The content of this presentation is the findings and opinion of the author and does not reflect the views of St. Joseph Hospital.
CMS Reference

- 494.40 Condition: Water and dialysate quality
  - 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
<table>
<thead>
<tr>
<th>Fluid</th>
<th>Bacteria (CFU/ml)</th>
<th>Endotoxin (EU/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water used for dialysate, reprocessing of hemodialyzers, germicide production</td>
<td>200 / 50 action level</td>
<td>2 / 1 action level</td>
</tr>
<tr>
<td>Dialysate</td>
<td>200 / 50 action level</td>
<td>2 / 1 action level</td>
</tr>
<tr>
<td>Minimum Frequency</td>
<td>Monthly</td>
<td>Monthly</td>
</tr>
</tbody>
</table>
V178 Bacteriology of Water

- Corrective actions shall be taken “promptly”
- Use of water outside of AAMI standards
• 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
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
  - $\leq 1$ 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
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
5.3.2 Water storage tanks

- conical or bowl shaped, drain from the lowest point of base, tight-fitting lid and 0.2µm 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
5.4.5 Additives: *mixing spikes*

- Labeling (electrolyte added, date/time, person spiking, final concentration, +logged)
- Prescription medication
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
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 by 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.
Standard: In-center use of preconfigured hemodialysis system

• Annual chemical analysis, quarterly bacteriological, each use chlorine/chloramine