

Health Requirements, Technical Standards and Safety Requirements to be Available in the Premises and Fittings of Healthcare Facilities

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Introduction

These requirements and standards are based on Decision No. (2) Of 2019 issued by the Supreme Council of Health on the classification of health facilities, health requirements, technical standards and safety requirements needed to be to be available in its premises and fittings.

This guide describes all the conditions and technical and standards required to be met in all health facilities, including safety, staffing, medical supplies and medical equipment requirements.

The design of any Health facility should be based on the type, category and scope of services provided. It should also take into account infection control and patient safety at every section in the facility, including interior design.

The interior design of the facility must provide a sense of security and comfort in both internal and external spaces, and should consider the needs of elderly and disabled in the design of all facility premises, as the facility environment and its design can have a positive impact on the services outcome and on both the patients as well as the health care providers, if its designed in such a way as to facilitate the delivery of the service, provide comfort and safety to its employees, and ensure their safety and the safety of patients and clients.

The engineering, the design and operation of a health facility can save a lot of effort and cost by following the standards set out in this guide. These requirements and standards have been developed based on international standards in terms of design and have taken into account the requirements of the Supreme Council of the environment, civil defense, municipal requirements and the Gulf infection control guide. (Posted on NHRA website).

These requirements and technical standards aim to ensure a safe environment for employees and visitors to health facilities and to ensure the quality and safety of the health services provided.

The requirements of the buildings and facilities, administrative conditions, quality management, security, safety, information management, health records and standards for medical, nursing and allied health professions are applicable to all health Facilities in all their various classifications.

Annex No. (1) General requirements for the Buildings and Premises of Health Facilities

A. The following general requirements must be met in all health facilities

- 1. The site should be appropriate, while adhering to the building regulations adopted in the area in terms of heights, construction ratios and rebound, in accordance with the requirements of the concerned authorities, and be away from hazard places such as storage of petroleum materials, gases, workshops, and sources of hustle, the building and the surrounding areas are free from risks.
- 2. The international specifications and standards for mechanical and engineering technical details should be adopted in the building as a whole, so as not to interfere with the conditions required.
- 3. Take into consideration that the entrances and exits are directed to the main road only, and not direct to the sub-road.
- 4. The building should be independent and not connected to a residence or other place of business, and be designed so that all functions can be done in a safe, comfortable and secure manner, and not be overcrowded.
- 5. Provide suitable parking according to the requirements of the concerned authorities
- 6. The facility internal design should give a sense of safety and comfort both in internal and external spaces for the patient, and allow easy moving between the departments of the facility, and must take into consideration the needs of the elderly and persons with disabilities in all sections of the facility by placing the slopes resistant to slip and avoid having steps in the engineering design in all premises of the facility.
- 7. To study the areas and dimensions of the elements and their relationship with each other and the width of the corridors and doors and the necessary electrical, sanitary and mechanical extensions and materials used, in accordance with the types and specifications and measurements of the medical equipment used and the services to be provided in the building
- 8. The main entrance should not be less than 2 meters in width, with a ramp for people with disabilities.
- 9. The intensity of lighting (natural or industrial) in all parts of the facility according to the International standard specifications .
- 10. The walls and ceilings of the premises allocated for the treatment, patients' admission, and the operating rooms of the facility should be painted with a medical coating which allows easy cleaning, and bears the repetition of cleaning, and the floors are designed to be smooth and easy to clean and anti-slip.

- 11. The roofs of the premises of the facilities should be smooth and do not allow the accumulation of dust and germs.
- 12.Provide a waiting area for men and women with a minimum area of 1 square meter per seat.
- 13.In accordance with decision No. 3 of 2006 on the management of hazardous waste, a room for the waste of health care and the means of disposing of the general and medical waste must be provided, taking into consideration the complete separation of medical waste from general residues. As in Annex (26).
- 14. The use of new and unused devices in accordance with the authority standards and regulations approved for the quality and safety.
- 15. Provision of storage rooms for medical devices with electrical handles for charging.
- 16. The doors used for the treatment and consultation rooms should not be less than 1 meter, and a width of 2 m in the rooms where there is a need to transfer beds to facilitate the patient transfer easily.
- 17. The width of the internal corridors between clinics should not be less than 1.5 meters, and the wards should be at least 2 meters, taking into consideration the existence of corridors or rooms for the storage of the beds and carriages on each floor.
- 18. The net width of the staircase shall not be less than 1.5 meters and the width of a staircase landing must not be less than the width of the staircase.
- 19. Availability of an elevator in buildings consisting of more than one floor, taking into consideration the possibility of placing the bed and wheelchair in a safe and smooth way, and the entrance of the elevator shall not less than 1.370 meters and has an area of at least (2.4 x1.4).
- 20. The building should be equipped with a source of pure water, for both washing and cleaning, or drinking, as well as a suitable means of sanitation.
- 21. Take into account the design and installation of electricity, water and sewage connections, according to the specifications of the concerned authorities
- 22.Supplying the sections with distilled water according to the requirements of the infection control guidelines, taking into account the ratio of minerals to the requirements of medical devices in the laboratory and pharmacy in case of preparation of medicines, critical care unit, operating rooms and sterilization section.
- 23.All electrical panel are firmly sealed
- 24. The environment of the facility shall be safe for patients, visitors and employees through the availability of the following requirements:
 - 24.1 The appropriate access and entrances to the building should accommodate the passage of fire trucks to ensure their arrival at the hospital and to the balconies and windows as part of the rescue means.
 - 24.2 The emergency exits should be as far apart as possible and the number of exits on each floor should not be less than two, leading to the escape route.
 - 24.3 The end of the emergency way will lead to final exits arriving outside the building, with specifying places for the Assembly of the evacuated persons.

- 24.4 The emergency doors are easy to open from the inside and fire resistant for at least an hour, and open to the outside by pushing, installation of mirrors or reflective materials near the doors is prohibited so as not to result in disturbances or error in determining exit directions.
- 24.5 The distance that a person takes to the emergency exit or the stairs should not exceed 15 meters.
- 24.6 Take into account the construction of emergency stairs, so that the stairs are made from non-flammable materials, equipped with the necessary railings of good design and security, and that its openings are small to avoid accidents.
- 24.7 The width of the corridor leading to the emergency exit should not be less than 2 meters.
- 24.8 The exits and the ways of survival, corridors and stairs both provided with signs and illuminated arrows to be clearly indicated, so that all visitors and patients can see them clearly.
- 25.Placing a sign at the entrance of the facility stating its name and specialization according to the license granted and the working hours.
- 26.Placing of guidance board inside the facility showing the location of clinics, departments and other sections of the facility.
- 27.A reception desk should be at the entrance of each section, and the presence of guiding signs in the building both in Arabic and English languages.
- 28.To follow a procedure to prevent non-staff from entering the pharmacy, laboratories, operating rooms, technical rooms and to protect the information and devices inside.
- 29.Commitment to the designation of rooms, which prevents the use of one room for more than one purpose at the same time, while the same room may be used at different times for different purposes without prejudice to the standards approved by NHRA.
- 30. The furniture used in the treatment rooms of the health facility should be easy to clean and smooth and free of meandering and holes and maintained periodically.

B. In addition to the requirements referred to in paragraph (A) of this annex, the following criteria must be available in hospitals:

- 1. In addition to the main hospital store, a dedicated storage room must be available in each section of the building and not be used for another purpose.
- 2. Adherence to the health and safety standards in air quality, temperature, humidity, lighting, noise and building vibration, by measuring 6 air units per hour at a minimum, and having a humidity level of 30% to 50%, and must provide ventilation and natural lighting for the patients' accommodation rooms and waiting rooms and For offices and lounges, with adaptation of NHRA standards for isolation rooms and

to infection control of the places designated as operating rooms, laboratory and critical care.

- 3. The patients' rooms should be as far away from the streets and parking spaces as possible, and the wall should prevent the sound from being transmitted from one room to another.
- 4. Provide a backup generator that is automatically operated when the general power is shut down and with sufficient power to operate the main sections of the hospital, especially the operating and delivery rooms, blood bank emergency, critical care and main corridors in the hospital and to carry out frequent testing for this generator to maintain its validity. See annex (40)
- 5. Provision of ensuite toilet for each of the private and isolation room in hospitals, taking into account the persons with disabilities, and the size of the toilets for persons with disabilities should not be less than the following sizes:
 - -1.5 x 1.2 meters.
 - -1.5 x 1.5 meters.
 - -1.7 x 1.2 meters.
- 6. Provision of toilets, washbasin and a waiting room in each section.
- 7. The hospital can be designed as one or several buildings, and can include as well accommodation premises for physicians and other health professionals within the boundaries of the hospital, taking into account the attainment of privacy, provided that the entrance and exits for the staff accommodation should not be connected to the hospital or one of its services.
- 8. Provide a wash basin in all the observation or treatment rooms, in accordance with the approved safety requirements of the equipment used in the room.
- 9. Allocating a place for the medical staff in each section not to be used for any other purpose.
- 10.Not to crowd the corridors with any materials or furnishings that hinder the movement.
- 11.Provide dedicated and separate lifts for services, patients and visitors.

Annex (2)

Quality Management, Security, Safety, Infection Control and Prevention, Sterilization, and Medical Waste Disposal Services

I. **Quality Management**

Health facilities classified as hospitals or medical centers shall have the following:

1. The Facility shall develop a systematic and comprehensive plan for improving the quality and safety of patients. The plan shall include, but is not limited to:

- 1.1. Setting goals and objectives.
- 1.2. Determine the scope of activities.
- 1.3. Identification of all levels of staff roles and responsibilities.
- 1.4. Defining educational activities related to quality concepts.
- 1.5. Description of the criteria used for the selection of indicators, data collection and analysis, implementation and evaluation of improvements
- 1.6. Identification of key performance indicators (including high-risk operations).
- 1.7. Develop a mechanism to show how the improvement projects are identified and prioritized by the Facility leadership.
- 1.8. To provide continuous training and educational activities for all staff in terms of quality concepts and tools.
- 1.9. Identify a person responsible for coordinating and organizing quality concepts and principles within the hospital or medical center.

2. The facility shall have a risk management plan that addresses all the operational, financial and clinical risks and potential safety risks faced by the Corporation. This plan includes the following:

- 2.1. Scope and objectives of the plan.
- 2.2. The staff responsible for this plan
- 2.3. Systematic process to identify and analyze potential risks in terms of risk and likelihood of occurrence.
- 2.4. Develop risk management interventions.

3. The facility supports the safety of patients through the appointment of staff, or the formation of a patient safety team comprising representatives of the medical staff, nursing staff, pharmacy and safety department to implement and monitor patient safety goals and periodically recommend specific actions to improve, taking into account staff training.

4. The management of the Facility shall establish a clear mechanism for the storage and handling of medicines and medical devices, especially narcotic drugs, therapeutic creams, intravenous fluids and other medical preparations.

II. <u>Security and safety requirements</u>

The following security and safety requirements are required in health institutions that are classified as hospitals and medical centers:

- 1. A qualified person to work full-time or contract with a third party to take responsibility for managing the organization's safety program.
- 2. Conduct periodic maintenance preventive and corrective maintenance in all electrical and mechanical systems with the need for documentation.
- 3. Training all staff on health and safety field.
- 4. The Foundation shall follow a fire prevention program to include the following:4.1 Training the staff on the evacuation plan in the event of a fire and the exercises shall be conducted regularly.

4.2 Barrier-free survival methods.

- 5. Proper storage of medical equipment and supplies, and to be implemented correctly, and not to store on the floors or in the corridors, leaving at least 30 cm from the ceiling of the room and 15 cm from the floor.
- 6. Provide fire systems, including fire alarm and fire-fighting equipment, and to ensure that they do not interfere with the safety of the medical equipment used.
- 7. The facility shall be insured and shall protects its users through the following:
 - 7.1 Appointment of security personnel in a number commensurate with the size of the facility, its departments and services.
 - 7.2 Insurance of the facility's equipment and data.
 - 7.3 To enforce a non-smoking policy.
- 8. The existence of an operational plan and program for the installation, inspection, testing and maintenance of medical equipment, including the following:
 - 8.1. The installation of medical devices shall be after the approval of the Authority and shall be used, stored and transported according to the manufacturer's standards.
 - 8.2. Provision of an inventory of all medical equipment.
 - 8.3. Medical equipment shall be subject to regular maintenance and preventive maintenance and shall be numbered accordingly.
 - 8.4. No worn equipment shall be kept in the premises of the facility.
 - 8.5. Electric transformers shall not be used.
 - 8.6. Ensure that all devices are equipped with an internationally approved G-type plug.

8.7. Provision of temperature recording devices (Temp. Logs) in pharmacy, laboratory coolers and freezers.

9. The facility shall have a plan for the disposal of hazardous health care waste, including the following:

- 9.1. Keep a record of all hazardous substances.
- 9.2. Training employees to deal with hazardous materials and irregularities.
- 9.3. Control of hazardous materials and wastes.
- 9.4. Provide a place for eye wash and shower area for emergencies as per need.

10. There is a plan for actions to be taken in case of malfunction of utilities or power outages.

III. Infection control & Prevention (including central sterilization)

The following requirements must be met in all health care facilities to ensure infection control & Prevention:

- 1. Identify a person responsible for infection control.
- 2. The existence of an infection control policy in the facility that includes the following:
 - 2.1. Health awareness for the employees.
 - 2.2. Personal protection equipment and methods of use. (Annex 40)
 - 2.3. Hand hygiene technique.
 - 2.4. Safety of sharp items.
 - 2.5. Cleaning, decontamination, disinfection and sterilization.
 - 2.6. A mechanism to monitor the implementation of infection control policies and procedures and how to deal with infections associated with health care.
 - 2.7. Dealing with blood spills / body fluids.
 - 2.8. Procedures for dealing with infectious diseases.
 - 2.9. Laundry procedures.
 - 2.10. Precautions for infection prevention and control during renovation and construction.
 - 2.11. A mechanism for documenting incidents or violations related to infection control and reporting to NHRA in case of impact on the health of patients or employees.

3. The facility provides suitable environment for hand hygiene such as sinks and alcohol for hand cleaning.

4. Provide regular soap and disinfectant and paper towels (do not use cloth towels) for hand washing.

5. Provide a sufficient number of hand sanitizers in each clinic and changing room.

6. Hospitals that provide dialysis services are required to implement a monitoring program on the quality of water used in dialysis and to perform periodic examination in an accredited laboratory.

7. The existence of a policy to maintain the cleanliness of the facility, and in case of outsourcing the service, the existence of a contract with the cleaning companies.

8. The existence of written policy and procedures for the management of clothing, bedsheets and special sterile clothing that are used in the operation theater, including the way they are transported, handled and stored, and the handling mechanism for contaminated cloths.

9. When catering is provided in a health facility, a policy should be developed to deal with food preparation, distribution, storing according to the requirements of the Public Health Law.

IV. Sterilization standards and requirements:

- **A.** The following requirements must be met in the central sterilization section in the health facility which includes operating rooms and are classified as hospitals and big medical centers (where applicable):
 - 1. The design of the section should be suitable for its intended purpose in accordance with international standards. It is preferable to follow the one-way route, sequentially from the delivery area of dirty tools to the cleaning area, to bags to sterilization to storage. This pattern should be clearly defined and the decontamination area shall be completely separated from areas where the clean material is placed in bags, the sterilization and the storage area.
 - 2. The sterilization room should be separate and suitable for the performance of packaging and sterilization tasks
 - 3. The ventilation system in the sterile room must be positive. (not applicable for small rooms) and should be equipped with the required devices.
 - 4. The room should contain sufficient equipment to ensure sterilization of the tools.
 - 5. The use of sterilizing materials for medical instruments shall be in accordance with the manufacturer's standards.
 - 6. Install, use and maintain equipment in the room in a manner consistent with the manufacturer's standards.
 - 7. The existence of written policies and procedures for the central sterilization section for cleaning, decontamination, sterilization and storage of sterile materials.
 - 8. Assigning a supervisor in the central sterilization section who has an experience and knowledge in the practice of sterilization.

- 9. The existence of written policies and procedures related to the withdrawal of sterile substances if proved that the sterilization or disinfection processes are subsequently inefficient.
- 10.Keep records of sterilization for one year to allow a chance for auditing and evaluation.
- 11.Preserving sterilizers in a good condition with instructions on how to use them.
- 12.Use chemical indicators in each pack and use biological indicators periodically.
- 13.Labeling of equipment.
- 14.Create a controlled environment that meets the requirements of temperature, humidity, airflow and storage.
- 15.Setting the dates of the sterilization process on the materials' preserving bags.
- 16.Place a sticker with the last maintenance date conducted for the sterilization device.
- 17.Follow the sterilization technique to comply with the requirements of the manufacturer.
- 18. The Central Sterilization Section applies measures to ensure the safety and proper functioning of staff. These measures include:
 - 18.1 Personal protection equipment.
 - 18.2 Approved policies and procedures that strictly observed.
 - 18.3 When using ethylene oxide, safety and health risks are taken into consideration.

B. In small medical centers and clinics where simple operations are performed, a sterilization room must be provided, which shall be isolated, with washbasin and suitable sterilization devices and equipment according to the type of tools used.

V. Disposal of hazardous health care waste

The following conditions must be met in all health facilities were hazardous medical waste are produced from their health services:

1. Medical waste shall be managed in accordance with the law and the provisions of Decree No. (3) for the year 2006 regarding the management of hazardous wastes and the decisions and instructions issued by the Supreme Eenvironment Council.

2. The site should have adequate cleaning tools, disinfectants, cleaning materials used in the cleaning the facilities on an ongoing basis, in case of emergency and in case of waste is spills.

3. The existence of a written policy to deal with the spillage of blood / body fluids and waste.

4. Policies and procedures dealing with sharp objects, including:

- 4.1. Provision of suitable sharps containers for disposal of sharp objects.
- 4.2. The sharps container used shall be anti-puncture and leak proof and shall not pose any risk to employees or patients.

4.3. A sufficient number of sharps containers (at least one container in all places dealing with patients) and placed appropriately away from traffic (under eye level and within reach).

5. Sharps containers should be disposed of when the contents are $\frac{3}{4}$ of their size or after 30 days from the commencement of their use, in accordance with Decision No. (3) of 2006 on Hazardous Waste Management and the Unified System for the Management of Health Care Waste in the GCC States Issued by the Royal Decree No. M / 53 dated 16/9/1426, the Council of Ministers Resolution No. 240 dated 14/9/1426, or in accordance with the resolutions and instructions regulating the Council.

6. The policy of safe disposal of medical waste should be implemented according to the regulations of the unified system for the management of health care waste in the GCC States or in accordance with the decisions and instructions issued by the Gulf Cooperation Council, using the colored waste bags. Yellow, red and sharps container.

7. The facility must contract with a waste management company for waste disposal, and in case of waste transfer from a health facility to another health facility licensed by NHRA, the conditions of transport issued by the Supreme Council for the Environment must be followed.

8. Provide containers for transporting health care waste to waste storage site with the following specifications:

- 8.1 Made of a material resistant to rust and not affected by acids and alkalis.
- 8.2 Powerful and designed in such a way as to ensure their efficiency when loading and unloading.
- 8.3 Leakproof and fitted with a cover that can be secured.
- 8.4 Surfaces and angles easy to clean and disinfect.
- 8.5The size of the containers shall be suitable to the rate of waste generated and shall not exceed its capacity during each transfer process.
- 8.6. Characterized by easy movement within the facility.

9. The existence of the medical waste room must be separate from any other services and meet the following conditions:

- 9.1 Provide a special site for storage within the health facility to be a center for the collection of hazardous health care waste resulting from that facility.
- 9.2 The storage location is easily accessible for the purpose of storage, transport and cleaning.
- 9.3 The storage location should be away from food stores, kitchens, food preparation areas and away from patient care.
- 9.4 The provision of containers for transport and storage of all types of waste, except for general waste, which are transported directly to municipal waste containers.
- 9.5 The storage location is suitable so as not to cause any pollution or damage to human health and the environment.

- 9.6 The storage location should be in a sealed building, equipped with a proof against water leakage, rain, foul odors, rodents, insects, birds and stray animals. It has a solid surface that is resistant and bear washing and disinfection and is equipped with good means of sanitation.
- 9.7 The storage location shall be equipped with safety and fire protection tools.
- 9.8 The storage location shall be equipped with suitable air conditioning, good lighting and temperature between 15-18 ° C, with daily temperature recording at the site.
- 9.9 Red bags should be disposed of within 24 hours of being in the health facility or frozen in special refrigerators.
- 9.10 Access to the storage site is restricted to authorized employees only.
- 9.11 Keeping a clear sign in both Arabic and English on the storage site, indicating its contents.

10. The medical waste transfer form issued by the Supreme Council for the Environment must be completed and kept in a special registry in the facility.

11. All garbage pins in medical rooms shall be with a foot paddle.

Annex (3) Management of Medical Information and Records

All facilities shall adhere to the following:

1. Availability of appointment system

2. Maintain a hard or electronic medical record in which facility patients or clients' data and information, including their medical reports, are recorded. This shall include the following data:

- 2.1 The patient's name and CPR/ ID number.
- 2.2 The date of admission/ visit to the facility.
- 2.3 Provisional diagnosis on admission/visit.
- 2.4 The medical history and date of each visit.
- 2.5 Radiology and laboratory Investigations conducted for the patient.
- 2.6 The prescribed treatment in each visit.
- 2.7 Referrals to other specialties, if any.
- 2.8 Treatment plan.

2.9 Informed consent in the event of interventions requiring the informed consent in accordance with NHRA policy.

- 2.10 Daily follow-up report of the patient's condition.
- 2.11 Final diagnosis.

2.12 Summary of the medical condition when the patient discharged from the facility and the date of discharge.

3. Medical prescriptions shall include the following data:

- 3.1 The patient's triple name and personal (CPR/ID) number.
- 3.2 Date of examination.
- 3.3 The name of the medicine prescribed in clear letters and the method of use.
- 3.4 Duration of medication.
- 3.5 Name of the facility and address, and the name of the treating physician.
- 3.6 Signature and stamping of the doctor.
- 4. The doctor should follow the following instructions when writing sick leaves:
 - 4.1 The number of days of the sick leave and diagnosis according to the type and nature of work. The duration of the sick leave begins on the day of the medical consultation and not retrospectively, and general practitioners may grant a sick leave not exceeding (3) days, while specialists and consultants are permitted to grant more than (3) days in accordance with the Guidelines adopted by the Supreme Council of Health and published on NHRA web site.
 - 4.2 The doctor must adhere to a clear diagnosis in all sick leave.

4.3 The patient's certificate must be signed by the treating physician and stamped with the facility's stamp.

5. The facility shall implement a policy on how to maintain the confidentiality of data and information. This policy includes the following:

5.1 Identify individuals who can access all data and information and their different categories and identify measures to impose it on employees who violate security and confidentiality of data and information.

5.2 Determining levels of access to patient information when needed.

5.3 Determine access policy for parents and family members to patient information. 6. In the case of electronic data recording, a documented and planned data recovery system used in the event of a computer failure. This system includes computers connected to the system and independent computers.

7. The facility shall apply a system for direct notification of urgent cases to the responsible consultant from any physician who is informed the diagnosis of the patient so that the situation calls for rapid intervention to preserve the patient's life or a member of the patient.

8. Patient files shall be kept either on paper files or electronic, as follows:

8.1 Births and deaths registrations throughout the period of the facility existence, and in case of closure of the facility, the files shall be delivered to NHRA.

8.2 Patients files for five years from the date of the last visit, and when discarded after this period to keep the summary of the medical history for reference when needed.

9. In case of external record keeping, the facility has to follow the laws and regulations in the Kingdom.

Annex (4) Medical, Nursing and Allied Staff

Health Facilities must comply with the following general requirements:

- 1. No medical, nursing or technical staff employed before obtaining a license to practice the profession from NHRA.
- 2. All staff records should be kept in the Human Resources Department of the facility, containing the following information:

2.1. The employee's name, CPR number, license number, approval of the LMRA (for non-Bahrainis) and work contract.

2.2 Curriculum vitae of each employee and certificates obtained.

2.3 Pre-employment medical examination, including preventive immunizations record.

2.4 Privileges granted to practitioners and proof of their periodic review.

2.5 Any other information related to any disciplinary action taken on the employee.

3. In addition to the general requirements referred to in (1) and (2), the following conditions must be met in the medical, nursing and allied professions"

II. <u>Hospitals</u>

Medical staff

- 1. The hospital must have sufficient number of medical staffs from consultants, specialists and residents according to specialization, so that the consultant does not supervise more than 30 beds and the specialist has not more than 20 beds, and providing at least one resident doctor for every 25 beds in a shift.
- 2. Appointed medical staff in each department shall be according to the approved qualifications approved by NHRA, and job description approved by the hospital, and shall not exceed the classification of the license issued by NHRA.
- 3. To appoint a medical director not less than Consultant level with appropriate administrative experience. His/her role in the facility is for the management and supervising on medical staff. Medical Director's responsibilities include overseeing the organization of health care services provided by doctors and working on developing them and ensuring their compliance with the regulations, laws and ethics of the profession in the Kingdom. Moreover, he/she is responsible for any failure or defect in medical care services in the hospital.

- 4. The head of the department should be a full-time consultant doctor and responsible for the obligation of the doctors in the department to provide appropriate health care and workflow and to report any problems that may hinder the work in the department to the medical director. The head of the department is responsible for all medical procedures conducted in the department. The head of department may be replaced by a doctor of the same degree or with a specialist in the event that he/she is on leave or absent for any reason.
- 5. Each hospital must appoint at least one consultant doctor for each existing specialty.
- 6. The admission of patients in the hospital should be under the name of the consultant doctor, who should be responsible for following the patient's condition during their admission in the hospital, and to ensure availability of a physician to follow up the cases on 24 hours base.
- 7. A decision taken in the treatment of a patient should be decided by a no less than a specialist in the usual cases and to be referred to the concerned consultant in complex or critical cases, while the resident doctor should follow up the patient's condition and report to the specialist or consultant if necessary.
- 8. In the case of providing dental services, a general dentist must be provided with at least five (5) years of experience, or specialist or consultant, depending on the type of service, and one dental assistant for each dentist.
- 9. In the absence of the consultant doctor for more than a month must be assigned a doctor of the same specialty to follow up patients.

Nursing staff

- 1. The presence of a qualified head and supervisor of nursing with the appropriate education and experience.
- 2. The number of staff nurses should be suitable to the number of patients as shown in the table below:

Position of health care	Number of	Number of
	patients	Nurses
ICU & Neonatal ICU	I	I
Step down Unit	3	-
CCU Unit	-	—
Operation Theater	-	—
Recovery Room	2	-
Internal Medicine & Surgery	5	-
A&E	4	I
Critical Care in Emergency		-
Delivery Room	2	Midwive I
Antenatal Care	4	I
Psychiatric Ward	6	-
Pediatrics	4	
Other Health care services	4	

3. 20% of the minimum number of nurses should be added to accommodate the annual leave.

Other technical staff

- 1. The necessary technical staff should be provided according to the scope of services provided by the hospital and include, at a minimum, the following:
 - Dental.
 - Laboratory
 - Radiology
 - Pharmacy
 - Physiotherapy
 - Nutrition
 - Ambulance
 - Anesthesia and operation room technicians
 - Respiratory devices
- 2. The person in charge of each department providing these services should have at least a bachelor's degree in the field of specialization, in addition to a qualified technician who is not less than a diploma degree a in a field of specialization.
- 3. The necessary technical teams should be available according to the services provided by the facility. They should include, as a minimum, for every work shift:
 - Technicians / Laboratory Technologist.

- Technician/ Radiology Technologist
- Pharmacist and Pharmacy Technicians.

II. Medical Centers

In addition to the general requirements referred to in (1) and (2), the following conditions must be met in the medical, nursing and allied professions in medical centers:

Medical staff

- 1. The center must have sufficient number of medical staffs from consultants, specialists and residents according to scope of services provided.
- 2. Appointed medical staff must be according to the .approved qualifications approved by NHRA, and job description approved by the center, and shall not exceed the classification of the license issued by NHRA.
- 3. To appoint a medical director of no less than a specialist with a 5 years' experience level with appropriate administrative experience. In specialized or multi- specialized centers and of a GP or a general dentist with 10 years' experience in
- 4. General medical or general dental centers. His/her role in the center is for the management and supervising on medical staff. Medical Director's responsibilities include overseeing the organization of health care services provided by doctors and working on developing them and ensuring their compliance with the regulations, laws and ethics of the profession in the Kingdom. Moreover, he/she is responsible for any failure or defect in medical care services in the hospital.

Nursing staff

- 1. The presence of a qualified head and supervisor of nursing with the appropriate education and experience.
- 2. The number of staff nurses should be suitable to the scope of services and size of the center.

Other technical staff

The necessary technical staff should be provided according to the scope of services provided by the center.

II. <u>Clinics</u>

In addition to the general requirements referred to in (1) and (2), the following conditions must be met in the medical, nursing and allied professions in the clinics:

- 1. A Clinic is licensed only to one doctor
- 2. Clinics are allowed for the following categories:
 - General practitioner with at least 10 years' experience.
 - Specialist.
 - Consultant.
 - General Dentist with at least five years of experience.
- 3. The doctor can work in two separate clinics maximum, in this case the doctor must provide NHRA with a detailed working hours schedule showing the days and hours of work in each of the two clinics.
- 4. Physicians whose specialties require surgical or diagnostic intervention in other health facilities, must obtain the approval of NHRA before commencing work in those facilities accompanied with a copy of the written contract. A consultant physician shall supervise the Specialist doctor in the same specialty.
 - 5. In case the clinic owner is not present in the Kingdom for more than one month, he/she must notify NHRA in writing document not less than two weeks from the date of closure of the clinic.
 - 6. The clinic may be operated by another physician of the same specialty during the owner absence.
 - 7. In the absence of a physician to cover, or in case of NHRA rejection, or when the owner absence exceeded more than a month, the owner should close the clinic during his absence.

Annex (5) Clinics

The following conditions must be met in the clinics:

1. An appointment system. (for private clinics)

2. Policies and procedures applied to all services provided.

3. The medical consultation, examination and treatment rooms shall meet the following requirements:

- 3.1 The area of the examination room shall be not less than 9 square meters in the absence of an examination couch. In the case of presence of a couch, the area shall be not less than 12 square meters, taking into consideration to leave a suitable space to move around the examination couch or chair.
- 3.2 The existence of a sharps waste container and other non-sharp medical waste containing human body fluids
- 3.3 Take in consideration the privacy, confidentiality and safety of patients in the design of rooms.
- 3.4 Provide anti-bacterial and fire curtains in patient care areas.
- 3.5 Provision of single-use inspection bed covers.
- 3.6 There is a two steps ladder and a curtain or a medical barrier for the examination couch.
- 3.7 A washbasin is available in all rooms in the case of direct examination of the patient. The basins shall be deep enough and made of porcelain, stainless steel or solid surface materials and shall be inconsistent with the requirements needed for the medical equipment used.
- 3.8 The availability of examination set sufficient to diagnose the patient correctly according to the specialization of the clinic.
- 3.9 Provide dispensers for hand sanitizers.
- 3.10 Providing education and teaching materials to the patients.

4. The clinic must have the technical equipment according to the specialty of the clinic, including but not limited to the following:

4.1Stethoscope.

4.2Blood pressure device.

4.3 Weighing scale.

4.4 Oral and rectal thermometer.

4.5 Hammer, and tuning fork.

4.6 The Ear, Nose and Throat Examination Kit and Eyes.

4.7 Tongue depressor.

4.8 Single use syringes with sterile needles.

4.9 Oxygen with valves and masks.

4.10 Gloves.

4.11 The minimum amount of Medicines needed to safe patients in emergencies.

4.12 Glucometer.

4.13 A crash-cart with its supplies in the 24-hour clinics.

5. The intravenous solutions and they should not be retained for more than 24 hours after opening.

6. The date of opening should be written on all medicines and preparations used in the clinic.

7. Water placed in oxygen delivering device only when needed.

8. A thermometer provided to record temperature and humidity twice daily in all drug storage locations.

9. If samples of free medicines are accepted, they should have a free sample label and are given free of charge to the patients. If used for educational purposes, the medicine should be removed from the box.



Annex (6) Radiology Services

The following requirements must be met in health facilities that provide radiology services:

I. <u>ESSENTIAL STANDARDS:</u>

1. The facility shall have a manual of radiology services that shall be updated, provided and informed to the concerned staff, such manual should include:

1.1 Scope of radiology services, patient data information forms and preexamination instructions for patients.

1.2 Policies and procedures for radiology services, emergency and radiation leakage policies.

1.3 Instructions for performing radiology tests for women, that includes (a copy of the pregnancy test if available, or consent form).

- 1.4 Roles and responsibilities of the staff concerned;
- 1.5 Records required for radiological examinations and their storage.
- 1.6. The infection control policy adopted by NHRA.
- 1.7 Incident reporting policy adopted by NHRA.
- 1.8 Quality control policy.
- 1.9 Radiation safety policy.
- 1.10 Indicators of performance monitoring, evaluation and improvement
- 1.11 Policy for reporting critical results.
- 1.12 Monitoring TAT (time between collection or receipt of the request and sending out the report);
- 1.13 A list of the equipment, user manual and the means of communication with the maintenance engineer / company.
- 1.14 Quality Evaluation and monitoring with documentation of results and actions taken.

2. Policies and protocols based on the scope of service provided that includes the following:

- 2.1 Administration of intravenous Contrast Media; provided that the patient's signature on a consent is taken indicating that the doctor has explained to him/her the importance of taking contrast media and its potential complications).
- 2.2 Providing check lists for magnetic resonance imaging and any other relevant areas.
- 2.3 Providing consent forms for interventional tests, biopsies and contrast Media

3. Availability of devices and supplies necessary to provide radiology services, depending on the scope of service provided by the facility.

4. The existence of a radiation safety protocol or plan for the protection of staff, patients and the environment that includes at least the following:

4.1 Maintenance of all equipment in accordance with the manufacturer's instructions, compliance with regulatory requirements, inspection of equipment, regular checking by experienced personnel and provision of an updated inspection record.

4.2 Use all radioactive materials in accordance with the manufacturer's guidelines.

4.3 Safety warnings should be posted on doors in clear and appropriate places with an external light that illuminates when radiation is used.

4.4 Take all safety precautions for MRI (metal detector, beds, crash cart, wheelchairs and anesthesia equipment) compatible with the MRI device.

4.5 Monitor the exposure of the employees to radiation regularly by using the thermoluminescent dosimeter (TLD), for all employees in the radiology department and notify the competent authorities in the event of any harm due exposure of an employee and keep a periodic record of the tests.

4.6 Personal radiation protection measures for staff and patients, to limit the amount of exposure to radiation and the use of radiation protection equipment, with its periodic examination and record keeping.

4.7 The availability of a notifying system to the concerned authority of any radiation leak or exposure to any hazardous or radioactive material.

5. Availability of A picture archiving and communication system (PACS)

II. General Engineering Requirements

1. The location of the radiology services should be within easy reach of the emergency department, the operating room and the outpatient clinics, in the event that radiation services are in a hospital or medical center.

2. Radiology department preferably be located on the ground floor of the building. It may be located on the first floor and above if the facility adopted the international vibration and safety standards.

3. Allocation of the area of radiology services in proportion to their function with the need to organize and maintain the devices so as not to affect the quality of work and safety of staff. The following is required in the area allocated to radiology services:

3.1To be adequate and suitable for work.

3.2 Availability of an appropriate storage area.

3.3 Availability of a digital filmless image recording

3.4. Provide a dressing area for patients with privacy.

4. The height of the roof of the radiological room shall comply with the requirements of the manufacturer of medical devices.

5. The radiology room must be designed so that there is sufficient space for movement in the perimeter of the device. The walls of the radiology room shall be shielded with lead to prevent any radioactive leakage according to the manufacturer's standards, and periodic inspection shall be conducted for radiation leakage where applicable.

Consideration should be given to the high probability that the area will require renovation, expansion and / or equipment replacement in the future.

6. The X-ray equipment should be positioned facing a movement-free area, the thickness of the protective lead shield should be doubled if the unit faces otherwise.

7. The area of the radiology room should allow the admission of patient's bed and the crash cart

8. The temperature of each device must be adhered to according to the manufacturer standards and is to be recorded daily.

9. It is prohibited to install or use any device before adhering to the following:

- 9.1 Obtain NHRA and other concerned authorities' approval prior to importation, in accordance to NHRA medical devices regulations guide.
- 9.2 Obtaining the approval of the Authority and other concerned authorities before changing the location of the device or transferring it to another site in the same facility.
- 9.3Following the general rules for avoiding the dangers of electric shock and fire, because of the presence of high electric current, and to place electric transformers in a position that is on the ground and away from water.
- 9.4The facility shall have periodic maintenance of the equipment with a record of the maintenance procedures and dates.

II. <u>Requirements for medical devices</u>

The following conditions shall be met for CT scanning, MRI, nuclear medicine and ultrasound devices:

- 1. CT scan must have a minimum requirement of 16 slices and an MRI should have a magnetic resonance force of at least 1.5 Tesla with the specific required magnetic coils for imaging and specified software for CT and magnetic scans.
- 2. Preservation of the Contrast media for the examination in an appropriate place.
- 3. If there is a need for injecting Contrast media a doctor should be present to inject the patient and to ensure that there is no hypersensitivity of the dye before the injection.
- 4. The need for MRI compatible wheelchair and stretcher bed
- 5. The existence of policies for the handling and transport of radioactive materials used in nuclear imaging of the patient.

- 6. Examine the source of radiation and the rate of radiation emitted from the device on a daily, monthly and annual basis, and maintaining a special record of the readings.
- 7. The presence of a personnel responsible for quality and radiation protection specifying his role in reporting any radiation leakage at the facility.
- 8. The presence of a medical physicist in the department if nuclear radiation services are provided.
- 9. Provide accessories for each device according to the manufacturer specifications.
- 10.Provide detailed instructions to the patient explaining the type of examination and precautions to be taken before and after the examination.
- 11.Crash cart for emergency cases should be allocated close to the radiology department in hospital, and independent radiology centers.
- 12. The ultrasound shall be used according to the scope of service provided by the facility as follows:

12.1.The quality and strength of the device shall be commensurate with the services provided to patients.

12.2.Provide suitable probes according to the services advertised.

12.3. Provide software for the tests offered.

12.4 Provide a digital system for saving images.

12.5 To provide a detailed report on all tests being conducted.

V. Medical and Associate Staff

1. The Radiology Department must have qualified professionals who are licensed to practice the by NHRA

2. The head of radiology services in health facility must be a specialized radiologist with not less than five (5) years of experience.

3. In the event of the provision of radiology services for CT or MRI, a consultant is required to read and write the reports either in a full or par-time job or through outsourcing contract.

4. In the case of the provision of ultrasound services, the radiology technician must be specialized in the field of ultrasound and must operate under the supervision of a radiologist or a doctor who is trained in the service provided

5. The medical centers may contract with specialized radiology centers or teleradiology centers licensed in the Kingdom to report the radiology images acquired by the centers (except for ultrasound).

6. In case of the provision of plain X-ray services only, the facility shall have a certified radiology technician licensed by NHRA to perform the examination provided that the facility contracts with a specialized radiology center or teleradiology center licensed by NHRA for reporting.

V. Requirements to be met in the centers specialized in providing Radiology Referral Services:

In addition to all above requirements, the following specialized requirements shall be available in the radiology referral centers:

- 1. The medical and technical staff shall be managed by a radiologist with a consultant degree.
- 2. The Center shall provide or contract with a sufficient number of consultants, specialists, and technicians according to the workload and scope of service provided.
- 3. The existence of procedure manuals for the various imaging modalities in the Center.
- 4. The existence of policies for the handling and transport of radioactive materials used in nuclear imaging of the patient.
- 5. The Center shall have clear policies defining the responsibility for reporting any radiology images referred to the center from health facilities and the TAT (time between collection or receipt of the request and sending out the report)
- 6. In addition to the above medical imaging devices specifications, an additional magnetic resonance machine (MRI) with less power may be installed only if the main device is at least 1.5 Tesla. It should be used in very limited cases and should not the primary imaging device of the center.

Annex No.7 Laboratory Services

The following conditions should be fulfilled in lab services, whether such lab is an independent or attached to a health facility:

I. Essential Standards

The following requirements must be met in the laboratory services whether the laboratory is independent or affiliated to a health Facility.

- 1. An updated and organized guideline of lab policies and procedures should be available.
- 2. The lab should have a program for quality management, endorsed by the facility management, and available for all the staff working in the lab.
- 3. A laboratory organizational structure should be available in the facility.
- 4. The lab should determine, supervise and manage a documented safety program in accordance with safety instructions of the facility, the program should include the following:
 - 4.1 Providing a comprehensive, updated and endorsed guideline for lab staff safety.
 - 4.2 Applying a fire safety program in accordance with facility's general fire safety plan.
 - 4.2 Labeling all the doors leading to the lab to indicate that such area is dangerous.
 - 4.3 Disposing all sharp wastes (syringes, injections, blades and scalpels) in a fixed anti-perforation, container, labeled with bar code.
 - 4.4 In independent laboratories, eye and body wash areas are available in case of emergency.
 - 4.5 Examining and approving fume suction devices and biological safety chambers, when available at the location.
 - 4.6 Having a system to report on all occupational injuries or diseases that require medical treatment, and register them in special records.
 - 4.7 Having an effective plan to deal with chemical materials management.
- 5. The lab should apply all infection control roles and guiding principles as follows:
 - 5.1 Personal protective equipment, such as (gloves, masks and eye goggles\ facemasks, clothes and lab gowns) should be available and worn if necessary. See Annex No. 40.
 - 5.2 Prohibition of eating and drinking in the laboratory.

- 5.3 All blood samples and body fluids should be transferred properly in leakproof containers.
- 5.4 To determine the scope of clean and contaminated work areas.
- 5.5All the staff should be vaccinated with Hepatitis B vaccine.
- 5.6 Urine and stool samples should be put in fume hood or in a place of negative ventilation to control infection.
- 5.7 Compliance with procedures and regulations for examination, Prevention, treatment and reporting of diseases prescribed by the Regulations and Rules complies with the provisions of Article (50) of the Public Health low promulgated by low No. (34) Of 2018.

6. The lab should set clear and written instruction on the proper way of collecting, dealing with, transferring, and preparing samples. Such instructions include the following:

- 6.1 Patient identification.
- 6.2 Preparing patient methodology.
- 6.3 Collecting samples and labeling them with IDs.
- 6.4 Samples saving.
- 6.5 Storing samples.
- 6.7 Sample transfer conditions.
- 6.8 The method of receiving samples in the laboratory.
- 6.10 Method of disposal of samples after completion of examination

7. The owner of a private lab should keep electronic or paper record to register the following data for each examination that has been conducted in the lab:

7.1 Serial number.

- 7.2 Date of starting the test.
- 7.3 The patient's full name, nationality, age and personal ID number.
- 7.4 Name of treating physician who has requested the test and his address.
- 7.5 Type of required test.
- 7.6 Date of receiving the sample and date of sending its result to the treating physician.

8. The lab should keep instruments and devices in a good functional condition through establishing a system of operating all the devices properly, cleaning them, and monitoring their quality and maintenance. Such system should include, for example, but not limited to the following:

8.1 A guideline of operation and maintenance.

8.2 A maintenance schedule.

8.3 Maintenance records.

- 9. The lab should follow a clear system to get the results of reports including:
 - 9.1 Specified time required for all lab services.
 - 9.2 Determining critical results and the way of reporting them.

10- All solutions and laboratory reagents and materials used for sample testing must be valid.

11. Internal quality check done periodically.

12. The laboratory passes the external quality inspection and the National quality Measurement program for medical laboratories with NHRA and public health.

13. The laboratory provides a barcode system for the registration of samples, which includes the following:

- 13.1. Name.
- 13.2. Personal number.
- 13.3. Date of birth.
- 13.4. Nationality
- 13.5. The file number.
- 13.6. Visit number.
- 13.7. Type of inspection required.

II. Engineering requirements

1. The lab entrance should be firmly closed and entry should only be permitted for staff members.

2. An office should be provided for the manager of the lab and a room for technicians.

3. The ceiling of the Laboratory of histopathology and chemistry laboratories is made of aluminum and equipped with HEPA filter, while simple laboratories have ceilings painted with antibacterial and fungus coating.

4. The area of the laboratory shall be suitable for its function and shall be well organized and shall not affect the quality of the work and the safety of the employees, providing sufficient space according to the services provided in the laboratory, the area allocated to the services of the laboratory is characterized by:

4.1. The presence of water taps and basins made of stainless steel and sufficient sinks.

4.2. The taps should be designed for hand free/ automatic usage according to the standards of infection control.

43. Sufficient number of electricity sockets, and electricity source should be available for use in case of emergency.

4.4. A proper ventilation should be available besides temperature and moisture control.

4.5. A device to monitor temperature, moisture and air pressure should be available.

4.6. Appropriate lighting should be available.

5. Closets and worktables should be designed for medical use, so that they prevent accumulation of germs at the corner and are easily cleaned.

6. A room for washing instruments should be available. As needed.

7. Provision of a sampling room taking into account the patient's safety so that the patient chair easily movable and supports the patient in case of fainting, taking into account the privacy of the patient and persons with disabilities.

8. The highly contagious sample room must be with negative Hepa Filter and staff dressing space before and after entry.

9. Highly contagious specimens must be sterilized before disposal.

10.Maintain passive pressure in the laboratory when dealing with highly contagious substances.

11. Drainage of sewage discharged from the laboratory shall be isolated from the general drainage pipes of the hospital.

12. The devices should be installed and distributed in accordance with the standards of the manufacturer.

13.Customized hand washing area and use of personal protective equipment.

<u>III. Technical Team</u>

1. Unqualified and unlicensed staff are prohibited from working in the lab.

2. A consultant in pathology or a licensed physician in the specialty of the laboratory with a minimum of five (5) years of experience shall supervise general and specialized laboratories and hospital laboratories.

3. The responsibility of supervising and managing the primary laboratories in the private clinics and the clinics of companies, bodies and medical centers is of the doctor in charge of the clinic.

4. A lab technician holding a Bachelor degree should work at the lab with enough number of technician and assistants.

Annex (8)

The facility pharmacy (private pharmacy) and its stores

The following requirements must be met in the private pharmacy services of a health facility

I. Essential Standards

1. The facility must have policies and procedures applied and updated to determine the mechanisms of supervision and control of the management of medicines and their disposal methods, including:

- 1.2 Requesting medicines.
- 1.3 Protection and safety of medicines.
- 1.4 Labeling of medicines.
- 1.5 Dispensing medicines and educating patients on methods of use.
- 1.6 Storage of medicines.
- 1.7 Emergency medicines.
- 1.8 Identification and reporting of drug errors.
- 1.9 Identify report and respond to the adverse effects of medicines.
- 1.10 Recovery and management of drugs withdrawn from the market.
- 1.11 Management of controlled drugs.

2. The facility is committed to selling medicines and medical supplies to its own patients and clients only.

II. <u>Engineering requirements</u>

- 1. The entrance of the pharmacy must within inside the health facility and not from the outside.
- 2. The engineering design of the premises of the pharmacy shall be sufficiently spacious and suitable to allow for adequate movement of the dispensing and preparation of the medicines, with adequate storage space and adequate lighting and ventilation.
- 3. It is preferable to have the pharmacy allocated on the ground floor so that it is accessible from outpatient clinics and departments that benefit from the pharmacy services. In the absence of adequate storage of medicines, the pharmacy's extension shall be vertical, so the principle of accessibility and easy reachability remains.
- 4. Availability of adequate equipment and supplies in pharmacy for the disbursement and preparation of various types of pharmaceuticals.
- 5. Availability of the requirements for keeping records and pharmaceutical prescriptions and other documents.

- 6. The pharmacy should have an electronic library or electronic system for pharmaceutical references to make access to pharmaceutical information easy and accessible to both the pharmacist and the doctor and related services.
- 7. Working hours in the pharmacy clearly defined in the policy and procedures and are advertised and displayed at the entrance to the pharmacy.

III. <u>Safety and security measures</u>

- 1. Security measures shall be taken, including the following:
 - 1.1 Limited access to clinical drugs.
 - 1.2 The existence of clear badges for the names of all workers in the pharmacy.
 - 1.3 Appropriate procedures to close the pharmacy after working hours.
 - 1.4 Locking the doors of the pharmacy and windows during working hours.

1.5 To determine the eligibility of individual members of the pharmacy to carry the pharmacy keys.

1.6 There is a clear policy for employees who are not working in the pharmacy who are authorized to enter the pharmacy after working hours in case of emergency (fire and others).

2. Safety measures that shall be applied shall include but not limited to:

2.1 A list of hazardous substances should be placed in areas where they are stored or used.

2.2 Place safety bulletins for materials in the areas where they are stored or used.

2.3 Provide safety tools to deal with hazardous material spillage in areas where such materials are stored or used.

2.4 Training all employees on how to deal with cases of hazardous materials spillage.

3. The pharmacy should have a system for storing regular medicines (pharmacy, storage area and patient care areas), including

3.1 Storage area suitable for regular medicines with temperature control ranging from 18 to less than 25 ° C around the clock.

3.2 The drugs are stored in an orderly manner to avoid confusion. An information label shall be placed on the name of the medicine and its expiry date. No medicines shall be placed on the ground or stacked on the upper shelves, and a distance of 45 cm should be kept away from the ceiling.

3.3 Chemical disinfectants, sterilizers and medicines intended for external use shall be stored separately from drugs for internal use and injectable drugs.

3.4 The pharmacy should have a system of storage of medicines and vaccines that need storage at cold temperatures in the pharmacy, storage area and patient care areas, including:

3.4.1 Providing refrigerators to store vaccines and medicines that need to be stored at cold temperatures.

3.4.2 Lists the contents of the refrigerator (medicines and pharmaceutical products) and their expiry dates on the refrigerator door.

3.4.3 The temperature and humidity of refrigerators are recorded twice a day (morning and evening).

3.4.4 Maintain appropriate temperature and humidity for refrigerators between 2 and 8 $^{\circ}$ C.

3.4.5 Maintain the appropriate temperature for freezers between -10 to -25 degrees Celsius.

3.4.6 Provide all refrigerators and freezers with a suitable thermometer or similar devices to measure temperature and humidity as well as to maintain records of these temperature and humidity rates.

3.4.7 The existence of policies and procedures applied and documented to deal with medicines in the event of a power outage or when the temperature or humidity exceeds the permissible limit.

3.4.8 It is prohibited to place foods, beverages, and biological samples in pharmaceutical refrigerators.

4. The pharmacy must have a system to ensure the supply of medicines, bags and medications for emergencies and crash carts. This system shall include the following:4.1. Develop and observe a set of guidelines for the crash cart and its medicines.

4.2. To prevent the loss of emergency medicines or stealing them from the cart by using a safety plastic locker.

4.3. The safety plastic lockers shall be stored in a safe place supervised by the pharmacy or nursing staff.

4.4. Monitor emergency medicines and replace them in a timely manner after use, expiry or damage.

4.5. Documenting the periodic examination of the crash cart and emergency bag (not less than once per month) and keep records at the pharmacy.

- 5. The existence of a system or a record to identify expired and damaged medicines and how to deal with them.
- 6. The existence of a system and record for the description, treatment and disposal of narcotic drugs, sedatives and other drugs under the laws and regulations.

IV. The technical staff

- 1. The pharmacy shall have qualified personnel and hold licenses to practice the profession.
- 2. The director/head of the pharmacy department should be a registered pharmacist (holds a bachelor's degree in pharmacy and holds a license to practice the profession from NHRA).
- 3. If the pharmacy is operating 24 hours, at least one pharmacist should work in each shift.
- 4. If a pharmacy technician appointed to work in a pharmacy, their work shall be under the supervision of a qualified pharmacist.
Annex (9) Emergency and Ambulance services and their Medical, Nursing & Allied health staff

I. <u>Emergency services</u>

The following requirements must be met in hospital emergency department:

1. Essential standards

Having policies and procedures to show how to provide clinical care in emergency department; such policies and procedures include but not limited to the following: Procedures for evaluating emergency cases, and patient triaging policy.

- 1.1. Management of traumas.
- 1.2. The procedures in dealing with the patients who leave against medical advice.
- 1.3. Providing care for patients who are not qualified to take care of themselves.
- 1.4. Providing care for underage patients.
- 1.5. Protocols of managing some urgent and common emergency cases, such as asthma, chest pains, coma and stroke...etc.
- 1.6. Managing the cases of suspicious medico-legal nature, such as alcoholism, drug addiction, sexual abuse, and family violence and child abuse...etc...
- 1.7. Policies to deal with infectious diseases.
- 1.8. Having a written policy for health care professionals that determine the various roles assigned to the health care team on how to transfer patients if the facility cannot provide them with necessary care.

2.Technical and engineering preparations:

- 2.1. The following general requirements must be met:
 - 2.1.1. Easy access to the emergency department.

2.1.2. There is a dedicated entrance for the emergency department and the doors are automatically opened.

- 2.1.3. Provide a slope at the emergency entrance.
- 2.1.4. The width of the corridor shall not be less than 3 m.
- 2.1.5. Provide a consultation room in the emergency department.

2.2. Emergency room should be supplied with crash cart equipped with the following supplies:

- 2.1. Crash cart medications.
- 2.2. Equipment to examine and manage the patient
- 2.3. ECG device.
- 2.4. Equipment to measure the patient's vital signs
- 2.5. Cardiopulmonary resuscitation instruments.
- 2.6. All emergency drugs (such as Valium, Morphine and Adrenaline, etc.)

3. The emergency room should be supplied with equipment and instruments determined by World Health Organization For example, it should be supplied with the following equipment proper for all ages:

3.1. A Portable X-ray machine.

3.2. Equipment for continuous patient monitoring (Central Station)

3.3. Resuscitators.

3.4. Cardiopulmonary resuscitation equipment.

3.5. Examinations and treatment instruments.

3.6. Set of instruments for gastric wash.

3.7. Intravenous injection pumps.

3.8. Ventilator.

7.9. Medical gas with a pipeline hanged on the wall

7.10. Patient stability instruments: hardboards and neck collars, etc.

7.11. A set of emergency obstetric instruments.

3.12. Emergency bed (stretcher)

4. The hospital emergency department must have at least one isolation room that meets the following requirements:

4.1 The room dimensions should be 4x4 meter at a minimum and should have a separate bathroom.

4.2 Equipped with passive pressure system.

4.3 A buffer zone between isolation room and the rest of the department should exist. It should also have isolating doors and should be Supplied with bacterial purifier, washbasins and allocated area to wear the personal protective equipment. (PPE).

II. Ambulance services

The facility should provide an ambulance according to the specifications of Gulf Cooperation Council (GCC) countries and terms stipulated in legislations, including:

1. Ambulances should be type 2 or 3 with the length of 135 or 155 cm based on uses. Patient's compartment dimensions should, at least, be as follows:

1.1 The length is 295 cm.

1.2 Width is 260 cm.

1.3 The height is 190 cm.

1.4 The international standards (KKK) of ambulance design should be adopted. The period from the year of manufacturing the ambulance to using it should not exceed more than (5) years.

1.5 The word "ambulance" should be written down using a clear color in both Arabic and English on the two sides of the ambulance, on its back and on its top.

1.6 The light bar should be fixed on the top of the car.

1.7 The ambulance should be supplied with a warning siren to warn the other drivers on the road that the ambulance is approaching.

1.8 The car interior should be prepared for at least a patient and a paramedic and should enable the driver and the paramedic to communicate freely.

2. The ambulance should be well-equipped with the following equipment that should be firmly fixed inside the ambulance and that should be proper for all ages and weights

2.1 Vital signs monitoring instruments and electrocardiogram.

2.2 Patient stability instruments: hardboards and neck collars, stroller, back support, different sizes of splints.

2.3 Portable oxygen cylinder.

2.4 Apparatus to supply Carbon Dioxide and different sizes of medical masks.

- 2.5 Tracheostomy tubes (sizes proper for adults, children and babies).
- 2.6 Medical gas and suction.
- 2.7 Cardiopulmonary resuscitator.
- 2.8 A ventilator.
- 2.9 A fully equipped accidents and injuries kit.
- 2.10 Medical gloves of different sizes.
- 2.11 Medical supplies, such as injections, syringes and bandages
- 2.12 Fire extinguisher, etc.

3. The ambulance and its preparations should be subject to periodical, regular maintenance, and the hospital should maintain a record to prove implementing such procedures of maintenance.

III. The medical, nursing and allied health staff

The following requirements must be met in the medical and nursing staff in emergency and ambulance services Department:

1. The head of the emergency department should be a medical consultant, specialized, qualified and licensed from the NHRA to practice the profession. A specialized, qualified, licensed physician with sufficient experience should be available in each shift.

2. The nurse in charge at emergency department should be licensed and qualified nurse with experience and qualification; assign Sufficient number of nurses in accordance with the scope of provided service.

3. A qualified licensed paramedic, emergency technician or licensed nurse should be available.

4. All emergency staff should be certified with Basic Cardiac Life Support (BCLS) · of Advanced Cardiac Life Support (ACLS) Advanced Trauma Life Support training course (ATLS) ·Cardiac Life Support of Children (PALS) and (PHTLS) for paramedics

Annex 10

Physiotherapy services and rehabilitation

The following requirements shall be fulfilled for the physiotherapy services provided in an independent center or a part of a health facility:

I. <u>Policies and procedures of the provided treatment</u>

should include the following, but not limited to :

- 1. Referral procedures by the doctor and the mechanism of communicating with doctors.
- 2. Safety procedures.
- 3. Infection control guiding principles.
- 4. Injuries and accidents management.
- 5. Dealing with patients and post-operative cases.
- 6. Treatment procedures of outpatient department and in-patients.
- 7. Periodical examination of the water of hydrotherapy and sterilizing it.
- 8. Disinfecting and cleaning procedures for electrotherapy apparatuses and their accessories.

II. <u>Engineering requirements for physiotherapy services</u>

The following requirements shall be available in facilities providing physiotherapy services:

- 1. Upon designing the physiotherapy department, it should be taken into consideration that it is located at the ground floor, and to be as much as possible close to the entry of the facility and the area of getting the patient on/off and car parking area., and to be well exposed for sun and air.
- 2. Consider an entrance with automatic doors with width of 2 meters to enable the patients to get in and out easily with the least assistance, putting into consideration to that other doors in the department are wide enough (not less than 1.2 meters) to permit the wheel chair to pass through.
- 3. Provide A reception office and waiting halls for the outpatients.
- 4. The space allocated for the bed in the room should not be less than 8 m², while the space of the private rooms should be 12 m^2 at a minimum
- 5. Provided a close by crash cart. (in hospitals only)
- 6. Each room should be furnished with furniture that is easy to clean and disinfect.
- 7. The patients' beds level should be automatically controlled
- 8. All rooms should be provided with air conditioning that can be controlled from inside the rooms.

- 9. The floors should be smooth and easy to clean, and the walls of treatment and admission rooms in the facilities shall be coated with antibacterial paint, which can be cleaned easily and withstand repeated cleaning.
- 10.Means to get rid of wastes, bandages and surgical wastes should be provided.
- 11.Provide Enough toilets for men and women.
- 12.Proper changing rooms before and after the therapy session should be provided, taking into consideration the privacy of each patient.
- 13. Toilets should be suitable and prepared for those with special needs, and should permit wheel chairs to get in\out.
- 14. Providing a room for storing devices and equipment.
- 15.Providing rooms for the keeping staff's personal items (women\men)
- 16.Providing toilets for the staff (women\men)
- 17.Providing hand sanitizer in all rooms and treatment areas
- 18.If a physiotherapy unit is provided in outpatient clinics, the following shall be considered:
 - 18.1. An allocated room for examination and electrotherapy.

18.2 Allocated rooms of certain examination types, supplied with specific devices for evaluation, such as neurological, muscular, equilibrium examinations and walk analysis... etc.

18.3 Leaser treatment room; taking into consideration that the necessary requirement and the safety of staff and patients should be fulfilled.

18.4 Work desks should be available for physiotherapists.

18.5 Semi-private rooms allocated together in the same treatment area close to the open exercise treatment hall (within a specific area in a way that permits monitoring of patients and supervising their treatment).

18.6 Providing a room for wax devises, heat compresses, ice and towels.

19. Open exercise treatment hall:

19.1 The area of the hall shall be proportional to the equipment and tools used for the treatment.

It should contain at least one wall covered with mirrors.

19.2 The floor should be suitable for exercise halls and easy to be disinfected and clean.

19.3 The availability of a wall television\ projector to motivate the patients

19.4 Consider the availability of a minimum number of Wall barriers and columns 20. When providing a Hydrotherapy treatment unit, it should include:

20.1 Swimming pool for hydrotherapy size shall be compatible with the number of patients expected to be received at the unit: small (enough for 5 patients), or medium (enough for 20 patients), or large (enough for more than 20 patients).

20.2 Changing rooms for patients containing closets for the patient's belonging.

20.3 Bathrooms to be used before\after therapy: at least 2 for the small swimming pools, 4 for the medium swimming pool and 6 for the large swimming pools, considering that the treatment sessions are separated for both sexes.

20.4 Separated toilets for both men and women.

20.5 Lifting device for hydrotherapy patients.

20.6 Providing a room for the equipment, tools of hydrotherapy

20.7 Pump room.

Areas for clean towels and another for the unclean ones.

21. Rehabilitation premises for in-patients, shall include:

21.1 Equipped exercise hall suitable for the type of the provided treatment.

21.2 A workstation for the physiotherapy with the percentage of 1:1 for each therapist.

21.3 Linen and towels.

22. Neurological physiotherapy and or Children physiotherapy unit shall contain a semiprivate room allocated together in the same treatment area close to the open exercise treatment hall (within a specific area in a way that permit monitoring of patients and supervising their treatment). It should be equipped with the necessary equipment and devices

23. Occupational therapy unit shall be allocated in appropriate place and well equipped. 24. Paraffin wax treatment: Wax bath should be kept at temperature between 42-52

25 Hydro-collator heating machine: Hot packs are submerged in water and left to obtain an ambient temperature between 75-80

III. Medical Equipment and supplies

The department should be equipped with new equipment installed and used according to the standards of the manufacturer to facilitate all kinds of physiotherapies, including but not limited to:

- 1. Medical weights cart.
- 2. Climbing exercising Ladders.
- 3. Exercise mats.
- 4. Treadmills.
- 5. Exercise bikes.
- 6. Stairs machines.
- 7. Balance bars and corridor
- 8. Wheel chairs, crutches and walking frames.
- 9. Water analyzer for hydrotherapy pool.
- 10.Movable lifting patient's devices, especially for in-patients, neurological and bedridden patients.
- 11.Balance exercises equipment.
- 12. Medical adhesive tapes Kinsio-taping
- 13.Electrotherapy devices, including but not limited to:
 - 13.1 Leaser.
 - 13.2 Shortwaves.
 - 13.3 Paraffin wax.
 - 13.4 Ice and hot compresses devices.

13.5 Infrared rays.13.6 Ultra violet rays13.7 Ultrasound.13.8 Electric activators.13.9 Radial shockwave therapy.

IV. <u>Physiotherapy professionals</u>

The following are required in the physiotherapy professionals of health facilities providing physiotherapy and rehabilitation services:

1. The position of the department/center chairman should be assigned to a specialized physiotherapist who has a bachelor degree and has a minimum of two-year-experience in his field of specialization. He/she should assign an appropriately qualified staff experienced to provided physiotherapy and rehabilitation services according to the specialties in the facility; (Orthopedic, neurology, pediatrics and newborn, elderly, sport injuries, cardiac and respiratory, woman health, hydrotherapy and occupational therapy).

2. Licensed Physiotherapists should be available in the department of physiotherapy/center; they should have practical experience according to the profession classification accredit by NHRA. The number of the physiotherapists should be compatible with the work load and the quantity of the provided services based on the facility classification, category and specialty.

Annex (11) Operations Theater Room

The following conditions must be met in the operations rooms of hospitals and medical centers providing surgical services:

I. Policies and procedures for Major and minor surgery rooms:

Policies and procedures define responsibilities in operating theaters and include but not limited to the following:

1. Verifying patient's identity, operation and its site, must be by at least two persons (the correct patient, the correct position and the correct surgery).

2. Infection control guidelines.

3. Sterilization of equipment and surgical instruments

4. Surgical supplies and the number of surgical instruments and documents required for them.

5. Medical and technical responsibilities.

6. Policies dealing and maintenance of medical devices.

II. Engineering requirements to be available in the room of major and minor surgeries

- 1. Taking into account easy accessibility to the room location from the ICU, emergency and words.
- 2. Availability of sterilization capabilities for sterilizing modern machines, tools, equipment, dressings and medical supplies.
- 3. There must be a clear segregation between the operating rooms and the rest of the facility, to insure sterility.
- 4. The floor of the operating room shall be covered with an easy to clean and smooth material.
- 5. The doors of the operating room shall be efficient and covered with melamine or stainless steel, one piece, free of edges and spaces.
- 6. The operating room door shall be wide with a width not less than 2.1 meters and open automatically.
- 7. The width of operating bed shall be between 0.9 to 1.2 meters, and may reach 2.1 meter in surgeries that needs 2 nurses,
- 8. Electrical connections shall be covered to avoid any electrical contact.
- 9. The operating room shall be equipped with a strong, round and large light, installed in the ceiling above the operating table. It can be moved in all directions as needed, and the lighting shall be sufficient and from different angles and lamps shall not reflect any shadow.
- 10.A room for changing clothes, and for washing the hands of surgeons and nurses to be attached to the major and minor operating room.
- 11. The room should be curved at angles.

12. The room shall be equipped with a stainless-steel washbasin and edges free.

13. The walls and floors shall be covered with a smooth anti-bacterial coating (GLOSS PAINT OR SEMI-GLOSS PAINT).

III. Engineering requirements for the major surgery rooms:

1. The major operations room shall not be less than 30 square meters and the length of any side not less than 5 meters.

2. Adequate ventilation and changes are recommended and air change is recommended 15 times per hour (acceptable range is 12-20 times per hour according to the American Heating Association).

3. The operating room shall be equipped with central air conditioning to allow the air to be replaced with 100% pure air with the use of the HEPA (positive) air filter relative to the adjacent preparation areas, with two air supply ports with HEPA filters placed in the ceiling or near it, and not directed at the surgical table.

4. The availability of a special generator that works automatically in case of power failure.

5. Attach to the operating room, a recovery room equipped with all the necessary equipment for the ambulance.

6. Provide the room with modern anesthesia and recovery devices and various means of dealing with emergencies, and to provide centralized sources of medical gases used in anesthesia.

7. The presence of a room for medical waste close to the major operating room.

8. A room for the cleaners to be close to the operating room.

9. A special outlet for waste disposal, bandages, clothing and used surgical waste should be available.

10. Taking into account the separation of sterile areas.

11. Preparation of a special corridor for the transfer of waste of non-sterile materials from the operating room to the waste room and sterilization section.

12. The presence of a room for medical staff close to the major operating room.

13. A store for medical devices and another for medical supplies.

14. Toilets must be inside the section.

15. The sterilization room should be close to the operating room and the air pressure should be negative compared to any neighboring area, with a minimum of 10 air changes per hour.

16. The recovery area should be equipped to meet the needs of the patient (minimum of one bed per operating room).

17. The presence of an office of the head of operations.

IV. Medical equipment and supplies for the operating rooms:

1. The major surgical rooms:

The Anesthesia Room, the Recovery Room and the Operating Room are equipped with the following equipment to meet the patient's needs, including, but not limited to:

1.1 Device to examine the vital signs of the patient.

1.2 Audio-visual oxygen Failure Warning System with Pressure, inadequate volume delivery, and devices disconnection alarm.

1.3 System of safety of delivery of medical gases.

1.4 Medical extension devices and suction in the wall.

1.5 Monitoring devices for analyzing anesthetics

1.6 ECG device.

1.7 Cardiac and pulmonary resuscitation equipment.

1.8 Ventilators.

1.9 Crash cart with supplies and a cardiopulmonary resuscitator.

2. Minor operations rooms:

2.1 The room in which the minor operations are carried out shall not be less than 16 square meters and the length of any side shall not be less than 4 meters.

2.2 Provide the room with the necessary means to deal with emergencies.

2.3 A waste disposal room, not required to be close to the minor operating room.

3. Medical devices and supplies:

3.1 A list of all medicines used in the anesthesia process should be available, including the methodology of anesthesia when they are performed and appropriate dosage for the age groups, the date of expiry and quantity, and are reviewed periodically (twice daily).

3.2 To examine and undergo regular maintenance of all anesthesia devices and to establish a record of preventive maintenance and regular examination.

V. medical and nursing staff

1. A properly qualified medical consultant shall manage the operating theaters, while minor surgery room in medical centers may be managed by a specialist doctor.

2. A qualified nurse / nurse trained to provide appropriate care when performing surgeries in the operating room.

Annex (12) Intensive Care Units

The following conditions must be met in the hospital's intensive care units:

I. Policies and Procedures

Policies and procedures define responsibilities in intensive care units that include, but are not limited to:

- 1. Procedures for transfer, admission and discharge of patients.
- 2- Medical and technical responsibilities for the staff in the unit.
- 3. Conditions and controls of the visit.
- 4. Infection control guidelines.
- 5. Policies dealing with and maintenance of medical devices.

II. Engineering requirements for units / department of Intensive care

In addition to the general requirements set forth in Annex 1, the following special requirements shall be met in the intensive care units:

One bed is available with intensive care for every ten beds in the hospital.

2- The location of the unit / department should be near the operation room and emergency.

3 - The beds should be separated from each other taking into account the privacy of the patient.

4 -The total area of the room should be 12 square meters per bed.

5 -Hand-washbasins are made of stainless steel with a washbasin for every four beds.

6 -At least one insulation chamber equipped with a passive pressure system.

7 - Bed to be placed in the direction of the Qiblah according to Islamic law whenever possible.

8 -Visible by nurses (glass wall or closed window).

9-Allocating a hand-washing area and using personal protection equipment.

III. <u>Medical devices and supplies</u>

1. The intensive care units shall be supplied with the following medical devices and supplies:

- 1.1 Artificial ventilation equipment
- 1.2 Tracheotomy tool kit.
- 1.3 Crash cart equipped with all emergency supplies and medicines.
- 1.4 Pulmonary resuscitation equipment.
- 1.5 Blood oxygen saturation and biometric indicators.
- 1.6 Continuous monitoring system (Central Station).
- 1.7 Blood transfusion supplies.

1.8 Medical gas supplies and suction double the number of supplies available in other departments.

1.9 The provision of all necessary instruments and supplies needed for tracheostomy and ventilator; and checked regularly.

2. The neonatal intensive care unit shall be provided with the necessary equipment and supplies, including at least the following:

- 2.1 Respirators.
- 2.2 Artificial ventilation equipment
- 2.3 Crash cart equipped with all emergency supplies and medicines.
- 2.4 Blood oxygen saturation.
- 2.5 Neonatal resuscitation equipment.
- 2.6 Incubators.

2.7 Medical gas supplies and suction double the number available in other departments.

- 2.8 Portable incubator with portable respirator.
- 2.9 Injection pumps.
- 2.10 Tracheotomy tools kits.

3. The provision of all needed instruments; tracheostomy kits and respirators shall be checked regularly.

V. Medical and nursing staff

- 1. The head of the intensive care unit shall be a consultant who is qualified in the field of intensive care or anesthesia, has the experience, and licensed by NHRA.
- 2. The head of the neonatal intensive care unit shall be a qualified doctor and trained in the field of newborns.
- 3. A nurse shall be assigned for each patient for 24 hours period; in accordance with the table in Annex (4).

- 4. The Unit shall have sufficient qualified, experienced and trained staff in the field of intensive care and licensed by NHRA.
- 5. All Professionals working in the unit must receive training and certificates approved in ACLS, CPS and neonatal resuscitation (NRP) as appropriate.
- 6. Doctors must be available on 24 hours bases in the intensive care unit.



Annex (13) Labour Department

The following conditions should be met in the labor department of Labour in hospitals only:

I. <u>Policies and Procedures</u>

Policies and procedures define responsibilities in the Labour department which include, but are not limited to:

- 1. Procedures of admission, referral and discharge.
- 2. Medical and technical responsibilities.
- 3. Visiting hour's conditions and controls.
- 4. Infection control guidelines.
- 5. Policies dealing with and maintenance of medical devices.
- 6. Policy of communication with other disciplines and specialties.

II. Engineering Requirements

In addition to the general requirements mentioned in Annex 1, the following special requirements should be met:

- 1. The maternity rooms should be separated from each other, taking into consideration patient's privacy.
- 2. Internal control of room air condition according to patient needs, taking into consideration not to be less than 24 degrees Celsius to ensure the safety of supplies or medicines in the room.
- 3. The entrance of the department shall be limited to the employees only.
- 4. An operating room should be available inside or near the department.
- 5. Preferably the location of the department near the emergency, operations and inpatient wards.
- 6. Availability of calling system for the nurses by the patient.
- 7. Availability of a private toilet in each room in the Department, taking into account the existence of hand support to help people with disabilities.
- 8. The interior design of the rooms should be comfortable and safe for the patient, taking into account their needs.
- 9. The size of the room should not be less than 12 square meters.
- 10. The door width should not be less than 2 m.
- 11. The floor of the room must be smooth and easy to clean, and the walls should be coated with antibacterial paint and easily to clean.
- 12. Allocate a hand washbasin and personal protection equipment specified area.

VI. Equipment and medical supplies

The Labour department must be equipped with the following equipment:

- 1. A fully equipped crash cart with emergency supplies, medicines, and defibrillator.
- 2. A screen for monitoring vital signs.
- 3. IV injection pumps.
- 4. Blood glucose meter.
- 5. Screen of fetal ECG / FIT for twins.
- 6. Hook of amniotic fluid.
- 7. Surgical aids (surgical forceps).
- 8. Neonatal Incubators.
- 9. Neonatal ventilator supplies.
- 10. Provision of the following medicines:
 - Centocinone.
 - Methergine
 - Magnesium sulphate.
 - Calcium gluconate.
 - Ritodrin.
 - Zylocene.
 - Hydralazine.
 - Valium.
 - Prostaglandin.
 - Narcan.

VII. Medical and Nursing Staff

- 1. A qualified gynecologist and obstetrician shall be appointed as head of obstetrics and gynecology department.
- 2. A qualified midwife, trained in Labour and childbirth will be responsible for the unit or trained nurse to assist the doctor, provided that the doctor performs the full delivery.
- 2. A sufficient number of staffs in the unit and during work shifts to suit the number of patients and the severity of their condition.
- 3. The presence of a pediatrician to attend Labour and delivery and must be presented in the case of a caesarean section.

Annex (14) Inpatient ward

Inpatient ward shall be available only in hospitals, and the following requirements shall be met:

I. Policies and Procedures:

Policies and procedures define the responsibilities in the inpatient ward that include, but are not limited to, the following:

- 1. Procedures of referring, admitting and discharging patients.
- 2. Medical and technical responsibilities.
- 3. Terms and controls of the visit.
- 4. Infection control guidelines.
- 5. The management of dealing with accidents and injuries.
- 6. Incidents and medical errors reporting policy.
- 7. Policies of dealing with stored drugs in the ward, and the policy of medical devices and their maintenance.
- 8. Policy of communication with other specialties.
- 9. Policies of emergency conditions alert.

II. Medical devices and Supplies:

- 1. Inpatient ward shall be supplied by the necessary requirements, which shall include at least:
 - 1.1 Crash cart prepared with the supplies and drugs of emergency cases.
 - 1.2 CPR equipment.
 - 1.3 Blood transfusion pumps.
 - 1.4 To Regular ensure the availability and functionality of all instruments and devices that are necessary for the endotracheal procedure and ventilation.
- 2. Rooms shall be provided with the necessary requirements, including at least:
 - 2.1 Oxygen saturation measure and vital signs monitoring screen.
 - 2.2 Providing the patient with a system to call the nurses.
 - 2.3 Supplies of medical gas and suction for each bed.

III: Engineering requirements:

- 1. The space around the bed in the ward or in the shared room should not be less than nine square meters. The private rooms shall not be less than 12 square meters.
- 2. Hand washbasins and/or hand sanitizer should be available in each room.
- 3. Each room should be supplied with furniture that is easy-to-clean and disinfect.
- 4. The room should be painted with an easy-to-clean paint.
- 5. Provide sufficient general lighting and movable central illumination.
- 6. The size of the doors of the rooms should be 2 meters for easy access of patient's bed.

- 7. The room's windows should provide natural lighting.
- 8. Anti-bacteria, or washable and easy to clean curtains should be available.
- 9. Patients' beds levels should be automatically controlled.
- 10. All rooms should be supplied with air conditioning that can be controlled from inside the rooms.
- 11.Provide adequate toilets appropriate to the beds numbers in the shared rooms and suites, provided that the ratio of toilet to beds is not less than 1:6.
- 12.A space of not less than one meter and a half between each two beds if there is more than a bed in the room.
- 13.All rooms must have for each bed at least a closet and a chair for the companion.
- 14. The nurse's office should be located in the middle of the ward for easy and quick movement between the rooms.
- 15.A room for doctor on call should be provided in the department or nearby to it.
- 16.Inpatient rooms should be as far away as possible from streets and parking. The wall should be sound-proof in order not to permit the sound to pass through rooms. The head of the beds of those patients who cannot move should be put towards Qibla.
- 17.An isolation room should be and should meet the following requirements:

17.1 The dimensions of the room should not be less than 12 square meters with a toilet.

17.2 Have a separate air conditioning with negative pressure.

IV. Medical and nursing staff:

1. A consultant should be assigned as a head for each specialty department in accordance with the department specialty.

2. At least one resident doctor is assigned for each ward.

3. The chief of nursing team in each department should be a qualified nurse with not less than a bachelor degree.

4. Each department shall be allocated a sufficient number of nursing staff as provided in Annex number (4).

Annex (15) Oral and dental clinics

The following requirements should be met in oral and dental clinics in health facilities providing oral and dental services:

I. <u>Policies and Procedures</u>

Define policies, procedures and responsibilities in dental clinics which include, but are not limited to:

- 1. The policy of reporting medical errors.
- 2. Policies dealing with and maintenance of medical devices.
- 3. Policy of communication with other disciplines.
- 4. Medical and technical responsibilities.
- 5. Infection control guidelines.
- 6. Dealing with accidents and injuries.
- 7. Dealing with medical emergencies
- 8. Policy of Assessment the need for prophylactic antibiotics for each patient.
- 9. Policy of dental treatment
- 10. Policy of Dental Records documentation
- 11. Policy on procedural sedation/anesthesia which includes I.V. sedation and/or nitrous oxide and only privileged dentists (who are trained & certified) are allowed to administer it.

II. Medical devices and equipment to be available in dental clinics

The dental unit with its accessories, other diagnostic and treatment devices are equipped in the dental clinic to carry out the work in a safe and healthy manner according to the international quality and safety standards. To consider that the dental chair must fit the work of the dentist's hand whether it is from the left or right side.

A. The dental unit shall include:

1. **Dental chair:** where the patient set on it to receive the dental treatment accordingly.

2. Dental Chair right/left hand accessory:

- 2.2 Patient's waste wash basin with cup holder and water supply.
- 2.3<u>Saliva Suction Ejector:</u> Standard suction device for suctioning of the saliva.
- 2.4 <u>Surgical Suction Ejector</u>: High-speed surgical suction device for suctioning of the blood and other material when needed.

- 3 Dental Cart Unit left/right hand accessory:
 - 3.1 Hand control panel: has control buttons to fill the water cup or move the dental chair or control lighting as required.
 - 3.2 High-speed dental drill or hand-piece: A large number of high-speed dental drill or hand-piece used to perform a variety of common <u>dental procedures</u>, easy to be sterilized and should be one hand piece per patient.
 - 3.3**Low-speed dental drill or hand-piece:** A sufficient number of low-speed dental drill or hand-piece with either straight or contra angle heads, easy to be sterilized and should be one hand piece per patient.
 - 3.4<u>An ultrasonic hand piece scalar</u>: to remove calculus and calcification from the tooth surfaces works with acoustic oscillations and has a suitable number of metal scalar tips/heads easy to be sterilized and only one tip per patient.
 - 3.5 Three ways Air & Water Syringe and its Nozzles: to pump air, water, and the two together, that are easy to sterilize and one nozzles per patient.
- 4 **Foot control Pedal:** This control to dental chair unit movement and its accessories power as required.
- 5 **Dental light device:** this fixed on a free-motion holder with shadow less lighting and prevents eye strain
- 6 **Dental stools:** Two dental stools, one for dentist and another for the dental assistant that can be moved up and down and back adjusted as required.
- 7 **Mobile Dental Cabinet:** is a mobile storage cabinet for dental instruments and medical and chemical materials and to be allocated close to the dentist to facilitate his work.
- 8 **Mounted Dental Tray Holder:** for the placement of dental instruments close to the hand of the dentist to easily treat the patient.
- 9 **Compressor Machine:** to pump air to the whole dental unit in order the dental unit can easily operate and dentist can perform dental treatment. It should be placed in a safe place outside the dental clinic.
- 10 **Suction Aspiration Machine:** have a power to aspire patient's saliva, fluids and blood connected directly to the dental unit but should be kept in a safe place outside the dental clinic.

B. <u>Dental Diagnostic Devices:</u>

- 1. <u>Per-Apical X-ray:</u> a wall mounted regular or digital Per-Apical X-ray device adjacent to the dental chair. The standard x-ray arm is easy to move to the other side of the patient's head. In case of digital Per-Apical X-ray, the adult and pediatric sensors should be connected to a computer and color printer.
- 2. <u>Ortho-Pantomo-Ggram device (OPG)</u>: should be placed in a separate room away from the dental clinic with its wall and door is lined with led material, according to Supreme Council for the Environment.
- 3. <u>Leaded Aprons</u> for patient radiation protection.

C. Dental Treatment Devices, materials & Instruments:

- 1. Dental Light Cure Device: this device is used for composite fillings material that used to treat the anterior and posterior teeth.
- 2. <u>Amalgamator Device</u>: this device is used for Amalgam fillings material that used to treat the anterior and posterior teeth.
- 3. <u>Specialized dental treatment devices</u>: for the treatment of patients based on the dental specialty clinic (such as the treatment of periodontal disease, dental implants, orthodontics, oro-maxillofacial surgery, prosthodontics, restorative dentistry and others).
- 4. <u>Dental Materials</u>: dental, medical and chemical materials are used in dental clinic for various oral and dental disease accordingly.
- 5. **Dental Instruments:** are used in the dental clinic for the purpose of diagnosis, treatment the patient. Those dental instrument must be made from anti-rust material and should be used one instrument per patient.
- 6. <u>Sharp Container:</u> to store the sharp wastes marked with the date of commencement of use.
- 7. <u>Medical & Biological Waste Containers:</u> to store dental waste, including paper, gloves, x-ray films, ruminants of amalgams materials and other to store the biological dental waste, including liquids / parts of the human body such as teeth.
- 8. <u>**Refrigerator**</u>: to store dental, medical and chemical materials.

- 9. <u>Thermo-Luminescent Dosimeter (TLD)</u>: for both the dentist and the dental assistant if radiology service provided are in the clinic.
- 10.<u>Aluminum cabinets</u>: for the storage of dental, medical and chemical tools and materials for the use in dental clinic.

II. <u>The engineering requirements to be available in the dental clinic</u>

- 1. The clinic should not be less than 12 square meters in size, leaving one square meter around the chair for the freedom of movement and safety of both the dentists and the assistant. The area of the clinic should be suitable for the care of patients with disabilities and wheelchair access.
- 2. The wall must have a barrier for radiation leakage and confirmed by a license from the Supreme Environment Council. (according to type of radiology device)
- 3. The floor of the room must be smooth and easy to clean. The walls of the treatment room shall be coated with antibacterial paint, which can be cleaned easily and can be repeated for cleaning.
- 4. In case that the clinic is allocated in the upper floors, elevators must be Available.

Take into account the privacy and confidentiality and safety of patients in the design of rooms, so that the direction of the dental chair opposite the door of the room.

Annex (16) Dental lab

The following conditions must be met in the dental lab:

1. <u>Area</u>

The laboratory must have sufficient space so that the technicians can move easily, as well as for the equipment used so that it can be transported anywhere in a safe and correct manner. The area allocated for each activity shall be proportional to the nature, number and size of tools, machines and materials and the number and movement of workers.

2. Equipment

The laboratory must contain the equipment necessary to operate it as a dental laboratory. In addition, contain special dental tables with special chairs for the type of laboratory in order to maintain the occupational health of technicians. All equipment arranged in an easy, safe, for the movement of workers in the lab freely.

<u>3. Metals / Gypsum / Wax</u>

Allocation of isolated places from the rest of the laboratory for the dental technician to perform the following tasks: melting of metals, casting gypsum and waxing.

4. Storage

Provide refrigerators, cabinets and suitable storage areas as needed.

5. Ventilation

The laboratory should have natural ventilation through doors, windows or roof openings and mechanical ventilation by fans, air conditioners and air suction fans.

6. Laboratory Rooms

The floor of the room must be smooth and easy to clean, and the walls shall be coated with antibacterial paint that allows for easy and repeated cleaning.

7. Fire extinguisher

Provide a fire extinguisher that is usable and has a date of production and expiry date.

8. Chimney

Provide a special chimney to withdraw the gases from the smelting of metals out of the laboratory.

9. The existence of an area for washing the eye

Must Provide an area for eyewash.

10. Laboratory Record

The dental laboratory must maintain a special record serially numbered with the following data for each dental impressions receives:

- 1. The name of the owner of the impression and the CPR / ID number.
- 2. Name of the treating dentist who sent the impression and his address.
- 3. The type of work required and the date of receipt.
- 4. The date of sending the impression to the dentist concerned.

Annex (17) Health facilities operating 24 hours

I. <u>Policies and Procedures</u>

Policies and procedures define responsibilities in health facilities that operate 24 hours and include, but are not limited to:

- 1. Emergency assessment procedures and patient triaging policy.
- 2. Trauma management.
- 3. Protocols for some important and common emergencies such as asthma, chest pain, coma, stroke and others.
- 4. Dealing with cases of lego-medical aspects such as alcoholism, drug abuse, sexual abuse, domestic violence, child abuse and others.
- 5. Dealing with infectious diseases.
- 6. A written policy setting out the different roles assigned to the health care team in terms of how to transfer patients if the facility is unable to provide the necessary care.
- 7. Issuing a monthly bulletin of the work system of the facility, including the identification of work shifts, and doctors are distributed, so that no shift exceeds eight hours a day.
- 8. The names of doctors and the timing of their shifts is publicized in a prominent place inside and outside the facility

II. <u>Medical devices and supplies</u>

In addition to the requirements set forth in Annex 5, the facility which operates 24 hours must have:

1. A fully accessible and fully equipped CPR trolley, checked and provided by all emergency supplies and medicines.

- 2. Instruments for examination and treatment of the patient.
- 3. ECG device.
- 4. Devices for measuring vital signs of the patient.
- 5. Cardiac and pulmonary resuscitation devices.
- 6. All emergency medicines (e.g. valium, morphine, adrenaline, etc.).
- 7. Stomach washing kit.
- 8. Intravenous injection pumps.
- 9. Medical gas with suction hanging on the wall.
- 10. Patient stabilization equipment (steel plate, cervical vertebrae, neck, etc.).
- 11. Emergency labour Tool Kit.

III.Medical and technical staff

Doctors who are licensed to work in a clinic/ center operating for 24-hour must:

- 1. A licensed specialist doctor according to the scope of the center or clinic or a general practitioner in case of in a general health center with a least five years post qualification practical experience.
- 2. The licensed doctor must be a full-time doctor in the health center or clinic.
- 3. In case of a 24 hours center, two doctors should be available per shift, and in case of a 24 hours clinic, at least one doctor and one nurse per shift should be available.
- 4. NHRA should be notified If the clinic owner or one of the doctors in it or in the center, leave the kingdom for more than one week, in such case the Facility should stop the services unless authorized by NHRA upon the request of the owner of the facility to replace another doctor licensed to practice the profession in a private clinic, and this has to be announced by the clinic or center.

Annex No. 18

Health units in schools, authorities, companies and other entities.

I. <u>Policies and procedures</u>

The health units in schools, authorities, companies and other entities are limited to provide nursing services, first aid and health education services were a doctor is not available, the following should be adhered to:

- 1. Infection control measures provided for in this resolution.
- 2. Procedure for medical waste disposal if any.
- 3. A health record for the auditors.

II. <u>Unit Specification</u>

- 1. Building Specification
 - 1.1 The building should be saved, easy to reach and takes in consideration people with special needs.
 - 1.2 The area of the room should not be less than 9 square meters.
 - 1.3 Room should be well ventilated.
 - 1.4 Wall and the floor areas are easy to clean and antibacterial according to standards
- 2. Annual maintenance of the building and medical devices should be carried out periodically.
- 3. The need for internal policies and procedures of the facility that fits the policies and standards of the infection control and quality department.
- 4. Fire extinguishing requirements shall be provided according to the standards of the civil defense authorities
- 5. At least the following medical devices and supplies are required:
 - First aid kit.
 - Oxygen source (cylinder and mask)
 - Steam device (Nebulizer).
 - Medical bed for examination.
 - Blood pressure device.
 - Thermometer.
 - Diagnostic set.
 - A wheelchair.
 - Provide tools for stabilizing limbs in case of injuries (fractures / bruises / neck and spine injuries).
 - Provision of medicines and supplies listed in the table below.

III. Professionals:

Ensure that all professionals working in the unit are licensed by the NHRA.

	Paracetamol tab 500mg	21	Pocket mask
2	Paracetamol Syrup	22	Bag valve mask
3	Povidone Iodine Solution	23	Stethoscope
4	Panthenol Cream	24	Alcohol or non-alcohol antiseptic wipes
5	Normal Saline 500ml	25	Adhesive plasters
6	Aludrox Suspension	26	Cotton Balls and Swabs
7	hyocine butyle (Buscopan)	27	Bandages
8	Ibuprofen Tablet 200mg	28	Gauze
9	Salbutamol Solution	29	Dressing sets
10	Methyle Spirit	30	Gloves
11	Savlon 1%	31	Scissors / Syringe
12	Calamine Lotion	32	Clear tape
13	Crotamiton Cream	33	Mep <mark>ore Pla</mark> ster
14	Bonjela Gel	34	HGT Strips and Lancets
15	Ethyl Chloride Spray	35	Sharp Container
16	Vaseline Gelly	36	Bed Roll Sheet
17	ORS Solution	37	VITAL Signs Machine
18	Neomycin Ointment	38	Nebulization kit
19	Oxygen Cylinder and Face Mask	21	Wheelchai <mark>r / Stre</mark> tcher
20	Cervical collar and other orthopedic Stabilizer	22	AED (Preferable)

Annex (19) Hospital kitchen

Taking into account all provisions of the Public Health Law and the license from the relevant Department in the Ministry of Health, the following requirements must be met in the hospital kitchen:

- 1. Healthy source of clean water and sewage should be provided, and sufficient lighting and ventilation should be provided.
- 2. Doors and windows should be well-made and airtight, doors should be provided with insect nets and external doors with air-curtains devices to prevent flies.
- 3. All kitchen walls should be covered with smooth tiles and the floor should be covered with easy to clean tiles, provided with a water valve and drainage holes.

- 4. The kitchen and the preparation room should be provided with a sufficient number of high-efficiency air suction fans.
- 5. All cooking utensils and container should be easy to clean.
- 6. Enough refrigerators provided to keep the food.
- 7. A waste treatment device provided in the kitchen, and wastes kept tightly covered until it is disposed.
- 8. The kitchen should be provided with a separate place for dishes and cooking utensils washing in an accurate and safe manner.
- 9. A special room should be provided for washing, cutting, preparing and peeling raw food before cooking, as well as for washing the vegetables and fruits that are eaten without cooking; a sufficient number of stainless washbasins and tables with smooth surfaces should be provided too.
- 10. A separate store provided to the preserve raw food.
- 11. All chefs and their assistants in the kitchen should be checked periodically to ensure that they are free of any infectious diseases and have fitness certificates.
- 12. Fire extinguishing requirements shall be provided according to the standards of the civil defense authority.



Annex (20) Pre-employment Services for Expatriates

Private health facilities providing pre-employment services should be committed to the following:

I. All private health facilities licensed by the NHRA wishing to add the activity of providing pre-employment service to expatriates must apply to NHRA for permission to add this activity.

II. The provision of pre-employment service for expatriates is limited to hospitals and medical centers only.

III. In addition to the health and technical requirements mandatory for licensing private health facility mentioned in this guideline or other resolutions issued by NHRA, the following conditions should be fulfilled for providing pre-employment services:

- 1. The health facility have a written and approved policy that clarifies all procedures for examining expatriates and the roles and responsibilities of all employees concerned with the examination.
- 2. The health facility shall implement a mechanism to ensure the security and confidentiality of information concerning the examination of expatriates and the identification of persons authorized to do so.
- 3. There is periodic audit by the medical director / quality supervisor to match the reports issued by the Center and the results of examinations of expatriate labor.
- 4.Adhering to the guidance manual issued by the Public Health Laboratory at the Ministry of Health.
- 5. The medical examination service for expatriates must be separate from other services.
- 6. Availability of an independent specialized clinic for pre-employment services.
- 7.Availability of Licensed professionals to conduct the service in accordance with NHRA terms and conditions.
- 8.A licensed physician permitted from NHRA to conduct pre-employment services should work in the clinic.
- 9. Availability of a waiting room with a size and area that are proportional with the capacity for providing the service according to NHRA terms and conditions.
- 10. Availability of a personal identification system (fingerprint system and coding).
- 11. Availability of radiology services in the healthcare facility.
- 12. Availability of X-ray machine (DR, CR quality minimum of 300Ma).
- 13. Availability of blood drawing services.
- 14.Providing laboratory services in the facility or contacting the lab services with an accredited and licensed external lab in according to annex (8) of this guideline.
- 15.It is preferable to have an internal electronic system to link the different departments of the health facility.

16. Availability of an electronic database including:

- 16.1 The name of the expatriate and his/her gender.
- 16.2 Personal Identification Number.
- 16.3 Passport number.
- 16.4 Nationality.
- 16.5 Final medical report.
- 17. The facility shall maintain a database of the information and the results of blood testing and radiological examinations for at least five years from the date of the medical examination.
- 18. The capacity of the health facility should be determined according to the number of available clinics, the working times and the number of medical staffs.
- 19. Submit a request to renew the permit to provide the pre-employment services on an annual basis.



Annex (21) High dependency Unit

The unit provides advanced care services in order to maintain the stability of the critical patient condition until recovery or transfer to the intensive care unit. The establishment of a high dependency unit is allowed in hospitals that do not have an intensive care unit and do not perform major operations.

I. <u>Policies and Procedures</u>

- 1. Policies for accepting, discharge, management and referral need to be specified.
- 2. Operation, pharmacy, laboratory, physiotherapy, and radiation services must be provided for 24 hours preferably close to the unit
- 3. Provide services to transport the patient to the intensive care unit in case of need, either within the facility itself or through contracting with other facilities provide intensive care services.
- 4. Constant auditing of its activities and results.
- 5. Procedures for disposal of medical waste.
- 6. Procedures for infection control and isolation.

II. <u>Engineering requirements</u>

- 1. There must be 2-4 beds according to the size of the hospital and the range of services provided by the facility.
- 2. The area allocated for each bed shall be 12 square meters.
- 3. Provide at least two oxygen generators, one for air and the other for suction, and at least twelve energy points per bed
- 4. Stainless steel washbasins shall be available with a washbasin for every four beds.
- 5. The unit should be visible by nurses (glass wall or closed window).
- 6. The bed should be placed towards the qibla according to Islamic law whenever possible.

III. Medical devices

High dependency Units shall be provided with the necessary equipment and supplies:

- 1. Respiratory ventilators.
- 2. Tracheotomy tool kit.
- 3. Crash cart equipped with all emergency supplies and medicines.
- 4. Pulmonary resuscitation devices.
- 5. Oxygen saturation measurement device and biometric indicators screen.

- 6. Central Station monitoring system.
- 7. Blood transfusion supplies.
- 8. Medical gas supplies and suction are twice the number of supplies available in other sections.
- 9. Enssuring the availability and function of all necessary instruments and equipment for trachea intubation and ventilators regularly.

IV. <u>The technical staff</u>

- 1. The unit shall be supervised s by a licensed fulltime or par-time consultant who is qualified and experienced in the field of intensive care or anesthesia or general surgery.
- 2. A maximum of 2 nurses assigned to each patient according to the schedule referred to in Annex 4 at any time within 24 hours.
- 3. The Unit shall have a sufficient number of qualified, experienced and trained personnel in the field of intensive care and shall have a license from NHRA
- 4. All employees working in the Unit should receive training and certificates approved in ACLS, PALS and NRP as appropriate.
- 5. Doctors must be available 24 hours a day.

Annex (22) Telemedicine Centers

Telemedicine: The provision of medical consultation by a licensed physician through means of communication such as telephone, e-mail video conferences or any other electronic means.

The remote health service center : The center responsible for providing the service and has the right to contract with the specialized doctors to provide the consultation. **The recipient of the service**: The person utilizing the telemedicine services

The manager of telemedicine center shall comply with all the following requirements and criteria:

<u>I. Policies and Procedures</u>

- 1. No one may set up, operate or provide telemedicine services except after obtaining a license from NHRA or a license issued by the licensing authority in their country if they are working outside the Kingdom. All professionals providing the services shall be licensed by NHRA or country of origin authority
- 2. Develop an electronic system that enables access to service recipients in case of need.
- 3. To enable the service provider's system to integrate with the payment provider's system, in case of electronic payment.
- 4. The existence of an entry system for the program that allows tracking the user and the information obtained and the timing.
- 5. The existence of a policy that defines roles, responsibilities, administrative and technical privileges.
- 6. Develop comprehensive policies for the mechanism for responding to communications and dealing with counseling or the limits of consultation; the responsibilities of the doctor providing the service and a mechanism for reporting and dealing with complaints.
- 7. The existence of contracts showing the limits of responsibilities and tasks between the center and doctors providing the service.
- 8. Develop a policy to evaluate the quality of the services provided, including surveying the opinions of the customers.
- 9. The service should be available to its recipients in both Arabic and English.
- 10.Verbal consent must be taken from the recipient of the service indicating the limits of the distance consultation and the risk of not seeing a doctor in case the situation worsens
- 11.Prices for health services and consultations should be clearly stated.
- 12. Consultation should not include treatments requiring prescriptions.
- 13.To follow the professional ethics in dealing with the recipient of the service and maintaining the confidentiality of his information.

- 14.Consultation must be provided honestly and safely; and the service should not be used as a promotion for a doctor facility.
- 15. The responsible director shall bear legal responsibility in the event of a violation in the procedures of the center. The doctors contracted with the center shall be responsible for the medical error in the case of consultation that led to the occurrence of harm or complications to the patient as a result of following the doctor's advice through the use of this service.
- 16.Sick leave is not allowed through this system.
- 17.Grant NHRA access to the program to see the stored calls for reasons of scrutiny or investigation of complaints received.
- 18. The existence of an internal audit system to ensure the quality of services provided.
- 19.Inform NHRA of any violations resulting from the use of the system such as violating the profession's ethics or exceeding the limits of the license granted to the doctor.

III. <u>Security and confidentiality standards</u>

- 1. Strong encryption of data stored in the database shall be used.
- 2. Encryption must at least be based on SHA 256 encryption.
- 3. Appropriate security measures should be put in place to ensure that only authorized physicians are allowed access to the recorded calls.
- 4. Patients' consent to register the calls must be obtained, ad calls must be kept for at least one year from the date of registration, for review and audit.
- 5. Registrations should be encrypted and prohibited from being transferred to a third party, to avoid potential leakage and misuse of information.

Annex (23) Endoscopy Unit

II. <u>Policies and Procedures</u>

The policies of the Endoscopy Unit, which include, but are not limited to, the following:

- 1. Criteria for admission and discharge of patients.
- 2. Verification of patient identity by at least two persons.
- 3. Anesthesia procedures.
- 4. Policy of Dealing with pulmonary heart failure and emergency transfer.
- 5. Guidelines for infection control.
- 6. Systems and processes of drying, transport and storage of contaminated endoscopes.
- 7. Policies for the sterilization of tools used to carry out endoscopy.
- 9. Policy of Dealing with infectious diseases such as HIV / HCV / HBV.
- 10. Managing of complications during the endoscopy procedure.
- 11. Periodic examination of endoscopy devices.

III. <u>Engineering requirements</u>

In addition to the general requirements mentioned in Annex No. (1), the following special requirements must be met:

- 1. The area of the endoscopy room should not be less than 16 square meters and each side should not be less than four meters long.
- 2. The location should be near to the emergency unit, intensive care unit and operating room in the case of hospitals.
- 3. Segregation of sterile area and non-sterile.
- 4. Allocate an area for hand washing and use of personal protection equipment.
- 5. There should be a red line between the endoscopy room and the entrance of the non-sterile unit to prevent and reduce risk of contamination.
- 6. Two separate entrance/exit doors should be provided to allow for the entry of clean instruments and for the removal of used endoscopes at the end of the procedure.
- 7. The floor of the room shall be smooth and easy to clean, and the walls should be coated with antibacterial paint that allows easy cleaning.
- 8. Supplied with a special generator that is automatically operated in case of power failure.

- 9. To be equipped with central air conditioning, which allows air to be replaced with 100% pure air with the use of the HEPA Filter
- 10. Provide fire alarm and fire-fighting equipment that work well, with consideration that they do not interfere with the safety of the medical equipment used.
- 11. The doors and windows should be well-made and firmly locked.
- 12. The following premises should be available:
- 12.1 Reception section.
- 12.2 An area for hand washing and changing.
- 12.3 Preparation room.
- 12.5 Endoscopy procedure room
- 12.6 Recovery room equipped with all necessary equipment.

IV. <u>Medical devices and supplies</u>

- 1. Cardio pulmonary resuscitation Trolley.
- 2. A crash cart equipped with all emergency medicines and supplies.
- 3. Pulse-oximetry device for measuring the oxygen saturation ratio in blood and the screen of vital indicators
- 4. Medical gas supply and suction in the wall.
- 5. Ventilators.
- 6. Periodic maintenance of all devices and medical supplies.
- 7. A complete endoscopy device with multiple dimensions of endoscopic tubes (upper and lower gastrointestinal or colorectal system for adults or children) accompanied by a high-quality video monitor to monitor the direction of the endoscope as well as an electronic system that allows to keep the records for at least 5 years.
- 8. The existence of Diathermy Device linked to the bed of patients in the endoscopic room and connected to the endoscope when needed.
- 9. The light source is focused on the instruments used by the nurse and does not interfere with the procedure of the endoscope.

V. <u>Medical and Nursing staff</u>

- 1. The head of the endoscopy unit should be a consultant gastroenterologist and endoscopy licensed by NHRA.
- 2. An anesthesiologist or an authorized physician to conduct procedural sedation should be presented during the endoscopy procedure.
- 3. The head of the endoscopy unit should be a licensed nurse with experience of gastrointestinal diseases and endoscopy.

Annex (24) Dialysis unit

I. <u>Policies and procedures</u>

Policies for the dialysis unit, which include but are not limited to:

- 1. Criteria for admission and discharge of patients.
- 2. Standards for Evaluation and reassessing the patient's condition.
- 3. Reevaluation of patients with AV Fistula and AV Graft.
- 4. Preparation of the device for dialysis.
- 5. Dialysis procedure.
- 6. Policies for dealing with pulmonary heart failure and referral policies in case of emergency.
- 7. Infection control policies and procedures should be provided.
- 8. Providing policies for periodic inspection of water treatment.
- 9. Policies to deal with infectious conditions such as HBV / HCV / HIV.

II. <u>Engineering requirements</u>

In addition to the general requirements mentioned in Annex 1, the following special requirements must be met:

- 1. The area around the bed should be 12 square meters per bed.
- 2. Hand-wash basins are available with a basin for every four beds.
- 3. Bed placed towards the Qibla according to Islamic law whenever possible.
- 4. To separate the devices used for patients from those used for patients infected with blood-transmitted diseases.
- 5. Availability of at least one isolation room equipped with a negative pressure system or an alternative way to ensure to care for infected cases until the patient can be transferred to a suitable place for his condition.
- 6. The presence of a room for the water treatment plant with a minimum area of 9 m, and increase according to clinical capacity

III.<u>Hospital Dialyses Unit</u>

For a Hospital dialysis unit, the following are required:

- 1. Easy access to the unit.
- 2. Preferably near the emergency department or the intensive care unit.
- 3. Easy access to support services.
- 4. The design should contain minimum wall barriers and columns.
- 5. The presence of emergency call at the medical and nursing staff station (to provide a quick and appropriate response).
- 6. Provide a paging system near each bed and in the toilets.

IV. Security and safety requirements

- 1. Provide the necessary equipment for people with disabilities, elderly and children.
- 2. Provide the necessary signs to guide the patients.
- 3. Allocation of parking for dialysis patients.

4. Provide fire alarm and fire-fighting equipment that work well, keeping in mind that they do not interfere with the safety of the medical equipment used.

V. <u>Medical devices and supplies</u>

The following equipment and supplies shall be available:

- 1. Cardio pulmonary resuscitation equipment.
- 2. A crash cart equipped with all emergency medicines and supplies.
- 3. Pulse-oximetry device for measuring the oxygen saturation ratio in blood and the screen of vital indicators
- 4. Patient monitoring system, central station if the rooms are separate from the nursing office.
- 5. Blood transfusion pumps.
- 6. Medical gas supply and suction in the wall.
- 7. Weighing scale.
- 8. Blood glucose meter.
- 9. Provide the necessary tools for the withdrawal of blood samples for the necessary tests when needed.
- 10.Periodic maintenance of all devices and medical

VI. Medical and Nursing staff

1. The head of the dialysis unit should be a nephrologist licensed by NHRA.

2. The chief of nursing should be a NHRA licensed nurse with experience in dialysis unit.

3. It is prohibited to employ unqualified staff and without a license from NHRA to practice in the unit.

4.All working health personnel must have a valid certificate in BLS.

5. Medical checkup should be done to all staff in the unit to detect hepatitis B, C-HIV. In addition, all should be immunized against hepatitis B on a regular basis.

6. All staff who have been vaccinated are tested for antibodies to evaluate the response, and all non-responders are given a second series of hepatitis B vaccine.

Annex (25) Medical Incubators

Medical Incubator: A health facility licensed by NHRA as a medical center. In addition to its basic scope of work, it includes a number of clinics and health units fully equipped; licensed independently form the center (the incubator). The independent license is granted for three years only to one of the professions licensed by NHRA to practice the profession of medicine, dentistry or one of the allied professions in the Kingdom.

The following conditions are required:

- 1. The 73ealth facility shall be licensed by NHRA to provide health services as a general medical center or a general dental center.
- 2. The Center provides support services in addition to having at least two permanent general clinics working full-time to ensure continuity of service.
- 3. In addition to the basic scope of services provided by the Center, it is allowed to provide a number of medical clinics or health units, each licensed separately as a separate license with a separate commercial register.
- 4. Licenses to work in clinics / independent units are professionals holding a license to practice the profession independently according to the requirements and standards issued by NHRA.
- 5. Doctors authorized to practice the profession in the independent clinics must be a consultant or specialist in medicine or dentistry or a general practitioner with at least ten years of experience or a dentist with experience of not less than five years, according to the standards issued by NHRA.
- 6. The center and all independent clinics and unit should follow policies and procedures for infection control, waste management and incident reporting policies.
- 7. The Medical/administrator director of the facility shall be responsible for the supervising clinics of the center, medical, nursing services, allied health staff, reception, sterilization room and medical waste.
- 8. Every professional licensed to practice the profession independently is fully responsible for his profession and practice as an independent facility.
- 9. The medical records of the center shall be separate from the medical records of the clinics and independent units.
- 10. The clinic is licensed to only one doctor for a limited period of time (3) years by NHRA.
- 11.All practitioners of the Center, clinics and independent units shall be subject to the provisions of Law No. (38) For the year 2009 establishing NHRA and all rules and regulations for organizing and licensing the practice of the profession issued by the NHRA, and to all regulations in this guideline.

Annex (26) Chemical waste room

The following requirements are needed in the chemical waste room:

I. Engineering Requirements

- 1. The storage room location should be allocated in separate buildings away from the important and vital places, and at a safe distance from the borders of the neighboring facilities.
- 2. The room should be of one floor only.
- 3. The room should not be underground
- 4. The construction materials including those used for the ceiling, flooring and walls, shall be non-flammable and fire resistant for at least two hours.
- 5. The floor should be of reinforced concrete and covered with a soft finishing layer.
- 6. Emergency equipment should be available nearby.
- 7. The steps in front of the door not less than 10 cm high.
- 8. A wall of bricks and cement should surround the storage room at least two meters from the surface of the earth.
- 9. The electrical wiring shall be at least two meters above the ground level, the electrical installations shall be of a non-heat type, covered with a wire layer, the fittings should be separated, and the lighting should be off if not needed.
- 10.Provide appropriate ventilation inside the room according to the standards and ensure that the internal air change from 10 to 12 times per hour.
- 11. The number of exits should not be less than two exits far away from each other; each of them should lead to the outside.
- 12. The exit door should not be less than 2 meters, the width of the main corridors should not be less than 2.5 meters, and the internal corridors should be less than 1.5 meters.

II. Storage Requirements

- 1. The materials should be classified according to the risk and the category, not based on the alphabetic order.
- 2. Materials should not be exposed to sunlight or heat.
- 3. Maintain a proper temperature of the stored materials according to their type.
- 4. Make sure it is sealed.
- 5. The material should be handled carefully to ensure that it does not fall to the ground.
- 6. Place the containers on a step not less than 10 cm high.

- 7. Do not place material near the door and floor either permanently or temporarily.
- 8. The room should be equipped with suitable fire extinguishers according to the type of the stored materials (with caution of using water with some chemicals, as they react with it and release dangerous gases and vapors).

Annex (27) Sleep Labs

Requirement for the Sleep laboratories shall include the following:

I. Policies and Procedures

The following policies and procedures, shall include, but not limited to:

- 1. Admission of patients.
- 2. Monitoring mechanism.
- 3. Mechanism for analyzing the results and writing the report.
- 4. Instructions for patients.
- 5. Consent to be signed by the patient to carry out the examination.

11. Technical requirements

- 1. Sleep laboratories, whether independent or affiliated to a health facility, must have the following requirements:
- 2. Single rooms measuring not less than 12 square meters, the lighting and sound is lessened to degrees that allow comfort and equipped with a temperature controller and ventilation
- 3. Equipped with the equipment required for the examination as shown in the table below
- 4. To be supplemented by private bathrooms for patients.
- 5. The presence of appropriate surveillance video equipment.
- 6. The existence of communication devices from both parties (to communicate between the observer and the patient).
- 7. The presence of technical staff to monitor and provide monitoring devices.

III.<u>The professional staff</u>

- 1. A licensed doctor shall be available, who has a sleep medicine qualification.
- 2. On duty doctor for emergency.
- 3. Availability of full-time sleep therapy technicians, and qualified nurses licensed from NHRA with certificates and training on the control of the devices.
- 4. Secretariat / receptionist to receive requests and arrange files for clients.

IV. Technical equipment required in sleep laboratories

A. The minimum standard for polysomnography

- 1. 2 EEG (e.g. C3-A2 (C4-A1)
- 2. 2 EOG
- 3. 1 mentalis /sub mentalis EMG
- 4. SaO2 5. Snoring signal
- 6. Body position sensor
- 7. Nasal pressure/flow signal (thermistors are no longer acceptable as a single recording method in adults)
- 8. Validated method of respiratory effort
- 9. 2 EMG *itibialis* anterior
- 10. ECG one channel
- 11. Video monitoring with possibility of recording

B. Non-exhaustive list of supplementary signals to be recorded (depending on the clinical specialization of the center)

- 1. Esophageal
- 2. Esophageal pH
- 3. Body core temperature
- 4. Penile tumescence
- 5. Non-invasive blood pressure
- 6. Long-term blood pressure
- 7. Extended ECG •multichannel
- 8. Transcutaneous O2 ·CO2
- 9. Extended EEG
- 10. Extended EOG (vertical eye movements)
- 11. Extended EMG (multichannel (other extremities
- 12. Video-metry (synchronous image and signal recording)
- 13. Pulse plethysmography or tonometry
- 14. Pulse-transit time

Annex (28) Laboratory consulting services and center

These centers shall only be providing advisory services and /or delivery of investigations to external laboratory, and shall meet the following requirements:

- 1. Providing an office with a receptionist to handle the applications
- 2. The professionals cooperating with the center shall be licensed by NHRA, those professionals should provide the services they are licensed to only.
- 3. Determine the professional legally responsible for the representing the facility at NHRA.
- 4. Availability of a written agreement between the Office and the client, indicating the rights and responsibilities.
- 5. Clear policies for all analysis, transporting and reporting.
- 6. There are clear guidelines for patients about the investigations provided and its nature.
- 7. Clarification of the scope of the Center's services.
- 8. Clarify the method of transporting the samples in detail with the established standards.
- 9. Identify the person responsible for the sampling and his/her qualifications.
- 10. Adopt a consent form for the client for taking and using the sample.
- 11.Obtaining informed consent from the client.
- 12. Availability of agreements with doctors or clinics to refer patients when necessary.
- 13. Availability of contracts documented between the licensed health facility and the facility where the samples are sent for analysis.

Annex (29) Prosthetics & Orthotics Center

The following conditions for Prosthetics & Orthotics center should be fulfilled,

I.Policies and Procedures

Policies and Procedures should include the following, but not limited to:

- 1. Manual for the design and application of prostheses and orthosis
- 2. Availability of an updated and organized guideline for safety inside the center.
- 3. Fire safety plan.

4. A system for properly operating, cleaning, and monitoring the quality and maintenance of all devices. Such system should include, but not limited to the following:

- 4.1 A guideline of operation and maintenance.
- 4.2 A maintenance schedule.
- 4.3 Maintenance records.

II. Engineering and technical requirement

The following requirements should be fulfilled in the prosthetics and orthotics center:

1. There is a slope at the entrance of the center, and the doors and corridors must have sufficient space for the wheelchair.

2. The workshop space should be sufficient to enable technicians to move easily as well as for the devices and equipment in use, so that they can be safely and duly moved to any place in a safe and correct manner. The space of each activity should be proper for the type, number and size of instruments, equipment, materials and the number of the staff and their movement in accordance with the detailed proposal of the Center.

3. Examination and fitting Room: The examination room space should be sufficient, and the floor should be non-slip. A large mirror and a walkway should be provided to train the patient for walking. Both sides are fitted with tight-fitting barriers to help the patient to balance, and medical furniture should be used only.

4. The workshop in the center should contain the equipment and instruments necessary to operate it as a prosthetic and orthotic center. It should also contain tables and chairs made for such workshops. All equipment should be arranged in an easy, proper, not crowded safe way, and does not obstruct the free movement of the workshop staff.

5. The walls and floors of the workshop should be from material easy-to-clean with a smooth layer that does not absorb fluids. Taking into consideration that the floor free from slip. Carpets should not be placed in the workshop to prevent fires.

6. Places, isolated from the rest of the workshop, should be allocated for the technician to do the following tasks: melting plastics, pouring plaster.

7. Natural ventilation should be available through doors, windows or roof openings, in addition to mechanical ventilation through fans, air conditionings, and machines\fans of air suction.

8. Flammable materials should be allocated in special places designated for them.

9. A functional fire extinguisher should be available, and its production and expiry dates written down on it.

10. Providing a place for eye and body washing in case of emergency.

11. Availability of first aid kit.

12. Sufficient number of electricity sockets, and electricity source should be available for use in case of emergency.

13. A proper ventilation should be available besides temperature and Humidity control. In addition, appropriate lighting.

14. Devices should be installed and distributed in accordance with the standards of the manufacturer.

15. Availability of patient changing rooms close to the measuring room, and provide patient storage cabinets, hand and body wash areas as needed.

16. The Center applies all infection control principles and guidelines, in particular the provision of personal protective equipment (gloves, masks, glasses, facemasks, and clothing and laboratory coats) and worn as appropriate. See Annex 40.



Annex (30) Import and sale of medical contact lenses

The following requirements are required in the centers of the import and sale of medical contact lenses:

1. Only ophthalmologists and opticians who are licensed by the NHRA shall be authorized to prescribe non-cosmetic medical contact lenses.

2. All devices used in the facility to be licensed by the NHRA.

3. The temperature in the storage area shall be in accordance with the manufacturer's instructions.

4. The storage should be arranged and all lenses classified by type and grade.

5. Cleaning and maintenance of the place from any bacteria or fungus.

6. Taking into consideration the expiration date of lenses and application of a disposal mechanism.

7. The lenses should be transported in the correct manner in accordance with the manufacturer's instructions.

Annex (31)

Cardio-Pulmonary resuscitation (CPR) Trolley

The following conditions must be met in the CPR trolley:

- 1. The crash cart trolley should be available within easy access and ready for any emergency occurrence at any time.
- 2. The nurse in charge shall be responsible to check the trolley daily for the medication availability, validity and for the device's effectivity.
- 3. A daily checklist (once a day), the CPR trolley should be checked for availability, readiness, effectivity including the equipment, devices and medication if used or opened.
- 4. The CPR trolley drawers should be locked and easy to open in case of emergency.
- 5. Availability of a record for the temperature and humidity measurement for the crash cart medication. (frequency depends on the working hours)
- 6. Monthly cleaning checklist should be carried out for the trolley drawers and to check the medication expiry date.
- 7. In case anything used from the trolley, it should be re-filled as soon as possible to be always ready (within a day).
- 8. There should be periodic regular visits by the pharmacist to ascertain the validity of the drugs and how to get rid of expired medication.
- 9. To prevent the loss of emergency medicines or stealing them from the cart by using a safety plastic locker.
- 10. The safety plastic lockers shall be stored in a safe place supervised by the pharmacy or nursing staff.



The following tables shows the medicines and supplies to be provided in the CPR trolley:

Emergency medicine				
Atropine Sulfate	Ephedrine Sulfate	Verapamil		
Phenylephrine hydrochloride	Heparin sodium	Injection Phenergan		
Protamine Sulphate	Digoxin	TAB Amlodipine		
Xylocaine IV	Lasix IV	INJ Primperan		
INJ Adrenaline	INJ noradrenaline	INJ Dopamine		
INJ Dobutamine	Morphine	INJ Phenytoin		
TAB Aspirin	Magnesium sulfate	Chlorpromazine hydrochloride		
Ephedrine sulfate	Epinephrine	Sodium bicarbonate		
K-Y gel	Calcium gluconate	Xylocain ointment		
Hydrocortisone	lidocaine	Potassium chloride		
TAB Concor	Aminophylline	INJ Zydacc		
INJ Aminophylline	INJ Soul-Cortef	INJ Stemetile		
INJ Xylocaed	TAB Glyceryl			
Fluids (all sizes)				
IVF Dextrose 5%	IVF Dextrose 50%	IVF Sodium Chloride		
IVF ringer lactate	IVF DNS	Water Purified		

Emergency tools/equipment			
Cardiaa pagamakar	Defibrillator	ECG strips&	
	with pads	paper roll	
		Endotracheal	
Ventilation bag & mask for all ages	Intubation set	tubes(different	
		Sizes)	
The second second	Catheterization set	Foleys	
Inoracotomy		catheter	
		(sizes)	
Stathogoona	Alfways	Ambu hag	
Stemoscope	(unrerent	Allibu bag	
	Sizes)	Suringes all	
Sterile gloves different sizes	(sizes)	sizes	
	Needles all	Needle holder	
Stopcock	sizes		
	Forceps	Gauze	
Suture needle		bandage	
Suturing sots	Intravenous	Blades	
Suturning sets	tubing		
IV cannula all sizes	3-way adaptor	scalp vein (all	
		sizes)	
	Suction		
Al cohol swab	catheter with	Razor	
The control Swat	connection	italoi	
	tube		
Tourniquet	Bougie	Tounge	
1		depressor	
	Laryngeal mask	NEB.Mask	
Tourch		(Adult &	
		PED)	

Annex (32)

Mobile / home care center (Nursing / Physiotherapy / Other)

The following requirements must be met at the mobile / home care center:

I. <u>General requirements</u>

- 1. Providing an office with a receptionist to handle the applications.
- 2. All professionals must obtain a license from NHRA, and comply with the requirements and limits of the license granted.
- 3. To determine the scope of services provided and licensed by NHRA.
- 4. A medical record must be maintained for each patient recorded in it; his personal information; the medical history and services provided to him; the name and means of communication with his physician.
- 5. Follow the infection control standards.
- 6. Follow the rules of the disposal of medical waste.
- 7. A written consent from must be signed by the patient or his / her family accepting the care provided.
- 8. A clear policy for referral when in need of medical consultation.

II. <u>Technical requirements for mobile / home health care</u>

- 1. **Giving injections and medicines:** should be with a stamped and signed medical prescription by a licensed physician.
- 2. Suction of fluid from the throat and trachea: carried out and instruments removed safety in accordance with infection control standards. (GCC infection control) published on NHRA site (www.nhra.bh)
- 3. **Changing dressing, remove sutures, and burns care**: Change dressings and burn care according to doctor's instructions or in accordance with the hospital discharge instructions, taking into account infection control standards, with assessment of the wounds and patient condition if medical intervention is required.
- 4. **Insertion of urinary catheters:** to be inserted by a nurse for a female patient only, with the consideration of sterilization and infection control measures, and to ensure the rest of the procedures and periodic change of the catheter according to the doctor's instructions and to keep a copy of these instructions in the medical record of the patient file.

For male patients, male doctor only can install a catheter. The nurse can just change the urine bag and evaluate the patient's condition if there are abnormal signs (color change, smell, blood, etc.).

- 5. **Colonic colostomy:** The nurse is only allowed to change the special bag with the colorectal ring and cleaning the catheter area with proper consideration of infection control measures.
- 6. Any additional service must be within the scope of a licensed nurse.
- 7. If any other services (physiotherapy, massage or other) added, qualified professionals must be available and licensed by NHRA to practice the profession in the field of their license only.
- 8. If there is any equipment at the center, periodic maintenance must be carried out to ensure patient safety.
- 9. If injection or suction supplies are provided by the center, they must be stored and disposed of in a safe manner. An approved company for medical waste should be contracted for disposal of sharps and medical waste.
- 10.Physiotherapy services shall be provided according to the medical condition and instructions of the treating physician.

Annex (33) Laser Hair removal services

The following requirements must be met in laser hair removal services:

I. <u>General requirements</u>

- 1. Provide a suitable place to follow the engineering requirements of the device.
- 2. All professionals who use the device must obtain a valid license from NHRA, and work within the limits of the granted license.
- 3. The existence of written and adopted policies to deal with complications or burns resulting from the use of the laser device.
- 4. Provide a personal record for each patient including: personnel information, health status and the instructions of the treating physician

II. Special requirements for the professional of laser hair removal

- 1. The professional or technician must have a training certificate in this field from the company supplying the machine with experience of not less than one year.
- 2. The patient must be presented to the appropriate doctor before subjecting him to hair removal to determine the instructions to be followed.
- 3. Infection prevention procedures should be followed.
- 4. The professional or technician must follow the instructions and special information before and after the use of the laser and should provide advice to the client.
- 5. The technician should be supervised by the responsible physician and report of any complications.
- 6. Comprehensive documentation of care and services shall be provided.
- 7. Use of preventive personal protection equipment.

III. Special engineering requirements

- 1. All devices to be used should be approved by the Authority prior to importation.
- 2. The presence of signs and warnings on laser rooms (guidance of pregnant women in Arabic and English).
- 3. Absence of any reflective surfaces (door floor walls).
- 4. Maintain periodic maintenance of the equipment used in the center, in order to protect the safety of patients.

Annex (34) Speech and hearing center

The following requirements must be met in the Center:

I.Policies and Procedures

- 1. A record of periodic maintenance of medical devices (if any).
- 2. The availability of an updated infection control policy and procedures followed by the Center.
- 3. The availability of policy and procedures to deal with patient with endotracheal tube.
- 4. The availability of policy and procedures on how to deal with out of control /panic patients.
- 5. The availability of accidents/ incident record.
- 6. Standardized and / or non-standardized measures of specific aspects
- 7. Availability of complete medical records stored in a safe and confidential manner.

II. Technical and engineering requirements

In addition to the general requirements in Annex 1, speech and audiology management centers and clinics must have the following requirements:

- 1. The facilities of the Center shall be equipped for receiving patients with disabilities.
- 2. A ramp must be provided at the entrance of the center, and the doors with the corridors should have sufficient space for the wheelchair.
- 3. Provides a list of types of cases can be received by the Center; the scope of treatment provided by the Center; the timing of the treatment sessions and the prices.
- 4. Availability of appropriate medical equipment (depending on the type of treatment provided (voice swallowing stuttering rehabilitation audiovisual pronunciation and others).
- 5. Treatment rooms should be suitable for the age of the patient (children adults).
- 6. Provide a treatment table for children.
- 7. The treatment rooms should be preferably be soundproofed.
- 8. The tools used for treatment (standards, assessment tools, educational games) are available in a number adequate for the workload.
- 9. A special refrigerator for patients should be provided in case food need to be kept for patient and should have identification information (If swallowing treatment is provided and who will provide the food).
- 10. Availability of Autoclave (if evaluation tools are available), or manufacturer's policy of disinfection of used instruments, especially in Oral motor Kit Prosthetic / Adaptive Device.

Annex (35) Optics Shop

In addition to the general requirements set forth in Annex 1, the health facilities providing the optics services shall have the following requirements:

I. Examination room

- 1. Availability of the appropriate advertisement banner (name, specialization and working hours).
- 2. The presence of signs and guidance within the facility to clarify sections and other services
- 3. The storage should be suitable and the floors of the examination room should not be used for storage.
- 4. Availability of periodic preventive maintenance of all medical devices and the label of maintenance should put on the devices
- 5. Availability of a non-smoking sign.
- 6. Commitment to the name of the rooms, and not to use one room for more than one purpose at the same time.
- 7. Electrical transformers should not be used.
- 8. Provide a handwash basin and provide regular soap, disinfectant and paper towels for hand washing
- 9. Single-use sheets shall be provided on the chin support bracket attached to the examination device.
- 10. Availability of functioning fire extinguisher, be installed in a safe manner.
- 11.Examination devices shall be installed in a safe manner and follow the requirements of the manufacturer for the areas.
- 12.Infection control policy shall be followed.

II. Medical glasses and lenses lab

- 1. There is a guiding sign on the door of the laboratory room.
- 2. There is a handwash basin with suspend paper tissues and liquid soap.
- 4. Provide a closed garbage bin preferably with a foot pedal.
- 5. The floor of lab should be easy to clean and slip-resistant.
- 6. The floor should not be used for storage.
- 7. The equipment used shall be licensed by NHRA.

III.Technical staff

Availability of the required technical staff and to be e licensed by the NHRA according to the services provided by the facility.

Annex (36) Laundry Services

The following requirements should be available in the laundry services:

I. <u>Policies and Procedures</u>

Policies and procedures for the collection, transportation and washing of textiles should be available, and all the workers and the employees should be aware of, followed and adhered to it. It Shall include the following policies and procedures to ensure infection control and safety of laundry workers:

- 1. Contaminated linen should be bagged at the site of collection in a manner that minimizes and prevents contamination of the environment and personnel.
- 2. Care should be taken before placing soiled linen in a laundry bag to ensure that all non-textile items, including instruments, needles, or plastic single-use under pads, are removed. These items can cause extensive damage to laundry equipment.
- 3. Provide a sharps container in the soiled linen area to dispose of any sharps found in the linen.
- 4. Collect soiled linen in water-soluble bags.
- 5. Place full and tied off soiled linen bags in the dirty utility room or a designated area for pickup by laundry staff. Linen bags must not be placed on the floor; use a bin or rack to keep the bags 8 to 10 inches off the floor.
- 6. Soiled linen and linen from patient under isolation precaution are cautiously handled and to follow personal protection standards e.g. (with, full personal protection equipment (PPE), using special color-coded bags and water-proof laundry bags).
- 7. Linen should not be sorted or pre-rinsed in-patient care areas.
- 8. Bags can be transported from the point of collection to the laundry or to another designated holding area by covered handcart.
- 9. Bagged textiles should be transported to the laundry at regular intervals or at least daily.
- 10.Carts, liners, and bags should be washed and disinfected daily and when visibly soiled.
- 11.High temperature: A temperature of at least 71°C (160°F) for a minimum of 25 minutes is normally recommended for the hot water wash cycle.
- 12.Low temperature: A lower temperature of 22°C-50°C (71°F-77°F) can satisfactorily reduce microbial contamination in the washer.
- 13. The amount of residual chlorine (bleach) should be between 50 and 150 ppm and must be monitored and controlled.

- 14.Separate the areas for sorting and processing soiled linens from the areas for ironing, folding and storing clean linen.
- 15.Maintain areas receiving soiled linen at negative air pressure relative to clean areas or ensure positive airflow from the clean linen area to the soiled linen area.
- 16. The laundry areas must have hand hygiene facilities (soap, water, paper towels, or alcohol hand rub) and PPE available for workers.

II. Laundry Workers

- 1. There should be a supervisor to monitor the laundry procedures and the commitment of the employees to it.
- 2. All staff must be trained in the collection, transport, sorting and washing of soiled linen using the appropriate infection control measures, such as hand hygiene, wearing PPE.
- 3. Personal protective equipment should be provided, and all laundry workers must be trained of how to wear them properly and when they can use them. (overalls, mask, head cover, heavy-duty gloves, and boots) and adhering to standard precautions. (Refer to annex 40)
- 4. There should be a place allocated for disposal of the used personal protective equipment.
- 5. Laundry employees must report any sharps injury occurring when handling linen as well as any improperly disposed sharps or needles.
- 6. All Laundry stuff should be vaccinated.

Annex (37) Medicines delivery service

The delivery service does not include the dispensing of narcotic drugs and medicines that have restrictions on their dispensing. Licensed facility is obliged to provide the drug delivery service with the following requirements:

I. General requirements

1. It is not permissible to provide the drug delivery service without obtaining approval from NHRA.

2. The delivery company/pharmacy shall have a continuous 24 hours communication service that allows the applicant to communicate with the company/pharmacy.

3. Existence of delivery policies and procedures.

4. In medicines that are dispensed only by prescription, the following should be followed:

- 4.1Requesting the original prescription from the patient and handing it over to the pharmacy for which the drug dispensed from, while keeping it for review when necessary.
- 4.2When dispensing medicine from the pharmacy; method of use and allimportant medical information for the patient must be written on the back of the copy of the prescription
- 4.3The copy of the prescription should be signed by the pharmacist who dispensed the medicines and stamped by the pharmacy stamp (on both sides) and to include the pharmacy contact details.
- 4.4A record of dispensed prescriptions to patients should be preserved in pharmacy.

5. The existence of agreements between the company and pharmacies determining the tasks and responsibilities.

6. Provide a price list for delivery services provided.

II. The requirements to be met in the medicine transport vehicles

1. Commitment to the annual inspection of the vehicle and ensure its validity and conformity with the approved specifications.

2. The medicines must be kept during the delivery process inside an equipped container; that has the ability to control the temperature and humidity.

3. The existence of a permanent device to measure the temperature and humidity inside the container used to transfer drugs.

4. The temperature inside the medicine transfer container should be consistent with the conditions of storage of all medicines (less than 25 $^{\circ}$ C for medicines that do not require special storage shelves; 2 $^{\circ}$ C to 8 $^{\circ}$ C for medicines kept in the refrigerator).

5. Record the temperature and humidity inside the container from the beginning of the movement to deliver the medicine until they reach the delivery point, and this reading should be kept in special records signed by the drug delivery agent.



(Annex 38) Remote teleradiogy services

Teleradiogy services: the transfer of digitized medical images (such as X-rays and CT scans) and radiology reports of patients over safe electronic networks for the purpose of interpretation of the transmitted images for diagnostic purposes

Health facility providing for service: A facility licensed by the NHRA to provide consultation and issue radiology reports on studies conducted at the same Facility or in at another licensed Facility inside or outside the Kingdom.

Electronic system: Shared system for the exchange of radiology images and reports, for example, but not limited to (PACS SYSTEM - CDs - Internet browser, etc.).

The Facility requirements and standards of the teleradiology services

- 1. A facility may not operate or provide a teleradiology service unless it obtains a license to provide the service from the NHRA. All employed radiologists must also be licensed by NHRA.
- 2. The licensed service provider in the Kingdom shall be legally and technically responsible for the service provided and the reports issued.
- 3. Shall provide contracts between the facility providing the service and the facility requesting the service, clarifying the responsibilities, roles, mechanism of service requestd, its duration and medical responsibility.
- 4. Shall provide the NHRA with a copy of the contract between the health facilities.
- 5. If the service is requested directly by from the patient from the facility providing the service, the patient must be clearly informed of all prices of the teleradiology service provided and the mechanism of payment.

The requirements and standards of the licensed doctor to provide the service

1. A doctor may not perform teleradiology services except through centers authorized for this service under his NHRA license to practice the profession.

2. In case of contracting for the service from outside the Kingdom, the contract must be directly with the consultant doctors who are licensed to practice the profession in their country according to their specialization. Each doctor must be registered in the Kingdom according to the procedures and regulations issued by the Authority

3. The level of the physician should not be less than that of a general consultant radiologist for reporting of general X-rays and shall be a subspecialized consultant in a subspecialty of radiology for magnetic resonance imaging, CT scan, mamography, and other adavanced specialties.

4.Reports should be issued by each radiologist according to his/her subspecialty only.

5. Ultrasound reports cannot be issued remotely, as they should be read on spot by the performing professional.

6. The need for means of direct communication between the consultant radiologist and the requesting physician/facility.

7. Code of ethics must be considered in providing teleradiology services with mainatiend respect for the recipients of the service and the confidentiality of his/ her information8. In the event of the provision of other radiology services, the facility providing teleradiology services shall be subject to the requirements of the Authority in respect of the provision of any other radiology services

Policies and procedures

1. Develop quality assurance policy.

2. Establish a clear policy for the type of imaging studies to be received and reported, and cases in which the writing is refused or advised with clear acceptance and rejection criteria.

3. Establishing a clear mechanism for direct communication between the treating physician and the reproting radiologist, as well as between the radiologist and the technician performing the examination. This can be for example by email and telephone so as to ensure the availability of adequate clinical information regarding the case, means of futher discussions and study palnning and supervision.

4. Develop imaging and follow-up protocols with the radiology technician with clear communication pathways during the performance of the radiology study.

5. Develop policies that indicate the operating hours and the report turn around time.

6. Develop a policy for dealing with emergency cases if such a service is provided at the facility.

7. Develop a policy that ensures the safe transmission and exchange of data and information ensuring the protection of patient privacy and confidentiality in additon to a clear policy with regards to reporting and documneting any changes in the radiology report

8. Develop a storage policy for saving radiology images and reports.

9. Setting up a policy for saving and retrieving information in the event of a defect in the electronic system.

10. Develop an opertaional plan/ policy that outlines the legal responsibilities in the exchange of information between health institutions.

The requirements and standards of the electronic system:

1. An electronic system should be provided to enable the requesting facility to access reports.

2. The facility shall maintain an electronic record in which patients data and information shall be recorded and accompanied by medical reports, which shall include the following data:

2.1 Patient's First, middle and family name.

2.2 A unique patient ID such as The Population Census number (CPR) or the medical record number or, hospital 2.4 Identification number)

2.3 The date of the imaging procedure.

2.4 Clinical indication and Provisional diagnosis of the referred case if from facility/ physician.

2.5 The name of the referring physician, stanmp/ signature and the license number if referred from from facility/ physician.

3.Name and stamp (or electronic signature) of the radiologist on the final report.

4. A backup system should be provided between the facilities determining the duration of the retrieval of radiological images and reports in the event of a defect in the electronic system.

5. Data protection and storage rights shall be observed in the process of exchanging radiological images and reports of patients. This shall also ensure that no information is changed or ammended unless clearly recorded and registered on an adendum that includes (but is not limited to) the following information:

5.1 The name and job description of the person/s carrying out the change.

5.2 The actual changes carried out on the information.

5.3 Day, date and time of the change.

5.4 A mechanism should be in place to inform the recipient of the service in the event of any change in the report, while retaining the original report.

6. The establishment of a mechanism for the recording and preservation of information/ instructions exchanged between the facilities taking into account that no verbal instructions are to be taken reports should be determined in the event of a defect in the electronic system.

(Annex 39) Reserved generator room

The following requirements shall be available in the reserved generator room:

- 1. It is preferable to be in a room isolated from the building and open to the outside and to be near the main entrances.
- 2. Customize the tank under the generator for assembling the oil in case of leakage.
- 3. Easy unloading and cleaning.
- 4. Separate ventilation must be provided for the room.
- 5. Provide necessary fire extinguishing equipment.
- 6. The floor should be coated by cement soft layer

<u>Guidelines for safe operation and maintenance of generators (for operating and maintenance specialist)</u>

- 1. Ensuring the amount of diesel in the main tank and the cleanliness of it and the access for the generator tank
- 2. Make sure the machine level is horizontal
- 3. Check the water level of the radiator and the presence of rust prevention.
- 4. Make sure there is no oil or water Leakage.
- 5. Any failure or an emergency dysfunction should be recorded.
- 6. Ensure that the generator rooms are clean and tidy.
- 7. The necessity of having a specialist dedicated to operating the generators and monitoring them according to the mentioned procedures.
- 8. It is necessary to inspect the status of the generator and the room designated for it by the section concerned in the facility to record the notes and make the prevent maintenance
- 9. Apply general maintenance and preventive maintenance if necessary

Storage of compressed gases in hospitals and health centers:

Compressed gases are classified according to the international classification No. 1-2 and consist of:

- Flammable gases
- Non-flammable gases

The following requirement shall be applied in the stores of compressed gases used in hospitals:

Storage Conditions:

1. The store building should be independent from clinics and patients' locations.

2. Labelling the high risk compressed gases stored.

3. The store should be dry, free of moisture, to protect the cylinder and the safety devices from rustiness.

4. Electrical connections shall be protected (in underground or inside walls).

5. Provide suitable ventilation that works on renewing the air 10 times per hour (10times / hrs.)

Storage Procedures:

1. Keep away sources of flammability and flame, and oxidizing sources.

2. Place it in a secure place to prevent it from falling

3. Monitor containers continuously to avoid leaks

4. Do not expose the stored materials to sun and heat.

5. Minimize the size of the materials stored in accordance to the need.

6. Repainting (containers) cylinders shall only be done by the supplier.

7. Ensure that the data on the cylinder body matches the contents of the cylinder.

8. Protection of valves, instruments, measuring instruments and other accessories from tampering and damage and avoid storing it underground

9. Do not remove the cylinder cover (valve protector) except in cases of use.

10. The oxygen cylinders shall be kept away from other flammable gas cylinders at least a distance about 10 cm or building around it a concrete brick wall of 2 meters Hight.

11. Commitment to colors that distinguish gas cylinders

12. The cylinders shall be kept in a well-ventilated place, away from sources of sparks, flammability and heat sources.

13. Cylinders shall be stored vertically and sealed.

14. Cylinders containing the same gas shall be stored in one location in groups, separate as: flammable, oxidizing, toxic, corrosive materials as inactive gasses storage can be stored (INERT GAS) with any combination of compressed ends.

15. Put in a security place to prevent it from falling

16. Allocate an area within the store for the empty cylinders.

17. Do not store cylinders in the corridors, pathways or elevators.

18. Do not store flammable materials (petroleum materials) or combustible materials with cylinders

19. When moving cylinders from one location to another: Be sure to:

19.1 Do not roll, throw, or collide with each other or with hard surfaces.

19.2 Use the appropriate vehicle to transport the cylinders with a cylinder fixator.

19.3 Leave the lid of the valve and safety devices on the cylinder to keep them from being damaged while moving and / or moving them.

19.4 Moving the cylinders from one location to another by a dedicated vehicle



Annex (40) Personal protective equipment (PPE)

The following safety equipment shall be available in accordance with the services provided:

- Head protection equipment
- Respiratory system protection equipment
- Eye protection equipment
- Hearing protection equipment
- Accessories of Protecting the legs and feet
- Accessories for Body protection

