Annex 41
Cardiac Investigations Unit

Health Facilities providing Cardiac Investigations services and subject to provisions hereof should meet the following conditions:

Policies

Besides other related polices in previous annexes, the following policies and procedures that define responsibilities and requirements should include but not limited to:

1. Verifying patient's identity, procedure type and its site, must be done by at least two persons (the correct patient, the correct position and the correct procedure).
2. Infection control procedures.
3. Sterilization of equipment and surgical instruments.
4. Surgical supplies and the number of surgical instruments and documents required.
5. Medical and technical responsibilities.
6. Dealing with and maintenance of medical devices.
7. Policies of inclusion and exclusion criteria.
8. Policy to ensure the continuity of the procedures in the event of main power failure.
9. Policies of transferring patient for tertiary facilities when needed with a contract between the two facilities.
10. Policies of internal referring of the patients.

The Cardiac Investigation Unit provides diagnostic procedures, interventional treatments and consultation for patients with cardiac conditions. The Unit consists of three major components:

1. Cardiac Catheter Suite
2. Cardiac Diagnostic Unit
3. Outpatient Clinics

This guideline will address the following components of a cardiac investigation service primarily for secondary and tertiary healthcare facilities:

1. Cardiac Catheter Laboratories (CCL)– diagnostic and interventional
2. Electrophysiology (EP) laboratory
3. Echocardiography – trans-thoracic (TTE), trans-esophageal (TOE) and stress echocardiography
4. Exercise stress testing
5. Electrocardiography (ECG)
6. Holter monitoring
7. Ambulatory blood pressure monitoring
8. Pacemaker and defibrillator implantation and follow-up
9. Outpatient clinics.

Hours of Operation

The Cardiac Investigation outpatient's area will generally operate up to 8 hours a day, five-days a week. The diagnostic and interventional areas of Cardiac Investigations Unit may operate up to 12-hours a day, seven-days a week, depending on the Operational Policy. If percutaneous coronary intervention (PCI) is offered in the CCL – the lab must operate 24/7, 365 days/year.

A. Models of Care

The Cardiac Investigation Unit may incorporate the following Models of Care for specific components:

Cardiac Catheter Laboratories

Catheter laboratories, depending on their role within the service plan, may be:

1. Integrated into an interventional imaging suite in a Medical Imaging Unit
2. A component of a Cardiac Precinct
3. A component of an interventional floor that incorporates operating theatres and cardiac investigations with access to a 23 hour or short stay ward.

The number of laboratories will be determined by the service plan, but laboratories should operate at near-optimum capacity to justify the expense of operation, maintain the skills

and teamwork of the operators and staff, and provide maximum patient and operator safety.

Cardiac Diagnostic Unit

Cardiac diagnostic services may be provided:

1. Within a fully integrated Cardiac Investigation Unit
2. As a part of a general Clinical Measurement Unit that can include diagnostic facilities for other units such as neurology and respiratory function testing
3. Within an outpatient clinic (depending on the range of tests to be provided by the unit).

Cardiac Outpatient Clinics

Cardiac Outpatient Clinics can be conducted through:

1. A general Outpatient Unit
2. Consulting rooms provided within a Clinical Measurement Unit that can be shared with other disciplines
3. Dedicated consulting rooms within a Cardiac Precinct. The provision of dedicated cardiac clinics should be based on throughput requirements and service planning.

Access to ECG testing is required as a minimum in all forms of cardiac outpatients clinics.

B. Location

The relationships required between the Cardiac Investigation Unit and other units within the health facility will determine the most appropriate location for the unit. The models of care, described above, will impact on the location of the unit in relation to other units, particularly if areas such as diagnostic units, are shared. If the Unit is not on the ground floor, consideration should be given to outpatient volumes in regard to vertical access to clinics.

Access to Cardiac Surgery

Although it may be possible for a cardiac catheter laboratory to function well in an institution without a cardiac surgery program, such laboratories will only offer limited services. A formal arrangement is required between the laboratory and a healthcare facility with cardiac surgery capacity. The unit should exercise particular caution to not accept unstable, acutely ill, or other high-risk patients for studies. However, the risks and benefits of early intervention should also be considered.

C. Configuration

Staff, patients and the general public should not need to use the Cardiac Investigation Unit as a thoroughfare to other units of the healthcare facility as it could adversely impact on issues relating to security, privacy and stock control.

The diagnostic and clinic rooms that are less complex and more frequently used should be located closer to reception/ waiting areas, while the catheterization suite should be located in a more private zone.

It would be preferable if staff and patient paths are separate and a discreet access for inpatients is provided. Figure 1 shows a sample layout of a cardiac investigations unit.

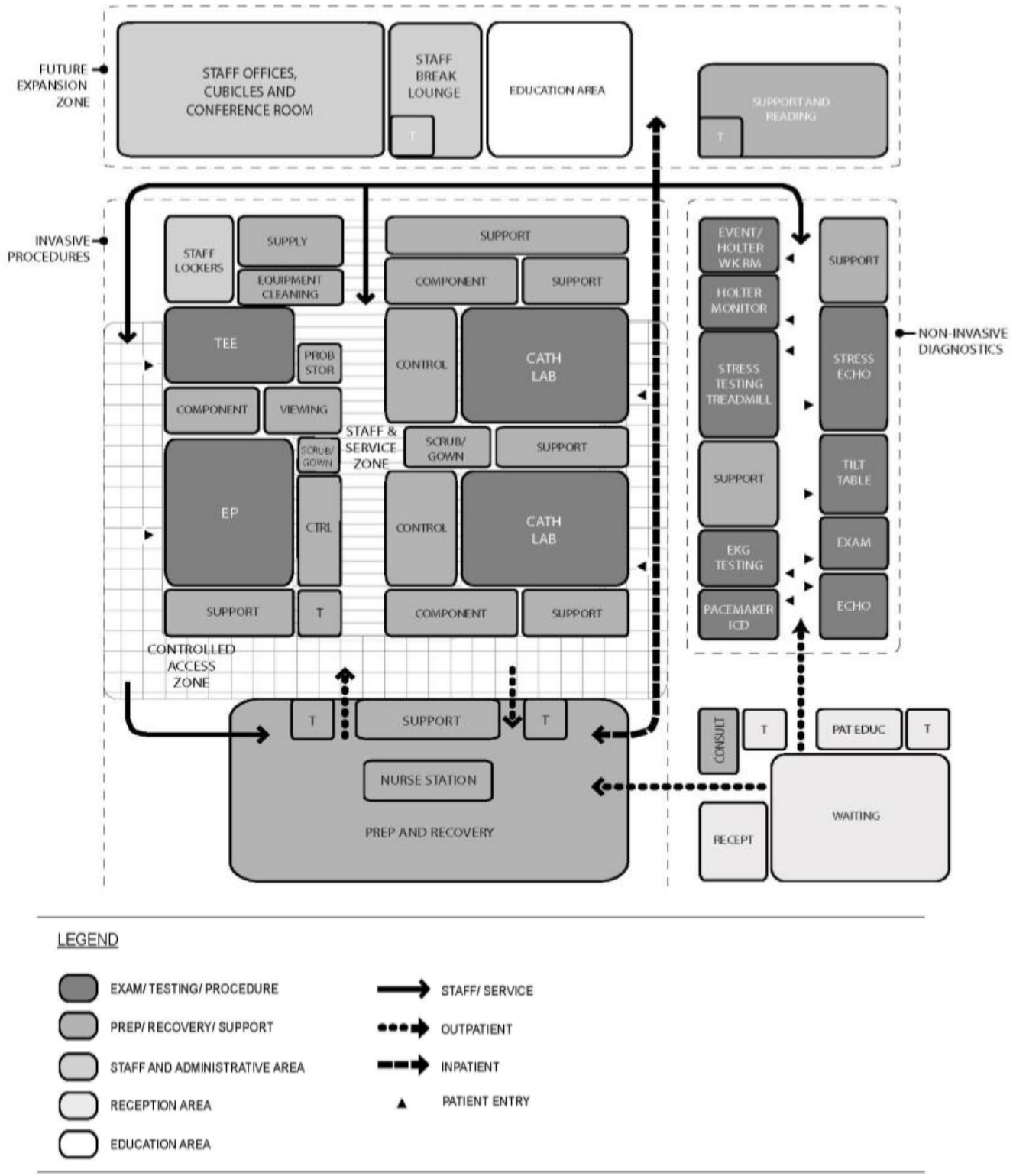


Figure 1: Sample layout of a cardiac investigations unit

D. Radiation Safety

Each CCL facility must establish a radiation safety education. Documentation of personnel training in radiation safety must be provided. The facility must monitor staff radiation dose through the use of personal dose monitors. Follow up should occur if an individual's dosimeter readings are substantially above or below the expected range for their laboratory responsibilities.

Patient radiation dose needs to be monitored and recorded. This should include fluoroscopic time (FT, min) and total air kerma at the interventional reference point (Ka,r,Gy) and /or kerma area product (PKA, $Gycm^2$). Peak skin dose (PSD,Gy) should be included if technology permits its measurement. A surveillance program should be in place for patients whose recorded total air kerma at the interventional reference point (Ka,r) is 5 Gy or greater, PKA of 500, $Gycm^2$ and/or fluoroscopy doses that exceed 60 minutes.

This program should include the dose and a reason for this dose, patient notification, medical physicist / health physics involvement for Ka,r > 10Gy, and a mechanism for patient follow up of potential adverse effects from radiation.

E. Cardiac Arrest and Resuscitation

Cardiac services and associated tests present a higher than usual likelihood of cardiac arrest, and resuscitation equipment should always be immediately accessible.

An electrophysiology or implantable cardioverter defibrillator (ICD) implanting laboratory should contain, or have access to, two external cardiac defibrillators as multiple use during procedures increases the incidence of equipment failure.

Cardiopulmonary resuscitation (CPR) is best performed on a hard surface wherever possible. Therefore, in diagnostic rooms such as those for echocardiography and ECG (particularly stress testing) the room size should be sufficient to allow access to a patient in the event of cardiac arrest without requiring the major movement of equipment.

Cardiology staff may be part of a team attending medical emergencies within the healthcare facility, although individual units should have resuscitation trolleys available for access in each unit.

F. Staffing

A staff establishment should be developed early in the planning process in order to assess the office space, workstations and amenities that will be required.

Staffing levels will vary for each unit, depending on the size of the unit; the operational policies; availability of staff and differing skill mix; levels of supervision

required; clinical case mix; and dependency and unit activity levels.
The unit should provide sufficient functional area to support the number of staff in the safe and efficient delivery of care.
The environment should be secure and facilitate effective emergency responses to acute situations on each shift. Designing the unit on this basis will support efficient unit operation without imposing additional costs whilst enabling compliance with security and occupational health and safety requirements.

Staff Establishment

The staff establishment may include (on a permanent and visiting basis) the following:

1. Cardiologists (Consultants, Specialists, and Residents)
2. Radiographers
3. Cardiac Technicians, Technologists
4. Cardiac Sonographers
5. Nursing Staff
6. Administrative Staff
7. Allied Health Professionals

If PCI procedures are performed, it is expected that the Head of Department be appropriately trained and certified in interventional cardiology. He/she should have a minimum of 5 years work experience in interventional cardiology, with strong leadership skills, qualities and no undisclosed conflicts of interest related to the CCL.

G. Inclusion / Exclusion Criteria

1. Diagnostic procedures excluded from the facilities without onsite surgery, include patients with pulmonary edema due to ischemia, complex congenital heart disease and all pediatric procedures.

2. Therapeutic procedures excluded from facilities without on site surgery, are therapeutic procedures for pediatric and adult congenital heart disease. Elective and primary PCI procedures are permitted in sites without onsite cardiovascular surgery, if there is strict and a documented working relationship with a tertiary cardiac center. There must also be a tested emergency transport system in place.

3. Elective high-risk patients and high-risk lesions may be unsuitable for intervention at facilities without onsite cardiovascular surgery.

   High risk patients are defined by:

   a. Decompensated CHF (Killip class 3-4)
   b. Recent (< 8 weeks), cerebrovascular accident
   c. Known clotting disorder

d. Left ventricular ejection fraction ≤ 30%
e. Chronic kidney disease (creatinine > 2.0 mg/dl or creatinine clearance < 60ml/minute)
f. Serious ongoing ventricular arrythmias

High lesions are defined by:

a. Left main stenosis > 50% or 3 – vessel disease (> 70% proximal or mid lesions) unprotected by prior bypass surgery, diffuse disease
b. Target lesion that jeopardizes an extensive amount of myocardium
c. Diffuse disease (> 20mm length)
d. Extremely angulated segment or excessive proximal or in-lesion tortuosity (defined as > two 45-degree bends before the target stenosis
e. Greater than moderate calcification visible proximal and at the target stenosis
f. Inability to protect major side branches
g. Older degenerated vein grafts with variable lesions
h. Thrombus in the target vessels or at lesion sites
i. Chronic total occlusions (defined as > 3 months in duration and/or bridging collaterals)
j. Vessel characteristics that, in the operators judgement, would impede stent deployment
k. Anticipated probable need for rotational or other atherectomy device, cutting balloon or laser

4. CCL's without onsite surgery must have an internal audit process to validate that >90% of PCI procedures meet their defined inclusion / exclusion criteria for procedures that can be performed in a facility without onsite surgery.

Functional Areas

The Cardiac Investigation Unit can include the following functional zones, arranged in relation to each other depending on operational policies, service delineation and relationships to other services:

Outpatient/ Diagnostic Facilities – Non-interventional

Cardiac Outpatient/ Diagnostic facilities will generally comprise:

1. Entry Reception including:

- Waiting with beverage bay and drinking water facilities if required
- Public amenities, if not located in close proximity
- Interview room
- Patient bed bays, for holding pre-procedure and recovery following procedures
- Storage for files and stationery

2. Outpatient/ Diagnostic areas that may incorporate the following rooms or diagnostic testing specialties according to the Service Plan:

   - Consult rooms
   - ECG cubicles
   - Stress testing
   - Echocardiography
   - Holter monitoring application room
   - Tilt table testing
   - Reporting areas with workstations

3. Support areas including:

   - Patient amenities that may have showers for post exercise hygiene
   - Patient change rooms, that may be located within the diagnostic rooms
   - Storage for linen, equipment, consumables, mobile equipment, resuscitation trolley
   - Clean-up room.

Depending on the model of care, every opportunity should be taken to share facilities such as:

Public waiting areas and amenities
Reception
Support areas
Staff offices and amenities.

Reception/ Waiting

The Reception/ Waiting area of the Cardiac Investigation Unit may be shared by all

sections of the unit and should provide convenient access to both the diagnostic areas and procedural areas such as cardiac catheter laboratories, as well as allowing access to public and disabled amenities for patients and visitors. The Reception area may include patient registration, a patient queuing system and cashier facilities where appropriate.

Waiting areas may be designed with separation to meet cultural requirements where appropriate. Waiting areas should accommodate a range of occupants including children, those less mobile or in wheelchairs.
A separate Reception/ waiting area may be provided for the Catheterization Suite in order to offer discreet access to patients.

Cardiology Outpatient Clinics

Multi-function consultation rooms can sufficiently serve cardiology outpatient clinics. They may be scheduled for use by other disciplines and the number and size of rooms provided will be determined by throughput and relationships to other units as outlined in the service plan. If a pacemaker clinic is included in the service plan, there should be access to a room for testing equipment and access to an external defibrillator.

If the consulting rooms are part of a general outpatient area that is shared with other disciplines, the location/ layout of the rooms should allow ready access to ECG facilities.

ECG Cubicles

A room or bay for undertaking resting electrocardiograms is required, with ready access from the waiting area and outpatient area as ECGs are routinely performed in a cardiac clinic. This may be provided as a single room/ cubicle or may be designed as two patient bays. If two bays are designed, curtain tracks and screens will be required for patients' privacy. A handwashing basin will be required in close proximity.

Stress Testing

Stress testing rooms should be located with ready access to change facilities.

Echocardiography

Echocardiography room size may be adjusted according to equipment to be used.

Holter Monitoring/ Ambulatory Monitoring/ BP Application Room

A room for attaching Holter monitors or blood pressure cuffs for ambulatory monitoring of patients may be required. Note that a multi-disciplinary Consult room may be suitable for this purpose. The room should be located with ready access to the Waiting Area.
The Room will require Body Protected power in accordance with local authority requirements. Furniture, Fittings and Equipment within the room will include:

1. Examination Couch/ table

2. Holter monitoring equipment (ECG leads and monitors) and blood pressure equipment
3. Small desk and technician chair or stool
4. Patient chair
5. Hand basin
6. Clothes hook/s for patient clothing
7. Storage for leads, equipment parts and consumable stock.

Rehabilitation services

Cardiac patients may require access to a group room or gymnasium for the purpose of rehabilitation. This will usually be provided from a central rehabilitation facility. Access to an outdoor walking circuit is desirable. (Decision No. 2 for 2019: Physiotherapy services and Rehabilitation Annex No.10)

Procedural Areas (Cardiac Catheter Laboratories)

The service plan, capability (secondary, tertiary) and anticipated caseload will determine the number and type of laboratories required. Cath Labs without on – site cardiac surgery must perform no less than 400 diagnostic coronary angiograms and 200 PCIs of which 36 PCIs are primary PCIs for acute myocardial infarction annually documented satisfactory outcomes.

Procedures Undertaken in Catheter Laboratories:

Catheter laboratories can be used for a range of invasive cardiac investigations and treatments including:

1. Coronary Angiography;
2. Percutaneous Coronary Interventions (PCIs);
3. Transesophageal Electrocardiograms (TOES);
4. Electrophysiology Studies (EPS);
5. Radiofrequency Ablations (RFAS);
6. Implantable Cardioverter Defibrillators (ICDS);
7. Insertion of Implantable Devices (Including Complex Devices).

They may also be required to undertake noncardiac procedures such as endovascular coiling.

The Cardiac Catheterization Suite requires the following functional areas as a minimum:

1. Entry/ Reception, which may be shared with an adjacent unit along with:

- Patient /visitor waiting area
- Change cubicles
- Interview room for patient/ family discussions
- Patient bed Bays for holding and post-procedure
- Patient amenities

2. Treatment Area:

- Catheter Laboratory/s (diagnostic, interventional)
- Electrophysiology Laboratory (EP) rooms as required
- Computer equipment rooms (generators, computer modules for imaging equipment)
- Control room/s (Note: it is not recommended that control rooms are shared;
- Scrub bay/s for catheter laboratories (should be located external to laboratories)

3. Support Areas will include:

- Beverage bay for patient refreshments as required
- Clean-up and Dirty Utility rooms
- Clean Utility area that may be collocated with the staff station for ease of staff access
- Handwashing bays with close access to bed bays
- Staff station with observation of holding and recovery bed bays
- Storage for linen, blanket warmer, sterile stock, equipment, consumables, lead aprons, resuscitation trolley and files
- Set-up area for procedure set-up as required
- Viewing/ reporting room

4. Staff Area:

- Change rooms with showers, toilet and lockers
- Offices/ workstations, according to the service plan
- Staff Room and amenities

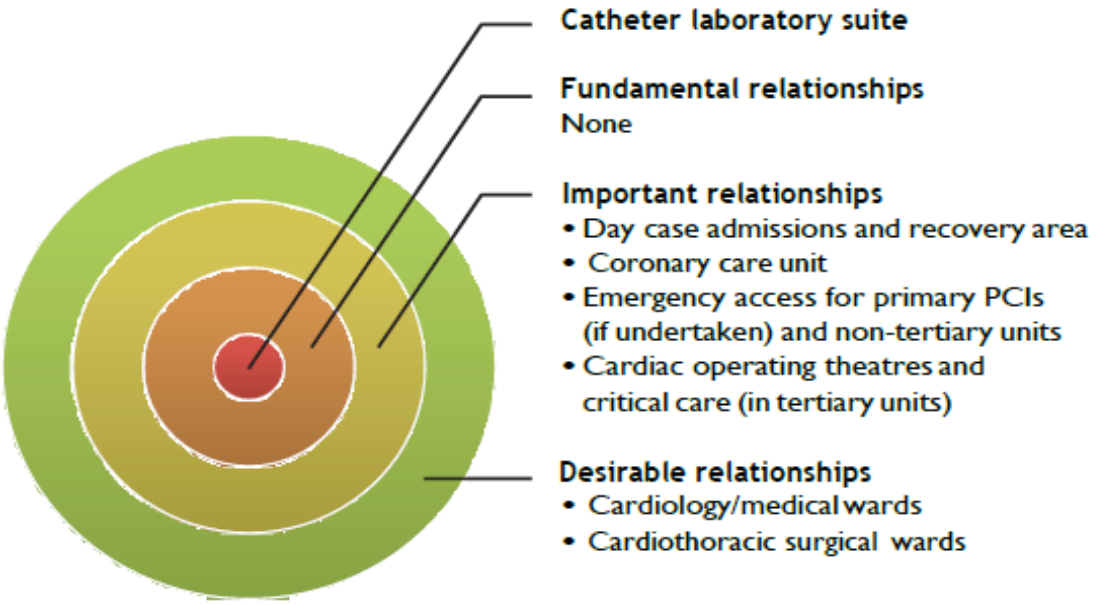
Whole unit planning and design considerations

Departmental relationships

1. The catheter laboratory suite should be as close as possible to a day case admissions and recovery area to provide immediate access to stage two recovery facilities. This area will also be used for stage three recovery and pre-procedure paperwork and clinical checks.
2. The catheter laboratory suite should also be as close to the CCU as possible
3. If primary PCIs are undertaken in the catheter laboratories, the catheter laboratory suite should be close to the hospital's emergency department or providing direct ambulance access. The emergency access route is also important in non- tertiary units to allow for immediate patient transfer to a tertiary unit, when required.
4. There should be good access to and from the cardiology/medical wards

Catheter Laboratory Suite

The catheter laboratory suite should have the following relationship to other departments (Figure 2)



Fundamental relationships = immediately adjacent – same level, no public corridors or other departments to traverse

Important relationships = nearby – immediately across a public or main communication corridor, or one floor difference and immediately accessible, or less than 20 meters along a corridor

Desirable relationships = less than four floors or less than 40 meters horizontal travel, or combination of these

Figure 2: Departmental relationships for a catheter laboratory suite

Engineering & medical equipment requirements:

Each catheter laboratory should accommodate the following requirements:(See Figure 3).

1. A multi-angular digital angiographic X-ray system (single or biplane) comprising a C-arm (X-ray source and detector),
2. A fully-adjustable patient table and ceiling-mounted flat panel monitors for angiography work, PCIs, EPS (electro physiology studies) and RFAs (radio frequency ablations) (up to eight, if EPS and RFAs are undertaken); consideration should be given to a table that can tilt.
3. Computer workstations

4. A separate scrub trough and associated facilities for scrub-up and gowning.
5. A worktop for drugs preparation and documentation (alternatively, a separate preparation room may be provided).
6. Enclosed storage for equipment and consumables, including a rack for catheters.
7. A controlled drugs cupboard.
8. A heated lotion cabinet for the preparation of contrast media.
9. A powered injector for use during the procedure (optional) – this may be floor or ceiling mounted.
10. Where EPS and RFAs are undertaken, stimulators, ablators and mapping systems should be mounted on trolleys or within specially designed shelving units that can be moved to be near the patient.
11. A minimum size of 50 m2 is recommended in order to accommodate the above equipment and up to eight members of staff (needed if EPS and RFAs are undertaken).
12. Most angiographic X-ray systems are floor-mounted, although ceiling-mounted options are available. Where ceiling-mounted systems are used, additional reinforcement of supporting structures may be required. Floor-mounted components are normally fixed to the floor by secure heavy-duty fixing devices, capable of retaining a moving mass weighing up to 3 metric tons with high residual torque.
13. Biplane equipment is needed to support treatments of congenital cardiac disorders, for EPS, TAVIs (trans catheter aortic valve implantation) and, if undertaken, neurovascular angiography and endovascular coiling. Where biplane equipment is to be installed, consideration should be given to making the room longer along the table axis to allow for the movement of the second C-arm.
14. The arrangement should allow the patient table to be capable of multi-directional movement and operating in conjunction with an iso-center positioned at or near the patient's heart.
15. The position of the table should allow for movement of the C-arm and provide operator access to both sides.
16. Tilting tables are available that allow tilting along both axes. (Consideration may need to be given to the treatment of overweight patients. Some patient tables have low weight limits).
17. Monitors display real-time, digitally recorded angiographic images and basic physiological data (or advanced data in the case of monitors for EPS and RFAs).
18. The current monitor systems allow for very large devices to be used. Consideration should be given during the design phase to ensure that the monitor can be correctly located for all procedures, both to the left and the right of the patient table.
19. A leaded apron rack is required, ideally located at the entrance to the catheter laboratory, outside the control area. Wall-mounted racks may require reinforcements to wall structures due to the weight of the aprons. Alternatively, floor-mounted racks may be installed. Key engineering considerations include:

    a) Each laboratory should be equipped with a ceiling-mounted minor operating light selected to meet the clinical function of the particular catheter laboratory.
    b) Medical oxygen, medical compressed air and medical vacuum, together with

nitrous oxide and active anesthetic gas scavenging, may be required. Input from the clinical team should be sought at the earliest stages so that the design can accommodate all necessary features.

c) Illuminated safety signs and/or warning lamps are required outside the main doors into each catheter laboratory and also at the entrance to each laboratory from the respective control area. The warning lamps must give a clear indication in red when they are energized and the illuminated signs should incorporate legends as determined by the supreme council of environment, visible only when illuminated. Warning lamps may have incandescent filaments, or more preferably be LEDs, and be correctly energized in line with the local requirements of the supreme council of environment. In general, this is a permanently energized 'room in use' section when the x-ray system is capable of operating, and a red 'do not enter' section when the radiation is being emitted.

d) All alarms should be visual as well as audible.

e) It is essential to establish the range of procedures to be undertaken to determine ventilation requirements. Many simple procedures of short duration, such as inserting temporary pacemakers and simple implantable devices, only require ventilation to treatment room standards. Lengthy procedures, however, including PCIs, RFAs will require ventilation to operating theatre standards.

Control rooms (Figure 4)

a) Each laboratory should be served by an X-ray system control room. It is possible that one control room may serve up to two laboratories. If shared between laboratories, the control room should be large enough to enable two teams with their monitoring equipment to operate independently and maintain unimpeded access to the appropriate laboratory.

b) The control room should provide a viewing window into the respective laboratory when needed. This should provide a clear view of the patient table in the laboratory. The preferred position for the control room in relation to the laboratory is at the foot end of the patient table.

c) The control room requires radiation protection and good voice contact with the laboratory.

d) Consideration should be given to the design to allow direct access to the control room without entering the laboratory.

e) Two computer workstations are required; one for viewing, capturing and annotating pressure and ECG data; the other for entering data about the procedure.

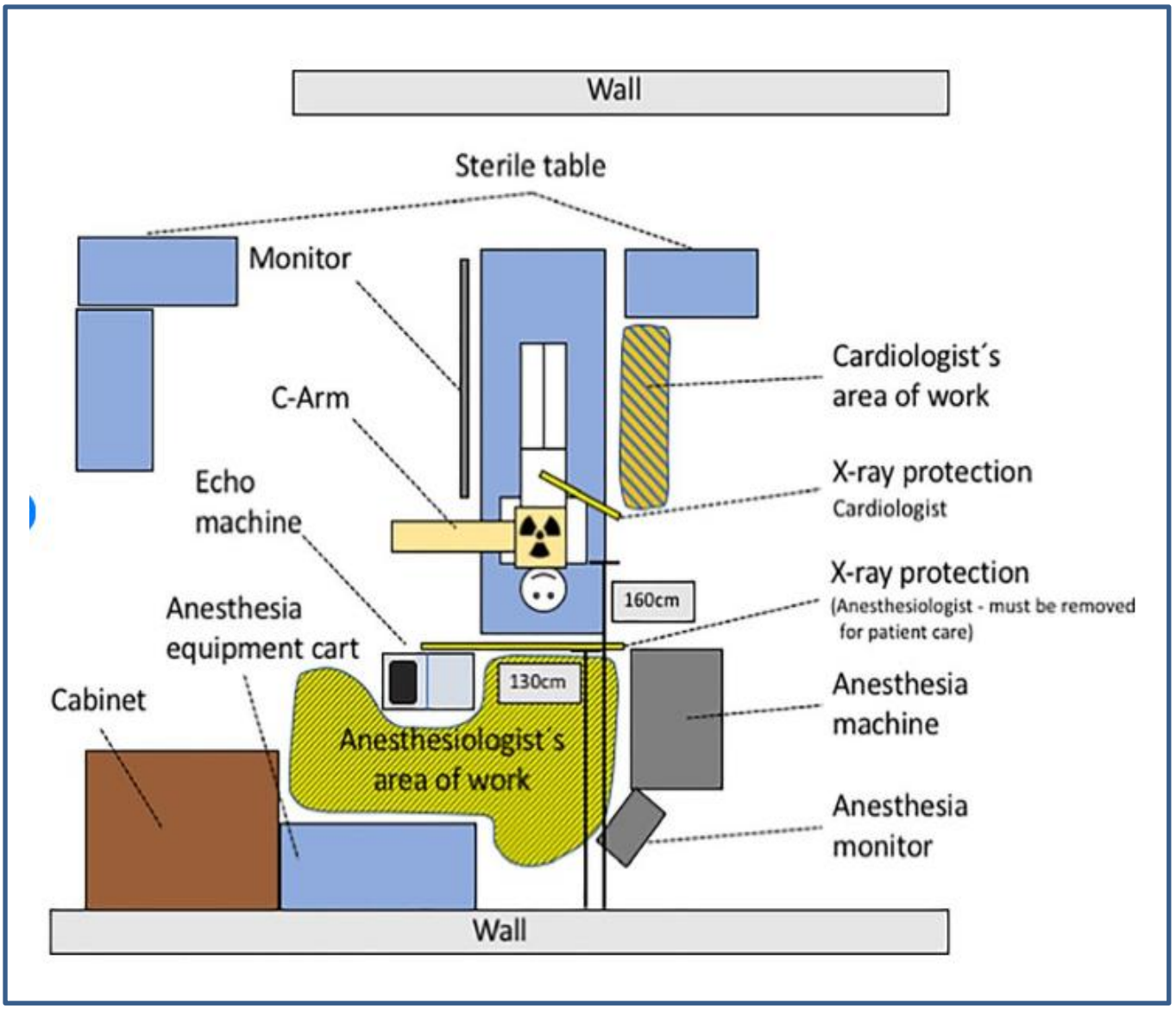


Figure 3: Sample Catheter Laboratory Set up

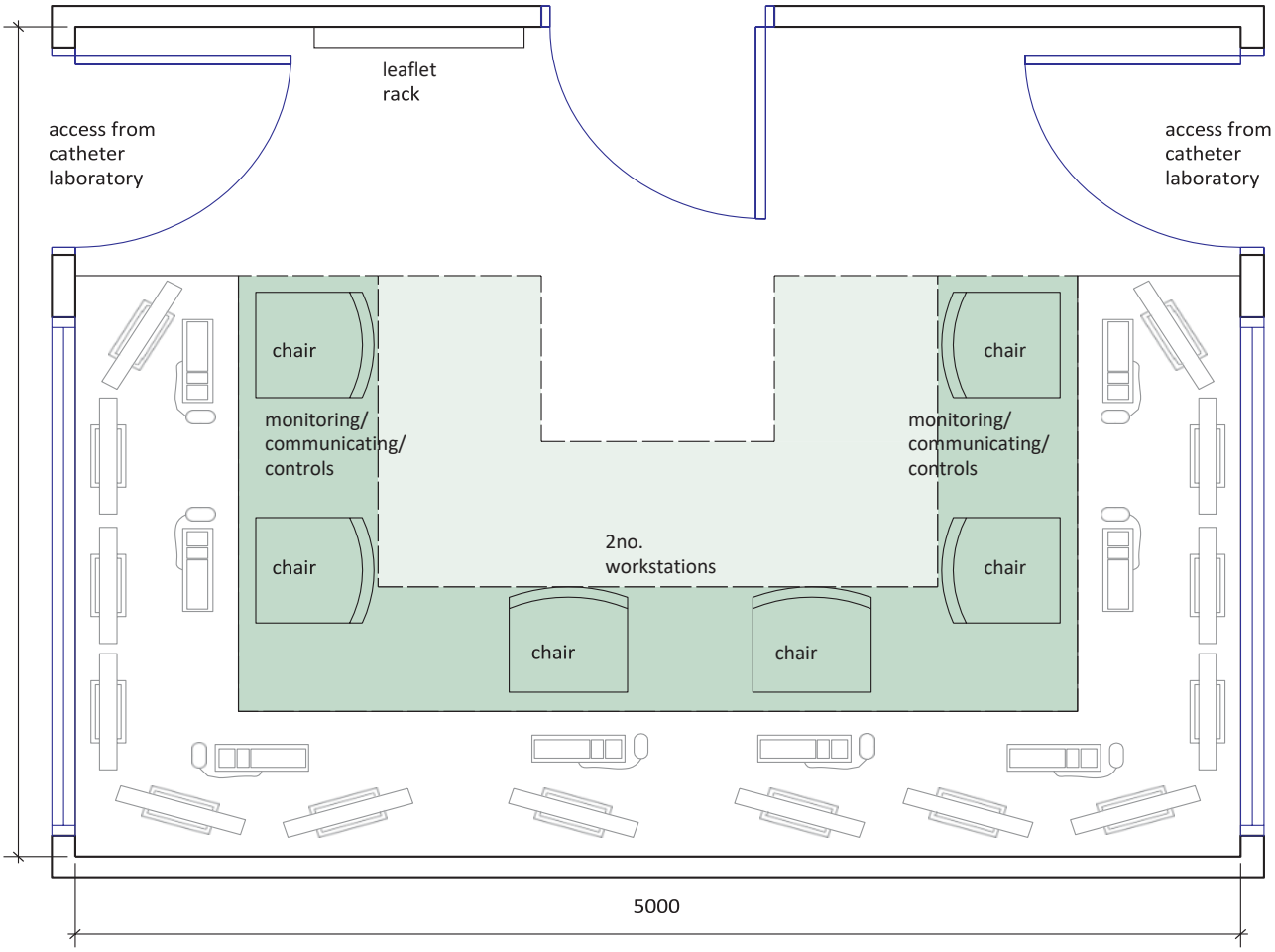


Figure 4: Sample Control room serving two catheter laboratories

Clinical support areas

1. Trolley/bed parking area
   These areas are not intended to provide for immediate post-procedure stage two recovery, which should take place in a day case recovery area. They are intended for bed or trolley storage while the patients are in the catheter laboratories.

2. Dirty utility room
   - Most procedures use fully disposable supplies. (Decision No. 2 for 2019: Quality Management, Security, Safety, Infection Control and Prevention, Sterilization and Medical Waste Disposable Annex No.2)

3. Storage for equipment and consumables
   - The example layout of the catheter laboratory is based on the assumption that a core supply of consumables and equipment, including catheters, is held within the room.
   - The example schedules include an additional space allowance for a central stock of consumables and less frequently used bulky equipment, such as intravascular ultrasound (IVUS) machines, rot ablation, robotic equipment, pressure wire workstations, balloon pumps and implantable devices. Facilities for charging syringes and IV pumps should be provided.

4. Perfusion room
   - A perfusion workroom is required for the cleaning and setting up of perfusion machines.

   - There should be at least one perfusion machine for each theatre, plus one spare.

   - The room should contain computer workstations for accessing patient records, work surfaces of sufficient height to store trolleys underneath, and should be fitted with cupboards and shelving.

5. An adjacent area should be provided for the storage of perfusion machines, balloon pumps and cell savers when not in use. Storage for large quantities of disposable packs and volumes of fluids should be provided. This will require heavy-duty shelving.

6. An office may be provided according to local project requirements, for use by the perfusionist and other theatre staff.

7. Image review/meeting room
    - An image review/meeting room may be required. The room should support multidisciplinary case reviews. It should accommodate approximately eight staff and include space for multiple workstations with access to PACS and any other systems necessary to access radiological images including CT, MRI, echo and angiography imaging.

    - In small units, the room may not need to be located in the catheter laboratory suite itself.
    - Variable lighting level control and avoidance of reflection on monitors through selection and positioning of luminaires is essential. Consideration should be given to the use of LED lighting.

8. Computer/imaging equipment room

    - Space is needed to house the X-ray imaging generators and computers that run the imaging systems. It should not be possible to enter this space while any of the catheter laboratories are operational.

    - The presence of high-tension electricity, and the need for radiation protection for persons working here, should be noted. Careful consideration should also be given to effective environmental control to prevent overheating of imaging equipment

Patient Recovery and Discharge Management

Patients are monitored for a minimum of four hours following cardiac catheterization procedures. Inpatients will return to their own unit.

Options for recovery of day patients include:

1) recovery area in the cardiac catheter laboratory;
2) CCU or cardiac inpatient unit; and/or
3) extended day only (23 hour) or cardiac inpatient unit, with full cardiac monitoring capacity.

Once stable, patients referred from other hospitals may be transported back to the referring institution, transferred to another healthcare facility with access to appropriate monitoring, or may be discharged home. However, overnight beds should be available for patients from geographically isolated areas who may not be able to return home immediately or following complications.

For the first twenty-four hours following angiography, day patients should remain within an accessible distance of a service that is able to manage relatively common complications. They also need to be accompanied by a responsible adult to and from the facility.

Cardiac Operating Theatre Suite

1. The following licensed Medical professionals should be assigned to work in the cardiac operating theatre:

    - Consultant cardiothoracic surgeon
    - Specialist cardiothoracic surgeon.
    - Consultant cardiologist.
    - Specialist cardiologist.
    - Consultant anesthetist.
    - Specialist anesthetist.
    - anesthetist's assistant
    - Anesthesia technician.
    - Consultant radiologist.
    - Radiology technician.
    - Perfusionist technician.
    - Cardiology Nurses.
    - lead and one or two support surgeons with a scrubbed practitioner and non-scrubbed 'runner';
    - An anesthetist and anesthetist's assistant;
    - A monitoring technician.
    - When a coronary bypass operation is being undertaken, that occupancy will be increased by: a second surgeon & A perfusionist to operate the heart bypass machine.

2. Whole unit planning and design considerations

    Procedures undertaken in cardiac theatres should provide a safe environment for patients to undergo cardiac procedures including closed and open-heart cardiac and thoracic surgery, and heart and heart/lung transplants. Aside from the regulations of a standard Operating Room (Decision No. 2 for 2019: Operation Theater Room Annex No.11) the following requirements are also required for a Cardiac Operating Theater Suite.

    a) Departmental relationships (Figure 2)
    b) The cardiac operating theatre room should:
        - be immediately adjacent to cardiac critical care (fundamental relationship);
        - be close to the catheter laboratories, allowing for transfers for emergency

surgery;
- provide close, simple access to and from the cardiothoracic wards, ideally located on the same floor – if not – with an immediately-accessible lift connection;
- have good access from the emergency department;
- have good access to and from the CCU and the cardiology/medical wards;
- Provide good connections with sterile services.

c) The number of items placed against the wall should be limited to provide safety for staff and patients, with less risk of a plug being inadvertently disconnected.

d) It is important that access is possible without crossing sterile areas.

Figure 5 below illustrates, as a guide, the various functional zones within a typical Cardiac Operating Theater Suite

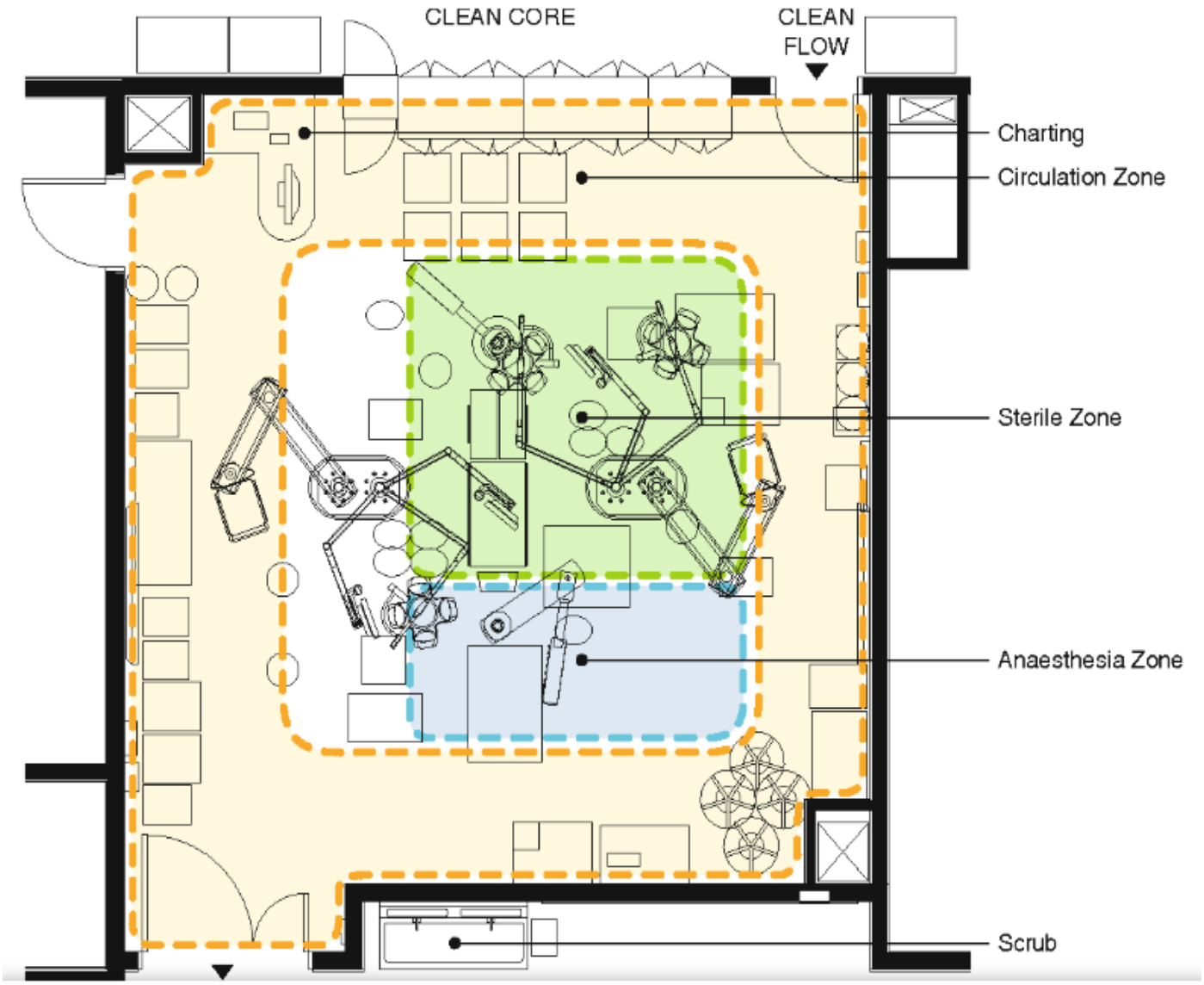


Figure 5: A Guide to illustrate the various functional zones within a typical Cardiac Operating Theater Suite

3. Engineering requirements for Cardiac operating theatres:

a) Cardiac theatres should be at least 600 sq. feet, broadly rectangular and with a minimum dimension in any single direction of 22 feet.
b) In addition to machines, standard monitors, and intravenous infusion pumps, space allotment for additional monitors and supportive devices needs to be considered.
c) The anesthesia machine requires a minimum of 10 sq. ft. A standard anesthesia cart with storage space requires a 2 × 5 ft space, while a double cart requires a 2 × 7–ft space.
d) A transesophageal echocardiography (TEE) machine requires a 4 × 2 ft space.
e) Rapid infusion machines require a 2 × 2 ft space.
f) An airway cart requires a 3 × 2 ft space.
g) Access to the room needs to consider the size of the patient bed and any support equipment that may be brought into the room with the patient, such as a ventricular-assist device.
h) Appropriate support beams in the ceiling to bear the load of ceiling-mounted equipment
i) When coronary bypass operations are being undertaken, it is necessary to accommodate two surgical teams with their support apparatus working on the patient simultaneously, and it is this requirement that has the greatest significance for the design and layout of the room, including the need for one main operating light and two smaller (satellite) lights.

4. Medical Equipment Requirements

a) Each cardiac theatre requires two ceiling-mounted twin-armed pendants to accommodate a range of equipment and for the provision of medical gases and electrical and data connectivity.

b) Cardiac theatres also require a single ceiling-mounted vertical pendant for the perfusionist. The following equipment will need to be connected to the vertical pendant:

- perfusion machine (heart/lung machine);
- Balloon pump;
- Cell savers;
- Echocardiography machine;
- Mobile C-arm X-ray unit and monitors.

c) Most theatres will not require a fixed C-arm. Where provided, it should be ceiling-mounted to minimize the obstruction that it may cause to the surgical team.

d) The pendants should be positioned so that during bypass operations all teams

have access to their pendant without impeding the surgical fields.

e) Modern techniques may require minimally invasive ‘stacks’ and numerous sterile trolleys.

f) The heart-lung machine needs an electrical plug, preferably on a dedicated circuit so the machine does not impact another device.

g) The cardioplegic pump requires its own electrical plug.

h) The heater-cooler system needs its own electrical plug.

i) The cell saver needs its own electrical plug.

j) A TEE machine draws a large electrical load and should not be plugged into the same circuit as the life-preserving pumps, ventricular-assist devices, and intra-aortic pumps.

k) An intra-aortic pump or ventricular-assist device may require a dedicated electrical circuit to avoid disrupting power to other devices.

l) A space of at least 8 × 8 ft will be required for the perfusionist and his/her equipment.

m) At least three vacuum outlets (two vacuum and one waste anesthetic gas outlet) will be required for scavenging anesthetic gases and the cell save

n) An ultra-clean ventilation canopy is not an essential requirement in most cardiac theatres, although it should be seriously considered in theatres in which transplant work will be undertaken.

o) The theatre will need to accommodate a sterile trolley for examining specimens.

Figure 6 below illustrates, as a guide, a typical Cardiac Operating Theater Suite

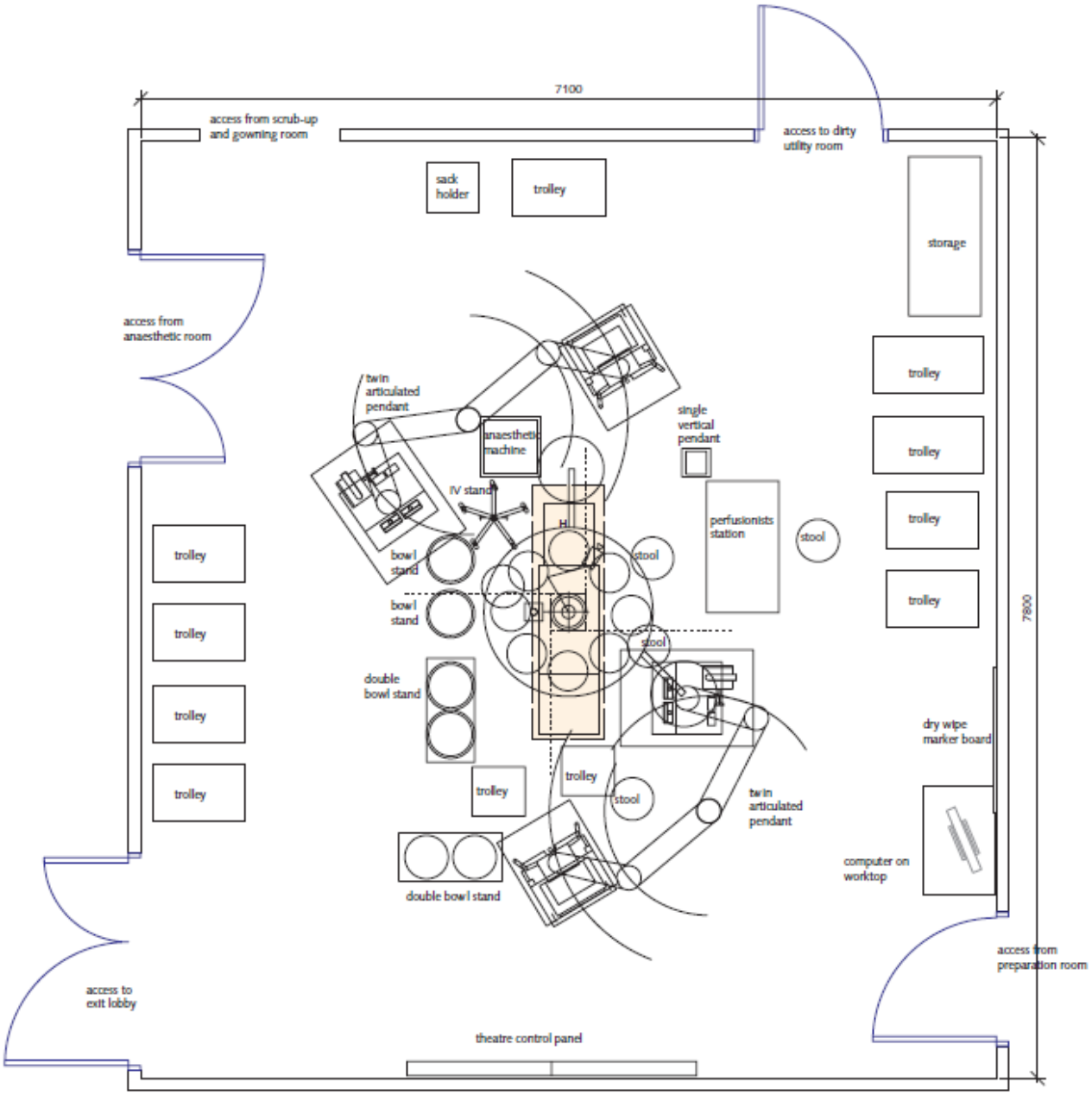


Figure 6: A Guide to illustrate a typical Cardiac Operating Theater Suite

Recovery room (Decision No. 2 for 2019: Operation Theater Room Annex No.11)

1. One post-anesthetic recovery room is recommended for every two cardiac theatres. This is based on the assumption that a large proportion of cardiac surgical patients will go directly to critical care rather than remaining in theatre recovery. It is less than the two recovery places per theatre recommended for general operating theatre suites.

2. Most thoracic cases require post-anesthetic recovery. If a high proportion of thoracic patients are being seen, the ratio of recovery rooms will need to be increased. Equally, if cardiac patients are not transferred immediately to critical care, the ratio of recovery rooms will need to increase.

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