



# **IAC Standards for Hemodialysis Access Intervention**

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# Introduction

The Intersocietal Accreditation Commission (IAC) accredits centers that provide hemodialysis access evaluation, management and/or treatment procedures. IAC accreditation is a process by which centers can evaluate and demonstrate the level of patient care they provide.

This program is designed to accredit facilities that evaluate and manage hemodialysis access sites to ensure that the facility meets benchmarks for quality based on published guidelines, resources, training and outcomes. Medical knowledge for the evaluation and management of hemodialysis access disorders is required.

A hemodialysis access center is defined as a center where hemodialysis access evaluation and management and/or treatment procedures are performed and is composed of, at a minimum, a qualified Medical Director (MD or DO) and appropriate equipment to perform the procedures. Under the supervision of the qualified Medical Director, there may be additional medical staff (MD or DO), Advanced Practice Providers, ARRT technologists, nurses, ultrasound technologists/sonographers and/or ancillary personnel. All physicians who perform hemodialysis access interventions in the facility must be included in the application for accreditation as part of the medical staff. The center must meet the organizational requirements defined in this document.

These accreditation Standards represent the minimum requirements to which an accredited hemodialysis access facility is held accountable. These Standards are not intended to be a comprehensive list of requirements to perform a procedure. In addition to all Standards listed below, the facility, including all staff, must comply 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.

## **Hemodialysis Access: Primary Procedures**

The following procedures are available for accreditation:

- a. Dialysis access angiography and/or intravascular ultrasound (IVUS)
- b. Endovenous arteriovenous access creation/insertion
- c. Dialysis access angioplasty
- d. Dialysis access stent/stent graft placement
- e. Treatment of Dialysis access thrombosis via thrombolysis/thrombectomy (pharmacologic, mechanical, pharmacomechanical)
- f. Dialysis access embolization/injection therapy
- g. Dialysis access catheter placement or revision, tunneled and non-tunneled
- h. Dialysis access catheter removal, tunneled and non-tunneled

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.

**Standards that are highlighted are content changes that were made as part of the April 1, 2023 revision. These Standards become effective April 1, 2023. Facilities applying for accreditation after April 1, 2023 must comply with these new highlighted Standards.**

# Part A:

## Organization

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### Section 1A: Personnel and Supervision

#### STANDARD – Medical Director

1.1A The Medical Director must be a licensed physician (MD or DO) in the state or jurisdiction of the center.

1.1.1A Medical Director Required Training and Experience:

1.1.1.1A Must be board certified by the American Board of Surgery (ABS), the American Board of Radiology (ABR), the American Board of Internal Medicine (ABIM) or the American Osteopathic Board in one of the following medical specialties:

- i. General Surgery
- ii. Interventional Cardiology
- iii. Interventional Radiology
- iv. Interventional Nephrology
- v. ABVM Endovascular Examination Diplomate
- vi. Vascular Surgery

1.1.1.2A Must have performed at least 60 cases in total over the previous three years. Cases must be documented with a case log (only up to three codable procedures may be counted separately even if performed on the same patient at a single setting):

- i. dialysis access angiography and/or intravascular ultrasound (IVUS);
- ii. endovenous arteriovenous access creation/insertion (if performed) minimum of five proctored cases per device and until certified by manufacturer;
- iii. dialysis access angioplasty (if performed);
- iv. dialysis access stent/stent graft placement (if performed);
- v. treatment of Dialysis access thrombosis via thrombolysis/thrombectomy (pharmacologic, mechanical, pharmacomechanical) (if performed);
- vi. dialysis access embolization/injection therapy (if performed);
- vii. dialysis access catheter placement or revision, tunneled and non-tunneled (if performed);
- viii. dialysis access catheter removal, tunneled and non-tunneled (if performed).

1.1.1.3A The Medical Director must have current Advanced Cardiac Life Support (ACLS) certification. If performing procedures on children, medical staff member must follow state regulations (PALS).

1.1.2A Medical Director Continuing Medical Education (CME) Requirements:

1.1.2.1A The Medical Director must obtain a minimum of 30 Category 1 CME credit hours related to hemodialysis access management/treatment in the past three years.

- i. At least two hours of fluoroscopy radiation safety training must be obtained as part of the 30 hours of required CME.

Comment: A facility-based radiation safety program, which provides a minimum of two hours of training every three years will satisfy the radiation safety CME requirement. Documentation of who provided the training, when training occurred, and topics covered must be available for review.

- ii. If the Medical Director has successfully completed an Accreditation Council for Graduate Medical Education (ACGME) approved residency or fellowship in one of the accepted medical specialties within three years prior to the application date, the CME requirement will be waived with the exception of at least two hours of radiation safety training unless the residency or fellowship explicitly included fluoroscopic radiation safety in its curriculum and there is demonstrative documentation of such
- iii. Documentation of CME credits must be kept on file and available for review.

#### 1.1.3A Medical Director Responsibilities:

1.1.3.1A The Medical Director is responsible for implementing measures to achieve and maintain compliance with the Standards for all services provided, including compliance, radiation safety, outcomes, quality control and quality of care and appropriateness of care provided. The Medical Director responsibilities include but are not limited to:

- i. The Medical Director must provide oversight of patient safety and is responsible for a monthly walkthrough with attestation.
- ii. The Medical Director (or their designee) must review all updates to all manuals at least annually and as new policies are introduced. This review must be documented, signed, and dated on the reviewed document or manual.
- iii. The Medical Director must be present at all required Quality Improvement (QI) meetings and must review and sign off on QI documentation. QI documentation must meet the requirements listed in [Part C: Quality Improvement](#).
- iv. The Medical Director may supervise the entire operation of the facility or delegate specific operation and is responsible for a monthly walkthrough (Form MDWT) with attestation and is also responsible for assuring compliance of medical and other staff to the Standards outlined in this document. In addition to adherence to the Standards, the Medical Director must participate in regular QI meetings, case study review conferences, personnel interviews, and other facility operations.

## **STANDARD – Medical Staff**

1.2A The medical staff member must be a licensed physician (MD or DO) in the state or jurisdiction of the center.

#### 1.2.1A Medical Staff Required Training and Experience:

1.2.1.1A Must be board certified or board eligible by the American Board of Surgery (ABS), the American Board of Radiology (ABR), the American Board of Internal Medicine (ABIM), or the American Osteopathic Board in one of the following medical specialties:

- i. Vascular Surgery
- ii. ABVM Endovascular Examination Diplomat
- iii. General Surgery

- iv. Nephrology with added specialty training in interventional nephrology
- v. Interventional Radiology
- vi. Interventional Cardiology

1.2.1.2A Must have performed at least 60 cases in total over the previous three years. Cases must be documented with a case log (only up to three codable procedures may be counted separately even if performed on the same patient at a single setting).

- i. dialysis access angiography and/or intravascular ultrasound (IVUS);
- ii. endovenous arteriovenous access creation/insertion (if performed) minimum of five proctored cases per device and until certified by manufacturer;
- iii. dialysis access angioplasty (if performed);
- iv. dialysis access stent/stent graft placement (if performed);
- v. treatment of Dialysis access thrombosis via thrombolysis/thrombectomy (pharmacologic, mechanical, pharmacomechanical) (if performed);
- vi. dialysis access embolization/injection therapy (if performed);
- vii. dialysis access catheter placement or revision, tunneled and non-tunneled (if performed);
- viii. dialysis access catheter removal, tunneled and non-tunneled (if performed).

1.2.1.3A All medical staff must have current Advanced Cardiac Life Support (ACLS) certification. If performing procedures on children, medical staff member must follow state regulations (PALS).

1.2.2A Medical Staff Continuing Medical Education (CME) Requirements:

1.2.2.1A Medical staff must obtain a minimum of 30 Category 1 CME credit hours related to hemodialysis access management/treatment in the past three years.

1.2.2.2A At least two hours of fluoroscopy radiation safety training must be obtained as part of the 30 hours of required CME.

Comment: A facility-based radiation safety program, which provides a minimum of two hours of training every three years will satisfy the radiation safety CME requirement. Documentation of who provided the training, when training occurred, and topics covered must be available for review.

1.2.2.3A If the medical staff member has successfully completed an Accreditation Council for Graduate Medical Education (ACGME) approved residency or fellowship in one of the accepted medical specialties within three years prior to the application date, the CME requirement will be waived with the exception of at least two hours of radiation safety training unless the residency or fellowship explicitly included fluoroscopic radiation safety in its curriculum and there is demonstrative documentation of such.

1.2.3A Provisional Medical Staff:

1.2.3.1A The qualified Medical Director may appoint a qualified staff member(s) as provisional staff who meets all the above criteria with the exception of the required procedure performance volumes at that institution. Provisional medical staff member must perform a minimum of five cases under direct supervision by a qualified medical staff. The Medical Director will be responsible for review of the provisional staff member including biannual review of case log including outcomes. The provisional medical staff member must attain full medical staff status prior to reaccreditation.

1.2.4A Medical Staff Responsibilities:

- 1.2.4.1A The medical staff is responsible for performing hemodialysis access evaluation, management, and treatment. Responsibilities must include, but are not limited to:
- i. Compliance with all the facility's policies, procedures and/or protocols and to the Standards outlined in this document.
  - ii. Responsible for equipment training and inspection to ensure safe operating conditions as specified by the manufacturer's guidelines and the Medical Director.
  - iii. Participation in the facility's comprehensive Quality Improvement (QI) program.

## **STANDARD – Interventional Technical Staff**

1.3A Interventional technologist(s) at the facility must meet the following qualifications:

1.3.1A Interventional Technical Staff Required Training and Experience:

- 1.3.1.1A Must be a registered radiologic technologist with the American Registry of Radiologic Technologists (ARRT(RT)(R)) or the Canadian Association of Medical Radiation Technologists (CAMRT(ARRT(CV)) or (ARRT(CI)) is recommended.
- 1.3.1.2A Hands-on training and/or experience in fluoroscopically guided interventions is recommended.
- 1.3.1.3A Must have current Basic Life Support (BLS) certification.

1.3.2A Interventional Technical Staff Continuing Education (CE) Requirements:

- 1.3.2.1A Must obtain a minimum of 15 hours of Category I AMA or RCEEM approved CE in the past three years.
- 1.3.2.2A Fluoroscopy radiation safety training must be part of the CE and not be less than two hours of the 15 hours required.
- 1.3.2.3A Documentation of CE credits must be kept on file and available for inspection.

Comment: If the interventional technologist staff member has successfully attained an appropriate technical credential within the three years prior to the application date, the CE requirement will be considered fulfilled with the exception of at least two hours of radiation safety training.

1.3.3A Interventional Technical Staff Responsibilities:

- 1.3.3.1A The interventional technologist(s) responsibilities may include, but are not limited to:
- i. reporting to the Medical Director or medical staff;
  - ii. obtaining a record of anatomical, pathological and/or physiological data for interpretation by the physician;
  - iii. positioning of the patient, selection of radiation exposure parameters, imaging of the patient and archiving of the images;
  - iv. maintaining a high degree of awareness of all radiation and patient safety issues involved with any invasive procedure;

- v. demonstrating a thorough understanding and working knowledge of normal and abnormal anatomy, physiology, radiation safety, interventional supplies, and equipment operation;
- vi. recognizing and resolving equipment problems and discrepancies, anticipating patient needs and concerns and communicating the appropriate care needed;
- vii. scrubbing in and assisting the physician in the procedure when necessary;
- viii. circulating within the procedure room and procuring equipment needed for any given procedure; and
- ix. performing other duties, as assigned.

## STANDARD – Medical Physicist

1.4A A qualified medical physicist must be appointed for the facility and meet the following qualifications.

1.4.1A Medical Physicist(s) Required Training and Experience:

The medical physicist(s) must meet one of the following criteria:

- 1.4.1.1A Board certification by the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP) or the Canadian College of Medical Physics (CCMP) in diagnostic imaging.
- 1.4.1.2A A physicist who has passed Part 2 of the ABR examination and successfully completed a CAMPEP approved residency in a discipline of medical physics that includes diagnostic imaging is acceptable. Full certification by a recognized board as outlined above is required prior to the next accreditation cycle.
- 1.4.1.3A Licensed or certified in accordance with state and local regulations as a diagnostic physicist. Full certification by a recognized board as outlined above is required prior to the next accreditation cycle. Individuals listed in the National QMP Registry maintained by the Conference of Radiation Control Program Directors for a subspecialty of medical physics in diagnostic imaging are acceptable.

1.4.2A Medical Physicist(s) Continuing Education (CE) Requirements:

- 1.4.2.1A The medical physicist must obtain at least 15 AMA PR Category 1 credits hours of CE or at least 15 CE credits approved by the Commission on Accreditation of Medical Physics Education Program (CAMPEP) in diagnostic imaging including fluoroscopy, every three years.
- 1.4.2.2A The 15 CE hours should include education in radiation dosimetry, radiation protection and equipment performance related to the use of fluoroscopy. The medical physicist should regularly perform a sufficient number of radiation measurements, dosimetry calculations and equipment performance evaluations of fluoroscopic equipment to maintain competence in the performance of these activities.
- 1.4.2.3A Documentation of CE credits must be kept on file and available for inspection.
- 1.4.2.4A If the medical physicist has successfully attained board certification within the three years prior to the application date, the CE requirement will be considered fulfilled.

1.4.3A Medical Physicist(s) Responsibilities:

The medical physicist(s) responsibilities include, but are not limited to:



- 1.4.3.1A Perform acceptance tests and annual surveys (or more frequently as governed by state and local law) for equipment performance evaluation including:
- i. fluoroscopic radiation output measurements: at minimum to include one maximum fluoroscopy mode output rate in a clinically used setting, two typical fluoroscopy mode output rates in clinically used settings, and one typical acquisition output rate in a clinically used setting (typical meaning using a patient equivalent phantom);
  - ii. accuracy assessment of all fluoroscopes reported or displayed radiation dose indices;
  - iii. system quality control tests ensuring proper functionality and operation of the fluoroscope for safe and effective operation;
  - iv. assessment of image quality in at least one clinically used fluoroscopy mode setting and one clinically used acquisition mode setting;
  - v. evaluation of the radiation shielding adequacy and integrity ensuring necessary radiation protection to individuals in all adjacent areas (only necessary at initial survey, after any modifications to the structural shielding, or replacement of the imaging equipment); and
  - vi. analyze all data collected.
- 1.4.3.2A Provide a written summary report to the Medical Director and/or radiation safety committee, include in the summary report any identified issues requiring corrective action or recommendations for improvement.
- 1.4.3.3A Provide guidance for any patient and/or staff dosimetry issues.
- 1.4.3.4A Provide radiation training for facility physicians and staff as required.
- 1.4.3.5A Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, may assist the medical physicist in the collection of data under the direct supervision of the medical physicist (physicist must be on premises and immediately available). The medical physicist must review and approve all such data. The medical physicist remains personally responsible for the performance quality of the assigned tasks.
- 1.4.3.6A A process must be in place for the management, review, report and documentation, by the radiation safety committee/medical physicist/radiation safety officer, of the following:
- i. staff radiation badges;
  - ii. radiation protective garments and accessories:
    - vests;
    - skirts;
    - aprons;
    - thyroid shields;
    - gloves; and
    - protective eyewear;
  - iii. pull-down shields
  - iv. table side shields
  - v. patient radiation exposure; and
  - vi. other.

- 1.4.3.7A All radiation protective garments and accessories must be examined annually by visual/tactile evaluations, use of fluoroscopy, and/or radiography for cracks, tears, detachment, or other form(s) of damage. A log of this inspection must be available in the facility.
- 1.4.3.8A The physicist should observe at least one procedure with fluoroscopy per year.

## **STANDARD – Advanced Practice Provider (APP)**

1.5A The Advanced Practice Provider (APP) works under the direction of the Medical Director or a medical staff member who is listed in the application. The APP must be a licensed professional who possesses knowledge in the treatment of hemodialysis access disorders and meets the required certification and experience qualifications as outlined in this document and the required certification and experience qualifications determined by local, state and/or federal regulations within the scope of practice of an APP.

### 1.5.1A APP Required Training and Experience:

1.5.1.1A The APP must meet one of the following criteria for required certification:

- i. Physician Assistant (PA)
- ii. Nurse Practitioner (NP)

1.5.1.2A The APP must have current Basic Life Support (BLS) certification, and if performing procedures with moderate/IV sedation, Advanced Cardiac Life Support (ACLS) certification is required.

1.5.1.3A The APP must perform, under the direct supervision of a qualified physician, evaluation of a minimum of 50 hemodialysis access patients in the previous three years including obtaining a history, performing a physical examination, and making medical decisions including the assessment of pertinent diagnostic studies and forming a treatment plan. The qualified physician must be present in the office suite; immediately available.

### 1.5.2A APP Continuing Medical Education (CME) Requirements:

1.5.2.1A The APP must obtain a minimum of 30 Category I CME credit hours or dedicated CME for APP related to hemodialysis access management/treatment in the past three years.

1.5.2.2A At least two hours of CME must be dedicated to fluoroscopy radiation safety.

1.5.2.3A Documentation of CME credits must be kept on file and available for inspection.

### 1.5.3A APP Responsibilities:

1.5.3.1A APP responsibilities may include, but are not limited to:

- i. participation in hemodialysis access procedure safety practices including, but not limited to, safe use of equipment and review of patient outcomes and complications;
- ii. administering and monitoring moderate sedation;
- iii. monitoring and assessing clinical status of patient;
- iv. cardiovascular and hemodynamic monitoring and management;
- v. monitoring, assessing and management of emergency care;
- vi. advising patient care team and treating patient appropriately;

- vii. post-procedure discharge instructions;
- viii. patient education;
- ix. demonstrating familiarity and proficiency with the setup and operation of all equipment associated with procedures performed in the facility;
- x. may assist with procedures under personal supervision of a qualified medical staff member; and
- xi. performing other duties, as assigned.

1.5.4A Provisional APP:

1.5.4.1A The qualified Medical Director may appoint a qualified APP as provisional staff who meets all of the above criteria with the exception of the required patient evaluation volumes. The Medical Director will be responsible for review of the provisional APP including biannual review of the case log including outcomes. The provisional APP must attain full APP status prior to reaccreditation.

## STANDARD – Nursing Staff

1.6A A nurse works under the direction of the Medical Director or a medical staff member who is listed in the application. The nurse must be a licensed registered nurse (RN) or licensed practical/vocational nurse (LPN/LVN) who possesses knowledge in the treatment of hemodialysis access disorders and meets the required certification and experience qualifications as outlined in this document.

1.6.1A Nursing Staff Required Training and Experience:

1.6.1.1A The nursing staff must have current Basic Life Support (BLS) certification, and if performing procedures with moderate/IV sedation, Advanced Cardiac Life Support (ACLS) certification is required.

1.6.2A Nursing Staff Continuing Education (CE) Requirements:

1.6.2.1A The nurse must obtain a minimum of 30 contact hours/Category 1 CE related to hemodialysis access management/treatment in the past three years. All CE hours must be approved (i.e., AMA Category I, Society of Vascular Ultrasound (SVU), Society of Diagnostic Medical Sonography (SDMS), American Nurses Credentialing Center (ANCC-Category I), Society for Vascular Nursing (SVN)).

1.6.2.2A At least two hours of CE/CME each cycle must be dedicated to fluoroscopy radiation safety.

1.6.2.3A The CE/CME requirement will be waived (with the exception of at least two hours of radiation safety training) if, in the previous three years, the nurse has:

- i. completed formal training;
- ii. acquired an appropriate vascular credential (Registered Vascular Technologist (RVT), Registered Vascular Specialist (RVS), Registered Technologist Vascular Sonography [RT(VS)]; and
- iii. has been employed in the facility less than a year.

1.6.2.4A Documentation of CE/CME credits must be kept on file and available for inspection.

1.6.3A Nursing Staff Responsibilities:

1.6.3.1A Nursing staff responsibilities may include, but are not limited to:

- i. administering and monitoring moderate sedation;
- ii. performing cardiovascular assessment;
- iii. monitoring and assessing clinical status of patient;
- iv. cardiovascular and hemodynamic monitoring and management;
- v. advising patient care team and treating patient appropriately;
- vi. demonstrating familiarity and proficiency with the setup and operation of all equipment associated with the hemodialysis access procedures performed in the facility; and
- vii. may assist with procedures under personal supervision of a qualified medical staff member.

## **STANDARD – Ancillary Personnel**

1.7A The facility must ensure that adequately trained and experienced ancillary personnel are available to perform safe and effective patient care appropriate for the level of service as designated by the Medical Director or a qualified designee. The specific needs of a facility must be determined by an evaluation of the types and volumes of procedures as well as facility configuration.

1.7.1A Ancillary personnel may consist of, but are not limited to:

- 1.7.1.1A advance practice nurses (APRN);
- 1.7.1.2A certified registered nurse anesthetist (CRNA);
- 1.7.1.3A radiologist assistant (RA);
- 1.7.1.4A clinical pharmacist;
- 1.7.1.5A technical assistants;
- 1.7.1.6A clerical and administrative assistants;
- 1.7.1.7A computer support staff; or
- 1.7.1.8A equipment support staff (i.e., biomedical, x-ray service).

1.7.2A All ancillary personnel within the department must be supervised by the Medical Director or a qualified designee. The supervisor must document/verify proper training at least annually and current competence of their ancillary personnel appropriate to the assigned duties.

## Section 2A: Physical Facilities

### STANDARD – Physical Space

2.1A Adequate space must be provided for all operations of the facility so that patient comfort, safety, dignity, and privacy are ensured as well as staff comfort and safety. Procedure areas must have sufficient space, be well-maintained and clean and meet all state guidelines.

2.1.1A Physical space requirements include, but are not limited to:

2.1.1.1A in case of emergency, there must be adequate space for performing resuscitation;

2.1.1.2A adequate space, facility configuration and doorways for the emergency transport of patients from patient care areas and for the emergency exit of staff;

2.1.1.3A reception and patient/staff bathroom;

2.1.1.4A private patient examination areas;

2.1.1.5A readily accessible hand washing/sanitation stations for staff;

2.1.1.6A procedure room (must meet standards for fluoroscopy);

2.1.1.7A recovery area;

2.1.1.8A patient records, reports and digital data must be backed up according to standardized protocols for patient confidentiality;

i. The storage must ensure confidentiality of data and should be safe from fire/flood/power outage/natural disasters.

2.1.1.9A administration records and support areas; and

2.1.1.10A equipment/supply storage areas.

### STANDARD – Medications, Supplies and Equipment

2.2A A facility performing procedures that require the administration of contrast drug administration, sclerosants, embolizing agents and/or exams requiring sedation, must have the following emergency supplies and equipment readily available and in close proximity to where procedures are performed:

2.2.1A **Routine medications** must be available and include, at a minimum:

2.2.1.1A normal saline;

2.2.1.2A anti-hypertensive medications;

2.2.1.3A local anesthetics;

2.2.1.4A sedatives;

2.2.1.5A anxiolytics;

2.2.1.6A antihistamines/anaphylactic medications;

2.2.1.7A diabetic medications;

- 2.2.1.8A analgesics;
  - 2.2.1.9A contrast agents; and
  - 2.2.1.10A anticoagulation medications and reversal agents (Heparin and Protamine).
- 2.2.2A **Routine instruments and supplies** must be available and include, at a minimum:
- 2.2.2.1A diagnostic and therapeutic needles, sheaths, wires, snares and catheters;
  - 2.2.2.2A FDA-approved devices and implants;
  - 2.2.2.3A blood pressure cuff(s);
  - 2.2.2.4A stethoscope;
  - 2.2.2.5A flashlight/extra batteries;
  - 2.2.2.6A needles and syringes; and
  - 2.2.2.7A oximetry monitor.
- 2.2.3A **Emergency equipment** must be readily available within the facility and in close proximity to where procedures are performed:
- 2.2.3.1A Emergency cart/kit:
    - i. Must be opened and its contents inspected by the authorized personnel monthly. The monthly inspection must be documented and include:
      - listing of all emergency supplies and equipment;
      - a master list of emergency medication(s), including strength, quantity, lot number and expiration date;
      - staff member's name who performed the inspection;
      - inspection date.
  - 2.2.3.2A All emergency equipment must be clearly labeled and be for emergency use only.
  - 2.2.3.3A Emergency equipment and medications must be secured with a disposable plastic lock.
  - 2.2.3.4A Required **emergency intubation equipment** at a minimum must include:
    - i. Ambu Bag with HEPA filter;
    - ii. End tidal CO2 detection device;
    - iii. suction devices;
    - iv. endotracheal tubes;
    - v. laryngoscopes;
    - vi. oropharyngeal airways;
    - vii. nasopharyngeal airways;
    - viii. bag valve mask apparatus that are patient-size specific;
    - ix. nasal cannula, mask and/or nasal airway for oxygen administration; and
    - x. Personal Protective equipment (PPE) to ensure staff safety.

2.2.3.5A Required **resuscitative medications** per ACLS protocol. Protocol must be reviewed (at a minimum) annually. Additional agents should be available as deemed appropriate based on anticipated need and scope of practice including:

- i. Albuterol inhaler;
- ii. Calcium chloride 10% (10 ml);
- iii. Dopamine 200 mg (at a minimum);
- iv. Flumazenil 0.1 mg/ml (5 ml x 2);
- v. Furosemide 40 mg;
- vi. Lidocaine 100 mg;
- vii. Magnesium sulfate 1 gm x 2;
- viii. a beta blocker;
- ix. Sodium bicarbonate 50 mEq/50 ml;
- x. Succinylcholine (1 vial);
- xi. Vasopressin 20 units x 2;
- xii. Verapamil 5 mg x 2; and
- xiii. Hydralazine.

2.2.3.6A **Oxygen:**

- i. must be supplied by tank or wall-mounted oxygen;
- ii. must be inspected by authorized personnel monthly; and
- iii. testing and maintenance per the manufacturer's specifications, must be documented.

2.2.3.7A **Automated External Defibrillator (AED):**

- i. must be inspected by authorized personnel every month or per state mandate; and
- ii. testing and maintenance per the manufacturer's specifications, must be documented.

2.2.3.8A **Monitoring Equipment:**

- i. For intravenous moderate sedation or greater, all local/state guidelines must be followed. In the absence of such guidelines, [American Society of Anesthesiologists \(ASA\) Guidelines](#) are recommended. At a minimum, the following must be available:
  - noninvasive blood pressure;
  - pulse oximetry; and
  - ECG monitoring.
- ii. All equipment and instrumentation must be routinely inspected for safety and proper functionality and records of the inspections kept on file.

2.2.4A **Sterilization of Medical Instruments:**

2.2.4.1A The reuse of an FDA-approved single use device is not permitted **unless it is done in compliance with FDA requirements.**

2.2.4.2A Single use products must be used prior to expiration date.

- 2.2.4.3A Products approved by the FDA for multiple use must be re-sterilized by the process approved by the FDA or Center for Disease Control (CDC), as applicable.
- 2.2.4.4A Sterilization, if performed on site, the facility must have a written protocol/policy. The policy must include, but is not limited to:
- i. comprehensive training for all staff assigned;
  - ii. reprocessing instructions (provided by the instrument/sterilization manufacturer);
  - iii. sterilizer maintenance as needed with records of service;
  - iv. a system of process monitoring;
  - v. visual inspection of packaging materials including heat sensitive indicators inside each package treated with steam sterilization;
  - vi. results of periodic biological monitoring performed at least weekly;
  - vii. retainment of sterilization records for a time period that complies with the CDC standards (e.g., three years), statutes of limitations and state and federal regulations; and
  - viii. an established blood borne pathogen exposure control plan in accordance with OSHA Bloodborne Pathogens Standards and must use universal precautions.



# Section 3A: Facility Safety

## STANDARD – Patient and Facility Safety

- 3.1A Safety policies must be enforced, reviewed, and documented annually by the Quality Improvement (QI) Committee or the Medical Director. All safety policies must adhere to state laws.
  - 3.1.1A Adherence to process that assures accurate patient identification prior to initiating the procedure. Two independent patient-specific identifiers must be used.
  - 3.1.2A There must be at least one ACLS or PALS (if required by age) certified staff member on site.
- 3.2A Radiation Safety
  - 3.2.1A The facility must follow state and federal safety mandates for radiation safety.
  - 3.2.2A All facility professionals must have a general understanding of the occupational and patient radiation protection for the procedure(s) being performed.
  - 3.2.3A A separate, radiation-shielded, or appropriately distanced control room or area must be used by non-procedural staff during acquisition mode of imaging (cine, DSA, CBCT, etc.).
  - 3.2.4A Procedural staff radiation exposure must be monitored and reviewed by the QI Committee. The results must be communicated to the staff member. The facility must comply with the currently published ALARA recommendations for personnel.
    - 3.2.4.1A Pregnant procedural staff members should be identified and appropriately shielded. Pregnant procedural staff must have two radiation exposure badges, one affixed near the level of the neck and one attached under the shield in the abdominal area. Exposure must be monitored, and the results must be communicated to the staff member.
  - 3.2.5A There must be restriction of the public to radiation areas that includes appropriate signage.
  - 3.2.6A Radiation dose rates must be set at the lowest values that are consistent with satisfactory image quality for the procedure being performed and the patient specific variables.
  - 3.2.7A Modifications to the manufacturer’s protocols that increase or decrease patient dose above the site appointed physicist recommendation must be reviewed by a medical physicist prior to implementation of the proposed change(s) in order to assess impact on radiation dose and image quality. The physicist must review standard guidelines annually to ensure appropriateness.
  - 3.2.8A If the physicist deems that the proposed change(s) is appropriate, the facility must maintain documentation of the protocol change(s) that includes the rationale for the change, including the details of the change (exactly what changes were made to the technical parameters for the scans), and the physicist review of impact on dose and image quality.
  - 3.2.9A If a procedure is needed for a pregnant patient, knowledgeable staff (i.e., Medical Director, medical staff and/or physicist) must discuss the potential risk to the fetus and document the general content of the discussion.
  - 3.2.10A If determined that the study will not be performed, then the patient must receive options for alternative care from their health care provider.

## STANDARD – Contrast

- 3.3A If intravascular contrast media are used, the facility or imaging department must have written policies, protocols and procedures regarding the administration.
  - 3.3.1A Vascular access must be established or confirmed using the facility’s protocol.
  - 3.3.2A Patients with a known adverse reaction to contrast will be pre-medicated with a standard protocol based on their previous history.
  - 3.3.3A Protocols must be in place for treating patients with adverse events.
  - 3.3.4A Reactions and treatment must be documented in the procedure report and/or the patient’s medical record in compliance with the operating policies and procedures of the facility.
  - 3.3.5A Emergency equipment and medications listed in [Section 2.2A](#) must be immediately available to treat adverse events related to contrast media administration
  - 3.3.6A Documentation of contrast name and volume administered must be documented in the patients’ medical record.
  - 3.3.7A Contrast material as well as any other injectables must be clearly labeled on the procedure table.

# Section 4A: Fluoroscopy

## STANDARD – Personnel

- 4.1A Each facility must have a radiation safety policy that includes training and education requirements for all facility staff that perform or are involved in fluoroscopic procedures.
- 4.1.1A Fluoroscopic equipment used for interventional procedures may only be operated by:
- 4.1.1.1A A licensed physician with training and experience in fluoroscopic procedures.
- OR**
- 4.1.1.2A A registered radiologic technologist [RT(R)].
- AND**
- 4.1.1.3A 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.
- 4.1.2A Personnel Required Training and Experience:
- 4.1.2.1A All individuals in the fluoroscopic procedure room during the procedure must have documentation of a minimum of two hours of training in fluoroscopic radiation safety provided by a medical physicist or qualified expert and received a passing score on a written examination administered by the provider of the radiation safety training program. Courses may be attended virtually.
- 4.1.3A All individuals operating the fluoroscopy equipment must have machine specific training for each make and model of the fluoroscope the operator uses.
- 4.1.4A Continuing Education (CE) Requirements:
- 4.1.4.1A Any staff member operating the fluoroscope must have a minimum of two hours of CE in radiation protection per year related to the use of fluoroscopy in addition to requirements by state and federal guidelines.
- 4.1.5A Personnel Responsibilities:
- 4.1.5.1A Personnel responsibilities may include, but are not limited to:
- i. All personnel in the room during fluoroscopic procedures must wear appropriate radiation protective apparel or have radiation safety equipment (i.e., lead shields, lead barriers) appropriate to the procedure.
  - ii. The garment and/or devices must be tested yearly.
  - iii. Each person actively involved in fluoroscopic procedures must also be provided with at least one personnel radiation monitor approved by National Voluntary Laboratory Accreditation Program (NVLAP). Individuals must comply with state regulations regarding monitor placement, dosage monitoring and reporting of dosage exposure.
  - iv. radiation doses should be monitored and should be kept as low as possible while maintaining sufficient image quality to ensure a successful procedure.
  - v. Procedure radiation dose data indices must be recorded for each procedure in the patient medical record and be available for review. For fluoroscopes manufactured before 2006 that do not provide radiation dose data, the

fluoroscopic exposure time, and the number of acquisition (cine, DSA, CBCT) images must be recorded in the patient's medical record.

## **STANDARD – Examination Areas**

- 4.2A In addition to the requirements listed in if fluoroscopy is being used, the following requirements apply:
  - 4.2.1A procedure room/area must have radiation shielded barriers that meet state and federal requirements;
  - 4.2.2A signage to identify the area as one with active use of x-ray equipment;
  - 4.2.3A radiation shielding for patient's vulnerable organs if practical with the procedures;
  - 4.2.4A there must be restriction of the public to radiation areas.

## **STANDARD – Equipment and Instrumentation**

- 4.3A Fluoroscopes used for these procedures should comply with International Electrotechnical Commission (IEC) Standard 60601-2-43: Requirements for the basic safety and essential performance of X-ray equipment for interventional procedures:
  - 4.3.1A digital subtraction imaging of at least two frames per second;
  - 4.3.2A high quality, subtracted digital radiographs;
  - 4.3.3A last image hold is desirable;
  - 4.3.4A pulsed fluoroscopy is desirable;
  - 4.3.5A provide one or more radiation dose indices;
  - 4.3.6A Digital Imaging and Communications in Medicine (DICOM) compatible digital image storage with capability of storing uncompressed images on portable format without loss of image resolution;
  - 4.3.7A ability to display and review prior relevant images during the procedure;
  - 4.3.8A the image receptor must be capable of at least a 22cm (or 9in) field of view;
  - 4.3.9A minimum contrast resolution to see the 1.5 mm hole in a standard phantom;
  - 4.3.10A image monitor performance using the Society of Motion Picture and Television Engineers (SMPTE) pattern, AAPM TG 272 or TG 18 patterns, or equivalent; and, at minimum, measuring the maximum luminance and display uniformity;
  - 4.3.11A for equipment manufactured before 2006 that does not display cumulative air kerma and or air kerma area product (AKAP, sometimes referred to as DAP), documentation of fluoroscopy time and the number of images per procedure is acceptable.
- 4.4A Ancillary equipment as appropriate (e.g., monitoring equipment, blood coagulation testing equipment, workstations, picture archiving communication system (PACS), radiation protection for personnel (aprons and thyroid shields, portable shield either on wheels or suspended from ceiling).

## **STANDARD – Equipment and Instrumentation Quality Control**

- 4.5A There must be a comprehensive Quality Improvement (QI) program to provide a standard of measurement for system performance and the documentation of any variance thereof.
  - 4.5.1A Fluoroscopic system QC testing must include a comprehensive evaluation of the system components, image performance, and radiation output limits as outlined in the Suggested State Regulations for Control of Radiation (CRCPD) SSR, Part F, Medical Diagnostic and Interventional X-ray and Imaging Systems.
  - 4.5.2A Image quality requirements, radiation output limits, and other fluoroscopic performance requirements must also comply with the health-code regulations of the state in which the facility is located.
  - 4.5.3A A medical physicist meeting the previously established requirements must complete the performance evaluations at equipment installation and annually unless state regulations require more frequent testing. Equipment performance evaluations are recommended semiannually to include radiation output measurements, system quality control tests and image quality performance measurements.
  - 4.5.4A The medical physicist must perform a radiation safety barrier survey to ensure the integrity and adequacy of any structural shielding which shall include all occupiable adjacent areas. This survey must be performed during acceptance testing and prior to patient use. A summary report of this survey must be provided to the Medical Director and/or radiation safety committee and explicitly state that the existing shielding is or is not adequate and any necessary corrective action. A documented radiation safety barrier survey of the procedure room and adjacent areas that has been accepted by the State Radiation Program fulfills this requirement.
  - 4.5.5A A radiation safety barrier survey must be performed on all renovated or newly constructed procedure rooms and adjacent areas. This must be performed prior to first patient use. This survey must confirm that the levels of radiation protection are in conformance with the State Radiation Program.
  - 4.5.6A All adjacent areas, including the control room, where radiation workers are expected to routinely occupy, shall be assigned an occupancy factor of one for purposes of shielding design.
  - 4.5.7A Preventive maintenance (PM) service is required per the manufacturers' recommendations or at least annually for each fluoroscope used for accredited procedures at the facility.
  - 4.5.8A Ancillary equipment (e.g., monitoring equipment, blood coagulation testing equipment, injectors, workstations, PACS, lead aprons, suction, oxygen lines, etc.) should also be included in a PM program.

## **STANDARD – Quality Control Documentation**

- 4.6A All QC results must be documented and reviewed.
  - 4.6.1A Documentation of the physicists' evaluation, preventative maintenance and quality control tests performed, and service records for all angiographic systems and ancillary equipment must be maintained at the facility and available for review. The reports must be signed and dated by the person(s) performing the tests.
  - 4.6.2A All items requiring corrective action shall be addressed in a timely manner with appropriate documentation indicating that the performed corrective action has adequately addressed the identified issue.

## **Section 5A: Administrative**

### **STANDARD – Patient Confidentiality**

- 5.1A All facility personnel must ascribe to professional principles of patient-physician confidentiality as 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 licensing, certification and training of all staff members and any other direct patient care providers.

### **STANDARD – Record Retention**

- 5.4A All medical records, including archived images, must be retained in accordance with applicable state or federal guidelines for medical records, generally five to seven years.

# Part B: Process

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## Section 1B: Procedures

### STANDARD – Procedure Overview

- 1.1B These Standards include the minimum requirements for the performance of hemodialysis access interventional procedures. The Standards are not intended to be a comprehensive list of requirements to perform a case, nor does it list every step necessary for every patient. It represents an overview of the general steps to perform a typical elective case in order to provide a context for the overall requirements of this accreditation program. A facility may find it helpful to use this description to create an institutional template to be used as a reference when analyzing outcomes.
- 1.1.1B The facility must assure that appropriate staff members with BLS, ACLS or PALS certification are present during the procedure.
- 1.1.2B Appropriate staff must be available to assist the patient should an adverse event occur during the procedure and/or recovery.
- 1.1.3B All staff must adhere to:
- 1.1.3.1B standardized uniformly applied universal precautions in every aspect of patient care;
  - 1.1.3.2B national patient safety goals (e.g., medication safety);
  - 1.1.3.3B infection control measures consistent with CDC and OSHA guidelines;
  - 1.1.3.4B When in the presence of ionizing radiation, all staff must observe proper radiation safety techniques to include, but not limited to:
    - i. wearing radiation protective garments; thyroid shield, vest with skirt or full-length apron or full-length jacket. Garments must meet a lead equivalent of 0.5mm with a weight per unit area of 7 kg/m<sup>2</sup>.
  - 1.1.3.5B Alternatively, staff may use a floor-mounted/portable radiation protection cabin and a ceiling- or gantry-mounted suspended radiation protection system. However, all staff using these systems must be able to completely fit behind these lead barriers whenever radiation is being used.

### STANDARD – Procedure Requirements

- 1.2B FDA-approved devices must be used when feasible.
- 1.3B Appropriate surgical instruments, equipment, and medical supplies, as defined by the procedure, including but not limited to:
- 1.3.1B fluoroscopic equipment with digital subtraction capability;
  - 1.3.2B appropriate radiation protection for patient and provider;
  - 1.3.3B pharmacologic and anesthetic agents and supplies:
    - 1.3.3.1B premixed pharmacologic and/or anesthetic agents must be clearly labeled with content, concentration and expiration date.

- 1.3.4B appropriate monitoring equipment;
- 1.3.5B appropriate supplies for performance of the procedure;
- 1.3.6B adherence to published guidelines for the performance of all procedures;
- 1.3.7B ultrasound imaging as defined by the procedure;
- 1.3.8B review of preoperative history and imaging;
- 1.3.9B appropriate baseline labs, as indicated;
- 1.3.10B reconciliation of medications;
- 1.3.11B sterile prep and drape; and
- 1.3.12B appropriate sedation monitoring, based on ASA guidelines.

## **STANDARD – Documentation**

### 1.4B Pre-Treatment Documentation

1.4.1B A clinical evaluation of each patient being considered for treatment must be performed and documented in their medical record and must include, but is not limited to:

- 1.4.1.1B chief complaint(s);
- 1.4.1.2B complete history that includes:
  - i. a review of past medical history:
    - medications; and
    - allergies.
  - ii. hemodialysis access symptoms and treatment history;
  - iii. anticoagulation medication and treatment duration; and
  - iv. a directed physical examination that includes a cardiac and pulmonary examination.

Comment: Any changes in medical history, medications, allergies must be documented with each encounter.

1.4.1.3B disease-specific QOL measures should be documented at baseline, repeat at completion of treatment, or as indicated. Any protocol validated by practice is acceptable. KDQol survey is a recommended option.

1.4.1.4B additional imaging and/or consultations;

1.4.1.5B indication for procedure and treatment plan;

1.4.1.6B Laboratory studies, when clinically indicated, must be completed within 30 days of procedure and must be documented in the medical record to include, but not limited to:

- i. electrolytes;
- ii. blood urea nitrogen (BUN);
- iii. creatinine;



- iv. complete blood count (CBC);
- v. blood type and screen (if indicated);
- vi. Prothrombin time (PT) (INR), if taking warfarin;
- vii. pregnancy test performed within 24 hours of procedure (in all females of childbearing age);
- viii. AntiXA level (when appropriate); and
- ix. additional procedure-specific documentation as required.

1.5B Pre-Procedure Documentation:

1.5.1B Must be documented in the medical record:

- 1.5.1.1B signed and dated complete procedure-specific informed consent;
- 1.5.1.2B name of treating physician and patient;
- 1.5.1.3B list of patient allergies (if any);

Comment: No known allergies must also be documented.

- 1.5.1.4B Mallampati score when patient is being sedated;
- 1.5.1.5B ASA score when patient is being sedated; and
- 1.5.1.6B additional procedure-specific documentation as required.

1.6B Intra-Procedure Documentation:

1.6.1B Procedural time out:

- 1.6.1.1B Assessment and documentation of the correct patient, verification of allergies, correct site and procedure must occur immediately before initiation of the procedure.

1.6.2B Vital signs must be documented at least every 10 minutes or when significant physiologic changes occur (when indicated and when/or moderate sedation is use):

- 1.6.2.1B blood pressure;
- 1.6.2.2B continuous pulse oximetry;
- 1.6.2.3B pain scale assessment (if patient is able to report);
- 1.6.2.4B patient level of consciousness;
- 1.6.2.5B continuous EKG tracing; and
- 1.6.2.6B respiratory rate.

1.7B Procedure Documentation:

1.7.1B Must be documented in the medical record.

- 1.7.1.1B Operative report (or nursing record, if relevant) must include:
  - i. indications for the procedure;
  - ii. detailed description of the procedure;

- iii. structures imaged;
- iv. operative findings;
- v. treatment performed with success/inadequacy;
- vi. all complications of intervention;
- vii. sedation/monitoring provider, number of minutes of sedation and agents(s) used;
- viii. documentation of sterile skin preparation and drape;
- ix. devices used;
- x. access site, technique (ultrasound-guided), access needle and sheath;
- xi. all medications administered pre and intraprocedural including but not limited to:
  - sedation (total time, type and dose);
  - sclerosant dose and type; and
  - anticoagulants/antithrombotics.
- xii. fluoroscopy exposure:
  - fluoroscopy time; and
  - radiation dose indices.
- xiii. treated vessel(s)
  - devices used; and
  - implantables placed.
- xiv. estimated blood loss;
- xv. contrast type and volume;
- xvi. patient status at end of procedure;
- xvii. name of person performing procedure; and
- xviii. surgical assistant and/or circulator.

1.7.2B Additional information to be documented in the procedural medical record:

- 1.7.2.1B additional procedure-specific documentation as required;
- 1.7.2.2B procedure start and end time;
- 1.7.2.3B anticoagulation; and
- 1.7.2.4B additional medications administered intraoperatively.

1.8B Patient Instructions:

1.8.1B Must be documented in the medical record and include:

- 1.8.1.1B procedure performed;
- 1.8.1.2B management of post-procedure pain;
- 1.8.1.3B anticoagulation or antiplatelet therapy and monitoring instructions;
- 1.8.1.4B access site, dressings and wound care;
- 1.8.1.5B compression instructions (if needed);
- 1.8.1.6B bathing/showering instructions;

- 1.8.1.7B patient activity, ambulation and exercise;
- 1.8.1.8B air and car travel restrictions;
- 1.8.1.9B possible adverse events or complications which may require contact with a health care provider;
- 1.8.1.10B directions and contact information to access the health care team;
- 1.8.1.11B follow-up office visit instructions; and
- 1.8.1.12B follow-up duplex ultrasound examination appointment, if appropriate.

## **STANDARD – Required Protocols and Policies**

- 1.9B There must be a written protocol for each procedure performed in the facility with indications, contraindications, pretreatment evaluation and reporting outcomes including, but not limited to:
  - 1.9.1B treatment of allergic reactions or toxicity that results from the use of any administered medications during the procedure and/or during recovery ensuring patient safety, including supplies to be used, staff to be present and medications for administration.
  - 1.9.2B intravenous fluid and medication(s) to include access and management;
  - 1.9.3B contrast use and protection protocols;
  - 1.9.4B monitoring patients undergoing procedures using sedation and anxiolysis;
  - 1.9.5B compliance with state regulations and [American Society of Anesthesiology \(ASA\) Guidelines](#) when moderate sedation or greater is used; and
  - 1.9.6B Patient Identification – At least two independent patient-specific identifiers must be used.
- 1.10B There must be written policies for:
  - 1.10.1B Incident Report/Adverse Events Policy – A policy for documentation of adverse events (i.e., contrast reactions, patient falls, emergencies) must be in place.
  - 1.10.2B Patient Pregnancy Policy – For all clinical procedures there must be a process that assures that patients who could be pregnant are identified. This must be documented and contain the signature/initials of the patient and a member of the medical team, verifying the information. This procedure must include an explanation of the proper steps to be taken if a patient may be or is pregnant, explanation of shielding and recording of estimated fetal radiation dose of procedure is performed.
  - 1.10.3B Patient Pre-Procedure Preparation Policy – There must be a policy in place for determining and administering any necessary pre-test preparations including:
    - 1.10.3.1B education/instructions such as dietary or medication restrictions, examination specific preparation or other relevant information;
    - 1.10.3.2B sufficient time must be allowed for adequate patient preparation; and
    - 1.10.3.3B any other types of necessary pre-test preparation must be assessed prior to the start of the examination.

- 1.10.4B Contrast/Medication Administration and Supervision Policy – This policy must address the following, but is not limited to:
- 1.10.4.1B the steps taken to identify patients with documented or possible sensitivity to contrast and/or at increased risk for renal toxicity and protocols in place to treat these patients.
  - 1.10.4.2B medication and contrast administration procedures and the oversight of the contrast/medication administration and must include, but is not limited to:
    - i. IV access including location of insertion site and size of catheter;
    - ii. medications, including contrast, used in the procedure (i.e., beta blockers, conscious sedation);
    - iii. dosage, timing, route of administration;
    - iv. patient instruction;
    - v. patient monitoring;
    - vi. any precautions or restrictions needed; and
    - vii. treatment of adverse reactions.
- 1.10.5B Protocol for patients requiring escalation of care:
- 1.10.5.1B must have transfer agreement with a hospital;
  - 1.10.5.2B must have a protocol in place for transport to a higher level of care;
  - 1.10.5.3B must include appropriate documentation for transfer of information to the receiving facility; and
  - 1.10.5.4B must maintain a log of all patients requiring escalation of care and their outcomes following state mandates for review and reporting.
- 1.10.6B Patient radiation dose evaluation:
- 1.10.6.1B must have a policy which identifies patient radiation dose indices that trigger patient education and follow-up for a potential radiogenic tissue reaction; and
  - 1.10.6.2B must have a summary of patients/procedures exceeding the identified level. Summary must be reviewed monthly by the Medical Director and/or the radiation safety committee.
- 1.10.7B Patient post-procedure follow-up policy:
- 1.10.7.1B At a minimum, the facility must contact the patient the next business day or per state mandate following the procedure to follow up on patients' condition and ensure no complications.
  - 1.10.7.2B Patient must be seen within six weeks post-procedure in person or by televisit to ensure efficacy and no complications.
  - 1.10.7.3B Must be documented in the medical record.
  - 1.10.7.4B Recommended follow-up should occur at an appropriate interval of time. Possible follow-up procedures are per the KDOQI) or individual practice patterns.
    - i. Dialysis access angiography and/or intravascular ultrasound (IVUS)
      - Recommend follow up by dialysis center or medical care team

- ii. Percutaneous arteriovenous access creation/insertion
  - Physical examination must be performed on a regular basis.
- iii. Dialysis access angioplasty
  - Recommend follow up by dialysis center or medical care team.
- iv. Dialysis access stent/stent graft placement
  - Recommend follow up by dialysis center or medical care team.
- v. Dialysis access pharmacomechanical thrombectomy/thrombolysis
  - Recommend follow up by dialysis center or medical care team.
- vi. Dialysis access embolization/injection therapy
  - Recommend follow up by dialysis center or medical care team.
- vii. Dialysis access catheters tunneled and non-tunneled
  - Recommend follow up by dialysis center or medical care team.

# Part C:

## Quality Improvement

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### Section 1C: Quality Improvement Program

#### STANDARD – QI Program

- 1.1C The facility must have a written Quality Improvement (QI) program to evaluate all types of procedures performed in the facility on an ongoing basis. The QI program must include the QI measures outlined below, but may not be limited to the evaluation and review of:
- 1.1.1C procedure appropriateness;
  - 1.1.2C technical performance of the procedure;
  - 1.1.3C patient safety;
  - 1.1.4C procedure outcomes including complications and any adverse events; and
  - 1.1.5C medical record completeness and timeliness.

#### 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 2C: Quality Improvement Measures

## STANDARD – General 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 2.1.5C. All measures described need to be measured for consecutive cases over a period of time. A minimum of 30 cases must be reviewed annually.

### 2.1.1C Procedure Appropriateness:

2.1.1.1C The facility must evaluate the appropriateness of the procedures performed and categorize as:

- i. appropriate/usually appropriate;
- ii. may be appropriate;
- iii. rarely appropriate/usually not appropriate.

### 2.1.2C Technical Performance of the Procedure:

2.1.2.1C completeness of the procedure;

2.1.2.2C documentation of adverse technical events such as equipment or device failure;

2.1.2.3C failure to perform the procedure;

2.1.2.4C quality of pre-procedure diagnostic testing; and

2.1.2.5C adherence to the facility protocols.

### 2.1.3C Patient Safety:

2.1.3.1C Accuracy of patient identification:

- i. Use at least two patient identifiers when providing care, treatment, or service.

2.1.3.2C Medication safety:

- i. Label all medication with name, concentration, and expiration date.
- ii. Premixed pharmacologic and/or anesthetic agents must be labeled with content, concentration and expiration date if not prepared immediately before use.

2.1.3.3C Infection control measures consistent with CDC and OSHA guidelines.

2.1.3.4C Adherence to National Patient Safety Goals must be documented.

2.1.3.5C Review of patient radiation doses will be monitored and reviewed when exceeding 5 Gy.

### 2.1.4C Medical Record Completeness and Timeliness:

2.1.4.1C Time from completion of procedure to signature of final documentation must be completed within two business days.

2.1.5C Procedure Outcomes:

- 2.1.5.1C The facility must have a written policy and process to track and document the outcomes of all patients evaluated and/or treated.
- 2.1.5.2C All procedural outcomes in the patient medical record must be documented.
- 2.1.5.3C All adverse events that occur within (30 days) post-procedure must be documented in a centralized location or in retrievable electronic medical records for review.
- 2.1.5.4C Each case requiring referral outside the center for treatment of complications must be reviewed.
- 2.1.5.5C End-State Kidney Disease (ESKD) Life-Plan must be regularly reviewed, updated and documented in their medical record, when appropriate.
- 2.1.5.6C Each patient's vascular access functionality, complication risks and potential future dialysis access options must be reviewed and updated quarterly.
- 2.1.5.7C QoL and post procedure imaging outcomes are suggested.
- 2.1.5.8C Each center should have a peer review process to review adverse outcomes and a sample of each providers interventions on a bi-annual basis with recommendations for mentorship remediation and suspension of privileges leading to termination if recurrent issues occur.



## Section 3C: Quality Improvement Meetings

### STANDARD – QI Meetings

- 3.1C The facility must have a minimum of two QI meetings per year, and must include the following:
  - 3.1.1C Case review of QI measures outlined in sections 2.1.1C through 2.1.6C.
  - 3.1.2C Review and documentation of every significant complication.
  - 3.1.3C Review and documentation of procedures exceeding established radiation dose thresholds (5Gy).
  - 3.1.4C Review and documentation of the monthly emergency medication inspection log.
  - 3.1.5C Verification of routine inspection of medical supplies/equipment must be documented.
  - 3.1.6C Each of the clinical staff must participate in at least one meeting per year
  - 3.1.7C Additional QI-related topics, as appropriate.

# Section 4C: Quality Improvement Documentation

## STANDARD – QI Documentation

### 4.1C QI Documentation and Record Retention

4.1.1C The facility QI documentation must include, but is not limited to:

4.1.1.1C the data for all of the QI measures;

4.1.1.2C changes in procedures or policies as a result of this analysis;

4.1.1.3C minutes from the QI meetings; and

4.1.1.4C participant list (may include remote participation and/or review of minutes).

- i Attestation must be obtained from staff members who cannot participate but have reviewed the documentation.

4.1.2C The QI documentation must be maintained and available for all appropriate personnel to review.

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