



AAMI Update

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CMS Reference

- 494.40 Condition: Water and dialysate quality
- RD52:2004 and RD62:2001
 - V175 “should” or “recommend”



494.40 Condition: Water and Dialysate Quality

- RD52:2004: Dialysate for hemodialysis
- Tags V176 to about V278 (>102 - 185)
- Includes for the first time specific regs for dialysate
 - Labeling
 - Mixing
 - Distribution
 - Use
 - Staff training/qualifications on water treatment
 - Water treatment equipment requirements



Conditional Level

- Demonstrated lack of knowledge or training
- Failure to perform and document
- Unsafe practices in the preparation, labeling or delivery of dialysate
- Failure to address out of range results



<i>Fluid</i>	<i>Bacteria (CFU/ml)</i>	<i>Endotoxin (EU/ml)</i>
<i>Water used for dialysate, reprocessing of hemodialyzers, germicide production</i>	200 / 50 action level	2 / 1 action level
<i>Dialysate</i>	200 / 50 action level	2 / 1 action level
<i>Minimum Frequency</i>	Monthly	Monthly



V178 Bacteriology of Water

- Corrective actions shall be taken “promptly”
- Use of water outside of AAMI standards



V182

- 5.1 General *back up plan*
 - V408 Emergency preparedness

...immediate action must be taken to ensure prompt restoration of these treatments or to plan for the safe transfer of patients to alternate location(s) for their treatments.



510K

- V101 The facility and its staff must operate and furnish services in compliance with applicable Federal , State, and local laws and regulations...
- 5.2 Water purification system
 - May 30, 1997

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8 Environment

- V184 Secure & restricted
- V185 Access to ports/meter
- V186 Alarms in treatment area
- V187 Schematic diagrams/labels



V190 – V191 Softeners

- 6.2.4 Timers checked at the beginning of each day and interlocked
- Hardness check
 - ≤ 1 grain/gal
 - End of the day
- Salt level



V192 – V197 Carbons

- 5.2.5 Carbon adsorption two tanks in series
- V494.100 Condition: Care at home
 - V595 RD52:2004/Annex C:Special considerations for home hemodialysis
 - C.5.3 well/municipal



V196

- *6.2.5 monitoring, testing, frequency*
 - Prior to each shift or every 4 hours
 - 15 minutes
 - Total chlorine acceptable(0.1mg/L)
 - 72 hours
 - Qualitative/quantitative



V199 – V201 R.O.

- 5.2.7 a means to prevent patient exposure to unsafe product water, such as diversion of the product water to drain...
- 6.2.7 chemical analysis
 - Installation, membrane replacement, seasonal variations, <90% rejection



V202 – V206 Deionization

- 5.2.8 alarms/divert to drain
 - Alarm must be audible in the patient care area
 - Shall divert product water to drain or otherwise prevent product water from entering the distribution system
 - DI tanks should be stored “wet” i.e., filled with stagnant water



V208 – V213 Water storage and distribution

5.3.2 Water storage tanks

- conical or bowl shaped, drain from the lowest point of base, tight-fitting lid and 0.2 μ m air filter
- UF distal to the storage tank
- Direct feed, A.5.3 dual check valves to prevent retrograde



V213 – V220 Bacterial control

7 Strategies for bacterial control

- Dead-end and unused branches
- Flow velocity
- Monthly disinfection
 - Includes machine water line



V234

5.4.5 Additives: *mixing spikes*

- Labeling (electrolyte added, date/time, person spiking, final concentration, +logged)
- Prescription medication



V245

5.5.3/5.5.4 Acid/Bicarb concentrate distribution systems: *Acid: labeled & color-coded red, Bicarb: color-coded blue*

- Point of use

5.5.4 Bicarbonate concentrate

5.5.5 Concentrate outlets:
separate/labeled/connection safety

- Proportioning ratio symbol



V696

494.140 Condition: Personnel qualifications
(f) Standard: Water treatment system technician.

Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing board.



Continued

IG: Any staff member who operates the water treatment system must complete a training program approved the medical director and the governing body prior to independently performing water treatment tasks.



V260

9 Personnel: *training program/periodic audits*

Training program to include: quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues is mandatory.



V276

Standard: In-center use of preconfigured hemodialysis system

- *Annual chemical analysis, quarterly bacteriological, each use chlorine/chloramine*

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