

Dialysis Water Quality: AAMI Standards, RO System Design, and Microbiological Monitoring

THE DIRECT ANSWER

Dialysis water must meet chemical and microbiological limits before it ever reaches a dialyzer, because up to hundreds of liters cross the membrane each week. US ESRD Conditions for Coverage at 42 CFR 494.40 still incorporate ANSI/AAMI RD52:2004, while current engineering practice follows the ANSI/AAMI/ISO 23500 series (2024 editions), especially ISO 23500-3 for water limits and ISO 23500-2 for treatment equipment. A typical central plant combines pretreatment, reverse osmosis, storage, recirculation, point-of-use filtration, and scheduled culture/endotoxin testing tied to action levels.

WHY DIALYSIS WATER IS DIFFERENT FROM OTHER HEALTHCARE WATER

- Dialysis water sits in a narrow category of healthcare water systems : it becomes part of the extracorporeal circuit. Bacteria or endotoxin that survive treatment can reach blood directly.

STANDARDS MAP: ISO 23500, LEGACY AAMI DOCUMENTS, AND CMS

- ISO 23500-1:2024 — general quality management from municipal entry through dialysate preparation
- ISO 23500-2:2024 — water treatment equipment design and performance (manufacturer-facing, but facilities use it in procurement specs)
- ISO 23500-3:2024 — chemical and microbiological limits for dialysis water
- ISO 23500-4 and -5:2024 — concentrates and final dialysis fluid quality

FIELD QUESTION

Where does this come from?

This sheet distills the full Healthcare Facility Hub article linked below, which carries the complete text, references, and sourcing.

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Caution: codes, editions, and targets vary by facility and authority having jurisdiction (AHJ). Figures marked as common practice are facility targets, not code requirements. Confirm against your AHJ and the current code text before acting.

healthcarefacilityhub.org/dialysis-water-quality-aami-standards-ro-system-microbiological-monitoring/

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