

IAC Standards and Guidelines for Pediatric and Congenital Echocardiography Accreditation

Accreditation Standards

APRIL 2025

Introduction

The Intersocietal Accreditation Commission (IAC) accredits imaging facilities specific to echocardiography. IAC accreditation is a means by which facilities can evaluate and demonstrate the level of patient care they provide.

An echocardiography facility is defined as an entity located at one postal address, composed of at least one ultrasound instrument, a Medical Director and a Technical Director. There may be additional physicians and sonographers. The designation of the title of Medical Director and Technical Director are for IAC accreditation purposes only. An accredited pediatric and congenital echocardiography facility requires that the interpreting physicians and practicing sonographers be adequately trained and experienced to interpret and perform pediatric and congenital echocardiograms.

Published documents recognize that echocardiography in pediatrics and congenital heart disease 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 helpful but not sufficient by themselves to assure clinical competence. It is recognized that many echocardiography facilities will perform echocardiograms on children and adults and it is likely in this setting that the pediatric echocardiograms will represent a minority of the studies performed in that facility.

The intent of the accreditation process is two-fold. It is designed to recognize facilities that provide quality echocardiographic services. It is also designed to be used as an educational tool to improve the overall quality of the facility.

The following are the specific areas of pediatric and congenital echocardiography for which accreditation may be obtained:

- Pediatric and congenital transthoracic
- Pediatric and congenital transesophageal
- Fetal

These accreditation Standards and Guidelines are the minimum standards for accreditation of echocardiography facilities. Standards are the minimum requirements to which an accredited facility is held accountable. *Guidelines are descriptions, examples, or recommendations that elaborate on the Standards. Guidelines are not required, but can assist with interpretation of the Standards.* Standards are printed in regular typeface in outline form. *Guidelines are printed in italic typeface in narrative form.*

New or emerging technologies, protocols and other novel imaging or interventional approaches not included in guidelines published by professional societies must have supporting documentation that demonstrates adherence to manufacturer's training, safety specifications and quality control specifications as applicable. Facilities are encouraged to contact the IAC for guidance related to utilization of new technology not currently addressed in the IAC Standards.

Minor revisions to the Standards shown in highlighting were published and effective on April 1, 2025. Revisions include the addition of an Artificial Intelligence (AI) Guidance Document.

In addition to all Standards listed below, the facility, including all staff, must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations and billing requirements.

Part A: Organization	3
Section 1A: Personnel and Supervision	
STANDARD – Medical Director	
STANDARD – Technical Director	
STANDARD – Medical Staff	
STANDARD – Technical Staff	
STANDARD – Support Services	
Section 2A: Facility	
STANDARD – Examination and Interpretation Areas	
STANDARD – Storage	
STANDARD – Instrument Maintenance	
Section 3A: Examination Reports and Records	
STANDARD – Records	
STANDARD – Examination Interpretation and Reports	
Section 4A: Facility Safety	
STANDARD – Patient and Facility Safety	
Section 5A: Administrative	
STANDARD – Patient Confidentiality	16
STANDARD – Patient or Other Customer Complaints	
STANDARD – Primary Source Verification	
Section 6A: Multiple Sites (Fixed and/or Mobile)	
STANDARD – Multiple Sites	17
Bibliography	18
Part B: Examinations and Procedures	10
Section 1B: Pediatric Transthoracic Echocardiography Testing	19
STANDARD - Instrumentation	
STANDARD – Procedure Volumes	20
STANDARD – Indications, Ordering Process and Schedding	
STANDARD – Components of the Transthoracic Echocardiogram	
Bibliography	
Section 2B: Pediatric Transesophageal Echocardiography Testing	
STANDARD – Instrumentation	
STANDARD - Procedure Volumes	
STANDARD – Indications, Ordering Process and Scheduling	
STANDARD – Training	
STANDARD – Techniques	
STANDARD – Components of Transesophageal Echocardiograms	27
STANDARD – Focused Pediatric TEE	28
Bibliography	30
Introduction to IAC Standards for Fetal Echocardiography Testing	
Section 3B: Fetal Echocardiography Testing	
STANDARD – Instrumentation	
STANDARD – Procedure Volumes	ے۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔۔
STANDARD – Tridications, Ordering Process and Schedding	
STANDARD – Components of the Fetal Echocardiogram	33
Bibliography	
Part C: Quality Improvement	
Section 1C: Quality Improvement Program	
STANDARD - QI Program	
STANDARD – QI Oversight	
Section 2C: Quality Improvement Measures	
STANDARD – QI Measures	
Section 3C: Quality Improvement Meetings	
STANDARD - QI Meetings	
Section 4C: Quality Improvement Documentation	
STANDARD – QI Documentation and Record Retention	41
Artificial Intelligence (AI) Guidance Document	42

Part A: Organization

Section 1A: Personnel and Supervision

STANDARD – Medical Director

- 1.1A The Medical Director must be a licensed physician.
 - 1.1.1A <u>Medical Director Required Training and Experience</u>

The Medical Director must meet one of the following criteria:

- 1.1.1A Advanced Level of Expertise: High level of expertise in all aspects of pediatric echocardiography. Physicians with this level of training are expected to be able to perform independently and to interpret echocardiograms in patients with all forms of congenital and acquired pediatric heart disease, and to supervise and train others. In addition to the core requirement of 150 studies, each advanced level physician must perform and interpret at least 200 additional pediatric transthoracic echocardiograms and review, or perform and interpret, another 200 pediatric echocardiograms. At least 50 must be done in infants one year of age or younger.
- 1.1.1.2A Three years of echocardiography practice experience with at least 1,800 echocardiogram/Doppler examination interpretations in infants, children and patients with congenital heart disease.

Comment: It is recognized that some facilities performing pediatric echocardiograms, particularly those that perform a majority of adult studies, will not achieve the above numbers. However, the individual Medical Director must possess the outlined experience, while it is not necessary that it be obtained at a single institution.

1.1.2A <u>Medical Director Responsibilities</u>

The Medical Director responsibilities include but are not limited to:

- 1.1.2.1A all clinical services provided and for the determination of the quality and appropriateness of care provided;
- 1.1.2.2A supervising the entire operation of the facility as it relates to pediatric echocardiography or may delegate specific operations to associate directors and the Technical Director;
- 1.1.2.3A assuring compliance of the medical and technical staff to the Standards outlined in this document and the supervision of their work; and
- 1.1.2.4A must be an active participant in the interpretation of studies performed in the facility.

6.1.1A Continuing Medical Education (CME) Requirements

- 1.1.2.5A The Medical Director must document at least 30 hours of CME relevant to cardiac imaging over a period of three years. CME credits must be earned within the three-year period prior to application submission.
 - i. 15 hours must be relevant to pediatric/congenital echocardiography

1.1.2.6A Yearly accumulated CME must be kept on file and available to IAC when requested.

(See Guidelines on Page 7 for further recommendations.)

Comment: If the Medical Director has completed formal training as specified under 1.1.1.1A in the past three years, the CME requirement will be considered fulfilled.

STANDARD - Technical Director

1.2A A qualified Technical Director(s) must be designated for the facility. The Technical Director is generally a full-time position. If the Technical Director is not on-site full time or serves as Technical Director in another facility, an appropriately credentialed sonographer who is a member of the technical staff must be present in the facility in the absence of the Technical Director and assume the duties of the Technical Director.

Comment: In a facility with no sonographers, the Medical Director serves as Technical Director and must assume the responsibilities of Technical Director.

1.2.1A <u>Technical Director Required Training and Experience</u>

The Technical Director must meet the following criteria:

- 1.2.1.1A The Technical Director must have an appropriate credential in echocardiography:
 - Registered Diagnostic Cardiac Sonographer (RDCS) in Pediatric Echocardiography (PE) from American Registry of Diagnostic Medical Sonography (ARDMS)
 - ii. Registered Congenital Cardiac Sonographer (RCCS) from Cardiovascular Credentialing International (CCI)
- 1.2.1.2A In a facility with no sonographers, the physician Technical Director must have either Advanced Level of Expertise or three years of echocardiography practice experience with at least 1,800 echocardiogram/Doppler examination interpretations in infants, children and patients with congenital heart disease or an appropriate sonographer credential from ARDMS, CCI or Sonography Canada.
- 1.2.2A <u>Technical Director Responsibilities</u>
 - 1.2.2.1A The Technical Director reports directly to the Medical Director or his/her delegate. Responsibilities may include, but are not limited to:
 - i. performance of echocardiograms in the facility;
 - ii. general supervision of technical and ancillary staff, if applicable;
 - iii. the delegation, when warranted, of specific responsibilities to the technical staff and/or the ancillary staff;
 - iv. daily technical operation of the facility (e.g., staff scheduling, patient scheduling, facility record keeping, etc.);
 - v. operation and maintenance of facility equipment;
 - vi. compliance of the technical and/or ancillary staff to the Standards outlined within this document:
 - vii. working with the Medical Director, medical staff and technical staff to ensure quality patient care; and
 - viii. technical training.
- 6.1.2A Continuing Medical Education (CME) Requirements

- 1.2.2.2A The Technical Director must document at least 15 hours of echocardiographyrelated CME during their credentialing triennial cycle. 10 hours must be relevant to pediatric/congenital echocardiography.
- 1.2.2.3A Yearly accumulated CME must be kept on file and available to IAC when requested.

(See Guidelines on Page 7 for further recommendations.)

STANDARD – Medical Staff

- 1.3A All members of the medical staff must be licensed physicians.
 - 1.3.1A Medical Staff Required Training and Experience

The medical staff must meet one of the following criteria:

- 1.3.1.1A Advanced Level of Expertise: High level of expertise in all aspects of pediatric echocardiography. Physicians with this level of training are expected to be able to perform independently and to interpret echocardiograms in patients with all forms of congenital and acquired pediatric heart disease, and to supervise and train others. In addition to the core requirement of 150 studies, each advanced level physician must perform and interpret at least 200 additional pediatric transthoracic echocardiograms and review, or perform and interpret, another 200 pediatric echocardiograms. At least 50 must be done in infants.
- 1.3.1.2A Core Level of Expertise: Basic set of technical and interpretive skills required for graduation from a pediatric cardiology training program accredited by ACGME and includes four to six months of echocardiography, performance and interpretation at least 150 pediatric echocardiograms, including at least 50 in patients one year of age or younger, under the supervision of the facility director or other qualified staff pediatric cardiologist echocardiographer(s). Physicians with this level of expertise are expected to be able to perform and interpret TTEs in normal infants, children and adolescents, and in those with childhood heart disease with consultation as needed.
- 1.3.1.3A Three years of echocardiography practice experience with at least 450 echocardiogram/Doppler examination interpretations in infants, children and patients with congenital heart disease.

Comment: It is recognized that some facilities performing pediatric echocardiograms, particularly those that perform a majority of adult studies, will not achieve the above numbers. However, the individual pediatric medical staff member must have this experience, even if it is not achieved at a single institution.

1.3.2A <u>Medical Staff Responsibilities</u>

Medical staff responsibilities include but are not limited to:

- 1.3.2.1A The medical staff interprets and/or performs clinical studies.
- 6.1.3A Continuing Medical Education (CME) Requirements
 - 1.3.2.2A The medical staff must document at least 15 hours of CME relevant to cardiac imaging over a period of three years. CME credits must be earned within the three-year period prior to application submission.
 - i. 10 hours must be relevant to pediatric/congenital echocardiography

1.3.2.3A Yearly accumulated CME must be kept on file and available to IAC when requested.

(See Guidelines on Page 7 for further recommendations.)

Comment: If the medical staff has completed formal training as specified under 1.3.1.1A in the past three years, the CME requirement will be considered fulfilled.

STANDARD - Technical Staff

- 1.4A All members of the technical staff must be qualified sonographers.
 - 1.4.1A Technical Staff Required Training and Experience

The technical staff members must meet one of the following criteria:

- 1.4.1.1A An appropriate credential in echocardiography:
 - i. Registered Diagnostic Cardiac Sonographer (RDCS) from American Registry of Diagnostic Medical Sonography (ARDMS)
 - ii. Registered Cardiac Sonographer (RCS) or Registered Congenital Cardiac Sonographer (RCCS) from Cardiovascular Credentialing International (CCI)
 - iii. Canadian Registered Cardiac Sonographer (CRCS), Sonography Canada
 - iv. Advanced Cardiac Sonographer (ACS) from Cardiovascular Credentialing International (CCI)
 - v. For technical staff performing fetal echocardiography only, and not transthoracic echocardiography (i.e., OB/MFM sonographers): Registered Diagnostic Medical Sonographer Fetal Echocardiography (RDMS FE) is acceptable.

(See Guidelines on Page 7 for further recommendations.)

1.4.1.2A Provisional Staff

- i. New graduates of a cardiac ultrasound program who are employed in an accredited facility must obtain an appropriate credential within one year from the date of graduation. These individuals must be listed on the application as provisional technical staff who are eligible for credentialing, and must only work under appropriate supervision of a credentialed sonographer.
- ii. Individuals employed in an accredited facility who are cross-training in echocardiography or working to fulfill clinical experience pre-requisites for a credentialing examination must obtain an appropriate credential within two years from the start date of training. These individuals must be listed on the application as provisional technical staff who are eligible for credentialing, and must only work under appropriate supervision of a credentialed sonographer.

1.4.2A <u>Technical Staff Responsibilities</u>

Technical staff responsibilities include but are not limited to:

- 1.4.2.1A must report to the Technical Director; and
- 1.4.2.2A assumes the responsibilities specified by the Technical Director and, in general, is responsible for the performance of clinical examinations and other tasks assigned.

1.4.3A Continuing Medical Education (CME) Requirements

1.4.3.1A The technical staff must document at least 15 hours of echocardiography-related CME during their credentialing triennial cycle.10 hours must be relevant to pediatric/congenital echocardiography.

(See Guidelines below for further recommendations.)

STANDARD – Support Services

- 1.5A Ancillary personnel (clerical, nursing, transport, etc.) necessary for safe and efficient patient care are provided.
 - 1.5.1A Clerical and administrative support must be sufficient to ensure efficient operation and record keeping.
 - 1.5.2A Nursing and ancillary services sufficient to ensure quality patient care are available when necessary.
 - 1.5.3A Supervision: The Medical Director must ensure that support services appropriate for and in the best interest of patient care are provided.

Section 1A: Personnel and Supervision *Guidelines*

1.1.3A, 1.2.3A, 1.3.3A and 1.4.3A One hour of CME or non-CME work-related musculoskeletal disorder (WRMSD) training is recommended for all staff. This can be fulfilled through CME, in-service training or IAC webcast.

1.4.1.1A For technical staff performing fetal echocardiography, a credential in fetal echocardiography is also recommended.

Comment: A credential in pediatric or congenital echocardiography is also recommended.

Section 2A: Facility

STANDARD - Examination and Interpretation Areas

- 2.1A Examinations must be performed in a setting providing patient and technical staff safety, comfort and privacy.
 - 2.1.1A The adequate performance of an echocardiogram requires the proper positioning of the patient, the echocardiographic system and the sonographer. For this reason, adequate spacing is required for inclusion of a patient bed, which allows for position changes, an echocardiographic imaging system and patient privacy.
 - 2.1.1.1A It is understood that many echocardiographic studies are performed on a portable basis, requiring performance of the studies in less than optimal conditions. All studies, regardless of the location, must be performed with adequate room for patient positioning and equipment use.
 - 2.1.1.2A Patient privacy must be assured with the use of either appropriate curtains or doors.
 - 2.1.1.3A A sink and antiseptic soap must be readily available and used for hand washing in accordance with the infection control policy of the facility.
 - 2.1.1.4A The facility must establish and/or adhere to an infection control policy.
 - 2.1.1.5A Adequate designated space must be provided for the interpretation of the echocardiogram and the preparation of reports.

(See Guidelines on Page 9 for further recommendations.)

STANDARD - Storage

2.2A Space permitted for storage of records and supplies must be sufficient for the patient volume of the facility.

(See Guidelines on Page 9 for further recommendations.)

STANDARD - Instrument Maintenance

- 2.3A Instrumentation used for diagnostic testing must be maintained in good operating condition. The accuracy of the data collected by ultrasound instruments is paramount in the interpretation and diagnostic utilization of the information collected. Guidelines for equipment maintenance include, but are not limited to, the following:
 - 2.3.1A Recording of the method and frequency of maintenance of ultrasound instrumentation and digitizing equipment.
 - 2.3.2A Establishment of and adherence to a policy regarding routine safety inspections and testing of all facility electrical equipment.
 - 2.3.3A 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. The cleaning schedule must be frequent enough to allow for accurate collection of data.

Section 2A: Facility *Guidelines*

- 2.1.1A Approximately 150 square feet is recommended for a transthoracic echocardiography examination room.
- 2.1.1.3A A sink and antiseptic soap should be in or immediately outside of the examination room.
- 2.2A Space should be provided for data evaluation, interpretation and discussion of the study with the sonographer and/or referring physician as needed.

Section 3A: Examination Reports and Records

STANDARD - Records

- 3.1A Provisions must exist for the generation and retention of examination data for all echocardiograms performed. Measures for HIPAA compliance and IT security must be in place.
 - 3.1.1A A system for recording and archiving echocardiographic data (images, measurements and final reports) obtained for diagnostic purposes must be in place.
 - 3.1.2A A permanent record of the images and interpretation must be made and retained in accordance with applicable state or federal guidelines for medical records. Records for pediatric patients may need to be retained for a longer period of time than those of adult patients. Echocardiographic data, images and interpretations must be retrievable for comparison with new studies.
 - 3.1.3A Acceptable archiving media includes videotape and digital storage (including PACS, CD/DVD or other digital archiving media). Digital storage will be required by January 1, 2025.

STANDARD – Examination Interpretation and Reports

- 3.2A Provisions must exist for the timely reporting of examination data.
 - 3.2.1A There must be a policy in place for communicating critical results.
 - 3.2.2A The findings of a STAT echocardiogram must be made available immediately by an interpreting physician.

Comment: Sonographer worksheets, comments (verbal or written) or electronic summary of findings must not be provided to anyone other than the interpreting physician.

(See Guidelines on Page 13 for further recommendations.)

- 3.2.3A Preliminary reports can only be issued by a physician. There must be a policy in place for communicating any significant changes between the preliminary and final reports.
- 3.2.4A Routine inpatient echocardiographic studies must be interpreted by a qualified physician within 24 hours of completion of the examination. Outpatient studies must be interpreted by the end of the next business day. The final verified signed report must be completed within the longer of 48 hours, or the next business day, after interpretation.

(See Guidelines on Page 13 for further recommendations.)

- 3.3A Echocardiography reporting must be standardized in the facility. All physicians interpreting echocardiograms in the facility must agree on uniform diagnostic criteria and a standardized report format.¹
 - 3.3.1A The report must accurately reflect the content and results of the study. The report must include, but may not be limited to:
 - 3.3.1.1A Demographic Data:
 - i. date of study;
 - ii. name and/or identifier of the facility;
 - iii. name and/or identifier of the patient;
 - iv. date of birth and/or age of the patient;

- v. gender;
- vi. name of the performing sonographer and/or identifier; and
- vii. name of the ordering physician and/or identifier.

3.3.1.2A Clinical Data:

- i. primary indication for the study;
- ii. patient height and weight for determination of BSA; and
- iii. blood pressure systolic and diastolic blood pressure must be obtained on or around the time of the study and displayed on the report.

Comment: The information must be sufficient to allow for the identification and retrieval of previous studies on the same patient.

Please note: The reporting requirements above (3.3.1.1A and 3.3.1.2A) are for <u>pediatric TTE and TEE only</u>. For the fetal requirements, please refer to Fetal Echocardiogram Report Components on page 15 of this document.

3.3.1.3A A summary of the results of the examination. Summary comments must include any pertinent or positive and negative findings, particularly those relevant to the indication for the examination, and communication of critical findings.

(See Guidelines on Page 13 for further recommendations.)

3.3.1.4A The final report must be completely typewritten, including the printed name of the interpreting physician. The final report must be reviewed, signed and dated manually or electronically by the interpreting physician. Electronic signatures must be password protected and indicate they are electronically recorded. Stamped signatures or signing by non-physician staff is unacceptable.

3.4A Pediatric Transthoracic Echocardiogram Report Components

- 3.4.1A The report must accurately reflect the content and results of the study. The report must comment on whether a given measurement is abnormal. If any structure is not well visualized this must be noted. The report text must be consistent with the quantitative and Doppler data. This must include location and quantification of abnormal findings.
 - 3.4.1.1A The report for a comprehensive study must include the following numerical data:
 - i. relevant measurements performed;
 - ii. numerical data for transthoracic echocardiograms, must include, but not be limited to (except where technically or anatomically unobtainable or not applicable in the clinical setting):
 - measurements of the left ventricular internal dimension or volume at enddiastole;
 - left ventricular internal dimension or volume at end-systole;
 - left ventricular posterobasal free wall thickness and septal thickness or left ventricular mass at end-diastole;
 - aortic root dimension at the level of the sinuses of Valsalva; measurements of sinotubular junction and mid-ascending as clinically indicated; and
 - additional measurements may be indicated and when performed must be included.

Comment: Examples of exceptions to the above include:

right ventricular hypertension;

- hypoplastic left heart syndrome;
- tetralogy of Fallot; and
- · other pathology.
- 3.4.1.2A A report of the Doppler evaluation must include, but not be limited to:
 - the evaluation of peak and/or mean gradients (if stenosis is present or when clinically indicated);
 - ii. degree of regurgitation;
 - ii. peak tricuspid regurgitation velocity for estimation of right ventricular systolic pressure where obtainable or applicable in the clinical setting; and
 - iv. other pathology.

(See Guidelines on Page 13 for further recommendations.)

- 3.5A Pediatric Transesophageal Echocardiogram Report Components
 - 3.5.1A The report must accurately reflect the content and results of the study and must be consistent with the quantitative and Doppler data. Where appropriate, this must include location and quantification of abnormal findings. The report text must include, but may not be limited to:
 - 3.5.1.1A complications of the procedure (yes or no);
 - 3.5.1.2A comments on all structures evaluated in the examination.

(See Guidelines on Page 13 for further recommendations.)

- 3.6A <u>Fetal Echocardiogram Report Components</u>
 - 3.6.1A The report must include, but may not be limited to:
 - 3.6.1.1A Demographic Data:
 - i. date of study;
 - ii. name and/or identifier of the facility;
 - iii. name and/or identifier of the patient;
 - iv. date of birth and/or age of the patient;
 - v. name of the sonographer/physician performing the study; and
 - vi. name of the ordering physician(s) and/or identifier.
 - 3.6.1.2A Clinical Data:
 - i. primary indication for the study;
 - ii. last menstrual period or estimated date of delivery; and
 - iii. fetal number (if more than one).
 - 3.6.1.3A The report of measurements must include but not be limited to:
 - i. The measurements performed in the course of the examination appropriate to the clinical issue or area(s) of abnormality.
 - 3.6.1.4A The report of the Doppler evaluation must include, but not be limited to:
 - i. The Doppler values, normal and abnormal, obtained in the course of the examination appropriate to the clinical issue or area(s) of abnormality.

3.6.1.5A The report text must include comments on:

- i. components of procedure (i.e., color flow Doppler, PW/CW Doppler);
- ii. all structures evaluated in the examination as specified in the IAC Echocardiography Standards;
- iii. fetal heart rate and rhythm; and

Fetal Reports – If any structure is not well visualized this should be noted.

iv. the report text must be consistent with the quantitative and Doppler data.

Where appropriate, this must include localization and quantification of abnormal findings.

(See Guidelines below for further recommendations.)

Section 3A: Examination Reports and Records *Guidelines* 3.2.2A Suggested method for reporting life-threatening findings: Optimally, the interpreting physician in the facility will call the appropriate physician. Rarely, after conferring with the interpreting physician, the sonographer or another designee may communicate critical findings to the appropriate physician. 3.2.4A Comment: An interpretation can be in the form of paper, digital storage or an accessible voice system. 3.3.1.3A When available and relevant, comparison with a prior echocardiographic study and/or report should be done and noted in the final report. 3.4.1.2A Pediatric Transthoracic Reports – If the examination is abbreviated for any reason (i.e., patient uncooperativeness secondary to an unsedated exam) it should be noted in the report text. 3.5.1.2A Pediatric Transesophageal Reports – If any structure is not well visualized this should be noted. If the examination is abbreviated for any reason it should be noted in the report text.

3.6.1.5A

Section 4A: Facility Safety

STANDARD – Patient and Facility Safety

- 4.1A Patient and employee safety is ensured by written policies and procedures approved by the Medical Director.
 - 4.1.1A Personnel Safety Policy (Ergonomics) A policy must be in place to address technical staff safety, comfort and avoidance of work-related musculoskeletal disorders (MSD).
 - (See Guidelines on Page 15 for further recommendations.)
 - 4.1.2A When in the presence of ionizing radiation, all staff must observe proper radiation safety techniques as prescribed by the facility's policies.
 - 4.1.3A Standard echocardiograms are safe to both patients and sonographers. Special echocardiographic procedures, such as transesophageal echocardiograms, sedated echocardiograms and stress echocardiograms, pose potential risks to the safety of the patient due to either their semi-invasive nature, or the physiologic stress placed on the cardiovascular system of the patient. For this reason, an echocardiography facility providing special echocardiographic procedures must have an emergency procedure plan and the following emergency supplies must be readily available for transesophageal and sedated echocardiograms:
 - 4.1.3.1A a fully equipped cardiac arrest cart (crash cart):
 - i. The size and dosage differences between pediatric and adult patients must be recognized.
 - ii. Pediatric dosing information and/or appropriate pediatric dose of emergency medications must be available.
 - 4.1.3.2A a defibrillator;
 - 4.1.3.3A appropriate sized pediatric equipment for starting and maintaining intravenous access;
 - 4.1.3.4A oxygen tanks or wall mounted oxygen sources with appropriately sized cannulae and/or masks; and
 - 4.1.3.5A suction equipment.
 - 4.1.4A The facility must meet the standards set forth by the Occupational Safety and Health Administration (OSHA) and by the Joint Commission (JC), where applicable.
 - 4.1.5A The facility must have a written procedure in place for handling acute medical emergencies.
 - (See Guidelines on Page 15 for further recommendations.)
 - 4.1.6A The facility must recognize the potential need for patient sedation in pediatrics to obtain an adequate examination. Written policies must exist for the use of moderate sedation in children including but not limited to:
 - 4.1.6.1A type of sedatives and appropriate dosing for age and size;
 - 4.1.6.2A monitoring of children during and after the examination; and
 - 4.1.6.3A training requirements for personnel providing moderate sedation.

Section 4A: Facility Safety *Guidelines*

- 4.1.1A Comment: For additional information regarding MSD, please visit: www.cdc.gov/niosh/docs/wp-solutions/2006-148/ www.sdms.org/pdf/wrmsd2003.pdf
- 4.1.5A Post sedation: After sedation is administered, provider or designee should consider a follow up phone call or secure communication with the patient to ensure that there were not any late developing complications or the patient has any further questions related to the procedure.

Section 5A: Administrative

STANDARD – Patient Confidentiality

5.1A All facility personnel must ascribe to professional principles of patient-physician confidentiality as legally required by federal, state, local or institutional policy or regulation.

STANDARD – Patient or Other Customer Complaints

5.2A There must be a policy in place outlining the process for patients or other customers to issue a complaint/grievance in reference to the care/services they received at the facility and how the facility handles complaints/grievances.

STANDARD – Primary Source Verification

5.3A There must be a policy in place identifying how the facility verifies the medical education, training, appropriate licenses and certifications of all physicians as well as, the certification and training of all technical staff members and any other direct patient care providers.

Section 5A: Administrative *Guidelines*

Sample documents are available for each of the required policies listed in Section 5A on the IAC website at intersocietal.org/helpful-resources/sample-documents-repository.

Section 6A: Multiple Sites (Fixed and/or Mobile)

STANDARD - Multiple Sites

- 6.1A When testing is performed at more than one physical facility, the facility may be eligible to apply for a single accreditation as a multiple site facility.
 - 6.1.1A All facilities have the same Medical Director.
 - 6.1.2A All facilities have the same Technical Director.
 - 6.1.3A Identical testing protocols are used at all sites.
 - 6.1.4A Identical diagnostic criteria are used at all sites.
 - 6.1.5A For multi-site facilities, each site must be represented in the Quality Improvement (QI) process at least annually, whether done locally or centrally. All areas of testing (Pediatric Transthoracic, Pediatric Transesophageal and Fetal) at each site must be represented in this annual evaluation.
 - 6.1.6A Equipment of similar quality and capability must be used at all sites.

Section 6A: Multiple Sites (Fixed and/or Mobile) Guidelines

Facilities needing complete details on adding a multiple site should review the current IAC Policies and Procedures available on the IAC website at intersocietal.org/legal/policies-procedures.

Bibliography

- ACC/AHA/AAP Recommendations for Training in Pediatric Cardiology Task Force 2: Pediatric Training Guidelines for Noninvasive Cardiac Imaging endorsed by the American Society of Echocardiography and the Society of Pediatric Echocardiography. Sanders, S., et al., *J Am Coll of Cardiol*, 2005;46(7);1384-1388.
 content.onlinejacc.org/article.aspx?articleid=1136952
- Guidelines and Standards for Performance of a Pediatric Echocardiogram: A Report from the Task Force of the Pediatric Council of the American Society of Echocardiography. Lai, W., et al., J Am Soc of Echocardiogr, 2006;19(12);1413-1430. www.onlinejase.com/article/S0894-7317(06)00936-9/fulltext
- 3. Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnosis and Therapeutic Procedures Committee on Drugs for the American Academy of Pediatrics. Coté, C., et al., *Pediatrics*, 2006;118(6);2587-2602. pediatrics.aappublications.org/content/118/6/2587
- Guidelines and Recommendations for Digital Echocardiography: A Report from the Digital Echocardiography Committee of the American Society of Echocardiography. Thomas, J., et al., J Am Soc Echocardiogr, 2005;18(3):287-297. www.onlinejase.com/article/S0894-7317(05)00019-2/fulltext
- Recommendations for Quantification Methods During the Performance of a Pediatric Echocardiogram: A Report from the Pediatric Measurements Writing Group of the American Society of Echocardiography Pediatric and Congenital Heart Disease Council. Lopez, L., et al., J Am Soc Echocardiogr, 2010;23(5):465-495. www.onlinejase.com/article/S0894-7317(10)00266-X/fulltext
- Radiation Safety for the Cardiac Sonographer: Recommendations of the Radiation Safety Writing Group for the Council on Cardiovascular Sonography of the American Society of Echocardiography. McIlwain, E., et al., *J Am Soc Echocardiogr*, 2014;27(8):811-6. www.onlinejase.com/article/S0894-7317(14)00432-5/fulltext
- Industry Standards for the Prevention of Work Related Musculoskeletal Disorders in Sonography: Developed Through A 2016
 Consensus Conference Hosted by the Society of Diagnostic Medical Sonography. www.sdms.org/docs/default-sources/industry-standards-for-the-prevention-of-work-related-musculoskeletal-disorders-in-sonography.pdf

Part B: Examinations and Procedures

Section 1B: Pediatric Transthoracic Echocardiography Testing

STANDARD – Instrumentation

- 1.1B <u>Cardiac Ultrasound Systems</u>
 - 1.1.1B Ultrasound instruments utilized for diagnostic studies must include, at a minimum, hardware and software to perform:
 - 1.1.1.1B M-Mode imaging;
 - 1.1.1.2B 2-D imaging (the system must include harmonic capabilities);
 - 1.1.1.3B spectral display for pulsed (PW) and continuous wave (CW) Doppler studies;
 - 1.1.1.4B color flow Doppler;
 - 1.1.1.5B monitor or other display method of suitable size and quality for observation and interpretation of all modalities;

Comment: The display or DICOM header must identify the parent institution, the name of the patient, second patient identifier (such as MRN or DOB), the date and time of the study. The ECG must also be displayed.

- 1.1.1.6B range or depth markers must be available on all displays;
- 1.1.1.7B 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;
- 1.1.1.8B transducers, which can provide adequate imaging across the wide range of depths encountered in pediatrics, must be available.
 - Multiple imaging transducers, ranging from low frequency (2-2.5 MHz) to high frequency (7.5 MHz or higher) or a multi-frequency transducer which includes a range of frequencies specific to the clinical needs in pediatric echo
 - ii. A transducer dedicated to the performance of non-imaging continuous wave Doppler must be available at each site.
- 1.1.1.9B an audible output must be present at the time of acquisition;
- 1.1.1.10B machines with some, but not all of the above, equipment may be used for focused or directed echocardiographic examinations. However, machines utilized for comprehensive diagnostic procedures must include all of the above listed capabilities.

(See Guidelines on Page 23 for further recommendations.)

STANDARD – Procedure Volumes

1.2B The annual procedure volume is sufficient to maintain proficiency in examination performance and interpretation.

STANDARD – Indications, Ordering Process and Scheduling

- 1.3B Transthoracic echocardiography testing is performed for appropriate indications.¹
 - 1.3.1B <u>Verification of the Indication</u> A process must be in place in the facility for obtaining and recording the indication. Before a study is performed, the indication must be verified and any additional information needed to direct the examination must be obtained.¹
- 1.4B Echocardiography testing is appropriately ordered and scheduled.
 - 1.4.1B Ordering Process The echocardiogram order and requisition must clearly indicate the type of study to be performed (i.e., complete or limited), the reason(s) for the study and the clinical question(s) to be answered. The signed (electronic or handwritten) order/requisition must be present in the medical record of the patient.
 - 1.4.2B Definition of Procedure Types and Protocols
 - 1.4.2.1B Comprehensive Study: A comprehensive imaging study is one that defines the cardiac and visceral position and a complete segmental image analysis of the heart from multiple views and also defines the cardiac anatomy and physiology as fully as possible using imaging and Doppler modalities.
 - 1.4.2.2B Focused Study: A focused study generally examines a specific region of interest of the heart and/or addresses a defined clinical question. Focused studies are not sufficient if the patient with suspected congenital heart disease has never had a comprehensive echocardiogram before.
 - 1.4.3B Scheduling Sufficient time must be allotted for each study according to the procedure type. The performance time allotted for a comprehensive (imaging and Doppler) pediatric transthoracic examination is 45 to 60 minutes from patient encounter to departure. Additional time may be required for complicated studies or sedated patients.
 - 1.4.3.1B An urgent study must be performed in the next available time period.
 - 1.4.3.2B A stat study must be performed as soon as possible, preempting routine studies.
 - 1.4.3.3B Availability for Emergencies: Qualified personnel and equipment must be available for urgent or stat studies outside normal working hours in inpatient facilities or where appropriate.

(See Guidelines on Page 23 for further recommendations.)

STANDARD – Techniques

- 1.5B Examination performance must include proper technique.
 - 1.5.1B All procedures must be explained to the patient and/or parents or guardian.
 - 1.5.2B Elements of study performance and quality include, but are not limited to:
 - 1.5.2.1B optimizing patient position and environment with careful attention to comfort and safety;

Comment: This is particularly important in vulnerable patients such as critically ill neonates.

- 1.5.2.2B appropriate patient distraction such as movies or sedation utilizing institutional protocols;
- 1.5.2.3B correct transducer selection for patient size;
- 1.5.2.4B optimization of equipment settings and display of ECG;
- 1.5.2.5B performance of a comprehensive 2-D/M-Mode/Doppler imaging and hemodynamic examination according to the facility specific protocols that incorporate all views and imaging planes mandated by Standards 1.6.1.1B, 1.6.1.2B, 1.6.1.3B, 1.6.1.4B, 1.6.1.5B;
- 1.5.2.6B storage of all images and data; and
- 1.5.2.7B timely report generation and communication of results.

STANDARD – Components of the Transthoracic Echocardiogram

- 1.6B Transthoracic echocardiograms must be comprehensive and include standard components.
 - 1.6.1B <u>Components of the Examination</u> A protocol must be in place that defines the components of the standard examination.

(See Guidelines on Page 23 for further recommendations.)

- 1.6.1.1B The comprehensive examination, when applicable or available, must include the following standard views when cardiac anatomy allows:
 - i. inferior and superior vena cava;
 - ii. hepatic veins;
 - iii. pulmonary veins;
 - iv. right, left or single atrial morphology;
 - v. atrial septum;
 - vi. atrioventricular valve morphology and function;
 - vii. right, left or single ventricular morphology;
 - viii. ventricular septum;
 - ix. semilunar valve morphology and function;
 - x. coronary arteries when visible;
 - xi. ascending, transverse and descending aorta with demonstration of arch sidedness and branching pattern;
 - xii. main pulmonary artery and proximal branch pulmonary arteries;
 - xiii. pericardium; and
 - xiv. measurements of the cardiac chambers and ventricular function where standard measurements are available.
- 1.6.1.2B Comprehensive Doppler Study: Includes spectral Doppler and/or color flow interrogation of all normal and abnormal flows within the heart including:
 - i. atrioventricular valves;
 - ii. semilunar valves;
 - iii. atrial septum;

- iv. ventricular septum;
- v. great vessels.
- 1.6.1.3B Standard views for the comprehensive examination of the anatomically normal heart must include the following standard 2-D views (except where technically unobtainable):
 - i. parasternal long axis view; (including evaluation of the right ventricular inflow and right ventricular outflow);
 - ii. parasternal short axis view (including evaluation at the level of the aorta and pulmonary valves, mitral, mid papillary muscle level and apex);
 - iii. apical four-chamber view;
 - iv. apical long axis view;
 - v. subcostal long axis view (also known as subcostal coronal);
 - vi. subcostal short axis view (also known as subcostal sagittal) including evaluation of the SVC, IVC, hepatic veins and descending aorta;
 - vii. suprasternal long axis view;
 - viii. suprasternal short axis view;
 - ix. right parasternal view (when indicated).
- 1.6.1.4B The following 2-D, 3-D or M-Mode measurements of the left heart (where appropriate):
 - i. left ventricular internal dimension and/or volume at end-diastole;
 - ii. left ventricular internal dimension and/or volume at end-systole;
 - iii. left ventricular posterobasal free wall thickness and ventricular septal thickness at end-diastole or left ventricular mass;
 - iv. aortic root dimension;
 - v. left atrial dimension or left atrial volume index at end-systole (when clinically indicated).
- 1.6.1.5B The following standard Doppler evaluations:
 - i. color Doppler interrogation of all four cardiac valves in at least two imaging planes;
 - ii. Spectral Doppler interrogation of all four cardiac valves including forward flow and regurgitation;
 - iii. tricuspid regurgitation velocity when available to estimate the systolic right ventricular pressure in patients with anatomically normal hearts;
 - iv. color mapping of the atrial and ventricular septa to exclude defects;
 - v. spectral Doppler interrogation and color mapping for the ventricular outflow tracts, pulmonary arteries and aortic arch;
 - vi. spectral Doppler interrogation of the abdominal aorta.

Comment: These may be different in congenitally malformed and/or surgically repaired complex malformations and cases with abnormalities of cardiac position.

(See Guidelines on Page 23 for further recommendations.)

Section 1B: Pediatric Transthoracic Echocardiography Testing Guidelines

1.1.1B Cardiac Ultrasound Systems

- Instrument settings to enable optimization of ultrasound enhancing agents.
- There should be a system setting to display low frequency Doppler filtering for tissue Doppler display.

1.4.3B <u>Scheduling</u>

- Additional time should be allocated for technical staff to complete analysis and documentation for each study.
- A routine study on an inpatient should be performed on the same working day as ordered, unless
 otherwise specified. Outpatient studies should be assigned priority as defined by the referring physician
 and/or the indication of the study. The facility should have a policy defining STAT echocardiogram
 indications.
- 1.6.B Use of Ultrasound Enhancing Agents (UEAs) for Suboptimal Image Quality –UEAs should be considered when the LV cannot be visualized adequately for the assessment of LV function including global and regional wall motion assessment.
 - If UEAs are used, there must be a written policy for the use of UEAs. Although hypersensitivity reactions are rare, laboratories that use UEAs must have policies in place for emergent resuscitation of patients who may experience serious side effects.
 - Cardiopulmonary resuscitation personnel and equipment must be readily available prior to ultrasound enhancing agent administration.

1.6.1B <u>Components of the Examination</u>

For all imaging protocols, if any required view or Doppler signal cannot be adequately obtained, it should be recorded and labeled in order to demonstrate that it was attempted.

- Strain imaging should be considered when clinically indicated. If strain is performed it should be reported.
- 3D imaging should be performed when clinically indicated and should be reported.
- Diastolic Function Evaluation LV diastolic function should be evaluated through a combination of PW and tissue Doppler techniques where appropriate.
- Spectral Doppler interrogation and color mapping of the systemic and pulmonary veins may be helpful in some cases.
- Use of a dedicated non-imaging CW Doppler transducer to assess stenotic valves or valvular regurgitation may be helpful in some cases.

Bibliography

- 1. Guidelines and Standards for Performance of a Pediatric Echocardiogram: A Report from the Task Force of the Pediatric Council of the American Society of Echocardiography. Lai, W., et al., *J Am Soc of Echocardiogr*, 2006;19(12);1413-1430. www.onlinejase.com/article/S0894-7317(06)00936-9/fulltext
- 2. Recommendations for Quantification Methods During the Performance of a Pediatric Echocardiogram: A Report from the Pediatric Measurements Writing Group of the American Society of Echocardiography Pediatric and Congenital Heart Disease Council. Lopez, L., et al., *J Am Soc Echocardiogr*, 2010;23(5):465-495. www.onlinejase.com/article/S0894-7317(10)00266-X/fulltext
- ACC/AAP/AHA/ASE/HRS/SCAI/SCCT/SCMR/SOPE 2014 Appropriate Use Criteria for Initial Transthoracic Echocardiography in Outpatient Pediatric Cardiology. Campbell, R., et al., J Am Coll of Cardiol, 2014;64(19):735-1097. www.onlinejacc.org/content/64/19/2039
- 4. ACC/AHA/ASE/HRS/ISACHD/SCAI/SCCT/SCMR/SOPE 2020 Appropriate Use Criteria for Multimodality Imaging During the Follow-Up Care of Patients With Congenital Heart Disease: A Report of the American College of Cardiology Solution Set Oversight Committee and Appropriate Use Criteria Task Force, American Heart Association, American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Pediatric Echocardiography. Sachdeva, R., et al., *Journal of the American College of Cardiology*, 2020; 75;657-703. www.jacc.org/doi/pdf/10.1016/j.jacc.2019.10.002
- 5. Clinical Applications of Ultrasonic Enhancing Agents in Echocardiography: 2018 American Society of Echocardiography Guidelines Update. Porter, T., et al., *J Am Soc Echocardiogr*, 2018;31:241-274. www.asecho.org/guideline/clinical-applications-of-ultrasonic-enhancing-agents-uea-in-echocardiography-2018-update
- Expert Consensus Statement from the American Society of Echocardiography on Hypersensitivity Reactions to Ultrasound Enhancing Agents in Patients with Allergy to Polyethylene Glycol (Peg). www.asecho.org/wpcontent/uploads/2021/04/ASE-2506 FDA-EDC-Document 42921.pdf
- 7. Three-dimensional echocardiography in congenital heart disease: an expert consensus document from the European Association of Cardiovascular Imaging and the American Society of Echocardiography. Simpson, J., et al., *J Am Soc Echocardiogr*, 2017;30:1-27. www.asecho.org/wp-content/uploads/2017/01/3D-Echo-in-CHD.pdf

Section 2B: Pediatric Transesophageal Echocardiography Testing

STANDARD – Instrumentation

2.1B <u>Cardiac Ultrasound Systems</u>

2.1.1B Ultrasound instruments utilized for pediatric transesophageal echocardiographic studies (TEEs) must include the echocardiographic imaging system requirements, as outlined in the Section 1B: Pediatric Transthoracic Echocardiography Testing, STANDARD – Instrumentation.

2.2B Transesophageal Ultrasound Transducer

- 2.2.1B Transesophageal ultrasound transducers must be those manufactured for the ultrasound system used in the facility.
- 2.2.2B Pediatric transesophageal ultrasound transducers must incorporate multiplane imaging capabilities where the patient is of sufficient size to allow such probe use. In cases where extremely small infants are examined, the use of a "mini" single plane TEE transducer may be appropriate.
- 2.2.3B Pediatric transesophageal ultrasound transducers must be small enough to be used in a safe and prudent manner in infants and children and appropriate for their body weight.
- 2.2.4B A written policy must be established for cleaning/decontaminating the TEE transducer, ultrasound system, cables, etc., between patient use in accordance with local infection control policies/procedures.
- 2.2.5B The manufacturer's guidelines must be followed for the appropriate care and cleansing of the TEE transducer and adhere to the appropriate infectious disease standards to prevent the transmission of disease. The structural and electrical integrity of the transducer must be checked between each use, using an ultrasound transducer leakage tester. "Passed" or "Failed" must be documented in the routine TEE probe cleaning / maintenance log along with action taken if "Failed."

STANDARD – Procedure Volumes

2.3B The annual procedure volume must be sufficient to maintain proficiency in examination performance and interpretation.

STANDARD – Indications, Ordering Process and Scheduling

- 2.4B Transesophageal echocardiographic testing is performed for appropriate indications.¹
 - 2.4.1B <u>Verification of the Indication</u> A process must be in place in the facility for obtaining and recording the indication. Before a study is performed, the indication must be verified and any additional information, including pertinent clinical history, needed to direct the examination should be obtained. If the indication for the examination and/or clinical history are not clear, the physician performing the TEE must verify the clinical history and an appropriate indication before proceeding with the examination.

(See Guidelines on Page 29 for further recommendations.)

2.5B Transesophageal echocardiographic studies are appropriately ordered and scheduled.

- 2.5.1B Ordering Process The TEE order and/or requisition must clearly indicate the type of study to be performed, reason(s) for the study and the clinical question(s) to be answered. The order/requisition must be present in the medical record of the patient.
- 2.5.2B <u>Definition of Procedure Types and Protocols</u>
 - 2.5.2.1B A TEE examination is one that examines all of the cardiac chambers, valves and great vessels from multiple imaging planes, and then uses the information to completely define any recognized abnormalities. This examination must include appropriate Doppler interrogation of all cardiac valves and structures (e.g., pulmonary veins and atrial appendage) and provide any hemodynamic data felt to be of importance for patient care.
 - 2.5.2.2B The TEE is an invasive examination performed using general anesthesia or moderate sedation. The facility must demonstrate that all medical and technical staff routinely adhere to the global moderate sedation policies in place for the medical facility as required by the Joint Commission or other appropriate accrediting organizations.
- 2.5.3B Scheduling Sufficient time must be allotted for each study according to the procedure type. The performance time allotted for an uncomplicated, comprehensive study (outside of the OR or interventional lab) is estimated to be 45 to 60 minutes, with an additional 15 to 30 minutes for complicated studies from patient encounter to departure. Sufficient time must be included in the scheduling process for adequate post-sedation monitoring.

(See Guidelines on Page 29 for further recommendations.)

STANDARD - Training

- 2.6B Transesophageal echocardiography is an invasive examination, which, if performed incorrectly, can lead to serious harm to patients and therefore, must be performed by appropriately trained physicians.
 - 2.6.1B A TEE facility requires that the performing physicians are adequately trained and experienced to perform and interpret the study. All physicians performing TEE must meet published guidelines.¹
 - 2.6.2B All assisting sonographers and nurses must be adequately trained to assist in invasive procedures using moderate sedation or general anesthesia.

STANDARD – Techniques

- 2.7B Examination performance must include proper technique.
 - 2.7.1B Elements of study performance and quality include, but are not limited to:
 - 2.7.1.1B correct transducer selection;
 - 2.7.1.2B atraumatic probe insertion and manipulation with maintenance of patient stability;
 - 2.7.1.3B optimization of equipment settings and display of ECG;
 - 2.7.1.4B performance of a transesophageal examination according to the facility specific and appropriate protocol that incorporates all views and imaging planes mandated by the IAC Echocardiography Standards.
 - 2.7.1.5B optimal and lesion specific utilization of appropriate imaging and Doppler techniques and measurements; and
 - 2.7.1.6B safe transducer removal, image storage and timely reporting of results.

STANDARD – Components of Transesophageal Echocardiograms

- 2.8B Transesophageal echocardiograms must be comprehensive and include standard components.
 - 2.8.1B <u>Technical Personnel</u> Due to the complexity of the TEE study, appropriate technical personnel must be available to assist the performing physician. These personnel may include a sonographer and a nurse. The duties of these individuals include, but are not limited to:
 - 2.8.1.1B preparing the patient for the test;
 - 2.8.1.2B assisting the physician with the ultrasound equipment;
 - 2.8.1.3B monitoring the patient during and after the examination; and
 - 2.8.1.4B administration of anesthetic medication and airway management.
 - 2.8.2B <u>Preparation of the Patient</u> To perform TEE studies safely, appropriate safety guidelines must be in place. Patients must have a functioning intravenous access in place. Cardiac monitoring with standard ECG telemetry leads must be utilized. Instrumentation to monitor the oxygen saturation of the patient before, during and after the examination must be available, as well as oxygen with appropriate delivery devices if needed.
 - 2.8.3B Procedural Sedation The facility must recognize the potential need for patient sedation in order to obtain an adequate examination. This may be provided by the anesthesia service or by a licensed provider. If moderate sedation is utilized there must be methods in place to assess the patient's level of consciousness pre-procedure and throughout the procedure. All procedures must be explained to the patient and/or the parents or guardians of those unable to give informed consent. Consent must be obtained in a manner consistent with the rules and regulations required by the hospital or facility. Written policies must exist for the use of moderate sedation including but not limited to:
 - 2.8.3.1B type of sedatives and appropriate dosing; and
 - 2.8.3.2B monitoring during and after the examination.
 - 2.8.4B Monitoring the Patient During the procedure, the vital signs and physiologic status of the patient must be continually evaluated and recorded per institutional policy. The development of instability in either the comfort or vital signs of the patient must be addressed by the performing physician and/or other attending staff providing sedation or anesthesia. Facility guidelines for the monitoring of patients who receive intravenous anesthetic agents are required. These written guidelines must be in place and available for all facilities where TEEs are performed. A list of peri-procedural complications must be maintained.
 - 2.8.5B Recovery of the Patient Prior to discharge from the TEE facility, the patient must be monitored for a sufficient amount of time to assure that no complications have arisen either from the procedure or the medication administered. The patient and/or the family must be instructed on any post-procedure care that the physician feels is necessary. Information must be given that will allow them to recognize potential complications or side effects and contact the performing physician or physician on call should complications arise after patient discharge. A method to track procedural complications must be maintained.
 - 2.8.6B Components of the Examination A protocol must be in place that defines the standard views and components of a comprehensive TEE examination. Indications for performance of a TEE examination must be included. A comprehensive TEE and TEE-Doppler examination includes standard views from multiple planes including views of all cardiac structures and selected extracardiac structures.

(See Guidelines on Page 29 for further recommendations.)

2.8.7B The comprehensive examination, when applicable or available, must include the following standard views when cardiac anatomy allows: multiple imaging planes and "4 chamber" equivalent scanning showing the right, 2.8.7.1B left sided or single atrial and ventricular anatomy and function; 2.8.7.2B multiple imaging planes of the pulmonary venous connections bilaterally, with appropriate Doppler; 2.8.7.3B multiple imaging planes of the connections of the proximal inferior and superior vena cavae and hepatic veins; 2.8.7.4B multiple imaging planes of the atrial septum, foramen ovale and the entire ventricular septum, with appropriate Doppler; multiple imaging planes of the right, left or single atrio-ventricular valves, with 2.8.7.5B appropriate Doppler; 2.8.7.6B multiple imaging planes of the right, left or single ventricular outflow tracts; 2.8.7.7B short and long axis views of the aortic valve including coronary artery origins, with appropriate Doppler; 2.8.7.8B longitudinal view of the pulmonic valve, with appropriate Doppler; 2.8.7.9B short and long axis views of the ascending aorta; 2.8.7.10B short and long axis views of the main pulmonary artery and proximal portions of the right and left pulmonary arteries when possible; 2.8.7.11B gastric short axis and long axis views of ventricles and outflow tracts; 2.8.7.12B imaging of the pericardial space and pericardium; and 2.8.7.13B evaluation of extracardiac structures visualized when appropriate.

STANDARD – Focused Pediatric TEE

- 2.9B It is recognized that many TEEs are performed in situations (i.e., in the OR or interventional catheterization suite) that may limit or prevent complete evaluation due to time constraints or are focused studies to answer specific clinical questions. The focused examination when applicable or available must include the following standard views when cardiac anatomy allows:
 - 2.9.1B multiple imaging planes and "4 chamber" equivalent scanning showing the right, left or single atrial and ventricular anatomy and function;
 - 2.9.2B multiple imaging planes of the atrial septum, foramen ovale and the entire ventricular septum with appropriate Doppler;
 - 2.9.3B multiple imaging planes of the right, left or single atrio-ventricular valves with appropriate Doppler;
 - 2.9.4B multiple imaging planes of the right, left or single ventricular outflow tracts;
 - 2.9.5B short and long axis views of the aortic valve with appropriate Doppler;
 - 2.9.6B longitudinal view of the pulmonic valve with appropriate Doppler; and
 - 2.9.7B gastric short axis and long axis views of ventricles and outflow tracts.

Section 2B: Pediatric Transesophageal Echocardiography Testing Guidelines

2.4.1B <u>Indications</u>

In general, a TEE should be performed to answer clinical questions that cannot be answered by transthoracic imaging.

2.5.3B Scheduling

- An urgent or stat TEE study should be performed as soon as possible and may preempt other clinical facility activities.
- Availability for Emergencies: Qualified personnel and equipment should be available for urgent or stat studies outside of normal working hours in most tertiary inpatient facilities or where appropriate in other medical facilities offering TEE services.

2.8.6B Components of the Examination

The examination should be performed in a methodical fashion although the order of imaging plane acquisitions and Doppler may vary so as to answer the question at hand in an expeditious fashion. Although focused TEE examinations may have a role in specific clinical situations, a facility should generally perform comprehensive examinations routinely, due to the high yield of unexpected findings.

Bibliography

1.	Guidelines for Performing a Comprehensive Transesophageal Echocardiographic Examination in Children and All Patient with Congenital Heart Disease: Recommendations from the American Society of Echocardiography. M. Puchalski, et al., <i>J AM Soc Echocardiogr</i> , 2019; 32(2)173-215. www.asecho.org/wp-content/uploads/2019/02/TEE-Ped-and-CHD.pdf

Introduction to IAC Standards for Fetal Echocardiography Testing

The fetal echocardiogram is an important diagnostic imaging test, which is used to evaluate the fetal heart for the presence of structural or functional abnormalities. As with other aspects of medical care involving the fetus, it is inadequate to consider either the fetus or the pregnant individual as the sole patient. Rather, the maternal-fetal relationship must be carefully considered for the respective impact of both the pregnant individual and fetus on each other.

It has been difficult within the practice of medical care to define personnel with the appropriate training and expertise to address the issues involved both in the care of the maternal-fetal patient as well as the often complex issues faced by the fetus after birth when complex problems or anomalies are present. Therefore, the training and practice of fetal echocardiography often requires a team approach, encompassing the skills of both the obstetrical and pediatric aspects of medical care. Perinatologists and specialists in maternal-fetal medicine in many instances have become very skilled at imaging fetal structures, including the heart, but often lack the knowledge and experience of the care and long-term management of the infant after birth. Conversely, the pediatric cardiologist and echocardiographer have an understanding of the anatomy and physiology of congenital heart problems, but often lack formal training in the issues surrounding the care of the pregnant individual and imaging other fetal structures.

These Standards are being offered as an adjunctive accreditation to the pediatric transthoracic echocardiography facility accreditation. Therefore, an intimate relationship with a pediatric cardiology facility will be needed for this accreditation. However, the IAC recognizes the unique nature of fetal echocardiography and has allowed flexibility for a variety of practice situations.

Section 3B: Fetal Echocardiography Testing

STANDARD – Instrumentation

3.1B <u>Cardiac Ultrasound Systems</u>

3.1.1B Ultrasound instruments utilized for fetal echocardiographic studies must include the echocardiographic imaging system requirements, as outlined in Section 18: Pediatric Transthoracic Echocardiography Testing, STANDARD – Instrumentation.

3.2B Fetal Ultrasound Transducer

- 3.2.1B Ultrasound transducers must be those manufactured for the ultrasound system of the facility.
- 3.2.2B M-Mode, Doppler, color-flow Doppler and image enlarging (zoom) are features which must be incorporated into each fetal ultrasound imaging system.

STANDARD – Procedure Volumes

3.3B The annual procedure volume is sufficient to maintain proficiency in examination performance and interpretation.

STANDARD – Indications, Ordering Process and Scheduling

- 3.4B Fetal echocardiographic testing is performed for appropriate indications.¹
 - 3.4.1B <u>Verification of the Indication</u> A process must be in place in the facility for obtaining and recording the indication. Before a study is performed, the indication must be verified and any additional information needed to direct the examination must be obtained.¹
- 3.5B Fetal Echocardiography studies are appropriately ordered and scheduled.
 - 3.5.1B Ordering Process The echocardiogram order and requisition must clearly indicate the type of study to be performed, the reason(s) for the study and the clinical question(s) to be answered. The order/requisition must be present in the medical record of the patient.
 - 3.5.2B <u>Definition of Procedure Types and Protocols</u>
 - 3.5.2.1B A comprehensive fetal echocardiographic study is one that examines all of the cardiac chambers, valves, great vessels, septa and venous connections from multiple imaging planes. The examination must include an assessment of cardiac position, ventricular function, extracardiac fluid and heart rhythm. This study must include appropriate Doppler interrogation of all cardiac valves and structures and provide any hemodynamic data felt to be of importance for patient care.
 - 3.5.2.2B A follow-up or repeat fetal echocardiographic study may contain all of the elements found in a comprehensive study, but is more often used to re-examine specific elements of cardiac structure or function or to evaluate the changes in the abnormal or suspected abnormal fetal heart which have may have occurred with fetal growth or to evaluate the effects of therapy (e.g., fetal arrhythmia treatment).

3.5.3B Scheduling – Sufficient time must be allotted for each study according to the procedure type. The performance time for an uncomplicated, comprehensive study is estimated to be 45 to 60 minutes. Additional time may be required for complicated studies.

STANDARD – Techniques

- 3.6B Examination performance must include proper technique.
 - 3.6.1B All procedures must be explained to the patient (pregnant individual) and/or parents or guardian.
 - 3.6.2B Echocardiogram examinations of the fetal heart must examine all cardiac chambers and structures and areas of abnormality. The course and extent of disease must be documented.
 - 3.6.3B Elements of study performance and quality include, but are not limited to:
 - 3.6.3.1B optimizing patient position with careful attention to comfort and safety;
 - 3.6.3.2B correct transducer selection for patient size;
 - 3.6.3.3B optimization of equipment gain and display setting;
 - 3.6.3.4B performance of an examination according to the facility specific and appropriate protocol that incorporates all views and imaging planes mandated by the IAC Echocardiography Standards outlined in 3.7B;
 - 3.6.3.5B representative image storage of all images and data; and
 - 3.6.3.6B timely report generation and communication of results.

STANDARD – Components of the Fetal Echocardiogram

- 3.7B Fetal echocardiograms must be comprehensive and include standard components.
 - 3.7.1B <u>Patient Preparation</u> To perform fetal echocardiography the patient (pregnant individual) must be comfortably positioned and adequate privacy maintained.
 - 3.7.2B <u>Technical Personnel</u> These personnel may include a sonographer and a nurse. The duties of the technical personnel may also include, but are not limited to, preparing the patient for the test, performing the examination, assisting with the ultrasound equipment, and monitoring the patient's well-being and comfort during and after the examination.
 - 3.7.3B <u>Components of the Examination</u> Components of the standard fetal examination must be defined for the facility. A technical protocol including the components of the examination must be written and adhered to in the facility. Indications for the performance of a fetal examination must be included.
 - 3.7.3.1B A comprehensive examination of the fetus includes standard views from multiple planes including views of all cardiac structures and selected extracardiac structures. It is recognized that the orientation of the fetus does not always allow the examiner to obtain "standard" images as in transthoracic echocardiography. Therefore, imaging views may be defined by their functional components rather than their specific orientation.
 - 3.7.4B The comprehensive examination, when applicable or available, must include the following standard views when cardiac anatomy allows:

3.7.4.1B	presence of single or multiple gestations and the locations of fetus(s) relative to pregnant individual (and each other);
3.7.4.2B	survey of fetal lie and position defining fetal orientation;
3.7.4.3B	fetal cardiac position and visceral situs;
3.7.4.4B	measurement of chest and heart circumference and area for calculation of size ratios;
3.7.4.5B	assessment of fetal heart rate and rhythm using appropriate M-Mode/Doppler techniques;
3.7.4.6B	assessment of fetal umbilical cord vasculature with spectral Doppler evaluation of flow in the fetal umbilical vessels and ductus venosus;
3.7.4.7B	imaging of the pericardial and pleural spaces, (additional assessment of the abdomen and skin for fluid or edema, if indicated);
3.7.4.8B	imaging and Doppler/color flow Doppler interrogation of the systemic veins, their course and cardiac connection;
3.7.4.9B	imaging and Doppler/color flow Doppler interrogation of the pulmonary veins, their course and cardiac connection;
3.7.4.10B	multiple imaging planes of the atria, atrial septum, foramen ovale, ductus arteriosus and ventricular septum, with appropriate Doppler assessment of flow direction and velocity;
3.7.4.11B	multiple imaging planes of the atrioventricular (mitral and/or tricuspid) valves, with appropriate Doppler evaluation;
3.7.4.12B	"four-chamber" or equivalent and short axis views of the heart for assessment of cardiac chamber size and function;
3.7.4.13B	assessment of ventricular outflow and semilunar valves including the ventriculo- arterial connections with appropriate Doppler/color flow Doppler;
3.7.4.14B	short and long axis views of the ascending, descending and transverse arch of the aorta and ductus arteriosus with appropriate Doppler/color flow Doppler;
3.7.4.15B	2D three vessel view and the three-vessel tracheal view with appropriate Doppler/color flow Doppler;
3.7.4.16B	short and long axis views of the main pulmonary artery and proximal portions of the right and left pulmonary arteries; and
3.7.4.17B	additional fetal examination elements, such as, evaluation of the middle cerebral blood flow Doppler for evidence of redistribution of flow (i.e., brain sparing) may also be performed at the discretion of the operator.

(See Guidelines on Page 35 for further recommendations.)

Section 3B: Fetal Echocardiography *Guidelines*

3.7.4B	Measurement of biparietal diameter (BPD), head circumference or other measures for estimation of fetal size/gestational age may be performed as clinically indicated.

Bibliography

- 1. American Society of Echocardiography Guidelines and Standards for Performance of the Fetal Echocardiogram. Rychik, J., et al., *J Am Soc Echocardiogr*, 2004;17(7):803-810. www.onlinejase.com/article/S0894-7317(04)00382-7/fulltext
- 2. AHA Scientific Statement Diagnosis and Treatment of Fetal Cardiac Disease: A Scientific Statement from the American Heart Association. Donofrio, M., et al., *Circulation*. 2014;129:2183-2242 www.ahajournals.org/doi/10.1161/01.cir.0000437597.44550.5d

Part C: Quality Improvement

Section 1C: Quality Improvement Program

STANDARD – QI Program

- 1.1C The facility must have a written Quality Improvement (QI) program for all imaging procedures. The QI program must include the QI measures outlined below but may not be limited to the evaluation and review of:
 - 1.1.1C technical quality and, if applicable, safety of the imaging;
 - 1.1.2C interpretive quality review;
 - 1.1.3C report completeness and timeliness;
 - 1.1.4C correlation.

STANDARD - QI Oversight

1.2C The Medical Director, staff and/or an appointed QI Committee must provide oversight to the QI program including but not limited to review of the reports of QI evaluations and any corrective actions taken to address any deficiencies.

Section 1C: Quality Improvement Program Guidelines

The IAC Quality Improvement (QI) Self-Assessment Tool may be utilized that includes all Quality Improvement measures. Learn more at www.intersocietal.org/QITool.

Section 2C: Quality Improvement Measures

STANDARD – QI Measures

2.1C Facilities are required to have a process in place to evaluate the QI measures outlined in sections 2.1.1C through 2.1.4C. A minimum of two cases per modality (TTE, TEE, Fetal) per quarter must be evaluated and the same cases may be used for the first three measures.

(See Guidelines on Page 39 for further recommendations.)

2.1.1C <u>Technical Quality Review</u>

- 2.1.1.1C The facility must evaluate the technical quality of the images and, if applicable, the safety of the procedure. The review must include but is not limited to the evaluation of:
 - the clinical images for clarity of images and/or evaluation for suboptimal images or artifact;
 - ii. completeness of the study; and
 - iii. adherence to the facility imaging acquisition protocols.
- 2.1.1.2C A minimum of two cases per modality (TTE, TEE, Fetal) per quarter must be reviewed for image quality, completeness of the study and adherence to the facility protocol. The cases must represent as many sonographers as possible. Discrepancies in acquisition quality and variability must be reconciled to achieve uniform examination quality.
- 2.1.2C <u>Interpretive Quality Review (Physician Interpretation Variability)</u>
 - 2.1.2.1C The facility must evaluate the quality and accuracy of the interpretation based on the acquired images.
 - i. A minimum of two cases per modality (TTE, TEE, Fetal) per quarter must be evaluated for the quality and accuracy of the interpretation based on the acquired images. The cases must represent as many physicians as possible. Differences in interpretation must be reconciled to achieve uniform examination interpretation.

2.1.3C Final Report Completeness and Timeliness

- 2.1.3.1C The facility must evaluate the final report for completeness and timeliness as required in the Standards.
 - i. A minimum of two cases per modality (TTE, TEE, Fetal) per quarter must be evaluated for completeness and timeliness of the final report as required in the Standards. The reports must represent as many physicians as possible.

2.1.4C Correlation

2.1.4.1C Correlation must be performed with any appropriate imaging modality, surgical findings or clinical outcomes for a minimum of four cases annually with at least two cases per relevant testing area to be reviewed in QI meetings.

(See Guidelines on Page 39 for further recommendations.)

Section 2C: Quality Improvement Measures *Guidelines*

- 2.1C The facility should evaluate the appropriateness of the initial outpatient transthoracic echocardiogram performed and categorize as:
 - appropriate;
 - may be appropriate; or
 - rarely appropriate.

There should be a mechanism for education of referring physicians to improve the appropriateness of testing.

2.1.4C Correlation and Confirmation of Results

Correlation of Transthoracic Echocardiograms: For those patients who have undergone transthoracic echocardiograms and other diagnostic procedures (such as cardiac catheterization, MRI, CT), surgical intervention or post mortem examination, the results of transthoracic echocardiograms and other procedures should be routinely compared. Correlation data for each physician responsible for the interpretation of transthoracic echocardiograms in the facility should be accumulated by the facility and distributed to the interpreting physician. A process for addressing discrepancies between echocardiogram examination results and results of other procedures should be in place. Appropriate components and areas for correlation of transthoracic studies include, but are not limited to:

- Echocardiographic studies which are the primary diagnostic imaging utilized prior to surgical repair*
- Semilunar valve stenosis
- Selected anatomies or functional evaluations which are of diagnostic interest to the facility

<u>Correlation of Transesophageal Echocardiograms (if performed)</u>: For those patients who have undergone transesophageal echocardiograms and surgical repair or other diagnostic procedures such as coronary angiograms the results of transesophageal echocardiograms and other procedures should be routinely compared with regard to valvular abnormalities, left ventricular function and abnormalities of the aorta. Comparison studies for each physician responsible for the performance of transesophageal echocardiograms in the facility should be accumulated by the facility and distributed to the physician. Statistics should be generated to ascertain the overall accuracy of the transesophageal echocardiograms being performed in the facility. A process for addressing discrepancies between echocardiogram examination results and results of other procedures must be in place. Appropriate components and areas for correlation of transesophageal echocardiograms include, but are not limited to:

- left ventricular function and regional wall motion analysis;
- left or right ventricular function;
- presence and severity of valvular dysfunction;
- defects of atrial and ventricular septa;
- presence or absence of thrombi or vegetations;
- presence or absence of anomalous venous connections.

<u>Correlation of Fetal Echocardiograms (if performed)</u>: For those patients who have undergone fetal echocardiograms and other diagnostic procedures (such as postnatal echocardiography, postnatal cardiac catheterization or angiography), or post mortem examination, the results of fetal echocardiograms and other procedures should be routinely compared with regard to the accuracy of the fetal echocardiography examination. Comparison studies for each physician responsible for the performance/interpretation of fetal echocardiograms in the facility should be accumulated by the facility and distributed to the physician. Statistics should be generated to ascertain the overall accuracy of the fetal echocardiograms being performed in the facility. A process for addressing discrepancies between echocardiogram examination results and results of other procedures should be in place.

Section 3C: Quality Improvement Meetings

STANDARD – QI Meetings

- 3.1C Quality Improvement (QI) Meetings
 - 3.1.1C The facility must have a minimum of two QI meetings per year, one of which is to review the results of the QI analyses and any additional QI-related topics.
 - 3.1.2C All staff must participate in at least one meeting per year.

Section 4C: Quality Improvement Documentation

STANDARD - QI Documentation and Record Retention

- 4.1C The facility QI documentation must include, but is not limited to:
 - 4.1.1C the data for all of the QI measures above;
 - 4.1.2C minutes from the QI meetings; and
 - 4.1.3C participant list (may include remote participation and/or review of minutes).
- 4.2C The QI documentation must be maintained and available for all appropriate personnel to review.

Artificial Intelligence (AI) Guidance Document

To assure the quality and safety of care delivery when using AI applications for direct-patient care (clinical*) purposes, each facility should create and follow policies and procedures that address:

- 1. Training for personnel who use AI;
- 2. Security of AI software, updates, HIPAA considerations, etc.;
- 3. AI for Quality Improvement (if applicable);
- 4. Appropriate use for each AI application; and
- 5. Governance (authority to make decisions regarding AI implementation).

^{*}Clinical use of AI includes image acquisition, image processing/enhancement, image interpretation, report generation, risk assessment of prognosis, patient history, identification of critical values/results and equipment quality control.