



Ohio Administrative Code

Rule 3701-84-38 Facilities, equipment, and supplies - open heart surgery service.

Effective: May 15, 2023

(A) Operating rooms used for open heart surgery:

(1) Standard operating rooms will:

(a) Have a minimum floor area of four hundred fifty 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.

(2) Operating 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.

(3) Hybrid operating rooms will meet the minimum floor area and clearances of paragraphs (A)(1)(a) and (A)(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.

(4) Fixed encroachments into the minimum floor area are permitted to be included when determining the minimum clear floor area for an operating room as long as:

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



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

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

(5) 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 open heart surgery team; and

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

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

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

(B) Each operating room used for open heart surgery will have appropriate numbers of oxygen and vacuum outlets and proper operating room lighting. Fiber optic headlights will be provided.

(C) Equipment and technology described in this paragraph may be replaced by newer technology and equipment with equivalent or superior capability. In assessing this new equipment and technology, consideration should be given to the recommendations of recognized professional societies and accrediting bodies. An open heart surgery service will have at least the following:

(1) Two fully operational cardiopulmonary bypass machines equipped with;

(a) A time and temperature module;



- (b) An air bubble and level detector system;
 - (c) A blender (air and oxygen mixer);
 - (d) An oxygen analyzer;
 - (e) A saturation monitor;
 - (f) Two pressure monitors;
 - (g) A back up pump head; and
 - (h) A heater/cooler (one back up).
- (2) Appropriate patient monitoring equipment with overhead slave, electrocardiogram, three pressure reading, and cardiac output;
- (3) An electrocauter;
- (4) A heat exchanger;
- (5) Drug infusion equipment;
- (6) Transportable monitoring equipment including electrocardiogram, defibrillator, oxygen saturation monitor, and pressure transducer;
- (7) An intra-aortic balloon pump or other percutaneous mechanical circulatory assistance device of superior capability;
- (8) The availability of a transesophageal echo;
- (9) A cardiac pacemaker;



(10) Routine blood gas analysis and chemistry including blood sugar analysis in the operating room;

(11) Defibrillators;

(12) A heating blanket;

(13) An ice bath;

(14) An automated coagulation timer (ACT) machine; and

(15) A cell saver.

(D) Each open heart surgery service will ensure that a fully equipped and staffed cardiac surgical intensive care unit that meets the needs of the cardiac surgery patient is available in the building and accessible by gurney from where the open heart surgery is performed. The cardiac surgical intensive care unit will ensure that a sufficient number of intensive care unit beds are available to meet the needs of open heart surgery patients each week, however, the beds are not required to be dedicated only to cardiac surgery patients.

(E) Each open heart surgery service will ensure that a post-intensive care "step-down" unit with telemetry is available in the building and accessible by gurney from where the open heart surgery is performed. The number of "step-down" beds will be sufficient to meet the needs of open heart surgery patients each week, however, the beds are not required to be dedicated only to cardiac surgery patients.