



Ohio Administrative Code

Rule 3701-84-32 General facilities, equipment, and supplies - adult cardiac catheterization service.

Effective: May 15, 2023

(A) Each adult cardiac catheterization service, or "service" shall provide adequate, properly designed space to perform cardiac catheterization procedures safely and effectively. The amount of space may vary with the types of procedures performed and the nature of the facility (e.g., interventional versus diagnostic, teaching versus non-teaching).

(B) Each service shall utilize the following:

(1) Procedure rooms will:

(a) Have a minimum floor area of four hundred square feet;

(b) Have the following minimum clearances:

(i) If anesthesia is utilized, six feet at the head of the operating table. This dimension will result in an anesthesia work zone with a clear floor area of six feet by eight feet; and

(ii) Sufficient footage on each side of the procedure table to ensure that movement around and in the sterile field does not compromise or contaminate the sterile field.

(c) Procedure rooms utilizing image-guided surgery or procedures requiring more space for personnel or equipment will be sized to accommodate the personnel and equipment planned to be in the room during procedures and have a minimum floor area of six hundred square feet with a minimum clear dimension of twenty feet.

(d) Hybrid procedure rooms will meet the minimum floor area and clearances of paragraphs (B)(1)(a) and (B)(1)(b) of this rule and include at least the additional minimum floor area, clearances, and storage requirements for the imaging equipment contained in the room.



(e) Fixed encroachments into the minimum clear floor area are permitted to be included when determining the minimum clear floor area for a procedure room as long as:

(i) There are no encroachments into the sterile field;

(ii) The encroachments do not extend more than twelve inches into the minimum clear floor area outside the sterile field; and

(iii) The encroachment width along each wall does not exceed ten percent of the length of that wall.

(2) Control rooms, if utilized, will:

(a) Accommodate the imaging system control equipment;

(b) Be sized and configured in compliance with manufacturer recommendations for installation, service, and maintenance;

(c) Have view panels that provide for a view of the patient and the cardiac catheterization team;

(d) Be permitted to serve more than one hybrid procedure room, provided that manufacturer recommendations for installation, service, and maintenance are accommodated for all rooms served; and

(e) Be physically separated from a hybrid procedure room with walls and a door.

(f) A door is not required where a control room serves only one procedure room and is built, maintained, and controlled the same as the procedure room.

(3) Clean utility rooms that can sufficiently and efficiently supply the procedure rooms.

(C) A general radiology room cannot be used as a cardiac catheterization procedure room.

(D) Equipment described in this paragraph may be replaced by newer technology that has equivalent



or superior capability as determined by the provider of the service. In assessing these new technologies, consideration should be given to recommendations of recognized professional societies and accrediting bodies (e.g. the American college of cardiology). All services will, at a minimum have the following equipment:

- (1) High quality x-ray imaging with mutiaxial position capability;
- (2) A three-phase, twelve pulse generator with an output of eighty to one hundred kilowatts or a constant potential generator with an output of at least one hundred kilowatts at one hundred kilovolts;
- (3) Multimode or cesium iodide image intensifiers;
- (4) High-quality matched optics;
- (5) Appropriate imaging modality for review and storage of images;
- (6) Digital imaging equipment;
- (7) Carbon-fiber table tops;
- (8) A mechanism for continuous monitoring of a patient's blood pressure and electrocardiogram;
- (9) An adequate supply and variety of catheters, guide wires, and sheaths;
- (10) A crash cart with equipment for ventilatory support;
- (11) A defibrillator;
- (12) A temporary pacemaker; and
- (13) An intra-aortic balloon pump or other percutaneous mechanical circulatory assistance device of superior capability.



(E) Each adult cardiac catheterization service will provide and maintain radiation generating equipment in accordance with applicable state and federal requirements as specified in Chapter 3748. of the Revised Code and the rules adopted thereunder.