criteria for inspection and acceptance or rejection of the equipment and/or capital item.
23.3.3 Verification that equipment and/or capital item received meets the performance requirements and specifications identified in the selection process.
23.3.4 There is a process for resolving non-compliance or quality issues with the vendor in a timely manner.
24.0 The pulmonary function laboratory selects or actively participates in the selection of consumable supplies through a fair, transparent and accountable process.

24.1 There is a defined process for the selection of consumable supplies that could affect the quality of the studies that includes:

- Identifying and documenting performance requirements and specifications.
- Communicating performance requirements and specifications to those individuals involved in the purchasing and/or contracting process.
- Active participation by the pulmonary function laboratory in decision-making when the consumable supplies are critical to the operation of the pulmonary function laboratory.
- Disclosure of potential or real conflict of interest by individuals involved in the selection process.
- Controlling and protecting documents and information related to the selection process and awarding of the contract.

24.2 The pulmonary function laboratory has processes to ensure consumable supplies that could affect the quality of the studies are verified prior to use:

- Consumable supplies are inspected upon receipt by the pulmonary function laboratory.
- The pulmonary function laboratory has procedures and criteria for inspection and acceptance or rejection of the consumable supplies.
- Verification that consumable supplies received meet the performance requirements and specifications identified in the selection process.
- There is a process for resolving non-compliance or quality issues with the vendor in a timely manner.

24.3 The pulmonary function laboratory has processes to regularly monitor and evaluate its suppliers and equipment vendors:

- A designated individual has responsibility for ensuring the process of monitoring and evaluating suppliers and equipment vendors takes place on a regular basis.
-反馈 is provided to suppliers and vendors based upon results of the monitoring and evaluation process.
25.0 The pulmonary function laboratory has a clearly defined and coordinated quality management program to continually monitor, evaluate and improve quality.

25.1 There is an established quality management program:

25.1.1 [ ] Leadership for the quality management program is described and assigned.

25.1.2 [ ] There is a quality improvement plan for the service that outlines priorities and targets.

25.1.3 [ ] Procedures are regularly assessed to identify any opportunities for improvement.

25.1.4 [ ] Progress with plan implementation is systematically measured and actions taken as required.

25.1.5 [ ] The quality management program is regularly reviewed and assessed against best practice.

25.2 The pulmonary function laboratory conducts internal quality assessments at regular time intervals

25.2.1 [ ] Technical and medical staff participates in facility education sessions, clinical rounds and/or continuing education programs.

25.2.2 [ ] Therapists are given feedback on the quality of studies.

25.2.3 [ ] Processes are in place to ensure the correlation of interpretations with other diagnostic examinations, pathology/surgical results and/or patient outcomes.

25.2.4 [ ] Documented, regularly scheduled facility meetings are held to discuss quality assurance.

25.2.5 [ ] Records pertaining to Quality Assurance are retained for three years.

25.3 Quality improvement initiatives are planned, implemented and evaluated:

25.3.1 [ ] Appropriate people (staff, stakeholders, clients) are involved in improvement initiatives and are assigned responsibilities.

25.3.2 [ ] Clear, measurable statements are developed explaining what is to be accomplished with each improvement initiative.

25.3.3 [ ] Plans for the improvement initiative are developed, documented and implemented.

25.3.4 [ ] Post-implementation, the improvement initiative is evaluated and further modified, if necessary.

25.3.5 [ ] Improvement activity that includes preventive action includes the application of controls to ensure effectiveness.

25.3.6 [ ] The results of improvement initiatives are documented and communicated to staff, stakeholders and clients.
25.4 The pulmonary function laboratory develops and defines a set of indicators to monitor and improve performance. These indicators:

- 25.4.1 Are used to identify current status and areas for improvement.
- 25.4.2 Have accepted definitions acknowledged by the pulmonary function laboratory community, provincial and/or federal governments.
- 25.4.3 Allow for internal and external comparison.
- 25.4.4 Are rate-based (indicator has a numerator and denominator) to allow for comparison.
- 25.4.5 Give direction to quality improvement activities.
- 25.4.6 Monitor the pulmonary function laboratory’s contribution to patient care, to the extent possible.

26.0 The pulmonary function laboratory management demonstrates commitment to the quality improvement system.

26.1 Management fosters and supports a quality improvement culture by:

- 26.1.1 Having direct involvement in improvement initiatives.
- 26.1.2 Developing structures and processes to discuss quality improvement.
- 26.1.3 Engaging staff in continuous quality improvement activities.
- 26.1.4 Promoting teamwork and open communication.
- 26.1.5 Sharing the responsibility, accountability and leadership for improvement throughout the pulmonary function laboratory.
- 26.1.6 Recognizing staff for their quality improvement activities.

26.2 Resources and training to support staff involved in quality improvement initiatives are provided through:

- 26.2.1 Access to information required to implement changes.
- 26.2.2 Access to additional resources (human, physical or financial resources) authorized by the management.
- 26.2.3 Ongoing continuous quality improvement training.
When developing pulmonary function laboratory policies, processes and protocols, it is useful to review the following resources for more information:

- American Thoracic Society/European Respiratory Society (ATS/ERS) Society Standards
- HS4-A2 Application of a Quality Management System Model for Respiratory Services (CLSI, 2006)
- WorkSafeBC Occupational Health and Safety Regulations
- C66-A2 Blood Gas and pH analysis and Related Measurements (CLSI 2009)

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ACCREDITATION STANDARDS
PULMONARY FUNCTION TESTING

27.0 **Procedure requests are standardized and ensure that accurate, comprehensive and appropriate information is clearly relayed.** (Requests include paper requisitions as well as electronic and verbal requests).

27.1 **Processes are in place to ensure the procedure request meets the needs of the laboratory, clients and patients.**

27.1.1 □ Request formats are standardized, unambiguous and easy to follow.

27.1.2 □ Request format is designed with input from users.

27.1.3 □ Guidelines for testing are communicated to users of the laboratory.

27.1.4 □ Guidelines for testing are reviewed and updated as appropriate.

27.1.5 **M** □ Procedures are only performed when ordered by authorized individuals as defined under relevant legislation.

27.1.6 **M** □ There is a process to deal with verbal requests.

27.2 **Procedure requests contain appropriate information.**

27.2.1.0 □ The request includes relevant clinical and other information including:

27.2.1.1 **M** □ unique identifiers (patient name, a personal identifier such as PHN or hospital number, birth date, gender).

27.2.1.2 □ request date.

27.2.1.3 **M** □ requesting/attending physician.

27.2.1.4 □ procedure requested.

27.2.1.5 **M** □ clinical indications for testing.

27.2.1.6 □ specific instructions or conditions of testing where applicable (e.g. reversible airflow obstruction-omit all bronchodilator).

27.2.1.7.0 □ Pertinent patient history/patient requirements including:

27.2.1.7.1 □ smoking history.

27.2.1.7.2 □ allergies.

27.2.1.7.3 □ special needs.

27.2.1.7.4 □ mobility issues.

27.2.1.7.5 □ current medications.

27.2.1.7.6 **M** □ infectious diseases if known (e.g. MRSA, TB, SARS).

27.2.1.7.7 □ surgery.

27.2.1.7.8 □ associated medical problems (e.g. CHF, MI, previous lung resection etc.).

27.2.1.7.9 □ translation requirements.

27.2.1.7.10 □ previous pulmonary function testing.

27.2.2 □ Additional copies (carbon copy, cc) when appropriate.

27.2.3 □ Procedure requests indicate urgency.

27.2.4 □ There is a process in place for clarification of unclear requests, requests that lack the necessary information or requests that contain errors.
27.3 Patient preparation instructions are clearly communicated to the patient prior to arriving at the pulmonary function laboratory. (Instructions commonly on the request form).

- **27.3.1** Patients and/or supporting individuals are advised of patient preparatory instructions prior to the procedure, where appropriate.
- **27.3.2** Patient instructions are available in a variety of languages considering the population served.
- **27.3.3.0** Patient instructions include where appropriate:
  - **27.3.3.1** avoiding alcohol within four hours of testing.
  - **27.3.3.2** avoiding vigorous exercise within 30 minutes of testing.
  - **27.3.3.3** avoiding clothing that substantially restricts full chest and abdominal expansion.
  - **27.3.3.4** avoiding a large meal within two hours of testing.
  - **27.3.3.5** smoking.
- **27.3.4.0** Patients are instructed to abstain from medications where appropriate:
  - **27.3.4.1** inhaled bronchodilators, short-acting: 4-8 hours.
  - **27.3.4.2** inhaled bronchodilators, long-acting: 24 hours.
  - **27.3.4.3** anticholinergics: 6 hours.
  - **27.3.4.4** oral short-acting bronchodilators: 8 hours.
  - **27.3.4.5** sustained release beta-agonists: 24 hours.
  - **27.3.4.6** theophylline, twice-daily preparations: 24 hours.
  - **27.3.4.7** theophylline, once-daily preparations: 24 hours.
- **27.3.5** There are processes to identify and work with patients who do not speak English.

28.0 Procedure manuals are current, accurate, controlled and available.

- **28.1** The pulmonary function laboratory uses documentation to ensure consistency.
  - **28.1.1** All procedures are documented and available to staff performing the procedure.
  - **28.1.2** Documents are reviewed and approved by the medical and technical leaders prior to issue.
  - **28.1.3** Procedures are consistent with the ATS/ERS standards and current literature.
  - **28.1.4** There is evidence of document review at regular intervals.
  - **28.1.5** A written protocol is available that documents the order of testing and important points to cover during testing.
  - **28.1.6** Procedures are performed as documented.
  - **28.1.7** Documentation follows a standardized template.
  - **28.1.8** If documentation is electronic, there are methods to provide procedure details in the event of an information system failure.
  - **28.1.9** There are processes to address the amendment of documents by hand.
  - **28.1.10** Procedural job-aides are dated and associated to the full procedure.
28.2 Procedure manuals contain all the relevant information necessary to perform
the procedure such as:

- 28.2.1 M title.
- 28.2.2 ☐ purpose or principle.
- 28.2.3 ☐ policy.
- 28.2.4 ☐ indications.
- 28.2.5 ☐ equipment and supplies.
- 28.2.6 ☐ patient preparation.
- 28.2.7 ☐ assessment of patients.
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- 28.2.12 ☐ method limitations.
- 28.2.13 ☐ procedure notes.
- 28.2.14 ☐ references.
- 28.2.15 ☐ appendices and examples.

29.0 Pulmonary function diagnostic equipment is operated, maintained and
monitored in a manner that ensures performance specifications are met.

29.1 Pulmonary function equipment is selected and put into operation according to
best practices.

- 29.1.1 M ☐ The pulmonary function laboratory uses equipment that meets current ATS/ERS
precision and accuracy criteria standards.
- 29.1.2 M ☐ Results of testing on equipment is verified with an appropriate number of controls
and compared with existing equipment if applicable.
- 29.1.3 M ☐ Equipment is CSA approved.
- 29.1.4 ☐ Acceptance testing of equipment is done upon installation of new equipment or
new software.
- 29.1.5 ☐ Equipment is used only as intended by the manufacturer.
- 29.1.6 ☐ Equipment manufactured for diagnostic testing is used for diagnostic purposes.
(Intent: Equipment designed for monitoring should not be used for diagnostic
purposes).
- 29.1.7 ☐ Pulmonary function equipment contains reference equations appropriate to the
targeted population.
- 29.1.8.0 ☐ Descriptions of equipment are listed in an equipment log including:
  - 29.1.8.1 ☐ model.
  - 29.1.8.2 ☐ type.
  - 29.1.8.3 ☐ age.
  - 29.1.8.4 ☐ software version.
  - 29.1.8.5 ☐ entry dates for equipment are recorded.
- 29.1.9 ☐ Equipment that is new, relocated or entering into service after repair, is
calibrated, validated, and verified as appropriate, before patient results are
reported.
29.2 Pulmonary function equipment is appropriately used, maintained, and monitored.

29.2.1 Equipment is given adequate time to warm up prior to testing (as per manufacturer's recommendations).
29.2.2 Specialized equipment and instrumentation are operated by competent staff with the necessary education, knowledge, skills and certification.

29.2.3 M Documented preventative maintenance, QC and calibration schedules exist.
29.2.4 Instructions for maintenance, QC, calibration and monitoring are readily available.
29.2.5 Maintenance is performed at regular intervals by appropriately trained staff.
29.2.6 QC, installation, service, repair, troubleshooting and maintenance records are readily accessible and retained for the lifetime of the equipment.
29.2.7 There is a process to address and resolve issues with equipment when biological and physical controls are outside acceptable limits.
29.2.8 When a problem is suspected, calculations are manually performed.
29.2.9 Pulmonary function equipment is evaluated regularly:
   29.2.9.1 quality of tracings/test results.
   29.2.9.2 age.
   29.2.9.3 safety parameters.
   29.2.9.4 software and equipment upgrades.
   29.2.9.5 electrical safety inspections are routinely performed by biomedical electronics.

29.3 Pulmonary function equipment and procedures are operated in suitable environments.

29.3.1 M Pulmonary diagnostic equipment is calibrated or verified for accuracy and precision. This information is documented and retained.
29.3.2 Appropriate environments for the optimal operation of equipment are defined and maintained.
29.3.3 Ambient temperature, barometric pressure and relative humidity are monitored.
29.3.4 There is a process for corrective action when ambient conditions fall outside of the recommended range.
29.3.5 Barometric readings are performed daily.
29.3.6 All calibration gases meet manufacturer's requirements.
29.3.7 Gas concentration is monitored where required.
29.3.8 Gas pressure is monitored where required.
29.3.9 Gas pressure is set according to manufacturer recommendations.
29.3.10 Negative air pressure is maintained and monitored where required.

29.3.11 M Internal temperatures of refrigerators storing testing agents or medications are monitored.

29.3.12.0 Calibration and other devices are regularly checked and records are maintained:
   29.3.12.1 syringes are validated annually.
   29.3.12.2 treadmill speeds and grades are calibrated every 3 to 6 months.
   29.3.12.3 ergometers are calibrated every 3 to 6 months.
29.3.13.0 Dedicated time is made available to perform QC procedures:
   29.3.13.1 linearity tests.
   29.3.13.2 inhalation challenge delivery devices.
   29.3.13.3 leak tests on syringes.

29.3.14 M Equipment is given adequate time to warm up prior to testing (as per manufacturer's recommendations).
30.0 Biologic controls are used to ensure Quality Control (QC) testing of pulmonary function equipment follows current ATS/ERS standards and best practice.

30.1 Appropriate QC is performed by biologic controls.

30.1.1 M QC policies and procedures for biologic controls are documented and maintained.

30.1.2.0 M A biologic control is used to assess and maintain the quality of testing.

30.1.2.1 Normal lung function (no asthma or other respiratory problems).

30.1.2.2 Multiple control subjects are regularly used.

30.1.2.3 Control subjects span a range of values (e.g. a 62" female and a 72" male).

30.1.2.4 Control testing uses the same protocols as applied to the patient population.

30.1.2.5 Control measurements meet all criteria for acceptability and repeatability.

30.1.2.6 Testing is performed at the same time of day to minimize diurnal variation.

30.1.2.7 If there are multiple pulmonary function systems, controls are tested on each instrument on the same day.

30.1.3.0 Biological controls are performed at intervals appropriate for the testing modality:

30.1.3.1 spirometry – weekly.

30.1.3.2 diffusing capacity – bi-weekly.

30.1.3.3 plethysmography – monthly.

30.1.3.4 helium dilution - initially and every 6 months.

30.1.3.5 software and hardware changes or upgrades.

30.1.4.0 Comparability of biologic control data between similar or identical instruments performing the same test is performed and verified at regularly defined intervals.

30.1.4.1 QC and patient data from all equipment and analyzers performing the same test are compared on a regular basis and inconsistencies are investigated.

30.1.5 Where analysis is performed using different methodologies, procedures or instruments, a defined procedure exists to verify comparability of methods throughout clinically appropriate intervals.

30.2 Biologic control data is managed to ensure the quality of the pulmonary function laboratory.

30.2.1 M QC data is recorded and charted in such a way that allows for review and the detection of trends and outliers.

30.2.2 QC results and worksheets are reviewed and verified.

30.2.3 When QC problems are identified, procedures are implemented to determine cause(s).

30.2.4 Roles and responsibilities for QC are well defined.

30.2.5 A hierarchy of QC review is established that includes appropriate staff from therapists to medical leaders.

30.2.6 Procedures are in place for the appropriate handling of patients while QC problems are investigated.

30.2.7 There is a process in place to address QC results that fall outside acceptable criteria.

30.2.8 M QC data is collected and submitted to the Diagnostic Accreditation Program of B.C. as required.
31.0 Solutions, medications and supplies are monitored and handled in a safe way that reduces or eliminates shortages and waste.

31.1 There is an inventory control system in place.
31.1.1 □ Inventory control practices ensure continuity of supply, eliminate shortages, and minimize overstocking and waste.
31.1.2 □ Inventory control problems and actions taken are documented.
31.1.3 □ Receipt and service entry dates of solutions, medications and supplies are recorded as necessary.
31.1.4 M □ Expired medications are promptly discarded.
31.1.5 M □ Solutions, medications and supplies are labeled, transported and stored appropriately.
31.1.6 M □ Policies and procedures address the disbursement or use of solutions and supplies that are recycled or out-dated.
31.1.7 M □ There are policies and procedures for the disposal of solutions, medications and supplies where appropriate.
31.1.8 □ There is appropriate and adequate training of staff performing disposal duties.

31.2 Bronchodilators are used in accordance with ATS/ERS standards and best practice.
31.2.1 □ There is a policy to administer a bronchodilator using standardized procedures and techniques.
31.2.2 □ There is a policy and procedure for repeated administration of a bronchodilator.
31.2.3 □ The bronchodilator, dosage and means of delivery are standardized.
31.2.4 □ Spirometry or plethysmography is performed prior to administering the bronchodilator.
31.2.5 □ A spacer is used in conjunction with a meter-dose inhaler (MDI).
31.2.6 □ Post-bronchodilator testing is not performed until 15 minutes after administration of the bronchodilator.
32.0 Pulmonary function patient preparation and testing is performed according to current ATS/ERS standards and best practices. (NB These criteria and descriptors apply to the specific testing listed in 33.0 - 41.0).

32.1 Procedure preparation is delivered in a manner that meets patient needs and test requirements.

- **32.1.1** M □ There is a process in place to ensure positive patient identification.
- **32.1.2** M □ Patient exclusion criteria have been established.
- **32.1.3** M □ Staff are aware of exclusion criteria.
- **32.1.4** □ Detailed patient histories are obtained when appropriate.
- **32.1.5** □ There are processes in place to ensure that patients have followed the preparation instructions.
- **32.1.6** □ Indications and contraindications for testing are documented and available to staff.
- **32.1.7** □ There are processes to deal with borderline contraindications.
- **32.1.8.0** □ Patients are assessed for contraindications for the procedure or other exclusion criteria:
  - 32.1.8.1 □ consuming alcohol.
  - 32.1.8.2 □ performing vigorous exercise.
  - 32.1.8.3 □ wearing clothing that substantially restricts full chest and abdominal expansion.
  - 32.1.8.4 □ eating a large meal.
  - 32.1.8.5 □ smoking.
  - 32.1.8.6 □ non-compliance in withholding medication.
- **32.1.9.0** □ Other factors that affect the test are documented and considered including:
  - 32.1.9.1 □ anemia.
  - 32.1.9.2 □ polycythemia.
  - 32.1.9.3 □ diurnal variation (if serial measurements are anticipated, the time of day is kept the same).
  - 32.1.9.4 □ claustrophobia.
  - 32.1.9.5 □ morbid obesity.
  - 32.1.9.6 □ heavy exercise prior to testing.
- **32.1.10** □ The patient’s physical and developmental status to undergo the diagnostic test is assessed to determine if special arrangements are required.
- **32.1.11** □ If postponement is necessary the ordering physician is contacted to determine if rescheduling is necessary.
- **32.1.12** □ If the ordering physician cannot be contacted, the laboratory medical leader or designate determines if testing should proceed.
- **32.1.13** □ There are processes that address instances when there is deviation from the protocol.
- **32.1.14** □ There are procedures to identify possible communicable diseases prior to the procedure.
- **32.1.15** □ The patient’s height and weight are determined and recorded.
- **32.1.16** □ There is a process to obtain height and weight when patients are unable to stand or when there is a spinal deformity.
- **32.1.17** □ Race is recorded and considered in the selection of reference values and interpretation of the results.
- **32.1.18** □ When appropriate, procedures are in place for patients receiving supplemental oxygen.
32.2 Testing is performed according to best practice.

32.2.1 M ☐ Staff performing test are aware of indications for immediately stopping test.
32.2.2 M ☐ The test is explained and demonstrated to the patient just prior to the procedure.
32.2.3 ☐ Patient positioning is assessed and corrected if necessary.
32.2.4 ☐ Nose clips are used and checked for correct positioning (excluding 6 minute walk testing).
32.2.5 M ☐ During the procedure the therapist appropriately coaches the patient.
32.2.6 ☐ Patients are monitored during testing where appropriate.
32.2.7 M ☐ The patient is observed during the procedure.
32.2.8 ☐ Time interval between repeated tests is in compliance with ATS/ERS standards.
32.2.9 ☐ Post-bronchodilation testing is not performed for 15 minutes after the bronchodilator is given.
32.2.10 ☐ Reversibility testing follows ATS/ERS standards.
32.2.11 ☐ Patients and or caregivers are given instructions on post-procedural care when warranted (e.g. after blood gases, methacholine and exercise testing).

33.0 Spirometry is performed according to current ATS/ERS standards and best practices.

33.1 Calibration of spirometry equipment follows current ATS/ERS standards and best practices.

33.1.1 ☐ Calibration syringes are maintained at the same temperature and humidity as spirometers.
33.1.2 ☐ Calibration or calibration verification is performed every day of patient testing.
33.1.3 ☐ Calibration checks on flow measuring devices include flow ranges between 0.5 and 12 L/sec.
33.1.4 ☐ Recalibration is performed if temperature changes 2°C or relative humidity changes 5%.
33.1.5.0 ☐ Calibration checks are repeated as appropriate:
33.1.5.1 ☐ when large numbers of patients are tested.
33.1.5.2 ☐ there is a change in environmental conditions.
33.1.5.3 ☐ a problem is suspected with equipment.
33.1.6 ☐ A log of calibration checks is maintained.
33.1.7 ☐ Calibration syringes are leak tested regularly, and volume is verified and recalibrated annually.
33.1.8 ☐ Calibration checks are performed when equipment is changed or relocated.
33.1.9 ☐ Calibration checks are performed with the filter in line, if filters are used during patient testing.
Pulmonary Function Testing

33.2  The performance of spirometry follows current ATS/ERS standards and best practices.

33.2.1  M  □ The test is explained and demonstrated to the subject prior to the procedure:
            □ correct posture with head slightly elevated.
            □ inhale rapidly and completely.
            □ position of the mouthpiece.
            □ exhale with maximal force.

33.2.2  □ Testing is done in a chair with arms and no wheels.

33.2.3  □ Nose clips are used and checked for correct positioning.

33.2.4  □ Inspiration is rapid and full.

33.2.5  □ Three acceptable FVC maneuvers are obtained.

33.2.6  □ After eight maneuvers a clinical judgment to stop or proceed is made, as per defined laboratory practice.

33.2.7  □ Acceptability and repeatability criteria are well-defined:
            □ 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.
            □ no coughing during the first second of an FVC maneuver.
            □ no glottis closure that influences the measurement.
            □ a plateau of one second is achieved with no change in volume in the volume-time spirogram and a duration of six seconds in the volume-time curve.
            □ a minimum of three acceptable full efforts are recorded with the two largest values (FVC, FEV1) agreeing within 150 mL.
            □ If FVC, FEV1 are less than 1L, then agreement is within 100mL.
33.3 The reporting of spirometry results follows current ATS/ERS standards and best practices.

33.3.1 All volumes and flows are reported at body temperature and pressure saturated with water vapor (BTPS) conditions.

33.3.2 The largest VC from at least two acceptable maneuvers is reported; the same value is used for lung volume calculations.

33.3.3 The largest FVC and largest FEV$_1$ from acceptable maneuvers are reported, even though the values may not come from the same maneuver.

33.3.4 The largest PEF obtained is reported.

33.3.5 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$_1$.

33.3.6 All inspiratory measurements (e.g., FIVC, PIF, and FIF$_{50}$) are the largest values obtained.

33.3.7 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$_1$.

33.3.8 Expiratory and inspiratory flow-volume curves from different acceptable efforts may be combined to produce a flow-volume loop. Laboratories are strongly encouraged to print (display) at least three acceptable maneuvers.

33.3.9 If reporting, the highest acceptable MVV (L/min) and MVV rate (breaths/min) are used.

33.3.10 Volume versus time tracings from at least two acceptable maneuvers are retained and available.

33.3.11 Therapist’s comments on patient effort and cooperation, and/or grading scores or codes regarding the acceptability and repeatability of the data are reported.

33.3.12 The instrument’s software version is reported.

33.3.13 Date, time, and results of most recent calibration are reported.

33.3.14 The reference values used are reported.
34.0 Lung volume testing is performed according to current ATS/ERS standards and best practices.

34.1 Equipment preparation and calibration for dilutional lung volume testing follows current ATS/ERS standards and best practices.

34.1.1 □ The system is checked daily to ensure it is leak-free.
34.1.2 □ Volume calibration (verification) is performed at least once each day testing is performed using a calibrated 3L syringe.
34.1.3 □ The accuracy validation limit for recovered volume is ±3.5% of the standard. (e.g. for a 3.0 L calibrated syringe, the recovered volume is between 2.9 L and 3.1 L).
34.1.4 □ Recalibration is performed if temperature changes 2°C or relative humidity changes 5%.
34.1.5.0 □ For a nitrogen washout system:
34.1.5.1 □ a 100% O₂ gas source is available for a 10 minute (minimum) test.
34.1.5.2 □ the demand valve allows adequate flow with minimal resistance.
34.1.5.3 □ a three point calibration is performed prior to each procedure on systems using a nitrogen washout method.
34.1.6.0 □ For a helium dilution system:
34.1.6.1 □ CO₂ and water (H₂O) absorbers are fresh (replace according to manufacturer’s recommendations) and placed in the proper order.
34.1.6.2 □ the fan (to mix and circulate gases) is operational.
34.1.7 □ Two-point (zero to full scale) calibration of the He analyzer is performed at least once each day prior to testing patients.
34.1.8 □ A lung analog (calibrated syringe or similar device) test is performed at least monthly on systems using the He dilution and N2 washout methods.
34.2 Measurement of dilutional lung volume testing follows current ATS/ERS standards and best practices.

34.2.1 There is a process to address patients with severe COPD factors undergoing multiple-breath dilution or washout methods.

34.2.2 The patient is seated upright. If another position is used, it is noted.

34.2.3 When appropriate, earplugs are provided for patients with perforated eardrums.

34.2.4 The facility has a process that dictates at what point during the procedure slow vital capacity maneuvers are performed.

34.2.5.0 For a nitrogen washout system:

34.2.5.1 if nitrogen washout is to be performed, the patient should not have supplemental O₂ for at least 15 minutes.

34.2.5.2 there are processes to deal with patients with very severe lung disease or hypoxemia when discontinuation of supplemental O₂ is contraindicated.

34.2.5.3 test completion is identified as a nitrogen concentration of less than 1.5% for three successive breaths.

34.2.5.4 if more than one nitrogen washout test is performed, then there is a 15 minute interval between tests

34.2.6.0 For a helium dilution system:

34.2.6.1 the fan (to mix and circulate gases) is operational.

34.2.6.2 only 1 FRC is performed in helium dilution. Note: only one acceptable FRC maneuver is required.

34.2.6.3 test completion is defined as a helium concentration within 0.02% for 30 seconds (helium dilution).

34.2.6.4 if more than one FRCₜₑₛ is performed then there is at least a 5 minute interval between tests, and the repeatability is within 10%. The 5 minute interval between tests may be extended if maldistribution of gas is present.

34.3 The reporting of dilutional lung volume testing follows current ATS/ERS standards and best practices.

34.3.1 The mean Functional Residual Capacity (FRC) is reported when multiple acceptable trials are performed.

34.3.2 The method for calculating and reporting TLC is defined.

34.3.3 The largest VC is reported.
34.4 Equipment preparation and calibration for lung volume testing by plethysmography follows current ATS/ERS standards and best practices.

34.4.1 Volume calibration (verification) is performed at least once each day testing is performed using a calibrated 3L syringe.

34.4.2 The accuracy validation limit for recovered volume is ±3.5% of the standard (e.g. for a 3.0 L calibrated syringe, the recovered volume is between 2.9 L and 3.1 L.)

34.4.3 Recalibration is performed if temperature changes 2° C or relative humidity changes 5%.

34.4.4 The mouth occlusion shutter has minimal resistance to opening and closing (i.e. the shutter does not stick).

34.4.5 Pressure transducers are correctly aligned.

34.4.6 The door seal is adequate.

34.4.7 An isothermal lung simulator is used at least monthly to verify volume accuracy for plethysmography methods.

34.4.8.0 Calibration of mouth pressure and box pressure transducers is performed:

34.4.8.1 once each day prior to testing patients.

34.4.8.2 every 4 hours during testing.

34.5 Measurement of lung volume testing by plethysmography follows current ATS/ERS standards and best practices.

34.5.1.0 There are processes to address factors that limit the patient’s access into the chamber:

34.5.1.1 claustrophobia.

34.5.1.2 upper body paralysis.

34.5.1.3 obtrusive casts.

34.5.1.4 other factors.

34.5.2 The patient is seated upright. If another position is used, it is noted.

34.5.3 Baseline and panting maneuvers are well defined.

34.5.4 The facility has a process that dictates at what point during the procedure slow vital capacity maneuvers are performed.

34.5.5 Staff edits VTG slopes as appropriate.

34.6 The reporting of lung volume testing by plethysmography follows current ATS/ERS standards and best practices.

34.6.1 The mean Functional Residual Capacity (FRC) is reported.

34.6.2 The mean FRC is reported if more than two tests are performed with results agreeing within 5% (Plethysmography).

34.6.3 The method for reporting IC, ERV and TLC is defined with linked methods preferred.

34.6.4 The largest VC is reported.

34.6.5 Therapist’s quality statements are used to clarify which method was used for reporting IC or ERV and the reasons for selecting the method (e.g., “Patient had difficulty providing consistent ERV values, but IC was highly repeatable”).
35.0 Diffusing capacity testing is performed according to current ATS/ERS standards and best practices.

35.1 Equipment preparation and calibration for Diffusing Capacity (DLCO) testing follows current ATS/ERS standards and best practices.

35.1.1 ☐ The cylinder(s) of test gas are appropriate for the testing system.
35.1.2 ☐ The system is checked to ensure it is leak-free daily.
35.1.3 ☐ Gas conditioning devices are changed as per manufacturer’s recommendations (i.e. gas chromatograph columns, permeable tubing, CO₂ and H₂O absorbers).
35.1.4 ☐ All devices maintain the required volume accuracy regardless of the gas mixture.
35.1.5 ☐ Linearity of analyzers is maintained and verified.
35.1.6 ☐ Non linearity of the analyzers does not exceed 0.5%.
35.1.7 ☐ A calibration check (verification) with a validated known-volume syringe (e.g. 3.0 L) is performed each day of testing. The accuracy validation limit for recovered volume is ±3.5%.
35.1.8 ☐ For large surveys or high patient loads this volume calibration check is done more frequently.
35.1.9 ☐ A two-point (zero and full scale) calibration of the gas analyzer(s) is done just prior to testing each patient.
35.1.10 ☐ Testing systems are checked with a DLCO simulator.
35.2 The measurement of diffusing capacity (DLCO) and results review follows current ATS/ERS standards and best practices.

35.2.1 The patient is asked if they have complied with preparation criteria and have:

- refrained from smoking on the day of testing.
- The time of the last cigarette smoked is recorded.
- A correction for CO back-pressure is made for recent or heavy smoking, as defined by laboratory procedures.

35.2.2 The patient is refrained from heavy exercise immediately prior to testing.

35.2.3 The patient is refrained from eating a large meal at least 2 hours prior to testing.

35.2.4 The patient is refrained from drinking alcohol for 4 hours prior to testing.

35.2.5 Mouthpiece, nose clip, carbon dioxide (CO₂) and water absorbers, and other miscellaneous supplies (e.g., tissues, chart paper) are available as needed.

35.2.6 Infection control supplies: disposable in-line filters (if used), gloves, gowns, masks, and protective eye wear (if applicable) are available as needed.

35.2.7 Testing is done in the sitting position, with the patient sitting quietly for a minimum of 5 minutes before testing.

35.2.8 No supplemental oxygen is given for 10 minutes preceding the test if possible.

35.2.9 There are mechanisms to recognize patients with mental confusion or poor muscular coordination that prevent the patient from adequately performing the maneuver or the inability to adequately seal their lips on the instrument mouthpiece.

35.2.10 Acceptability criteria for individual test maneuvers are defined:

- inspired volume of test gas is at least 85% of the largest VC in less than 3 seconds.
- The breath time hold (Jones-Mead technique) is 8-12 seconds.
- No evidence of leaks or Valsalva or Mueller maneuvers during breath hold.
- Expiration after breath hold in less than 4 seconds with appropriate clearance of dead space before sampling the alveolar gas.
- The washout volume of anatomical and mechanical dead space is 0.75 to 1.0 L before the alveolar sample is collected.

35.2.11 There are at least 4 minutes between maneuvers.

35.2.12 There are two acceptable maneuvers that agree within 3 mL CO/min/mmHg or within 10% of the highest value.

35.2.13 No more than 5 maneuvers are performed.

35.2.14 Significant discrepancies are recorded:

- when inspired volume is less than 85% vital capacity.
- when alveolar volume is greater than total lung capacity.
35.3 The reporting of DLCO testing follows current ATS/ERS standards and best practices.

35.3.1 The average of at least two acceptable maneuvers that meet the repeatability requirement are reported.

35.3.2 The report includes:
- measured, uncorrected DLCO.
- predicted DLCO.
- percent predicted DLCO.
- DLCO/VA (also known as KCO).
- VA and IVC.

35.3.3 Any adjustments (e.g., Hb, COHb, PO2) are reported separately along with the data used to make the adjustment.

35.3.4 There is a procedure for adjustment of sampling windows in real time analyzers.

35.3.5 The reason for adjusting the sampling window is documented.

36.0 Maximum respiratory pressure testing is performed according to current ATS/ERS standards and best practices.

36.1 Maximum Respiratory Pressures testing and results review follows current ATS/ERS standards and best practices.

36.1.1 PEmax is measured at or near total lung capacity (TLC).

36.1.2 Plmax is measured near residual volume (RV).

36.2 The reporting of Maximum Respiratory Pressure testing follows current ATS/ERS standards and best practices.

36.2.1 The most negative Plmax in cmH20 that can be sustained for 1.0 to 1.5 seconds is reported.

36.2.2 The most positive PEmax in cmH20 that can be sustained for 1.0 to 1.5 seconds is reported.

36.2.3 The number of efforts, degree of repeatability, percent of predicted, and lower limit of normal are reported.

36.2.4 Pressures are presented as percent of predicted TLC at which they were measured to adjust for differences in body size and varied levels of lung capacity, caused by disease states.
37.0 Six minute walk testing is performed according to current ATS/ERS standards and best practices.

37.1 Six minute walk testing follows current ATS/ERS standards and best practices.

- The test is performed indoors, along a flat, long, straight, corridor with a hard surface with little traffic.
- The walking course is approximately 30 meters (100 feet) in length.
- The course is marked with visible markers (e.g., traffic cones).
- A starting line, which marks the beginning and end of each 60 metre lap, is marked on the floor.
- Incremental distance markers are used (e.g., every 10 metres) to help measure the distance walked.
- A stopwatch is used to time the test.
- A mechanical counter is used to count laps.
- Blood pressure, heart rate and Borg dyspnea scale results are recorded prior to the test.
- Procedures are explained and/or demonstrated to patients.
- Patients use their usual walking aids during the test (cane, walker etc.).
- Procedural sources of variability are controlled as much as possible, (including the use of standard phrases).
- Patients wear loose-fitting, comfortable clothing and shoes suitable for exercise.
- The results from a resting ECG done during the previous 6 months is reviewed.
- Continuation of patient medications is addressed.
- Patients with stable, exertional angina will perform the test with anti-angina medication.
- Supplemental oxygen is continued unless otherwise indicated.
- Staff has appropriate training to support the patient: (Basic Life Support - minimum, ACLS preferred).
- There is a process in place to remove supplemental oxygen if indicated.
- Testing is performed in a location where a rapid emergency response is possible.
- A telephone or other means is available to call for help.
- A medical doctor with a rapid response time is available on-site.
- Procedures and equipment are available to deal with acute adverse events.

37.2 The reporting of six minute walk testing follows current ATS/ERS standards and best practices.

- Reports contain the following:
  - the total distance walked.
  - oxygen use if applicable.
  - litre flow (e.g. continuous or pushed).
  - delivery device (e.g. nasal cannula, oxygen pendant).
  - mode of transport (e.g. carried or pushed/pulled).
  - Borg scale.
- reason for early termination if applicable.
38.0 Methacholine bronchoprovocation testing is performed according to current ATS/ERS standards and best practices.

38.1 Equipment preparation and calibration for methacholine bronchoprovocation testing follows current ATS/ERS standards and best practices.

38.1.1 Methacholine is stored at 4º - 8º C and warmed to room temperature prior to patient use.

38.1.2 The nebulizer and compressed gas systems are checked to ensure they are working properly.

38.1.3 The pulmonary function testing system is calibrated each day of use and before the challenge.

38.1.4 The testing area is large enough to accommodate equipment, personnel and emergencies.

38.1.5 The testing room has adequate ventilation (i.e., at least two air exchanges/hour).

38.1.6 Exhalation filters are used on nebulizers to minimize the chance that the therapist will be exposed to the methacholine aerosol.

38.1.7.0 Procedures, medications and equipment are available to deal with acute adverse events including:

38.1.7.1 M ☐ oxygen and appropriate delivery devices, a stethoscope, a sphygmomanometer and a pulse oximeter.

38.1.7.2 M ☐ medications to treat an acute bronchospasm attack including epinephrine for subcutaneous injection, and albuterol and ipratropium bromide in either metered dose inhaler and/or premixed solutions.

38.1.8 M ☐ a medical doctor experienced in acute bronchospasm reversibility on-site.
38.2 Methacholine bronchoprovocation challenge testing follows current ATS/ERS standards and best practices.

38.2.1.0 The laboratory has established criteria for withholding medications from patients:

38.2.1.1 short-acting inhaled bronchodilators (e.g., albuterol): 8 hours.
38.2.1.2 long-acting inhaled bronchodilators (e.g., salmeterol): 48 hours.
38.2.1.3 anticholinergics: 24 hours, or as defined by the laboratory.
38.2.1.4 cromolyn sodium: 8 hours.
38.2.1.5 nedocromil: 48 hours.
38.2.1.6 liquid theophylline: 12 hours.
38.2.1.7 intermediate-acting theophylline: 24 hours.
38.2.1.8 long-acting theophylline: 48 hours.
38.2.1.9 leukotriene modifiers: 24 hours.
38.2.1.10 corticosteroids: Not usually withheld, or withheld only on day of test.
38.2.1.11 antihistamines: Not usually withheld for methacholine challenge.

38.2.2 Patients are given instructions as to which medications/items to avoid prior to testing.

38.2.3 A screening spirometry test with pre and post bronchodilator maneuvers is performed prior to a methacholine challenge test.

38.2.4 Procedures are explained to patients and consent forms are obtained.

38.2.5 Therapists are familiar with safety and emergency procedures.

38.2.6 Aerosolized methacholine exposure is minimized when staff have asthma or symptoms suggestive of hyper-reactive airways.

38.2.7 Therapists who perform methacholine challenges have a negative methacholine challenge at entry.

38.2.8 Dosing protocols are in compliance with ATS/ERS standards.

38.2.9 Signs and symptoms of acute bronchospasm are recorded.

38.2.10 The time interval between methacholine doses does not exceed five minutes.

38.2.11 Criteria are clearly defined for the end of a methacholine challenge test.

38.2.12 A bronchodilator is administered (if applicable) and post-bronchodilator spirometry performed, and FEV₁ at least 90% of baseline.

38.2.13 Patients are not released until post-test values are within 10% of pre-test values.

38.2.14.0 When shortening the test procedure, a two-fold increase in methacholine dose is used for the following patients:

38.2.14.1 a child.
38.2.14.2 a patient known to have moderate to severe asthma.
38.2.14.3 a patient with airflow obstruction on baseline spirometry.
38.2.14.4 in patients where the FEV₁ fell by more than 10% after the previous methacholine dose.

38.2.15 The laboratory has a defined quality assurance process in place for methacholine dosing, dilution, and labeling of specific concentration containers.
38.3 The test results review and reporting of methacholine bronchoprovocation testing follows current ATS/ERS standards and best practices.

38.3.1 Assure acceptable and repeatable spirometry data at baseline and/or control (post-diluent) stages.
38.3.2.0 Assure at least two acceptable spirometry trials are performed at each stage.
38.3.2.1 Repeatability of FEV₁ (i.e., two highest within 150 mL) if possible.
38.3.3 Data is expressed as a percent of baseline or the post-diluent value.
38.3.4 If more than one diluent stage is used, the percent change is calculated from the final post-diluent stage.
38.3.5 Data is presented for each step in the protocol, including bronchodilator reversal.
38.3.6 The FVC, FEV₁, and FEV₁/FVC ratio (if complete FVC maneuvers were performed) are reported for spirometry.
38.3.7 The specific conductance (sGaw) or specific resistance (sRaw) is reported for plethysmography measurements.
38.3.8 The dose is expressed as mg/mL concentration of inhaled methacholine.
38.3.9 Graphic and tabular displays showing percent change and absolute values are presented in the report.
38.3.10 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.
38.3.11 The concentration that caused a 20% fall in FEV₁ (PC₂₀) in mg/mL is reported.
38.3.12 If sGaw or sRaw is measured, the concentration that causes a 40% fall in sGaw or a 40% rise in sRaw is reported.
39.0 Exercise-induced bronchospasm testing is performed according to current ATS/ERS standards and best practices.

39.1 Equipment used for exercise-induced bronchospasm testing follows current ATS/ERS standards and best practices.

- □ Treadmills are in compliance with ATS/ERS standards.
- □ Speed range 0 to 8 mph.
- □ Grade range 0 to 20%.
- □ Emergency stop button.
- □ Padded hand rails (front and sides).
- □ ECG system meets American Heart Association specifications:
  - □ continuous oscilloscopic monitoring of a minimum of three leads.
  - □ 12-lead printed-copy capacity.
- □ The testing area is large enough to accommodate equipment, personnel and emergencies.
- □ O₂ and appropriate O₂ delivery devices, a stethoscope and sphygmomanometer to auscultate the chest and to measure blood pressure, and a pulse oximeter to ensure adequate O₂ delivery are readily available.

M □ A medical doctor experienced in acute bronchospasm reversibility is present on-site.

M □ Procedures, medications and equipment are available to deal with acute adverse events:
  - □ airway management equipment.
  - □ defibrillator.
  - □ suction.
  - □ emergency medications (e.g. epinephrine and lidocaine).
  - □ bronchodilators.
  - □ oxygen equipment and delivery systems.
  - □ airway management equipment.

M □ The resuscitation cart is checked regularly:
  - □ an inventory checklist accompanies the cart.
  - □ the cart is checked daily or weekly (according to institution policy) for missing or outdated medications.

M □ the operation of airway-management equipment is checked.

M □ Staff performing testing are able to recognize basic ECG arrhythmias.

M □ Staff performing testing are trained in advanced cardiac life support and certified to perform CPR.

M □ The absolute water content of the inspired air is below 10 mg/L or relative humidity (RH) less than 50% between 20° and 25° C when appropriate.

M □ A dry gas source (e.g., compressed air cylinder) with reservoir bag, valves and tubing, or demand valve is used if not using room air.

M □ A cold-air generating device is used when the patient’s complaints specifically relate to symptoms by cold air inhalation when appropriate.
39.2 Exercise-induced bronchospasm testing follows best current ATS/ERS standards and best practices.

39.2.1 □ Patients are evaluated for their ability to perform exercise-induced bronchospasm testing.

39.2.2 □ The patient’s medical history is reviewed by a trained physician.

39.2.3 □ Past ECGs are obtained and reviewed when available.

39.2.4 □ ECG monitoring is used when appropriate.

39.2.5 □ Procedures are explained to patients and consent forms are obtained as appropriate.

39.2.6 □ Equations to predict the maximum heart rate are documented.

39.2.7 □ The patient exercises at a moderate to heavy intensity level for approximately 6 to 8 minutes.

39.2.8 □ Two or three acceptable spirometry tests are obtained at each testing interval.

39.2.9 □ If EIB is documented by pulmonary function testing, a bronchodilator is administered as needed.

39.2.10 □ The indications for stopping an exercise test are documented.

39.2.11 □ M □ Patient release criteria have been developed (i.e. when the patient can be released from the pulmonary function laboratory).

39.3 The reporting of exercise-induced bronchospasm testing results follows current ATS/ERS standards and best practices.

39.3.1.0 □ The reported results of exercise induced bronchospasm testing include:

39.3.1.1 □ pre-exercise value.

39.3.1.2 □ M □ the lowest repeatable post-exercise value.

39.3.1.3 □ M □ the percent change.

39.3.1.4 □ FVC expressed in L (BTSP).

39.3.1.5 □ FEV1 expressed in L (BTSP).

39.3.1.6 □ PEFR expressed in L/s (BTSP).

39.3.1.7 □ raw recorded in cmH₂O/L/sec.

39.3.2.0 □ Variables that need to be recorded include:

39.3.2.1 □ the type of exercise device.

39.3.2.2 □ sustained work rate.

39.3.2.3 □ total exercise time.

39.3.2.4 □ maximum heart rate and length of time at target heart rate.

39.3.2.5 □ interpretation of the ECG.

39.3.2.6 □ oxygen saturation via pulse oximetry, if measured.

39.3.2.7.0 □ environmental factors including:

39.3.2.7.1 □ room temperature.

39.3.2.7.2 □ relative humidity.

39.3.2.7.3 □ barometric pressure.

39.3.2.8.0 □ additional provocations if applicable:

39.3.2.8.1 □ dry air.

39.3.2.8.2 □ cold air.

39.3.2.8.3 □ delivery method.

39.3.3 □ clinical signs and symptoms.

39.3.4.0 □ bronchodilators or other medications administered if applicable:

39.3.4.1 □ spirometry data from post-bronchodilator stage.
40.0 Conductance/resistance testing by body plethysmography is performed according to current ATS/ERS standards and best practices.

40.1 Equipment used for conductance/resistance testing by body plethysmograph, follows current ATS/ERS standards and best practices.

40.1.1 Pressure, volume, or flow-type plethysmographs are used.

40.1.2 Transducers in the plethysmograph meet the following specifications:

- mouth pressure: ± 20 to 50 cmH₂O
- box pressure: ± 2 cmH₂O (with a 500 L box)
- flow: < 2 L/s
- the pressure transducer tubing is connected in proper sequence according to manufacturer recommendation.

40.1.3 The door seal of the plethysmograph is checked to ensure it is leak free each day of use.

40.1.4 The mouth shutter closing speed and ease of activation, closure and release is checked.

40.1.5 Calibration of the volume, flow and pressure measuring components is performed at least once each day before testing patients and every 4 hours during use.

40.1.6.0 Volume measuring-device calibration is performed daily with a 3.0 L syringe.

40.1.6.1 The accuracy limit for recovered volume is ±3.5% of the syringe.
40.2 Conductance/resistance by body plethysmograph testing follows current ATS/ERS standards and best practices.

40.2.1.0 The patient is asked if they have complied with preparation criteria:
- retrained from smoking for at least one hour prior to testing.
- the time of the last cigarette smoked is recorded.
- retrained from heavy exercise for one hour prior to testing.
- retrained from eating a large meal at least one hour prior to testing.
- supplemental oxygen and intravenous infusions are discontinued before entering the plethysmograph when possible.

40.2.2 Bronchodilators are avoided prior to testing if pre- and post-bronchodilator testing is to be performed.

40.2.3 The patient pants small and uniformly between 1.5 - 2.0 breaths per second.

40.2.4 Open shutter loops are closed or nearly closed and linear.

40.2.5 The entire tracing is visible and within the calibrated pressure range.

40.2.6 Once two to three acceptable open-shutter loops have been collected, close the mouth shutter and instruct the patient to continue panting.

40.2.7 The displayed Pao/Pbox loop is closed or nearly so.

40.2.8 Acceptable pressure changes are within the calibrated pressure range of each transducer.

40.2.9 The entire tracing is visible.

40.2.10 During closed-shutter loop data collection, the shutter is closed for only a brief period of time and generally at least 2 to 3 breaths should be collected.

40.2.11 The mouth shutter is opened and the patient is instructed to return to normal breathing.

40.2.12 If serial measurements are to be performed, the panting frequency is kept the same to aid in the interpretation.

40.3 The reporting of Conductance/Resistance by body plethysmograph testing results follows current ATS/ERS standards and best practices.

40.3.1.0 Each maneuver is visually inspected to ensure:
- it meets acceptability criteria.
- there was no evidence of thermal drift.
- the panting frequencies were similar.
- angles adjustments are reviewed and consistent.

40.3.2.0 The raw and related indices are calculated appropriately:
- from the ratio of open- and closed shutter tangents for each maneuver.
- are averaged from 3 - 5 separate, acceptable maneuvers.
- have an open shutter tangent measured between +0.5 to -0.5 L/s.

40.3.3 Report of test results should contain a therapist’s statement about test quality, patients’ understanding of testing process, and, if appropriate, which criteria were not achieved.
41.0  Arterial blood gas analysis is performed according to current ATS/ERS standards and best practices.

41.1  Samples for blood gas analysis are collected and handled according to ATS/ERS standards and best practice.

41.1.1  ☐ Staff performing arterial punctures are aware of procedure dangers and precautions to minimize hazards to the patient.

41.1.2  ☐ There is a policy that defines the qualifications, training and competency assessment for staff collecting arterial punctures.

41.1.3  ☐ Appropriate collection material is available.

41.1.4  ☐ Patient identification is confirmed by the collector using a minimum of two identifiers prior to collection of the sample.

41.1.5.0  ☐ Acceptable identifiers are defined and listed and at a minimum include:

41.1.5.1  ☐ first and last name.

41.1.5.2  ☐ identification number.

41.1.6  ☐ The patient is examined for the presence of a radial artery occlusion prior to arterial puncture using a modified Allen’s test.

41.1.7  ☐ Routine precautions are used in the collection of blood.

41.1.8  ☐ Unaltered gloves are worn during phlebotomy.

41.1.9  ☐ Safety engineered needles are used during the arterial puncture.

41.1.10  ☐ Site selection for arterial puncture is appropriate.

41.1.11  ☐ The puncture site is properly cleaned.

41.1.12  ☐ Appropriate precautions are taken to prevent post-arterial puncture bleeding.

41.1.13  ☐ Special instructions are available for patients on blood thinners.

41.1.14  ☐ There is a process that addresses instances when arterial puncture is difficult.

41.1.15  ☐ Blood samples are labeled immediately after the collection process in the presence of the patient by staff collecting the sample.

41.1.16  ☐ Samples are labeled during the collection process in a manner that connects the patient to that sample (Intent: It may not always be possible to label a sample in the presence of the patient or other types of samples may be collected by non-laboratory staff).

41.1.17  ☐ The identity of the staff member collecting the sample is recorded.

41.1.18  ☐ The date and time the sample is collected is recorded in the information system or on the sample label.

41.1.19  ☐ Sample collection devices are disposed of in an appropriate and safe manner.

41.1.20  ☐ The sample is analyzed promptly (within 30 minutes) or precautions are taken to maintain the PaCO₂ and PaO₂ levels.
41.2  Appropriate QC and proficiency testing is performed for arterial blood gas analysis

41.2.0  Internal QC is performed for blood gas analysis including:
41.2.1  the mean and standard deviation for each constituent (pH, PCO₂, PO₂) is established for each new lot of QC material.
41.2.2  QC policies and procedures are documented and maintained.
41.2.3  QC results are reviewed and verified at regular intervals to detect trends and outliers.
41.2.4  when QC problems are identified, procedures are implemented to determine cause(s).
41.2.5  QC data is summarized monthly.
41.2.6  the medial leader establishes the acceptable range for QC.
41.2.7  QC material is analyzed every eight hours or on day of testing.
41.2.8  QC records are maintained for a minimum of two years.
41.2.9  QC material characteristics are similar to patient samples, where possible.
41.2.10  procedures are in place for the appropriate handling of patient samples while QC problems are investigated.
41.2.20  Proficiency testing (PT) is performed as appropriate:
41.2.21  the laboratory participates in the appropriate mandatory PT programs.
41.2.22  PT samples are handled in the same manner as patient samples.
41.2.23  PT results are regularly monitored by the medical leader or designate.
41.2.24  unacceptable results are investigated.
41.2.25  preferential conditions for PT are avoided.
41.2.30  If other analytes are reported out (e.g. ionized calcium, electrolytes) appropriate QC and PT is performed for those analyses.
41.2.31  A record of corrective action is maintained and filed with the Diagnostic Accreditation Program of B.C., if appropriate.

Internal QC is performed for hemoximetry/co-oximetry including:

41.2.4.1  The mean and standard deviation for each constituent (tHb, COHb, MetHb) is established for each new lot of QC material.
41.2.4.2  An adequate number of samples (e.g. 20) of each level of the new lot number is analyzed.
41.2.4.3  The values for each constituent at each level are statistically analyzed for mean and SD.
41.2.4.4  The acceptable range for each constituent is defined, ensuring it is consistent with the clinical needs for analytic inaccuracy.

Commonly used rules define when quality assurance actions should be taken when analyzing QC materials:

41.2.4.5.1.  When one observation exceeds the mean ±2 SD, a “warning” condition exists and usually a repeat run is made.
41.2.4.5.2  When one observation exceeds the mean ±3 SD, an “out of control” condition exists.
41.2.4.5.3  When two consecutive observations exceed the mean ±2 SD, an “out of control” condition exists.
41.2.4.5.4  When four consecutive observations exceed the mean ±1 SD in the same direction, an “out of control” condition exists.
41.2.4.5.5  When 10 consecutive observations fall on the same side of the mean, an “out of control” condition exists.
41.2.4.5.6 M If an “out of control” condition exists, equipment troubleshooting should be performed and quality control verified to assure an “in control” condition exists prior to analysis of specimens.

41.2.4.5.7 M Appropriate documentation of actions taken and results of verification are required.

41.2.4.5.8 M Duplicate sample analysis is performed on different instruments to verify acceptable inter-instrument variance.

41.3 Arterial blood gas analysis is performed according to CLSI standards and best practice

41.3.1.0 □ Calibration of the blood gas analyzer is performed as appropriate:
41.3.1.1 □ a one point calibration is performed every 30 minutes or prior to every sample.
41.3.1.2 □ a two point calibration is performed every 8 hours or on the day of testing.
41.3.1.3 □ calibration material is labeled with initial date of use and expiration date.
41.3.1.4 □ each new lot of calibration material is validated or verified prior to use.
41.3.2 □ The manufacturer’s step-by-step instructions or a detailed procedure are followed.
41.3.3 □ Blood samples are mixed thoroughly prior to analysis.
41.3.4 □ The internal temperature of the analyzer is checked and the data recorded.
41.3.5 □ Co-oximetry and hemoximetry samples are analyzed two or more times until two successive tHb results are within 0.2mg/dL.

41.4 Arterial blood gas analysis is reported according to CLSI standards and best practice.

41.4.1.0 □ Blood gas results are checked and repeated, or not reported if they are:
41.4.1.1 □ internally inconsistent (e.g. pH 7.40, pCO₂ 25 mmHg [3.3 kPa] and a reported bicarbonate of 24 mmol/L).
41.4.1.2 □ at the extremes of the range of expected values.
41.4.2.0 □ The complete report contains other relevant information:
41.4.2.1 □ collection date and time.
41.4.2.2 □ collection site.
41.4.2.3 □ the source of the sample (e.g. arterial, capillary).
41.4.2.4 □ the FIO₂ level.
41.4.2.5 □ ventilator settings.
41.4.2.6 □ comments regarding the quality of the sample.
41.4.2.7 □ delays in analyzing the sample.

Hemoximetry and co-oximetry is reported according to ATS/CLSI standards and best practice:

41.4.2.8 □ the sample is analyzed according to specific manufacturer’s recommendations.
41.4.2.9 □ there are procedures to address O₂Hb and COHb in the presence of HbF.
41.4.2.10 □ there are procedures to address MetHb values >10%.
41.4.2.11 □ a comment is included that addresses MetHb elevation due to the presence of MetHb, SulHb or any of several medical dyes such as methylene blue.
41.4.2.12 □ if methylene blue is used to treat the high MetHb levels, report that all parameters are not valid and type in comment section: “Another method of analyzing MetHb should be used”.
41.4.2.13 □ There are processes to correct for interfering substances (e.g. HbF, bilirubin).
42.0 Reports are in a standardized format that provides necessary information for clinical decision making. (NB These criteria and descriptors apply to the specific reporting listed in 33.0 - 41.0).

42.1 Reports are comprehensive and include appropriate information.

- Reporting of results follows ATS/ERS standards.
- Reports are clear and legible.
- Reports identify the patient, requestor, report recipients and the laboratory performing the procedure, name of the exam/procedure/test, date.
- Every procedure requested is reported (with data or comments).
- Clearly understood predicted values are provided when appropriate.
- Therapist and/or physician comments are provided when appropriate.
- Final reports contain staff comments assessing patient effort and performance.
- Reports indicate data that does not comply with ATS/ERS criteria.
- Patient results are correlated before reporting.
- Multiple page reports include patient identifiers on each sequentially numbered page.
- Reports indicate when performance or technical difficulties are suspected to contribute to a compromised result.
- Reports indicate when a non-standardized or alternative method is used (e.g. patient breathing through a tracheostomy, patient standing during the test).
- The staff performing the procedure is recorded.
- Test results from other agencies or facilities are accurately recorded when necessary (e.g. blood gas).
- Previous reports are included with current results to enable comparison interpretation.
- Reversibility criteria have been established and follow ATS/ERS standards.

42.2 There are policies and procedures in place to deal with corrected reports.

- Procedures or mechanisms are in place to detect and correct reporting errors.
- Corrected and addendum reports are clearly identified.
- Both the original result and the corrected result are reported.
- The date and time the change was made is noted.
- Notification of clinical staff is recorded.
- Corrected reports are reviewed by the medical leader or designate as appropriate.
- Corrected reports are investigated as necessary.
42.3 Reports and reporting processes meet the needs of test requestors.

- Abnormal results are reported by rapid mechanisms.
- Feedback from end users is considered when developing critical values, criteria and comments.
- The pulmonary function laboratory shares responsibility with the requester for ensuring that reports are received by the appropriate individuals.
- Reported results can be promptly retrieved.
- When appropriate, an interim report of results is distributed.
- Individualized narrative results contain the identification of the person interpreting the results.
- Results are reported in an appropriate time frame.
- Reports and tracings are reviewed for completeness, accuracy and timeliness.
- The appropriate length of data and information storage is defined by the medical leader considering all relevant requirements.

42.4 There are policies and procedures in place to deal with critical results.

- Critical results are established for procedures as appropriate.
- Critical results are reported in real time to a real person.
- Contingency plans are available in the event that the requesting physician cannot be contacted.
- Actions taken in response to critical results are documented.
- Criteria are established for the notification of a respirologist.
- There is a mechanism to address significant discrepancies between emergency/preliminary reports and final reports.
- Urgent, unexpected or unusual findings that require immediate patient management decisions are reported to the referring physician rapidly.

Pulse Oximetry

43.0 Pulse oximetry testing is conducted in a way that ensures meaningful, relevant data is reported.

43.1 Pulse oximeters are validated and used correctly to ensure the accuracy of test data.

- M The pulse oximeter and related accessories have been validated by the manufacturer by a comparison of values and calibration curve.
- M Pulse rate and oxygen saturation are sampled at least every six seconds. *Guidance: Sampling time should be frequent enough to ensure that significant events are not missed.*
- The ability of the oximeter to quantitate the degree of hypoxemia has been assessed.
- M Assessment of the agreement between the SpO₂ and the actual SaO₂ result is initially performed with intermittent reevaluation.
- When disparity exists between SpO₂ and SaO₂ reading, or disparity exists between the SpO₂ and the clinical presentation of the patient, possible causes are explored before results are reported.
- Measurements are correlated with the patient’s clinical condition when appropriate.
43.1.7 Monitoring at other sites or appropriate substitution of instruments or probes is used to reduce discrepancies.

43.1.8 Situations that may affect pulse oximetry results are defined (e.g. abnormal hemoglobins, intramuscular dyes, external sources of motion, ambient light, electrical interferences).

43.1.9 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.

43.1.10 The probe is cleaned between patient applications according to manufacturer recommendations.

43.1.11 If the sensor is damaged in any way it is replaced.

43.2 Oximetry tests are set up in a manner that ensures accurate results.

43.2.1 An appropriate probe (e.g. finger, ear, nose or forehead) is selected based on the clinical requirements of the patient.

43.2.2 Nail polish and/or artificial acrylic nails are removed when finger probes are used.

43.2.3 Good blood flow is encouraged for a peripheral site probe. Guidance: Actual physical rubbing may be required to stimulate blood flow.

43.2.4 The instrument is allowed to search for and lock onto the pulsatile portion of the perfusion.

43.2.5 The accuracy of capture is evaluated by comparing the palpated pulse to the reported heart rate on the device.

Overnight Oximetry

44.0 Overnight oximetry tests are conducted and reported in a manner that ensures accurate results.

44.1 The patient receives instruction on pulse oximeter use.

44.1.1 turning the oximeter on and off.

44.1.2 placing and securing the probe.

44.1.3 ensuring that a good signal is achieved.

44.1.4 maintenance of a diary to record events that may affect test interpretation.

44.1.5 precautions to prevent motion artifact.

44.1.6 precautions to avoid exposure of the measuring probe to ambient light.

44.1.7 New batteries are used for every overnight oximetry test.

44.1.8 The date and time settings of the oximeter are verified prior to testing.
44.2 Data from overnight oximetry is effectively incorporated into the report.

44.2.1 M Pulse rate and oxygen saturation data are collected for at least four hours.  
*Guidance: Six hours of data is preferable.*  
This data includes:  
- SpO₂% mean.  
- SpO₂% minimum.  
- time the SpO₂ is below 88%, 85%, and 80%.  
- desaturation index (the number of 4% desaturations/hour).  
- rate, mean, minimum and maximum.  
- plot of SpO₂ and cardiac rate for the duration of the test.  
- interpretation of findings.  
- any pattern of clustering events or bursts of desaturation interspersed with more normal saturation.

When required, additional information is obtained that may facilitate improved interpretation of overnight oximetry studies including:  
- medical history and physical examination findings.  
- body mass index.  
- indication that Continuous Positive Airway Pressure (CPAP) was used in cases of CPAP therapy.  
- sleep history (including Epworth Sleepiness Scale or other sleep questionnaires).  
- spirometry.  
- ECG and or LVEF.  
- confirmation from the patient that sleep actually took place in studies that are apparently normal or close to normal.

**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 37.1 - 37.3 for specific details on the Six Minute Walk Test.*

45.0 Exercise testing for the assessment of desaturation is safe and conducted in a way that ensures meaningful, relevant data is reported to determine the oxygen requirements of patients.

45.1 Patient exclusion criteria for exercise testing for the assessment of desaturation have been established.

Patient resting parameters are recorded including:  

- M SpO₂.  
- heart rate.  
- blood pressure.  
- perceived dyspnea on the Borg and/or visual analog dyspnea scale.  
- arterial blood gases and/or co-oximetry are performed prior to testing.  
- pre-test oximetry is performed to assess the severity of hypoxemia and anticipate the oxygen level during testing.  
- M exclusion criteria are defined.
Absolute contraindications for testing include:

45.1.8 M ☐ unstable angina.
45.1.9 M ☐ uncontrolled systemic hypertension.
45.1.10 M ☐ recent systemic or pulmonary embolism.

Relative contraindications for testing include:

45.1.11 ☐ resting diastolic blood pressure >110 mmHg or resting systolic blood pressure >200mmHg.
45.1.12 ☐ unstable (fluctuating) pulse oximetry reading.
45.1.13 ☐ significant weakness, pain, fever, dyspnea, lack of coordination, or psychosis that renders the patient incapable of performing the test.
45.1.14 ☐ recent myocardial infarction.

Guidance: Myocardial infarction (MI) within the previous 4 weeks is a relative contraindication. However, the test may be indicated in MI patients with coexisting lung disease to ascertain the need for supplemental O₂ during ambulation.

45.1.15 ☐ pH <7.30 or >7.50.
45.1.16 ☐ partial pressure of carbon dioxide in the arterial blood (PaCO₂) >50 mmHg with pH <7.30.
45.1.17 ☐ carboxyhemoglobin (COHb) >8%.
45.1.18 ☐ methemoglobin (METHb) >5%.
45.1.19 ☐ total hemoglobin (tHb) <80 g/L.

45.2 Criteria are established for the use of supplemental oxygen during exercise testing.

Oxygen titration is initiated when indicated:

45.2.1 ☐ partial pressure of oxygen in the arterial blood (PaO₂) <55 mmHg
45.2.2 ☐ saturation level of oxygen in hemoglobin (SaO₂) <87%
45.2.3 ☐ saturation level of oxygen in hemoglobin by oximetry (SpO₂) <88%

Guidance: If these values are obtained while the patient is resting, and breathing room air, the exercise test should be performed with supplemental oxygen.

45.2.4 ☐ The approach to determine the lowest oxygen flow rate required is established.

Guidance: Oxygen may be adjusted while the patient continues to exercise or exercise is stopped, the flow rate is adjusted and exercise is resumed after equilibration.

45.2.5 ☐ 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.

45.2.6 ☐ Oxygen is increased in 0.5-1.0 L/min increments until the SpO₂ just exceeds 90%.
45.2.7 ☐ The patient is observed for SpO₂ stability.
45.2.8 ☐ The SpO₂, litre flow, mode of delivery and time on oxygen are recorded.

If supplemental oxygen is used, relevant details are recorded including:

45.2.9 ☐ flow rate.
45.2.10 ☐ delivery device.
45.2.11 ☐ details of how the tank was carried (e.g. by patient, by staff etc.).
Exercise testing for the assessment of desaturation is safe, standardized and ensures meaningful data is accumulated.

45.3.1 Exercise is performed on a treadmill.
   Intent: Although exercise can be performed in a hall corridor, both treadmills and cycles provide a better monitoring environment. The major disadvantage of informal corridor walks is the lack of information about subtle physiologic changes during exercise, and information on the relationship of work rate to desaturation. Cycle ergometer testing does not mimic daily living conditions and with some patients it is difficult to reach a desaturation point, since they are not carrying their own body weight. In cases where it is difficult for a patient to reach desaturation, on a cycle ergometer (e.g. morbid obesity or interstitial lung disease, corridor or treadmill walking should be attempted).

For corridor testing:

45.3.2 the patient walks (without running) at a vigorous pace that they can maintain for 5-10 minutes.
45.3.3 a minimum of 30 metres of flat, unobstructed corridor is available to conduct the test.

For cycle ergometer testing:

45.3.4 handlebars and saddle heights are adjusted to the appropriate level.
45.3.5 instructions addressing the recommended cycling rate (RPM) are given.
45.3.6 the beginning workload is 40-80 RPM at 15-20 watts.
   Guidance: This workload could be lower based on patient ability.

For treadmill testing:

45.3.7 treadmill-walking techniques are explained or demonstrated.
45.3.8 patients are advised not to talk during the exercise testing unless necessary to inform the therapist of adverse symptoms.
45.3.9 a brief trial walk is used to familiarize the patient with the equipment.
45.3.10 a spotter is positioned at the rear of the treadmill.
45.3.11 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.
45.3.12 the patient rests a minimum of 5 minutes prior to starting the test.
45.3.13 the patient exercises 5-10 minutes.
45.3.14 a minimum of three minutes of exercise is achieved.
45.3.15 the workload is increased or decreased as tolerated by the patient.
   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.

Exercise parameters are recorded during testing at 30 second intervals:

45.3.16 $\text{SpO}_2$
45.3.17 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.
Exercise endpoints are defined including:

- completion of the predetermined exercise time.
- $\text{SpO}_2 < 88\%$ (80% in the case of home oxygen assessment).
- adverse symptoms (e.g. severe angina, tightness or wheezing; confusion, nausea or ataxia; tachycardia > 160 bpm).
- patient cannot continue with testing.

Exercise parameters are recorded including:

- total exercise time.
- end of exercise $\text{SpO}_2$.
- end of exercise heart rate.
- blood pressure.
- Borg Scale or visual analog scale results.
- any symptoms such as shortness of breath and/or leg fatigue.
- workload in watts (for ergometer cycle testing).

45.4 The reporting of exercise testing for the assessment of desaturation assists in the interpretation of patient’s oxygen requirements.

- The patient’s position and activity level is reported.
- If used, supplemental oxygen flow rate and delivery device is reported.
- The oximeter type, probe type and placement is reported.
- If performed, arterial blood gas results and directly measured saturations of $\text{O}_2\text{Hb}$, $\text{COHb}$ and $\text{MetHb}$ are reported.
- The stability and range of fluctuation of readings is reported as well as the length of observation of readings.
- The clinical appearance of the patient is included if significant, including peripheral perfusion, skin temperature, cyanosis and other signs and symptoms.
- Correlation of the heart rate readout on the oximeter with the actual palpated heart rate is reported.

Cardiopulmonary Exercise Testing

46.0 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 and certified in advanced cardiac life support. The degree of supervision will be determined by the clinical condition of the patient being tested.

46.1 Patient exclusion criteria and criteria for discontinuing cardiopulmonary exercise testing have been established.

Patient resting parameters are recorded including:

- resting ECG.
- resting blood pressure.
- pre-exercise spirometry including maximum voluntary ventilation (MVV).
46.1.4 Resting Arterial Blood Gas results.  
*Guidance: See standards on arterial blood gas and co-oximetry testing 41.1 – 41.4*

46.1.5 Pulse oximetry if indicated.  
*Guidance: See standards on pulse oximetry 44.1 - 44.2*

46.1.6 Exclusion criteria are defined. Absolute contraindications for testing include:
- recent complicated myocardial infarction.
- changes in the resting ECG that suggest an acute or recent myocardial event.
- unstable angina.
- uncontrolled cardiac arrhythmias.
- severe aortic stenosis and known or suspected dissecting aortic aneurysm.
- active or suspected acute pericarditis or myocarditis.
- acute congestive heart failure.
- acute febrile illness.
- acute asthma.
- recent systemic or pulmonary embolus.
- psychosis.

Relative contraindications for testing include:
- systemic hypertension with a resting systolic blood pressure >200mmHg or diastolic >120 mmHg.
- resting tachycardia (>120 beats per minute).
- frequent ventricular or atrial ectopy.
- moderate aortic stenosis.
- other moderate or severe valvular heart disease.
- known electrolyte abnormalities.
- uncontrolled diabetes.
- orthopedic limitations to exercise.
- neuromuscular, musculoskeletal or rheumatoid diseases that are exacerbated by exercise.
- advanced or complicated pregnancy.
- cardiomyopathy.

Criteria for stopping the exercise test (other than the patient’s fatigue and inability to continue) are defined:
- chest pain suggestive of ischemia.
- ischemic ECG changes.
- complex ectopy.
- second or third degree heart block.
- fall in systolic blood pressure >20 mmHg from the highest value during exercise.
- hypertension (>250 mmHg systolic; >120 mmHg diastolic).
- severe desaturation: SpO₂ ≤ 80% when accompanied by symptoms and signs of severe hypoxemia.
- sudden pallor.
- loss of coordination.
- mental confusion.
- dizziness or faintness.
- signs of respiratory failure.
46.1.41 When exercise is terminated because of the above criteria, the patient is observed until stable and physiologic variables have returned to baseline conditions. 
See standards on handling medical emergencies 18.5.

46.2 Patients are monitored during Cardiopulmonary Exercise Testing.
Routine measurement by electrocardiogram (ECG) are used during Cardiopulmonary Exercise Testing.

46.2.1 M □ Standard placement of ECG leads are used.
46.2.2 □ Chest hair is removed when required.
46.2.3 M □ A clean razor is used and then discarded into an appropriate sharps container.
46.2.4 □ The skin is cleansed and prepped as needed to eliminate artifact in the tracing.
46.2.5 M □ Limb leads are attached to both arms and legs.
46.2.6 M □ Precordial leads are attached to the correct anatomical positions.
46.2.7 □ Cable stabilization is used to reduce motion artifact.
46.2.8 □ There is a job aide that demonstrates the correct placement of Precordial leads.
46.2.9 M □ Changes on the ECG that require urgent medical attention are identified and advice is sought from the medical leader or other appropriate clinician.

Routine measurements of an exhaled gases are used during Cardiopulmonary Exercise Testing.

46.2.10 □ 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.
46.2.11 □ The mouthpiece is placed in the patient’s mouth and a nose clip is applied. Guidance: If a mask is used, ensure that it fits correctly and that no leaks are present.
46.2.12 □ The patient is instructed to maintain a tight seal around the mouthpiece to reduce the incidence of an air leak.
46.2.13 □ The patient is instructed to breathe quietly for 2 to 3 minutes. Feedback may be needed to avoid inappropriate breathing patterns (e.g. hyperventilation).
46.2.14 □ End-points are explained to the patient (attainment of maximal heart rate, development of limiting symptoms, or blood pressure, ECG or O₂ saturation out of range) and the patient is reassured about safety.
46.2.15 □ Exercise protocols designed to determine VO₂ max as one end point typically last about 10 minutes and the protocol is modified with this total expected exercise time in mind.

The patient is instructed about the use of symptom scales.

46.2.16 □ The rate of perceived exertion (Borg scale).
46.2.17 □ Other symptom scales (e.g. visual analog scale to score breathlessness); chest pain, chest tightness, asthma score, lightheadedness, leg fatigue.

46.3 The exercise methodology is safe and standardized.
For treadmill testing:

46.3.1 M □ the patient is instructed about the use of the treadmill.
46.3.2 □ treadmill-walking techniques are explained or demonstrated.
46.3.3 □ a brief trial walk is used to familiarize the patient with the equipment and check the ECG signal for motion artifact.
46.3.4 □ a spotter is positioned at the rear of the treadmill.
46.3.5 □ 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$_2$max and exercise time. In addition, the use of upper extremities increases the muscle artifact in the ECG tracing.

46.3.6 □ maximal incremental protocols are established.
  Guidance: The treadmill protocol should be appropriate for the patient and clinical questions to be answered. Treadmill protocols may be based on the Bruce, Balke, and Naughton or other protocols.

46.3.7 □ Modification of treadmill protocols are performed to meet the exercise limitations of the patient.

46.3.8 □ Any modification of the treadmill protocol is documented.

For cycle ergometer testing:

46.3.9 □ the patient is instructed about the use of the cycle ergometer.

46.3.10 □ the handlebar and saddle height are adjusted appropriately.

46.3.11 □ when the pedal is at bottom center, knee flexion should be about 20°.

46.3.12 □ the patient is instructed on pedal speed (appropriate to ergometer) with a typical target of 60 rpm.

46.3.13 □ 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.

46.3.14 □ maximal incremental protocols are established.
  Guidance: The cycle ergometer protocol should be appropriate for the patient and clinical questions to be answered. Typically a ramp protocol is used for a cycle ergometer.

46.3.15 □ the protocol includes 3 minutes of unloaded pedaling.

46.3.16 □ 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.

46.3.17 □ the incremental exercise period is approximately 8-12 minutes in duration.
  Guidance: With computer-controlled cycle ergometers, it is possible to increase the work rate continuously, usually every 1 to 2 seconds in a ramp-like fashion (ramp protocol). However, the total increment per minute should be 5 to 25 W/minute.

46.3.18 □ the work rate is decreased for patients suspected of having reduced exercise tolerance and the work rate is increased for very fit patients.

Cardiopulmonary exercise testing using an arm ergometer is used when appropriate including:

46.3.19 □ patients with lower extremity impairment.

46.3.20 □ occupational evaluation in patients whose work primarily involves upper body activity.

46.3.21 □ 10- to 25-Watt increments in 2 minute intervals are recommended.

46.3.22 □ VO$_2$max for arm exercise is generally equal to about 70% of that for leg exercise.
46.4 Patient parameters are monitored and documented during Cardiopulmonary Exercise Testing.

46.4.1 ☐ ECG data is collected at 1 to 2 minute intervals during exercise and at the maximal work rate.

46.4.2 ☐ ECG data is monitored continuously for 10 minutes post exercise.

46.4.3 ☐ Blood pressure is measured every 1 to 2 minutes during exercise, at the maximal work rate, and during the recovery phase.

46.4.4 ☐ Subjective measurements (e.g., RPE) are measured at rest, during exercise and immediately post exercise.

46.4.5 ☐ 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.

46.4.6 ☐ 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.

46.4.7 ☐ Recovery values are stable before discontinuation of monitoring.

   Intent: Recovery values do not have to reach pretest levels but should be stable.

46.5 The reporting of cardiopulmonary exercise testing results provides meaningful cardiac and pulmonary function data to clinicians.

Data is reported at a minimum from:

46.5.1 ☐ rest.

46.5.2 ☐ near or at the anaerobic threshold (AT) if identifiable.

   Guidance: The conventional method for determining AT uses ventilatory equivalents plotted against VO₂. Usually, data are smoothed or averaged to reduce breath-by-breath variability, facilitating location of the AT. The AT coincides with the minimum of VE/VO₂. The VE/ VCO₂ should either be constant or declining in the region around the AT. An increasing VE/ VCO₂ suggests the increase in both parameters is due simply to hyperventilation rather than to a change caused by lactic acidosis. AT can also be located using V-slope analysis, where the VCO₂ (vertical axis) is plotted versus the VO₂ (horizontal axis). The AT is the point where the slope of VCO₂ versus VO₂ increases; this can be located either manually or by using computerized analytic routines. If computerized analysis routines are used, the AT should always be verified by visual inspection of the data.

46.5.3 ☐ VO₂ max and V CO₂ are reported at STPD conditions in L/min.

   Guidance: VO₂max may also be normalized for body weight (mL/min/kg). However, this may be misleading in obese individuals.

46.5.4 ☐ Vₑ is reported at BTPS conditions in L/min.

46.5.5 ☐ PaO₂, PaCO₂ (if obtained) and PₑCO₂ are reported in mmHg.

46.5.6 ☐ SpO₂ and SaO₂ (from CO-oximetry) are reported as percent.

46.5.7 Variables are defined to detect maximal performance.

46.5.8 ☐ Heart rate is close to the maximal predicted: (210 - 0.65 x (age), (preferred), or 220 – age).

46.5.9 ☐ Vₑ,max: between 60% - 80% of ventilatory capacity (Ventilatory Capacity = MVV or FEV₁ X 35 to 40).

46.5.10 ☐ SpO₂ <80% (In cases of severe hypoxemia a patient may terminate exercise.)

46.5.11 ☐ Metabolic work: RER equal to or greater than 1.10 to 1.15; lactate equal to or greater than 7 mMol.
LEADERSHIP AND MANAGEMENT STANDARDS

The Leadership and Management Standards examine those practices related to effective leadership and operation of the pulmonary function laboratory. The standards examine key issues such as:

- Assigning key staff to management responsibilities
- Planning for services that meet client and patient needs
- Planning and acquiring the necessary resources to deliver services
- Addressing issues related to values and ethics
- Motivating staff through participation
- Managing risk and identifying practices for the appropriate disclosure of risk related information
- Managing information used for decision making

HUMAN RESOURCES STANDARDS

The Human Resources Standards examine the practices of planning for staff and achieving performance through people. The Standards address the pulmonary function laboratory management activities of:

- Assessing and obtaining human resources required to provide service
- Achieving excellence through people
- Fostering and supporting an environment that encourages people to reach their full potential
- Treating people with respect and trust and encouraging them to contribute ideas or speak out on issues of concern without fear of retribution
- Building and maintaining a work environment and staff support climate conducive to personal and organizational growth

SAFETY STANDARDS

The Safety Standards examine those practices related to keeping patients and health care providers safe. The standards examine key issues such as:

- General safety considerations to minimize potential hazards and risks
- Appropriateness of the physical environment
- Disaster and emergency preparedness

References:

REFERENCES AND RESOURCES
PULMONARY FUNCTION TESTING

PATIENT AND CLIENT FOCUS STANDARDS

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

SUPPLIERS AND PARTNERS STANDARDS

The Suppliers and Partners Standards examine the external relationships that the pulmonary function laboratory has with other organizations, institutions and/or alliances that are critical to its successful functioning. Included in these standards are the relationships that the pulmonary function laboratory has with its suppliers and equipment vendors. In some organizations, the pulmonary function laboratory will have authority to enter into relationships with suppliers and equipment vendors. In other organizations, this function may be centralized within a purchasing/procurement department or administration. In this latter situation, it is the expectation that the pulmonary function laboratory management is involved in the identification of performance requirements and the criteria for selection decisions.

QUALITY IMPROVEMENT STANDARDS

Key foundations of providing a high quality service are the ability to monitor performance and to identify opportunities to continually improve. Improvement opportunities may relate to the outcome of the service, or to the way the service is delivered (process improvement).

The Quality Improvement Standards examine how the pulmonary function laboratory ensures continuous improvement. The standards examine how management supports a continuous quality culture, how improvement activities are planned, and how the pulmonary function laboratory monitors and evaluates improvement activities and service delivery through the use of information and indicators. Measurement and evaluation is a critical success factor for quality improvement. Measurement of a limited number of select indicators provides the pulmonary function laboratory with information to support quality improvement activities. A linkage should exist between the measured process and desired outcome or result.

PULMONARY FUNCTION TESTING STANDARDS

When developing Pulmonary Function Testing policies, processes and protocols, it is recommended that the following resources are reviewed:

- American Thoracic Society/European Respiratory Society (ATS/ERS) Standards
- HSA4-A2 Application of a Quality Management Model for Respiratory Services, Clinical Laboratory Standards Institute 2006
- C46-A2 Blood Gas and pH Analysis and Related Measurements, Clinical Laboratory Standards Institute 2009
- ATS Pulmonary Function Laboratory Management and Procedure Manual, 2005
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.

¹ Institute of Medicine
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.

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.