



Sultanate of Oman
Ministry of Health

Directorate General of Private Health
Establishments

Requirements for Health Establishments

2016

DGPHE /HER/1.0

Overview

It is the responsibility of establishment owners and operators to ensure they provide;

A safe place of care; complying with all laws and regulations and equipped and furnished as a Healthcare provider

Safe people; properly licensed by MoH where appropriate or properly trained, and operating within their scope of practice

Safe Processes and procedures; including monitoring activities by operators to ensure compliance.

The information in this document does not replace your responsibility, though it gives guidance on certain key areas which you must address if you wish to provide a new facility or extend existing services.

All types of establishments must have managed arrangements and policies in place to ensure patient safety

This will include

- Clear Governance and Management structure,
- DGPHE Approved Scope of Practice,
- Fire Safety,
- Control of Infection,
- Patient Records,
- Staff Safety,
- Untoward Incident Reporting,
- Code Blue,
- Patient Identification process, with at least two identifiers used.

The Directorate general of Private Health establishments will provide guidance and advice throughout the development process, but the ultimate responsibility for providing safe care lies with the owner and operator

Licensing process DGPHE, MoH, Sultanate of Oman

The submission of drawings is not in itself adequate information for consideration of granting of licence.

It must also be clear which clinical services are to be provided, the staffing structure, Operational Policies in relation to Patient Safety, e.g. Infection Control, Risk Management, and Quality Management.

It must also be made clear at time of submission of drawings, which Building Codes and Technical Memoranda have been used to guide the design process.

It is also necessary to be able to understand proposed patient flow and the positioning of key equipment.

Required At Initial Submission

1. Scope of Practice for the proposed unit – which clinical and support services are proposed.
2. Full Staffing schedule – numbers of staff, management structure
3. Key Operational Policies – infection Control, Patient Safety, Risk Management (including Fire Plan), Quality Management.
4. Architect narrative stating which Building and Design codes have been used to govern the design process. Any areas where compromise in design has been necessary
5. Loaded Room Data sheets or expanded drawing showing position of all key equipment.
6. Company Registration
7. Contact details and Project Manager, who will be responsible for ensuring DGPHE Standards are met

Table of Contents

No.	Subject	Page
1	Minimum Specifications: OPD	5
2	Minimum Specifications: Hospital	6
3	Staff Requirements	7
4	Minimum Laboratory Requirements	9
5	Minimum Imaging Requirements	10
6	Minimum Infection Control Requirements	12

Requirements

Items	General Specifications	Met	Not Met	Comments
Location	The facility should be located on the ground floor; otherwise there must be a lift suitable for wheelchair users. It is subject to municipality's rules and regulations, and must meet the fire regulations required of a healthcare facility. There must be adequate parking including disabled parking.			
Lighting & Ventilation	Proper day lighting, ventilation, and temperature control within the clinic premises are obligatory, windows which can be opened must be fitted with an insect screen.			
Walls, Floor & Ceiling	Walls must be painted with easily washable paints (light colour is preferred), with no sharp edges on walls or corners and suitable for healthcare use. Floor and ceiling finishes shall be selected for Healthcare use.			
Corridors & Doors	Corridors and Doors must be wide enough to permit wheelchair and trolleys (at least 90 cm of clear opening for doors and 150 cm for corridors in clinics, 120 and 150 for hospitals), of normal height, and provide turning space for wheelchairs and stretchers. Doors must be sound reducing to ensure patient confidentiality.			
Reception + Waiting Area	This area must allow patients to move comfortably and provide confidentiality. It must be wheelchair user friendly. The area must have enough seating to accommodate the maximum number of anticipated patients and attendees with appropriate privacy			
Consultation/ Treatment/ Observation/ Examination Rooms	The number and functions of these rooms should be appropriate to the services provided. Rooms must have relevant equipment and facilities for the services provided. All rooms must allow easy patient movement and accommodate wheelchair users. All rooms must have wash hand basin with elbow operated taps, elbow operated soap dispenser, paper towel dispenser, height and weight scale, examination couch or chair, examination light and disposal bins for clinical and non-clinical waste. Patient privacy must also be ensured by curtain or similar.			
	At least one room must accommodate Crash Cart and CPR equipment			
Medical records	Medical records system must comprise a Master Patient Index showing each individual unique patient number and demographic details. Storage must be adequate to allow storage of anticipated number of patients for seven years. Filing system must reduce risk of misfiling and provide easy retrieval of records. Confidentiality of patient information must be ensured. A Computerised medical records system is preferred			
Medical equipment	All electronic clinical equipment must have maintenance contracts which should include calibration and testing.			

Hospital Classifications and Requirements

Classification	Staff	Facilities and Services Required
Non Surgical/ Medical unit (minimum 10 beds)	<ul style="list-style-type: none"> • Nursing – Minimum 2 nurses on all shifts at all times. Training relevant to services. Minimum ratio 1 nurse to 6 patients 08.00-22.00. 1:12 22.00-08.00) • Nominated Patient Safety/Infection Control Officer • RMO (with ACLS) • Access to Specialists in relevant Specialty, e.g. Internal Medicine, Care of the Elderly, Neurology, Psychiatry, Cardiologist, Physiotherapist, etc. • Radiologist • Pharmacist 	<ul style="list-style-type: none"> • Code Blue/Patient Emergency arrangements and equipment • Hotel Services (Cleaning, laundry, catering) • Engineering Support (inc. fire protection and testing) • Ambulance • Clinical Waste disposal • Laboratory (must have basic point of care testing on site for Haematology and Biochemistry.) • Imaging service, minimum X-ray. • Pharmacy
Hospital plus Surgical Specialty (cold)	<p>As above Plus</p> <ul style="list-style-type: none"> • Theatre trained nurses: minimum 3 nurses per operating list, plus 1 for recovery • Surgical Recovery area: ICU trained nurses (minimum ratio 1 trained nurse to 2 patients, but 1 to 1 if high acuity of patients). • Trained CSSD staff • Formally on-call Senior Surgeon • Formally on-call Anaesthetist 	<p>As above plus</p> <ul style="list-style-type: none"> • 2 Operating Theatres (1 may be adequate if approved by DGPHE in view of Scope of Practice) • Full surgical equipment relevant to scope of Service • Anaesthetic equipment relevant to practice • CSSD • ICU or Surgical High Dependency Unit • Medical Gasses • Ultrasound • Full back-up facilities
Hospital plus OB/GYN (cold)	<p>As above plus</p> <ul style="list-style-type: none"> • 2 Midwives for 3 delivery rooms, plus on call staff (can also be used on wards). Must be 1 to 1 when Delivery in progress • SCBU Nursing ratio 1 nurse to 2 babies • Pediatrician with SCABU experience. 	<p>As above plus</p> <ul style="list-style-type: none"> • Delivery suite • SCBU
Hospital plus Cardiology	<p>As 1. Plus</p> <ul style="list-style-type: none"> • Physiological Measurement Tech/ Cardiac technician 	<p>As 1. Plus</p> <ul style="list-style-type: none"> • ECG • Echo
Hospital plus	<p>As 1 and 2 plus</p> <ul style="list-style-type: none"> • Radiographers (minimum of 2) 	<p>As 1 and 2 plus</p> <ul style="list-style-type: none"> • Physiotherapy

Orthopaedic Surgery (cold)	<ul style="list-style-type: none"> Physiotherapists (minimum of 2) 	<ul style="list-style-type: none"> Image Intensifier + C-Arm
Hospital plus Other Specialist services	As 1 plus <ul style="list-style-type: none"> Staffing appropriate to service and as approved by with DGPHE 	As 1 plus as appropriate to service provided.

Staff:

Institutions must provide adequate staffing levels to ensure that patients are treated within a professional standard of care in organizations that meet required levels of safety and quality.

Patient care can be compromised by low staffing levels. It is important to ensure that the correct staffing, skill mix and experienced staff is always available to reduce the risk to patients and staff.

Hospital Nurse to patient ratios:

Care Environment	Nurse to patient ratio		
	Morning	Evening	Night
Acute wards	1: 6 + nurse in charge	1:6 + nurse in charge	1:12 + nurse in charge
Ante/postnatal wards	1:5 + nurse in charge	1:6 + nurse in charge	1:8 + nurse in charge
Delivery suite	2 midwives to 3 delivery rooms	2 midwives to 3 delivery rooms	2 midwives to 3 delivery rooms
NICU/ SCBU	1: 2 + nurse in charge	1: 2 + nurse in charge	1:2 + nurse in charge
High dependency units/ ICU	1: 2 + nurse in charge	1:2 + nurse in charge	1:2 + nurse in charge
OT	3 per functioning theatre	3 per functioning theatre	3 on call
Recovery	1:1 for non-conscious patients	1:1 for non-conscious patients	1 on call
Accident and Emergency	1: 3 + nurse in charge 1:1 for trauma patients 1 for triage	1:3 + nurse in charge 1:1 for trauma patients 1 for triage	1: 3 + nurse in charge 1:1 for trauma patients 1 for triage

These are minimum staffing levels.

Staffing should always relate to activity and acuity or patient special needs.

Skill mix and experience should also be considered when staffing units/wards.

Minimum of two staff on duty at any time even when there is only one patient. If suitable cover is available elsewhere within the institution this could be used as an alternative.

Staffing requirements	Met	Not Met	Comments

Clinic and Polyclinic nurse patient ratios

Care Environment	Staff Requirements		
	Morning	Evening	Night
Polyclinic	2 Registered Nurse + Nurse in charge 1 Medical Orderly to 2 consulting rooms.	2 Registered Nurse + Nurse in charge 1 Medical Orderly to 2 consulting rooms	2 Registered Nurses 2 Medical Orderlies
Health Centre	1 to 2 Registered Nurse + Nurse in charge 1 Medical Orderly to 3 consulting rooms	1 to 2 Registered Nurse + Nurse in charge 1 Medical Orderly to 3 consulting rooms	

This is the minimum staffing levels.

Staffing should reflect the activity in the unit or the services being provided.

There should be a minimum of 2 Registered Nurse at all times.

Minimum requirement: Laboratory (for detailed requirements refer to General Private Laboratories Manual)

		Met	Not Met	Comments
Space / Room	<ol style="list-style-type: none"> 1. Clinic -Total 25 square meters with neither width nor length less than 4 meters. 2. Hospital – Two rooms minimum size as above 			
Staff	<ol style="list-style-type: none"> 1. Clinic - Two Lab tech. Minimum Diploma holder or above 2. Hospital 4 lab techs. 3 with Diploma, 1 with BSc, and Pathologist 			
Medical Equipment	<ol style="list-style-type: none"> 1. Three differential-part hematology analyzer. 2. Fully automated biochemistry analyzer minimum specification 120t/h. 3. One microscope. 4. One lid lock centrifuge. 5. Lid lock Centrifuge. 6. Water bath. (If applicable). 7. Calibrators and controls (all tests) 8. Specimen collection chair. 9. Spill kit. 10. First aid kit. 11. Sharp container. 12. In addition Hospital must have Class B Safety Cabinet if Microbiology provided <p>Note: all lab equipment should have valid maintenance contract and reagent supply contract issued from Sultanate of Oman</p>			
Equipment Non-Medical	<ol style="list-style-type: none"> 1. Refrigerator. 2. Freezer. 3. Ceramic or Granite work benches. 4. Exhaust fan. 5. Waste bins (clinical/yellow and general). 6. Soap (medical Chlorohexidine) and tissue dispenser (in each room). 			
Documents	<ol style="list-style-type: none"> 1. SOP (Standard Operation Procedure). 2. Investigation list. 3. Equipment list. 4. QC files. 5. Local valid maintenance contracts. 6. Local valid reagent supply contract. 			
Design and construction guidelines	Please refer to the policy chapter 2, pages 21-25			

Minimum requirement: Imaging

		Met	Not Met	Comments
Room Size	<p>Ideally 5x5m, but must not be less than 18 square meters for general purpose radiography. 2mm lead shielding.</p> <p>Patient gowning area: at least 1.5 meters x 1.2 meters, with lockable valuables storage.</p> <p>Control Room: The control panel of X-ray equipment operating up to 125 kVp; can be located in the X-ray room. The distance between the control panel and X-ray unit/chest stand shall be not less than 3 m for general purpose fixed X-ray equipment. The protective control room shall contain 2mm lead equivalence to the wall lead and a window with a clear view to the room so that the radiographer can observe the patient during an x-ray exposure X-ray room shall be located as far away as practicable from maternity and paediatric wards.</p>			
Staff	One Radiographer/ qualification :Minimum diploma or above with three years experience			
Equipment and supplies	<ol style="list-style-type: none"> 1. X-ray machine with X- Ray table, and chest wall bucky unit. (Floor-to-ceiling tube stand, ceiling suspended over-table tube). 2. Lead aprons. 3. Gonad shields 4. Immobilizer devices. 5. Cassette (detector) and grids. 6. Emergency trolley. 7. Working table with bench. 8. X-ray viewer. 9. Foot step to help Patients to step in to X-ray table. 10. Computed Radiography (CR), and or Digital Radiography (DR) 11. Lead apron hanger. 			

	<ul style="list-style-type: none"> 12. Computer work station. 13. Red warning light sign indicating when the X-ray beam is OFF/ON. 14. X-ray caution sign on the tube housing. 15. Radiation warning signs on doors. 16. TLD for radiation operation staff. 			
X-Ray Machine details	<ul style="list-style-type: none"> 1. Power should be 3 phases for 300mA units and above- ideally separate electric line for x-ray is recommended. 2. Filtration: Total 2.5mm of A1 above 100KV (1.5mm permanent filtration) increased at the rate of 0.01mm per kVp. 3. Cable length more than 2m to enable operation from a minimum distance of 3 meters from the x-ray tube. 			
Documents	<ul style="list-style-type: none"> 1. Radiation safety policy. 2. TLD report. 3. Equipment maintenance records 4. Radiation devices QC reports 5. Rejects Analysis QC 			
Design and Construction Standards	<ul style="list-style-type: none"> 1. Structural support for equipment including equipment mounted to ceilings level floor for equipment positioning and safe patient movement. 2. Provision for cable trays, ducts or conduits should be made in floors, walls, and ceilings as required. 3. Trench with cover on the Floor. 4. Trench with cover on the wall up to main supply. 5. Lead Glass opening 800mmW x 600mmH 2mm lead equivalent. 			

All imaging post processing should be digitalized either with CR or DR system no dark room facilities allowed.

Minimum Infection Control Requirements for Clinics

		Met	Not Met	Comments
Hand Washing Facility	<ul style="list-style-type: none"> – Hand washing sink or basin (size big enough that will prevent spillage of water while doing the process of hand washing) – Elbow operated tap or tap with sensor – Wall mounted paper dispenser with paper towel – Foot operated waste bin with lid cover, lined with black bag – Wall mounted soap dispenser with antimicrobial soap – Hand washing technique or steps poster 			
Infection Control Focal Point	<ul style="list-style-type: none"> – Responsible to look after the Infection prevention and control issues in the facility. This can be part of his/her role in addition to her/his main responsibility 			
Documents	<ul style="list-style-type: none"> – Latest GCC Infection Control Manual – Infection Prevention and Control Policies and Procedures related to the specific services rendered in the facility (example dressing, cannulation, injection safety, etc.) – Audit tools (specifically hand hygiene and environmental cleaning audit tool) – Accidental Inoculation Injuries (AII) and spillage of blood and body fluids Standard Operating Procedure (SOP) and Exposure Control Plan. – AII incident reporting form and statistics of AII – Form for the notification of reportable infectious diseases – Record of staff vaccination – Record of Sterilizers and the Sterilizing Process Effectiveness Verification (physical, chemical and biological indicators) Note: applicable if autoclaving done in the facility 			
Consultation/ Observation and Treatment Room	<ul style="list-style-type: none"> – Hand washing facility (Please refer to the above Hand washing facility requirements) – Alcohol based hand rub (with 60 to 70 % alcohol) – Spillage Kit and First Aid kit – PPE (gloves and mask) – Waste bins with appropriate color coded bags (black for general waste and yellow for infected waste) – Paper roll on top of couch or examination bed's linen – Fridge for drugs with thermometer and temperature graph – Sharp bin (above the floor, in the trolley or wall 			

	<ul style="list-style-type: none"> mounted) – Instruments and equipment that can stand chemical or thermal disinfection 			
Waste Management	<ul style="list-style-type: none"> – Written Contract from the company who collects and manage the waste of the facility – Pedal Bins with working lids – Waste Bags (Yellow and Black) preferably with 150 micron thickness or thick enough to hold the weight of the wastes – Puncture resistant sharp bins or containers – Waste storage with lock 			
Laundry Service (applicable if laundry service not outsourced)	<ul style="list-style-type: none"> – washing machine and dryer to specification for health institution – Ironing board meant for health institution – Fabric detergent and disinfectant as per the manufacture’s recommendation and instruction – Trained Laundry Staff – Clear work process to separate clean and dirty linens at all times – Separate Carts for clean and used linens – Red bag for infected or soiled linen (with blood and body fluid) – Hand washing facility 			
Equipment and Supplies for CSSD Note: Clinics with one or two wound dressings per week are advised to use disposable dressing sets.	<ul style="list-style-type: none"> – Personal Protective equipment (PPE) such as gloves, mask, goggle and apron – Ultrasonic cleaner machine for fine and delicate instruments – Cleaning Brushes with bristles good enough for the removal of soiled materials and safe to use for delicate instruments – Enzymatic and disinfectant solutions – Wrapping materials – Pouches (either self sealing or sealed with sealant) – Autoclave tape – Bowie Dick test – Bench or table top Autoclave (Type B) – Chemical indicator strip – Biological indicator or spore test – Incubator for biological indicator – Marker pen – Waste bins (with yellow bag for hazardous/infected waste and black bag for general waste) – Sharp bin – Covered plastic or metal container for the used instruments – Cabinet for storage of items/materials/consumables – Washer disinfectant (optional) – Staff hand washing area 			

CSSD Structure/ Layout (from dirty to clean area)	<ul style="list-style-type: none"> – Receiving or soiled area for used instruments with sink (big enough to accommodate the proper soaking of instruments) – Drying and packing area – Location of Bench or Table Top Autoclave (Type B) separated or away from the receiving or soiled area – Sterile storage area – Hand washing facility 			
Environmental Cleaning Equipment and Supplies	<ul style="list-style-type: none"> – Disinfectant solution and disinfectant wipes – Personal Protective equipment (PPE) such as heavy duty gloves – Microfiber wet dusting clothes – Mops and bucket , toilet brush, detergents 			
Dirty Utility	<ul style="list-style-type: none"> – Storage space for soiled linen, etc. – Facility for washing urinals, vomit cups, bed pans, etc. – Hand washing facility 			
Clean Utility	<ul style="list-style-type: none"> – Storage for clean linens, curtains, etc. 			
Cleaner’s Room	<ul style="list-style-type: none"> – Cleaning materials, supplies and other cleaning equipment – Facility for washing mops and microfibers clothes – Hand washing facility 			
Storage Room	<ul style="list-style-type: none"> – Supplies, consumables, etc. 			

Requirements for Approval of New Medical Equipment

<ul style="list-style-type: none"> – All medical equipment must have an authorized local agent within the GCC. – All medical equipment must be able to be maintained by an authorized agent of the manufacturer, based in the GCC – There must be FDA or CE Approvals for each item of equipment, and appropriate certification must be available on site for Inspection by DGPHE – Organizations must maintain a register of all medical equipment including manufacturer, country of origin, make, and model. – Catalogues must be available on site for each medical device which includes all technical specifications. – Pre-installation approval must be secured from DGPHE for all major medical equipment – Medical equipment must be installed and operated according to the manufacturer's instructions, and must be maintained in line with manufacturer' requirements. A record of maintenance must be retained on site for Inspection purposes. – Staff must receive training in the operation of all medical equipment, and this must be recorded in staff files. – All equipment must be maintained by an in house qualified biomedical engineers or a maintenance contract with a specialized company through a formal written agreement and should include calibration and testing where appropriate.
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Owner/Provider

Declaration

I confirm that I have read and understood all the requirements in this document and that I undertake to meet all requirements to ensure the provision of Safe care to the patients in my establishment

Signed.....Date.....

Name, title and position/capacity.....

Inspection Result

Can open

Can open but with minor conditions

Cannot open unless requirements fulfilled

Comments:

Names & Signatures of the Auditors

Name	Designation	Signature	Date & Time

Approved By:

Name	Designation	Signature	Date & Time