

# **Regulation for Renal Dialysis Unit**

**Health Regulation Department**

**Dubai Health Authority**

**2013**

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## Acknowledgment

Dubai Health Authority (DHA) is pleased to present the DHA “Regulation for Renal Dialysis Unit”, which represents a milestone towards fulfilling the DHA strategic objective in providing “A world class integrated health system that ensures excellence in health and healthcare for the Emirate of Dubai” and promotes Dubai as a “Globally recognized destination for healthcare”.

This regulation places an emphasis on facility design and services criteria with a focus on quality of services and safety of patients and healthcare professionals, based on the international standards of best practices in this domain, while taking into consideration the local and federal laws. Therefore, this document provides a base for the Health Regulation Department (HRD) to assess the Renal Dialysis Unit performance in Dubai and to ensure a safe and competent delivery of services.

It will also assist renal dialysis providers in developing their quality management systems and in assessing their own competence to ensure compliance with DHA regulatory requirements and the United Arab Emirates (UAE) federal laws.

This was developed by the HRD in collaboration with Subject Matter Experts (SMEs) whose contributions have been invaluable. The HRD would like to gratefully acknowledge those professionals and to thank them for their dedication to quality in health and their commitment in undertaking such a complex task.

**The Health Regulation Department**

**Dubai Health Authority**

## I. Scope

This regulation applies to dialysis units operating under the Dubai Health Authority (DHA) establishment law which includes semi-governmental and private healthcare facilities operating in Dubai and in free zone areas. This regulation may be amended from time to time at the discretion of DHA. The latest edition of the document shall be accessed through the DHA website [www.dha.gov.ae](http://www.dha.gov.ae).

## II. Purpose

DHA through the development and establishment, of the regulation for renal dialysis units shall ensure the provision of the highest level of safety and quality of patient care at all times.

## III. Definitions

**Dialysis** means the process of removing blood from an artery (as of a kidney patient), purifying it by dialysis, adding vital substances, and returning it to a vein—called also hemodialysis.

**Dialysis Stations** means a number of smaller units or cubicles within the Renal Dialysis Unit where individual patients receive their dialysis treatment.

**Renal Dialysis Unit** means a center that provides overall dialysis treatment.

**Disabled People** (also known as special needs) means a personal condition or situation that could make it difficult for a patient to participate fully in their health care, which include disability (physical, intellectual or sensory disability), age affected (either elderly or very young), affected by trauma or affected by medications/drugs.

**Healthcare professional** means healthcare personal working in healthcare facilities and required to be licensed as per the applicable laws in United Arab Emirates.

**Health Care Worker (HCW)** shall mean an individual employed by the health facility whether directly or by contract with another entity to provide direct or indirect patient care. This includes but is not limited, healthcare professionals, medical and nursing students, administrative staff and contract employees who either work at or come to the health facility site.

**Licensure** means issuing an official permission to operate a health facility to an individual, government, corporation, partnership, Limited Liability Company (LLC), or other form of business operation that is legally responsible for the facility's operation.

**Patient** means any individual who receives medical attention, care or treatment by any healthcare professional or admitted in a health facility.

**Chronic Renal Failure** means the slow loss of kidney function over time. The main function of the kidney is to remove wastes and excess water from the body.

**Sentinel Event** means an unanticipated occurrence involving death or major permanent loss of function unrelated to the nature course of the patient illness or underlying condition.

#### IV. Acronyms

AAMI :	Association for the Advancement of Medical Instrumentation
AII :	Airborne Infection Isolation
ACLS :	Advanced Cardiac Life Support
AV :	Arteriovenous
BLS :	Basic Life Support
CSSD :	Central Sterile Supply Department
CRRT :	Continuous Renal Replacement Therapy
DED :	Dubai Economic Department
DHA :	Dubai Health Authority
DM :	Dubai Municipality
ECG :	Electrocardiography
EMT :	Emergency Medical Technician
EtCo2 :	End Tidal Carbon dioxide
HBV :	Hepatitis B virus
HCV :	Hepatitis C virus
HIV :	Human Immunodeficiency Virus
HRD :	Health Regulation Department
LLC :	Limited Liability Company
ICU :	Intensive Care Unit
IPPV :	Intermittent positive pressure ventilation

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IV	:	Intra Venous
LLC	:	Limited Liability Company
LFT	:	Liver Function Test
MOH	:	Ministry of Health
NIBP	:	Non Invasive Blood Pressure
PALS	:	Pediatric Advanced Life Support
QAP	:	Quality Assurance Program
RDU	:	Renal Dialysis Unit
RN	:	Registered Nurse
RO	:	Reverse Osmosis
RTA	:	Road Traffic Authority
SIMV	:	Synchronized intermittent mechanical ventilation
SLED	:	Sustained low-efficiency dialysis
SME	:	Subject Matter Expert
UAE	:	United Arab Emirates
UPS	:	Uninterrupted Power Supply

## CHAPTER ONE: LICENSURE AND ADMINISTRATIVE PROCEDURES

## 1. Introduction

Renal dialysis services can be provided either in an independent facility or as part of a healthcare facility such as hospitals, day surgical centres or rehabilitation centres. A person or entity must obtain a license from Dubai Health Authority (DHA) to operate a Renal Dialysis Unit (RDU) in the Emirate of Dubai. This applies to governmental, semi-governmental, private RDUs and those operating in free zone areas.

## 2. Registration and Licensure Procedures

- 2.1. Submission of an application to the Health Regulation Department (HRD) is a requirement for licensure in order to establish a new RDU in the Emirate of Dubai. The health facility licensing procedures are described in the Health Regulation Section of the DHA website. For further information visit [www.dha.gov.ae](http://www.dha.gov.ae).
- 2.2. In case of building a RDU, the application file shall include both the preliminary and final architectural plans with specifications showing the proposed general location, accessibility, physical features of the site, means of electrical and water supply, sewage disposal, medical equipment, furniture and other utilities including the following:
  - 2.2.1. The land plot allocated to the dialysis unit shall be approved for commercial use by Dubai Municipality (DM).
  - 2.2.2. The RDU shall have easy and independent access to its premises with access to the building for stretcher from ambulance service.
  - 2.2.3. The RDU must have disabled access to accommodate wheel chair patients.
  - 2.2.4. The RDU shall have hospital-type elevators in case it is not located on the ground floor or not a part of a Hospital or a Day Surgical Center, to accommodate patient bed at least 1.73 meters (5 feet 8 inches) wide by 2.74 meters (9 feet) deep.
- 2.3. Upon receipt of a completed applicant's file, the HRD shall conduct a detailed review of the submitted material to determine compliance and suitability for further processing.
- 2.4. The HRD shall issue an initial approval letter for the facility, with defined services and restrictions particular to the applicant request.
- 2.5. This letter will be required to complete the dialysis unit's licensing procedures by local and federal authorities including, but not limited to:
  - 2.5.1. The Department of Economic Development (DED) in Dubai or equivalent licensing bodies (i.e. free zones authorities).



2.6. In case of rejection of application, a detailed list of issues will be provided for corrective action and the applicant is required to re-submit a new application with applicable fees.

**For further details regarding the application form, ownership, licensure procedures, application fee and design re-submission fee please click here or visit the Health Regulation on the DHA website [www.dha.gov.ae](http://www.dha.gov.ae).**

### 3. Facility Name

- 3.1. During the initial registration process, the name of the RDU will be tentatively under the owner name which is in accordance to the rules and regulations of the DED.
- 3.2. The independent RDU shall be issued a permanent and distinctive name by the DED following the final approval issued by HRD. This name must not be changed without prior notification.
- 3.3. Name of the RDU shall not tend in any way to mislead the public as to the type or extent of care provided by the facility.

### 4. Final Inspection and Issuing the License

- 4.1. An online request for Final Inspection through Sheryan, the online licensing system, shall be submitted by the applicant, upon which an onsite pre-operational assessment will be conducted by HRD.
- 4.2. Applicant shall submit the detailed scope of services provided in the dialysis unit along with final layout in Auto-Cad format prior to final inspection.
- 4.3. To obtain the DHA license, the applicant must meet the following:
  - 4.3.1. Appoint a Medical Director- DHA licensed consultant Nephrologist.
  - 4.3.2. Employ a sufficient number of qualified and licensed consultant/specialist physicians and/or other healthcare professionals to satisfy the facility functional program and to meet patient needs for all services/procedures provided in the facility.
  - 4.3.3. Install and operate medical equipment required for provision of the outpatient health care services in accordance with manufacturer specifications.
  - 4.3.4. Provide documented policies and procedures but not limited to the following:
    - 4.3.4.1. Infection control policy
    - 4.3.4.2. Hazardous waste management
    - 4.3.4.3. Patient Assessment
    - 4.3.4.4. Response to complications
    - 4.3.4.5. Medication management

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- 4.3.4.6. Patient health record/ Medical Record
  - 4.3.4.7. Patient transfer and emergency action plan
  - 4.3.4.8. Staff documentation
  - 4.3.4.9. Incident Reporting
  - 4.3.4.10. Disaster Management/ Emergency preparedness plan.
  - 4.3.4.11. Informed Consent
  - 4.3.4.12. Safety measures against Biohazards
  - 4.3.4.13. Safety while conducting all patient care activities
  - 4.3.4.14. Use, maintenance and documentation of the RO system.
  - 4.3.5. Maintain Charter of Patients' rights and responsibilities noticeably posted on the premises at least in two languages (Arabic and English).
  - 4.3.6. Maintain adequate lighting and utilities, including temperature controls, water taps, sinks and drains, electrical outlets and communications.
  - 4.3.7. Maintain a backup generator to ensure that power failure does not lead to machine and dialysis failure allowing adequate time for patients to be removed from the dialysis machines.
  - 4.3.8. Keep floors, work surfaces, and other areas clean and neat at all times. Flooring should be in accordance to the current DHA guidelines.
  - 4.3.9. Clearly display the hours of operation of the facility as well as the type of services available.
  - 4.3.10. Clearly display signage and direction for rooms and services provided in the facility at least in two languages (Arabic and English).
  - 4.3.11. Clearly displayed hazardous signs aimed to restrict access for the safety of patients, visitors and staff.
  - 4.3.12. Designate secured areas for the collection of medical waste, general storage facilities for supplies and equipment and storing area for hazardous materials.
  - 4.3.13. Provide a sufficient number of toilets for patients, their families, and staff.
  - 4.3.14. Access for disabled toilet within the facility is required for all dialysis units.
  - 4.3.15. Keep the facility accessible for handicapped and disabled individuals.
  - 4.3.16. Access to an emergency exit and clear signs to direct patients and staff towards the exit.

- 4.4. Based on the result of the onsite assessment and after meeting the DHA requirements and recommendation (if any), a DHA license will be issued by HRD. The RDU facility license shall be valid for one year.
- 4.5. Every license shall state the name and address of the facility, the DED license number, the period of licensure validity, the specific service(s) that the facility is licensed to deliver.
- 4.6. The facility license shall be visibly posted on the premises.
- 4.7. The RDU management shall maintain malpractice insurance for all licensed healthcare professionals as per article 25 and 26 of the UAE Federal Law number 10/2008 concerning Medical Liability.
- 4.8. Maintain Hepatitis “B” vaccination record of all staff.
- 4.9. Have an in house ambulance or have a contract with a licensed ambulance service of another facility not further than 15 minutes driving distance from the RDU.
- 4.10. Maintain documents with the Reverse Osmosis (RO) company regarding Machine maintenance contract and machine maintenance certificates.
- 4.11. If the RDU is located in a hospital, it should be preferably on the same level as the Intensive Care Unit (ICU) with easy access to the ICU.
- 4.12. In case of an independent RDU or if it is part of another healthcare facility, a contract with a hospital within 10-15 minutes driving time (close proximity) for emergency transfer of patients must be provided.
- 4.13. Record of BLS, ACLS and PALS for all licensed staff.
- 4.14. Record of PALS for enough staff to cover all shifts in case paediatric dialysis services are provided.
- 4.15. Contract for laundry services.
- 4.16. Contract for waste management services.
- 4.17. Contract with a Central Sterile Supply Department (CSSD unit) in case there is no in house CSSD unit.
- 4.18. Record of the presence of fire marshal to cover all shifts of the dialysis unit.

## 5. Management Responsibilities

Upon obtaining the DHA license the management of the facility has certain licensure responsibilities they must fulfil which include:

- 5.1. Comply with all applicable federal and local laws and regulations.

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- 5.2. Take necessary measures to distribute new DHA circulars and announcements among all facility professionals.
  - 5.3. Cooperate with HRD inspectors and/or any duly authorized representative and provide requested documentation or files.
  - 5.4. Avoid giving misleading information and false statements which may lead to legal action against professionals or the health facility.
  - 5.5. Settling of any violation fines related to professionals or the health facility.
  - 5.6. Use the DHA, Infectious Diseases Notification Service to report communicable disease required by the UAE Federal Law number 27/1981 concerning the Prevention of Communicable Diseases.
  - 5.7. Submit to the Health Data and Information Analysis Department in DHA the required statistical data of the facility.
  - 5.8. Obtain prior approval from the Ministry of Health (MOH) for media and advertisement materials, for further information regarding the media and advertisement materials approval procedures and requirements please visit the MOH website [www.moh.gov.ae](http://www.moh.gov.ae)
  - 5.9. Documents to be maintained by the Facility Management
    - 5.9.1. Copy of Staff CV
    - 5.9.2. Copies of credentials of Physicians, Nurses, Technicians
    - 5.9.3. Application of employment of all staff
    - 5.9.4. Medical Mal Practice Insurance for all Doctors, Nurses and Technicians
    - 5.9.5. Record of any Disciplinary action taken against any employee
    - 5.9.6. Up to date Basic Life support (BLS) training and Advanced Cardiac Life Support (ACLS) training for all Doctors, Nurses and Technicians.
    - 5.9.7. Paediatric Advanced Life support (PALS) trained staff in case paediatric patients are treated in the facility to be present at all times.
    - 5.9.8. Documentation of Health and vaccination records for all employees, including Volunteers.
    - 5.9.9. Up to date fire marshal training certificate.
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## 6. Compliance Review

- 6.1. At any time and upon reasonable cause, HRD may conduct random inspection to audit the RDU to determine the facility compliance with the DHA regulations, and take appropriate action if required.
- 6.2. The HRD inspectors and/or any duly authorized representative shall conduct regular onsite inspections to ensure compliance with the relevant DHA regulations.
- 6.3. The onsite inspections may be scheduled or un-announced.
- 6.4. After every inspection in which non-compliance to the DHA regulations has been identified, the authorized inspectors shall issue an onsite copy of the field inspection report followed by a letter stating the identified violations.
- 6.5. The facility management shall submit to the HRD a written plan of correction of violations cited within fifteen days after receiving the noncompliance letter stating the identified violations.
- 6.6. Violation fines shall be settled by the health facility.
- 6.7. A follow up visit maybe conducted by the HRD to confirm the correction.

## 7. Application for License Renewal

- 7.1. Application for renewal of the facility license must be submitted not less than 30 days prior to expiration of the license and shall conform to all renewal requirements.
- 7.2. The applicant's failure to submit the renewal licensing application within the given time shall result in expiration of the current license on its last effective date. In such cases, the RDU will be subjected to financial penalties and may lead to null and void of the facility license.
- 7.3. DHA facility license will be renewed for a period of one year after fulfilling the HRD requirements for re-licensure assessment.

## 8. Temporary Suspension of the License

- 8.1. If identified that the RDU poses an imminent risk to the safety of patients, employees or visitors of the facility; HRD shall assess the facility operations or specific service.
- 8.2. HRD may recommend to the Director General of DHA the temporary suspension of the facility license or specific services.
- 8.3. The Director General shall form an investigative committee and may issue a decree of temporary suspension.

## 9. Voluntary Cancellation of the License

- 9.1. Should a facility wish to cease its services, a voluntary cancellation request shall be signed by the owner of the RDU and must be submitted at least (30) days before closure of the facility.
- 9.2. The management of the facility shall comply with existing DHA regulations regarding cancellation of the health facility license.

## 10. Null and Void License

- 10.1. As per the UAE Federal Law number 2/1996 concerning Health Facilities, the health facility license is considered null and void by force of law in the following conditions:
  - 10.1.1. Transferring the health facility ownership to a different individual, corporation, Limited Liability Company (LLC), etc.
  - 10.1.2. Closure of the facility for a period of six months without presenting a valid and justified reason(s).
  - 10.1.3. The health facility is not operating for a period of six consecutive months from the date of issuing the facility license.
  - 10.1.4. Cancellation or liquidation of health facility Corporation, partnership or LLC.

## 11. Changes/Modifications Requiring DHA Approvals

- 11.1. The facility management shall obtain prior approval from the HRD for the following changes or modifications which include, but not limited to:
  - 11.1.1. Ownership
  - 11.1.2. Medical Director
  - 11.1.3. Facility trade name
- 11.2. Facility location
  - 11.2.1. Voluntary, permanent or temporary closure of the facility.
  - 11.2.2. Relocation of existing services.
  - 11.2.3. Major construction or renovation work in the facility.
  - 11.2.4. Adding an extension or annex to the existing health facility building.

## 12. Additions or Alterations to the Facility Building

Any renovation work that may involve change or addition to the premises shall require prior review and approval by the DHA and amendment of the facility license.

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- 12.1. The facility management must submit to the HRD an application file including both the preliminary and final architectural plans with specifications showing the proposed change or addition.
- 12.2. Any alterations or additions to the existing facility building shall comply with the construction standards and building codes of the Dubai Municipality (DM) and meet the DHA Health Facilities Guidelines: Planning, Design, Construction and Commissioning.

**For further information regarding the DHA Health Facilities Guidelines please click here or visit the Health Regulation site in DHA website [www.dha.gov.ae](http://www.dha.gov.ae)**

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## CHAPTER TWO: RENAL DIALYSIS UNIT DESIGN REQUIREMENTS



### 13. General Design Considerations

The RDU is responsible for the medical care of the patients including the management of complications arising from dialysis and end stage renal failure.

Whether the renal dialysis services will be provided in an independent RDU, or as part of a health facility such as Hospital or Rehabilitation Center with two specialties, the following general design considerations should be considered:

- 13.1. The location and access to the RDU shall be convenient both to people using public transportation and those using vehicles.
- 13.2. Freestanding dialysis units may provide parking on the facility premises to satisfy the needs of patients and staff, such parking area shall be acceptable to the local authorities having jurisdiction e.g. Road and Traffic Authority (RTA) and DM.
- 13.3. Consideration shall be given to the anticipated disabled patients as determined by the services provided in the facility.
- 13.4. Signage shall be provided to direct people unfamiliar with the facility to the entrance and facility parking areas (if provided).
- 13.5. Special consideration should be given to the choice of fireproof construction for the buildings according to the building and design codes of Dubai Municipality (DM) and Civil Defense Department requirements.
- 13.6. Each facility design shall ensure appropriate levels of patient acoustical and visual privacy and dignity throughout the care process, consistent with needs established in the functional program.
- 13.7. Each facility design shall ensure clear visibility of all dialysis stations from the nurse base station, other than isolation rooms. The nurse must be able to visualize both the patient and the dialysis machine and also be within hearing range of warning sounds from the machine.
- 13.8. The dialysis unit should be air-conditioned so as to achieve 21-22 Celsius temperatures and 55–60% humidity.
- 13.9. The design, construction, renovation, expansion, equipment, and operations of the facility are all subject to provisions of several local and federal laws environmental pollution control, this include, but not limited to, hazardous waste materials storage handling, and disposal; medical waste storage and disposal; asbestos use in building materials, etc.

- 13.10. Public corridors shall have a minimum width of 1.52 meters (5 feet). Items such as provisions for drinking water, vending machines, etc., shall not restrict corridor traffic or reduce the corridor width below the required minimum.
- 13.11. The minimum door opening width for patient use shall be 86.36 centimeters (2 feet 10 inches). If the facility serves patients confined to wheelchairs, the minimum width of door openings to rooms shall be 1.12 meters (3 feet 8 inches).
- 13.12. Door swings should be oriented to provide patient privacy.
- 13.13. The minimum ceiling height shall be 2.39 meters (7 feet 10 inches)
- 13.14. Color contrast between walls, floors and doors shall be considered as it may reduce falling risk of blurred vision patients.
- 13.15. Selected flooring surfaces shall be easy to maintain, readily cleanable, and appropriately wear-resistant for the location.
- 13.16. Slip-resistant flooring products shall be considered for flooring surfaces in wet areas (e.g. ramps, shower and bath areas) and areas that include water for patient services as well as stairways.
- 13.17. Highly polished flooring, walling or finishes that create glare shall be avoided.
- 13.18. Carpet cannot be used in examination and treatment rooms, if used in patient waiting areas and corridors carpet shall be glued or stretched tight and free of loose edges or wrinkles.
- 13.19. Wall finishes shall be washable, moisture-resistant and smooth, wall finish treatments shall not create ledges or crevices that can harbor dust and dirt.
- 13.20. Joints for floor openings for pipes and ducts shall be tightly sealed.
- 13.21. There must be an emergency exit within the facility with proper signs to direct towards the emergency exit. Building and Plumbing requirements
- 13.22. Design consideration shall be given to the disposal of liquid waste from the dialyzing process to prevent odor and backflow. The product water distribution system shall not contribute chemicals such as copper, zinc and lead, or bacterial contamination to the treated water.
- 13.23. In new construction and renovation, a separate water supply and a drainage facility that does not interfere with hand-washing shall be provided.
- 13.24. Reverse osmosis permeate water is to be circulated back to the reverse osmosis storage tank complete with ultraviolet light sterilization.
- 13.25. An Uninterrupted Power Supply (UPS) for backup, the power supply of which should be able to support all functions of the dialysis machines.

#### 14. Reception and Waiting Area

- 14.1. A reception/information counter or desk shall be located to provide visual control of the entrance to the RDU and shall be immediately apparent from that entrance; the information counter should provide access to patient files and records.
- 14.2. Male and female waiting area for patients may be provided or be shared with other adjacent departments in case the dialysis unit is not independent. Escorts will be under staff control.
- 14.3. Waiting area may be provided with provision of drinking water.
- 14.4. Facilities for alcohol-based hand rub/ sanitizer dispensers should be available in all patient areas.
- 14.5. The waiting area must accommodate the functional requirement of the facility with allocating at least two seats per each dialysis station (2:1).
- 14.6. Where pediatric service provided in the facility, a separate controlled area for pediatric patients shall be designated.
- 14.7. Wheelchairs shall be accommodated within the waiting area.
- 14.8. Toilet(s) for public use shall be conveniently accessible from the waiting area without passing through patient care or staff work areas. A hand-washing station shall be provided in the toilet room.

#### 15. Consultation or Examination Rooms

Room space requirements shall depend on the services provided, but at least shall meet the following:

- 15.1. Consultation or examination room(s) shall have a minimum floor area of 12 square meters (129 square feet).
- 15.2. Room arrangement shall permit a minimum clearance of 81.28 centimeters (2 feet 8 inches) on both sides and at one end of the examination table, bed, or chair.
- 15.3. A counter or shelf space for writing and documentation shall be provided.
- 15.4. A hand-washing station with a hands-free regulator (tap) and liquid or foam soap dispensers shall be provided in all examination room(s). Sinks shall be designed with deep basins, made of porcelain, stainless steel, or solid surface materials.
- 15.5. Hand sanitation dispensers shall be provided in addition to hand-washing stations.
- 15.6. Provisions for hand drying shall be available at all hand-washing stations.
- 15.7. The area below the hand washing station shall be free of clutter at all times.

## 16. Treatment Room

- 16.1. Rooms for minor treatments or procedure shall have a minimum floor area of 11.15 square meters (120 square feet). The minimum room dimension shall be 3 meters (9.8 feet).
- 16.2. Room arrangement shall permit a minimum clearance of 91.44 centimetres (3 feet) at each side and at the foot of the bed.
- 16.3. The treatment rooms shall be equipped with:
  - 16.3.1. Hand sanitation dispensers shall be provided in addition to hand-washing stations.
  - 16.3.2. Documentation space or counter for writing.
  - 16.3.3. A lockable refrigerator for medication use (the temperature of which is monitored twice a day and recorded).

## 17. The Dialysis treatment area/room

### 17.1. Layout

- 17.1.1. This area shall be separate from administrative and waiting areas.
- 17.1.2. The dialysis area specifications and requirements shall include:
  - 17.1.2.1. Enough space to accommodate the number of provided dialysis stations.
  - 17.1.2.2. The dialysis station shall be easily accessible in times of emergency and with adequate space for resuscitation to be carried out.
  - 17.1.2.3. The layout shall ensure visual and acoustical privacy for all patients.
  - 17.1.2.4. Hands free hand washing facility must be provided and easily accessible from all dialysis stations.
  - 17.1.2.5. Alcohol-based hand rub/ sanitizer dispensers should be available in all dialysis stations.
  - 17.1.2.6. Floor covering in the dialysis area/room shall be monolithic and joint free
- 17.1.3. The space occupied by each dialysis station shall be at least 7.44 sq. meters. (80 sq. ft.); large enough to accommodate the dialysis chair or couch dialysis machine as well as working room for 2 dialysis personnel.
- 17.1.4. A clearance space shall be at least 4 feet (1.2meters) between beds and /or lounge chairs.
- 17.1.5. Head end of each bed should have stable electrical supply with at least three outlet of 5/15 amps, oxygen and vacuum outlet, treated water inlet, and drainage.

- 17.1.6. Electric sockets must be provided and close to every dialysis station. The wires from the socket should be in such a way that they do not pose a threat or come in the way of the patient or staff during the whole dialysis process.
- 17.1.7. A dialysis station may be designed to have comfortable couches or chairs specially designed for dialysis purposes, however, it is recommended to have at least two (2) beds for elderly patients.
- 17.1.8. Every dialysis station must have a waste disposal bin.
  - 17.1.8.1. For a regular dialysis patient, the waste disposable bags used should be Black in colour.
  - 17.1.8.2. For patients with Communicable diseases, it is mandatory that the waste disposable bags used should be Yellow in colour.
  - 17.1.8.3. Waste disposal must be done after every 2 patients and must be taken outside to the soiled work room for disposal.

## **17.2. Nursing Station**

Nurse station(s) shall be located and designed to provide visual observation of all patients in all the dialysis stations of the dialysis treatment area. The nursing station should also be within the range of hearing warning sounds from the machines for prompt corrective action.

## **17.3. Equipment to be provided in the dialysis area/room**

- 17.3.1. Every dialysis station must have outlets for oxygen and vacuum (suction).
- 17.3.2. Airway equipment: appropriate sized oral airways, endo-tracheal tubes, laryngoscopes, normal masks and laryngeal masks
- 17.3.3. Defibrillator
- 17.3.4. Double tourniquets if the practice performs Bier blocks
- 17.3.5. Pulse oximeter
- 17.3.6. Electrocardiographic (ECG) monitor
- 17.3.7. Temperature monitoring system for procedures lasting more than 30 minutes
- 17.3.8. Blood pressure apparatus with different size cuffs
- 17.3.9. Emergency crash cart
- 17.3.10. A refrigerator for pharmaceuticals and double-locked storage for controlled substances shall be provided.

## 18. Isolation rooms

- 18.1. To ensure patients and healthcare professionals as well as other personnel safety; there should be separate areas/room(s) for dialyzing patients with conditions that require isolation. This area should have independent water supply and drainage facilities.
- 18.2. Isolation rooms must be in accordance with international guidelines and must be categorised as follows:
  - 18.2.1. Airborne Infection Isolation (AII) Room
  - 18.2.2. Blood borne Infection Isolation Room(s): Facilities that dialyze patients with known blood-borne pathogens shall have at least two separate rooms to use for those patients as follows:
    - 18.2.2.1. For HBV patients room shall be color coded with Blue Color
    - 18.2.2.2. For HCV patients room shall be color coded with Yellow Color

## 19. Storage room

- 19.1. The storage area should have easy access.
- 19.2. The storage area should be temperature controlled.
- 19.3. There should be adequate shelving for storage of dialysis fluids, membranes and catheters.
- 19.4. All material should be clearly marked with expiration dates.
- 19.5. Storage of medicines should be in accordance with current guidelines, including storage and dispensing of controlled medication.

## 20. Support areas for Dialysis Patient care

- 20.1. Administrative activities

Each dialysis unit shall make provisions to support administrative activities, filing and clerical work as appropriate. Administrative areas provided may include the following:

  - 20.1.1. Clerical space or rooms for typing and clerical work.
  - 20.1.2. Multiuse rooms for meetings, and health education.
- 20.2. Medication station/ medication preparation area- There shall be a medication dispensing station or a medication preparation area for the dialysis unit. Provisions shall be made for the controlled storage, preparation, distribution, and refrigeration of medications
- 20.3. Medicine Storage Area- An enclosed area close to the medication station or medication preparation area.

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- 20.4. Health records filing cabinets and storage shall be provided for the safe and secure storage of patient's health records with provisions for easy retrieval. Provisions shall be made for proper securing of the health records.
- 20.5. Nourishment area- A nourishment station for the dialysis service is provided.
- 20.6. Clean Supply room- This room is used for preparing patient care items, it shall contain the following:
- 20.6.1. Work counter
- 20.6.2. Hand-washing station
- 20.6.3. Storage facilities for clean and sterile supplies. This room is used only for storage and holding as part of a system for distribution of clean and sterile materials.
- 20.7. Soiled workroom -A soiled workroom shall be provided with in close proximity to the dialysis unit and shall contain the following:
- 20.7.1. A flushing-rim sink
- 20.7.2. A hand-washing station
- 20.7.3. A work counter
- 20.7.4. Storage cabinets
- 20.7.5. Waste receptacles
- 20.7.6. A soiled linen receptacle
- 20.8. Equipment and supply storage
- The RDU shall make provisions for the following requirements:
- 20.8.1. General storage area for supplies and equipment.
- 20.8.2. Special storage for staff personal belongings with lockable drawers or cabinets.
- 20.8.3. Storage areas for non-clinical records, documents, and office supplies.
- 20.9. Clean linen storage. If blankets or other linens are used, a clean linen storage area shall be provided. Location of the clean linen storage area within the clean workroom, a separate closet, or an approved distribution system shall be permitted. If a closed cart system is used, storage in an alcove shall be permitted. It must be out of the path of normal traffic and under staff control.
- 20.10. Wheel chair storage place- a designated area shall be provided out of the direct line of traffic for at least one facility-owned wheelchair. A designated area shall be provided for parking at least one patient wheelchair in a non-public area out of the direct line of traffic without interfering with egress paths.
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## 21. Water Quality

21.1. The water used for dialysis shall be treated by RO and/or deionizers to provide a quality of water which meets with the standards listed below.

a)

Contaminant	Maximal Allowable Level (mg/l)
<b>Contaminants with documented toxicity to hemodialysis</b>	
Fluoride	0.2
Chloramines	0.1
Copper	0.1
Aluminum	0.01
Lead	0.005
Total Chlorine	0.1
Nitrate (as N)	2
Sulfate	100
Zinc	0.1
Total dissolved solids	5-1000
<b>Trace elements</b>	
Antimony	0.006
Arsenic	0.005
Barium	0.1
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Mercury	0.0002
Selenium	0.09
Silver	0.005
Thallium	0.002



(Extracted from Association for the Advancement of Medical Instrumentation (AAMI) & CSA-ISO)

b) The water used to prepare the dialysate shall have a bacteriological count of less than 200 per ml after 48 hours of incubation (AAMI). Total viable counts shall be obtained using conventional microbiological assay procedures (pour plate, spread plate). The calibrated loop technique shall not be used.

Alternatively, the water shall have a bacterial lipopolysaccharide concentration of less than 1 ng/ml or 5 Endotoxin units as measured by the Limulus amoebocyte lysate assay.

21.2. Regular tests of the quality of the water for (a) and (b) must be carried out, at a minimum of one monthly intervals and recorded to ensure that standards are met.

21.3. Regular sterilization of the plant equipment and pipes at a minimum of monthly interval. Each water point has to be tested along with chemical analysis.

21.4. The nephrologist in charge or the medical director of the renal dialysis unit is responsible for ensuring that these tests are carried out by DHA licensed laboratory registered to perform these assays. An in house chemical laboratory is preferable. The records shall be kept and made available for inspection by DHA.

21.5. Temperature of the water needs to be regulated to avoid water related hyperthermia.

## 22. Dialysate Quality

22.1. The dialysate fluid shall be a non-sterile aqueous solution with an electrolyte composition near that of normal extracellular fluid.

22.2. The feed tank should have sufficient volume to supply the RO system. The RO system should supply water to the dialysis machines in accordance to the RO specifications.

22.3. The RO system should not be connected directly to the main supply and the water supply should be uninterrupted.

22.4. The RDU should be approved by DEWA to ensure uninterrupted flow of water.

22.5. The tank should be of an adequate size and that the pipe size of water supply to the RO is sufficiently large.

22.6. The feed from the RO must be sufficiently large.

22.7. The RO should be either in a separate room. In case of a portable RO, it should be within a recommended distance from dialysis machines as specified by the manufacturer.

22.8. The RO system must not be linked to general toilet facilities or placed in general bathrooms.

22.9. There should always be a backup machine available for patients.

22.10. The water used to prepare the dialysate must have a bacteriological colony count of less than 200/ml using the method as in section 6.2. b).

22.11. The composition of the dialysate fluid

22.11.1. The concentration of hemodialysis solutions shall be such that after dilution to the stated volume the final concentrations of the ions expressed as mmol/l are usually in the following ranges:

a)

<b>Cations</b>	
Sodium	135-145
Potassium	0-3.0
Calcium	1.0-2.0
Magnesium	0.25-1.0

b)

<b>Anions</b>	
Acetate or Lactate expressed as bicarbonate equivalents	32-40
Chloride	95-110

22.11.2. Sodium concentration may be adjusted to levels outside this range by hemodialysis machines with variable sodium capabilities when prescribed by physician in charge.

22.11.3. The final diluted dialysate shall be analyzed every 6 months, with every new batch of dialysate and after each major servicing/repair of dialysis machine.

22.12. Bacteriological Requirements

22.12.1. The colony count in dialysate samples collected at the termination of dialysis

22.12.1.1. In a single pass system or

22.12.1.2. In a recirculating single pass system at the periphery of the recirculating chamber containing the dialyzer shall be less than 2000 colony-forming units/ml (AAMI).

22.12.2. Bacteriological analysis of the dialysate shall be carried out at least 2 monthly.

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- 22.13. The nephrologist in charge or the medical director shall be responsible for arranging the analysis of the dialysate. Its chemical composition shall be clearly labeled. The results of analysis, bearing the name of the renal dialysis unit and the healthcare professional analyzing the dialysate shall be made available on request as and when required.
- 22.14. All chemical analysis test results for feed and dialysis water received from the in-house or third party testing laboratory must be documented. These results must be reviewed by the nurse in charge of the dialysis unit and reviewed and signed off by the medical director annually.

## CHAPTER THREE: RENAL DIALYSIS UNIT STANDARDS

## 23. Staffing

### 23.1. Physicians- Nephrologists

- 23.1.1. A DHA licensed consultant nephrologist should be nominated as the medical director of the dialysis unit who shall be responsible for overall management of the patients in the dialysis unit.
- 23.1.2. The DHA licensed consultant nephrologist shall have at least 2 years' experience in dialysis.
- 23.1.3. There must be one nephrologist on call per shift to troubleshoot problems of patients.
- 23.1.4. A DHA licensed paediatric nephrologist must be associated with the facility in case Paediatric dialysis services are provided (Children under the age of 16 years)
- 23.1.5. The Paediatric Nephrologist must be present when paediatric dialysis services are provided.
- 23.1.6. The nephrologist must ensure adequate monitoring of patients during dialysis, and subsequent outpatient aftercare.
- 23.1.7. Ratio of nephrologist to patients is one nephrologist to thirty five patients– 1:35
- 23.1.8. The responsibility of the nephrologists must cover dialysis access care (perform or arrange for insertion of vascular catheters, arrange for creation of arterio-venous fistula (AVF) and insertion of tenckhoff catheters).
- 23.1.9. The nephrologists shall be contactable at all times to render emergency medical care.
- 23.1.10. In the event that the nephrologist on duty is unable to fulfil his/ her full responsibility to the patients of the RDU, he/ she must make arrangements for a similarly qualified physician to be responsible for the total care of the patients in the dialysis unit.
- 23.1.11. In case of an emergency the attending nephrologist shall ensure that arrangements are made with hospitals for all patients in the dialysis unit to be expeditiously referred for emergency management.
- 23.1.12. The medical director is ultimately responsible in ensuring that the monitoring and safety devices and resuscitation equipment are in proper working condition at all times.
- 23.1.13. The need for dialysis treatment and choice of modality shall be based on sound clinical principles and a thorough clinical evaluation of medical condition and co-morbid by the attending nephrologist.

- 23.1.14. The attending nephrologist may recommend to the end stage renal failure patient the modality that is best suited to him/ her. This shall be based on the patient's renal, other co-morbid conditions, ability to comply with treatment, available family support and other social factors.
- 23.1.15. The patient shall be allowed to make a fully-informed choice of dialysis modality, after receiving adequate counseling from his/ her nephrologist on the different modalities available and the modality that is most appropriate for the patient's need.
- 23.1.16. There shall be a documented Quality Assurance Program (QAP) to ensure quality patient care through objective and systematic monitoring, evaluation, identification of problems and action to improve the level and appropriateness of care. The QAP shall include:
- 23.1.16.1. Documented policies and procedures related to the safety while conducting all patient care activities.
- 23.1.16.2. Documented regular biannual reviews of the policies and procedures.
- 23.1.16.3. Documented reviews of deaths, accidents, complications and injuries arising from dialysis treatment.

### **23.2. Nursing Staff**

- 23.2.1. The nurse in charge of the dialysis unit must be a qualified; DHA licensed Registered Nurse (RN), with at least 2 years of experience in Dialysis.
- 23.2.2. The ratio of trained RNs/ dialysis patients should be 1: 4. Among these staff there should be at least one nurse with a minimum of 6 months of training or experience/ training in dialysis to be physically present at the RDU at all times to monitor the patients throughout the dialysis procedure, to be available to deal with any emergencies that may arise and to alert the nephrologist when necessary.
- 23.2.3. The attending RN is responsible for the general checkup of the patient including vital statistics and maintaining the initial assessment in the medical records.
- 23.2.4. The RN shall possess appropriate training in handling resuscitation equipment and dealing with cardiac emergencies. All nursing staff shall have undergone formal certified training in cardiopulmonary resuscitation. The certified training in basic life support shall be current and up-to-date and available in case of DHA inspections.

### **23.3. Renal Dialysis Technicians**

- 23.3.1. The renal dialysis technician should be DHA licensed and competent in dialysis water practices.
- 23.3.2. The renal dialysis technician will collect water samples for chemical analysis, and to perform necessary actions should test results from the chemical contaminants exceed its acceptable limits.
- 23.3.3. The renal dialysis technician should be competent enough to cannulate the patient.
- 23.3.4. The ratio of the renal dialysis technician to the dialysis patients should be 1:2.
- 23.3.5. The renal dialysis technician must monitor the dialysis machine at all times and must be able to handle any complications related to the machine.
- 23.3.6. The renal dialysis technician must inform the nurse in case of any major problem that he/ she cannot handle.
- 23.3.7. Contents of training program for a renal dialysis technician
  - 23.3.7.1. Fundamentals of renal anatomy and physiology.
  - 23.3.7.2. Principle of dialysis.
  - 23.3.7.3. Water quality, water treatment, and water distribution.
  - 23.3.7.4. The dialysis machine: connectivity and upkeep of machines.
  - 23.3.7.5. Basics of vascular access.
  - 23.3.7.6. Dialyzers and tubes including cleaning and preservation.
  - 23.3.7.7. Anticoagulation.
  - 23.3.7.8. Dialysate: composition and ingredients.
  - 23.3.7.9. Common complications of dialysis: How to manage them at bedside.
  - 23.3.7.10. Basic evaluation of a patient before, during and after dialysis.
  - 23.3.7.11. Infection control and safety.
  - 23.3.7.12. Dialyzer reprocessing.
  - 23.3.7.13. Cannulation (vascular access): the broad principles; Critical care dialysis continuous renal replacement therapy (CRRT)/sustained low-efficiency dialysis (SLED)) and pediatric patient management.
  - 23.3.7.14. Universal precautions for prevention of transmission of infections.
  - 23.3.7.15. Basics of peritoneal dialysis.

#### **23.4. Dialysis Attendants/ Sanitation Personnel**

- 23.4.1. The ratio of dialysis attendants to dialysis station being 1:15.
- 23.4.2. There should be at least one sanitation personnel for every 8 patients.

23.4.3. The dialysis attendant/ sanitation personnel must be responsible to clear the waste from the disposable waste bins present in every dialysis station and take it to the soiled work room for proper disposal.

### **23.5. Dietician**

23.5.1. There should be at least one dietician, who should maintain progress notes of all patients treated in the RDU.

### **23.6. Pharmacist**

23.6.1. A DHA licensed pharmacist shall be in charge of maintaining the medicines and solutions that would be administered to patients.

### **23.7. Medical Social Worker**

23.7.1. There should ideally be some medical social workers associated with RDU. The medical social workers should be involved in psychosocial evaluation, case work counseling of patients and families, group work, evaluate and facilitate rehabilitation, team care planning and collaboration, facilitating community agency referral, improve communication with treating team. The social workers are required to maintain notes of the patients.

### **23.8. Infection Control Nurse**

23.8.1. To perform regular audits, conducts surveillance of cultures and insures best practice for patient access.

## **24. Dialysis equipment**

24.1. Dialysis machines shall be equipped with monitors and audio-visual alarms to ensure safe dialysis.

24.2. The nephrologist in charge is ultimately responsible to ensure that all dialysis equipment is in proper working condition and that the necessary safety devices are fitted and in working order.

## **25. Patient Assessment**

25.1. An effective patient assessment process aims to be comprehensive, includes multidisciplinary teams and is based on clinical and priority needs of each individual patient. Such assessment shall result in identification and decisions regarding the patient's condition and continuation of treatment as the need arise. The RDU shall have policies and procedures on patient assessment:

25.1.1. On admission



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- 25.1.2. Following a change of health status
  - 25.1.3. After a fall
  - 25.1.4. When patient is transferred from one level of care to another.
  - 25.2. The patient assessment shall include, but not limited to, medical history, physical, social and psychological assessment and identification of patients at risk.
  - 25.3. Patients conveying personal health information during any assessment should be accommodated in an area where privacy is assured.
  - 25.4. Discharge preparation starts at admission and includes various persons, information and resources. Consider discharge preparation:
    - 25.4.1. The pickup person
    - 25.4.2. Travel distance to home
    - 25.4.3. The carer's contact details and their awareness of possible issues and requirements following discharge
    - 25.4.4. Contact numbers after discharge, such as the doctor or emergency contact
    - 25.4.5. Discharge arrangements regarding home care where this is identified as required and available
  - 25.5. Healthcare professionals should use a formal risk assessment process to assess skin integrity and risk of falls of patients.
  - 25.6. A comfortable care environment shall be provided in the facility with focus on patient privacy. The plan of care must be determined and delivered in partnership with the patient and when relevant, patient's family/patient representative/legal guardian, to achieve the best possible outcomes.
  - 25.7. The patient has the right to refuse the plan of care but this has to be documented and signed by the patient.
  - 25.8. Patient's participation may include:
    - 25.8.1. Procedure date and admission/discharge time
    - 25.8.2. Physician selection
    - 25.8.3. Treatment preparation
    - 25.8.4. Choice of wound care or dressing type only related to dialysis to be performed with strict sterile techniques to prevent spread of infections. Wound dressing of ulcers not related to dialysis should not be performed in the dialysis cubicles.
  - 25.9. Post-discharge transport.
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25.10. Care shall be delivered by DHA-licensed and competent healthcare professionals and competent multidisciplinary teams and based on the best available evidence.

25.11. A comfortable treatment environment is provided in the facility with focus on patient privacy.

## 26. Outpatient Care

26.1. Outpatient Services, if provided, must be under the direction of qualified individual(s), as determined by the RDU and must be responsible for the quality and scope of outpatient services.

26.2. The outpatient care shall be provided in a distinct area on the dialysis unit premises.

26.3. The initial medical assessment may include, but not limited to: the reason for the visit, vital signs, medical history, pain assessment, physical, and psychological assessment of patient's needs.

## 27. Critical Care Services

27.1. The RDU must have an agreement with a Hospital with an Intensive Care Unit (ICU) which must be accessible within a maximum of 10 minutes' drive from it.

27.2. There must be a competent and DHA licensed RN with suitable training and experience in critical care on duty to provide the critical care services if required. The evidence of competency and training shall include but not limited to the following:

27.2.1. Recognizing arrhythmias

27.2.2. Infection control principles

27.2.3. Training in using defibrillator

27.3. Critical care equipment must be immediately available at the RDU for immediate and safe provision of care if required.

## 28. Emergency Services

The nephrologist in charge of the RDU shall ensure that there are facilities for emergency resuscitation, as well as documented protocols/procedures to deal with cardiopulmonary collapse and urgent medical treatment as patients may develop hypotension, fits or collapse during dialysis.

In addition, the nephrologist in charge must:

28.1. Ensure that there are prior arrangements made for patients receiving dialysis to be admitted in a hospital nearby, should the need arise within 10 minutes' drive maximum.

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- 28.2. Ensure that there are standing arrangements with other healthcare professionals to provide immediate medical care in the event that the nephrologist/ physician in charge are not available.
- 28.3. Ensure there is an ambulance available at any given time to transfer the patient to a hospital in case of any medical emergency.
- 28.4. Ensure that there is a contract with a facility that outsources ambulances in case there is no in-house ambulance.
- 28.5. Ensure that the ambulance service is accessible and at close proximity.
- 28.6. In case the RDU has its own ambulance service the ambulance services should be ready with licensed, trained and qualified Emergency Medical Technicians (EMT) for patient transportation if required, this service can be outsourced with a written contract with an emergency services provider licensed in Dubai. Clear patient transport protocol should be maintained.
- 28.6.1. Sets of instruments which shall include suturing set, dressing set, foreign body removal set or minor set and cut down set.
- 28.6.2. Disposable supplies which shall include suction tubes (all sizes), tracheostomy tube (all sizes), intravenous cannula (different sizes), IV sets, syringes (different sizes), dressings (gauze, sofratulle, etc.), crepe bandages (all sizes), splints (Thomas splints, cervical collars, finger splints).
- 28.6.3. Portable vital signs monitor (ECG, Pulse-Oximetry, Temperature, NIBP, and EtCO<sub>2</sub>).
- 28.6.4. Portable transport ventilator with different ventilation mode (IPPV, SIMV, spontaneous, PS).
- 28.6.5. Suction apparatus.
- 28.7. Emergency drugs, devices, equipment and supplies must be available for immediate use in the emergency area for treating life threatening conditions.
- 28.8. Storage areas for general medical or surgical emergency supplies, medication and equipment shall be under staff control and out of path of normal traffic.
- 28.9. A record must be kept for each patient receiving emergency services and must be integrated into the patient's health records, the record shall patient name, date, time and method of arrival, physical findings, care and treatment provided. Name of treating doctor and discharging/transferring time.
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## 29. Transfer Planning

- 29.1. The RDU shall maintain policies and procedures concerning patient transfer which reflect acceptable standards of practice and compliance with applicable regulations in Dubai.
- 29.2. If patient is transferred to another health facility and in order to insure continuity of patient care, the other facility shall be informed about the case and approval for transfer should be documented in the patient file.
- 29.3. The doctor present at the RDU is responsible for the coordination of the timely transfer of appropriate information and discharge notice from the RDU to hospital or another health facility.
- 29.4. A dialysis transfer sheet should be prepared for all patients being transferred from the unit requiring further dialysis.
- 29.5. Current Hepatitis serology and Hepatitis antibody level should be included in the Dialysis transfer sheet.
- 29.6. A referral letter shall be given to the patient or family/patient representative. Patient should not be sent under any circumstances to another facility without prior approval.
- 29.7. Mode of transport should be decided based on the condition of the patient, the treating physician and the ambulance team shall decide who should accompany the patient e.g. doctor present or trained nurse in emergency/critical care.

## 30. Infection Control Practices

- 30.1. General Precautions
  - 30.1.1. Standard Precautions shall be used on all patients regardless of whether the Hepatitis B, Hepatitis C and HIV status is known. During dialysis, blood is often spilt. It is therefore vital for staff to be adequately protected using impervious gowns/aprons, gloves and eye protection.
  - 30.1.2. Disposable gloves shall be worn by staff members for personal protection when performing procedures which are potentially bio hazardous.
  - 30.1.3. Staff should wash their hands and use a fresh pair of gloves with each patient to prevent cross-transmission. Gloves shall be removed when such procedures are interrupted (e.g. answering telephone calls, called away for other duties) to prevent contamination of surfaces uninvolved with the aforesaid procedure.

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- 30.1.4. Hepatitis B vaccination of all staff that has contact with blood and body fluids is strongly recommended. This applies to dialysis attendants / sanitation personnel of the renal dialysis unit. Routine screening of staff for anti-HCV may be done where necessary.
- 30.1.5. Blood samples for analysis shall be carefully taken, put in plastic vials and then placed in separate plastic bags. Individual vials shall be labeled and carefully checked after each blood sample is taken.
- 30.1.6. Only blood and blood products screened and found negative for HBsAg, anti-HCV and HIV shall be given.
- 30.1.7. Blood products should be stored, transferred and administered in accordance with the relevant authority guidelines.
- 30.1.8. Draining, disinfection and rinsing procedures shall be performed after each dialysis. If a blood leak occurs in a recirculating system, the usual rinsing and disinfection procedure shall be performed twice before the system is used on a different patient.
- 30.2. Acute Hemodialysis
- 30.2.1. Acute hemodialysis is often done for patients on an emergency or semi emergency basis. Under these circumstances, it may not be possible to have results of tests of blood-borne viruses. Dialysis shall proceed as is required on medical grounds. Isolation facilities are not required unless the patient has concomitant infection with another disease that requires isolation. Disposable dialyzers and bloodlines shall be used and the machine shall undergo complete chemical disinfection in accordance to manufacturer's recommendations after each use for patients with unknown HBsAg, anti-HCV and HIV status.
- 30.3. Chronic Hemodialysis
- 30.3.1. Patients who require chronic hemodialysis at dialysis centers shall be tested for Hepatitis B, Hepatitis C and HIV before they are admitted to the center. The dialysis center shall maintain records of patients' latest results in accordance to the current international guidelines.
- 30.4. Hepatitis B
- 30.4.1. Hepatitis B surface antibody should be performed at six months intervals and if the titre is low the patient should be administered a booster.

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- 30.4.2. All patients with Hepatitis B surface below 100 international units should be given a full course and booster of hepatitis B vaccine.
- 30.4.3. A Liver function Test (LFT) must to be conducted every month.
- 30.4.4. Patients who are seronegative (HBsAg and anti-HBs negative) shall be tested 6-monthly for HBsAg.
- 30.4.5. Patients who are HBsAg positive by 2 consecutive tests shall be tested 6- monthly or as clinically indicated.
- 30.4.6. Patients who are HBsAg and anti-HBs negative shall receive Hepatitis B-vaccination.
- 30.4.7. Patients who are HBsAg positive shall be isolated in a separate room that is colour coded (Blue) designated for HBsAg positive patients only.
- 30.4.8. Dedicated dialysis equipment shall be used for HBsAg positive patients. After each dialysis, non-disposable equipment shall be appropriately cleaned and disinfected or sterilized. Dialyzers and AV bloodlines must not be shared among patients. Bloodlines shall be used once and discarded.
- 30.5. Hepatitis C
- 30.5.1. Hepatitis C patients are to be dialyses in separate isolation rooms that have to be clearly colour coded (Yellow) and used only for Hepatitis C patients.
- 30.5.2. Patients shall be tested for Hepatitis C antibodies at 6-monthly intervals. In case of doubt they have to be verified with HCV, PCR assay.
- 30.5.3. The rooms for treating HBV and HCV patients should be colour coded and strictly used only for these patients.
- 30.5.3.1. HBV- Blue Colour
- 30.5.3.2. HCV- Yellow Colour
- 30.6. Patients who travel to high risk countries
- 30.6.1. Patients dialysed in high risk countries, or who leave the unit to travel to high risk countries and subsequently come back to the dialysis unit, should be dialysed on an isolation machine for three months until they are confirmed negative for Hepatitis B and Hepatitis C. This is a precaution taken to reduce the risk to other patients.

### 31. Safety

- 31.1. There must be provision for emergency electric power supply for life-saving equipment in case of power failure.

- 31.2. Presence of a fire marshal on site at all times is a must.
- 31.3. Fire precautions must be taken and fire escapes shall be clearly visible.

### **32. Death of Patient/ Care of Deceased Patients**

- 32.1. Death in a RDU would be considered a sentinel event. A policy for mortuary management covering this rare and tragic event shall be available in the facility.
- 32.2. In case of patient death, the RDU shall be responsible for overseeing the transportation of deceased patients from the dialysis unit to mortuary.
- 32.3. The RDU shall maintain a policy in handling dead bodies which assure respect and dignity of the deceased.
- 32.4. All dead bodies shall be considered infectious, strict infection control measures shall be considered during cleaning the body. Body should be cleaned and wrapped/placed on mortuary bag.
- 32.5. A record of such sentinel events shall be maintained by the RDU.
- 32.6. All deaths occurring whilst on dialysis or as a consequence of dialysis or any procedure related to dialysis must be reported immediately to the DHA.

### **33. Ethical Considerations**

- 33.1. Healthcare professionals working in the facility should be aware of their ethical responsibilities and comply with the ethical code of conduct which is governed by the principle of patient centeredness where the patient is the center of all activities.
- 33.2. Healthcare professionals should maintain patient's information confidentiality at all times.
- 33.3. Referring physicians are strongly prohibited from taking any commission for referring patient to specific clinical laboratory or diagnostic imaging service provider.
- 33.4. Unnecessary diagnostic imaging investigations and laboratory testing must be avoided as they pose serious health implications and a financial burden to the individual and community.

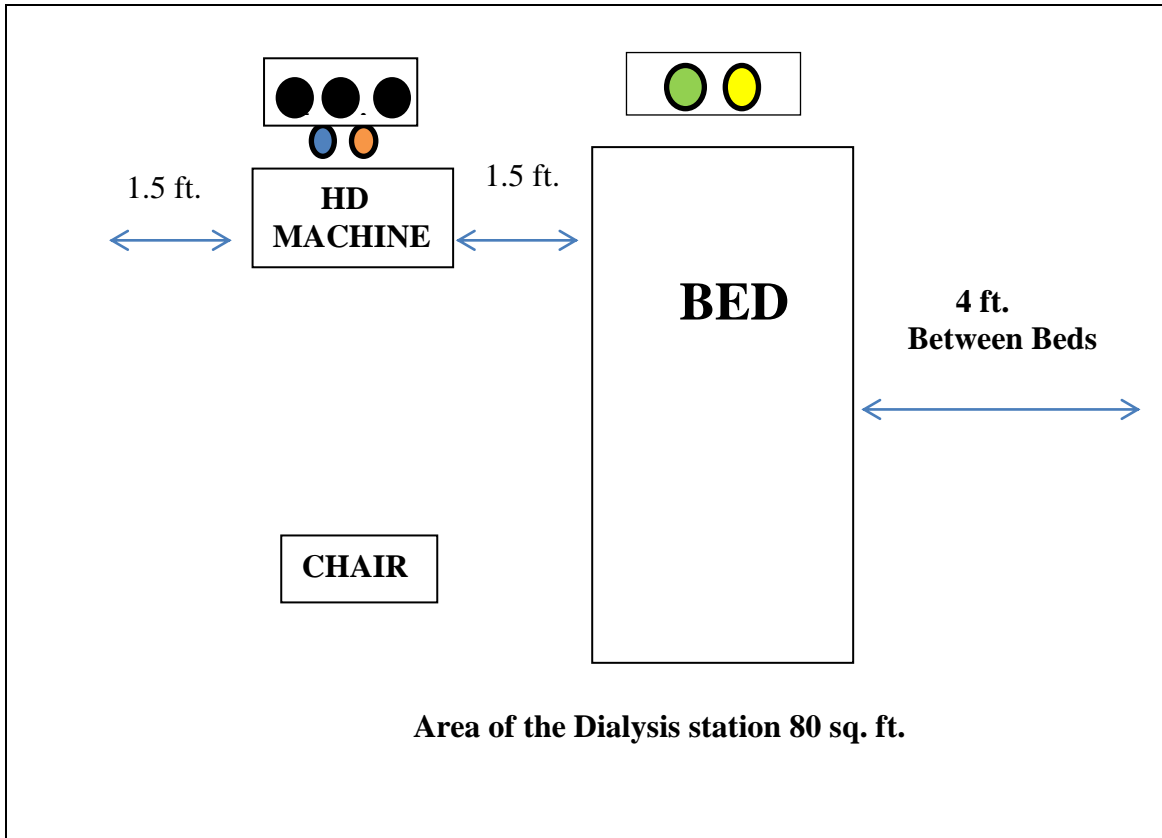
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### Appendix 1



Showing typical HD machine area, Black dots Electricity outlets, Green dot: Oxygen outlet, Yellow dot: Vacuum outlet, Blue dot: treated water inlet, Orange dot: drainage outlet.