Differences in Methods in Dialysis Standards:

AAMI, ISO, CMS
How to Cope

NANT 34th Annual Symposium
February 22, 2017
Centers for Medicare & Medicaid Services
CMS, AAMI, ISO--Who are they?

- CMS-Centers for Medicare & Medicaid Services
- AAMI-Association for the Advancement of Medical Instrumentation
- ISO-International Standards Organization
Background

- AAMI RD 52 due for its 5 year review/update in 2009
- Adopting ISO 23500 serves as a partial revision of RD 52
- ISO 23500 includes references to other ISO documents
  - ISO 13959:2009 (Water Quality),
  - ISO 13958:2009 (Concentrate Quality)
  - ISO 11663:2009 (Dialysate Quality)
  - ISO 26722:2009 (Water Treatment)
- These complete the revision of RD 52
## Chronology of Document Development

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<td>CMS Conditions for Coverage ESRD</td>
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<td>ISO 23500</td>
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<td>ISO 23500, 11663, 13958, 13959, 26722</td>
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<td>AAMI/ISO 23500, 11663, 13958, 13959, 26722</td>
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<td>X</td>
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<tr>
<td>AAMI 23500, 11663, 13958, 13959, 26722 (with U.S. deviation)</td>
<td></td>
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</tr>
</tbody>
</table>
CMS

- Develops Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that ESRD facilities must meet in order to begin and continue participating in the Medicare and Medicaid programs
- Adopts specific editions of referenced documents as regulation in the U.S.
- There is no “automatic” updating
- There is a formal process that must be followed to implement or update regulations:
  - “Notice of Proposed Rulemaking” (NPRM)
- Core Survey introduced in 2014
Notice of Proposed Rule Making

- CMS must publish a public notice of intent to make new rules in the Federal Register.
- There must be a comment period, usually 30-90 days.
- CMS then considers the comments in developing the final rule.
- Final rule published in the Federal Register with an implementation date.
What Does the CMS Conditions for Coverage Interpretive Guidance-ESRD Facilities Cover?

- Coverage more extensive than RD52 & RD62
- V tag based
- Topics included
  - Patient Safety
    - Infection control
    - Water & dialysate quality
    - Dialyzer & bloodline reuse
    - Physical environment
  - Patient Care
    - Patients’ rights
    - Patient assessment
    - Patient plan of care
    - Care at home
    - QAPI
    - Special purpose facilities
    - Laboratory services
  - Administration
    - Personnel qualifications
    - Medical director responsibilities
    - Medical records
    - Governance

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CMS Core Survey

- Presurvey preparation
- Introductions
- Environmental “Flash” Tour
- Water Tx/Dialysate Prep Area(s)
- Reuse Room
- Home dialysis training area
- Entrance Conference
- Observations of Hemodialysis Care & Infection Control Practices
- Patient Sample Selection

- Water Tx & Dialysate Review
- Dialyzer Reprocessing/Reuse Review
- Dialysis Equipment Maintenance
- Home Dialysis Training & Support Review
- Patient Interviews
- Medical Record Review
- Personnel Interviews
- Personnel Record Review
- QAPI Review (Segments I,II,III)
- Decision making
- Exit Conference

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AAMI

- Develops consensus standards for the medical device industry
- Renal Disease & Detoxification Committee develops
  - Standards
  - Recommended practices
  - Technical information reports
- Aims to harmonize as much as possible with International Standards

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ISO

- A Worldwide Federation of National Standards Bodies
- U.S. is an ISO member
- ISO has subcommittees like AAMI
  - ISO Cardiovascular Implants and Extracorporeal Systems Working Group is the ISO equivalent to the AAMI Renal Disease and Detoxification Committee
Important Terminology Differences

AAMI & ISO Standards

- **Shall**—Required
- **Should**—Recommended
  - Not requirement except if by CMS
- **May**—a permissible way to achieve compliance

CMS

- **Shall & Should**—Required
- **Condition level non-compliance**
  - Pervasive deficient practices
  - Serious in nature
  - Potential risk to patient health & safety
- **Standard level non-compliance**
- **V Tag** based
Summary

- CMS – Regulation
- AAMI -- U.S. Standards
- ISO — International Standards
- AAMI-ISO – Harmonized Standards
AAMI RD 52 → CMS Regulation

- AAMI RD 52 was adopted as part of the 2008 ESRD regulation
- Because AAMI RD 52 is now CMS regulation, it “must” be followed in dialysis units certified under the ESRD regulations
- Verbs like shall, should, may in RD52= MUST in CMS ESRD regulation
- RD62 adopted by CMS by reference
Comparing CMS Regs & ISO Standards

- International Standards which functions as a recommended practice
- Adopted by AAMI to replace RD 52 (along with the adoption of other ISO documents)
- NOT REGULATION
- Has not been adopted by CMS
- Remember, CMS has to follow that formal process; if it started tomorrow, it would take 18-24 months at a minimum to change current regulation and adopt all or part of the ISO standards.
Why Bother With ISO Standards?

- AAMI sets the Standards for our industry; has adopted ISO 23500 to replace RD 52
- RD 52 is now “obsolete;” not available from AAMI
- ISO quality standards are more stringent
- You may choose to adopt the more stringent quality standards to increase patient safety/enhance patient outcomes;
- Can still be in compliance with CMS requirements
Applicability of ISO Standards

- Out patient in-center hemodialysis
- Home hemodialysis
- Acute hemodialysis

ISO 23500 is:
- Not required but may be implemented
- Would be required if adopted by policy or inferred by statements of intent to follow the “standard of practice.”
Major Areas of Difference
CMS Regs & ISO Standards

- More stringent microbial limits for water & dialysis fluid
- Focus on Validation
- Emphasis on prevention & process control for consistent delivery of quality dialysis fluid not just periodic disinfection
- New strategies to ensure microbiological control
- New methods for culturing viable bacteria from water & dialysis fluid
- Use of Annexes for information & guidance
- Sections on Equipment moved to Annex B
<table>
<thead>
<tr>
<th>Contaminant</th>
<th>ISO Max Limit*</th>
<th>ISO Action Level*</th>
<th>CMS Max Limit</th>
<th>CMS Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Viable Bacteria Count (TVC)</td>
<td>&lt;100 CFU/mL</td>
<td>50 CFU/mL</td>
<td>&lt;200 CFU/mL</td>
<td>50 CFU/mL</td>
</tr>
<tr>
<td>Endotoxin</td>
<td>&lt;0.25 EU/mL</td>
<td>0.125 EU/mL</td>
<td>&lt;2 EU/mL</td>
<td>1 EU/mL</td>
</tr>
</tbody>
</table>

*Adapted from ISO 13959:2009
<table>
<thead>
<tr>
<th>Contaminant</th>
<th>ISO Max Limit*</th>
<th>ISO Action Level*</th>
<th>CMS Max Level</th>
<th>RD 52 Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total viable count (TVC)</td>
<td>&lt;100 CFU/mL</td>
<td>50 CFU/mL</td>
<td>&lt;200 CFU/mL</td>
<td>50 CFU/mL</td>
</tr>
<tr>
<td>Endotoxin</td>
<td>&lt;0.5 EU/mL</td>
<td>0.25 EU/mL</td>
<td>&lt;2 EU/mL</td>
<td>1 EU/mL</td>
</tr>
</tbody>
</table>

*Adapted from ISO 11663:2009*
What Is Different? Water ≠ Dialysis Fluid

<table>
<thead>
<tr>
<th>Fluid</th>
<th>ISO Max Endotoxin Limit</th>
<th>ISO Action Endotoxin Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>0.25 EU/mL</td>
<td>0.125 EU/mL</td>
</tr>
<tr>
<td>Dialysis fluid</td>
<td>&lt;0.5 EU/mL</td>
<td>0.25 EU/mL</td>
</tr>
</tbody>
</table>

**Note:** Allowable endotoxin levels for dialysis fluid are higher than for water because the concentrates can contribute to the dialysis fluid endotoxin load.
## Ultrapure Dialysis Fluid

<table>
<thead>
<tr>
<th>Contaminant</th>
<th>ISO Max Limit*</th>
<th>ISO Action Level*</th>
<th>CMS Max Limit</th>
<th>CMS Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total viable count (TVC)</td>
<td>&lt;0.1 CFU/mL</td>
<td>Typically 50% of Max Level</td>
<td>&lt;0.1 CFU/mL</td>
<td>Not established</td>
</tr>
<tr>
<td>Endotoxin</td>
<td>&lt;0.03 EU/mL</td>
<td>Typically 50% of Max Level</td>
<td>&lt;0.03 EU/mL</td>
<td>Not established</td>
</tr>
</tbody>
</table>

*Adapted from ISO 11663:2009

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## ISO Microbial Culture Conditions

Excerpted from ISO 23500:2014, 8.3.3.3

<table>
<thead>
<tr>
<th>Cultivation medium</th>
<th>Incubation temperature</th>
<th>Incubation time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tryptone Glucose Extract Agar (TGEA)</td>
<td>17 °C to 23 °C</td>
<td>7 days</td>
</tr>
<tr>
<td>Reasoner's Agar No. 2 (R2A)</td>
<td>17 °C to 23 °C</td>
<td>7 days</td>
</tr>
</tbody>
</table>
Preferred Culture Methods & Sample Volumes

- Standard dialysis fluid
  - Spread plate
    - 0.1mL-0.3mL
  - Pour plate
    - 0.1mL-1mL
- Ultrapure dialysis fluid
  - Membrane filtration
    - 10mL-1,000mL
- Substitution fluid
  - Not sampled or cultured

Excerpted from ISO 23500:2014, 8.3.3.2
# Table of Differences
CMS Regulation & ISO Documents

<table>
<thead>
<tr>
<th>V Tag #</th>
<th>CMS Requirement</th>
<th>ISO Recommendation</th>
<th>ISO Document #(s)</th>
<th>ISO meets/exceeds CMS?</th>
</tr>
</thead>
</table>
| V178 V180 | Bacteriology of Water & Standard Dialysate  
<200 CFU/mL microbial count;  
<2EU/mL endotoxin  
Action levels: 50 CFU/mL & 1EU/mL | <100 CFU/mL microbial count;  
<0.25 EU/mL endotoxin  
Action levels: 50% of max level | 13959  
11663 | Yes |

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<tbody>
<tr>
<td>V196</td>
<td>Carbon Adsorption Allows testing for both <strong>Chlorine</strong>—Limit 0.5 mg/L and <strong>Chloramines</strong>—Limit 0.1 mg/L</td>
<td>Allows for testing for <strong>Total Chlorine Only</strong> with limit of &lt;0.1 mg/L</td>
<td>26722</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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</table>
| V211   | Water distribution systems  
*Prescribes min velocities needed*                                                      | Strategies for microbial control (fluid system design):  
*It has been demonstrated that fluid velocity cannot control microbial growth & biofilm formation in hydraulic systems.* | 23500              | No                     |

Current data shows fluid velocity does not control microbial growth & biofilm

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<tbody>
<tr>
<td><strong>V200</strong></td>
<td>Requires <strong>alarm audible in patient care area</strong></td>
<td><strong>RO</strong> Recommends alarm sound level measure; verification of alarm signal after silencing</td>
<td>26722</td>
<td><strong>Yes</strong></td>
</tr>
<tr>
<td><strong>V201</strong></td>
<td>Requires <strong>chemical analysis if rejection rates fall below 90%</strong></td>
<td><strong>RO</strong> Recommends chemical analysis if rejection rates decrease &gt;10%</td>
<td>23500</td>
<td><strong>No</strong> If rejection rate was 95% &amp; fell to 89% this would be below 90% but not a drop of 10%</td>
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<tbody>
<tr>
<td>V209</td>
<td>Water storage tank: <strong>Bladder or surge tanks not addressed</strong></td>
<td>Storage tanks: <strong>Bladder tanks and pressurized surge tanks recommended to be used in the dialysis water distribution system</strong></td>
<td>26722</td>
<td>Yes</td>
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<tr>
<td>V225</td>
<td><strong>Safety requirements for mixing devices not addressed</strong></td>
<td><strong>Addresses safety requirements for mixing devices</strong></td>
<td>13958</td>
<td>Yes</td>
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</tbody>
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<tbody>
<tr>
<td>V213</td>
<td>Water distribution systems: <strong>Bacteria Counts ≤200 CFU/mL; Endotoxin ≤2EU/mL</strong></td>
<td>Monitoring water distribution system <strong>Bacteria counts ≤100 CFU/mL; Endotoxin ≤0.25 EU/mL</strong></td>
<td>23500</td>
<td>Yes</td>
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<tr>
<td>V213</td>
<td>Water distribution systems: <strong>Bacteria &amp; endotoxin testing at least monthly</strong></td>
<td></td>
<td>23500</td>
<td>Depends on validation data</td>
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</tbody>
</table>


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## Table of Differences
### CMS Regulation & ISO Documents

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<tr>
<td>V252</td>
<td>Microbial monitoring methods: Additional testing for evaluation of the disinfection program is not addressed</td>
<td>Monitoring of H2O distribution systems Additional testing &amp; troubleshooting strategy Need for additional testing based on original validation plan Risk analysis of impact of change on system performance</td>
<td>23500</td>
<td>Yes</td>
</tr>
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<tbody>
<tr>
<td>V256</td>
<td>Heterotrophic plate count—Allows use of dip samplers with conditions</td>
<td>Does <strong>not</strong> allow use of dip samplers</td>
<td>23500 Annex D Strategies for microbe control</td>
<td>Yes</td>
</tr>
<tr>
<td>V256</td>
<td>Heterotrophic plate count — <em>Incubate 48h, 35°C</em></td>
<td><em>Incubate 7 days, 17-23°C</em></td>
<td>23500 Annex D Strategies for microbe control</td>
<td>AAMI U.S. Deviation</td>
</tr>
<tr>
<td>V257</td>
<td>Heterotrophic plate count--Culture media: TSA, SMA, PCA</td>
<td>Culture media: TGEA, R2A or equivalent</td>
<td>23500 Annex D Strategies for microbe control</td>
<td>AAMI U.S. Deviation</td>
</tr>
</tbody>
</table>

1 AAMI—Dialysis Water and Dialysate Recommendations: A User Guide. Association for the Advancement of Medical Instrumentation, Arlington, VA.
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<tr>
<td>V240</td>
<td>Bicarbonate concentrate distribution systems—UV lamps should provide a radiant energy dose of <strong>30 milliwatt-sec/cm²</strong></td>
<td>Ultraviolet irradiators—UV lamps in concentrate storage &amp; distribution systems shall provide a radiant energy of <strong>16 milliwatt-sec/cm²</strong> if fitted with calibrated <strong>UV intensity meter</strong>. If not a dose of <strong>30 milliwatt-sec/cm²</strong> required</td>
<td>13958</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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<tr>
<td>V248</td>
<td>Dialysate proportioning—Expected dialysate pH levels between 6.9 &amp; 7.6</td>
<td>Expected dialysate pH levels between 6.9 &amp; 8.0</td>
<td>23500 Annex B Dialysis fluid proportioning</td>
<td>May follow ISO</td>
</tr>
</tbody>
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<tr>
<td>V253</td>
<td>Microbial monitoring methods—Dialysate requires retest of dialysis machine with results above action level; review compliance procedures; evaluate data trends</td>
<td>Requires retesting of the offending machine + additional machines</td>
<td>23500 Annex D Microbial monitoring methods—</td>
<td>Yes</td>
</tr>
</tbody>
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<tr>
<td>V595</td>
<td>Annex C: Carbon adsorption media: <strong>Does not address use of other means of chloramine removal</strong></td>
<td>Addresses the need for adequate flush time if a means other than 2 series connected carbon beds with 10min EBCT is used for chloramine removal</td>
<td>23500 Annex F</td>
<td>Yes</td>
</tr>
<tr>
<td>V595</td>
<td>Annex C: Home <strong>DI not required to have a means to prevent product H2O reaching point of use if resistivity is 1megohm-cm or less</strong></td>
<td></td>
<td>23500 Annex F</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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<tr>
<td>V595</td>
<td>Annex C: Equipment: Requires alarms to be audible &amp; visible in the patient Tx area</td>
<td>Equipment: Does not address visible and audible alarms in patient Tx area</td>
<td>23500 Annex F</td>
<td>No</td>
</tr>
<tr>
<td>V595</td>
<td>Annex C: Carbon adsorption media: Allows testing for both chlorine and chloramine</td>
<td>Carbon media: Recommends testing only total chlorine when the source water contains chloramine</td>
<td>23500 Annex F</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Evolution of AAMI & ISO Standards

- AAMI RD52:2004 “Dialysate for Hemodialysis”
- AAMI RD 62:2006 “Water Treatment Equipment for Hemodialysis Applications”
- AAMI:2009, ISO standards with U.S. deviation
AAMI/ISO Standards

- AAMI/ISO 11663: 2009 “Quality of Dialysis Fluid for Haemodialysis and Related Therapies”
- AAMI/ISO 26722: 2009 “Water Treatment Equipment for Haemodialysis”
ISO 2014 Dialysis Standards

ISO 2014 series of hemodialysis standards allow only for the following culture methods:

- TGEA or R2A (low nutrient media) or equivalent
- 7 days (168h) incubation
- 17-23°C

Rationale—Lower nutrients, lower temperature and longer incubation yields higher recoveries
Problem with ISO 2014 Approach

- Important for patient safety to know sooner than later if action level has been reached to allow for earlier intervention
- 7 days is a long time to wait for results
- No culture method recovers all bacteria present
- While higher recoveries may be ideal, shorter incubation methods allow for more rapid intervention
- Many of the bacteria harmful to patients (e.g. produce high activity endotoxin) grow at higher temperatures, on higher nutrient medium and in a shorter time
- How to establish equivalency to ISO 2014 recommended methods not defined
U.S. Deviation to AAMI/ISO 2014 Documents

- Deviation is related to acceptable culture method (media and conditions of incubation) for analysis of water and dialysis fluid samples for bacteria
  - Allows for use of
    - TSA (tryptic soy agar),
    - SMA (standard methods agar)
    - PCA (plate count agar)
  - Incubation at 35-37°C, 48h
AAMI 2014
(ISO Standards with U.S. Deviation)

- Deviation Related to Microbial Culture Methods
- ISO Standards
  - TGEA or R2A
  - 17-23°C
  - 7 days
- U.S. Deviation Adds
  - TSA
  - 35-37°C
  - 48 hours
## ISO Documents 2014 vs Next Revision

<table>
<thead>
<tr>
<th>ISO 2014</th>
<th>ISO 2018 expected</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ISO 23500</strong> Prep &amp; Quality Management of Fluids for HD…</td>
<td>23500-1 Guidance for prep &amp; quality management for HD…: <strong>General Requirements</strong></td>
</tr>
<tr>
<td><strong>ISO 26722</strong> Water Tx Equipment for HD</td>
<td>23500-2 Guidance for prep &amp; quality management for HD…: <strong>Water Tx Equipment</strong> for HD</td>
</tr>
<tr>
<td><strong>ISO 13959</strong> Water for HD…</td>
<td>23500-3 Guidance for prep &amp; quality management for HD…: <strong>Water</strong> for HD</td>
</tr>
<tr>
<td><strong>ISO 13958</strong> Concentrates for HD…</td>
<td>23500-4 Guidance for prep &amp; quality management for HD…: <strong>Concentrates</strong> for HD…</td>
</tr>
<tr>
<td><strong>ISO 11663</strong> Quality of Dialysis Fluid for HD</td>
<td>23500-5 Guidance for prep &amp; quality management for HD…: <strong>Dialysis Fluid</strong> for HD</td>
</tr>
</tbody>
</table>
Proposed Changes to Next Revision of ISO Haemodialysis Series Standards (2018?)

- TSA incubated at 35-37°C, 48h added as an acceptable culture method
  - Applies to Standard Dialysis Water & Dialysis Fluid Heterotrophic Plate Count and Bicarbonate concentrate
  - No supplementation is needed for bicarbonate containing samples

- Residual chlorine detection in rinse water following disinfection of a dialysis system with bleach per manufacturer’s instructions can be done by measuring for free chlorine at a limit of ≤0.5mg/L

- Consistency in use of “shall” and “should”
## ISO Document Methods: Requirement Level Discrepancies

<table>
<thead>
<tr>
<th>ISO Doc #</th>
<th>Subject Matter</th>
<th>Media</th>
<th>Requirement Level</th>
<th>Incubation Temp</th>
<th>Requirement Level</th>
<th>Incubation Time</th>
<th>Requirement Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>11663 23500-5</td>
<td>Dialysis Fluid</td>
<td>TGEA, R2A, or =</td>
<td>Shall</td>
<td>17-23°C</td>
<td>Recommended</td>
<td>168h (7days)</td>
<td>Recommended</td>
</tr>
<tr>
<td>13959 23500-3</td>
<td>Dialysis Water</td>
<td>TGEA, R2A, or =</td>
<td>Shall</td>
<td>17-23°C or equivalent results</td>
<td>Recommended</td>
<td>168h (7days) or = results</td>
<td>Recommended</td>
</tr>
<tr>
<td>23500-1</td>
<td>Dialysis Fluid</td>
<td>TGEA, R2A</td>
<td>Not specified</td>
<td>17-23°C</td>
<td>Not specified</td>
<td>168h (7days)</td>
<td>Not specified</td>
</tr>
<tr>
<td></td>
<td>NaHCO₃ Conc</td>
<td>TGEA, R2A + 4% NaHCO₃</td>
<td>Should</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13958 23500-4</td>
<td>NaHCO₃ Conc</td>
<td>TGEA or R2A, + 4% NaHCO₃, TSA, or = Membrane Filtration</td>
<td>Shall</td>
<td>17-23°C</td>
<td>Shall</td>
<td>168h (7days)</td>
<td>Shall</td>
</tr>
</tbody>
</table>
In Summary

- Differences exist between CMS, AAMI & ISO documents related to dialysis
  - CMS-Must Comply
  - AAMI-Shall or Should
    - Not regulation
    - Often meets or exceeds CMS requirements
    - Sometimes aligned with ISO
      - Goal: Harmonization with ISO
  - ISO-International Standards-Shall or Should
    - Not regulation
    - Recommended practices

- It is possible to incorporate some of AAMI &/or ISO practices and still be in compliance with CMS regulations
Acknowledgements & Resources

AAMI—information excerpted from webinars presented & use of AAMI logo (with AAMI permission):


AAMI publication:

Additional publication:

ISO logo (with permission from Secretariat)
Thank You

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