Cardiac Care Network

Standards for Provision of Echocardiography in Ontario

2012

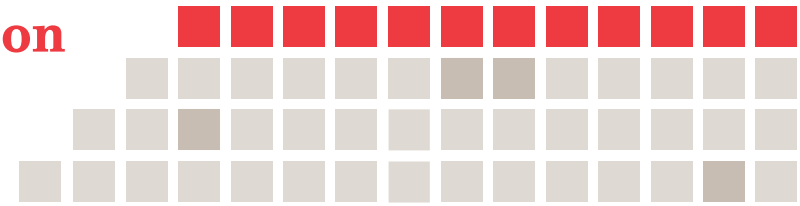

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TABLE OF CONTENTS

Introduction

The Cardiac Care Network of Ontario (CCN) serves as system support to the Ontario Ministry of Health and Long-Term Care (MOHLTC), Local Health Integration Networks and service providers and is dedicated to improving quality, efficiency, access and equity in the delivery of adult cardiovascular services in Ontario.

In January 2011, CCN was asked by the MOHLTC to convene an Echocardiography Working Group for the purpose of developing a report to include proposed standards of practice, guidelines, credentialing and accreditation criteria for echocardiography in Ontario. These standards were to be based on the guidelines published by the Canadian Society of Echocardiography (CSE), and where relevant, to include guidelines by other professional groups and associations.

The CCN Echocardiography Working Group was Chaired by Dr. Anthony Sanfilippo (Kingston, Ontario). Committee membership included clinical stakeholders in the delivery of echocardiography services in Ontario, in addition to representatives from the MOHLTC and Ontario Medical Association. Our final report was submitted to the MOHLTC in April 2012.

On behalf of CCN, I would like to thank Dr. Sanfilippo and the members of the CCN Echocardiography Working Group for their clinical expertise and countless hours contributed to this important initiative. We look forward to continuing to work with key stakeholders on the implementation of these standards and recommendations for echocardiography in Ontario.

Kori Kingsbury,
Chief Executive Officer
Cardiac Care Network

The history of Echocardiography over the past several decades is one of progressive technical development, occurring in tandem with increasing clinical relevance. It is now an essential component in the assessment and management of patients presenting with a wide variety of cardio-respiratory illness. It is also being increasingly used to identify patients who may benefit from an expanding array of medical and procedural therapies. These expanded applications have resulted in increasing financial impact, and a call from both physicians and providers for a more robust framework to ensure both quality and appropriate utilization.

It is in that context that a panel was convened in 2011 at the joint request of the Ministry of Health and Ontario Medical Association, and under the auspices of the Cardiac Care Network, to review and update standards of practice and to frame those standards in a way that would allow for evaluation and review. The panel took as its guiding principle the desire to ensure that patients undergoing echocardiographic examinations in Ontario would be assured of receiving quality, timely and clinically appropriate service. It is in that spirit of collaboration and mutual interest for the welfare of our patients that these recommendations are respectfully submitted.

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Standards for Provision of Echocardiography in Ontario

In 2005 the Canadian Society of Echocardiography and the Canadian Cardiovascular Society jointly published guidelines regarding the provision of echocardiography services in Canada[1]. Those guidelines, which were reviewed by a geographically and professionally diverse group of individuals involved in the practice of echocardiography, addressed all components of service delivery and were intended to promote quality and patient care. Since then, Echocardiography has become even more solidly entrenched as a key diagnostic procedure relevant to a wide spectrum of clinical disease. Its utilization has therefore continued to increase steadily and most provincial jurisdictions have imposed some form of regulatory framework to guide provision. In that regard, Ontario is a notable exception. The purpose of this document is twofold:

1. To update the guidelines provided in the 2005 document taking into account advances in technology and clinical applications that have developed since then.
2. To describe a process for accreditation of echocardiography laboratories that might be undertaken in Ontario.

For the purposes of this document the term Echocardiographic Laboratory will be defined as a facility whose primary purpose is to provide echocardiographic examinations. Such facilities may vary greatly in size (single to multiple imaging systems), site (office, clinic, hospital) and scope of examinations provided (inpatient, outpatient, emergent), but will be characterized by the following features:

- Provision of full transthoracic adult examinations
- Acceptance of referrals for echocardiographic examinations
- Space, equipment and procedures appropriate to provide such examinations
- Engagement of appropriately trained personnel to carry out and assist with the provision of echocardiographic examinations
- Engagement of appropriately trained physicians to interpret and supervise examinations
- Recording and reporting of the results of those examinations
- In addition, some laboratories may also provide the following services, which require additional service and professional considerations:
- Pediatric echocardiographic examinations
- Transesophageal echocardiography
- Intraoperative transesophageal echocardiography
- Stress echocardiography

[1]Can J Cardiol 2005 Jul; 21(9):763-80.

The framework of this document will follow from these requirements and the original 2005 document. It will therefore be structured in the following sections:

Section 1. Standards with respect to the echocardiographic examination.

Section 2. Standards for echocardiographic equipment, facilities and procedures.

Section 3. Standards regarding reporting of echocardiographic studies.

Section 4. Standards regarding personnel involved in echocardiographic examinations.

Section 5. Indications for echocardiographic examinations.

Section 6. Continuing quality assurance in the echocardiographic examination and laboratory.

Section 7. Framework for accreditation of echocardiographic facilities.

Within each of the first six sections, a conceptual framework will be provided, describing the specific characteristics of optimal service provision. In addition, **standards** will be described, which are defined as **demonstrable performance characteristics that could provide evidence of quality service provision**. In their entirety, standards provide a means of identifying appropriate service and ensuring all patients receive timely and effective assessment.

Section 1:

Standards Regarding the Echocardiographic Examination

The echocardiographic examination utilizes the full complement of imaging and non-imaging modalities to provide a comprehensive assessment of cardiac structure and function. Fundamental and harmonic imaging is used to optimize visualization of cardiac structures. When the imaging is suboptimal, the use of an echocardiographic contrast agent can be used to enhance visualization. Cardiac function and intracardiac hemodynamics are assessed by a comprehensive Doppler examination including pulsed-wave, continuous wave, and colour flow. Tissue Doppler imaging should be considered in most cases to provide additional information on systolic and diastolic function.

A **comprehensive (complete) study** is the goal in every patient. A complete study is defined as one that examines all the cardiac chambers and valves and the great vessels from multiple views, complemented by Doppler examination of every cardiac valve, the atrial and ventricular septa for antegrade and retrograde flow. When a specific view or Doppler signal is unavailable, the reason is to be documented.

A **focused study** is an examination limited to a single component of the cardiac assessment usually performed in the emergency situation to guide immediate management or to re-assess a specific and active clinical issue.

Proper performance of the study must include adequate explanation of the procedure and respectful interaction with the patient. Although the sequence of views may vary according to local practice, the full complement of views including Doppler tracings and measurements should be obtained and recorded in every patient. Specific comments on the quality of study are included with comments on technical deficiencies such as foreshortening and inadequate alignment in relation to Doppler assessment.

Standard E1: Echocardiographic facilities will have established protocols that describe the components of the comprehensive examination:

Laboratories must establish protocols for the acquisition and recording of echocardiographic examinations. These protocols should be reviewed and accepted by all sonographers and physicians involved and must be made available to all and reviewed on a regular basis.

Standard E2: The comprehensive echocardiographic examination will contain the following imaging components:

- Parasternal long axis of the left ventricle, left atrium and aorta.
- Parasternal short axis consisting of three short-axis cuts of the left ventricle (base, mid, apex), pulmonary artery view and aortic valve view.

- Right ventricular inflow view.
- Right ventricular outflow view.
- Apical four-chamber view.
- Apical two-chamber view.
- Apical three-chamber view (long-axis view).
- Apical five-chamber view.
- Apical imaging with particular attention the left ventricular (LV) apex.
- Subcostal long-axis view.
- Subcostal short-axis view.
- Subcostal inferior vena cava view.
- Suprasternal views of the aorta.

Standard E3: The comprehensive examination will contain the following Doppler components:

- Parasternal long-axis two-dimensional (2D) with colour screening for aortic insufficiency and mitral regurgitation.
- Parasternal short-axis 2D with pulmonary artery colour and pulsed wave Doppler.
- Right ventricle inflow view 2D with colour for tricuspid regurgitation.
- Apical-four chamber view 2D with colour for mitral regurgitation and tricuspid regurgitation; pulsed and continuous wave.
- Apical five-chamber view with colour for aortic and mitral regurgitation and pulsed/continuous wave Doppler of the aortic flow velocity.
- Apical three-chamber (long-axis) view 2D with colour and aortic flow velocity.
- Apical two-chamber with colour flow Doppler of the mitral valve.
- Subcostal view with colour Doppler of the interatrial septum.
- Suprasternal view with colour and pulsed wave/continuous wave Doppler of the descending aorta.

Standard E4: The comprehensive examination will contain the following standard measurements:

The following standard measurements must be obtained and recorded for all studies. Either M-mode or 2D can be used to obtain the measurements at end expiration, based on their respective strengths and limitations in specific situations.

- LV systolic and diastolic dimensions.
- LV diastolic wall thickness (septum and posterior wall).
- Ejection fraction (this should be quantitated whenever technically possible by one of the validated methods (preferably by Simpson's biplane Method of Discs) and the method used should always be identified. Visual estimation should be reserved for cases in which quantitative assessment is not technically feasible.
- Transvalvular aortic flow velocity.
- Pulmonary valve velocity.
- Diastolic parameters should be determined according to the current guidelines, and diastolic function classified into categories of normal, mild dysfunction (impaired relaxation), moderate dysfunction (pseudonormalization) and severe dysfunction (restriction). This assessment is based on consideration of the relevant parameters available from the Echocardiographic examination which can include mitral inflow velocities, mitral deceleration time, isovolumic relaxation time, pulmonary venous systolic and diastolic velocities, and tissue Doppler assessment of mitral annular motion.
- Tricuspid regurgitation velocity to calculate right ventricular (RV) systolic pressure.
- Measurements of the aortic root and ascending aorta (sinuses of Valsalva and proximal ascending aorta) and to include the annulus if indicated.
- Left atrial dimensions.

Standard E5: The facility will have established procedures to provide the following additional information where clinical indications or findings warrant:

- Blood pressure and heart rate should be included in the setting of valvular heart disease to allow proper assessment of intracardiac hemodynamics.
- Transvalvular mean and maximal gradients with continuous wave Doppler for stenotic valves and valvular prostheses, including views from multiple windows, such as the suprasternal and right sternal border.
- Spectral display of complete envelope of continuous wave Doppler signal of valvular regurgitation.
- Proximal isovelocity surface area calculation or other quantitative methods for assessment of valvular regurgitation.
- Respiratory variation of mitral and tricuspid inflow Doppler (eg, pericardial disease).
- Hepatic venous flow pattern and inferior vena cava collapse.
- Shunt calculation.
- Descending aortic velocity and presence of flow reversal, for assessment of aortic coarctation and regurgitation.
- Protocols to address the assessment of patients with technically inadequate images that do not allow for reliable evaluation of the clinical issue in question. This should include any or all of the following:
  - Saline contrast injection.
  - Use of contrast agents to improve endocardial visualization.
  - Referral to a reference laboratory.
  - Referral to alternative available imaging modalities.
  - Provision of transesophageal echocardiography.

Section 2:

Standards Regarding Echocardiographic Facilities, Equipment and Procedures

2.1 The Examining Room

A complete echocardiographic examination takes between 30 and 60 minutes. During this time, patient privacy and comfort must be maintained. In addition, the sonographer must be able to carry out the examination in a manner that minimizes physical stress and the risk of repetitive stress injury, and infection control practices must be provided.

Standard F1: Echocardiographic examining rooms must provide the following:

- Approximately 120 – 150 square feet of space with adequate ventilation and temperature control.
- An examining bed appropriate to echocardiographic image acquisition.
- Adjustable chairs for sonographers with back support.
- Patient privacy must be assured with the use of either appropriate curtains or doors.
- A sink and antiseptic soap must be readily available for handwashing in accordance with the infection control policy of the hospital or laboratory.

2.2 Echocardiographic Imaging Systems

Fully equipped, highly functioning and well maintained equipment is essential if optimal examinations are to be produced. Because echocardiography has been and continues to be the subject of rapid technological advances, the definition of "state of the art" is a moving target. In addition, although multiple manufacturers are known to produce excellent equipment, there is considerable variation as to configuration and specific analysis packages available.

Standard F2: Ultrasound instruments utilized for diagnostic studies must include, at a minimum, hardware and software to perform:

1. M-Mode imaging.
2. Two-dimensional (2-D) imaging. The system must include harmonic imaging capabilities, and as well should include instrument settings to enable optimization of ultrasound contrast agents.
3. Spectral display for pulsed (PW) and continuous wave (CW) Doppler studies. There should be a system setting to display low frequency Doppler filtering for tissue Doppler display.
4. Monitoring or other display method of suitable size and quality for observation and interpretation of all modalities. The display must identify the parent institution, the name of the patient, the date and time of the study.
5. Continuous ECG display.

6. Where data are derived from a given line of interrogation (e.g., M-Mode or PW Doppler), a reference line should be available on the screen within a frozen 2-D image, except for non-imaging CW Doppler.
7. Range or depth markers must be available on all displays.
8. Capabilities to measure the distance between two points, an area on a 2-D image, blood flow velocities, time intervals, and peak and mean gradients from spectral Doppler studies.
9. At least two imaging transducers, one of low frequency (2-2.5 MHz) and one of high frequency (3.5 MHz or higher); or a multi-frequency transducer which includes a range of frequencies specific to the clinical needs in adult echo. A transducer dedicated to the performance of non-imaging continuous wave Doppler must be available at each site.
10. An audible output must be present at the time of acquisition. A permanent recording of the Doppler waveform and corresponding image that utilizes a digital image storage method that should be compatible with DICOM standards.
11. Respirometry for selected indications.

Machines with some, but not all of the above, equipment may be used for limited or directed echocardiographic examinations. However, machines utilized for complete diagnostic procedures must include all of the above listed capabilities.

Standard F3: Equipment must be maintained in good operating condition:

The accuracy of the data collected by ultrasound instruments is paramount to the interpretation and diagnostic utilization of the information collected. Regular equipment maintenance by appropriately trained individuals is essential. This can be carried out either through maintenance and service agreements with manufacturers, or by other appropriately trained personnel.

Guidelines for equipment maintenance include, but are not limited to, the following:

- Recording of the method and frequency of maintenance of ultrasound instrumentation and digitizing equipment.
- Establishment of and adherence to a policy regarding routine safety inspections and testing of all laboratory electrical equipment.
- Establishment of and adherence to an instrument cleaning schedule that includes routine cleaning of equipment parts, including filters and transducers, according to the specifications of the manufacturer.

2.3 Operating Procedures

Echocardiographic examinations provide information important to patient management. In some cases, the findings are unexpected and can be critical to patient care. It is therefore essential that examinations be documented appropriately, sufficient time be provided to acquire full information, and reports be provided to referring physicians in a timely fashion. Studies must also be stored and available for future reference and comparison to subsequent examinations. Storage facilities must ensure patient confidentiality.

Standard F4: All orders or requisitions for echocardiographic procedures will include at a minimum:

- the type of study to be performed
- the indication or clinical question(s) to be addressed
- the name of the referring physician

Standard F5: Sufficient time must be allotted for each examination:

For complete (imaging and Doppler) transthoracic examination, 30 to 45 minutes from patient encounter to departure. An additional 10 - 15 minutes is generally required for offline measurements and analysis, preliminary report generation, and preparation for the next examination.

Standard F6: Echocardiographic reports must be provided within the following timeframes.

- Inpatient and urgent outpatient studies must be interpreted and the report made available to the referring physician by the end of the next working day from completion of the examination, and preferably by the end of the day of the exam.
- Outpatient studies must be interpreted by a qualified physician and be made available to referring physicians within five working days of the examination.
- Unexpected high risk findings should be communicated immediately by the interpreting physician to the referring physician

Standard F7: Echocardiographic data (images, measurements and final reports) obtained for diagnostic purposes must be recorded, stored and archived in a format that ensures ready retrieval (such that the parameters outlined in Standard F6 are met), complete review, communication and patient confidentiality.

Standard F8: A permanent record of the images and interpretation must be made and retained in accordance with provincial guidelines for medical records.

Standard F9: Laboratories will have protocols whereby unexpected high risk findings are communicated immediately by the interpreting physician to the referring physician and managed as required by the interpreting/responsible echo lab physician.

2.4 Additional Considerations for Laboratories Providing Transesophageal Examinations

Standard FT1: Appropriately trained and qualified personnel are required to provide sedation and monitoring of the patient through the procedure and recovery. The individual(s) carrying out the examination must not be expected to provide this monitoring function during the procedure.

Standard FT2: All TEE procedures must be explained to the patient and/or the guardian of those unable to give informed consent. Consent must be obtained in a manner consistent with the rules and regulations outlined by the hospital or facility. Where sonographers are involved in the consent process, procedures must be in keeping with the provisions of their credentialing body as well as relevant scope of practice principles established by the hospital or facility.

Standard FT3: In addition to the echocardiographic imaging system requirements, as outlined above, transesophageal transducers must be available which meet the following requirements:

- Transesophageal ultrasound transducers must be those manufactured for the ultrasound system of the laboratory.
- Transesophageal ultrasound transducers should incorporate multiplane imaging capabilities.

Standard FT4: Larger rooms must be provided to perform transesophageal echo, in order to accommodate extra equipment, personnel and potential resuscitation procedures. It is recommended that these rooms be at least 150 to 200 square feet.

Standard FT5: In addition to the standard features noted above, laboratories providing transesophageal echo require the following additional facilities:

- Blood pressure monitoring
- Suction
- Oxygen
- Pulse oxymetry
- Resuscitation medications and equipment
- Intravenous equipment
- Lockable cabinet for drugs
- A means of rapidly calling for help with an unstable patient (e.g. phone, intercom, arrest buzzer)
- A large sink

Standard FT6: The echocardiography laboratory must follow proper cleaning, disinfection, and maintenance procedures as stipulated by manufacturer and hospital or facility standards.

Standard FT7: Facilities and procedures must be available for observation and recovery of patients by appropriately trained and qualified personnel prior to discharge home or back to their referring location.

2.5 Additional Considerations for Laboratories providing Stress Echocardiography Examinations

Standard FS1: Appropriately trained and qualified personnel are required to monitor the patient, operate the treadmill or supine bicycle, record the electrocardiogram and, in the case of pharmacologic stress echo, administer medication. The individual(s) carrying out the examination must not be expected to provide these functions.

Standard FS2: All stress procedures must be explained to the patient and/or the guardian of those unable to give informed consent. Consent must be obtained in a manner consistent with the rules and regulations outlined by the hospital or facility.

Standard FS3: Larger rooms must be provided to perform stress echo, in order to accommodate extra equipment, personnel and potential resuscitation procedures.
It is recommended that these rooms be at least 150 to 200 square feet.

Standard FS4: Facilities and procedures must be available for observation and recovery of patients by appropriately trained and qualified personnel prior to discharge home or back to their referring location.

Standard FS5: In addition to the echocardiographic imaging system requirements, as outlined above, echocardiography equipment utilized for stress echo studies must:

- Allow for accurate "triggered" acquisition of images and side-by-side image display.
- Adequate memory to allow performance of multi-stage stress echocardiogram studies.
- Capability of side-by-side comparison of images from baseline and different stages of stress. Side by side review may be accomplished within the ultrasound stress package or on a dedicated offline workstation.

Standard FS6: In addition to the standard features noted above, laboratories providing stress echo require the following additional facilities:

- Treadmill/bicycle EKG monitoring
- Blood pressure monitoring
- Available oxygen
- Available resuscitation medications and equipment
- Available IV equipment
- A means of rapidly calling for help with an unstable patient (e.g. phone, intercom, arrest buzzer)

Section 3:

Standards for Reporting of Echocardiographic Examinations

The echocardiographic report should provide specific information for the referring physician, including the key elements of (1) demographics, (2) complete echocardiographic findings, and (3) a summary/interpretation statement, and is provided in a clinically relevant, useful and timely manner. Echocardiography reporting should be standardized in the laboratory. All physicians interpreting echocardiograms in the laboratory must agree on uniform diagnostic criteria and a standardized report process and format. The final report must be completely typewritten. The final report must be approved by the interpreting physician.

Standard R1: All echocardiographic reports must include the information outlined in Appendix A.

Standard R2: In addition to the standard information outlined in Appendix A, specific evaluation will be provided regarding the presenting problem.

Specific indications or pathology require further targeted imaging and/or hemodynamic assessment. Stated findings should be consistent with the quantitative data. A full review of the specific data required for evaluation of all possible pathologies is beyond the scope of this document, and the reader is referred to one of the many excellent comprehensive texts available.

Standard R3: An assessment of study quality will be included in every report and, where appropriate, a statement regarding any study limitations.

It is recognized that echocardiography is sensitive to various technologic limitations and the acquisition of a full set of interpretable data may not be possible for all patients. It is therefore important that such limitations be clearly stated within the report, in order to avoid the assumption of normality by the referring physician. Statements such as “imaging was suboptimal or impossible” or “reliable interpretation not possible” should be used where appropriate.

Standard R4: Amended reports must be identified as such and must include the date and time of the change, as well as the specific changes from the original report.

Standard R5: Final reports should be completed only after full review of all acquired data and must include the following:

1. Overall interpretation/summary of findings, including any pertinent positive and negative findings, as it relates to the assessment of presenting issue/reason for study. Should be consistent with the qualitative and quantitative data.
2. Interpretation/summary of other significant pathologic findings.
3. Relevant comparisons to prior studies or reports as available.
4. Study limitations.
5. Recommendations regarding alternative or additional investigations where appropriate.

Standard R6: That mechanisms be in place for immediate communication of urgent findings (Preliminary Reporting).

Echocardiography is able to quickly derive very valuable information regarding the status of critically ill patients. In order to avoid delays in transmitting valuable information (especially findings that immediately impact patient care) to referring physicians, it is imperative that a mechanism exists for the immediate communication of echocardiographic findings. Such mechanisms should be developed within each laboratory and hospital setting, in accordance with local practices. In doing so, it must be recognized that it is not the responsibility of the sonographer to generate final reports, nor should they be compelled to report preliminary findings if they are not confident or comfortable in doing so for any reason. In addition, such a mechanism should in no way be interpreted as a substitute for urgent access to physician backup and interpretation.

Section 4:

Standards Regarding Personnel Involved in Echocardiographic Examinations

An echocardiography laboratory is composed of at least one ultrasound instrument, a Medical Director and a Technical Director performing and/or interpreting transthoracic echocardiography, encompassing a single or multiple geographic sites. When multiple sites are utilized, it is understood that all sites fall under a common governance structure and fulfill all standards. There may be additional physicians and sonographers. The laboratory may also perform transesophageal or stress echocardiography.

An echocardiography laboratory requires the interpreting physicians and practicing sonographers to be adequately trained and experienced to interpret and perform echocardiograms.

Published documents recognize that echocardiography requires considerable training and expertise. Although published opinions vary with regard to the absolute numbers necessary for attaining and maintaining competence in echocardiography, all agree that numbers of studies performed or interpreted are not sufficient by themselves to assure clinical competence. In developing these standards, the CCS/CSE Guidelines for Training and Maintenance of Competency in Adult Echocardiography (Burwash IG et al, Can J Cardiol 2011; 27: 862-4) were utilized, including definitions of Level 2 and 3 training.

4.1 Standards Regarding the Medical Director

Standard P1: The echocardiographic laboratory will have a designated Medical Director, who must be a licensed physician and holds one of the following qualifications:

- Level 3 training in echocardiography.
- Level 2 training in echocardiography and continuing echocardiography practice including interpretation of at least 1800 Echo/Doppler examinations over the previous 3 years.

Standard P2: The Medical Director carries out or has oversight for the following:

- All clinical services provided and determination of the quality and appropriateness of care provided.
- Assuring compliance of the medical and technical staff to these standards and the supervision of their work.
- Active participation in the interpretation of studies performed in the laboratory.

Standard P3: **To ensure continuing maintenance of competence**, the Medical Director attends at least 24 hours of accredited CME activities relevant to echocardiography over a period of two years and interprets at least 400 transthoracic echocardiographic studies per year. **For laboratories carrying out transesophageal echo**, the Medical Director must perform and interpret at least 25 **transesophageal** examinations per year. **For laboratories providing stress echocardiography**, the Medical Director must interpret at least 75 **stress echocardiography** examinations per year.

4.2 Standards Regarding the Technical Director

Standard P4: **The laboratory must have a designated Technical Director who has credentialing from the American Registry of Diagnostic Medical Sonography (ARDMS) or equivalent credential, and experience as assessed and approved by the Medical Director. In laboratories with no appropriately qualified sonographers, a physician assumes the role of Technical Director and must have at Level 2 or 3 training.**

Standard P5: **The Technical Director carries out or has oversight for the following:**

- Performance of echocardiographic examinations.
- General supervision of the technical and support staff.
- The delegation, where appropriate, of specific responsibilities to the technical or support staff.
- Daily administration of the laboratory (scheduling, record keeping).
- Operation and maintenance of laboratory equipment.
- The compliance of technical staff to these standards.
- Maintenance of quality patient care.
- Technical training of all staff.

Standard P6: **The Technical Director documents at least 30 hours of echocardiography related continuing education over a period of three years.**

4.3 Standards Regarding Medical Staff

Standard P7: Members of Medical Staff must be licensed physicians who hold one of the following qualifications:

- Level 2 or 3 training in Adult Echocardiography.
- Documented performance in an established laboratory, with interpretation of at least 400 Echo/Doppler studies per year and maintenance of competence as defined in Standard P3 for the preceding 3 years.

Standard P8: Members of Medical Staff are responsible for:

- Interpretation of examinations.
- Reporting of examinations.
- Triaging of emergency requests.
- Supervision and support of sonographers carrying out examinations, to include availability for review of patients or acquired information before the patient is discharged from the facility.
- In laboratories providing procedural echo, carrying out or supervising transesophageal and ensuring appropriate supervision of stress echocardiography studies.
- Providing emergency assistance for patients as required.

Standard P9: Members of Medical Staff must undertake and document continuing maintenance of competence as described in Section P3.

4.4 Standards Regarding Technical Staff

Standard P10: All Technical staff performing echocardiographic examinations must meet one of the following criteria:

- Appropriate credentialing from ARDMS or equivalent agency, as approved by the Medical and Technical Directors.
- Successful completion of an accredited Echocardiography training program which includes both didactic teaching and supervised clinical experience.
- Completion of at least 12 months of full time (35 hours per week) clinical echocardiography performing echocardiographic examinations and completion of a formal 2 year program in another allied health profession.

Standard P11: Technical staff work under the direction of the Technical Director and are, in general, responsible for:

- Ensuring patient identity and documentation of information.
- Ensuring patient comfort and safety.
- Acquisition and recording of all echocardiographic images and data as defined by established laboratory protocols.
- Alerting supervising physicians as to any technical deficiencies in study acquisition.
- Alerting the supervising physician as to any urgent conditions identified in the course of the examination.
- Alerting the supervising physician as to any significant symptoms or distress experienced by the patient during the course of the examination or while in the echocardiography laboratory.

Standard P12: All Technical Staff must document at least 30 hours of echocardiography related CME every 3 years.

Section 5:

Indications for Echocardiographic Examinations

Echocardiography is a non-invasive, non-toxic, portable diagnostic technique that provides a great deal of imaging and quantitative information relevant to cardiac structure and function. It has therefore taken on a key role in the assessment of patients presenting with numerous clinical problems. Responsible utilization of this technology requires regular assessment of its appropriate indications. Such assessment should be based, where possible, on objective evidence supporting a significant impact on clinical practice. The absence of such evidence does not exclude benefit. Therefore, where such evidence is lacking, justification must be based on accumulated clinical experience.

Appendix B lists conditions in which echocardiography is known to have such an impact and is therefore indicated in the care of affected patients.

In developing this list, the authors were cognizant of the primary role of the treating physician in determining test utility and did not wish to either deny patients potential benefit of this technique, nor suggest that all patients presenting with particular issues would necessarily benefit from echocardiographic assessment.

As a guiding and overriding principle, the Authors advocate the use of echocardiography if, and only if, results have potential to influence clinical decisions and patient management.

Standard I1: Echocardiographic Laboratories will have mechanisms which ensure that an indication is documented as a component of every referral.

Standard I2: For referrals without a standard indication (as per Appendix B), laboratories will have mechanisms whereby referring physicians are contacted for clarification before the study is carried out. Based on that clarification, the study will be carried out at the discretion of the supervising physician.

Standard I3: Echocardiographic Laboratories will have mechanisms to:

- Track indications of completed studies.
- Ensure that at least 95% of studies carried out meet standard indications (as per Appendix B).
- Provide education of referring physicians regarding appropriate indication for echocardiography examinations.

Section 6:

Continuing Quality Assurance in the Echocardiographic Laboratory

Quality assurance (QA) is seminal to all medical activities and is particularly central to procedural activities such as echocardiography, which are frequently pivotal to high-impact clinical decisions. Every echocardiographic laboratory is expected to develop, describe and make available its own internal QA program, or partner with a reference laboratory with an established QA program. The QA program of the laboratory must include methodology, implementation, documentation and review that addresses the following standards:

Standard Q1: **Regular review of study acquisition**, including the quality and completeness of the images and the accuracy of the measurements by each sonographer, a function that might be satisfied by regular review of a set number of random studies over a set time-interval using a pre-defined point-score system and pre-set standards of accuracy under the auspices of the Laboratory Director or his/her designate.

Standard Q2: **Review of study interpretation**, including the accuracy, completeness and timeliness of the reports of each interpreting physician, a function that might be satisfied by a regular review of a set number of random interpretive reports over a set time-interval using a pre-defined point-score system and pre-set standards of accuracy by the Medical Director or his/her peer designate(s).

Standard Q3: **Staff meetings** to review and discuss the results of QA process and introduce system-wide remedial or improvement measures.

Standard Q4: **External Review.** Processes that allow for constructive feedback and review of either confirmatory or discordant findings by other laboratories.

Standard Q5: **Validation against other diagnostic modalities.** Processes for validating test findings by correlating them with other diagnostic procedure, such as hemodynamic caths, coronary angiography, nuclear perfusion studies, MRI and intra-operative findings and pathology.

Standard Q6: **Case Review.** Organization of and/or attendance at rounds and/or conferences focused on interesting case reports or series cases, or specific disease entities with an instructional content relevant to the activities of the laboratory.

Section 7:

A Process for Accreditation of Echocardiography Laboratories

In order to positively influence patient care and service delivery, methods must be developed whereby standards become implemented and thereby influence laboratory processes. In the case of Echocardiography, this can occur in one of three ways:

1. **Self Review:** The simple availability of these standards allows all operators of echocardiography facilities to utilize them to modify their processes and procedures in a way that will better assure optimal service delivery. Developing, accepting and publishing these standards will hopefully promote that process and thereby enhance quality in and of itself.
2. **Voluntary External Review:** This is a process whereby laboratories can choose to engage an external, arms length agency to review their operation with respect to accepted standards and provide constructive feedback as to their performance. In order to be effective, such feedback must include education and practical suggestions as to how full compliance can be achieved.
3. **Mandatory External Review:** This is a process whereby all laboratories providing echocardiography would require external accreditation which would attest that they are achieving all standards. The failure to achieve such external mandatory accreditation would result in the loss of public approval or reimbursement for echocardiography services.

The Authors recommend mandatory accreditation of all echocardiography facilities in Ontario.

Recognizing that implementation must be carried out in a manner that does not inhibit the provision of echocardiographic services, the authors advocate a phased implementation, as follows:

Phase 1: Publication and dissemination of these standards
This will provide all echocardiographic facilities a common reference to facilitate review of their procedures. This should be carried out immediately.

Phase 2: Provision of opportunities for Voluntary Review.
Voluntary external review requires a process whereby accepted standards are used to assess the performance of an echocardiography laboratory. In order to accomplish this, internal and external laboratory review as well as adjudication of that review by a qualified third party is required. The end result of the process should be the provision of instructive feedback to the laboratory regarding their performance with respect to all of the standards. That review should include suggestions as to how the laboratory can improve its performance with respect to standards in which it is found to be deficient. It is recommended that the period of Voluntary Review last no longer than 3 years.

Phase 3: Mandatory Review and Credentialing
Mandatory review or accreditation of echocardiography laboratories must evolve in Ontario. This will require a governmental regulatory framework, the development of which is beyond the scope of this paper.

In order to facilitate the voluntary and mandatory review processes, the following processes are suggested:

1. That an **Echocardiography Review Panel** be established to oversee assessment of echocardiography laboratories in Ontario.
2. That **Structured Review Templates** be developed based on the standards outlined in these documents. These templates should provide guidance as to how laboratories can demonstrate and provide evidence with regard to their performance in each standard.
3. That **Qualified Reviewers** be engaged to carry out and coordinate assessments of echocardiography laboratories. These reviewers would be both qualified and highly experienced in the application of echocardiography. They would assist the laboratory in development of their internal review and coordinate the review with the central panel.

4. The **Process for Review** would therefore take the following seven steps:

   Step 1 – During the voluntary phase, the laboratory identifies itself as wishing to undertake review. During the mandatory phase, laboratories would be notified of a scheduled review.

   Step 2 – The laboratory is provided with instruction and documentation templates necessary for carrying out its internal review.

   Step 3 – A reviewer is assigned to assist and guide the laboratory in the review process.

   Step 4 – The material is submitted to the central review panel.

   Step 5 – A laboratory visit is undertaken by the assigned reviewer and one member of the review panel.

   Step 6 – The review panel assesses the submitted material and results of the laboratory visit. Detailed feedback with respect to performance in all standards is provided to the laboratory. Where appropriate recommendations are made with respect to how the laboratory can improve its performance in areas of deficiency.

   Step 7 – If necessary a review visit is scheduled to reassess standards found to be in noncompliance.

Laboratories found to be in full compliance of standards would be entitled to be recognized as such in a variety of ways including publication on a public website and prominent displays within their laboratory and on their reports.

As a next step to establish quality assurance standards for echocardiography in Ontario, CCN will work with service providers and stakeholders to implement a system and resources that will support and facilitate self review and voluntary external review processes.

Appendix A:

The Standard Echocardiographic Report

Basic Information:

- Name and/or identifier of the laboratory, location, contact information.
- Study date.
- Patient identification and demographics, date of birth+/- age, gender.
- Patient location (inpatient vs. outpatient), study location (echo lab, portable – ICU, ER etc).
- Height, weight, body surface area.
- Rhythm and heart rate.
- Study indication.
- Referring physician identification.
- Interpreting physician identification.
- Sonographer ID.
- Type of study (e.g. adult TTE, neonatal TTE, TEE, stress echo etc).
- Study technical quality (e.g. teaching quality, good, fair, poor, incomplete) and limitations.

Cardiac Dimensions – Measurements:

- Left ventricular internal systolic and diastolic dimensions.
- Left ventricular (basal) septal and posterior wall thickness.
- Left atrial size (anteroposterior dimension).
- Aortic root and ascending aorta dimensions.

Note: Normal ranges should be included in the report. The text of the report should comment on whether a given dimension is within normal limits, or if abnormal, to what extent.

Evaluation of the structure and function of the anatomic components of the examination, to be included in the standard report, include the following:

Left Ventricle

- Assessment of left ventricular dimensions, wall thickness, global left ventricular systolic function and ejection fraction (and method used), and presence or absence of regional wall motion abnormalities.
- Evaluation of left ventricular diastolic function (if relevant to the clinical indication).

Right Ventricle

- Assessment of right ventricular size and systolic function, presence of right ventricular hypertrophy.

Left atrium

- Assessment of size.

Right atrium

- Assessment of size.

Aortic Valve

- Aortic valve cusp morphology, presence and severity of stenosis or regurgitation.
- Evaluation of gradients (peak and mean) and valve area, if stenotic.

Mitral Valve

- Mitral valve leaflet morphology, presence and severity of stenosis or regurgitation.
- Evaluation of gradients (peak and mean) and valve area, if stenotic.

Tricuspid Valve

- Tricuspid valve leaflet morphology, presence and severity of stenosis or regurgitation.
- Evaluation of gradients (peak and mean), if stenotic.
- Estimation of right ventricular systolic pressure, if sufficient tricuspid regurgitation is present.

Pulmonic Valve

- Pulmonic valve morphology, presence and severity of stenosis or regurgitation.
- Evaluation of gradients (peak and mean), if stenotic.

Aorta (including aortic root and ascending aorta)

- Dimensions.

Interatrial septum

- Intact – presence or absence of ASD/shunt.

Pericardium

- Presence and size of pericardial effusion, assessment of hemodynamic effects of pericardial effusion (if present).

Appendix B:

Indications for Echocardiography – Standards 2012

1. Heart Murmurs:

1.1. Initial evaluation of a murmur in a patient with cardiorespiratory symptoms.

1.2. A murmur in an asymptomatic patient where structural heart disease cannot be excluded by clinical assessment.

1.3. Re-evaluation of known valvular disease with a change in clinical status or cardiac exam.

2. Native Valvular Stenosis:

2.1. Initial assessment of etiology, severity, chamber dimensions, ventricular systolic function and overall hemodynamic impact.

2.2. Assessment of patients with known valvular stenosis of any severity and changing clinical status or discrepancy between clinical and echocardiographic severity.

2.3. Reassessment within 6-12 months of patients with an initial echocardiographic assessment indicating valvular stenosis of any severity.

2.4. Reassessment (>2 yr) of mild valvular stenosis without a change in clinical status or cardiac exam.

2.5. Reassessment (>1 yr) of moderate valvular stenosis without a change in clinical status or cardiac exam.

2.6. Reassessment (>6 mos) of severe valvular stenosis without a change in clinical status or cardiac exam.

3. Native Valvular Regurgitation:

3.1. Initial assessment of etiology, severity, chamber dimensions, ventricular systolic function and overall hemodynamic impact.

3.2. Assessment of patient with known valvular regurgitation of any severity and changing clinical status or discrepancy between clinical and echocardiographic severity.

3.3. Reassessment (>1 yr) of patients with asymptomatic moderate valvular regurgitation.

3.4. Reassessment (>6 mos) of patients with asymptomatic severe valvular regurgitation.

4. Known or Suspected Mitral Valve Prolapse:

4.1. Diagnosis and assessment of hemodynamic severity, leaflet morphology, ventricular cavity size and function in patients with physical findings of mitral valve prolapsed.

4.2. Patients with previous diagnosis of mitral valve prolapse and changing clinical status or physical findings suggestive of progressive valvular dysfunction.

4.3. To re-evaluate patients with prior echocardiographic diagnosis but no supporting physical findings.

4.4. Reassessment (>2 yrs) of patients with significant leaflet thickening or redundancy.

4.5. Periodic reassessment as required by severity of regurgitation (as per section 3).

5. Congenital or Inherited Cardiac Structural Disease (including Bicuspid Aortic Valve, Marfan's Syndrome, Atrial Septal Defect, Ventricular Septal Defect, Ehler's Danlos Syndrome):

5.1. Patients with known congenital or inherited structural heart disease and changing clinical status or symptoms.

5.2. Patients in whom clinical findings, the results of other investigations, or family history would suggest the presence of a congenital or Inherited Cardiac Structural Disease.

5.3. Reassessment (>2 yrs) of asymptomatic individuals with previously diagnosed congenital or Inherited Cardiac Structural Disease.

6. Prosthetic Heart Valves:

6.1. Assessment of a newly implanted prosthetic heart valve (baseline assessment).

6.2. Re-assessment (> 1 years) in asymptomatic, hemodynamically stable patients if no known or suspected prosthetic valve dysfunction.

6.3. Assessment of a prosthetic heart valve in patients with symptoms, clinical findings or prior echocardiogram suggestive of prosthetic valve dysfunction.

7. Infective Endocarditis:

7.1. Patients in whom endocarditis is suspected clinically.

7.2. In a patient with clinically proven or suspected endocarditis to assess the severity and hemodynamic impact of valvular lesions, and to detect other high risk lesions (e.g. fistulae, abscesses).

7.3. Re-assessment of patients at high risk for complications or with a change in clinical status or cardiac exam.

7.4. Reassessment in a clinically stable patient with prior echocardiographic evaluation to assess response to therapy or detect clinically silent disease progression.

8. Pericardial Disease:

8.1. Evaluation of patients with suspected pericarditis, pericardial effusion, tamponade or constriction.

8.2. Initial follow up of patients with no change in clinical status but a pericardial effusion of suspected clinical significance.

8.3. Follow up of any pericardial effusion in patients with changing clinical status suspected related to the effusion.

8.4. Reassessment at yearly intervals in patients with moderate or large pericardial effusion.

8.5. Echocardiographic guidance of pericardiocentesis for diagnostic or therapeutic purposes.

9. Cardiac Masses:

9.1. Evaluation of patients with clinical syndromes suspicious for an underlying cardiac mass.

9.2. Follow up following surgical removal of masses/tumours, intervals to be determined by the pathology, patient clinical status and known natural history of the lesion.

9.3. Patients with malignancies when echocardiographic assessment for cardiac involvement is part of the standard disease staging process.

9.4. Evaluation of cardiac mass detected by other imaging modalities.

10. Interventional Procedures:

10.1. To assist pre and peri-procedural decision making for percutaneous interventional and electrophysiologic procedures (e.g. valvuloplasty, closure device insertion, catheter ablation, mitral valve repair).

10.2. Post-intervention baseline studies for valve function, closure device placement and stability, and ventricular remodeling (e.g. within 3 months).

10.3. Re-evaluation of patients post interventional procedure with suspected surgical complication (e.g. valvular dysfunction, closure device erosion/migration, perforation).

11. Pulmonary Diseases:

11.1. Evaluation of suspected or established pulmonary hypertension.

11.2. Reassessment of pulmonary hypertension to evaluate response to treatment.

11.3. Evaluation of suspected acute pulmonary embolism.

11.4. Reassessment after initial treatment of pulmonary embolism.

11.5. Patients being considered for lung transplantation or other surgical procedure for advanced lung disease to exclude possible cardiac disease.

11.6. Patients with known chronic lung disease and unexplained desaturation.

12. Chest Pain and Coronary Artery Disease:

12.1. Evaluation of suspected aortic dissection.

12.2. Chest pain with hemodynamic instability.

12.3. Chest pain or ischemic equivalent suggestive of underlying coronary artery disease.

12.4. Heart murmur associated with acute or recent myocardial infarction

12.5. Assessment of infarct size and baseline LV systolic function post myocardial infarction.

12.6. Assessment of LV function post revascularization.

12.7. As a component of periodic (≥1 yr) reassessment of patients with known ischemic LV dysfunction.

12.8. Periodic (≥6 mos) reassessment of LV function to guide or modify therapy in patients with known severe ischemic LV dysfunction.

13. Dyspnea, Edema and Cardiomyopathy:

13.1. Assessment of patients with suspected heart failure.

13.2. Clinically suspected cardiomyopathy.

13.3. Patients with clinically unexplained hypotension.

13.4. Assessment of baseline LV function and periodic review when using cardiotoxic drugs.

13.5. Re-evaluation of LV function in patients with documented cardiomyopathy and change in clinical status or undergoing procedures that could potentially affect function such as alcohol septal ablation or surgical myomectomy.

13.6. Reassessment of patients with known cardiomyopathy to evaluate significance of symptoms and guide therapy.

13.7. Screening of relatives potentially affected by inherited cardiomyopathy.

13.8. Reassessment (> 1 yr) of asymptomatic cardiomyopathy patients for disease progression in order to assess suitability for medical or device treatment.

14. Hypertension:

14.1. Suspected left ventricular dysfunction.

14.2. Evaluation of left ventricular hypertrophy that may influence management.

15. Thoracic Aortic Disease:

15.1. Suspected aortic dissection.

15.2. Suspected aortic rupture/trauma.

15.3. Suspected dilatation of aortic root or ascending aorta for any cause.

15.4. Evaluation patient with known aortic pathology and change in symptoms or clinical findings suggestive of progression.

15.5. Suspected or proven Marfan Syndrome or other connective tissue disorder in which aortic pathology is a potential feature.

15.6. Reassessment of asymptomatic patients with aortic aneurysm (frequency dependent on aortic dimensions and rate of progression).

15.7. Baseline and continuing reassessment (>1yr) of patients with prior surgical repair of aorta.

16. Neurologic or Other Possible Embolic Events:

16.1. Patient of any age with abrupt occlusion of a major peripheral or visceral artery.

16.2. Stroke or TIA in the absence of established causative pathology

17. Arrhythmias Syncope and Palpitations:

17.1. Initial investigation of symptomatic arrhythmia.

17.2. Asymptomatic documented frequent premature atrial beats, chaotic atrial rhythm, paroxysmal or permanent atrial fibrillation or flutter, frequent ventricular premature beats, nonsustained VT, sustained VT.

17.3. Investigation of syncope of undetermined etiology.

17.4. Pre-procedural before electrophysiologic studies and procedures and before ICD or pacemaker implantation if not performed within 3 months.

17.5. Investigation of patients with LBBB, high grade AV block.

17.6. Investigation of patients with WPW pre-excitation.

17.7. Follow-up of patients with sustained tachycardia at risk for development of Cardiomyopathy.

18. Before Cardioversion:

18.1. Patients with atrial fibrillation of more than 48 hours duration requiring cardioversion and not chronically or adequately anticoagulated.

18.2. Patients for whom atrial thrombus has been demonstrated in previous study.

18.3. Precardioversion evaluation of patients who have previous echocardiographic evidence of structural heart disease.

19. Suspected Structural Heart Disease:

19.1. Where an investigation suggests possible structural heart disease and an echocardiographic study has not been previously performed or the finding has not previously identified.

20. Indications for Transesophageal Echo:

20.1. Non-diagnostic transthoracic study, either due to technical limitations or failure to fully characterize a potentially significant finding.

20.2. Assessment of structure and function of cardiac valves to assess feasibility of surgery or catheter-based intervention.

20.3. Patient selection, guidance and monitoring of interventional procedures including but not limited to device closure of intra-cardiac shunt and radio-frequency ablation.

20.4. Detection of cardiac source of embolus in the absence of established causative pathology.

20.5. Evaluation of patients with suspected aortic dissection or aortic disease not fully evaluated by other imaging modalities.

20.6. Detection of atrial thrombus in patients prior to cardioversion or interventional procedures.

20.7. Moderate or high risk for endocarditis when TTE is negative or inconclusive.

20.8. Detection of valvular and peri-valvular complications in high risk endocarditis patients such as patients with staphylococcal bacteremia.

21. Indications for Stress Echo:

21.1. Typical or atypical chest pain or ischemic equivalent syndrome.

21.2. Possible ACS with non-diagnostic ECG changes and negative or borderline significant troponin levels.

21.3. History of Congestive Heart Failure.

21.4. Known LV systolic dysfunction of unclear etiology.

21.5. Significant ventricular arrhythmia.

21.6. Syncope of unclear etiology.

21.7. Borderline or high troponin levels in a setting other than ACS.

21.8. Significant cerebrovascular or peripheral atherosclerosis.

21.9. Re-evaluation (≥1 yr) in patients with significant cerebrovascular or peripheral atherosclerosis.

21.10. Equivocal or non-diagnostic results from other stress modalities.

21.11. Initial evaluation of patients at intermediate or high global CAD risk.

21.12. Periodic (≥2 yrs) re-evaluation of patients with intermediate or high global CAD Risk.

21.13. New or worsening chest pain or ischemic equivalent.

21.14. Post MI or ACS for risk stratification (within 3 months).

21.15. Viability in patients with known significant LV dysfunction post re-vascularization.

21.16. Periodic (≥1 yr) re-evaluation of stable patients with known CAD (previous coronary angiography, CTA/EBCT, MI, ACS or abnormal stress imaging).

21.17. For physiologic assessment and/or symptom correlation in patients with moderate or severe Aortic Stenosis, Mitral Stenosis, Mitral Regurgitation, Aortic Regurgitation, Hypertrophic Cardiomyopathy.

21.18. Assessment of established or latent pulmonary hypertension.

Appendix C:

Summary of Standards

The Echocardiographic Examination

E1 Established Protocols

E2 Required Imaging Components

E3 Required Doppler Components

E4 Standard Measurements

E5 Additional Information

Echocardiographic Facilities, Equipment, Procedures

F1 Examining Room Requirements

F2 Imaging System Requirements

F3 Maintenance requirements

F4 Ordering of echo studies

F5 Providing sufficient time for examinations

F6 Timeframes for reporting

F7 Storage of echo examination data

F8 Record storage and availability

F9 Communication of high risk findings

FT1 Personnel for transesophageal studies

FT2 Informed consent for transesophageal studies

FT3 Equipment for transesophageal studies

FT4 Space requirements for transesophageal studies

FT5 Laboratory requirements for transesophageal studies

FT6 Cleaning and maintenance of transesophageal probes

FT7 Facilities for observation and recovery of patients

FS1 Personnel for stress studies

FS2 Informed consent for stress studies

FS3 Space requirements for stress studies

FS4 Facilities for observation and recovery of patients

FS5 Equipment requirements for stress studies

FS6 Laboratory requirements for stress studies

The Report

R1 Content of echo reports

R2 Content relevant to presenting problem

R3 Assessment of study quality and limitations

R4 Amended reports

R5 Requirement for conclusions

R6 Reporting of urgent findings

Personnel

P1 Medical Director requirement and qualifications

P2 Medical Director responsibilities

P3 CME requirements for Medical Director

P4 Technical Director requirement and qualification

P5 Technical Director responsibilities

P6 CME requirements for Technical Director

P7 Medical Staff qualifications

P8 Medical Staff responsibilities

P9 CME requirements of Medical Staff

P10 Technical Staff qualifications

P11 Technical Staff responsibilities

P12 CME requirements for Technical Staff

Indications

I1 Documentation of indication for all referrals

I2 Mechanisms to process studies order without a stated indication

I3 Tracking of indications

Quality Assurance

Q1 Examination completeness and quality

Q2 Study interpretation

Q3 Laboratory operation

Q4 External review

Q5 Validation of findings

Q6 Rounds and conferences

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