Standards

Office of Facilities Planning — Facilities Standards Service

Department of Veterans Affairs — Office of Construction & Facilities Management

CFM

ALERT

CARDIOVASCULAR LABORATORY SERVICE DESIGN GUIDE

ISSUE:

Resolving major disconnects between the Cardiovascular Laboratory Service Design Guide dated Nov 29, 2011, and the Surgical Services Design Guide dated April 2016, as the entire body of interventional cardiology services has been incorporated within the Surgical Services Design Guide as a single Integrated Interventional Services Platform. In particular the following interventional services have been moved and relocated:

1. Cardiac Catheterization Laboratory (XCCE1).
2. Procedure Room, Electrophysiology (XCEP1)
3. Transesophageal Echocardiograph (TEE) Procedure Room (TRTE1)
4. Delete Control Room Catheterization Laboratory (XCCC1)
5. Add Control Room, Hybrid OR-Cath-EP (ORHC1)
6. Add Decontamination, TEE Probe Room (TRTE2)
7. Add Storage, Clean TEE Probe Room (TRTE3)
8. Add Checklist for Cardiac Hybrid OR, Cardiac Catheterization / Electrophysiology Labs.

The current Interventional Services portion of the Cardiovascular Laboratory Service Design Guide is out of date with many clinical disconnects in particular the procedure room sizes have grown significantly and the organization of interventional radiology reflects the same organization as of surgery. There is no change to the non-invasive cardiology portion of the current design guide as it is located in an out-patient clinic environment.

DISCUSSION:

Healthcare delivery for the invasive procedures has evolved in recent years to a model of an integrated interventional platform where surgery, interventional as well as diagnostic radiology are co-located on the same platform sharing services such as the post anesthetic care unit (PACU), patient prep and phase II patient recovery as well as support spaces to economize on the scale of services and maximize workflow utilization including addressing ways and means to reduce hospital acquired infections (HAI).

REQUIREMENTS:
Refer to Surgical Design Standards, April 2016 and the attached excepts as the balance of the documents can be found in he new Surgical Design Standards:

1. Cardiac Catheterization Laboratory (XCCE1).
2. Procedure Room, Electrophysiology (XCEP1)
3. Transesophageal Echocardiograph (TEE) Procedure Room ((TRTE1)
4. Control Room, Hybrid OR-Cath-EP (ORHC1)
5. Decontamination, TEE Probe Room (TRTE2)
6. Storage, Clean TEE Probe Room (TRTE3)
7. Checklist for Cardiac Hybrid OR, Cardiac Catheterization / Electrophysiology Labs.

FOR ADDITIONAL INFORMATION:
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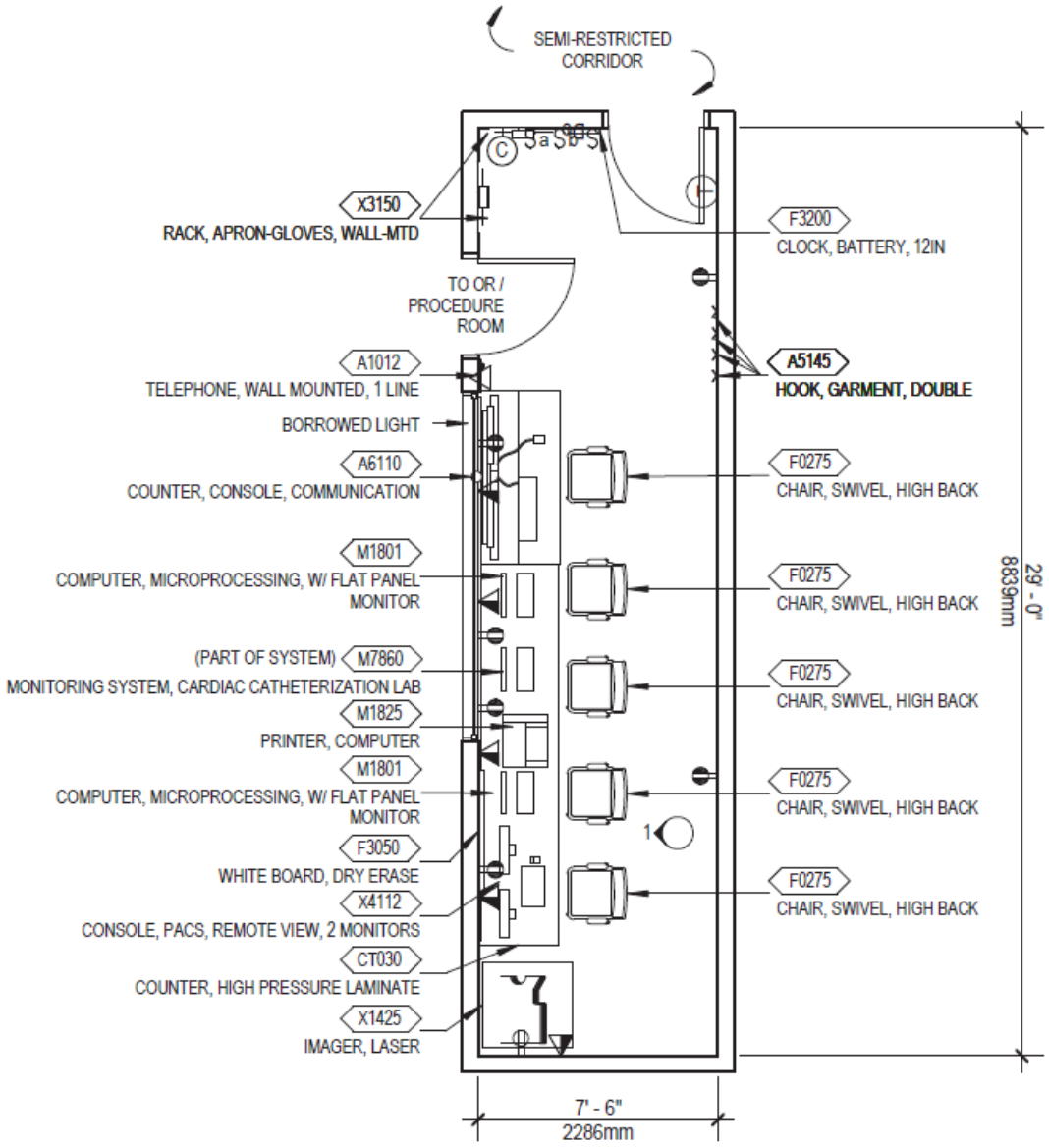
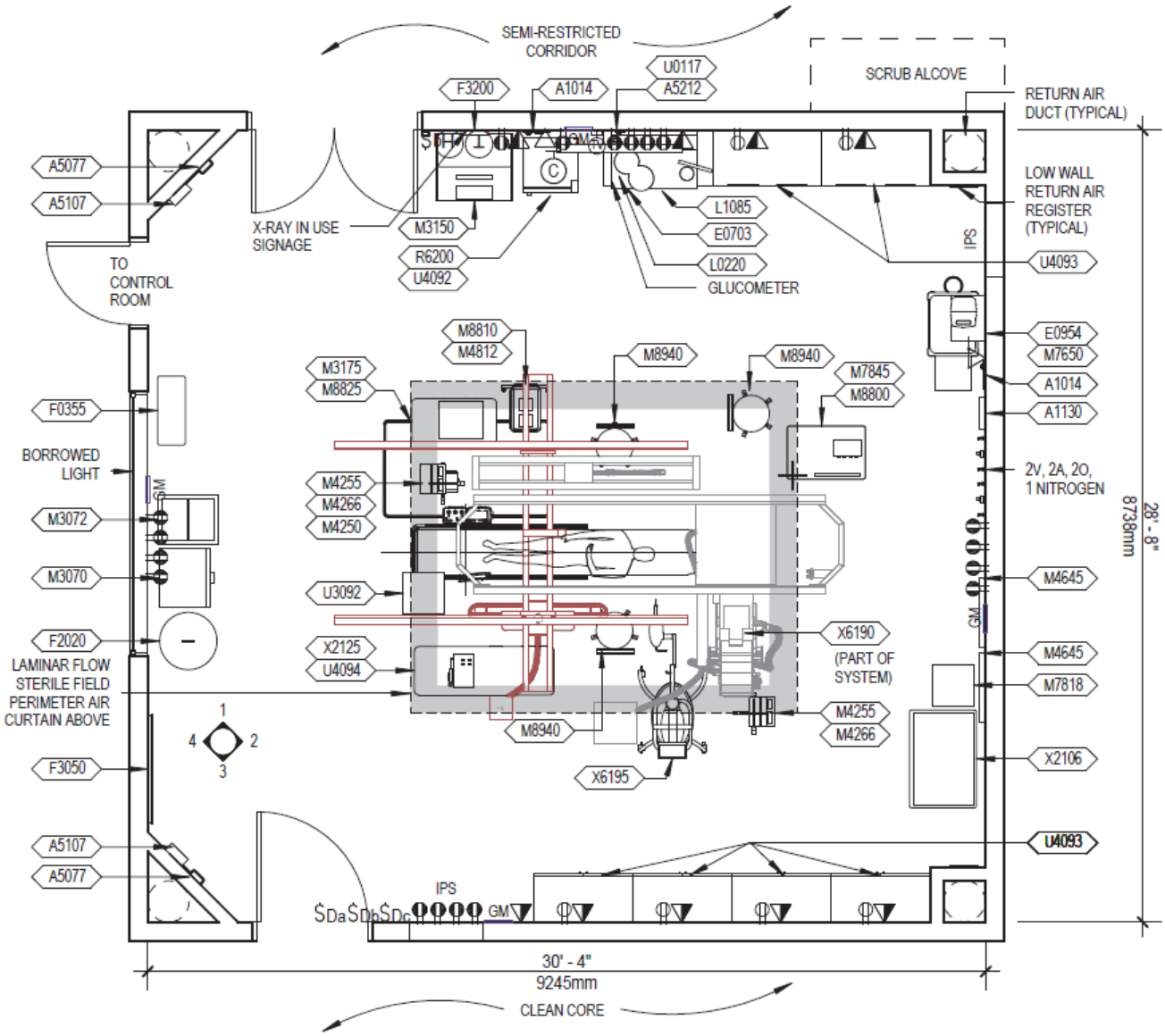
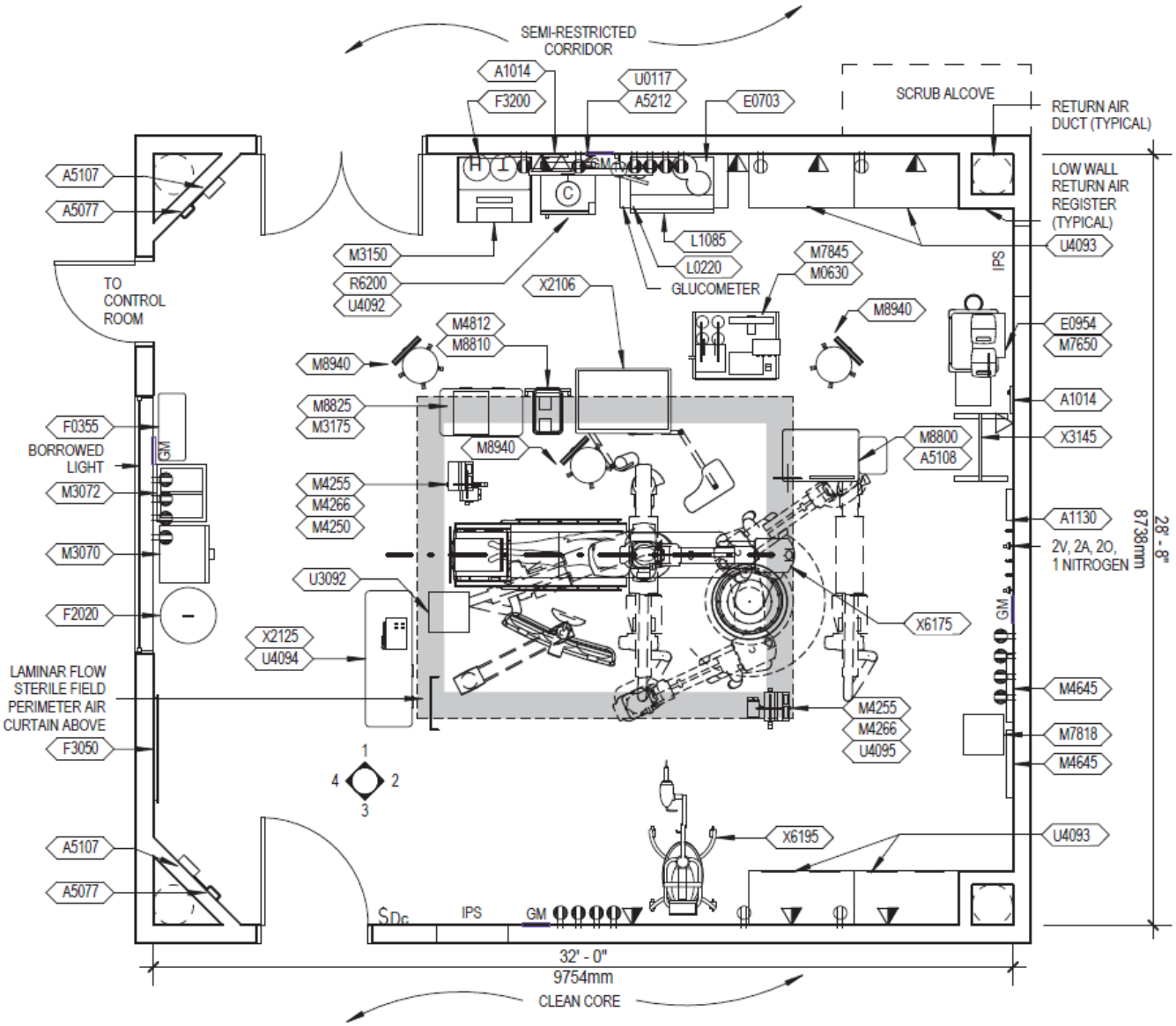
4.15. CONTROL ROOM, HYBRID OR (ORHC1)



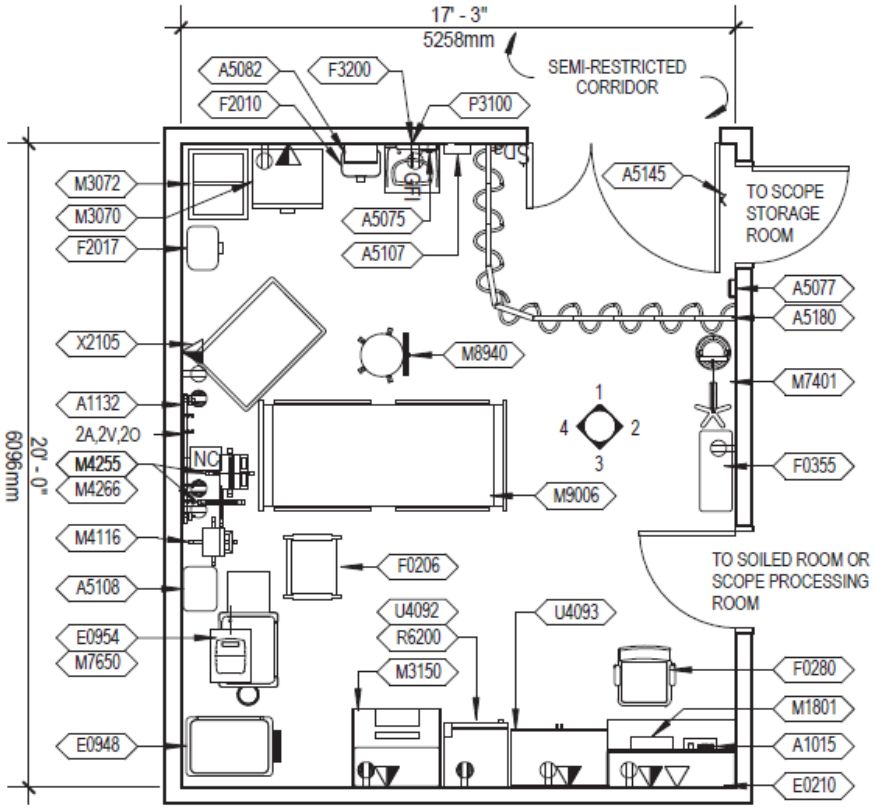
4.16. CARDIAC CATHETERIZATION LABORATORY (XCCE1)



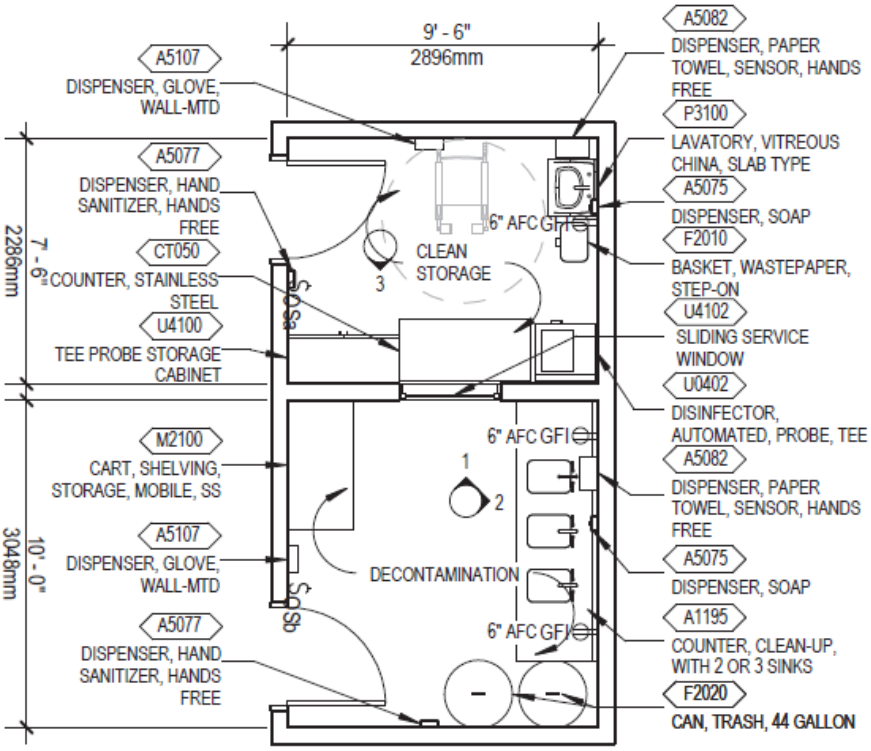
4.17. PROCEDURE ROOM, ELECTROPHYSIOLOGY (XCEP1)



4.18. TRANSESOPHAGEAL ECHOCARDIOGRAPH (TEE) PROCEDURE ROOM (TRTE1)



4.19. DECONTAMINATION, TEE PROBE (TRTE2) STORAGE, CLEAN TEE PROBE (TRTE3)



CARDIAC CATHETERIZATION, ELECTROPHYSIOLOGY LABORATORY AND HYBRID SURGERY REQUIREMENTS FOR OPERATIVE PROCEDURES

The fundamental precept of requiring Hybrid OR standards for Cardiac Catheterization and Electrophysiology Laboratories is to ensure safe, high-quality, care on patients undergoing operative procedures, irrespective of the specific physical location of the designated Lab. This includes anticipating the unforeseen events that may occur during an invasive procedure such as surgical implantations, etc. This check list was developed by the VA CFM (Office of Construction and Facilities Management).

1. EGRESS, ACCESS AND TRAFFIC PATTERNS

Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist	Yes	No
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.		

Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist	Yes	No
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

Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist	Yes	No
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

Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist	Yes	No
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.		

Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist	Yes	No
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.		
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.		
J. **Patient Skin Antisepsis:** Patients undergoing open Class I surgical procedures below the chin should have two preoperative showers with chlorahexidine 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.		
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.		

Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist	Yes	No
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).		
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.		
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.		
O. **Waste Disposal:** Hazardous waste must be identified and disposed of in a manner consistent with federal laws in the Laboratories		
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.		

4. THE BUILT ENVIRONMENT

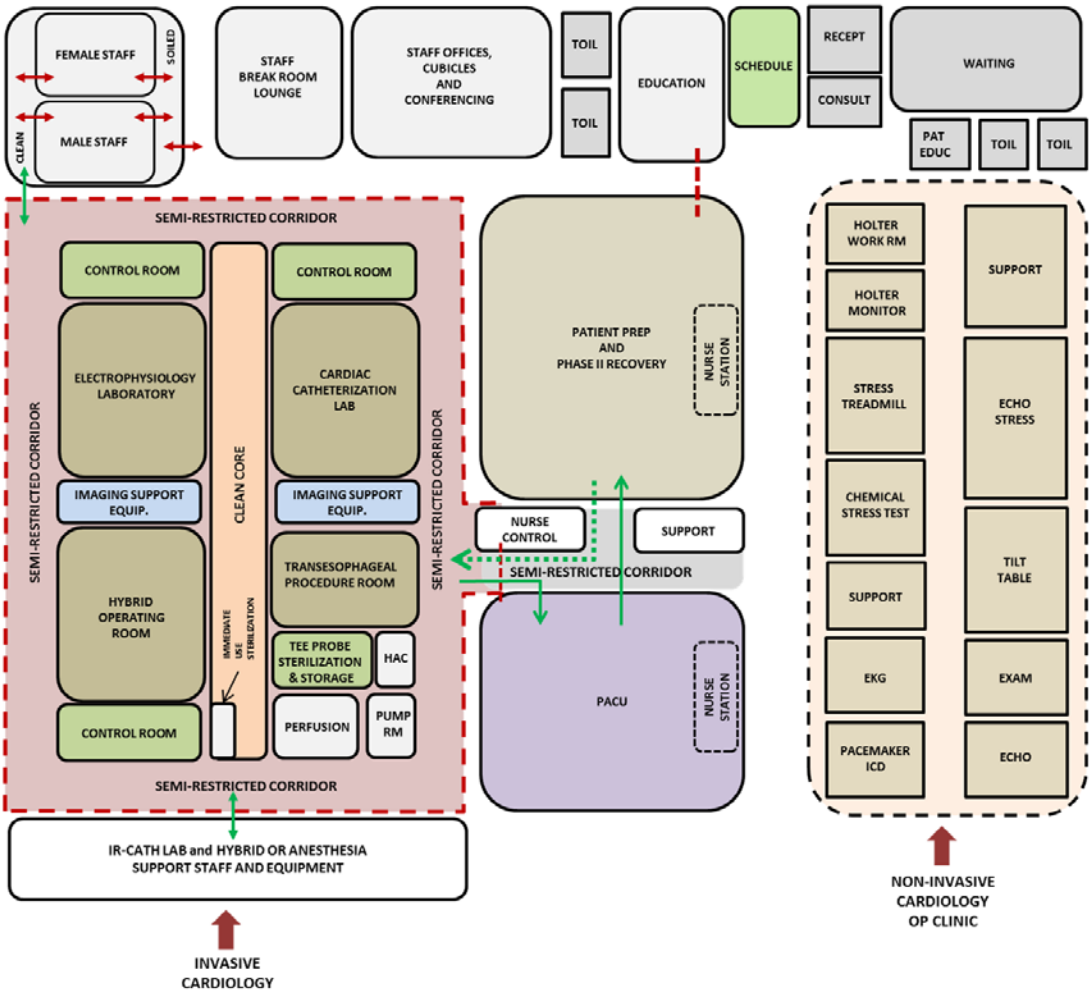
Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist	Yes	No
A. **Design Criteria Guidelines:** *1.* New Construction: Operating Room Guidelines shall comply with and follow FGI Guidelines for Surgery and CATH-EP Labs. For Transfemoral Aortic Valve Replacement (TAVR) procedures in 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***: 850 net square feet (78.97 net square meters) (29'-0" x 29'-0"), **24'-0" min dimension**		

Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist	Yes	No
• **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 *9.* Ceiling Access Panels: Minimum two foot by two foot for installation and maintenance of medical gases, electrical and data utilities to ceiling mounted booms, except in facilities having interstitial floor construction. *10.* The finished ceiling height minimum of 9'-6" feet clear. The ceiling shall be sealed, washable and homogeneous. *11.* HVAC 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. **** Note:*** *The* ***Philips Flexmove FD 20*** *Imaging Modality requires a* ***minimum 28'-0"*** *room width so as to provide sufficient room for the circulator to pass by when the C-Arm is positioned perpendicular to the procedure table.*		

Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist	Yes	No
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.		
F. **Booms:** (Preferred) Anesthesia Boom, (preferred) Utilities Boom, (required) Documentation Boom, (required) Display Monitor Boom. Booms must be either electro-magnetic (preferred) or pneumatically operated. If pneumatic, provide air compressor and air storage tank in proximal sound proof room		
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, ASHRAE 170-2013 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 Heating (30-60%) *6.* RH Cooling (20-60%) *7.* Total Air Exchanges: 20 air changes per hour minimum, (25 air changes per hour preferred). *8.* Minimum Outside Air: four (4) air changes per hour minimum (five (5) air changes per hour preferred). *9.* Dry Bulb Temperature Heating (75 degrees F) *10.* Dry Bulb Temperature Cooling (68 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 8” (460 mm) above the floor. The Laboratory room exhaust system should include a minimum of three (four best) low		

Cardiac Hybrid OR Cardiac Catheterization/Electrophysiology Lab Checklist	Yes	No
exhaust/return air grills located in opposite corners to minimize recirculation of contaminated air within the room.		
I. **Power Systems:** Line-isolation monitors should be provided for each isolated power system (preferred but not required). All Laboratories should be on an un-interrupted power supply (UPS). The power requirements for an operative procedure in the Catheterization or Electrophysiology Laboratories must exceed routine Catheterization Laboratories. Electrical feeders for the main distribution point may be required to boost the power needs. *1.* Minimum One 208-volt outlet is required *2.* "Code Blue" system is required in the event of a cardiac arrest summoning designated staff *3.* Follow requirements of National Electrical Code and NFPA 99.		
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 .		

FUNCTIONAL DIAGRAM CARDIOVASCULAR SERVICES



Invasive Cardiology is typically located in the hospital "in-patient" environment as patient safety and infection control are paramount. The functional diagram replicates and reflects the functional diagram of the surgical platform.

Non-Invasive Cardiology can be located either in the hospital or outpatient scenario an functions as diagnostic clinic. In many cases the non-invasive cardiology clinic may not be proximal to the invasive cardiology platform.