MINIMUM STANDARDS FOR PROVIDING DIALYSIS SERVICES IN THE MALDIVES

Quality Assurance and Regulations Division
Ministry of Health
Male', Republic of Maldives

RELEASE RECORD

Version No	Version Date	Description of change
1	8 September2024	Initial release

DOCUMENT NUMBER: MOH-QA/S/24/171-0

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Published by	Quality Assurance and Regulations Division Ministry of Health, Male, Republic of Maldives
Published date	8 September 2024

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1. Introduction

Dialysis is the process of removing waste products from blood and excess fluid from the body when the kidneys are not able to adequately filter the blood (Marks, 2024 & IHFG, 2023). This treatment is required for End-Stage Renal Disease (ESRD) where the function of the kidney to remove substances from the blood is replaced by the use of a dialysis machine. There are two types of dialysis. Haemodialysis and Peritoneal Dialysis (PD).

Peritoneal Dialysis (PD) is an alternative to Haemodialysis. Peritoneal dialysis involves the exchange of fluid to and from the abdominal peritoneum via an inserted peritoneal catheter 3 to 4 times each day with this being undertaken either manually Continuous Ambulatory Peritoneal Dialysis (CAPD) or with the assistance of a machine (Automated Peritoneal Dialysis – APD) for 8 to 10 hours, generally overnight after training from health professionals (National Kidney Foundation, 2024 and IHFG, 2023).

Given the critical nature of this treatment, ensuring high standards of care and operational consistency across all dialysis units is paramount. Therefore, national standards play a crucial role in ensuring consistency, safety, and quality. By setting clear guidelines and benchmarks, national standards help to streamline processes, enhance efficiency, and promote best practices. It ensures that products and services meet the minimum requirements necessary for protection of patient's well-being.

The National Standards for Providing Hemodialysis Services have been developed to establish a framework of best practices and quality benchmarks for the delivery of hemodialysis care. The standard aim to ensure that every patient receives safe, effective, and compassionate treatment, regardless of where they receive care. They reflect the latest advancements in medical knowledge, technology, and patient care practices, and are designed to enhance the overall quality of hemodialysis services across the country.

2. Purpose of the standard

1. Enhance Patient Safety: To provide guidelines that minimize risks and complications associated with hemodialysis, including infection control, equipment safety, and proper clinical practices.
2. Promote Consistency: To establish uniform procedures and protocols that ensure consistency in the quality of care provided by dialysis facilities, fostering equitable treatment outcomes across the country.
3. Support Clinical Excellence: To guide healthcare professionals in delivering high-quality, evidence-based care through adherence to best practices and the latest clinical guidelines.
4. Facilitate Compliance: To align with regulatory requirements ensuring that all dialysis units meet national and international benchmarks for quality and safety.
5. Improve Patient Outcomes: To provide a structured approach for the continuous improvement of patient care and treatment efficacy, ultimately enhancing the overall well-being and quality of life for individuals undergoing dialysis.

3. Scope and Application

By adhering to these national standards, dialysis units will be better equipped to deliver high-quality care, foster patient trust, and contribute to improved health outcomes for individuals with ESRD. The implementation of these standards is not only a professional obligation but also a commitment to advancing the field of dialysis and supporting the health and dignity of patients nationwide. This standard is intended for use by all healthcare facilities providing dialysis services in the Maldives.

4. Definitions

Unit	A stand alone or dedicated unit within a government or a private healthcare facility providing dialysis services
Dialysis	Dialysis in this standard is meant to be haemodialysis
PD	Peritoneal dialysis
Dialysis bay	The area where dialysis machine and chair/beds are arranged for dialysis
Water treatment	Means treatment of water up to the required standard for it to be used for dialysis.
High volume dialysis unit	In units where more than 100 sessions of dialysis are performed per week.

For the purpose of this standard, the auxiliary verb:

"MUST" means that compliance with requirements is mandatory for compliance with this standard and the unit cannot omit or use a part of those points.

"SHALL" means that compliance with a requirement or a test is recommended for compliance with this standard

"MAY" is used to describe a permissible way to achieve compliance with requirement or test.

5. Design Considerations

5.1 General

Design is a key factor when planning a health facility. This may include functional and operational requirements, material selection, safety regulations and cost effectiveness. Any unit providing dialysis services shall be designed to enhance:

a) Easey public access to patients using mobility equipment, wheel chair and stretchers, and

b) Easy transportation of large stock items.

All unit providing dialysis services in the Maldives MUST observe the following mandatory infrastructure requirements stipulated in chapter 3 of the Regulation No. 2021/R-28 (Regulation on Operating Healthcare Centres). They are:

S 10- Structural standards of health care centres

S 11- Hygiene maintenance standards

S 12- Safety standards

S 13- Reception and waiting area

S 14- Consultation rooms

S 18- Sterilization and disinfection

5.2 Planning models

Planning a dialysis unit requires special consideration for some factors, such as:

a) Age mix and sex of the patient group

b) Mental and social aspects of the patient group

c) Severity of the illness of the proposed patient group

d) Comorbidities in the patient group Rate of infectious disease expected in the patient group

When planning a dialysis unit, the models in figure 1 and 2 may be used as operational models.

a) A hospital (a unit within the hospital),

b) A satellite unit (on a hospital campus but not in a hospital unit),

c) A stand-alone unit (positioned in a community setting).

Figure 1: Hospital-based haemodialysis unit

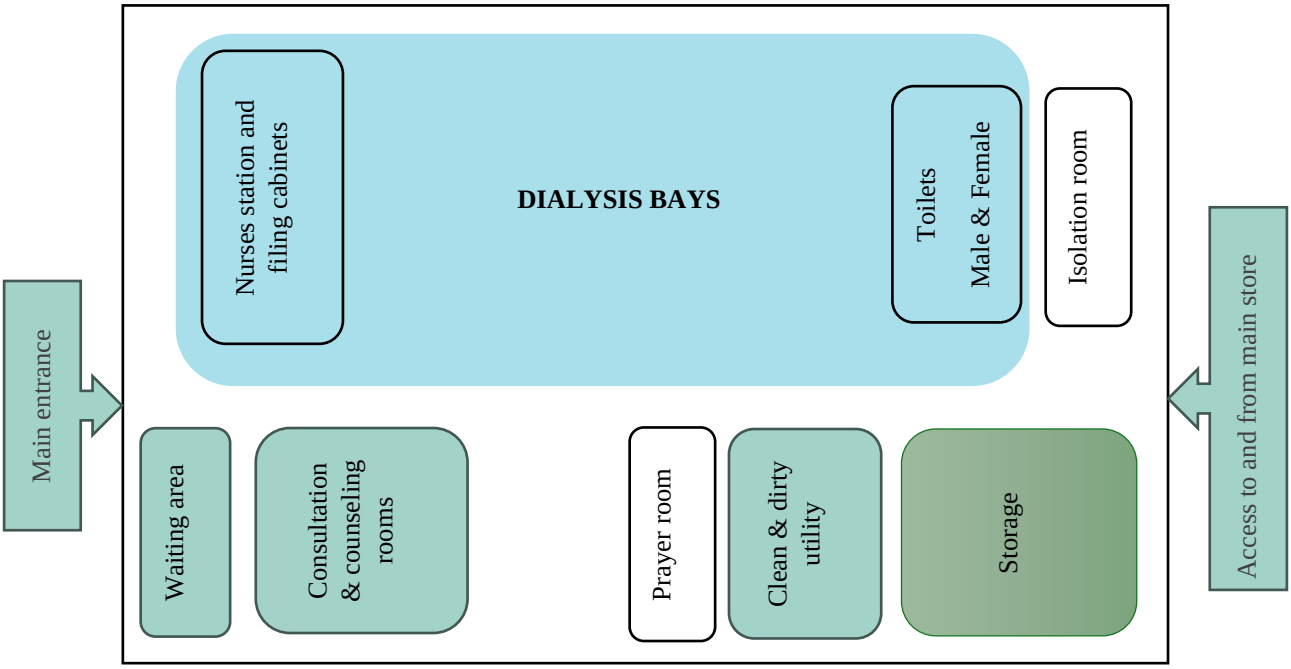
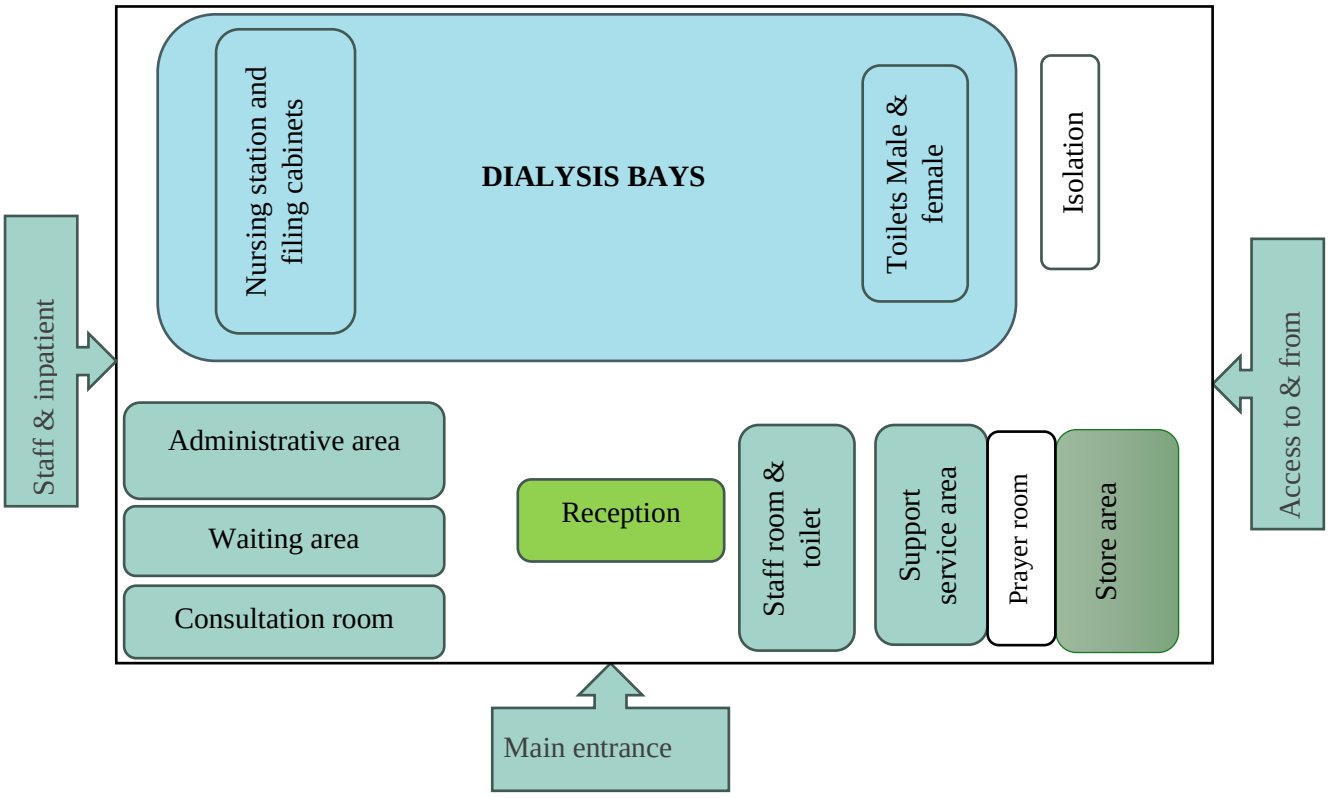


Figure 2: Stand-alone dialysis unit



5.3 Functional areas

The dialysis unit may consist of the following functional areas.

a) Main entry/reception area
b) Waiting area
c) Dialysis bays
d) Isolation room
e) Nursing station
f) Consultation rooms
g) Support service area
h) Storage area

Detailed requirements of functional areas are attached in annex 1.

6. General Requirements

The following general requirements are to ensure patient safety, quality of care and effective operations.

6.1 Facility requirements:

a) Shall ensure provision of emergency electric power supply for life saving equipment in case of power failure. An Uninterrupted Power Supply (UPS) back up for 15 minutes (not limited to institutional need) shall be desirable for each machine in case of power failure.
b) All hemodialysis machine areas, consultants & technicians'/nurses' rooms should have air conditioning.
c) Dialysis bays should have temperature of 70.0 to 72.^{0} F & 55% to 60% humidity.
d) The treatment area must be separate from administrative and waiting areas.
e) Hemodialysis bays shall be clear of cabinetry.
f) A hand washing station must be available near the entry to the dialysis bays.
g) A medication trolley/emergency cart shall be centrally located in the dialysis center and shall be located at least 6 feet from any individual dialysis bays.
h) Must have adequate space for every section of the unit. Please refer to Schedule of Accommodation (SOA) in annex 2 for general floor area requirements. This may vary

according to institutional requirements. However, the unit should not be less than the requirements in SOA. Section 5 also provides details of facility requirements.

6.2 Regulatory compliance: Adhering to provisions in relevant Laws and Regulations are a mandatory requirement. All healthcare facilities MUST obtain registration and operating license from Quality Assurance and Regulations Division (QARD) of Ministry of Health (MOH) prior to its operation. Units must also follow mandatory reporting for incidents, and other critical data. Please refer to section 7 for details.

6.3 Staffing: Each unit must be staffed with a sufficient number of professionals from the necessary fields of expertise. Please refer to section 8 for details on human resource requirements. All haemodialysis treatment shall be prescribed by a nephrologist.

6.4 Patient rights and education: There shall be dedicated programs to educate patients about their condition, treatment options, diet and lifestyle changes. Patient MUST be informed about the treatment risks and alternatives and then informed consent obtained. A summary of care provided shall be given to all patients after dialysis.

6.5 Quality assurance and improvements: Every unit MUST have their own schedule for internal and external audits to ensure compliance with standards. There shall be a system to collect and act on patient feedback to improve services. For the assessment of performance matrix, there shall be a tracking system for key performance indicators such as infection rates, patient outcomes, and treatment efficacy, etc.

6.6 Documentation and record keeping: All units shall maintain detailed and accurate patient records while ensuring compliance with Regulation No. 2019/R-1070 (Regulation on Medical records). Please refer to section 10 for details on health information management.

6.7 Equipment and supplies:

a) All units must abide by the equipment requirements stipulated in this standard. Please refer to section 12 for detailed requirement for equipment and supplies.

b) All units shall maintain a written preventive maintenance program for all medical and dialysis equipment and related procedures.

6.8 Written protocols: All units shall have written policies and procedures required for safe and effective care. Required policies and procedures are but not limited to:

a) Staff responsibilities and accountabilities
b) Informed consent for dialysis
c) Admission, continuity of care, referral and discharge policy
d) Care of patients with a communicable disease or are immune- suppressed
e) Care of high-risk patients
f) Incident reporting and sentinel events
g) Infection, prevention and control
h) Medication management
i) Medical Records management policy
j) AV fistula management.
k) Water quality testing policy
l) Preventive maintenance policy for equipment
m) Stock management policy
n) Staff training and competency assessment policy

7. Licensure Requirements

No unit shall be operated in the Maldives without obtaining registration and operating license from Ministry of Health under chapter 2 of the Act No. 29/2015 (Health Service Act) and Regulation No. 2021/R-28 (Regulation on Operating Healthcare Centres). The following are mandatory registration and licensure requirements.

7.1 Registration

7.1.1 Registration and operating license are required by units requesting to establish healthcare services for the first time. Existing health facilities/ hospitals with a valid registration and operating license requires new service approval.

7.1.2 Hospital-based dialysis unit requires new service approval (for dialysis service). Stand-alone units require registration and operating license.

7.1.3 All licensed health care centres must pay the prescribed annual fees as stipulated in chapter 4 of Regulation no. 2021/R-28 (Regulation on registration and licensing of healthcare Centres).

7.1.4 Registration shall be granted up on fulfilling all structural/design requirements stipulated in this standard.

7.2 Operating license

7.2.1 All registered units MUST obtain operating license before providing services. The units MUST satisfy the following requirements.

a) Valid health facility registration,

b) Human resource required for providing services who fulfil requirements stipulated in section 8 of this standard.

c) The Schedule of Equipments outlined in section 13 shall be available at the unit when obtaining operating license and service approval.

8 Human Resource

8.1 General requirements

8.1.1 All clinical staff in the unit must have valid registration and practicing license from their respective council of Ministry of Health.

8.1.2 All clinical staff at the unit shall have completed recommended training/clinical exposure from a recognized dialysis centre.

8.1.3 The trainings that clinical staff received shall be from a high-volume dialysis centre,

8.1.4 Number of staffing in the unit should resemble the workload of the unit, to ensure care and treatment are performed safely and effectively.

8.1.5 All units shall have documented process for determining its overall staffing needs, by number and type of staff for the provision of care.

8.1.6 All units providing dialysis services shall comprehensively and clearly define in writing the qualifications, clinical and management responsibilities, of its Head of Department (HOD),

8.1.7 There shall be one nephrologist per 35 patients per shift and should be physically in the facility.

8.1.8 There must be 1 (one) medical officer in each shift who can attend to emergencies if required.

8.1.9 The ratio of trained registered nurses per dialysis patient shall be 1:3 per shift with at least one registered nurse with 2 years of experience in dialysis physically present in the shift. In a hospital setting nurse patient ratio should depend on the acuity of the patient but should not exceed 1:4.

8.1.10 There shall be at least one (1) ACLS certified registered nurse per shift.

8.1.11 Staff involved in direct patient care shall receive basic training in CPR (Continuous Medical Education & Refresher training).

8.1.12 Pediatric nephrologist shall be available at the unit during dialysis of pediatric patients.

8.1.13 In places where dialysis technicians are employed, they should have competency in dialysis water, and ratio of dialysis technician per dialysis depends on the complexity of the machine.

8.1.14 Periodic skill enhancement/updating/refresher training shall be provided for all categories of the staff as relevant to their clinical practice.

8.1.15 All units shall have a reasonable level of proficiency by certified BLS, ACLS and PALS Healthcare Professionals for readiness and preparedness to emergency services.

8.1.16 All units shall establish and approve a program for Quality and Safety that includes both patient and staff, and includes its risk management and quality improvement activities.

8.1.17 Every staff in the unit holds certain qualification and responsibilities. Details of qualification and responsibilities are in table 1.

Table 1: Qualification for the clinical staff at the dialysis unit

Staff	*Specification*
Head of department (HOD)	*Qualification* - As assigned by the institution. *Responsibilities* Responsibilities of the in-charge include (but not limited to): - Oversee functions of the unit and deliver guidance for the staff. - Ensure proper functioning and maintenance of the unit and equipment. - Ensure that the unit complies with the requirements stipulated in this standard. - Ensure that there are standing arrangement/arrangements with other medical practitioners to provide immediate medical care, in life-saving measures. - Ensuring the safety of patients and staff of the haemodialysis unit. - Shall ensure all relevant and required clinical dialysis policies, standards and guidelines are adopted and periodically reviewed. - Shall facilitate and participate in the development of the unit, clinical governance with particular emphasis on risk management, clinical audits, medical records, documentation and staff competencies and performance evaluation.
Nephrologist	*Qualification* - Must hold registration and practicing license as a specialist in nephrologist from Maldives Medical and Dental Council *Responsibilities* Responsibilities of the specialist registrar in nephrology include (but not limited to): - Advise on the facilities, equipment and staffing requirements of the unit.

	- Advise on policies and standards for haemodialysis treatment in conformity with the requirements of the regulations and/or any nationally accepted guidelines - Plan clinical management of the dialysis patients. - Prescribing haemodialysis treatments. - Recommend changes or modifications to treatment as deemed necessary from time to time in order to maintain the quality of care
Medical Officer	*Qualification* - Must be a qualified medical doctor with a degree of medicine and registration and practicing license from Maldives Medical and Dental Council. - Shall have completed 3 (three) months of clinical experience in a high-volume dialysis unit. *Responsibilities* Responsibilities of the medical officer include (but not limited to): - Care of patients during dialysis - Assist in in-charge in duties of the unit.
Head nurse	*Qualification* - Must have registration and practicing license from Maldives Nursing and Midwifery Council. - Training in Advanced Cardiac Life Support (ACLS) is an additional requirement. - Shall fulfill the requirements of nurses' job structure. *Responsibilities* Responsibilities of the registered nurse include (but not limited to): - Perform and monitoring haemodialysis patients - Support in HOD in creating protocols and guidelines in the unit. - Stock management. Shall ensure 2 weeks stock items are available in hand.

	- Education of haemodialysis patients and their families. - Ensure nursing staff competencies are assessed on regular basis or by institutional policies.
Registered Nurse	*Qualification* - Must have registration and practicing license from Maldives Nursing and Midwifery Council. - Training in Advanced Cardiac Life Support (ACLS) is an additional requirement. - Shall have minimum of 3 (three) months of formal training/clinical experience in a high-volume dialysis unit. *Responsibilities* Responsibilities of the registered nurse include (but not limited to): - Performing haemodialysis treatment. - Monitoring of haemodialysis patients - Administration of medications - Care of dialysis equipment and systems - Education of haemodialysis patients and their families
Dialysis technician (optional)	*Qualification* Must have registration from Maldives Allied Health Council *Responsibilities* - Responsible for monitoring dialysis machines at all times and should be able to handle complications related to the machine. - Collect water samples for chemical analysis, and perform necessary actions in case test results from chemical contamination exceeds acceptable limits. - Alert nurses in the event of emergency.

9 Water Quality

All units providing dialysis services MUST abide by the following mandatory water quality requirements for the dialysis machines. The mandatory water quality requirements are derived from International Health Facility Guideline Part B: Health facility briefing and design, Renal dialysis unit, 2023, Ministry of Health, Singapore (2001) and AAMI 2020 ANSI/AAMI/ISO 23500-3:2019. Water quality testing and assessments are subject to changes depending on variations in international best practice.

9.1 Process of water production

There should be a dedicated secure area for water treatment with space to access to all components of the equipment.

9.1.1 Sequence for water treatment

Unit may undertake water treatment activities in different ways. The following are sequences used in general for treatment of water.

Sequence for water treatment

Phase 1: Particle filtration to 20 microns

Phase 2: Water softening to remove calcium and magnesium carbonate

Phase 3: Carbon filtration to remove chlorine. Chlorine is taken out as late as possible in the process so that its disinfection properties are utilized.

Phase 4: Particle filtration to 5 and 1 micron

Phase 5: Reverse osmosis

9.1.2 Installation of water pre-treatment

a) Water feed quality

b) Pressure of the feed water

c) Maximum water flow (considering growth of services)

d) Average water flow per day (considering growth of services)

e) Spatial requirement to safely install and operate water pre-treatment plant

f) Drainage requirements

g) Weight of the water pre-treatment plant and the ability of the floor to safely support that weight

h) Water quality monitoring system

i) Power supply requirements

j) Facilities and access to safely service and maintain the water pre-treatment plant

k) Water distribution loop

9.1.3 Components of water treatment services

Feed water temperature control: high feed water temperatures may require a heat exchanger to cool the feed water. If feed water is cold, it can be heated by mixing hot and cold water a thermostatic mixing valve.

Back flow preventer: this system is required in all pre-treatment systems. This device prevents the water in the pre-treatment system from flowing back into the source water supply system. A Reduced Pressure Zone Device (RPZD) or a break tank with an air gap may be used.

Multimedia depth filter: particulates of 10 microns or greater are removed by multimedia filter. These particulates may clog carbon and softener tanks, destroy the Reverse Osmosis (RO) pump and foul RO membrane.

9.2 Chemical contaminants

Permissible level of chemical contaminants is discussed in table 2. All units must observe and adhere to permissible levels of chemical contaminants and other trace elements are in table 3.

Table 2: Permissible levels of chemical contaminants and dialysis fluid electrolytes in dialysis water.

Containment	Maximal concentration (mg)
Contaminants with documented toxicity in haemodialysis	
Aluminum	0.01
Total chlorine	0.1
Copper	0.1
Fluoride	0.2

Lead	0.005
Nitrates	2
Sulphate	100
Zinc	0.1
Electrolytes normally included in dialysis fluid	
Calcium	2 (0.05 mmol/l)
Magnesium	4 (0.15 mmol/l)
Potassium	8 (0.2 mmol/l)
Sodium	70 (3.0 mmol/l)

Adapted from ANSI/AAMI/ISO 23500-3:2019. (Preparation and quality management of fluids for haemodialysis and related therapies-Part 3: Water for haemodialysis and related therapies.)

Table 3: Maximum allowable levels of other trace elements in dialysis water

Containment	Maximum concentration mg/l
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

Adapted from AAMI 2020 (Preparation and quality management of fluids for haemodialysis and related therapies-Part 3: Water for haemodialysis and related therapies)

9.2.1 Method of testing:

Chlorine and water hardening testing must be performed in accredited laboratories and acceptable analytic testing methods are summarized in table 4.

9.2.2 Frequency of testing:

Total chlorine and water hardening should be tested at least daily. Chemical analysis of water should be tested at least every 6 months.

9.2.3 Limits and action level:

Evaluate water treatment system and rectify as necessary.

9.2.4 Record:

Records of the test results must be maintained carefully and available for inspection.

Table 4: Analytical test method for chemical contamination

Contaminant	Analytic technique	Reference, method number
Aluminum	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)	ISO 17292:2016 American public health
Antimony	Inductively coupled plasma mass spectrometry or atomic absorption (platform)	ISO 17294-2:2016 US EPA
Arsenic	Inductively coupled plasma mass spectrometry or atomic absorption (gaseous hydride)	ISO 17294-2:2016 American public health
Barium	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)	ISO 17294- 2:2016 American public health
Beryllium	Inductively coupled plasma mass spectrometry or atomic absorption (platform)	ISO 17294-2:2016 US EPA
Cadmium	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)	ISO 17294- 2:2016 American public health
Calcium	Inductively coupled plasma mass spectrometry or EDTA (Ethylene diamine tetraacetic acid) titrimetric method or atomic absorption (direct aspiration) or ion specific electrode	ISO 17294- 2:2016 American public health
Total chlorine	DPD (N-Diethyl-p-Phenylenediamine) ferrous titrimetric method or DPD (N-Diethyl-p-Phenylenediamine) colorimetric method Thio-Michler's Ketone (TMK/MTK) colorimetric method	American public health
Chromium	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)	ISO 17294- 2:2016 American public health

Copper	Inductively coupled plasma mass spectrometry or atomic absorption (direct aspiration) or neocuproine method	ISO 17294- 2:2016 American public health
Fluoride	Iron chromatography or iron selective electrode method or sodium 2-(parasulfophenylazo)-1.8-diathyoxy-3.6-naphthalenedisulfonate (SPADNS) method	ISO 10304-1:2007 ISO 10359-1:1992 American public health
Lead	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)	ISO 17294- 2:2016 American public health
Magnesium	Inductively coupled plasma mass spectrometry or atomic absorption (direct aspiration) iron chromatography	ISO 17294-2:2016 American public health
Mercury	Flameless cold vapor technique (atomic absorption)	American public health
Nitrate	Iron chromatography or spectrophotometric method using sulfosalicylic acid or cadmium reduction method	ISO 10304-2:2007 ISO 7890-3:1988 American public health
Potassium	Inductively coupled plasma mass spectrometry or atomic absorption (direct aspiration) or flame photometric method or iron specific electrode	ISO 17294-2:2016 American public health
Selenium	Inductively coupled plasma mass spectrometry or atomic absorption (gaseous hydride) or atomic absorption (electrothermal)	ISO 17294-2:2016 American public health
Silver	Inductively coupled plasma spectrometry or atomic absorption (electrothermal)	ISO 17294-2:2016 American public health
Sodium	Inductively coupled plasma mass spectrometry or atomic absorption (direct aspiration) or flame photometric method or iron specific electrode	ISO 17294-2:2016 American public health
Sulphate	Iron chromatography or turbidimetric method	ISO 10304-1:2007 American public health
Thallium	Inductively coupled plasma mass spectrometry or atomic absorption (platform)	ISO 17294-2:2016 US EPA
Total heavy metals	Colourimetric	European pharmacopoeia 2.4.8 US pharmacopoeia 231
Zinc	Inductively coupled plasma mass spectrometry or atomic absorption (direct aspiration) or dithizone method	ISO 17294-2:2016 American public health

Adapted from ANSI/AAMI/ISO 23500-3:2019. Preparation and quality management of fluids for haemodialysis and related therapies-Part 3: Water for haemodialysis and related therapies)

9.3 Microbial contaminant

9.3.1 Microbial contamination test methods:

a) Methodology for microbial contaminant level is detailed in table 5. The culture medium and incubation period selected should be based on the type of fluid to be analyzed. The method selected should be based on the analysis of advantages, disadvantages and sensitivity.

b) Total viable microbiological counts in dialysis water shall be less than 100 CFU/ml. an action level shall be set based on the knowledge of the microbial dynamics of the system. Typically, action level will be 50% of the maximum allowable levels.

c) Endotoxin content in dialysis water shall be less than 0.25 EU/ml. an action level shall be set and typically, action level is 50% of the maximum allowable level.

d) Fungi (yeast and filamentous fungi) can coexist with bacteria and endotoxins in dialysis water. Currently there are no requirements for routine surveillance for the presence of fungi which can coexist with other microbial species. If surveillance is indicated, membrane filtration is the preferred method for provision of suitable sample. Culture media should be Sabouraud, or Malt Extract Agar (MEA) media. An incubation temperature of 17°C to 23°C and incubation time of 168 hours (7 days) are recommended. Other incubation times and temperature may be used, provided that it has been validated and are comparable to the cited method.

Table 5: Culture techniques

Culture medium	Incubation temperature	Incubation time
Tryptone glucose extract agar (TGEA)	17 °C to 23°C	7 days
Reasoner's Agar no 2 (R2A)	17 °C to 23°C	7 days
Sabouraud or Malt Extract Agar	17 °C to 23°C	7 days
Tryptic Soy Agar (TSA)	35 °C to 37 °C	48 ours

9.3.2 *Frequency of testing:*

Water testing for microbial contaminants and endotoxins must be carried out monthly. Additionally, water testing for chemicals shall be carried out every 6 months. Water should be treated as necessary to ensure a supply that is biologically and chemically compatible with acceptable standards. Total chlorine and water hardness should be tested at least daily.

Water testing should be performed monthly for bacteria and endotoxins and every 6 months for chemicals.

9.3.3 *Sites of sampling*

Minimum sites for sampling for testing include:

a) Post RO membrane
b) First point of the distribution loop
c) End point of distribution loop
d) Reprocessing bay

9.3.4 *Handling of water samples*

a) Sample shall be handed in to the laboratory as soon as possible or within 30 minutes of collection and immediately processed to avoid unpredictable changes.
b) If immediate processing is not possible, sample shall be refrigerated immediately at <100C and processed within 24 hours of collection.

Samples past 24 hours MUST be discarded.

9.3.5 *Limits and action level*

a) Refer to the maximum allowable limits and rectify.
b) If action levels are observed from the test results, disinfection and retesting shall be done immediately to restore water quality to acceptable levels.

9.3.6 *Records*

Results of the tests shall be maintained carefully and available for inspection when required.

9.4 Drainage system

The drainage system from dialysis machine MUST be ventilated to prevent condensation as condensation may lead to mold formation. This fact must be considered when designing covers for drainage system. Commercial brands which comply with relevant standards when planning a cover or screen for the drainage system shall be used. The dialysate and reprocessing effluent should drain into a separate drainage system with adequate capacity to handle the volume. The drainage shall be constructed in such a way to have minimum number of bends and blond loops.

10 Health Information Management

All units MUST comply with provisions in Regulation No. 2019/R-1070 (Regulation on Medical records), and must comply with Section. 11 of the "Regulation on Medical Records" which details minimum information required for every document prepared by healthcare centers.

10.1 The unit MUST ensure absolute confidentiality in health information and must abide by the provisions in chapter 2 of the Regulation no. 2019/R-1070 (Medical Record Regulation), when disclosing information.

10.2 All staff involved in patient care shall have access to necessary health information.

10.3 The unit shall ensure all documented evidence in patient's medical records, referrals to eternal healthcare services, informed consent and related healthcare outcomes to maintain continuity of care.

10.4 Following information are reported to Ministry of Health annually and when requested.

a) Total number of registered patients undergoing dialysis
b) New annual registrations
c) Average sessions per day
d) Adverse events during dialysis
e) All other information requested by Ministry of Health

11. Infection Control Measures

All units providing dialysis services shall have stringent Infection Prevention and Control (IPC) measures in place, to minimize the risk of cross infections within the unit. The following IPC measures shall be considered while designing a dialysis unit.

11.1 Prevention of transmission

a) Patients with increased risk for infection shall be identified and preventive measures implemented.

b) Isolation of patients with communicable diseases

c) Personal Protective Equipments (PPE) shall be duly available depending on the nature of dialysis and the risk of exposure to body fluids.

d) Hand washing facilities should be readily available for the staff. Liquid soaps, paper towels and waste basins shall be available in places where hand washing facilities are available.

e) Antiseptic hand rubs should be available to use at the point of care, at the end of patient beds and in high traffic areas.

f) Segregation, collection, transportation, storage and disposal of biomedical waste shall be as per national Infection Prevention and Control (IPC) guidelines.

g) Machine cleaning and disinfection shall also be carried out according to institutional policy.

11.2 Prevention of Hepatitis B and C infection

11.2.1 Regular serological screening according to hospital policy.

11.2.2 Screening for patients returning from another facility with high risk of hepatitis B transmission.

11.3 Prevention of HIV infection

11.3.1 Screening according to hospital policy

11.3.2 Dialyzer must not be re-used

11.3.3 Notification to national HIV program in case of seroconversion

11.4 Screening and vaccination of staff

11.4.1 Staff screening before working in the unit.

11.4.2 For staff with negative HBsAg screening, full course of vaccination shall be given.

11.4.3 Re-test of antibody screening1-2 months after the last dose of hepatitis vaccine

11.4.4 Staff positive for Hepatitis B and C or HIV shall not be involved in exposure prone procedures on patients in the unit.

11.5 Infrastructure considerations

11.5.1 Negative pressure isolation rooms for patients with communicable disease.

11.5.2 Infrastructure related IPC measures shall be considered while planning a dialysis unit.

11.5.3 Skirting: wall bases in treatment areas should be made integral to the floor, tightly sealed against the wall and constructed without voids.

11.5.4 All surfaces and infrastructure shall be designed to enable easy cleaning and shall withstand high-level disinfectant.

11.5.5 Availability of handwashing facilities and in all clinical areas.

11.5.6 Alcohol based hand sanitizers shall be available at entrance of treatment bays.

11.5.7 Air conditioning is preferable rather than natural ventilation.

11.5.8 Floors must be coved by impermeable material, capable to withstand heavy equipments

11.5.9 Wall finishes must be scrub able and be smooth water resistant.

11.5.10 Ceilings must be easy to clean and disinfected. Possible areas like conduits and pipes shall be covered.

12. Enforcement and Sanctions

Ministry of Health holds responsibility of enforcing Laws that protect health of the people. The aim is to use enforcement powers efficiently and effectively to secure compliance with Laws and regulations by health facilities. Therefore, the units providing dialysis services shall:

12.1 Comply with the terms and conditions of registration and licensure requirements outlined under chapter 2 of Act no. 29/2015 (Health Services Act).

12.2 The Ministry of Health may demonstrate that immediate enforcement action is necessary to prevent or respond to a serious breach of the law or regulations.

12.3 Note that a breach of Law may result in regulatory action being taken against licensees under Act no. 29/2015 (Health Services Act), including but not limited to:

a) Suspension or revocation of the licensee's operating license;

b) A direction requiring the licensee to rectify the contravention or prevent a recurrence of the contravention, and/or

c) A direction requiring the licensee to pay a financial penalty.

13. Schedule of Equipment

Schedule of equipment (SOE) is a list of equipment required for the unit.

13.1 The unit shall have adequate drugs and consumables commensurate to the scope of services and number of beds

13.2 Emergency drugs and consumables shall be available at all times.

13.3 Drug storage shall be in a clean, well lit, and safe environment and shall be in consonance with applicable laws and regulations.

13.4 Drug storage shall be in a clean, well lit, and safe environment and shall be in consonance with applicable laws and regulations.

13.5 All units shall have sufficient and appropriate equipment, instrument and supplies in accordance with service load of the unit.

13.6 Schedule of Equipment (SOE) underlined below is the list of major equipment and shall not be limited to institutional service load and shall be available at the units. List in annex 2.

14. References

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Annex 1: Requirements of functional areas

Area	Specification
A. Patient treatment areas	
Treatment bay	a) Size of the unit depends on number of staff and activities to be carried out within the unit. However, treatment bays shall have minimum of 80 square feet of clear floor area if chairs are used. And minimum of 90 square feet if beds are being used. This may change in accordance with the case load and proposed activities. b) There shall be minimum clearance of 4 feet between two dialysis bays. c) Patient treatment areas should have direct and indirect visualization for the staff, which allows patient monitoring in routine and emergency circumstances. d) Direct visualization of all patient treatment area is the preferred method of design. e) Space shall be available to accommodate provision of patient privacy when required f) Handwashing facilities shall be available in all clinical areas, with hand drying facilities. g) A dedicated area for emergency cart and resuscitation equipment in easy reach shall be available within the treatment bay. h) Male and female lavatory
B. Environmental considerations	
Privacy	a) The unit design should consider privacy of patients while giving consideration for the need for direct visualization of patient. b) Confidentiality is a high priority and shall ensure the following: i. Confidentiality of personal communications with patients and their medical records, ii. confidentiality of personal communications with patient,

	iii. Room for discreet discussions.
Lighting	a) Use of natural light shall be maximized as much as possible as it contributes a sense of well-being for the patient, staff and others. b) Halogen lamps with c) Colour Rendering Index (CRI) shall be above 90% to allow natural visualization. d) For treatment areas, a neutral white colour of about 4000k is recommended (VHHSB, 2020).
Acoustic	a) Unit planning shall address arrangements to minimize noise level within the unit and transmission of sound between patient areas, staff areas and other public areas. b) The following need to be considered for acoustically convenient environment. i. Selection of sound absorbing materials for finishes ii. Use of sound isolating constructions iii. Separate area for patients with special needs
Interior design	a) Interior finishing may be made attractive rather than a clinical environment. However, it should be easily disinfected. Seating should also be made with non-porous material to minimize infection. b) Cleaning and infection control, fire safety and a professional inviting environment should always be considered.
C. Safety and security	
The following safety and security measures shall be considered. a) Access control ingress and egress b) Similar functions shall be co-located in adjoining spaces/rooms for easy staff management c) Optimize visual observation of patients during dialysis	
D. Finishes	

Finishing shall be a conducive environment for patients, visitors and staff, and shall consider the following:

a) Aesthetic appearance
b) Acoustic properties
c) Durability
d) Easy cleaning & disinfection
e) Easy movement of equipment and traffic control
f) Lighting and colours of wall paint shall not impede skin colours
g) Lead free wall paints
h) Non-slip and impermeable flooring

E. Curtains and blinds

a) Dialysis bays with windows shall have curtains which allow reduction & or access to light as required to improve rest during dialysis procedure.
b) Bed screens must be washable & cleanliness maintained at all times.
c) Vertical blinds are preferred over horizontal blinds as it has less surfaces for collecting dust.

F. Fixtures and fittings

Fixtures and fittings in the unit shall meet intended patient load of the.

G. Accessibility

a) Easy vehicle drop-off zones to the unit.
b) Access to the Dialysis unit shall have easy and safe ingress & egress for the patients and visitors.
c) Ease of patients transfer to the unit bound by wheelchair and stretchers.
d) Controlled access to treatment areas for the general public.
e) Access designed for use by people with special needs, visitors and staff shall comply with relevant laws and regulations.

H. Mobility and Occupational Health and safety (OH & S).

Corridors:	a) In areas where trolleys, stretchers and beds are moved frequently, a minimum width of 2450mm is recommended.

	b) Special consideration shall be given to the width of doorways into the connecting rooms to allow easy turning of beds, trolleys and stretchers. c) Where an existing building is being redesigned, corridors width is smaller than the recommended dimensions may be permitted. However, special consideration should be given to emergency egress and evacuation. d) Corridors which may be used by patients for any purpose, width should not be less than 1850mm, except where written approval has been obtained. e) Corridors should always be free from items that may hinder movement.
Ceiling heights	a) Ceiling height of 2700mm is recommended in work areas such as patient treatment. b) Minimum acceptable ceiling height in occupied area is 2400mm, but consideration may be given to the size and use of the room.
Size	Size of the unit shall depend on the perceived role and expected patient load.
Grab Rails and hand rails	Grab rails/hand rail is required in places such as weight checking area and toilets.
Floor finishes	Flooring should enable easy cleaning, and the following should be considered: a) Water resistant and grease proof material b) Areas frequently washed should not be affected by germicidal cleaning agents c) Cove skirting should be used in areas where floor meets wall surfaces.
I. Functional areas	
Main	Main entrance is the main gateway to the dialysis unit and hence shall

Entrance/Reception area:	have: a) Easy access to patients who may arrive either walking, using mobility equipment, families with children, on an ambulance stretcher or patient trolley. b) Easy access to delivery of large amount of stock items. c) Adequate space for easy turning of stretcher and wheelchair. d) Clear view of entry and exit points of the unit from the reception area. e) Safe delivery of food, clean linen, pharmacy, consumables, disposable items and related removal of bulk waste and soiled linens. f) Access control to the general public via egress control system.
Waiting area:	a) A designated waiting area required for dialysis patients, family and visitors. Waiting area may preferably be designated within. b) If the waiting area is designated outside the unit, easy communication with patient family members shall be arranged. It can be via telephone or intercom.
Administrative area:	Administrative area is required for stand-alone units only. This area may include staff room, counseling and training room.
Dialysis and PD bay:	a) Dialysis bays shall $9m^2$ with a clear width of $3m^2$ along the back of the bay to ensure appropriate service placement, machine accommodation and curtain track placement. b) Dialysis bay shall include the following rooms within it. Treatment room, emergency cart, separate dialysis machine for seropositive patients, and patient toilet shall be available in this area. c) The unit shall achieve 70°F-72°F temperature and 55%-60% humidity. d) Each dialysis machine should be at the centre of sufficient area to allow easy movement for the staff, and resuscitation equipment

	when required. e) Isolation room (with negative pressure) for patients with communicable disease should be available in the dialysis unit with entrance and exit outdoor. f) Staff work station MUST have unobstructive visualization of patient treatment areas. this approach permits monitoring of patient status under both routine and emergency circumstances. Nursing station should be within a range of hearing alarms from machines. g) There shall be easy entrance to stretcher and wheelchair patients. h) Access to store area. i) Corridors to the treatment bays shall not be obstructed with machineries and stock items which will hinder turning of stretchers and wheel chairs. j) Headend of each bed should have stable electrical supply with at least six sockets, oxygen and vacuum outlet, treated water inlet and drainage. The wires should not pose any threat to the patient and staff. k) Minimum door opening in this area shall be 1.12m which allows sufficient room for easy transportation of patient by wheel chair and stretchers. l) Designated dialysis machine for Seropositive patients shall be available. m) Facilities for handwashing in all clinical areas are mandatory requirement. n) Area allocated for weighing machine and stadiometer.
Store area	a) In main general store, fluids and equipments to be located on the perimeter of the unit and accessible by a palette lifter. Shelving must have 100kg weight capacity and shelves need to be at least

	400mm apart and adjustable. b) Separate storage area may be used as dry and wet storage. c) Storage space for emergency equipment d) Dirty utility area should be designated in such a way that once dirty materials enter the room; they will not come back to the clean dialysis area.
J. Building Service requirements	
Communication and information technology	a) The unit shall maintain electronic/ manual medical record system b) Barcode system may be used for supplies and X-rays/records
Staff calls	Staff calls are an important component while planning a dialysis unit for safety of staff and patients. The following need to be considered: a) Nurse call/alert call in dialysis couch, toilets and bath rooms, and all treatment areas. b) The alert call to staff members should be done in a discreet manner. c) Combination of fixed and mobile alarm systems may be considered when planning the unit.

Annex 2: Schedule of Accommodation

Schedule of Accommodation (SOA) below is a generic requirement for dialysis units providing services in the Maldives. It defines the floor area required along with quantities.

Bed space/	5 beds	10 beds	20 beds	30 beds
	M2	M2	M2	M2
Main entrance	-	-	50	60
Reception area	10	15	20	20
Waiting area (shall have designated waiting space for patients with special needs)	12	12	18	18
Toilet Male & female	7	7	7	7
Elevator for patient and staff				
Wait for emergency cart	6	6	9	9
Corridors	25%	25%	25%	25%
Treatment bays	4X9	8X9	18X9	26X9
Isolation room	1X15	2X15	2X17	4X15
Nursing station				
Consultation rooms	1X12	1X12	1X12	2X12
Minor operation room	-	-	27	27
Filing room	7.5	7.5	7.5	7.5
Store for clean linen	1X6	2X6	2X6	2X6
Store for dirty linen	1X6	2X6	2X6	2X6
Water treatment plant room	12	12	16	16
Daily store room	2X5	2X5	2X5	2X7
General store area	25	25	25	35
Water pump room	25	25	25	25

Adopted from Standards guidelines for establishing, equipping and operating renal dialysis units. Ministry of Health, Saudi Arabia.

Annex 3: Schedule of Equipment

Furniture and fittings	
1	Chair, recliner
2	Nurses station
3	Filing cabinets (appropriate for service load)
4	Light examination, ceiling mounted lights
5	Sharps disposal
6	Table overbed
7	Dressing trolley
8	Waste collection bins
9	Air flowmeter
10	Cabinet for consumables
**Other equipment shall also be available in good working condition as per the scope of services and bed strength Indicative list given below*	
Emergency trolley/crash cart	
1	Laryngoscope
2	E.T Tubes/ stillets
3	Suction apparatus
4	Xylocaine jelly
5	Airways (different sizes)
6	Ambu bag
7	Oxygen cylinder with flow meter/connectors/tubings/facial mask/nasal prongs/venturi
8	Suction apparatus/ suction catheters
9	Defibrillation accessories
Dressing tray	
1	Kidney tray/bowl
2	Gause bandages
3	Micropore plaster
4	Sterile dressing cloths

5	Artery forceps
Patient monitoring	
1	Cardiac monitor
2	BP apparatus
3	Stethoscope
4	Weighing machine
5	Thermoscan
6	ECG machine
7	Pulse oximeter
8	Glucometer
9	Nebulizer with accessories
Drugs	
1	Inj. Diazepam
2	Inj. Ondansetron
3	Inj. Ranitidine
4	Inj. Noradrenaline
5	Inj. Phenytoin Sodium
6	Inj. Succinylcholine Chloride
7	Inj. Heparin
8	Inj. Iron Sucrose
9	Inj. Paracetamol
10	Inj. Alteplase
11	Inj. Vancomycin
12	Inj. Diclofenac
13	Inj. Deiphyllin
14	Inj. Chlorpheniramine Maleate
15	Inj. Hydrocortisone
16	Inj. Atropine
17	Inj. Adrenaline

18	Inj. KCL
19	Inj. Sodium bicarbonate
20	Inj. Dopamine
21	Inj. Dobutamine
22	Inj. Naloxone
23	Inj. Lignocaine
24	Asthalin/Ipravent solutions
25	Lignocaine jelly
26	RL 500ml
27	DNS 500ml
28	NS 500ml & 1000ml
29	NS 100ml
30	Dextrose 5% 500ml
31	Dextrose 10% 500ml
32	Dextrose 25% 100ml
	*Other drugs and consumables shall be available as per the scope of services, bed strength and patient turnover.