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The Dialysis Water & Equipment Playbook

AAMI water quality, RO maintenance, and CMS
Conditions for Coverage readiness

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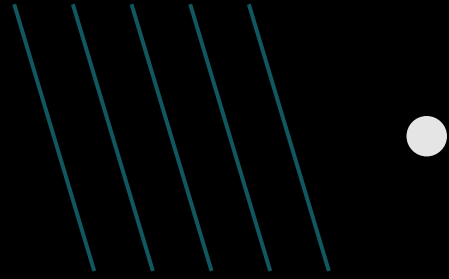
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Foreword

Equipment does not fail politely. It drifts, it degrades, and it usually chooses the worst possible moment to remind you that maintenance is not paperwork — it is patient safety. This field guide exists because dialysis water treatment sits at exactly that intersection, where a quiet calibration drift or a skipped preventive-maintenance visit can become a clinical event.

Everything in these pages is grounded in the standards and regulatory developments in force as of July 2026. We have tried to write the book we wish we'd had on our first solo service call: specific, checklist-driven, and honest about the difference between what the standard requires and what good practice adds on top.

Read it front to back once, then keep it on the bench. The checklists at the end of each chapter are meant to be photocopied, argued with, and improved for your own facility.

Chapter 1 — Water Is the Medicine

A hemodialysis patient is exposed to hundreds of liters of water per week across the dialyzer membrane. Contaminants that would be harmless to drink become clinically significant at that exposure. In dialysis, the water treatment system is not building infrastructure — it is part of the therapy, and it is maintained to that standard.

This playbook treats the RO system, the distribution loop, and the monitoring program as a single patient-safety system governed by the CMS Conditions for Coverage and the AAMI standards they incorporate.

Field Checklist

- Map the full water pathway from feed to reuse
- Identify every sample and monitoring point
- Confirm which AAMI standard your CfC references

Chapter 2 — The AAMI Limits, Memorized

Product water must contain fewer than 200 colony-forming units per milliliter of bacteria, with an action level at 50 CFU/mL that triggers investigation. Endotoxin must remain below 2 endotoxin units per milliliter, with an action level at 1 EU/mL. A defined list of chemical contaminants — heavy metals, fluoride, nitrates, sulfates, and others — is monitored on schedule.

The action levels matter more than the maximums. A result at the action level is not a failure; it is the system telling you to act before it becomes one.

Field Checklist

- Bacteria: < 200 CFU/mL (action 50)
- Endotoxin: < 2 EU/mL (action 1)
- Chemical contaminants monitored on the AAMI schedule
- Document sampling method and chain of custody

Chapter 3 — Reverse Osmosis Maintenance

The RO membrane is the heart of the system and the component most likely to degrade slowly. Rejection percentage, conductivity, and pressure differentials are the vital signs. A membrane rarely fails suddenly; it declines, and the decline is visible in the data long before it shows up in a water result.

Trend rejection and conductivity continuously. The membrane change you schedule during a maintenance window is a non-event; the one you do at 2 a.m. is a patient-safety incident.

Field Checklist

- Log RO rejection and conductivity every treatment day
- Track pre- and post-membrane pressures
- Schedule membrane changes on trend, not failure
- Verify disinfection cycles and residual testing

Chapter 4 — CMS Conditions for Coverage

The Conditions for Coverage under 42 CFR Part 494 establish the minimum standards a facility must meet to participate in Medicare, and they incorporate the AAMI water and dialysate quality requirements by reference. Water and dialysate purity is among the areas surveyors examine most closely, because the link to patient harm is direct.

The CY2026 ESRD Prospective Payment System final rule set a 2.2% payment update — payment stability that does nothing to relax the coverage conditions. If anything, stable payment removes the excuse for deferring water-system investment.

Field Checklist

- Align monitoring to the CfC-referenced AAMI edition
- Keep water and dialysate results survey-ready
- Document corrective actions to closure
- Maintain equipment logs for every treatment station

Chapter 5 — Dialysate and Concentrate Systems

Beyond water, the concentrate and dialysate delivery systems carry their own maintenance and verification obligations. Conductivity, temperature, and mixing accuracy affect every treatment, and the machines themselves require preventive maintenance on the manufacturer's schedule.

Verify dialysate conductivity independently of the machine's own display at defined intervals.

Field Checklist

- Verify dialysate conductivity and temperature
- Maintain machines on manufacturer PM intervals
- Confirm concentrate mixing and delivery accuracy

Chapter 6 — Disinfection and Biofilm Control

Biofilm in the distribution loop is the persistent enemy of a low bacteria and endotoxin count. Disinfection protocol, loop design, and flow velocity all bear on whether biofilm establishes. A rising bacteria trend with a healthy RO membrane usually points at the loop, not the source.

When numbers climb, interrogate the loop and the disinfection cycle before you blame the membrane.

Field Checklist

- Follow the disinfection schedule and verify residuals
- Maintain loop flow velocity to discourage biofilm
- Investigate rising counts at the loop first

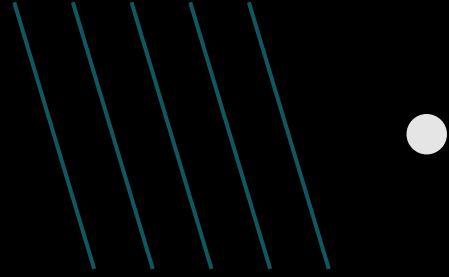
Chapter 7 — Building a Survey-Proof Program

A survey-proof program is one where any result, on any day, can be produced with its context: the reading, the action level, the response if one was needed, and the closure. Trending turns a pile of results into an argument that the system is under control.

The goal is not a perfect record of perfect numbers — it is a demonstrable habit of catching and acting on the imperfect ones.

Field Checklist

- Trend all water and dialysate data monthly
- Keep an action-level response tree posted
- Close every investigation with documentation



Conclusion: The Discipline of Boring Excellence

The best maintenance programs are boring. Nothing dramatic happens because the dramatic things were prevented three visits ago. The daily check that catches a 10 dB shift, the trend line that flags a tired membrane before it fails, the PM sticker that is current when the surveyor walks in — none of these make headlines, and that is precisely the point.

Regulators in 2026 are converging on the same message from different directions: show us the outcome, not just the binder. Joint Commission's consolidated Physical Environment chapter, CMS's continued scrutiny of the Conditions for Coverage, and FDA's servicing-versus-remanufacturing line all reward programs that can demonstrate — with data and disciplined records — that equipment is safe and ready.

Build the boring machine. Document relentlessly. Trend before you fail. That is the whole job, and done well, it is a genuine competitive advantage.

References & Sources

All developments summarized in this guide are grounded in the following publicly reported standards and rules, current as of July 2026:

1. NFPA 99, Health Care Facilities Code — current 2024 edition; 2027 edition in development (National Fire Protection Association).
2. ASA Standards & Practice Parameters; Anesthesia Patient Safety Foundation (APSF), ANESTHESIOLOGY 2026.
3. CMS, Calendar Year (CY) 2026 End-Stage Renal Disease (ESRD) Prospective Payment System Final Rule.
4. CMS Conditions for Coverage for ESRD Facilities, 42 CFR Part 494; AAMI water and dialysate quality standards.
5. The Joint Commission, 2026 Comprehensive Accreditation Manual for Ambulatory Care (CAMAC), released Oct 15, 2025.
6. ANSI/ASA S3.6-2025, Specification for Audiometers; OSHA 29 CFR 1910.95 Occupational Noise Exposure.
7. FDA, Remanufacturing of Medical Devices — Final Guidance (2024); FY2026 appropriations report language.