Standards & Guidelines

June 2017 v15



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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.

Cardiac Exercise Stress Testing 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 Medical Facility Accreditation Committee considers any issues regarding the provision of cardiac exercise stress testing services in private facilities, including, but not necessarily limited to the following:

- 1. Advise Council on accreditation standards for the ownership and operation of diagnostic and treatment facilities in Alberta;
- 2. Investigate and assess the ownership and operation of such facilities;
- 3. Establish, develop and administer a program of review and assessment of such facilities;
- 4. Confirm that the practice of medicine conducted in such facilities and the financial arrangements pertaining thereto are in accordance with the College's bylaws and Council's policies;
- 5. Advise Council on matters referred to the Committee regarding standards of practice for the use of new health technology in medical practice;
- 6. Advise Council on matters referred to the Committee regarding the qualifications of physicians for medical practice in addition to their recognized specialties.

All accredited medical facilities must have a Medical Director who is accountable for the practice of medicine within the facility. Medical Directors must also be satisfied as to the professional standing of other professionals working in the facility 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 <u>requirement</u> for accreditation;
- "should" is used when a section is <u>recommended</u>; and
- "may" is used when a section is <u>discretionary</u>.

These standards and guidelines are reviewed periodically and revised when necessary. Input from facilities is encouraged to assist in keeping the standards and this document up to date.

2.0 Role of the College

2.1 Accreditation of Facilities

- 2.1.1 All private facilities performing cardiac exercise stress testing shall register with and maintain accreditation by the College.
- 2.1.2 The College's Standard of Practice #20 Direction and Control of Medical Practice are applicable to privately owned facilities.
- 2.1.3 Accreditation involves verification of compliance with approved standards by way of one or more of the following processes at periodic intervals:
 - 1. Review of pre-assessment data verification form completed by the facility;
 - 2. Review of selected tracings, requisitions/in-house worksheets, reports and other records from the facility;
 - 3. Review of the facility's manuals of policies and procedures;
 - 4. Review of qualifications and training of medical and technical personnel;
 - 5. Assessment of the facility and medical equipment.
- 2.1.4 Each review is conducted by one or more physicians with expertise in cardiac exercise stress testing designated by the College.
- 2.1.5 "Provisional Accreditation" may be granted for up to a 1-month period until minor deficiencies are corrected. A written response to each deficiency is required from the Medical Director of the facility. A follow-up assessment may be required at the sole discretion of the College.
- 2.1.6 An audit of records will be performed by a reviewer for the College within three months of the facility commencing testing.
- 2.1.7 "Full Accreditation" will be granted when responses to deficiencies have been corrected to the satisfaction of the College.
- 2.1.8 The College may revoke accreditation at any time if practice in the facility is considered unsafe.
- 2.1.9 A "Certificate of Accreditation" will be issued by the College to all facilities with "Full Accreditation".
- 2.1.10 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 (refer to Section 2.1.3)
- 2.1.11 Payment to the College for the cost of the assessment is the responsibility of the Medical Director of the facility.
- 2.1.12 "Spot" assessments may be conducted without prior notice. 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 The College shall be advised of any change of ownership of the medical practice or Medical Director of the facility.
- 2.2.3 Each facility shall pay an annual fee, set by Council, for the administration of the accreditation program.

3.0 Personnel

3.1 Medical Director

3.1.1 Qualifications

- 1. The director of each facility shall be:
 - a. A physician licensed to practice medicine in Alberta,

-and-

 Qualified and approved by the College to supervise and interpret cardiac exercise stress tests.

3.1.2 Role

- 1. The Medical Director shall have direct control and be responsible for provision of medical services in the facility.
- 2. Responsibilities may include, but are not restricted to, the following:
 - a. The day to day direction and supervision of the practice of medicine.
 - Providing continuous, adequate and effective direction and supervision of clinical staff.
 - c. Ensuring an adequate quality assurance program is in place.
 - d. Selection of testing procedures and equipment used.
 - e. Ensuring these standards are met.
 - f. Establishing and maintaining effective and appropriate safety procedures.
 - g. Ensuring appropriate policy and procedure manuals are in place and up-to-date.
 - h. Remitting payment for the annual fee and accreditation review.
 - i. Making requested documentation available for accreditation.

3.2 Interpreters

· 3.2.1 Approval

- 1. A person approved to supervise and interpret cardiac exercise stress tests shall:
 - a. Be a physician licensed to practice medicine in Alberta,

-and-

Be recognized in Alberta as a specialist in cardiology.

-or-

b. Be a physician licensed to practice medicine in Alberta,

-and-

Be approved by the College to interpret ECG's,

-and-

Maintain up-to-date certification in advanced cardiac life support (ACLS),

-and-

Provide satisfactory evidence of training and competence assessment in cardiac exercise stress testing.¹

3.2.2 Re-approval

1. A physician who has been approved or grandfathered, but who has not been in the active practice² of cardiac exercise stress testing for the last <u>three years</u>, will be required to take additional training at a cardiac exercise stress testing facility approved by Council,

-and-

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

3.2.3 Supervision

1. A physician approved to supervise cardiac exercise stress testing shall remain in direct observation of patients undergoing testing.

3.3 Non-Medical Personnel

- 3.3.1 Cardiac Exercise Stress Test Assistant
 - An assistant to the supervising physician shall be immediately available to provide assistance during all tests.

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The minimum training acceptable includes 2 weeks of full-time participation with direct involvement in 100 studies under the supervision of a specialist in cardiology or a specialist in internal medicine with a faculty appointment. This minimum number is consistent with recommendations of the American Heart Association. The training program must include hands-on participation in decision-making. Applicant must provide written evidence of competence in selecting patients, conducting testing, interpreting tests and preparing recommendations. If testing includes pharmacological stress testing, then evidence of training and/or experience with that technique is also required.

² "Active practice" refers to physicians interpreting a minimum of 75 studies per year.

2. The assistant shall:

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

-and-

b. Have current certification in cardiopulmonary resuscitation.

4.0 Requests for Procedures

- 4.0.1 Information available prior to procedures being performed should include the following:
 - 1. Patient's name, address, date of birth, phone number
 - 2. Name of referring physician or nurse practitioner
 - 3. Tests requested
 - 4. Pertinent history including: medications; pre-test likelihood of ischemic heart disease.

5.0 Cardiac Exercise Stress Testing Equipment

- 5.0.1 Cardiac Exercise Testing Equipment appropriate for these facilities include:
 - 1. Treadmill and Cycle ergometer

6.0 Preparation

- 6.0.1 Each physician performing a cardiac exercise stress test shall ensure the following are completed and adequate for each patient before testing:
 - 1. A clinical history
 - 2. A physical examination
 - 3. A 12-lead electrocardiogram
 - 4. An assessment of the risk of stress testing

(When relying on a history or examination provided by the referring physician, the supervising physician is responsible for verifying the information and findings.)

7.0 Reports and Records

7.1 Log of Procedures

- 7.1.1 The facility shall keep a log containing all tests performed in the facility.
- 7.1.2 This log shall contain, at a minimum, the following:
 - 1. Name of the patient and second identifier (e.g. ULI, date of birth)
 - 2. Name of the supervising physician
 - 3. Date of the test
 - 4. Type of test (if more than one is performed in the facility)

7.2 Clinical Record

- 7.2.1 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. Clinical response during and after testing
 - 9. Presence or absence of arrhythmias
 - 10. Measurement and character of st-segments
 - 11. Heart rates: estimated age-predicted target heart rate, and heart rate achieved
 - 12. Blood pressure measurements before, during and after testing
 - 13. Reason for stopping the test
 - 14. Interpretation of test results
 - 15. Segments of electrocardiographic tracings from which interpretations are made.

7.3 Report to Referring Physician

- 7.3.1 The contents of reports to referring physicians shall include at a minimum:
 - 1. The name and second identifier of the patient
 - 2. The reason for performing the test
 - 3. The reason for stopping the test
 - 4. The interpretation of the test, including recommendations and any actions taken.
- 7.3.2 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).

7.4 Reportable Incidents

7.4.1 Medical Examiner

- 1. In the event of a death within the facility, the Medical Examiner shall be notified prior to moving the body or removal of any lines or tubes from the body.
- 7.4.2 College of Physicians and Surgeons of Alberta
 - 1. The Medical Director shall notify the College of Physicians and Surgeons of Alberta (Accreditation Department) within one working day of a reportable incident, including:
 - a. Deaths within the facility
 - b. Cases requiring cardiopulmonary resuscitation within the facility
 - 2. Within **two weeks** of notification, the following shall be submitted to the College:
 - a. Completed reportable incident form signed by the Medical Director
 - b. Copy of the facility clinical record
 - c. Narrative summary describing the incident by the most involved physician

The Registrar will review the circumstances with the Medical Director and may consult with other practitioners to determine the risk of harm to patients. If necessary, the Registrar may suspend the accreditation of any facility on a suspicion of continuing risk. An investigation of the facility will then be initiated as soon as is reasonably possible.

3. There shall be a log kept of any complications requiring transfer to hospital.

8.0 Retention of Records

- 8.0.1 The entire clinical record shall be retained for a minimum of ten years by electronic means or hard copy. In the case of minors, the records shall be retained for ten years or until the patient is at least two years beyond the age of majority, whichever is greater.
- 8.0.2 Records pertaining to quality assurance in the laboratory shall be kept for a minimum of two years.

9.0 Quality Assurance

- 9.0.1 A quality assurance program shall be in place to ensure compliance with these standards.
- 9.0.2 The content and format is flexible, but the program at a minimum shall monitor:
 - 1. Staff Competency
 - CEST Assistants
 - There shall be a process to ensure that cardiopulmonary resuscitation certificates held by CEST assistants are current.
 - There shall be an annual documented review of the performance of CEST assistants, which assesses their knowledge and performance in routine and difficult cases.
 - Physicians
 - A peer review process shall be in place for interpreting physicians to participate in the cross-reading of cases annually.
 - 2. Equipment Performance
 - There should be a schedule of preventative maintenance (including testing of cardiac defibrillator)
 - There should be documentation of all trouble shooting.
 - Equipment should be assessed at least annually and assessments and service should be documented.
 - 3. Laboratory Technique and Procedure
 - There shall be a process to review the adequacy of information available from which to estimate the pre-test likelihood of ischemic heart disease.
 - There should be procedural checklists available to ensure consistent technique.
 - 4. Reporting
 - The turn-around-time for reports following studies performed routinely and urgently, shall be monitored.
 - 5. Medical Records
 - There shall be regular audits of medical records to assess completeness/content.
 - Records shall be stored in such a way (medium) that they are readily retrievable and in a suitable environment to prevent damage or deterioration, loss, and unauthorized access.
 - 6. Safety
 - A distinct log of incidents, which either harmed or could have harmed a patient or staff, including the action taken to prevent future occurrences, should be maintained.
 - 7. Utilization (e.g. rates of abnormal findings, results of follow-up review of cases)
 - There should be a process to advise referring physicians of the indications, contraindications and preparation required for cardiac exercise stress testing.
 - 8. Client Satisfaction
 - CEST facilities should conduct patient and physician satisfaction surveys and document them on a yearly basis. Surveys should sample aspects of the medical service, directions to the facility, pre-test instructions, etc.

10.0 Equipment

10.0.1 Equipment should meet or exceed the standards of the Canadian Standards Association or its equivalent.

11.0 Safety

11.1 General Safety

- 11.1.1 The laboratory shall have a Safety Manual, which is specific to the laboratory. It should be readily available to all personnel and there should be evidence that they are aware of its content.
- 11.1.2 Policies and procedures should 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.

11.2 Fire Safety

11.2.1 This shall be specific for the facility and conform to regulations of the local fire department.

11.3 Electrical Safety

11.3.1 All equipment should be checked for grounding and checked for current leakage at least annually.

11.4 Medical Emergencies

- 11.4.1 The facility's design shall permit uninterrupted resuscitation to be performed on unconscious patients during extrication on a stretcher and loading into an ambulance.
- 11.4.2 There shall be policies and procedures in place to deal with medical emergencies.
- 11.4.3 The following medical emergency equipment and supplies shall be readily available:
 - 1. Stethoscope and portable sphygmomanometer with various cuff sizes
 - 2. Oral airways
 - 3. Bag-valve-mask device
 - 4. Endotracheal intubation equipment
 - 5. Intravenous equipment
 - 6. Appropriate syringes, tape, needles
 - 7. Oxygen supply
 - 8. Stretcher and backboard for CPR, if the stretcher is not suitable
 - 9. Emergency cardiac drugs
 - a. As required in current ACLS guidelines
 - b. ASA non-coated chewable tablets; 81 mg or 325 mg
 - c. Nitroglycerin spray
 - 10. Cardiac defibrillator

11.4.4 Mock Drills

Mock drills to prepare employees for emergency situations such as cardiac arrest, shall be conducted at least every six months. The type of drill and employee attendance shall be documented.

11.5 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.

11.5.1 Occupational Health/Immunization

The Occupational Health and Safety Act, Regulation and Code will also apply. Copies of the OHS Act, Regulation and Code, and "A Physician's Guide to Occupational Health and Safety Responsibilities" are available on-line at www.worksafely.org.

- 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.
- 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).

11.5.2 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 re-use of critical or semi-critical medical equipment labeled as single-use by the manufacturer.
- 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.

11.5.3 Additional Precautions

- 1. Airborne Transmission Precautions
 - 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 shall be worn by all healthcare workers who enter the examination room of a patient with infectious tuberculosis.
 - d. High efficiency dust/mist masks 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.
 - 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 know 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.
- 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.

11.5.4 General Environmental and Equipment Cleaning

- Chairs, cabinets and charts are not usually an infection risk, but should be cleaned on a regular basis.
- 2. Walls, blinds and curtains should be cleaned regularly and when soiled.
- 3. Floors should be cleaned regularly, with damp mopping preferred.
- 4. Carpets/upholstery should be vacuumed regularly and shampooed as necessary.
- Toys shall be regularly cleaned, disinfected with a low level disinfectant, thoroughly rinsed and dried.

11.5.5 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.phacaspc.gc.ca/dpg_e.html#infection.*
- 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.

12.0 Manuals

- 12.0.1 The facility shall have current policy and procedure manuals.
- 12.0.2 All procedures shall be approved and signed and reviewed annually by the medical director.
- 12.0.3 The following manuals shall be available in the laboratory:
- NOTE: The following headings may be used as a template. It is not the role of the College to prepare or provide manuals for facilities.

12.1 Policy Manual

- 12.1.2 This manual should include, as a minimum, the following sections:
 - Organizational chart
 - Staff/office policies including qualifications required
 - Procedure policies based on list of procedures offered

12.2 Procedure Manual

- 12.2.1 This manual should include, as a minimum, the following for each procedure performed:
 - Name and description of the procedure
 - Equipment used
 - Patient preparation
 - Reception/documentation
 - Indications for the procedure
 - Contra-indications to the procedure
 - Indications for termination of the procedure
 - Recording and documentation of Procedure

12.3 Safety Manual

- 12.3.1 This manual should include, as a minimum, the following sections:
 - Management of medical emergencies
 - Recording of incidents

12.4 Equipment Manual

- 12.4.1 This manual should include, as a minimum, for each piece of equipment:
 - List of contact personnel
 - Manufacturer operating and trouble shooting instructions
 - Copy of maintenance contract, if applicable
 - Preventative maintenance schedule
 - Daily
 - Weekly
 - Monthly
 - Annually
 - Preventative maintenance
 - Repairs
 - Electrical checks

13.0 Research

- 13.0.1 Research activities involving patients or information about patients, whether or not the results are submitted for publication, shall not be conducted in the facility unless approved by one of the following:
 - 1. The Research Ethics Review Committee of the College of Physicians and Surgeons of Alberta;
 - 2. The Health Research Ethics Advisory Board of the Capital Health Authority, University of Alberta, and Caritas Health Group;
 - 3. The Conjoint Health Research Ethics Board of the Faculty of Medicine, University of Calgary;
 - 4. The Alberta Cancer Board