1. EGRESS, ACCESS AND TRAFFIC PATTERNS

A. Egress: Cardiac Catheterization Laboratories shall be designed and perform as Surgical Operating Rooms as operative procedures are performed, and egress to these rooms shall meet the following traffic patterns standards which should be designated to clearly define specific areas. The separation of “unrestricted”, “semi-restricted”, and “restricted” space is required and defined as follows:

B. Unrestricted Area: Street clothes are permitted and traffic is not limited

C. Semi-restricted Area: This area includes the peripheral support areas of the Laboratories. This includes the corridors leading to the restricting area and is limited to personnel wearing surgical attire. Cover all head and facial hair (you may wear a jumpsuit designed to totally cover outside apparel).

D. Restricted Area: This includes the Laboratories where operative procedures will occur. Surgical attire, shoe covers, masks, and hair coverings are required.

E. Staff Traffic: Ideally there are two approved patterns of traffic flow for the staff. One pattern is from the staff lockers/lounge through the semi-restricted corridor to the Scrub Stations and then into the individual Laboratories with exit through the semi-restricted corridor. The second pattern of staff traffic is from the staff lockers/lounge directly into the clean core area to the Scrub Stations and then into the individual Laboratories. Possible exceptions to the flow are the “circulators”, who retrieve supplies and equipment from the clean core.

F. Patient Traffic: The patients are brought into the Laboratories from the Preparation Area on a gurney. Patients entering the Laboratories should have a clean gown, clean linens, and their hair covered. After the procedure the patient are transported through the semi-restricted corridor and taken to a Recovery Area.

G. Traffic Patterns: Traffic pattern policies and procedures shall be clearly defined and traffic control practices enforced. The Laboratories should be made secure. Movement of personnel should be kept at a minimum during the invasive procedure. Clean and sterile supplies should be separated from contaminated supplies, equipment and waste. Staff must have a clear understanding of equipment range of motion and possible collision points.

2. MOVEABLE EQUIPMENT AND CARTS

A. Case Carts: Case carts are to be utilized in operative procedures (implantations) and brought to the Laboratories via the clean core area on a dedicated cart lift or transferred to a clean case cart where the procedure is completed. These carts are returned to SPS (SPD) in a closed fashion. In the event that SPS (SPD) is not located below the Laboratories, an alternative traffic pattern for the case carts must be established that isolates the clean and soiled case cart traffic.

B. Linens: Linens are brought into the Laboratory area by way of the semi-restricted corridor. Soiled linen is bagged and removed from the Laboratories via the semi-restricted corridor.

C. Heart Pumps: When performing TAVR/TAVI and other cardiac procedures a Cardiopulmonary bypass (CPB) pump shall be readily available for use. Normally the pump is staged within the procedure room however in some instances it is located in the restricted corridor just outside the procedure room.

3. POLICIES AND PROCEDURES

A. Policies and procedures for Surgical Attire: Policies and procedures should be developed, reviewed periodically and readily available for the Laboratories where surgical attire must be worn, appropriate attire within the defined areas and cover apparel outside the Laboratories. This also includes the selection and use of surgical gowns and drapes for the operative procedure.

B. FDA-compliant Surgical Hand Antiseptic Agent: The surgical hand antiseptic agent must be approved by the facility’s Infection Control Personnel and used for all surgical scrubs in the Laboratories.

C. Policies and Procedures for Surgical Hand Antisepsis: Policies and procedures should be developed, reviewed periodically and readily available in the Laboratories.

D. Policies and Procedures for Maintaining a Sterile Field: Policies and procedures should be developed, reviewed periodically and readily available in the Laboratories. Included are policies for scrubbed persons functioning within the sterile field, sterile draping, transfer methods of items for the sterile field and constant surveillance of the sterile field.

E. Electrosurgery: Policies and procedures should be developed, reviewed periodically and readily available in the Laboratories for electrosurgical units. Proper care, training, competency, exposure to smoke plume generated should be minimized (smoke evacuation system utilizes) and tracking of the unit.

F. Policies and Procedures for Sponge, Sharps and Instrument Counts: Policies and procedures should be developed, reviewed periodically and readily available in the Laboratories.

G. Waste Disposal: Hazardous waste must be identified and disposed of in a manner consistent with federal laws in the Laboratories.

H. Quality Control Program: A Quality Assurance/Performance Improvement Program must be in place for the Laboratory procedures.
<table>
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<tr>
<th>Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist, continued...</th>
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<tbody>
<tr>
<td>I. Environmental Cleaning and Disinfection: The environmental cleaning and disinfection of the Laboratories is consistent with AORN Standards (after each case and terminal cleaning at the end of the day) with policies and procedures written, reviewed periodically, and readily available in the Laboratory's practice setting.</td>
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<td>J. Patient Skin Antisepsis: Patients undergoing open Class I surgical procedures below the chin should have two preoperative showers with chlorhexidine gluconate (CHG) before the procedure (when appropriate). Hair removal should follow AORN Guidelines. Personnel should receive education and competency of skin preparation, application and skin assessment. Policies and procedures should be in place for skin preparation and readily available in the Laboratory setting.</td>
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<td>K. Skin Quality Management Program: A Quality Management Program should be in place to evaluate skin care and identify any problems or areas for improvement in the Laboratories.</td>
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<td>L. Anesthesia Equipment: The Cardiac Catheterization and Electrophysiology Laboratories utilizing anesthesia equipment should follow the Occupational Safety and Health Administration for the use of anesthesia gases and equipment. This includes the removal of gases from the environment (anesthesia scavenging system is required).</td>
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<td>M. Instrument Care: Contaminated instruments must be contained during transport from the Laboratories and should be transported in a timely manner to a designated area for decontamination. Appropriate case carts and metal transportation carts should be provided that prevent contaminated instruments from being carried by hand through an open corridor.</td>
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<td>N. Fire Safety: A written fire prevention and management plan should be developed. A pre-procedure fire risk assessment must be completed and documented prior to any operative procedures.</td>
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<tr>
<td>O. Waste Disposal: Hazardous waste must be identified and disposed of in a manner consistent with federal laws in the Laboratories</td>
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<td>P. The Clinical Interventionalist should be consulted with prior to the design concept phase so that the type imaging modality can be identified and test fitted into the proposed room together with a reflected ceiling layout to identify any conflict.</td>
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4. THE BUILT ENVIRONMENT

A. Design Criteria Guidelines:

1. New Construction: Operating Room Guidelines shall comply with and follow FGI Guidelines for Surgery and CATH-EP Labs. For Transfemoral Aortic Valve Replacement (TAVR) procedures in Cardiac Catheterization Laboratories, Cardiothoracic Surgery Room specifications are required.
2. Renovation Projects: Laboratories will be evaluated on an individual case by case basis.
3. MEP and Electrical requirements shall be pursuant to the NEC and AHJ
4. Minimum 25 air changes per hour with four low returns preferable, three absolute minimum.

B. Provide laminar flow to extend beyond the sterile surgical field.

C. Specific Architectural Requirements:

1. Cardiac Procedure Hybrid Room:
   - Absolute Minimum for Existing Facilities: 750 net square feet (65.11 net square meters) (26'-0" x 29'-0"), 24'-0" min dimension
   - New and Existing Facilities: 900 net square feet (83.61 net square meters) (29'-0" x 31'-0"), 24'-0" min dimension.
   - Interstitial space above the finished ceiling line is a must to adequately install and distribute MEP infrastructure.
   - Reconstructed sites will be evaluated on an individual basis.

2. Control Room: 190 net square feet preferred, 120 NSF minimum
3. Equipment Room: Minimum 120 net square feet and accessible from the Control Room or the restricted corridor and not accessible from the procedure room.
4. Lead-lined walls, doors and window frames including leaded glass vision view panels. Physicist shielding report shall be submitted and approved by VAMC Chief Facilities Engineer prior to installation.
5. Scrub station located adjacent to the entry door of the Laboratory
6. Clean section (supply space) for surgical supplies, equipment, case carts, etc.
7. Area under the procedure table is restricted space and cannot be used to store equipment
8. Area at the end of the table is restricted space due to table movement
10. The finished ceiling height minimum of 9'-6" feet clear. The ceiling shall be sealed, washable and homogeneous.
11. VAC ductwork shall be fabricated of stainless steel
12. Flooring: Seamless membrane with minimum six inch high flash coving, sealed at intersection with wall surface.
13. Imaging equipment, ceiling booms, ceiling mounted lights, ceiling mounted utilities, hanging lead facial shield must be coordinated to prevent collision
14. Minimum 25 air changes per hour with four low returns preferable, three absolute minimum.

D. Surgical Lighting: Lighting should be in working order and adequate for illumination of the invasive field. General lighting and specialty lighting should be on separate circuits. Surgical lights must have a critical feature of reaching across the procedure table. General room lighting can be incandescent or fluorescent and must have the ability to dim.

E. Anesthetic Gases: Potential hazards associated with the use of anesthetic gases in the Laboratories should be identified and safe practices should be established. Anesthesia gases should be located at the head of the patient with enough swing to accommodate a room switch.


G. Medical Gas and Electrical Outlets: (Minimum)-Oxygen (2), Vacuum (5), Nitrous Oxide (1), Nitrogen (1) Electrical Receptacles (24) must be present in each Hybrid Cardiac OR Cath Laboratory Procedure Room.

H. HVAC Criteria: Proper air quality, air volume changes and air flow direction in the Laboratories must meet AORN Standards and VA HVAC Guidelines for Operative Surgical Suites. Ideally this includes the visual monitoring of temperature, humidity, and positivity in the Laboratories. Room readiness should be documented prior to case start. The following are required for operative procedures to be performed:
   1. Laminar Flow Ceiling with Laminar Flow Diffusers (clear of ceiling equipment)
   2. Low Return Air (3 minimum, 4 preferred)
   3. Room Pressure (+)
   4. Noise Criteria (35-45)
   5. RH Heading (30-60%)
   6. RH Cooling (20-60%)
   7. Total Air Exchanged (20L/minute minimum-25 L/minute preferred)
   8. Percentage Outside Air Changes (4)
   9. Dry Bulb Temperature Heating (68 degrees F)
   10. Dry Bulb Temperature Cooling (75 degrees F)
   11. Design Guide continues to recommend 25% outside air for HVAC systems
   12. During an operative procedure (implants, etc), all the space from the floor itself to a distance of 15” (380 mm) above is considered contaminated. Therefore, all exhaust/return grills positioned low on the wall approximately 18” (460 mm) above the floor. The Laboratory room exhaust system should include a minimum of three (four best) low exhaust/return air grills located in opposite corners to minimize recirculation of contaminated air within the room.

I. Power Systems:
   1. Minimum One 208-volt outlet is required
   2. “Code Blue” system is required in the event of a cardiac arrest summoning designated staff

J. Procedural Table: Capable to swing 90 degrees (preferred) radiotranslucent with “Slope-saddle” column design that allows for a maximum Trendelenburg/Reverse Trendelenburg of ≤80 degrees and simultaneous lateral tilt of ≤45 degrees in positioning support on the surgical table top.

**Courtesy of STERIS**