

# **Minimum Requirement Criteria for Operation Theatre**

**MINISTRY OF HEALTH**

Male' Maldives

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## 1. INTRODUCTION

An Operating Theatre (OT) (also known as an operating room (OR), or surgery suite) is a facility within a hospital where surgical operations are carried out in an aseptic environment. The number of OR and recovery beds and the sizes of the service areas shall be based on the service plan and expected surgical workload. The size, location, and configuration of the surgical suite and support service departments shall reflect the projected case load and service plan of the health facility. Therefore, the establishment and working of an OT needs specialized planning and execution.

As the governing body of health industry, Ministry of Health has the mandate of regulating health care provisions across the country. This standard for Operation Theatre (OT) outlines design requirements, specifications for materials/furniture and fixtures used in theatres, to ensure the services provided from operation theatres have uniformity across the Maldives. This standard applies to all exiting operation theatres and the health facilities intended to operate an operation theatre in the future.

## 2. DEFINITIONS

|                     |                                                                                                                                                                                                                                                                 |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Operation theatre   | The operating theatre is a complex, is a unit consisting of one or more operating suites with ancillary accommodation for the common use such as changing room, rest room, receptions, transfer, pre operative area, post operative area and circulating space. |
| Operating Room (OR) | A room that meets the requirements of a restricted area, is designated and equipped for performing surgical or other invasive procedures.                                                                                                                       |

|          |                                                                                                                                                                                                                      |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Minor OT | <p>A Minor theatre refers to less invasive procedures that require minimal nursing support and that are done under local anesthesia.</p> <p>Minor OT should not necessarily be in the operation theatre complex.</p> |
| Major OT | <p>A major theatre refers to invasive surgery, requiring full theatre staffing and general or regional anesthesia.</p> <p>Major surgeries require a hospital stay.</p>                                               |

“**must**” means that compliance with requirements is mandatory for compliance with this standard and the unit cannot omit or use part of those points;

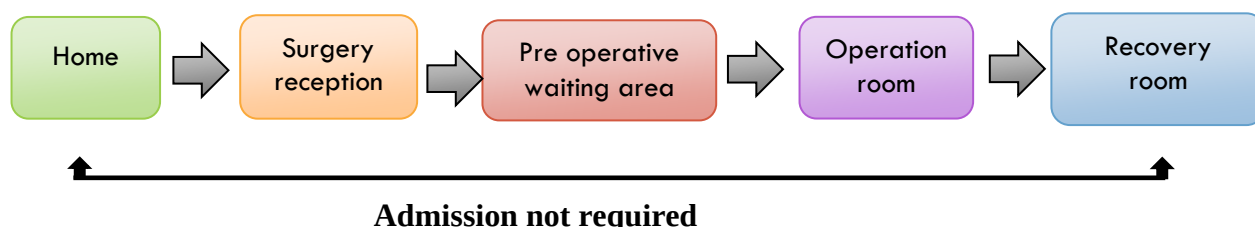
“**shall**” means that compliance with a requirement or a test is mandatory for compliance with this standard;

“**may**” is used to describe a permissible way to achieve compliance with a requirement or test.

### 3. CLASSIFICATION/OPERATIONAL MODELS

#### 3.1 CLASS A: MINOR OPERATION THEATRE

Minor surgeries are mainly considered as outpatient procedures done on superficial tissues but not limited to requiring mostly under local anesthesia. Equipped with a microscope an anesthetic machine and all the other routine equipment used to operate minor eye cases, foreign body removal etc. removal of suture and diagnostic procedure such as biopsy can also be done. Minor surgery or day surgeries do not require patient admissions. Figure 1 shows the flow chart for day surgeries.

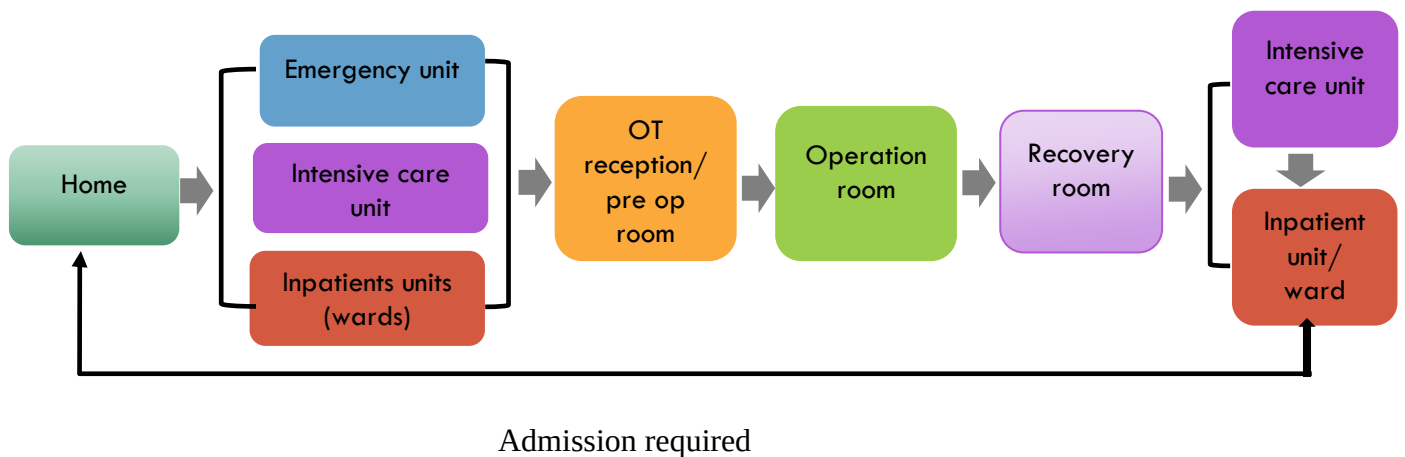


**Figure 1:** Patient flow for day surgeries

### 3.2 CLASS B: MAJOR OPERATION THEATRE

The OT are engaged with major surgeries conducted under the use of general anesthesia. The operation theatre is well equipped with all the necessary instruments and machinery.

Please follow figure 2 for patient flow movements for major surgical procedure.



**Figure 2:** patient movement for major surgeries in theatre complex

## 4. GENERAL PRINCIPLES

The existing and future OTs shall follow the following general principles.

4.1 All operation theater complexes must adhere to the mandatory infrastructure requirements in chapter 3 of the Regulation No. 2021/ R-28 (Regulations on Operating Healthcare centers) These include:

- i. Infrastructure standard of healthcare facilities
- ii. Hygiene standards
- iii. Safety standards
- iv. Invasive procedure room standards
- v. Sterilization and disinfection standard

- 4.2 If a new operation theater is being built in facility where surgical services were previously not available, requirements mentioned under approval for new services, in chapter 4 of the Regulation No. 2021/ R-28 (Regulations on Operating Healthcare centers must be followed.
- 4.3 When designing a theatre complex, the following points shall be considered.
- i. Determine suitable and appropriate Infection Prevention and Control (IPC) risks. And identify necessary steps to reduce or control risk of infection.
  - ii. Take record of the risks for infection and determine if further steps are required.
- 4.4 All OTs shall practice zero tolerance for non-adherence to infection prevention protocols.
- 4.5 Design and layout plan of an OT complex should be such that the complex is divided into four main zones i.e. Protective, Clean, Sterile and Disposal zones. All the movements with and to and from all zones shall ensure infection control measures are followed at all times.
- 4.6 Entry of patients and staff should be restricted and only those who are on duty or called for by the OT staff are allowed to enter the complex. Entry and exits should always be through the defined routes only.
- 4.7 OT staff once entered in the complex should leave it only after off duty except those who are required to accompany the patients for provision of medical care and services. However, any OT staff if re-entering the OT complex will have to follow the protocols of the OT including change of shoes, shoe cap and dress change, etc.
- 4.8 Cleaning protocols of various zones is very critical, in which the pathogen count progressively diminishes from the outer to the inner zones (operating area).
- 4.9 Supply and logistics for OT shall be replenished only during off hours preferably when surgeries are not in progress. Only vital equipment and logistic shall be allowed in during OT functional hours. In no circumstance, patients/attendants shall be asked to bring consumables, drugs etc. for any surgical procedure.
- 4.10 Temperature, humidity, number of air exchange per hour, maintaining positive pressure ventilation, shall always be maintained inside the OT complex. Rates are defined in the table number 2.



4.11 A dedicated Air Handling Units must be allocated.

4.12 A dedicated staff(s) (attendant) shall be given responsibilities for decontamination and sterilization of equipment and linen, regular and timely disposal of Biomedical waste.

4.13 Anesthesia trolley **MUST** be ready and WHO surgical checklist **MUST** be adhered to during all major surgical procedures.

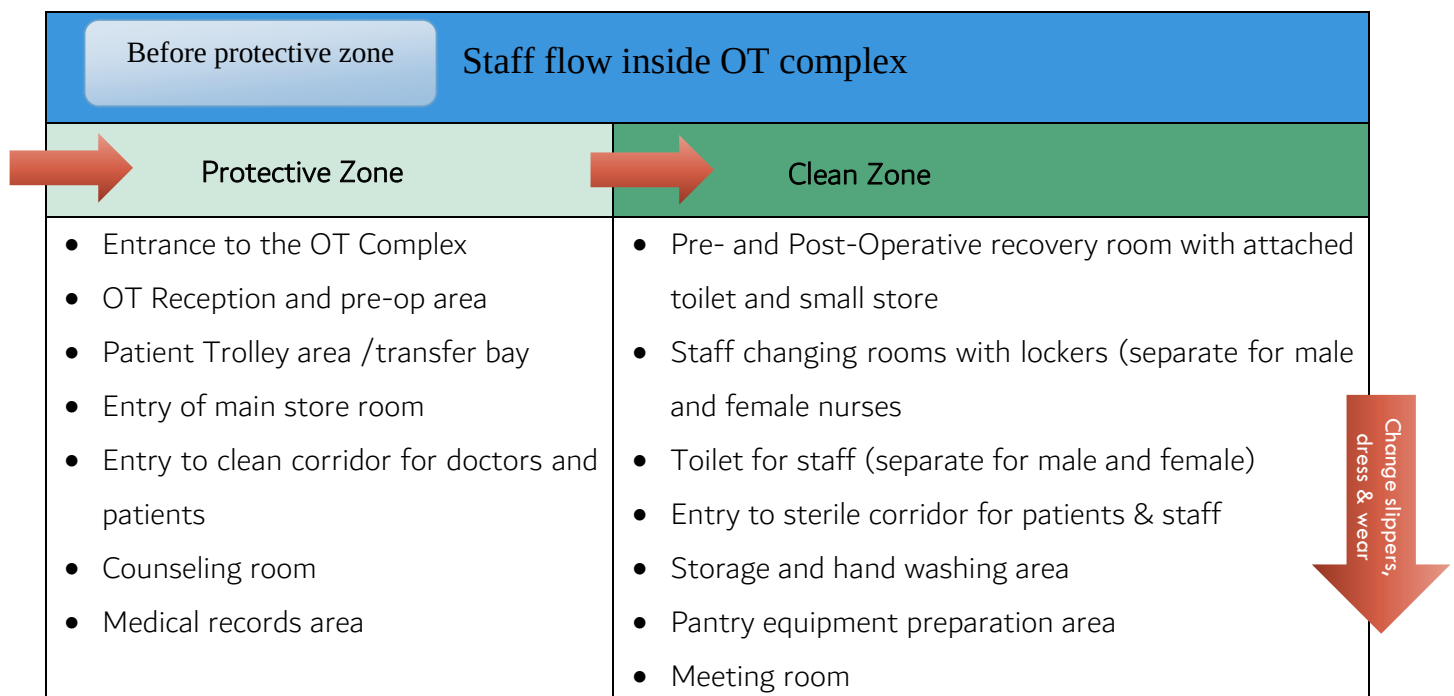
4.14 Back-up emergency power supply sufficient to ensure patient safety in the event of an emergency must be available.

4.15 When designing an operation theater complex it is crucial to ensure that it is in compliance with the standards mentioned in the Maldives Healthcare Quality Standards.

## 5. PROCESS FLOW IN THE OPERATION THEATRE COMPLEX

### 5.1 ZONING

Zoning is the process of division of space/area in which certain uses are permitted or prohibited. Zoning aims to achieve a high degree of asepsis, thereby eliminating chances of nosocomial infections. OT complex shall be divided into four zones.



| Disposal Zone                                                                                                          | Sterile Zone (aseptic area)                                                                                                                                                                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• Disposal corridor</li> <li>• Dirty utility area</li> <li>• Fire exit</li> <li>• Exit from OT complex through stairs or lift (use only for disposal)</li> </ul> | <ul style="list-style-type: none"> <li>• Operation rooms</li> <li>• Sterile equipment storage</li> <li>• Scrub and hand washing room with OT</li> <li>• Critical equipment and consumable in-charge</li> <li>• Passage to fire exit</li> </ul> |

**Figure 1: Zoning in OT complex**

Adapted from operational guidelines for operation theatre complex (Government of India)

## 5.2 MOVEMENT FROM CLEAN ZONE TO STERILE ZONE

Supporting staff spend their time in clean zone for pre-operative preparations for planned surgeries. Doctors spend their time in clean zone till OT and patients get ready for the surgery/procedure. Whenever doctors and nurses enter sterile zone from clean zone, they first wear masks properly and perform hand hygiene (follow 6 steps of hand washing). The inner most area in the complex where conditions are as sterile as possible. All staff who might handle instruments for surgery, in this zone must scrub and wear gowns. The sterile zone includes but is not limited to the following:

- The operating room
- Scrub room
- Entry of theatre supply room for sterilized instruments
- Sterilized equipment store room

This zone is maintained at high air pressure (25 pa, 25ACH) just below what is at the operation theatre room so as to exclude entry of air from the other zones. The sterile zone is connected to dirty corridor or disposal area through semi restricted area. Staff will enter sterile zone from a clean passage after washing hands and change to their respective OT slippers (second slipper change), move into the scrub area and wear respective sterile gown, cap and do surgical scrub for hands then wear surgical sterile gloves and enter into the OT.

## 5.3 FUNCTIONALITIES OF DIFFERENT ZONES

### 5.3.1 BEFORE PROTECTIVE ZONE

There shall be a dedicated space for protective zone where shoe change or shoe cap can be put on.

This shall be pre-requisite for entering into the protective area.

### 5.3.2 PROTECTIVE ZONE

- a) This is the area where OT reception, trolley area, patient transfer area, and counseling room is located.
- b) The air pressure in this area shall be slightly positive to the general hospital corridor.
- c) Employees and patients entering through this entrance shall comply with cleanliness standard of the hospital.
- d) Shoe cap/shoe change, masks, gloves, OT gowns and head caps shall be worn in this area.
- e) Outside trolleys shall not be allowed to go inside the protective zone without changing to an inside OT trolley.
- f) Patients records and documents shall be verified in this area.
- g) Patients' attendants who are permitted inside OT shall be given gown, mask, head caps and shoe change.
- h) Communication system shall be available in this zone which will allow easy communication with clean and sterile zones.
- i) When shifting to OR for surgery, the patient needs to be shifted from pre-operation area to sterile area. Therefore, a second trolley **MUST** be used.
- j) All trolleys need to be returned to its respective trolley bay after each use and thoroughly cleaned.
- k) Entry for staff and patient shall be separate for staff and patients from protective to clean and from clean to sterile zone.
- l) All staff shall adhere to the cleanliness procedures and infection prevention protocols of the OT complex.

### 5.3.3 CLEAN ZONE

Clean zone isolates sterile zone from protective zone and allow staff to move into sterile zone post change of attire. It includes staff changing room, pantry, staff toilets and post operative recovery room. The following standards shall be followed.

- m) The beds in this area shall preferably be beds/ trolley beds.
- n) Clear floor area of 9 square meters for each bed.
- o) Wall mounted monitors/pendants/ availability of patient monitors with electrical points shall be available in each bed.
- p) The post op recovery area shall have continues monitoring equipment and adequate patient support (ventilator usage if indicated) for hours after surgery should be available
- q) Each bed should have oxygen, suction and air outlets connected via a manifold facility. Facilities without a manifold shall have portable oxygen and suction in each bed.
- r) Recovery area air pressure should be kept at balanced pressure with respect to any adjoining areas and should have minimum 6 air changes per hour. Relative humidity should be maintained at 45% to 55%. High efficiency filters should be installed in the air handling system
- s) Toilets with wheel chair access should be available.
- t) Toilets air pressure should be kept negative pressure with respect to any adjoining areas and should have minimum 10 air changes per hour.
- u) A dedicated nursing station for continuous monitoring of post op patients shall be available.
- v) Number of nursing staff on duty in this room shall be dependent on the case load.
- w) The main store room of the OT may be located here. This will act as a transit area from hospital's general store, CSSD and the laundry.
- x) A dedicated space for medicine storage, consumables and linens shall be allocated within this area and the supply in the store room shall be restricted to 7 days and weekly replenishment for general items and daily supply for sterile items
- y) Sterilized items should be delivered to OT through covered trolley or through dumbwaiters.
- z) Movements from clean zone to sterile zone shall follow the following points.

- i. Nurses and doctors shall enter this area when the patient is ready or when the it is required to prepare the bed/patient or surgery.
- ii. Wear mask properly
- iii. Wash hands properly using 6 steps of hand hygiene.

#### **5.3.4 PRE AND POST OPERATIVE ROOMS**

The Pre- and Post-operative area must be separated. The beds in this room should preferably be beds/trolley beds and all beds should have a designated area with wall mounted monitors/ availability of vital monitoring equipment and provision of electrical points in sufficient number. The recommended number of bays/ cubicles is a ratio of 1:1 for each operating room (or procedure room). Availability of medical gases, suction and air outlets connected with central system in each bed. Availability of vitals monitoring equipment's.

- a. Patient toilets should be located nearby (Male, female, Handicapped)
- b. Storing facility for medicines (consumable and linens)
- c. Dedicated nurses' station
- d. Crash cart and normal cart
- e. Reliable source of oxygen, suction must be available in each bed
- f. Availability of medical gases

**Table 1**

| Sizes                                                                                                                              |                                                                                               |
|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Size (commensurate with beds, caseload and number of OTs) (suggested 1 bed for preop and 3 bedded for postoperative/recovery room) |                                                                                               |
|                                                                                                                                    | Clear floor area of 9 square meters for each bed                                              |
|                                                                                                                                    | In multiple-bed rooms and 11.35 square meters                                                 |
|                                                                                                                                    | clear width of 1.10 meters with a frame that is 2.15 meters high is required                  |
|                                                                                                                                    | In multiple-bed rooms, a clearance of 1.40 meters should be available at the foot of each bed |

### 5.3.5 CONSUMABLE STORAGE

This is the main storage area for whole OT complex. This will act as a transit area from hospital's general store. Staff and supplies coming from outside the OT complex will enter adhering to universal precautions and will not be allowed to go beyond the store room. The supply in the store shall be restricted to 7 days and weekly replenishment should be done for general supplies.

Storerooms and storage areas for:

- ✓ Anesthetic supplies
- ✓ Drugs
- ✓ Equipment, including mobile items, table accessories, loan equipment
- ✓ Perfusion equipment and supplies (if cardiac surgery is undertaken)
- ✓ Sterile stock and non-sterile stock

### 5.3.6 LINEN AND STERILE STORE ROOM

In addition to the central supply of sterile instruments and linen, provision for TSSU is given taking into consideration the requirement for sterilizing certain category of equipment where there is a low turn-around time than usual is expected.

### 5.3.7 EQUIPMENT PREPARATION ROOM (OPTIONAL)

### 5.3.8 STERILE ZONE

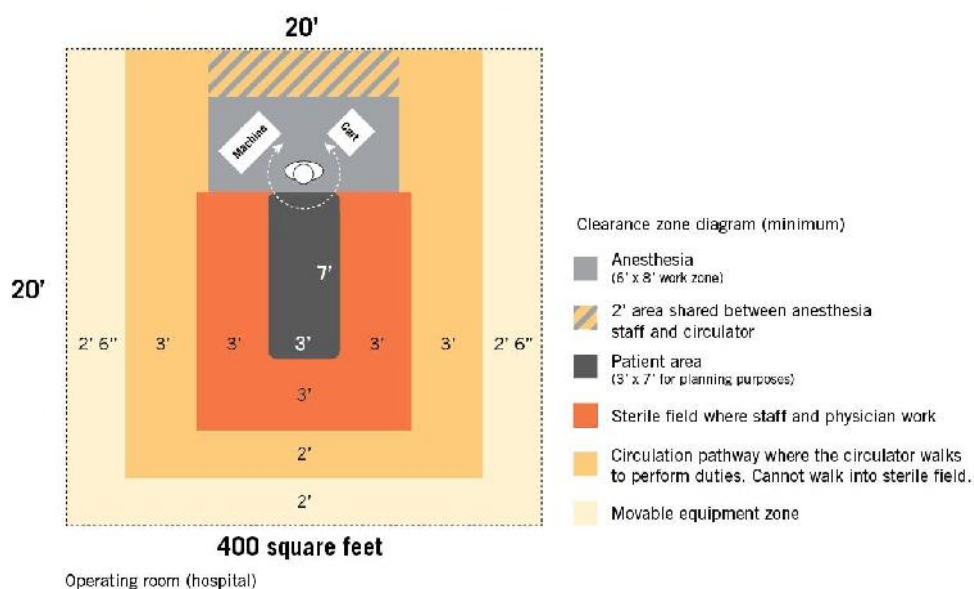
- All staff who may have to touch the instruments shall be scrubbed, gown and mask worn properly.
- This zone should have a high positive air pressure.
- Sterile zone shall be connected to dirty or disposal area to minimize cross contamination to other zones.

### 5.3.9 OPERATING ROOM

The operating room is designed around its centrally situated operating table with overhead lighting and ventilation systems.

An OR requires a minimum of four outside air changes per hour and 20 total air changes per hour, a unidirectional diffuser array and low sidewall returns, and a positive relationship to adjacent areas.

A 400-square-foot operating room requires a sterile field of 3 feet each side and foot of operating table, a circulation pathway of 3 feet both sides and 2 feet at foot of sterile field and movable equipment zone of 2 feet 6 inches clear on both sides and 2 feet at foot of the circulation pathway. Anesthesia work zone requires the same 6 feet by 8 feet clear at head of operating table.



### **5.3.10 SCRUB AREA**

Scrub area is situated in the sterile corridor. A dedicated scrub area for each operation room or a common Scrub area for 2 Operating rooms within the sterile area with foot operated or infrared sensor operated taps. It is essential to have non slippery flooring in this area. Scrub washbasin should have adequate depth and width allowing free hand and elbow movement at the same time preventing it coming in to contact while scrubbing. Design should also prevent/ minimize water spilling outside scrub basin.

### **5.3.11 DISPOSAL ZONE**

- a) Air pressure in this area shall be less than sterile zone.
- b) Used instruments, suction tubes and waste materials are temporarily stored in this area.
- c) It may be used as an exit walk way in the event of fire.
- d) There shall be no mixing/movement of staff from this zone with other zones of the operation theatre complex.

### **5.3.12 DIRTY UTILITY ROOM**

In this area, used instruments and equipment which are not planned/recommended to be sent to Central Sterile Services Department (CSSD) will be decontaminated and prepared for autoclave/sterilization. Disposal zone is the corridor from where used instruments and used linen and operating room debris is taken out. This zone must have an independent access to the outside corridor. Disposal zone has only one-way traffic. The air pressure has to be less than the sterile zone. Bio Medical Waste (BMW), used instruments, equipment and linens which are used during surgery and packed in the designated bags/buckets are kept in dirty utility room until they are sent to mechanized laundry and CSSD. BMW will be disposed as per BMW guidelines.



### **5.3.13 DISPOSAL CORRIDOR**

This corridor will run behind the OT rooms and will have common entry and exit gate near to dirty utility area. Ward boy/disposable collector can directly come into this corridor from the exit near to dirty utility area and collect the used/contaminated equipment, linens and (anatomical waste) disposal from here and take it to the CSSD/Laundry and dispose the waste as per the waste management guideline. The OT should be designed to facilitate movement of staff to and from OT areas without mixing.

### **5.3.14 CRITICAL EQUIPMENT AND CONSUMABLE IN-CHARGE ROOM (OPTIONAL)**

This room is for stand-by equipment which will be required for OT during surgery. The cleaning protocols of this area should be same as that of sterile zone. It will also be used by the OT technician/bio-medical engineer for repairing/testing the OT equipment. It will remain open (without door) and should have provision for multiple electrical points for need based repairing/testing of equipment.

## **6. FACILITY DESIGN**

### **6.1 ACOUSTIC**

Acoustic privacy is required in all places where confidential information will be discussed. The transfer of sound from clinical areas shall be minimized to reduce potential staff error from disruptions and miscommunications. Noisy places like staff rooms shall be away from procedural areas.

The World Health Organization advises noise levels to remain below 35dB in operating theatres to facilitate a peaceful environment for patients (McLeod et al., 2021).

### **6.2 NATURAL LIGHT**

External view from operation theatre complex is a preferable requirement. Vision from operation theater complex could be through a corridor or directly to the external environment. The window to recovery room, staff room and Theatre Sterile Supply Unit (TSSU) areas are important as staff spend majority of their duty hours in these areas.

### **6.3 PRIVACY**

When planning for a theatre complex, privacy shall be considered to reduce discomfort and stress for the patient.

### **6.4 INTERIOR DECOR**

This is the color, texture and surfaces of the OT complex. It also includes fixtures and furniture. The interior design shall be done with calming neutral colors, furniture and fixtures selected with ergonomics and feasibility of disinfection in mind.

### **6.5 SIZE OF THE OT COMPLEX**

All major operation theatres should have 30 to 50sq.ft per bed in accordance with Maldives Healthcare Quality Standards (MHQS). Size of different zones of OT complex and size allocation for other dedicated spaces must be adequate as per prevalent normal and case load of the operation theater complex.

### **6.6 ACCESSIBILITY**

The OT complex shall have easy access to Intensive Care Units (ICU), maternity ward, and CSSD. However, access to OT complex shall be restricted to only OT staff, patient undergoing surgery and patient attendants when required. The operation theater must be designed in a way that traffic can be managed. It should only allow access to staff, patients, and equipment through certain entrances and exits. Layout and design shall fulfill all criteria stipulated in section 5 of this standard. The design should ensure movements inside OT complex are in accordance with figure 1 in section 5 of this standard.

### **6.7 DOORS**

All doors in OT complex shall fulfill the following criteria

- a) The doors in areas where access to patient's beds and trolley are required to have 1400mm wide and 2140 mm height.
- b) The OT entrance door must be wide (about 2.15 meters width) and consisting of two parts, which can be opened in either side/sliding door.

- c) The door shall be unobstructed and preferably automatic touch/less sensor operated/ foot operated doors.
- d) Operation rooms and procedure rooms shall have observation glass. However, observation glass should have a cover to fully obscure the vision panel when laser is being used. Beam activated automatic sliding door or swing doors are highly preferable.
- e) Each theatre requires a warning light located in the corridor above the theatre doors which will be activated prior to laser surgery or X-rays being undertaken.
- f) Staff and the patient should wear appropriate eye protection when laser equipment is in use. The appropriate eye protection should be readily available at the entrance to each theatre.
- g) Operating theatres in which laser surgery is done shall have windows with laser-proof blinds.
- h) If laser surgery is being undertaken in the operating theatre it is important that reflective surfaces are kept to a minimum.
- i) Swinging doors shall not be used in the theatre complex as it the swinging motion creates more air turbulence and therefore it may affect infection control measures.

## **6.8 SAFETY AND SECURITY**

Authorized access control to the theatre complex is important, and electronic access to staff shall be available. Access log shall be maintained.

## **6.9 FINISHING**

The walls and ceiling often are used to mount essential devices and equipment to reduce crowding of the floor area therefore the walls must be solid and robust enough to carry the weight of equipment. All surface materials should be hard, nonporous, fire resistant, waterproof, seamless and easy to clean. In addition, the corners of the walls and the floor should be coved (round) and smooth for easy cleaning. Adequate electric points should be available on the wall at <1.5m height from the floor. The walls must be fitted with outlets for oxygen/availability of oxygen, medical gases and central suctioning must be included in pendants in each operating room. In pre operative room and postoperative room, Oxygen availability has to be there in each bed. Floors are smooth, stain free,

waterproof and non-slip continuous washable materials used. Walls and ceiling finishes are seamless, waterproof and washable.

Floors should be smooth, without cracks and breaks, made of materials that will reduce static and should not endanger the safety of personnel. It should be able to withstand repeated washing with germicidal agents. The floor surface must be suitably hard, nonporous and appropriate for frequent cleaning and there should be no cracks. The floors should have a nonslip surface, to prevent staff from slipping and injury

## **6.10 LIGHTING**

Some natural daylight is preferable where possible into the operation theater complex while also ensuring privacy.

- a. General lighting: Color corrected fluorescent lamps (recessed or surface ceiling mounted) to produce even illumination of at least 500 Lux at working height, with minimal glare are preferred.
- b. Operating light should be: (further specifications mentioned in Table 2)
  - a. Be freely adjustable to any position or angle. Overhead operating lights are ceiling mounted on mobile fixtures. It can be positioned so that light is directed into a single incision or two concurrent operative sites.
  - b. Be spark-proof where anesthetic gases are used.
  - c. Produces minimum heat to prevent injury to exposed tissues, to ensure the comfort of the sterile team, and to minimize airborne micro-organisms.
  - d. It can be easily cleaned. Tracks recessed within the ceiling virtually eliminate dust accumulation

## **6.11 FIXTURES, FURNITURE AND EQUIPMENT**

- a. Equipment, furniture and fittings shall be designed and constructed to be safe, and shall meet requirements of the users.
- b. Selection of furniture, fittings and equipment's shall be made with special consideration given to ergonomic, and occupational health and safety (OH&S) aspects.

### **6.13 COMMUNICATION**

The theatre complex shall fulfil the following requirements

- a. There may be picture archiving system in place (optional)
- b. Round the clock communication system via land line and mobile device.
- c. Internet or wireless network requirements
- d. Barcoding system (optional)

### **6.14 MEDICAL GASES**

The main storage of medical gas shall be situated outside OT complex. The Anesthetic Gas Scavenging (AGS) system which removes anesthetic gas mixtures from operating rooms and any other areas fitted with nitrous oxide terminal units.

- a. Anesthesia scavenging systems should be installed in all spaces used for administering inhalation anesthesia.
- b. Medical gases station, outlets for oxygen and vacuum (suction) shall be available.

### **6.15 RADIATION AND FIRE SAFETY**

- a. Operation theatres used for undertaking imagining procedure MUST have shielding for radiation.
- b. The experts shall decide on type, location and amount of protection required for areas according to the equipment and layout of the space.
- c. Consideration should be given to the provisions of floor and ceiling shielding if the rooms above and below are occupied.

Provision for an emergency exit is to be provided at the end of the sterile corridor. It should be ensured that the emergency exit is not blocked by keeping operation theater machines or trolleys. The fire detection and suppression system must be placed as per MNDF fire safety guideline..

## 6.16 HEATING VENTILATION AND AIR CONDITIONING (HVAC)

Adequate ventilation and air exchange requirement shall be maintained in the operation room which should be at positive pressure relative to the adjacent areas. Minimum of two air supply inlets with proper contamination control filters (High Efficiency Particulate Air (HEPA) filters) delivered at or near the ceiling in addition to a minimum of two exhaust outlets located near floor level. The OT complex require efficient ventilation that will control temperature and humidity in OT and dilute the contamination by microorganism and anesthetic agents. The main Operation rooms shall have higher positive pressure than other zones of the theatre complex. Temperature should be maintained inside the OT all the time with corresponding relative humidity. Window and split A/c should not be used in any type of OT because they are pure re- circulating units and have pockets for microbial growth which cannot be sealed.

## 6.17 PLUMBING AND WATER SUPPLY

Provision for adequate and continuous soft water supply. Sewerage shaft should not pass through operating room. Impervious lining to seal contamination. Toilets to be provided in changing room area.

**TABLE 2: TECHNICAL SPECIFICATION REQUIREMENT**

| Item                 | Minor OT                                                                        | Major OT                                                                     |
|----------------------|---------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| Doors                | About 2.15 meters width                                                         | About 2.15 meters width                                                      |
| Area                 | 16 square meters                                                                | 37.15 square meters.                                                         |
| Dimension            | ≥ 4.6m                                                                          | ≥ 4.6m                                                                       |
| Clear area           | ≥ 25m <sup>2</sup>                                                              | ≥ 33.0m <sup>2</sup>                                                         |
| Clear ceiling height | ≥ 2.7m                                                                          | ≥ 2.7m                                                                       |
| Temperature          | Between 18-22 degree Celsius                                                    | Between 18-22 degree Celsius                                                 |
| Floor                | -The floors, ceilings, and walls must be created by a monolithic, impervious to | -The floors, ceilings, and walls must be created by a continuous connection. |

|                               |                                                                                                                                                                 |                                                                                                                                                                                                                          |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                               | moisture with continuous connection.<br>-The floors and walls should be anti-static, heat resistant, anti-bacterial, anti-fungal and resistant to disinfectants | - Surfaces should be constructed of materials that are monolithic and impervious to moisture.<br>- The floors and walls should be anti-static, heat resistant, anti-bacterial, anti-fungal and resistant to disinfectant |
| Ventilation                   | Adequate ventilation and air exchange shall be maintained in the operation room with proper contamination control filters.                                      | Adequate ventilation and air exchange (with at least 25 air changes per hour as per (ASHRAE) requirement shall be maintained in the operation room which should be at positive pressure relative to the adjacent areas   |
| <b><u>Operation room</u></b>  |                                                                                                                                                                 |                                                                                                                                                                                                                          |
| Humidity                      | 40-60%                                                                                                                                                          | 40-60%                                                                                                                                                                                                                   |
| Minimum total ACH             | Positive pressure<br>20                                                                                                                                         | Positive pressure<br>20                                                                                                                                                                                                  |
| Minimum out door ACH          | 4                                                                                                                                                               | 4                                                                                                                                                                                                                        |
| <b><u>Recovery room</u></b>   |                                                                                                                                                                 |                                                                                                                                                                                                                          |
| Minimum out door ACH          | 2                                                                                                                                                               | 2                                                                                                                                                                                                                        |
| Minimum total ACH             | 6                                                                                                                                                               | 6                                                                                                                                                                                                                        |
| Humidity                      | 45%-55%                                                                                                                                                         | 45%-55%                                                                                                                                                                                                                  |
| <b><u>Protective Zone</u></b> |                                                                                                                                                                 |                                                                                                                                                                                                                          |
| Minimum out door ACH          | Positive pressure<br>2                                                                                                                                          | Positive pressure<br>2                                                                                                                                                                                                   |

|                                                                                                                                                          |                                                                                                                                                               |                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Minimum total ACH                                                                                                                                        | 12                                                                                                                                                            | 12                                                                                                                                                            |
| <u>Patient care area corridor</u>                                                                                                                        | Positive pressure                                                                                                                                             | Positive pressure                                                                                                                                             |
| Minimum out door ACH                                                                                                                                     |                                                                                                                                                               |                                                                                                                                                               |
| Minimum total ACH                                                                                                                                        | 2                                                                                                                                                             | 2                                                                                                                                                             |
| Adequate exhaust with active scavenging system for anesthetic gases<br>Medical gases station, outlets for oxygen and vacuum (suction) shall be available | -                                                                                                                                                             | Anesthesia scavenging systems should be installed in all spaces used for administering inhalation anesthesia                                                  |
| OT Light                                                                                                                                                 | CRI should be above 90%<br>Luminous intensity<br>Color temperature 3500K – 5500K or better (daylight)<br>Light intensity at 1m; 130,000-160,000 or more       | CRI should be above 90%<br>Luminous intensity<br>Color temperature 3500K -5500K or better (daylight)<br>Light intensity at 1m; 130,000-160,000 or more        |
| OT general ceiling lighting                                                                                                                              | Ceiling lights with adequate illuminance ensuring sufficient brightness for clear visibility and design shall be easy to clean and maintain. At least 500 lux | Ceiling lights with adequate illuminance ensuring sufficient brightness for clear visibility and design shall be easy to clean and maintain. At least 500 lux |
| X-ray illuminators/Screens for digital imaging                                                                                                           | 2 x-ray illuminators/ Screens for digital imaging                                                                                                             | 2 x-ray illuminators/ Screens for digital imaging                                                                                                             |



|                                                     |           |                                                                                                                                                                                                                                       |
|-----------------------------------------------------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electric clock with sweep secondhand/ Digital Clock | Minimum 1 | 1 present in each operating room and recovery room. Adequate number can be placed in other areas.                                                                                                                                     |
| <b><u>Operation room</u></b>                        |           |                                                                                                                                                                                                                                       |
| Oxygen port outlet                                  | 1         | 2                                                                                                                                                                                                                                     |
| Suction outlet                                      | 1         | 2                                                                                                                                                                                                                                     |
| Nitrous oxide                                       | -         | 1                                                                                                                                                                                                                                     |
| <b><u>Recovery area</u></b>                         |           |                                                                                                                                                                                                                                       |
| Oxygen port outlet                                  | 2         | Oxygen port outlet in each bed                                                                                                                                                                                                        |
| Suction outlet                                      | 2         | Suction outlet in each bed                                                                                                                                                                                                            |
| Storage for surgical supplies                       | Required  | Required                                                                                                                                                                                                                              |
| HEPA filter                                         | -         | Minimum of two air supply inlets with proper contamination control filters (High Efficiency Particulate Air (HEPA) filters) delivered at or near the ceiling in addition to a minimum of two exhaust outlets located near floor level |
| A manometer installed across the HEPA filter        | -         | A manometer installed across the HEPA filter                                                                                                                                                                                          |

## 7. INFECTION CONTROL

Special consideration MUST be given to infection prevention and controls protocols. The movements inside OT complex shall ensure cross contamination are avoided. The staff shall adhere to infection prevention and control standards and breach of adherence shall be responsible by the focal point.

## 8. STANDARD OPERATING PROCEDURES ( SOP ) AND POLICIES

The below mentioned SOP's and policies shall be developed by the respective healthcare facility and train the involved staff for proper implementation.

- Standard Operating Procedure (SOP) on functioning of OT, roles and, responsibilities of staff members, infection control measures, cleaning and sterilization of OT.
- A detailed cleaning protocol which includes frequency, cleaning agent and processes for various zones of the OT complex.
- Detailed process for sampling and fumigation.
- Practice of WHO safe surgery checklist in the OT/ establish a safe surgery checklist in the institute level.
- Records and registers in the OT.
- Surface cleaning protocol in OT.
- Waste management protocol in OT.
- Patient receiving procedure
- Operation theatre –repair and maintenance.
- Operation theatre scheduling and rescheduling
- Storage and handling of sterile stock
- Storage and management of implants
- Infection control in Operation theatre
- Policy on gowning and gloving and use of personal protective equipment's (PPE)
- Cleaning disinfection and sterilization of reusable medical equipment
- SOP for specimen and pathology collection and handling.

## 9. Human resource

Table 3

|                            | Minor surgery | Major surgery |
|----------------------------|---------------|---------------|
| Nurses                     | 2             | 5             |
| Surgeons                   | 1             | 1             |
| Anesthetist                |               | 1             |
| Housekeeping-1(OT trained) | 1             | 1             |

## 10. EQUIPMENT

The minimum essential equipment required for the operation theatre is provided in annex 2 of this document.

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## ANNEX 1: COMMON EQUIPMENT LIST FOR OT SUITE

|    |                                                                    |
|----|--------------------------------------------------------------------|
| 1  | OT Table with all accessories                                      |
| 2  | OT light - Ceiling Double Dome                                     |
| 3  | Mayo Stand                                                         |
| 4  | Surgical Trolley                                                   |
| 5  | Equipment Trolley                                                  |
| 6  | Emergency and Drugs Trolley                                        |
| 7  | Anesthesia Trolley (Complete with Ambu bags and other items)       |
| 8  | Difficult Airway Trolley- Bronchoscope, LMAs and intubating bougie |
| 9  | Anesthesia Circuits                                                |
| 10 | Anesthesia Monitor CO2 and agents                                  |
| 11 | Electrical Suction                                                 |
| 12 | Laryngoscope with 5 Blades (LED)                                   |
| 13 | Defibrillator (AED plus Manual with ECG)                           |
| 14 | Flash Autoclave - (Chamber capacity of app. 20 liters/cycle.       |
| 15 | Surgical Diathermy - Bipolar                                       |
| 16 | ECG Machine - 6 Channel (Optional)                                 |
| 17 | Crash Cart                                                         |
| 18 | Bowl Sterilizers – Different Sizes                                 |
| 19 | Oxygen Cylinder D type                                             |
| 20 | Patient stretcher                                                  |
| 21 | Blood Warmer                                                       |
| 22 | IV Stand/ IV Accessories                                           |
| 23 | Glucometer                                                         |
| 24 | Anesthesia Machine                                                 |
| 25 | Patient Stirrups                                                   |
| 26 | Laryngeal mask airways                                             |

|    |                                          |
|----|------------------------------------------|
| 27 | Positioning Pillows                      |
| 28 | Restraint Straps and Patient Positioners |
| 29 | Surgical Microscope                      |
| 30 | Cardiac Monitor                          |
| 31 | EKG Machine (Optional)                   |
| 32 | C-Arm                                    |
| 33 | Kick Buckets                             |
| 34 | Biohazard Waste Cans                     |
| 35 | Led apron                                |
| 36 | colla                                    |
| 37 | Patient Warmer                           |