

Ohio Administrative Code Rule 3701-84-77 Facilities, equipment, and supplies - pediatric cardiac catheterization service.

Effective: May 15, 2023

(A) Each pediatric cardiac catheterization service will 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 such as interventional versus diagnostic and teaching versus non-teaching.

(B) Each pediatric cardiac catheterization service will ensure the following:

- (1) Procedure rooms:
- (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.

(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) Utilizing image-guided surgery or procedures requiring more space for personnel or equipment are 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) Classified as hybrid procedure rooms, will meet the minimum clear floor area and clearances of paragraphs (B)(1)(a) and (B)(1)(b) of this rule and include at least the additional minimum clear floor area, clearances, and storage requirements for the imaging equipment contained in the room.



(e) Containing fixed encroachments into the minimum clear floor area are permitted to be include those fixed encroachments 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 per cent 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.

(e) Be physically separated from a hybrid procedure room with walls and a door. 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 can sufficiently and efficiently supply the procedure rooms.

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

(D) Each pediatric cardiac catheterization service will ensure that each laboratory where a cardiac



catheterization procedure is conducted is appropriately equipped to provide high quality pediatric imaging, physiological monitoring, and provision of emergency care.

(E) The equipment described in this paragraph may be replaced by newer technology that has equivalent or superior capability as determined by the pediatric cardiac catheterization 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; the American academy of pediatrics). All pediatric cardiac catheterization services will have the following equipment:

(1) Imaging equipment appropriate to the procedures performed;

- (2) Immediate replay capabilities;
- (3) A blood gas analyzer;
- (4) A pulse oximeter;
- (5) An infant warming device;
- (6) Pacing catheters;
- (7) An external pacemaker;
- (8) A defibrillator;
- (9) An emergency cart;
- (10) A comprehensive inventory of pediatric catheters and devices; and
- (11) Ultrasound.
- (F) Each pediatric 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.