You may download, print or make a copy of this material for your noncommercial personal use. Any other reproduction in whole or in part requires written permission from the College of Physicians & Surgeons of Alberta (CPSA) and the material must be credited to the CPSA.

Revision Date: November 2016 v22
Approval Date: 1992
Originating Committee: Advisory Committee on Pulmonary Function Laboratories
1.0 Introduction

Alberta’s Health Professions Act provides for the accreditation of medical services in non-hospital facilities by the College of Physicians and Surgeons of Alberta. Section 8.1 in Schedule 21 of the Act states:

8.1(1) A regulated member shall not provide a prescribed health service, or cause a prescribed health service to be provided, in a facility unless the facility is an accredited medical facility or a facility referred to in subsection (2).

(2) Subsection (1) does not apply with respect to a prescribed health service provided in

(a) an approved hospital within the meaning of the Hospitals Act,
(b) a hospital operated by the Government of Canada,
(c) a health care facility operated by the Government of Canada or the Government of Alberta,
(d) a hospital, clinic or centre operated by a regional health authority under the Regional Health Authorities Act,
(e) a facility within the meaning of the Mental Health Act or an accredited health centre established for the purpose of section 49(b) of the Mental Health Act, or
(f) a facility that is prescribed in the regulations.

Pulmonary Function Laboratory services are one of many health services for which the College requires accreditation. A complete list of prescribed health services is contained in the College’s by-laws and available on the College’s website.

The College also applies its accreditation standards to Pulmonary Function Laboratory services in approved hospitals through contract with Alberta Health Services.

The Advisory Committee on Pulmonary Function Laboratories is a standing committee of the College of Physicians and Surgeons of Alberta (hereinafter referred to as The College) which advises the Medical Facility Accreditation Committee (MFAC) of the College with respect to all matters pertaining to pulmonary function laboratories. The College provides this service to those facilities approved under the Hospitals Act through contract with Regional Health Authorities.

The Committee may consider issues related to the provisions of pulmonary services, and these issues may include, but are not restricted to the following:

1. Develop and maintain evidence based standards/guidelines for pulmonary function practice;
2. Monitor compliance with College approved standards through on-site assessments for accreditation;
3. Assess physicians’ qualifications and preparedness to interpret pulmonary studies against College approved training requirements;
4. Provide education to promote safety and quality improvement initiatives;
5. Facilitate the introduction of new services/technologies;
6. Respond to the needs of stakeholders for improved pulmonary services in Alberta;
7. Review and audit of the business practice of the facility to ensure compliance with relevant College by-laws.

The College requires that all accredited medical facilities have a Medical Director (i.e. a practitioner who is registered with the College) who is accountable for the practice of medicine within the facility. Medical Directors shall be satisfied as to the standing of other professionals with their respective regulatory bodies and as to the safety of their practices.
Note: This document incorporates standards and guidelines in a diagnostic and treatment facility approved by the MFAC/Council:

- “shall” is used when a section is a requirement for accreditation;
- “should” is used when a section is recommended; and
- “may” is used when a section is discretionary.

Due to the constantly changing spectrum of medicine, these standards/guidelines will be reviewed on a regular basis and revised when necessary. Input from facilities is encouraged to assist in keeping this document up to date.
2.0 Role of the College

2.1 Accreditation of Facilities

2.1.1 All pulmonary function laboratories shall register with and maintain accreditation by the College.

2.1.2 Applications for accreditation of new facilities shall be made to the College.

2.1.3 Requests for additional services shall be made to the College.

2.1.4 The Standard of Practice #20 – Direction and Control of Medical Practice as established by the Council of the College are applicable for privately owned pulmonary function laboratories.

2.1.5 Accreditation involves:

1. Completion of a pre-assessment data verification form;
2. An on-site assessment to:
   • assess laboratory appearance
   • observe testing procedures
   • assess quality assurance procedures and documentation
   • review manuals
   • assess equipment
   • assess laboratory safety

2.1.6 The assessment is completed by a physician (with expertise in the appropriate area of medical practice) designated by the College. An appropriate team is selected by the designated physician.

2.1.7 Following the assessment, a report which outlines the details of the assessment is prepared and subsequently reviewed by the Advisory Committee on Pulmonary Function Laboratories.

2.1.8 “Full Accreditation” is granted to those facilities with no identified deficiencies.

2.1.9 “Provisional Accreditation” may be granted for a 30-day period to those facilities with minor deficiencies to allow for their correction. A written response to each deficiency is required from the medical director/consultant of the facility. A follow-up assessment may be required at the sole discretion of the College. “Full Accreditation” will be granted when responses to deficiencies have been corrected to the satisfaction of the College.

2.1.10 Requirements shall be met before accreditation will be granted or renewed by the College.

2.1.11 The College may revoke accreditation if practice in the facility is considered unsafe.

2.1.12 A “Certificate of Accreditation” will be issued by the College to all facilities with “Full Accreditation”.

2.1.13 Accreditation is limited to 4 years from the last date of approval unless extended by the College and may be renewed through a process of re-accreditation which will follow the same steps as those for accreditation.

2.1.14 Payment to the College for the cost of the assessment is the responsibility of the Medical Director of the facility (private facilities only).

2.1.15 “Spot” assessments without prior notice may also be conducted. These are at no cost to the facility.
2.2 Administration

2.2.1 A record of each facility shall be kept on file at the College.

2.2.2 Reaccreditation

1. A physician who has been accredited or grandfathered, but who has not been in the active practice* of pulmonary function for the last three years, will be assessed and may require further training.

2. Upon completion of training, a letter attesting to competence from the supervising physician shall be provided.

Note: The following will be used as a guide in reviewing requests for reaccreditation:

- Original training
- Experience in practice
- Extent of related activity during time away from relevant practice.
- Content of a retraining program, including an expectation of:
  - Completion over a reasonably brief time (i.e. weeks or months, but not years);
  - Review of relevant current literature;
  - Degree of supervision;
  - Method of evaluation of competence.
- Credentials of the preceptor and details contained in the letter attesting to his or her satisfaction with the applicant’s abilities.

* "Active practice" refers to physicians who are actively reviewing pulmonary function studies as a consultant.

2.2.3 Each facility is required to pay an annual fee, set by Council, for the administration of the accreditation program (private facilities only).
A Pulmonary Function Laboratory provides services to assess the physiological performance of the lungs using a variety of testing procedures. These laboratories, which are under the supervision of a qualified physician, require accreditation and are subject to periodic assessment.

3.0 Procedures

Registered physicians and nurse practitioners may refer directly to the laboratory for medical diagnostic purposes.

3.1 Level I
No accreditation required. (Supervised & interpreted by a physician for his or her own patients only)

- Vital capacity (VC)
- Timed vital capacity
- Forced expiratory volume in the first second (FEV₁) (before and after bronchodilator)
- Forced vital capacity (FVC) (before and after bronchodilator)
- FEV₁/FVC (before and after bronchodilator)

3.2 Level II
(providing a PFT consultation for other physicians)

- Vital capacity (VC)
- Timed vital capacity
- Forced expiratory volume in the first second (FEV₁) (before and after bronchodilator)
- Forced vital capacity (FVC) (before and after bronchodilator)
- FEV₁/FVC (before and after bronchodilator)
- Inspiratory and expiratory flow volume loop (before and after bronchodilator)

3.3 Level III
Arterial blood gases
- Co-oximetry
- Oxygen saturation (pulse oximetry) with quantified exercise
- Lung volumes by gas dilution technique or nitrogen washout, or body plethysmography
- Carbon monoxide diffusion capacity
- Non-specific inhalation challenge - methacholine or histamine
- Inspiratory pressure (Pimax) and maximal expiratory pressure (Pemax)
- Exercise bronchoprovocation.

3.4 Level IV
Advanced cardiopulmonary exercise testing including serial measurements of: oxygen uptake, carbon dioxide production, arterial blood gases (if applicable), and cardiac output during progressive exercise.
- Lung compliance (with esophageal balloon for pleural pressure estimation) and pressure volume curve.
- Chemosensitivity assessment, including ventilatory response to hypercapnia and hypoxia and occlusion pressure (P₁).
- Xenon ventilation and perfusion studies.
- Specific inhalation challenge studies.
- Respiratory muscle assessment including one or more of: transdiaphragmatic pressure (Pdi), respiratory muscle EMG, magnetometer or impedance measurement of chest and abdominal movements.
- Respiratory resistance by oscillation or Mead/Whittenberg technique.
- In subjects under the age of 5 years: assessment of pulmonary function by impulse oscillometry, whole body plethysmography, or rapid thoracic compression.
- Transcutaneous measurements of oxygen and carbon dioxide.

Other tests for pulmonary function may be considered for accreditation upon application.
4.0 Personnel

4.1 Medical Director

4.1.1 Qualifications

1. Level II

The director of a facility performing Level II Procedures (refer to Section 1.0 Procedures) shall be a physician licensed to practice medicine in Alberta and certified as a specialist in:

a. Adult or pediatric Respiratory Medicine;
   - or -
   b. Internal Medicine, Anaesthesia or Paediatrics, or otherwise approved by Council

   - and -

   Have successfully completed a minimum of one month of approved training in a pulmonary function laboratory (or laboratory otherwise approved by Council), which performs a minimum of 500 complete Level III pulmonary function studies annually. This training must include competency in indications, instrumentation, quality assurance and interpretation.

2. Level III

The director of a facility performing Level III Procedures (refer to Section 1.0 Procedures) shall be a physician licensed to practice medicine in Alberta and certified as a specialist in:

a. Adult or pediatric Respiratory Medicine;
   - or -
   b. Internal Medicine, Anaesthesia or Paediatrics, or otherwise approved by Council

   - and -

   Have successfully completed a minimum of six months of approved training in a Level IV pulmonary function laboratory (or laboratory otherwise approved by Council), which performs a minimum of 500 Level III pulmonary function studies annually.

3. Level IV

The director of a facility performing Level IV Procedures (refer to Section 1.0 Procedures) shall be a physician licensed to practice medicine in Alberta and certified as a specialist in:

a. Adult or pediatric Respiratory Medicine.
4.1.2 Responsibility

The Medical Director shall have direct control and be responsible for provision of pulmonary function services. This may include, but is not restricted to, the following:

1. The day to day direction and supervision of the practice of medicine.
2. Providing continuous, adequate and effective direction and supervision of assistant pulmonologists and technical staff.
3. Ensuring an adequate quality assurance program is in place.
4. Selection of testing procedures and equipment used.
5. Ensuring minimal standards of the American Thoracic Society are met.
6. Establishing and maintaining effective and appropriate safety procedures.
7. Ensuring appropriate “manuals” are in place and up-to-date.
8. Remitting an annual fee as determined by Council. (Private facilities only)
9. Making available for accreditation the requested documentation.

4.2 Pulmonary Function Interpreters

4.2.1 Accreditation

1. Level II

An interpreter of pulmonary function studies for Level II Procedures (refer to Section 1.0 Procedures) shall be a physician licensed to practice medicine in Alberta and certified as a specialist in:

   a. Adult or paediatric Respiratory Medicine;

      - or -

   b. Internal Medicine, Anaesthesia or Paediatrics, or otherwise approved by Council

      - and -

Have successfully completed a minimum of one month of approved training in a pulmonary function laboratory (or laboratory otherwise approved by Council), which performs a minimum of 500 Level III pulmonary function studies annually. This training must result in competence in the indications and interpretation.

      - and -

Shall provide evidence of satisfactory completion of training.

2. Level III

An interpreter of pulmonary function studies for Level III Procedures (refer to Section 1.0 Procedures) shall be a physician licensed to practice medicine in Alberta and certified as a specialist in:

   a. Adult or pediatric Respiratory Medicine;

      - or -

   b. Internal Medicine, Anaesthesia or Pediatrics, or otherwise approved by Council
- and -

Have successfully completed a minimum of three months of approved training in a pulmonary function laboratory (or laboratory otherwise approved by Council), which performs a minimum of 500 Level III pulmonary function studies annually.

- and -

Shall provide evidence of satisfactory completion of training.

3. Level IV

An interpreter of pulmonary function studies for Level IV Procedures (refer to Section 1.0 Procedures) shall be a physician licensed to practice medicine in Alberta and certified as a specialist in:

i) Adult or pediatric Respiratory Medicine.

4. Clinical Doctoral Scientist

Notwithstanding the above, the Council may approve a Clinical Doctoral Scientist to perform interpretation of pulmonary function studies in a specified laboratory at the level for which they are qualified.

4.2.2 Reaccreditation

1. A physician who has been accredited or grandfathered, but who has not been in the active practice* of pulmonary function for the last three years, will be assessed and may require further training.

2. Upon completion of training, a letter attesting to competence from the supervising physician shall be provided.

Note: The following will be used as a guide in reviewing requests for reaccreditation:

- Original training
- Experience in practice
- Extent of related activity during time away from relevant practice.
- Content of a retraining program, including an expectation of:
  - Completion over a reasonably brief time (i.e. weeks or months, but not years);
  - Review of relevant current literature;
  - Degree of supervision;
  - Method of evaluation of competence.
- Credentials of the preceptor and details contained in the letter attesting to his or her satisfaction with the applicant’s abilities.

* "Active practice" refers to physicians who are actively reviewing pulmonary function studies as a consultant.
4.3 Consultant

4.3.1 Pulmonary Testing

1. Laboratories that Require a Consultant

In exceptional circumstances, when there is no local physician accredited to direct the laboratory, approval may be given for an appropriately qualified local physician to serve as the local medical director of the laboratory under remote supervision by a consultant physician accredited to direct a Level III or level IV laboratory.

2. Responsibilities of a Consultant

a. Ensure maintenance of standards set by provincial and federal authorities.

b. Institute and ensure maintenance of an adequate quality assurance program including the monthly review of quality control results.

c. Ensure appropriate manuals are in place and up-to-date.

d. Ensure appropriate interpretation of studies through an audit of reports in a timely manner at intervals dictated by the experience of the interpreter.

e. Visit the facility initially upon establishing a consultant relationship and subsequently as required.

Where the consultant is assisting the local physician to acquire the knowledge and skills to direct the laboratory, the frequency of the visits should be more often and appropriate to graded responsibility and independence.

f. Review an annual report of the facility which shall include, but is not restricted to:

- equipment evaluation
  - preventative maintenance
  - calibration
  - quality control
- review of quality control
- review of manuals
- assessment of technician technique/competency
- interpretive review
- consultant comments and advice

4.3.2 Arterial Blood Gases

Where the medical director is not a respirologist or pathologist with experience in blood gases, a consultant respirologist or pathologist, with experience directing a blood gas laboratory, is required.

The consultant shall evaluate the quality control procedures and results for arterial blood gases on a regular basis and provide a written report at least annually to the medical director.
4.4 Local Medical Director

To accommodate facilities requiring a Consultant to direct or to assist in the direction of a laboratory, a Local Medical Director shall be appointed to provide medical direction under the remote supervision of the Consultant.

4.4.1 Qualifications

1. The local medical director shall be licensed to practice in Alberta and shall be a member of the facility’s medical staff, who acts in concert with administration and the laboratory consultants.

4.4.2 Roles and Responsibilities

1. Oversees the medical aspects of the day-to-day operation of the facility.

2. Supervises the technical staff in regards to patient care issues.

3. Ensures required documentation is complete.

4. Communicates with the pulmonary laboratory supervisor at least monthly to determine if the laboratory is experiencing any problems or has any concerns.

5. Serves as the liaison for the pulmonary laboratory between the medical staff and local and regional administration.

4.5 Technical Personnel

4.5.1 Appropriate technical personnel for pulmonary function tests would be:

1. Level II Pulmonary Function Procedures (refer to Section 1.0 Procedures)
   a. Graduates of recognized science programs who have trained for at least 3 months in a pulmonary function laboratory.* The science program can be completed at a technical institute, college or university.
   b. Nurses who have trained in a pulmonary function laboratory* for at least one year.

2. Level III & IV Pulmonary Function Procedures (refer to Section 1.0 Procedures)
   a. Registered Respiratory Therapists with at least 3 months full time training in a pulmonary function laboratory.  *

      Registered Respiratory Therapists shall hold active registration with the Alberta College and Association of Respiratory Therapists of Alberta (CARTA)

      - or -

   b. Be an individual that holds active registration with the Canadian Association of Cardio Pulmonary Technology (CACPT) with a pulmonary or combined cardio/pulmonary registration.
4.5.2 Technical staff, other than the above, shall be approved by Council.

* The pulmonary function training laboratory should be an accredited laboratory which performs all the testing procedures the technologist will encounter in the pulmonary laboratory. A letter from the laboratory supervisor certifying the successful completion of training must be available.

4.5.3 All technical staff shall have up-to-date Health Care Provider level certified CPR.

4.5.4 Procedures shall be in place to ensure that staff are adequately trained.

4.5.5 All personnel in the facility shall have a job description.

4.5.6 Regular feedback shall be given to staff and this shall be documented at least annually.

4.5.7 All technical staff should participate in continuing education.

4.5.8 Technical personnel who have not been actively working in a pulmonary function laboratory for 3 years shall upgrade their training as seems appropriate to the director.

4.5.9 Certification/Recertification

If the laboratory performs arterial blood gases, non-specific inhalation challenge or exercise testing, the technical staff shall be certified by the medical director or his/her designate. A letter attesting to competence shall be provided by the medical director.

1. **Arterial Blood Gases**

   Evidence of a review of proficiency of technical staff in drawing and analyzing arterial blood gas samples shall be documented.

2. **Non-specific Inhalation Challenge** - A person designated by the physician to directly conduct non-specific inhalation challenge testing shall:
   a. within the past year, perform a sufficient number of inhalation challenge studies using the tidal breathing method described by Juniper, Cockcroft and Hargreaves (Canadian Thoracic Society) or an acceptable method of testing to be considered proficient. The method of procuring the histamine or methacholine must be detailed;
   b. be trained to treat acute bronchospasm;
   c. be trained to use resuscitation equipment;
   d. maintain current certification in Health Care Provider (HCP) CPR; and

3. **Exercise Testing** – A person designated by the physician to directly conduct cardiopulmonary exercise testing shall:
   a. within the past year, perform a sufficient number of exercise tests, appropriate to the level of accreditation, to be considered proficient;
   b. be competent in conducting the test;
   c. be competent in recognizing ECG and clinical signs requiring immediate intervention;
d. maintain current certification in Health Care Provider (HCP) CPR; and

e. receive training on the laboratory’s AED or defibrillator.
5.0 Facility Operation

5.1 Physical

5.1.1 The following shall be adequate in the facility:

1. Record storage
2. Room temperature control
3. Facility ventilation
4. Facility lighting
5. Cleanliness
6. Stretcher access
7. Electrical power supply

5.1.2 The following should be adequate in the facility:

1. Patient waiting facilities
2. Patient washroom facilities
3. Clerical facilities
4. Supply storage
5. Emergency lighting
6. Noise level
7. General appearance

5.2 Communication

5.2.1 There shall be sufficient telephones.

5.2.2 When an urgent findings/critical value is reported, there shall be a procedure for documenting the following:

1. The time of the report.
2. The reporter.
3. The referring physician shall be notified before the patient leaves the facility. The Medical Director or designate shall be notified if the referring physician is not available.
4. The action taken.

5.2.3 Confidentiality of results shall be assured.
6.0 Requests/Pre-Test Information

Requests/pre-test information shall include the following:
1. Laboratory name, address and phone number.
2. Identity of the patient.
3. Identity of the referring physician.
4. Test requested.
5. Special instructions, comments or history by referring physician.

7.0 Reports

7.1 Content

7.1.1 Reports shall include the following:
1. Laboratory name, address and phone number.
2. Patient's name.
3. Gender.
4. Second patient identifier (e.g. date of birth, personal health number)
5. Name of referring physician.
6. Date and time of procedure.
7. Name or initials of technologist.
8. Space for technologist’s comments.
9. Space for the interpretation of data.

7.2 Interpretation

7.2.1 A physician accredited by the College of Physicians and Surgeons of Alberta to interpret pulmonary function tests is responsible for the recorded interpretation of tests and reporting them to the referring physician.

7.2.2 There shall be guidelines in place for the interpretation of all pulmonary function tests.

7.2.3 All reports containing interpretations shall indicate authorship and whether or not the contents of the report have been verified by the author. (A signature means that the contents have been verified by the signator).

7.2.4 Interpretive reports should be typed.

7.2.5 Turn-around times for physician interpretation shall be no longer than one week for all tests.
8.0 Storage of Records

8.1 Test results and interpretation reports shall be retained for a minimum of ten years. In the case of minors, they shall be retained for either ten years or two years after the patient reaches the age of majority, whichever is longer.

8.2 Records pertaining to the function of the laboratory shall be kept for a minimum of two years.

8.3 The service provider shall maintain safeguards to protect the confidentiality of patient records and to protect against reasonably anticipated threats or hazards to the security, integrity, loss or unauthorized use, disclosure, modification or unauthorized access to health information. This applies to records in paper or electronic format.

8.4 Previous result data including electronically stored data, shall be readily retrievable and within a time frame consistent with patient care needs.

9.0 Quality Assurance

9.1 A quality assurance program shall be in place to ensure minimal standards of the American Thoracic Society are met.

9.2 The content and format may be flexible, but the program at a minimum shall monitor:

9.2.1 Staff competency

1. Professional (e.g. cross-reading of interpretations, chart audit, annual review of performance/CPL)
2. Technical (audit of procedures, annual performance review, record of continuing education)

9.2.2 Equipment Performance

1. Schedule of preventative maintenance – logs
2. Troubleshooting – logs
3. Regular calibrations – logs
4. Quality control cross-check on accuracy of computer-generated data

9.2.3 Laboratory Technique and Procedure

1. Patient preparation (e.g. checklists)
2. Testing procedure (e.g. quality of data)

9.2.4 Reporting

1. Turn-around time
2. Completeness/Content
3. Storage

9.2.5 Safety

1. Urgent Findings/Critical Values
   a. Results of follow up
2. Incident Reports
   a. Results of follow up
   b. Review of case
9.2.6 Utilization (e.g. rates of abnormal findings, results of follow-up review of cases)
10.0 Quality Control

10.1 Pulmonary Function Procedures

10.1.1 A quality control program for each testing procedure done shall be in place.

10.1.2 This shall include:

1. Protocol and frequency for calibration.
2. Protocol for testing standard subjects monthly to supplement spirometry, lung volumes and diffusing capacity.

10.1.3 Records of all daily calibrations and quality control shall be kept for each procedure.

10.1.4 There shall be evidence of review by the medical director.

10.1.5 Tolerance limits shall be defined for quality control checks for each procedure done.

10.1.6 There shall be a plan for corrective action when tolerance limits are exceeded.

10.1.7 Standard subjects shall be tested monthly and records kept.

10.1.8 A schedule for specific quality control checks shall be done for each procedure and this shall be documented.

10.2 Blood Gases/Co-Oximetry

10.2.1 General

1. There shall be a written quality assurance program for Blood Gases.

2. The quality assurance program shall include details for both internal or daily quality control and external quality assessment or proficiency testing.

**Internal Quality Control:**

Internal quality control is the daily process to ensure consistency of measurements or observations over time (e.g. day to day). Internal quality control is key to monitoring precision or agreement between replicate measurements or reproducibility.

Quality control material is often obtained from the reagent supplier. Data may be submitted at different intervals (e.g. monthly) to the supplier for comparison of performance to other laboratories using the same product. A summary of comparison is provided to participants.

**External Quality Assurance:**

External quality assurance is the process to monitor accuracy or how close the laboratory result is to the true value. Contract material is from a source independent of the reagent system and is provided at regular intervals (often quarterly). Results are often compared based on the same instrument types.
10.2.2 Calibration

1. There shall be written procedures for calibration.

2. The frequency of calibration shall be defined.

3. Criteria for recalibration/validation shall include:
   i. At change of reagents or membranes
   ii. When indicated by quality control data
   iii. After major maintenance or service

4. The calibration shall be rechecked periodically throughout the day utilizing barometric pressure.

5. The materials used for calibration of the pH, carbon dioxide, and oxygen sensors shall be traceable to NIST Standard Reference Materials.

6. There shall be documentation of all calibration results.

10.2.3 Internal Quality Control

1. Quality control specimens (tonometered samples or commercial control materials) analyzed and/or electronic checks (depending on the specific instrument) shall be performed at least once per shift for all parameters when patient specimens are tested.

2. Criteria for what is considered “out of control” shall be available at bench level.

3. A clearly defined plan of action shall be in place when the control result exceeds tolerance limits or is “out of control”.

4. The “action plan” shall define the points at which the supervisor is notified and intervenes.

5. There shall be criteria for follow-up/investigation of out-of-control results.

6. There shall be documentation for all “out of control” results. Documentation shall include:
   i. What is “out of control”
   ii. Why the analysis was “out of control”
   iii. Corrective action taken
   iv. Signature initials of individual responsible

7. The results of controls shall be verified for acceptability before reporting patient results.

8. All results, both “in” and “out” of control, shall be documented.

9. The threshold for seeking the medical director/consultant’s advice shall be defined.

10. The charts/tables/graphs shall document the QC reagent, SD and mean, record of significant changes in calibration, reagents, lot number, etc. and evidence of monthly review by supervisory staff.

11. Dates shall be documented on the quality control record when a new lot number of quality control material is used.
12. Statistical analysis of numerical data shall be done monthly or when a minimum of twenty points have been accumulated.

13. The medical director or designate shall review quality control results at least weekly.

14. Corrective and Investigative actions taken as a result of the regular quality control reviews shall be documented.

15. Quality control records shall be retained for two years.

16. Systems to detect clerical errors, significant analytical errors, unusual laboratory results and excessive delays shall be documented. These systems shall also provide for the timely correction of errors and analysis of results to identify trends.

10.2.4 External Quality Assurance

1. Laboratories shall participate in an external proficiency testing program to monitor blood gas analysis (PH, PO2, PCO2), as defined by the College.

2. The results of the external surveys shall be monitored by the Alberta Laboratory Quality Enhancement Program (ALQEP).

3. The laboratory shall integrate the external survey samples within the routine laboratory workload, and the samples shall be analyzed by personnel who routinely test patient samples, using the same primary method systems for patient samples.

4. Testing of survey samples shall be rotated among all laboratory technical personnel, when possible.

5. There shall be documented evidence of active review by the laboratory director/consultant or designate of the survey results.

6. There shall be documented evidence of evaluation and, if indicated, prompt corrective action in response to “unacceptable” results on survey reports.

7. All results shall be retained for 2 years.

10.2.5 Between Instrument Comparison

1. Laboratories with more than one instrument shall have a process to ensure reproducibility of results.

2. This shall include the frequency which should be a minimum of 2-3 times per week.

3. The allowable variation between instruments shall be defined.

4. There shall be an investigation plan when between instrument results exceed the allowable variation.

5. The investigation plan shall define the points at which the supervisor is notified and interviews.

6. There shall be documentation that supports the action steps as defined in the investigation plan.
11.0 Off-Site Testing

If off-site testing using mobile equipment is done from the "base" laboratory:

11.1 The role of the Medical Director shall apply.

11.2 Except as described below, all standards for a base pulmonary function laboratory shall apply to off-site pulmonary function testing services.

11.3 The requirements in section 5.0 (Facility Operation) with the exception of record and log storage shall apply to all off-site locations.

11.4 Calibration of equipment shall be performed at the off-site location.

11.5 Calibrations records shall be kept on file at the base laboratory.

11.6 The off-site testing site shall be easily identifiable on all reports and records.

11.7 Patient records (including copies of patient studies) shall be kept on file at the base laboratory.

11.8 Each off-site location shall be identified at the time of accreditation.

11.9 Studies performed at each off-site location shall be reviewed in conjunction with the base laboratory.

11.10 All off-site testing results shall be interpreted.

12.0 Equipment

12.1 The equipment used for all levels of testing shall comply with the standards of the American Thoracic Society.

12.2 There shall be a stadiometer or height rod to accurately measure a patient’s height at each facility and off-site testing location.
13.0 Testing Procedures

13.1 Pulmonary Function Procedures

13.1.1 The testing procedure for pulmonary function tests shall meet or exceed the minimum standards of the American Thoracic Society.

13.2 Blood Gases/Co-Oximetry

13.2.1 There shall be a written procedure in the manual.

13.2.2 Specimen collection, transport and storage requirements shall be included as part of the procedure.

13.2.3 There shall be written procedures for calibration.

13.2.4 Calibration checks shall be performed daily and at manufacturer's recommended frequency during the day and this shall be documented.

13.2.5 Quality control specimens shall be run daily or more frequently dependent on work load.

13.2.6 Statistical analysis of control data shall be done monthly and reviewed by the supervisor and periodically by the medical director/consultant.

13.2.7 Arterial puncture for blood gases is a medical procedure to be performed only by physicians or individuals who have had proper training.

13.2.8 Where there is a consultant for blood gases, a written report related to blood gases shall be provided to the Medical Director, at least annually.

13.3 Methacholine Challenge Testing

One of the following shall be immediately available during challenge testing:

1. The medical director or a designated medical colleague approved to read level IV pulmonary function tests;

   or

2. One of the following with current ACLS Certification:
   1. licensed physician,
   2. physician assistant,
   3. nurse practitioner,
   4. respiratory therapist, or
   5. cardio pulmonary technologist;

   or

3. A cardiac arrest response team.
13.4 Additional Testing Initiated by the Pulmonary Function Laboratory

13.4.1 A written algorithm shall be in place that identifies specific clinical findings that allow additional PFT testing to be performed beyond what was ordered by the referring physician/nurse practitioner.

13.4.2 The reason for the occurrence of the additional testing shall be specifically stated within the PFT report and provided back to the referring physician/nurse practitioner.

13.4.3 The medical director or physician designate shall annually review and document the additional tests and their results to evaluate the appropriateness beyond the referral source’s initial request.
14.0 Safety

14.1 General Safety

14.1.1 The laboratory shall have a Safety Manual which the laboratory staff shall follow. This shall be specific to the laboratory.

14.1.2 The safety manual shall be readily available to all personnel and evidence that they are aware of its content is recommended.

14.1.3 There shall be documentation of annual review by staff.

14.2 Incidents

14.2.1 Policies and procedures shall be developed regarding the documentation of all incidents.

NOTE: An incident is an occurrence, which either harmed or could have harmed a patient or a staff member.

14.2.2 There shall be a process to document corrective action taken.

14.2.3 There shall be a process to review/analyze incidents.

14.3 Fire Safety

14.3.1 This shall be specific for the laboratory and be in conformity with that of your institution and local fire department.

14.3.2 Adequate fire alarms shall be in place.

14.3.3 Fire extinguishers shall be of proper type, appropriately labelled and sufficient in number. There must be a record of their inspection within last year.

14.3.4 Staff shall know how to operate a fire extinguisher.

14.4 Electrical Safety

14.4.1 All equipment shall be checked for grounding and checked for current leakage at least annually.

14.4.2 All cords and plugs shall be checked for frayed wires and repaired as necessary.

14.4.3 Multiple receptacle electrical adapters shall be kept to a minimum.

14.5 Compressed Gas Safety

14.5.1 Compressed gas cylinders shall be identified as to their contents.

14.5.2 Instructions shall be available as to their proper use, storage and transportation in accordance with the manufacturer's specifications.
14.5.3 Compressed gas cylinders shall be secured and positioned well away from open flame or other heat sources, and not in corridors or outside exhaust canopies.

14.5.4 They shall be equipped with an approved functional valve system and that it be turned off when not in use and that the pressure in the hose be released before disconnecting the unit.

14.6 Infection Prevention and Control

These standards have been adapted from *Health Canada – Infection Control Guidelines – Hand Washing, Cleaning, Disinfection and Sterilization in Health Care* and *Health Canada – Infection Control Guidelines – Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care*.

Routine infection control practices should be incorporated into everyday patient/resident/client care. Institutional policy should provide for education of every care provider in the principles of routine precautions, provision of adequate equipment to implement them, and a means by which compliance with practice can be monitored and audited.

To minimize the risk of transmission of infection, patients/residents/clients (referred to henceforth as “patients”) should be assessed for infection or potential infections upon admission. Each facility should endeavor to have some assessment procedure in place; the results should be communicated to other personnel providing care and should be documented in the patient record.

In situations requiring additional precautions, these precautions must be instituted as soon as indicated by triggering mechanisms such as diagnosis, symptoms of infection, laboratory information, or assessment of risk factors.

The institution/facility is responsible for ensuring that appropriate precautions are taken for specific patients.

All personnel (physicians, nurses, technologists/technicians, students, volunteers and others) are responsible for complying with routine and additional precautions and for tactfully calling observed infractions to the attention of all offenders. There are no hierarchical exceptions to precautions, and everyone has a responsibility to monitor his or her own practice as well as the practice of other care providers. There are no exceptions, and all should teach by example.

14.6.1 Occupational Health/Immunization


1. All personnel, including physicians should have their immunization status reviewed and documented at the time they commence employment at the facility and periodically thereafter.

2. Personnel that are unable to provide acceptable evidence of adequate immunity against hepatitis B, influenza, measles, mumps, rubella, and varicella; should be advised to speak to their physician about immunization.

3. Employers should consider measles, mumps, rubella, hepatitis B and varicella immunity as a condition of employment.

4. Tuberculin skin testing is recommended for all personnel at the beginning of their employment.
5. All personnel shall understand and adhere to “Routine Practices” which incorporate universal blood and body fluid precautions such as described in the “Health Canada Infection Control Guideline: Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care. (This guideline is available on-line at http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/99pdf/cdr25s4e.pdf.)

6. There shall be a policy and procedure for the management of significant exposures (e.g. needle-stick injuries).

7. Consultation with a specialist in infectious disease shall be obtained prior to workers with blood-borne pathogens starting work in the facility. “Health care workers who perform exposure-prone procedures have an ethical obligation to know their serologic status for hepatitis B virus (HBV), human immunodeficiency virus (HIV) or hepatitis C virus (HCV) and to follow the recommendations in ‘Proceedings of the Consensus Conference on Infected Health Care Workers: Risk for Transmission of Bloodborne Pathogens,’ (This document is available on-line at http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/98vol24/24s4/24s4b_e.html).

14.6.2 General Infection Prevention Measures

1. Adequate hand washing sinks shall be appropriately located throughout the facility. Waterless, alcohol based antiseptic hand agents are an acceptable alternative to soap and water, if there is no visible soiling.

2. Hands shall be washed between patients, after removal of gloves, when visibly soiled and after contact with any contaminated objects.

3. Hand washing with an antiseptic agent shall be used:
   a. before performing invasive procedures;
   b. before contact with immunocompromised patients;
   c. before contact with patients with extensive skin damage.

4. There shall be no-reuse of critical or semi-critical medical equipment labeled as single-use by the manufacturer.

5. Masks, eye protection and face shields shall be worn for protection of mucous membranes of the eyes, nose and mouth during procedures likely to generate splashes or sprays of blood, body fluids, secretions or excretions.

6. Clean non-sterile gloves shall be worn:
   a. for contact with blood, body fluids, secretions and excretions, mucous membranes, draining wounds or non-intact skin (open skin lesions or exudative rash);
   b. when handling items visibly soiled with blood, body fluids, secretions or excretions;
   c. when the healthcare worker has open lesions on the hands.

7. Gloves are to be changed between care activities and procedures with the same patient after contact with materials that may contain high concentrations of microorganisms.

8. Gloves are to be removed immediately after completion of care or procedure, at point of use and before touching clean environment surfaces.

9. There should be a designated person responsible for the maintenance and enforcement of infection control and occupational health standards in the facility.
14.6.3 Additional Precautions

1. Airborne Transmission Precautions
   
   a. Patients with known or suspected infectious tuberculosis, measles, varicella or disseminated zoster should be placed directly in a single examination room and the door shall remain closed.
   
   b. Those patients shall wear a surgical/procedure mask during transport and movement through the facility.
   
   c. High efficiency dust/mist masks (N95 or >) shall be worn by all healthcare workers who enter the examination room of a patient with infectious tuberculosis.
   
   d. High efficiency dust/mist masks (N95 or >) shall be worn by non-immune healthcare workers who absolutely must enter the examination room of a patient with varicella, disseminated zoster or measles.

2. Droplet Transmission Precautions
   
   a. Patients with known or suspected meningococcal infection, rubella, mumps, pertussis, diphtheria, or hemorrhagic fevers should be placed in a single examination room. If this is not possible the patient shall maintain a one meter spatial separation between other patients.
   
   b. Surgical/procedure masks should be worn by all healthcare workers that must come within one meter of the patient.
   
   c. The patient shall wear a surgical/procedure mask during transport and movement through the facility.

3. Contact Transmission Precautions
   
   a. Patients with known or suspected diarrhea, extensive skin or wound infection not contained by dressings, hemorrhagic fevers, meningitis, hepatitis, herpes simplex-disseminated, scabies (extensive or Norwegian/crusted), varicella, disseminated or extensive uncovered zoster and Antibiotic Resistant Organisms (ARO) should be placed in a single examination room. If this is not possible, a spatial separation of one meter shall be maintained between patients.
   
   b. Gloves should be worn when entering the patient’s room or designated examination space.
   
   c. Gloves shall be removed before leaving the patient’s room or designated examination space.
   
   d. Hands shall be washed immediately, first with soap and water if visibly soiled, then an antiseptic agent.
   
   e. Equipment and surfaces in direct contact with the patient or infective materials shall be cleaned before the room is used by another patient.

14.6.4 General Environmental and Equipment Cleaning

1. Walls, blinds and curtains should be cleaned regularly and when soiled.

2. Floors should be cleaned regularly, with damp mopping preferred.

3. Carpets/upholstery should be vacuumed regularly and shampooed as necessary.

4. Toys shall be regularly cleaned, disinfected with a low level disinfectant, thoroughly rinsed and dried.
14.6.5 Equipment Cleaning, Disinfecting and Sterilization

1. There shall be written policies and procedures for cleaning and sterilizing specialized equipment as described in Health Canada – Infection Control Guidelines – Hand Washing, Cleaning, Disinfection and Sterilization in Health Care. This guideline is available on-line at www.phac-aspc.gc.ca/dpg_e.html#infection.

2. Personnel involved in the cleaning, disinfecting and sterilization of equipment shall be properly trained.

3. There shall be a designated area for soiled supplies. This area shall be physically separated from patient care areas and from areas housing clean and sterile supplies.

4. Personnel working in the soiled area shall have proper protective apparel for their personal protection.

5. Clean and sterile supplies shall be stored in an area protected from dust and moisture, with access limited to authorized personnel.

6. Sterile supplies shall be clearly marked.

7. Filters shall be used on all re-useable devices where there is potential for re-breathing through the device.

8. Mouth pieces and filters (if present) shall be replaced between patients.


14.7 Medical Emergencies

14.7.1 There shall be policies and procedures in place to deal with medical emergencies such as cardiac arrests.

14.7.2 There shall be a procedure in place for evacuating patients by stretcher.

14.7.3 Appropriate medical emergency equipment and supplies shall be kept in stock.

14.7.3.1 This shall include at a minimum:

1. oxygen;
2. appropriate sized masks based on study population;
3. salbutamol metered-dose inhaler with spacer device.

14.8 Cardiopulmonary Exercise Testing (Level III and IV)

14.8.1 Medical Supervision

1. A physician approved for Level III or IV pulmonary testing is responsible for assuring the competence of personnel involved in the conduct of cardiopulmonary exercise testing and that qualified medical care is available to the patient when urgently required.

2. The physician or an experienced person designated by the physician shall remain in direct observation of patients undergoing cardiopulmonary exercise testing;

3. One of the following shall be immediately available during challenge testing:
1. The medical director or a designated medical colleague approved to read level IV pulmonary function tests;

or

2. One of the following with current ACLS Certification:
   1. licensed physician,
   2. physician assistant,
   3. nurse practitioner,
   4. respiratory therapist,
   5. cardio pulmonary technologist;

or

3. A cardiac arrest response team.

14.8.2 Technical Personnel

Exercise Testing Assistant

An assistant to the supervising physician shall be immediately available to provide assistance during all tests. The assistant shall:

a. Be familiar with the conduct of exercise testing to the satisfaction of the physician supervising the test.

14.8.3 Preparation

1. The metabolic measurement system must be calibrated in accordance with the manufacturer’s instructions.

2. Each physician performing exercise testing shall ensure that following are completed and adequate for each patient before testing;

   1. A clinical history (When relying on a history or examination provided by the referring physician, the supervising physician is responsible for verifying the information and findings.)
   2. A physical examination;
   3. A 12-lead electrocardiogram;
   4. An assessment of the risk of exercise testing;
   5. Pulmonary Function Testing Reports
   6. Results of a resting oximetry.

14.8.4 Clinical Record

A clinical record shall be created for each patient which contains, at a minimum, the following;

1. Name of the patient and a second identifier;
2. Clinical history and physical examination;
3. Current medication list;
4. 12-lead electrocardiogram before and after the test;
5. Signed consent form;
6. Name of the test performed;
7. Total exercise time;
8. Exercise protocol used (mode and ramping protocol).;
9. Peak workload attained;  
10. Clinical response during and after testing;  
11. Oximetry results before, during and after testing;  
12. Respired gas exchange (VO2, VCO2, RQ) before, during and after testing if performed;  
13. Minute ventilation before, during and after testing;  
14. Blood gas exchange (PAO2 – PaO2) data, if performed;  
15. Spirometry results before and after testing, if performed;  
16. Presence or absence of arrhythmias;  
17. Measurement and character of ST-segments;  
18. Heart rates: estimated age-predicted target heart rate and heart rate achieved;  
19. Blood pressure measurements before, during and after testing;  
20. Reason for stopping the test;  
21. Interpretation of test results;  
22. Segments of electrocardiographic tracings from which interpretations are made.  
23. Name of Technician  
24. Name of Assistant  
25. Name of Supervising Physician  

14.8.5 Medical Emergencies  

1. The facility’s design shall permit uninterrupted resuscitation to be performed on unconscious patients during extrication on a stretcher and loading into an ambulance.  

2. In the absence of an on-site resuscitation team, the following medical emergency equipment and supplies shall be immediately available:  

   1. Stethoscope and portable sphygmomanometer with various cuff sizes;  
   2. Oral airways;  
   3. Bag-valve-mask device;  
   5. Endotracheal intubation equipment;  
   6. Intravenous equipment;  
   7. Appropriate syringes, tape, needles;  
   8. Oxygen supply;  
   9. Stretcher and backboard for CPR, if the stretcher is not suitable;  
   10. Emergency and cardiac drugs required for ACLS protocols; and  
   11. Cardiac defibrillator (Automatic External Defibrillators [AED] are acceptable).
15.0 Manuals

15.1 Laboratories shall have current and comprehensive manuals in place.

15.2 Manuals shall be site specific.

15.3 All procedures shall initially be reviewed and signed by the medical director.

15.4 Manuals shall contain the date of the original writing and dates of revisions.

15.5 Manuals shall contain the name and signature of the person who wrote the manuals and who performed each revision.

15.6 The manuals shall be readily accessible and all staff shall be aware of its content.

15.7 All procedures shall be reviewed annually and signed by the medical director or designate.

15.8 Any changes in the interim shall be approved and initialled by the director.

15.9 The following manuals shall be available in the laboratory:

15.9.1 Equipment Manual

1. Testing Equipment

   a. This manual shall include, as a minimum, for each piece of equipment:

      i. A list of contact personnel and phone numbers of appropriate maintenance personnel.
      ii. Manufacturer operating and troubleshooting instructions.
      iii. Preventative maintenance schedule and log
          • daily
          • weekly
          • monthly
          • annually
      iv. Record of repairs
      v. Location of software and back up disks or tapes.
      vi. Schedule for developing back up disks or tapes.
      vii. Procedure to be used in case of computer failure.
      viii. List of personnel who have access to information and software security codes.
      ix. Guidelines for protection of confidentiality of patient data.
      x. List of special procedures, calculations or results (e.g. back extrapolation method for calculation of FEV)
      xi. Location of software source code listing and, where appropriate, details of signal acquisition and processing algorithms should be described.
      xii. Schedules and procedures for routine maintenance of all equipment in the facility.
      xiii. A log detailing malfunctions which have occurred on each piece of equipment and maintenance procedures conducted.

   b. This manual should include a copy of any existing maintenance contracts.
15.9.2 Policy Manual

1. This manual shall include, as a minimum, the following sections:
   a. Organizational chart
   b. Staff/office policies
   c. Procedure policies

15.9.3 Procedure Manual

1. Pulmonary Function Procedures
   a. The manual shall contain a written procedure for each procedure done.
   b. This manual shall include, as a minimum, the following for each procedure:
      i. Name of Procedure
      ii. Principle - purpose of procedure
      iii. Equipment and supplies used
      iv. Patient preparation
      vi. Protocol and schedules for calibration checks
         • Log of calibration reports
      vii. Quality control protocol and schedules
         • Defined limits for control results or standards
         • Corrective action to be taken if results are outside defined limits
         • Log of quality control and standard subjects
      viii. All equations used for calculating results
      ix. Known interferences, limitations, or contraindications
      x. Special precautions
         • Safety
         • Sterilization Procedures
      xi. Reference Values
         • Age, gender and race specific, where applicable
      xii. Clinical significance
      xiii. Guidelines to recognize poor patient effort
      xiv. Guidelines to recognize test-induced alterations in lung function
      xv. Urgent findings e.g. Major changes from previous test: upper airway obstruction pattern.
      xvi. Reporting results
      xvii. References
   c. Procedures shall be in place for accommodating patients when equipment malfunction occurs.
2 Blood Gases/Co-oximetry
   a. Name of procedure
   b. Principle - purpose of procedure
   c. Equipment and supplies used
   d. Specimen requirements
       • Patient preparation
       • Amount and type of blood
       • Collection technique
       • Specimen handling
       • Labelling requirements
       • Criteria for specimen rejection
   e. Reagents, Standards, Controls
       • Source of supply
       • Storage requirements
       • Directions for preparation/use
       • Stability of product
   f. Procedure
       • Step-by-step directions
       • Calibration protocol
       • Use of controls - schedule and frequency
   g. Quality Control
       • Tolerance limits
       • Rules for assessing quality control results
       • Recording quality control results
       • Linearity
       • Precision
       • Corrective action for out-of-control results
       • Log recording quality control
   h. Known interferences of limitations
   i. Special Precautions
       • Safety
       • Cleaning and sterilizing equipment
   j. Normal reference ranges
   k. Clinical significance
   l. Critical values
   m. Reporting results
   n. References

15.9.4 Safety Manual

1. This manual shall include, as a minimum, the following sections:
   a. General Safety
   b. Incidents
   c. Fire Safety
   d. Electrical Safety
   e. Compressed Gases
   f. Infection Control
   g. Medical Emergencies
       • Contraindications to patients
       • CPR procedure
       • Procedure for evacuating patients by stretcher
       • List of emergency supplies/equipment to be kept in stock
       • List of emergency phone numbers
Appendix A - Cleaning, Disinfecting and Sterilizing Office Instruments

These guidelines have been developed out of concern for patient care, safety and infection control, especially in light of the increasing number of procedures done in physicians’ private offices.

I. Definitions

1. Cleaning

All instruments to be disinfected or sterilized must first be thoroughly cleaned to remove all organic matter (blood and tissue) and other residue. This must precede disinfection and sterilization procedures as organic matter shields organisms from destruction and may inactivate some disinfectants. Disinfection time increases when more organisms are present.

Technique:

- The cleaning process is carried out using appropriate protective apparel – gloves, mask and gowns or aprons if splashing is anticipated.
- Those personnel responsible for cleaning, disinfecting and sterilizing sharps should be urged to be immunized against Hepatitis B as should others who have direct contact with patients and biological specimens.
- The articles are washed in hot sudsy water with bottle or special brushes, scrubbers, etc. keeping below the water line when possible, to reduce aerosolization.
- Care must be taken to remove all organic matter as appropriate to the article, (eg. with fiberoptic endoscopes – getting into the ports and channels which should be flushed or suctioned with water immediately after use to prevent drying of organic materials, especially inside suction channels).

2. Disinfection

Process that eliminates many or all pathogenic micro-organisms on inanimate objects with the exception of bacterial spores.

Technique:

Use of liquid chemicals – 2% glutaraldehyde, 6% hydrogen peroxide, peracetic acid, chlorine dioxide are the only chemicals sufficiently sporicidal to accomplish sterilization with an exposure time of 6-10+ hours. In the case of critical items sterile water must be used for rinsing. Boiling – should be for 5 full minutes after water reaches the boiling point.

- disinfectant: a chemical agent that inactivates most recognized pathogenic micro-organisms (exception – spores) on inanimate objects.
- antiseptic: a chemical agent for use on skin or tissue; it should not be used as a disinfectant unless label instructions indicate this is permissible.

3. Sterilization

Complete elimination or destruction of all forms of microbial life.

Technique:
autoclave – steam under pressure – (Should be used unless the instrument will be damaged by heat, pressure or moisture.)
chemical sterilization – cold tray sterilization – (Use only for instruments intolerant of heat eg. fiberoptic endoscopes.)
dry heat sterilization – acceptable method but takes approximately 24 hours longer to produce sterility than steam autoclaving.
sterile items to be stored must first be completely dry, and should be packaged, sealed and dated before sterilization. Use should occur within 30 days.
if sterility need not be maintained (eg. speculums) such items can be stored in a clean cabinet or drawer in the examining room.

II. Rationale for cleaning, disinfecting, or sterilizing reusable patient care equipment can be understood more readily if medical devices, equipment and surgical materials are divided into three categories based on the potential risk of infection involved in their use.

Spaulding’s classification of devices/medical instruments

<table>
<thead>
<tr>
<th>Object &amp; Classification</th>
<th>Use of Item</th>
<th>Example</th>
<th>Decontamination required after cleaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Enters vascular system or sterile body tissues</td>
<td>scalpels and other surgical instruments such as biopsy forceps</td>
<td>Sterilization and holding in sterilized state. High level disinfection is not sufficient</td>
</tr>
<tr>
<td>Semi-Critical</td>
<td>Comes in contact with intact mucous membranes</td>
<td>thermometer, vaginal speculum, sigmoidoscope</td>
<td>High level disinfection (by heat or chemicals)</td>
</tr>
<tr>
<td>Non-Critical</td>
<td>Comes in contact with intact skin</td>
<td>examining table top, blood pressure cuff, baby weigh scale</td>
<td>Intermediate or low level disinfection</td>
</tr>
</tbody>
</table>

Spaulding’s Levels of Disinfection according to type of micro-organisms

<table>
<thead>
<tr>
<th>Levels</th>
<th>Vegetative Bacteria</th>
<th>TB</th>
<th>Spores</th>
<th>Fungi&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Lipid &amp; medium size viruses</th>
<th>Non Lipid &amp; small viruses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>2</td>
<td>+</td>
<td>3</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Intermediate</td>
<td>+</td>
<td>+</td>
<td>±&lt;sup&gt;4&lt;/sup&gt;</td>
<td>+</td>
<td>+</td>
<td>±&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td>Low</td>
<td>+</td>
<td>+</td>
<td>±</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
</tbody>
</table>

1 Includes asexual spores but not necessarily chlamydospores or sexual spores.
2 Plus sign indicates that a killing effect can be expected when the normal use concentrations of chemical disinfectants or pasteurization are properly employed. A negative sign indicates little or no killing effect.
3 Only with extended exposure times are high-level disinfectant chemicals capable of actual sterilization.
4 Some intermediate-level disinfectants can be expected to exhibit some sporicidal action.
5 Some intermediate-level disinfectants may have limited viricidal activity.

<table>
<thead>
<tr>
<th>Levels of Disinfection</th>
<th>Class of Disinfectant</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-level disinfectant</td>
<td>2% glutaraldehyde, 6% hydrogen peroxide, peracetic acid</td>
</tr>
<tr>
<td>Intermediate to high</td>
<td>Chlorine compounds</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Alcohols, Iodophors</td>
</tr>
<tr>
<td>Intermediate to low</td>
<td>Phenolics</td>
</tr>
<tr>
<td>Low</td>
<td>Quaternary ammonium compounds, “quats”</td>
</tr>
</tbody>
</table>

III. Disposable Items

Those labelled “Disposable, for single use only” by the manufacturer.

These items should only be reused with written manufacturers’ instructions or, in hospitals, under approval and policies of hospital “Reuse of Disposables” Committees.

IV. Policies and Procedures

Policies and procedures should be developed by each office concerning cleaning, disinfecting and sterilizing office instruments. These should be consistent with the above recommendations and/or manufacturers’ suggested guidelines for specific products. In addition, personnel should receive specific training regarding this responsibility.

Questions may be directed to Infection Control Practitioners and/or Sterile Processing Department (Central Supply) staff at the larger active treatment hospitals.

Acknowledgement to the Infection Control Unit, Caritas Health Group for assistance in preparing this document.
References

2. Laboratory Centre for Disease Control (LCDC), Health Services and Promotion Branch, Department of National Health and Welfare, Ottawa, 1985, Infection Control Guidelines: Cleaning, Disinfecting and Sterilizing Patient Care Equipment
7. D.C. Drummond, A.G. Skidmore by permission of the publisher, CMAJ 1991; 145(8) and The College of Physicians and Surgeons of British Columbia