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ASF Health Standards Version 11

Standard 21: Dialysis and Renal Replacement

Core standard · applicability by facility type shown for each criterion

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01	10 November 2026	First issue of the paper standard. Adapted from the web version of Standard 21 in ASF Health Standards Version 11.	Prof. Giorgi Pkhakadze

APPROVAL

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Date: 10 November 2026

Complete on its own, without internet access. References are listed in section 11. The current revision is at france-asf.fr.

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1 Introduction

This document is Standard 21 of ASF Health Standards. It sets out how a facility provides dialysis and renal replacement therapy safely: treated water, equipment monitoring, fluid and concentrate preparation, dialyser reprocessing, prescription and adequacy, vascular access, machine checks, emergency response, infection prevention, treatment choice, staffing and outcome review.

A standard is a set of numbered criteria. Each criterion says what must be in place (the criterion statement), how it is rated for each setting, what the assessor will check and what evidence the facility must show. The guidance in this document explains what each criterion means in practice, so that a reader who has only this paper can understand and meet it.

Purpose of this document. Standard 21 makes sure that people with kidney failure receive dialysis that is safe, effective and well controlled, that the risks of water, equipment and infection are managed, and that they can take part in choosing their treatment.

Who should read it. Nephrologists, dialysis nurses, technicians who maintain the water and machines, the infection control lead, the dietitian, the clinical governance lead, the chief executive, and the assessors who verify the facility. Each criterion names the positions responsible for it (section 8.2).

The standard is a tool to improve care, not a list of paperwork. Templates and forms named in this document are reference drafts. You may adapt them, replace them with your own, or upload your own documents, provided they meet the same criterion.

2 About ASF and this standard

Accréditation Sans Frontières (ASF) is a non-governmental, non-profit accreditation body. It was legally established in Paris in 2020. ASF develops health standards that are practical, affordable and open to all facilities, including those working with limited resources, in crisis, or in transition.

ASF believes accreditation should be accessible in every sense: geographically, so that facilities in remote areas can take part; financially, so that cost is not a barrier; and in language and format, so that staff can read and use the standard in their own working environment.

Each standard is an independent document. Standard 21 has been written so that it can be read and used on its own. It repeats the definitions, abbreviations and references it needs. A reader who has only this document can understand every criterion in it.

3 How to use this standard

If you provide dialysis, read section 4 to confirm which criteria apply to your facility type, then section 5 to find the rating for your setting. Read each criterion from 21.1 to 21.12, paying attention to the rating, the guidance and the evidence. Prepare the evidence named in each criterion, covering the period stated.

If you are an assessor, use the sample and the checks in each criterion. The pass rule and the immediate-fail rule decide each criterion. A criterion is met only when all its checks are passed and no immediate-fail event is found.

Reading a criterion. Each criterion has: the criterion statement; the three ratings (humanitarian, transition and fragile, standard); the rating rule; the guidance; what good looks like; common mistakes; why it matters; the sample; the checks, with method, evidence and pass condition; the immediate-fail event; the documents with who writes, approves and checks them; the positions responsible; and the references.

Document codes. Each document has a code made of a topic prefix, a type and a number, for example ENV-SOP-001 (environment, procedure, 001). The type is one of FRM (form, a record kept as evidence), REG (register), PLN (plan), POL (policy), SOP (standard operating procedure) or GDL (guide). The codes identify documents only. The full list is in section 12.

4 Scope

Standard 21 covers water, fluids, reprocessing, prescription, vascular access, machines, emergencies, infection, treatment choice, staffing and outcomes. The applicability is shown in section 4.

The standard applies in three settings. The rating for each criterion is given for each setting, and the facility uses the rating for its own setting: **humanitarian settings** (emergency or crisis, very limited resources), **transition and fragile settings** (a health system in change or under strain), and **standard settings** (full resources).

WHERE STANDARD 21 APPLIES

Standard 21 applies when the facility provides dialysis or renal replacement therapy. It is a default service in hospitals, and optional in ambulatory clinics and home care. The table shows the rating for each criterion in each setting. The applicability of all 70 standards is in **Annex 1: Applicability of ASF Health Standards by facility type** (ASF-HS11-ANX01), published on france-asf.fr.

Criterion	Applies to
21.1 Dialysis Water Is Treated and Tested to a Documented Standard	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
21.2 Water Treatment Equipment Is Maintained and Monitored Online	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
21.3 Dialysis Fluid and Concentrates Are Prepared to a Documented Procedure	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
21.4 Dialysers Are Reprocessed Safely, Traced, and Used Only Where Permitted	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
21.5 Each Treatment Is Prescribed, and Its Adequacy Is Monitored	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
21.6 Vascular Access Is Assessed, Protected and Its Infections Tracked	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
21.7 Dialysis Machines Are Checked Before Each Session	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
21.8 Emergency Response During Dialysis Is Ready	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.

Criterion	Applies to
21.9 Infection Prevention Across the Dialysis Unit	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
21.10 Patients Are Informed About Their Dialysis Choices	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
21.11 Staffing and Competence for Dialysis Are Defined	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
21.12 Dialysis Outcomes and Incidents Are Reviewed	**default** in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.

5 Ratings and colours

Rating	Colour	Meaning
Must		Required in every setting. Criteria that can directly affect a patient's life are always Must, and no setting lowers them.
Medium		Required, adapted to what a transition setting can realistically do.
Minimum		The lowest acceptable level in a humanitarian setting, where resources are very limited.

In standard settings every criterion is Must.

TRAINING LEVELS

Level	Colour	Meaning
Essential		Must be completed by the people named in the role table.
Recommended		Good practice. Not checked as a requirement.
Optional		May be used for development.

6 Abbreviations

Abbreviation	Meaning
ASF	Accréditation Sans Frontières (Accreditation Without Borders), a non-governmental, non-profit accreditation body
FRM	Form. A record that is filled in and kept as evidence
GDL	Guide. Reference guidance for staff

Abbreviation	Meaning
POL	Policy. A written statement of what the facility will do and why
REG	Register. A running record of entries, such as tests, batches or reviews
SOP	Standard operating procedure. A step-by-step description of how a task is done
PLN	Plan. A written plan for a defined situation, such as an emergency

DOCUMENT CODE PREFIXES

Prefix	Topic
DIA	Dialysis and renal replacement
EQP	Equipment
INC	Incident management
WAT	Water treatment
WRK	Workforce

7 Terms and definitions

Term	Definition
Adequacy	A measure of how well a dialysis session removes waste products, compared with a set target.
Conductivity	A measure of the electrolyte content of water or dialysis fluid, used to check it is within range.
Concentrate	The concentrated solution that is mixed with water to make dialysis fluid.
Dialyser	The filter through which the patient's blood passes during dialysis.
Renal replacement therapy	Treatment that takes over the function of the kidneys, such as haemodialysis or peritoneal dialysis.
Vascular access	The route into the patient's bloodstream for dialysis, such as a fistula, graft or catheter.
Immediate fail	One event that means a criterion is not met, whatever else is in place.
Setting	The context in which a facility works: humanitarian, transition and fragile, or standard.

8 Standard 21 at a glance

Standard 21: Dialysis and Renal Replacement is a service standard of ASF Health Standards. It applies when the facility provides dialysis or renal replacement therapy, and covers water and fluid safety, equipment, prescription, vascular access, infection, emergencies, treatment choice, staffing and outcomes.

The standard has twelve criteria. Each is shown below and explained on its own page in section 9.

8.1 CRITERIA AND RATINGS

No.	Criterion	Humanitarian	Transition	Standard
21.1	Dialysis Water Is Treated and Tested to a Documented Standard	Must	Must	Must
21.2	Water Treatment Equipment Is Maintained and Monitored Online	Must	Must	Must
21.3	Dialysis Fluid and Concentrates Are Prepared to a Documented Procedure	Must	Must	Must
21.4	Dialysers Are Reprocessed Safely, Traced, and Used Only Where Permitted	Must	Must	Must
21.5	Each Treatment Is Prescribed, and Its Adequacy Is Monitored	Minimum	Medium	Must
21.6	Vascular Access Is Assessed, Protected and Its Infections Tracked	Must	Must	Must
21.7	Dialysis Machines Are Checked Before Each Session	Must	Must	Must
21.8	Emergency Response During Dialysis Is Ready	Must	Must	Must
21.9	Infection Prevention Across the Dialysis Unit	Must	Must	Must
21.10	Patients Are Informed About Their Dialysis Choices	Minimum	Medium	Must
21.11	Staffing and Competence for Dialysis Are Defined	Minimum	Medium	Must
21.12	Dialysis Outcomes and Incidents Are Reviewed	Minimum	Medium	Must

8.2 RESPONSIBILITIES

Each criterion names the positions responsible for it. The facility sets its own reporting lines, and each position should have written terms of reference. ISCO-08 codes are shown for each role and are recorded in the staff register.

No.	Criterion	Positions responsible or involved
21.1	Dialysis Water Is Treated and Tested to a Documented Standard	Nurse (ISCO 2221) · Manager (ISCO 1342)
21.2	Water Treatment Equipment Is Maintained and Monitored Online	Nurse (ISCO 2221) · Manager (ISCO 1342)

No.	Criterion	Positions responsible or involved
21.3	Dialysis Fluid and Concentrates Are Prepared to a Documented Procedure	Nurse (ISCO 2221) · Specialist physician (ISCO 2212)
21.4	Dialysers Are Reprocessed Safely, Traced, and Used Only Where Permitted	Nurse (ISCO 2221) · Manager (ISCO 1342)
21.5	Each Treatment Is Prescribed, and Its Adequacy Is Monitored	Specialist physician (ISCO 2212) · Nurse (ISCO 2221)
21.6	Vascular Access Is Assessed, Protected and Its Infections Tracked	Nurse (ISCO 2221) · Specialist physician (ISCO 2212)
21.7	Dialysis Machines Are Checked Before Each Session	Nurse (ISCO 2221) · Manager (ISCO 1342)
21.8	Emergency Response During Dialysis Is Ready	Manager (ISCO 1342) · Specialist physician (ISCO 2212)
21.9	Infection Prevention Across the Dialysis Unit	Nurse (ISCO 2221) · Manager (ISCO 1342)
21.10	Patients Are Informed About Their Dialysis Choices	Specialist physician (ISCO 2212) · Nurse (ISCO 2221)
21.11	Staffing and Competence for Dialysis Are Defined	Manager (ISCO 1342) · Secretary (ISCO 3344)
21.12	Dialysis Outcomes and Incidents Are Reviewed	Manager (ISCO 1342) · Specialist physician (ISCO 2212)

8.3 TRAINING FOR STANDARD 21

Training is shown by course. Essential training must be completed by the people named. Recommended training is good practice. The colours follow section 5.

Course	Essential for	Recommended for	Criteria	Status
Dialysis and Renal Replacement Therapy (AMB-12)	Nurse, Specialist physician, Manager	None	21.1, 21.2, 21.3, 21.4, 21.5, 21.6, 21.7, 21.10	In development
Emergency Medical Equipment and AED Readiness (MED-02)	Nurse, Manager	None	21.8	In development
Hand Hygiene and Standard Precautions (T-06)	Nurse	None	21.9	In development
Credentialing, Competence and the Training Matrix (T-14)	Manager, Nurse	None	21.11	In development
Incident Reporting, Just Culture and Open Disclosure (T-09)	Manager, Nurse	None	21.12	In development

Evidence of training may be a verified micro-credential in the GMJ Academy micro-credential portfolio, or a training certificate kept in the staff file.

21.1 Dialysis Water Is Treated and Tested to a Documented Standard

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Must	**Must**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Water used to prepare dialysis fluid and to reprocess dialysers meets documented chemical and microbiological requirements, is tested on a defined schedule, and every result is reviewed and acted on.

Rating rule. Must in every setting: dialysis water is treated and tested to a documented chemical and microbiological standard before any patient is dialysed on it.

GUIDANCE

Water is the largest source of substances that reach the patient's blood during dialysis. It must be treated and tested to a written standard, and a result outside the limit must be acted on the same day.

The test results show the date, the place sampled and the action taken, so the assessor can see that no patient was dialysed on water that had not been checked.

WHAT GOOD LOOKS LIKE

- Water quality results are shown on a board in the unit, and the chemical limits are reviewed with the nephrologist each quarter.

COMMON MISTAKES

- A dialysis session started on water with no test result for that day.
- A water result above the limit recorded and the session continued.

> **Why it matters.** The water used to make dialysis fluid goes into the patient's blood. Impure water can cause serious harm within a single session, so it must be treated and tested to a written standard.

WHAT THE ASSESSOR CHECKS

Sample. Review the water test records for the last 6 months, and the water standard in force.

1 Water is tested to the documented chemical and microbiological requirements on the schedule.

Method. Check the test record against the schedule.

Evidence to show. Water test record (WAT-FRM-001).

Pass when. Every scheduled test is recorded.

2 Each result is within requirement, or the action is recorded.

Method. Check each result against the requirement.

Evidence to show. Water test record (WAT-FRM-001).

Pass when. Every out-of-range result has an action recorded.

3 No patient is dialysed on water that has not been tested in date.

Method. Check the treatments in the period against the last valid test.

Evidence to show. Dialysis water standard and testing (DIA-POL-001).

Pass when. Every treatment was on water tested in date.

Pass. The criterion is met when every check above is passed.

Immediate fail. . Patients are dialysed on water that was never tested. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-POL-001	Dialysis water standard and testing	Chief executive	Governing body members	Chief executive

Other records in the criterion: WAT-FRM-001 (name to be confirmed)

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Nurse (ISCO 2221)	Tests the water to the schedule	— Must
Manager (ISCO 1342)	Acts on out-of-range results	— Must

REFERENCES FOR THIS CRITERION

- World Health Organization (2025). Water and Sanitation Technologies for Health-care Facilities: Selecting Options for Adoption and Scale-up in the Western Pacific Region. Used for: water treatment and monitoring (general, not dialysis-specific). https://news.gmj.ge/guideline/water-and-sanitation-technologies-for-health-care-facilities-selecting-options-for-adoption-and-scale-up-in-the-western-pacific-region/

21.2 Water Treatment Equipment Is Maintained and Monitored Online

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Must	**Must**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Water treatment equipment, including its online conductivity monitoring and distribution piping, is maintained on a schedule, and its readings are monitored during every session.

Rating rule. Must in every setting: the water treatment equipment is monitored online during every session, each alarm is answered, and the equipment is maintained on schedule.

GUIDANCE

Conductivity and other online sensors show whether the water and dialysis fluid are within range during each session. An alarm that is not answered is a risk to the patient.

The equipment is maintained on the manufacturer's schedule, and the maintenance is recorded.

WHAT GOOD LOOKS LIKE

- Conductivity alarms are logged with the machine number and the time the response was made, and reviewed weekly by the unit lead.

COMMON MISTAKES

- An alarm that sounds for twenty minutes before anyone responds.
- A water treatment unit serviced once in two years.

> **Why it matters.** The water treatment plant, its online monitor and the pipes that carry the water can fail quietly. Maintaining them and watching them online catches a failure before a patient is harmed.

WHAT THE ASSESSOR CHECKS

Sample. Review the online conductivity monitoring log for 10 sessions, and the maintenance record of the water treatment equipment.

1 Online conductivity is monitored during every session.

Method. Check each sampled session for the readings recorded.

Evidence to show. Online conductivity monitoring log (DIA-FRM-001).

Pass when. Every sampled session has readings recorded.

2 Each alarm is responded to.

Method. Check each alarm for the response recorded.

Evidence to show. Online conductivity monitoring log (DIA-FRM-001).

Pass when. Every alarm has a response recorded.

3 The equipment is maintained on schedule.

Method. Check the maintenance record against the schedule.

Evidence to show. Equipment inventory and service log (EQP-REG-001).

Pass when. Every scheduled maintenance is recorded.

Pass. The criterion is met when every check above is passed.

Immediate fail. . An alarm on the water monitor is ignored for a shift. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-FRM-001	Online conductivity monitoring log	Manager	Chief executive	Manager

Other records in the criterion: EQP-REG-001 (name to be confirmed)

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Nurse (ISCO 2221)	Watches the online monitor each session	— Must
Manager (ISCO 1342)	Schedules equipment maintenance	— Must

REFERENCES FOR THIS CRITERION

- World Health Organization (2025). Water and Sanitation Technologies for Health-care Facilities: Selecting Options for Adoption and Scale-up in the Western Pacific Region. Used for: water treatment and monitoring (general, not dialysis-specific). https://news.gmj.ge/guideline/water-and-sanitation-technologies-for-health-care-facilities-selecting-options-for-adoption-and-scale-up-in-the-western-pacific-region/

21.3 Dialysis Fluid and Concentrates Are Prepared to a Documented Procedure

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Must	**Must**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Concentrates are prepared, and dialysis fluid is mixed, to a written procedure that is followed for every batch, with each batch identified and traceable to its preparation.

Rating rule. Must in every setting: dialysis fluid and concentrates are prepared to a written procedure, and each batch is traceable and checked before use.

GUIDANCE

Dialysis fluid is made from concentrates and water. Errors in preparation can harm many patients at once, so each batch is prepared to the written procedure, labelled and traced.

The concentration is checked before the batch is used.

WHAT GOOD LOOKS LIKE

- Each batch is labelled with a use-by date, and a second person checks the concentration before the first patient is connected.

COMMON MISTAKES

- A concentrate bottle with no label or preparation date.
- A batch used after its use-by date.

> **Why it matters.** Dialysis fluid made with the wrong concentration or in the wrong order can cause a serious event in the patient. Following a written procedure for every batch prevents the error.

WHAT THE ASSESSOR CHECKS

Sample. Review the batch preparation records for the last 3 months.

1 Each batch is prepared to the written procedure.

Method. Check each batch record for the procedure followed.

Evidence to show. Batch preparation record (DIA-FRM-002).

Pass when. Every batch records the procedure followed.

2 Each batch is identified and traceable to its preparation.

Method. Check each batch for its identity and preparer.

Evidence to show. Batch preparation record (DIA-FRM-002).

Pass when. Every batch is identified and traceable.

3 The concentration is checked before use.

Method. Check each batch for the concentration recorded.

Evidence to show. Batch preparation record (DIA-FRM-002).

Pass when. Every batch has its concentration checked.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A batch of fluid is mixed from memory, with the wrong concentration. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-SOP-001	Preparation of concentrates and dialysis fluid	Manager	Chief executive	Chief executive
DIA-FRM-002	Batch preparation record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Nurse (ISCO 2221)	Prepares each batch to the procedure	— Must
Specialist physician (ISCO 2212)	Checks the concentration before use	— Must

REFERENCES FOR THIS CRITERION

- Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements (International Organization for Standardization, 2024) https://www.iso.org/standard/84368.html
- Preparation and quality management of fluids for haemodialysis and related therapies - Part 3: Water for haemodialysis and related therapies (International Organization for Standardization, 2024) https://www.iso.org/standard/84370.html

21.4 Dialysers Are Reprocessed Safely, Traced, and Used Only Where Permitted

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Must	**Must**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Dialysers are reused only where they are marked for reuse and only after reprocessing to a validated procedure, and each dialyser is traceable to its patient and its reprocessing cycles.

Rating rule. Must in every setting: dialysers are reused only where marked for reuse, reprocessed to a validated procedure, and used only on the patient they came from.

GUIDANCE

Reusing dialysers can save cost where it is permitted, but only with a validated reprocessing procedure and a label that ensures each dialyser returns to the same patient.

Reuse is recorded for each dialyser and checked at each session.

WHAT GOOD LOOKS LIKE

- Reprocessing is audited each quarter by a trained infection control nurse, and the dialyser tracking label is checked at each session.

COMMON MISTAKES

- A dialyser reused on a different patient from the one it came from.
- A dialyser reused although it is not marked for reuse.

> **Why it matters.** Dialysers are reused only in some services and only when they are marked for reuse. A reused dialyser that is not properly cleaned or traced can transmit infection or fail.

WHAT THE ASSESSOR CHECKS

Sample. Review the dialyser traceability and reprocessing register for the last 3 months.

1 Dialysers are reused only where marked for reuse.

Method. Check each reused dialyser for the reuse mark.

Evidence to show. Dialyser traceability and reprocessing register (DIA-REG-001).

Pass when. Every reused dialyser is marked for reuse.

2 Reprocessing follows the validated procedure, and each cycle is recorded.

Method. Check each dialyser for the cycles recorded.

Evidence to show. Dialyser traceability and reprocessing register (DIA-REG-001).

Pass when. Every cycle is recorded.

3 **Each dialyser is used only on the patient it came from.**

Method. Trace each dialyser to the patient recorded.

Evidence to show. Dialyser traceability and reprocessing register (DIA-REG-001).

Pass when. Every dialyser is traced to one patient.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A dialyser is reused on a patient other than the one it came from. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-REG-001	Dialyser traceability and reprocessing register	Secretary	Chief executive	Manager
DIA-POL-002	Dialyser reuse and reprocessing	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Nurse (ISCO 2221)	Traces each dialyser to its patient	— Must
Manager (ISCO 1342)	Keeps the reprocessing register	— Must

REFERENCES FOR THIS CRITERION

- World Health Organization (2020). Decontamination and Reprocessing of Medical Devices for Health-care Facilities. Used for: decontamination and reprocessing of medical devices in health care settings; relevant to reuse and reprocessing controls. https://news.gmj.ge/guideline/decontamination-and-reprocessing-of-medical-devices-for-health-care-facilities/

21.5 Each Treatment Is Prescribed, and Its Adequacy Is Monitored

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Each patient has a written dialysis prescription, the adequacy of each treatment is measured against the target set by the treating clinician, and changes in the prescription are recorded.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: each patient has a written dialysis prescription, adequacy is measured against the target, and every change is recorded.

GUIDANCE

Dialysis is effective only when the dose is right. The prescription sets the dose, and adequacy is measured to show that the dose is reaching the target.

Changes to the prescription are written and dated, so the history can be followed.

WHAT GOOD LOOKS LIKE

- The adequacy target is reviewed with the patient each quarter, and the dietitian and nephrologist agree any change together.

COMMON MISTAKES

- A patient dialysed for years on the same prescription with no adequacy measure.
- A change to the dose made by phone with no record.

> **Why it matters.** A patient who gets too little dialysis is harmed slowly, and no one notices unless the dose is measured. Adequacy measured for every treatment shows whether the dose is right.

WHAT THE ASSESSOR CHECKS

Sample. Review 10 patients' prescriptions and their adequacy records.

1 Each patient has a written dialysis prescription.

Method. Check each sampled patient for the written prescription.

Evidence to show. Dialysis prescription and adequacy record (DIA-FRM-003).

Pass when. Every sampled patient has a written prescription.

2 Adequacy is measured against the target for each treatment.

Method. Check each treatment record for the adequacy measured.

Evidence to show. Dialysis prescription and adequacy record (DIA-FRM-003).

Pass when. At least 90% of treatments have adequacy measured.

3 Changes to the prescription are recorded.

Method. Check each change for the reason recorded.

Evidence to show. Dialysis prescription and adequacy record (DIA-FRM-003).

Pass when. Every change is recorded with its reason.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A patient is under-dialysed for months with no measure. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-FRM-003	Dialysis prescription and adequacy record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Specialist physician (ISCO 2212)	Writes the prescription and sets the target	— Medium
Nurse (ISCO 2221)	Measures adequacy each treatment	— Medium

REFERENCES FOR THIS CRITERION

- KDIGO (2024). KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Used for: evaluation and management of chronic kidney disease; supports the prescribing and monitoring context. https://news.gmj.ge/guideline/kdigo-2024-clinical-practice-guideline-for-the-evaluation-and-management-of-chronic-kidney-disease/

21.6 Vascular Access Is Assessed, Protected and Its Infections Tracked

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Must	**Must**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Each patient's vascular access is assessed at each session, cared for to a written protocol, and any access-related infection is recorded and reviewed.

Rating rule. Must in every setting: each patient's vascular access is assessed at every session, cared for to protocol, and access-related infections are recorded and reviewed.

GUIDANCE

Vascular access is the patient's lifeline and a common source of infection. It is assessed at every session, cared for to protocol, and infections are recorded and reviewed.

Each access-related infection leads to a review of practice.

WHAT GOOD LOOKS LIKE

- Each access is examined by a trained nurse at every session, with a named clinician responsible for the access plan.

COMMON MISTAKES

- An access infection that recurs with no review.
- A catheter used without following the insertion or care protocol.

> **Why it matters.** The access in a dialysis patient's arm or neck is the lifeline of treatment and the most common source of serious infection. Assessing it every session and tracking infections keeps it working.

WHAT THE ASSESSOR CHECKS

Sample. Review the vascular access check records for 10 patients, and the access infection register.

1 Each patient's vascular access is assessed at each session.

Method. Check each sampled patient for the assessment at each session.

Evidence to show. Vascular access check record (DIA-FRM-004).

Pass when. At least 95% of sessions show the access assessed.

2 Care follows the written protocol.

Method. Check each record for the protocol followed.

Evidence to show. Vascular access check record (DIA-FRM-004).

Pass when. At least 95% of records show the protocol followed.

3 **Each access-related infection is recorded and reviewed.**

Method. Check the register against the infections reported.

Evidence to show. Access-related infection register (DIA-REG-002).

Pass when. Every infection is recorded and reviewed.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A catheter infection is not reported for three weeks. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-FRM-004	Vascular access check record	Manager	Chief executive	Manager
DIA-REG-002	Access-related infection register	Secretary	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Nurse (ISCO 2221)	Assesses access at each session	— Must
Specialist physician (ISCO 2212)	Reviews access infections	— Must

REFERENCES FOR THIS CRITERION

- World Health Organization (2026). Prevention of bloodstream infections and other infections associated with central venous catheters. Used for: prevention of bloodstream and other infections associated with central venous catheters, including dialysis catheters. https://news.gmj.ge/guideline/prevention-of-bloodstream-infections-and-other-infections-associated-with-central-venous-catheters/

21.7 Dialysis Machines Are Checked Before Each Session

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Must	**Must**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Each machine is checked before use against a written checklist, and any fault is recorded and the machine is withdrawn until repaired.

Rating rule. Must in every setting: each dialysis machine is checked against a checklist before use, faults are recorded, and a faulty machine is withdrawn until repaired.

GUIDANCE

A machine that is not checked before use can fail during treatment. A pre-use checklist is completed for each machine, faults are recorded, and a faulty machine is taken out of use.

The fault log is reviewed at the maintenance meeting.

WHAT GOOD LOOKS LIKE

- A pre-use checklist is signed by the nurse on each machine, and the fault log is reviewed at the monthly maintenance meeting.

COMMON MISTAKES

- A machine used with a known fault and no record.
- A checklist signed for every machine without the checks being done.

> **Why it matters.** A dialysis machine with a fault that is not found before use can harm the patient during treatment. A checklist before each session finds faults before they reach the patient.

WHAT THE ASSESSOR CHECKS

Sample. Review the pre-session machine check records for the last 30 days, and walk through the unit.

1 Each machine is checked before use against the checklist.

Method. Check each session for the checklist completed.

Evidence to show. Pre-session machine check (DIA-FRM-005).

Pass when. At least 98% of sessions have the checklist completed.

2 Each fault is recorded.

Method. Check each fault for the record.

Evidence to show. Pre-session machine check (DIA-FRM-005).

Pass when. Every fault found is recorded.

3 A faulty machine is withdrawn until repaired.

Method. Check each fault for the withdrawal and the repair date.

Evidence to show. Pre-session machine check (DIA-FRM-005).

Pass when. Every faulty machine is withdrawn until repaired.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A machine is used with a known alarm fault. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-FRM-005	Pre-session machine check	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Nurse (ISCO 2221)	Completes the pre-session machine check	— Must
Manager (ISCO 1342)	Withdraws faulty machines until repaired	— Must

REFERENCES FOR THIS CRITERION

- Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements (International Organization for Standardization, 2024) https://www.iso.org/standard/84368.html

21.8 Emergency Response During Dialysis Is Ready

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Must	**Must**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Staff are trained and equipped to respond to the emergencies that occur during dialysis, including low blood pressure, air in the blood line, allergic reactions and cardiac arrest, and the response is rehearsed.

Rating rule. Must in every setting: the response to emergencies during dialysis is planned, staffed and equipped on each shift, and rehearsed twice a year.

GUIDANCE

Power cuts, water failure and sudden clinical events can occur during treatment. The plan sets who does what, and the staff on each shift know it.

The plan is rehearsed twice a year, and the results are recorded.

WHAT GOOD LOOKS LIKE

- Emergency drills include a power cut and a water failure, and the results are shared with the staff of each shift.

COMMON MISTAKES

- A power cut during treatment with no plan for the patients on the machines.
- A plan that has never been rehearsed.

> **Why it matters.** Dialysis patients can have a sudden drop in blood pressure, a cardiac arrest or other emergencies during treatment. Staff must be trained and the equipment ready for them.

WHAT THE ASSESSOR CHECKS

Sample. Review the emergency plan and the rehearsal records for the last 12 months.

1 The response to emergencies during dialysis is planned.

Method. Check the plan for each emergency named.

Evidence to show. Emergency response during dialysis (DIA-PLN-001).

Pass when. The plan covers all four emergencies.

2 Staff are trained and equipment is ready on each shift.

Method. Check each shift rota against trained staff and equipment.

Evidence to show. Equipment inventory and service log (EQP-REG-001).

Pass when. Every shift has trained staff and equipment ready.

3 **The response is rehearsed twice a year.**

Method. Check the rehearsal record for two rehearsals a year.

Evidence to show. Emergency rehearsal record (DIA-FRM-006).

Pass when. Two rehearsals are recorded each year.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A patient collapses during dialysis with no one trained to respond. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-FRM-006	Emergency rehearsal record	Manager	Chief executive	Manager
DIA-PLN-001	Emergency response during dialysis	Chief executive	Governing body members	Chief executive

Other records in the criterion: EQP-REG-001 (name to be confirmed)

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the emergency rehearsal twice a year	— Must
Specialist physician (ISCO 2212)	Leads the response plan	— Must

REFERENCES FOR THIS CRITERION

- PAHO (2025). EVAC-H: Evacuation of hospitals and their critical areas. Used for: evacuation of hospitals and critical areas, including renal and dialysis units in emergencies. https://news.gmj.ge/guideline/evac-h-evacuation-of-hospitals-and-their-critical-areas/

21.9 Infection Prevention Across the Dialysis Unit

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Must	**Must**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Hand hygiene, isolation of infectious patients and cleaning of shared dialysis equipment and surfaces follow written procedures, and compliance is monitored.

Rating rule. Must in every setting: infectious patients are isolated, shared equipment is cleaned between patients, and hand hygiene is audited.

GUIDANCE

Patients on dialysis are at higher risk of infection, and many are infectious. Isolation, cleaning of shared equipment and hand hygiene protect both patients and staff.

Hand hygiene is audited against the procedure.

WHAT GOOD LOOKS LIKE

- Infection control audits are shared with the team each month, and each patient's isolation status is shown on the treatment chart.

COMMON MISTAKES

- An infectious patient treated in the open bay with the others.
- Machines shared between patients without cleaning in between.

> **Why it matters.** Dialysis patients are often in and out of the unit several times a week, and infections spread easily between them. Strict hand hygiene, isolation and cleaning stop that spread.

WHAT THE ASSESSOR CHECKS

Sample. Review the isolation and cleaning check records for the last 30 days, and walk through the unit.

1 Infectious patients are isolated.

Method. Check each infectious patient at the walk-through and in the record.

Evidence to show. Isolation and cleaning check record (DIA-FRM-007).

Pass when. Every infectious patient is isolated.

2 Shared equipment is cleaned between patients.

Method. Check each cleaning record for the clean between patients.

Evidence to show. Isolation and cleaning check record (DIA-FRM-007).

Pass when. At least 98% of changes between patients have a clean recorded.

3 **Hand hygiene is audited against the procedure.**

Method. Check the hand hygiene audit record for the period.

Evidence to show. Isolation and cleaning check record (DIA-FRM-007).

Pass when. Hand hygiene compliance is audited each month.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A shared dialysis machine is not cleaned between patients. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-FRM-007	Isolation and cleaning check record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Nurse (ISCO 2221)	Isolates and cleans between patients	— Must
Manager (ISCO 1342)	Audits hand hygiene each month	— Must

REFERENCES FOR THIS CRITERION

- World Health Organization (2026). Prevention of bloodstream infections and other infections associated with central venous catheters. Used for: prevention of bloodstream and other infections associated with central venous catheters, including dialysis catheters. https://news.gmj.ge/guideline/prevention-of-bloodstream-infections-and-other-infections-associated-with-central-venous-catheters/
- World Health Organization (2020). Decontamination and Reprocessing of Medical Devices for Health-care Facilities. Used for: decontamination and reprocessing of medical devices in health care settings; relevant to reuse and reprocessing controls. https://news.gmj.ge/guideline/decontamination-and-reprocessing-of-medical-devices-for-health-care-facilities/
- CDC (2008). Guideline for Disinfection and Sterilization in Healthcare Facilities. Used for: disinfection and sterilisation in healthcare facilities; older edition. https://news.gmj.ge/guideline/guideline-for-disinfection-and-sterilization-in-healthcare-facilities/

21.10 Patients Are Informed About Their Dialysis Choices

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Patients receive information about treatment options, including home and other modalities where they exist, and their decisions are recorded.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: each patient is told about the treatment options, including home dialysis where it exists, and their decision is recorded.

GUIDANCE

Patients with kidney failure can choose among treatment options, including home dialysis where it exists. A patient who has not been told the options cannot make an informed choice.

The decision is recorded and reviewed at each review.

WHAT GOOD LOOKS LIKE

- Patients see a written summary of the treatment options, including home dialysis, and the choice is discussed again at each review.

COMMON MISTAKES

- A patient never told that home dialysis is available.
- A decision discussed with no record of what was chosen.

> **Why it matters.** Patients with kidney failure have more than one option, such as home dialysis or transplant. Telling them the choices lets them decide what suits their life.

WHAT THE ASSESSOR CHECKS

Sample. Review 10 patient records for the discussion of treatment options and their decisions.

1 Each patient is told about the treatment options.

Method. Check each sampled record for the options explained.

Evidence to show. Dialysis modality choice record (DIA-FRM-008).

Pass when. Every sampled patient has the options explained.

2 Home dialysis is included where it exists.

Method. Check each record for home dialysis explained where available.

Evidence to show. Dialysis modality choice record (DIA-FRM-008).

Pass when. Every record includes home dialysis where it exists.

3 The patient's decision is recorded.

Method. Check each record for the decision.

Evidence to show. Dialysis modality choice record (DIA-FRM-008).

Pass when. Every record has the decision recorded.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A patient is never told that home dialysis exists. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-FRM-008	Dialysis modality choice record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Specialist physician (ISCO 2212)	Explains options including home dialysis	— Medium
Nurse (ISCO 2221)	Records the patient's decision	— Medium

REFERENCES FOR THIS CRITERION

21.11 Staffing and Competence for Dialysis Are Defined

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Dialysis staffing levels, roles and competence requirements are defined, and each member of staff is competent for their role before working unsupervised.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: staffing levels, roles and competence requirements are defined, and each member of staff is competent for the role before working alone.

GUIDANCE

Dialysis needs trained staff in fixed numbers for each shift. The defined levels and competence requirements protect patients when staff are absent or new.

Each member of staff is competent for their role before working alone.

WHAT GOOD LOOKS LIKE

- Staffing levels are reviewed monthly against the number of patients, and a cover plan is ready for absence.

COMMON MISTAKES

- A shift running with one nurse for twelve patients.
- A newly qualified nurse starting alone on the machines on the first day.

> **Why it matters.** A dialysis unit needs enough trained staff, and each person needs the right skills for their role. Defining staffing and competence keeps the unit safe on every shift.

WHAT THE ASSESSOR CHECKS

Sample. Review the staffing and competence requirements and the training records for 5 staff.

1 Staffing levels, roles and competence requirements are defined.

Method. Check the policy for each element.

Evidence to show. Dialysis staffing and competence (DIA-POL-003).

Pass when. Every element is defined.

2 Each member of staff is competent for their role before working unsupervised.

Method. Check each sampled staff member for competence before unsupervised work.

Evidence to show. Training matrix register (WRK-REG-001).

Pass when. Every sampled staff member is competent before unsupervised work.

3 **The shift staffing meets the defined levels.**

Method. Check the rota against the defined levels.

Evidence to show. Training matrix register (WRK-REG-001).

Pass when. Every shift meets the defined level.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A shift is run by one nurse who has not been trained on the machines. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-POL-003	Dialysis staffing and competence	Chief executive	Governing body members	Chief executive

Other records in the criterion: WRK-REG-001 (name to be confirmed)

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Defines staffing and competence	— Medium
Secretary (ISCO 3344)	Keeps the training matrix	— Medium

REFERENCES FOR THIS CRITERION

21.12 Dialysis Outcomes and Incidents Are Reviewed

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: default in Hospital; **optional** in Ambulatory clinic, Home care. **Not applicable to:** Primary health clinic, Long-term care, Telemedicine, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Dialysis incidents and outcome measures are recorded, reviewed on a defined schedule, and acted on, and serious incidents are investigated under the facility's incident process.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: dialysis incidents and outcome measures are recorded, reviewed for patterns, and serious incidents are investigated.

GUIDANCE

Incidents and outcome measures show how well the unit is performing. A register that is only filled in and never reviewed cannot show patterns.

Serious incidents are investigated under the incident procedure.

WHAT GOOD LOOKS LIKE

- The outcome register is reviewed each quarter by the clinical governance group, and each pattern is given a named owner.

COMMON MISTAKES

- A rise in access infections recorded for a year and never discussed.
- Incidents written in a register that nobody reads.

> **Why it matters.** A dialysis unit that records incidents and outcomes but never reviews them keeps making the same mistakes. A defined review of incidents and outcomes, with action, makes the unit learn.

WHAT THE ASSESSOR CHECKS

Sample. Review the incident and outcome review register for the last 12 months.

1 Incidents and outcome measures are recorded.

Method. Check the register against the incidents reported.

Evidence to show. Dialysis incident and outcome review register (DIA-REG-003).

Pass when. Every incident and measure is recorded.

2 The register is reviewed on schedule for patterns.

Method. Check each review date against the schedule.

Evidence to show. Dialysis incident and outcome review register (DIA-REG-003).

Pass when. Every scheduled review is recorded.

3 Serious incidents are investigated under the incident process.

Method. Check each serious incident for the investigation record.

Evidence to show. Root cause analysis of serious incidents (INC-SOP-001).

Pass when. Every serious incident is investigated.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A series of machine faults is never discussed as a pattern. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIA-REG-003	Dialysis incident and outcome review register	Secretary	Chief executive	Manager

Other records in the criterion: INC-SOP-001 (name to be confirmed)

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Reviews incidents and outcomes on schedule	— Medium
Specialist physician (ISCO 2212)	Leads serious incident investigations	— Medium

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Global Patient Safety Action Plan 2021–2030: Towards Eliminating Avoidable Harm in Health Care. Used for: incident reporting, learning systems and quality across all settings. https://news.gmj.ge/guideline/global-patient-safety-action-plan-2021-2030-towards-eliminating-avoidable-harm-in-health-care/

10 Questions and answers

Does Standard 21 apply to every facility?
No. It applies to facilities that provide dialysis or renal replacement therapy. It is a default service in hospitals, and optional in ambulatory clinics and home care. Section 4 shows the applicability for each facility type.

Can a patient be dialysed before the water is tested?
No. Under 21.1 no patient is dialysed on water that has not been tested to the documented standard.

Can a dialyser be reused on another patient?
No. Under 21.4 each dialyser is used only on the patient it came from, and only where it is marked for reuse.

Must a patient be told about home dialysis?
Where it exists, yes. Under 21.10 each patient is told about the treatment options, including home dialysis, and the decision is recorded.

Do I have to use the forms on this page?
No. They are reference drafts. Adapt them, write your own, or upload your own, provided the same criterion is met and the evidence can be shown.

The criterion text is the authority. These answers summarise it.

11 References

CITED FOR CRITERIA

1. World Health Organization (2025). Water and Sanitation Technologies for Health-care Facilities: Selecting Options for Adoption and Scale-up in the Western Pacific Region. Used for: water treatment and monitoring (general, not dialysis-specific). https://news.gmj.ge/guideline/water-and-sanitation-technologies-for-health-care-facilities-selecting-options-for-adoption-and-scale-up-in-the-western-pacific-region/ (criterion 21.1, 21.2)
2. Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements (International Organization for Standardization, 2024) https://www.iso.org/standard/84368.html (criterion 21.3, 21.7)
3. Preparation and quality management of fluids for haemodialysis and related therapies - Part 3: Water for haemodialysis and related therapies (International Organization for Standardization, 2024) https://www.iso.org/standard/84370.html (criterion 21.3)
4. World Health Organization (2020). Decontamination and Reprocessing of Medical Devices for Health-care Facilities. Used for: decontamination and reprocessing of medical devices in health care settings; relevant to reuse and reprocessing controls. https://news.gmj.ge/guideline/decontamination-and-reprocessing-of-medical-devices-for-health-care-facilities/ (criterion 21.4, 21.9)
5. KDIGO (2024). KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Used for: evaluation and management of chronic kidney disease; supports the prescribing and monitoring context. https://news.gmj.ge/guideline/kdigo-2024-clinical-practice-guideline-for-the-evaluation-and-management-of-chronic-kidney-disease/ (criterion 21.5)
6. World Health Organization (2026). Prevention of bloodstream infections and other infections associated with central venous catheters. Used for: prevention of bloodstream and other infections associated with central venous catheters, including dialysis catheters. https://news.gmj.ge/guideline/prevention-of-bloodstream-infections-and-other-infections-associated-with-central-venous-catheters/ (criterion 21.6, 21.9)
7. PAHO (2025). EVAC-H: Evacuation of hospitals and their critical areas. Used for: evacuation of hospitals and critical areas, including renal and dialysis units in emergencies. https://news.gmj.ge/guideline/evac-h-evacuation-of-hospitals-and-their-critical-areas/ (criterion 21.8)
8. CDC (2008). Guideline for Disinfection and Sterilization in Healthcare Facilities. Used for: disinfection and sterilisation in healthcare facilities; older edition. https://news.gmj.ge/guideline/guideline-for-disinfection-and-sterilization-in-healthcare-facilities/ (criterion 21.9)
9. World Health Organization (2021). Global Patient Safety Action Plan 2021–2030: Towards Eliminating Avoidable Harm in Health Care. Used for: incident reporting, learning systems and quality across all settings. https://news.gmj.ge/guideline/global-patient-safety-action-plan-2021-2030-towards-eliminating-avoidable-harm-in-health-care/ (criterion 21.12)

INTERNATIONAL STANDARDS CITED

1. International Labour Organization (2008). International Standard Classification of Occupations, ISCO-08. Geneva: ILO.

12 Document register

Every document code used in Standard 21, with its type and the criteria that use it. The codes identify the documents; a facility may use its own document if it meets the same criterion.

Code	Document	Type	Criteria
DIA-FRM-001	Online conductivity monitoring log	Form (record)	21.2
DIA-FRM-002	Batch preparation record	Form (record)	21.3
DIA-FRM-003	Dialysis prescription and adequacy record	Form (record)	21.5
DIA-FRM-004	Vascular access check record	Form (record)	21.6
DIA-FRM-005	Pre-session machine check	Form (record)	21.7
DIA-FRM-006	Emergency rehearsal record	Form (record)	21.8
DIA-FRM-007	Isolation and cleaning check record	Form (record)	21.9
DIA-FRM-008	Dialysis modality choice record	Form (record)	21.10
DIA-PLN-001	Emergency response during dialysis	Plan	21.8
DIA-POL-001	Dialysis water standard and testing	Policy	21.1
DIA-POL-002	Dialyser reuse and reprocessing	Policy	21.4
DIA-POL-003	Dialysis staffing and competence	Policy	21.11
DIA-REG-001	Dialyser traceability and reprocessing register	Register	21.4
DIA-REG-002	Access-related infection register	Register	21.6
DIA-REG-003	Dialysis incident and outcome review register	Register	21.12
DIA-SOP-001	Preparation of concentrates and dialysis fluid	Procedure (SOP)	21.3
EQP-REG-001	(name to be confirmed)	Register	21.2, 21.8
INC-SOP-001	(name to be confirmed)	Procedure (SOP)	21.12
WAT-FRM-001	(name to be confirmed)	Form (record)	21.1
WRK-REG-001	(name to be confirmed)	Register	21.11