An AAMI Webinar Series:

ANSI/AAMI Dialysis Standards: 
A Detailed Review of ANSI/AAMI RD52, RD62, RD47, and RD61

ANSI/AAMI RD52:2004 
Dialysate for Hemodialysis

Speakers: 
Jo-Ann B. Maltais, Ph.D.  
Glenda M. Payne, MS, RN, CNN

October 5, 2010 
11:00 am – 1:00 pm   EDT  
10:00 am – 12:00 pm   CDT  
9:00 am – 11:00 am   MDT  
8:00 am – 10:00 am   PDT  
16:00 – 18:00 GMT

Presented by: 
AAMI  
Association for the Advancement of Medical Instrumentation
The Association for the Advancement of Medical Instrumentation (AAMI) has granted permission to the program speakers to quote from standards produced and published by AAMI. Views expressed by the speakers herein do not represent the views of AAMI or any AAMI Standards Committee or U.S. Technical Advisory Group administered by AAMI. Information concerning the content of draft standards that speakers may include within these materials is subject to change as a result of ballot and public review. Therefore, the content of a final standard could differ significantly from the content of its draft version.

AAMI is a not-for-profit association whose programs include the development of voluntary consensus standards for medical devices, and educational programs about medical devices for the healthcare community. AAMI does not test or otherwise evaluate specific products or services, endorse specific products or services, or attempt to monitor claims by manufacturers or consumers that certain products or services meet, or do not meet, AAMI standards.
AAMI’s STATEMENT OF QUALITY EDUCATION

The Association for the Advancement of Medical Instrumentation (AAMI) strives for the highest possible standards in its educational resources and programs. AAMI endeavors to offer timely, practical, innovative, and visionary educational opportunities so that individuals will be knowledgeable in medical device management, regulation, and standards, equipped with the tools necessary for effective and informed decision making, and recognized as an integral part of healthcare delivery worldwide.

GUIDING PRINCIPLES

Excellence: AAMI believes that excellence in education is fundamental to safe and effective design, production, and use of medical devices, essential to the pursuit of new innovations, and central to the assurance of positive healthcare outcomes for all individuals.

Fair Balance: AAMI maximizes fair balance in its educational programs in order to provide multiple perspectives from which its members can form professional opinions and become valuable resources in the healthcare continuum.

Integrity: AAMI seeks to maintain the respect of all healthcare professionals, faculty members, students, and others by constantly improving its educational programs, by providing the best educational services available, and by maintaining a professional and positive learning environment.

Value: AAMI strives to make high quality, accessible, and affordable education programs a top priority.

Collaboration and Cooperation: AAMI believes that a collaborative learning environment encourages communication among colleagues and contributes to the fulfillment of professional and personal educational goals. To this end, AAMI seeks ways to foster interaction among its members and others by optimizing opportunities for sharing ideas and exchanging valuable information and knowledge.

Responsibility: AAMI accepts its responsibility to contribute not only to the on-going learning of the medical device industry and individual healthcare technology managers and operators, but to the enrichment and advancement of the healthcare system. Through a commitment to offering excellent educational programs, it is AAMI’s goal to help its members exceed the expectations of those they serve and to improve patient outcomes.

Leadership: By occupying a position of unique leadership in education, AAMI members and all others who participate in its educational programs will meet new challenges with creative solutions, face new questions with in-depth knowledge, and embrace new opportunities with unbridled and open-minded enthusiasm.
ANSI/AAMI DIALYSIS STANDARDS WEBINAR SERIES CD ORDER FORM

<table>
<thead>
<tr>
<th>Pricing Fees</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>If you purchase a CD for one, two, three or each program separately, you pay a fee per CD of:</td>
<td></td>
</tr>
<tr>
<td>$75 per each recorded program</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Please indicate the CD(s) which you wish to purchase:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>October 5 – RD52</td>
<td>October 12 – RD62</td>
</tr>
<tr>
<td>October 19 – RD47</td>
<td>October 26 – RD61</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shipping Fees</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Ground Service - $21.00</td>
<td></td>
</tr>
<tr>
<td>☐ 2nd Day Service – $25.00</td>
<td></td>
</tr>
<tr>
<td>☐ Next Day Service – $30.00</td>
<td></td>
</tr>
<tr>
<td>☐ International Shipping – 25% of CD price for international addresses</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Your Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Name</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Company</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td>State</td>
</tr>
<tr>
<td>Phone</td>
<td>Fax</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Payment Method</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Payment enclosed (US dollars payable to AAMI)</td>
<td></td>
</tr>
<tr>
<td>Please charge my ☐MasterCard ☐VISA ☐American Express</td>
<td></td>
</tr>
<tr>
<td>Card number</td>
<td>Expiration Date</td>
</tr>
<tr>
<td>Name of cardholder</td>
<td>Authorized Signature</td>
</tr>
</tbody>
</table>

| Quantity | Total |  |
| --- | --- |  |

3 EASY WAYS TO ORDER

**By Fax**
Fax the completed order form and payment information to 301-206-9789

**By Phone**
Call, 877-249-8226 / 240-646-7031 to order with a credit card (AMEX, VISA, or MC)

**Send your completed order form and payment to:**
Dialysis Webinar CDs
AAMI Publications
PO Box 0211
Annapolis Junction, MD 20701-0211

Product Code: DSWCD
**Program Objectives:**

1. Describe the preparation of dialysate
2. Describe the operation of water treatment equipment
3. List best practices in handling of product water and dialysate concentrates
4. Identify high-risk issues, hazards of improper dialysate preparation, and how to mitigate
5. Create strategies for bacterial and endotoxin control
6. Identify CMS requirements and conditions likely to be cited

**Evaluate the presenters on a scale of 1-5**

(5=Strongly Agree, 1=Strongly Disagree)

<table>
<thead>
<tr>
<th>Knowledgeable of ANSI/AAMI RD52</th>
<th>Jo-Ann Maltais, Ph.D.</th>
<th>Glenda Payne, RN, MS, CNN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5 4 3 2 1</td>
<td>5 4 3 2 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Teaching strategies supported the objectives</th>
<th>5 4 3 2 1</th>
<th>5 4 3 2 1</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Overall effectiveness of presenter was excellent</th>
<th>5 4 3 2 1</th>
<th>5 4 3 2 1</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Objectives were relevant to the review of ANSI/AAMI RD52</th>
<th>5 4 3 2 1</th>
<th>5 4 3 2 1</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Met Objective #1: Describe the preparation of dialysate</th>
<th>5 4 3 2 1</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Met Objective #2: Describe the operation of water treatment equipment</th>
<th>5 4 3 2 1</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Met Objective #3: List best practices in handling of product water and dialysate concentrates</th>
<th>5 4 3 2 1</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Met Objective #4: Identify high-risk issues, hazards of improper dialysate preparation, and how to mitigate</th>
<th>N/A</th>
<th>5 4 3 2 1</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Met Objective #5: Create strategies for bacterial and endotoxin control</th>
<th>5 4 3 2 1</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Met Objective #6: Identify CMS requirements and conditions likely to be cited</th>
<th>N/A</th>
<th>5 4 3 2 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statement</td>
<td>Strongly Agree</td>
<td>Strongly Disagree</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>----------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Program was well organized</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Subject matter presented was relevant to my current practice</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Program objectives as advertised were met</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Overall content of the program was balanced (free of commercial bias)</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Ease of registration</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Audio quality of seminar</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Web quality of the seminar</td>
<td>5</td>
<td>4</td>
</tr>
</tbody>
</table>

Please list topics you would like to see at future AAMI, NANT, or ANNA meetings:

What was your overall impression of the program?

Name:  Fax:  E-Mail:
Would you like the ability to refer back to the information presented during today's webinar at a later date?

Or, do you know of someone who couldn't participate in the webinar but would find the materials presented informative and useful?

A recording of the program will be available in approximately one week. Full-webinar series registrants will automatically receive a link to the recording.

To purchase a CD of the program, please visit http://www.aami.org/meetings/courses/forms/web.2010.dialysis.pdf
Handouts

To download the slides presented during the webinar, please go to:
http://aami.confEdge.com/ap/eSite/?i=RD52

Audience Composition

We will now poll the audience to determine how many people are joining us today. Please enter the number of people at your site in the text box on your screen.
Presenters

Jo-Ann B. Maltais, Ph.D.  Glenda M. Payne, MS, RN, CNN

ANSI/AAMI Dialysis Standards

- RD52:2004 “Dialysate for Hemodialysis”
- RD62:2006 “Water Treatment Equipment for Hemodialysis Applications”
- RD47: “Reprocessing of Hemodialyzers”
  - Current RD47:2008
  - CMS adopted RD47:2002
- RD61:2006 “Concentrates for Hemodialysis”
Additional ANSI/AAMI Dialysis Standards

- RD5:2008 “Hemodialysis Systems”
- RD16:2007 “Cardiovascular implants and artificial organs—Hemodialyzers, hemodiafilters, hemofilters, and hemoconcentrators”
- RD17:2007 “Cardiovascular implants and artificial organs—Extracorporeal blood circuit for hemodialyzers, hemodiafilters, and hemofilters”

ANSI/AAMI Dialysis Standards Webinar Series Schedule

- October 5th — RD52:2004 “Dialysate for Hemodialysis”
- October 12th — RD62:2006 “Water Treatment Equipment for Hemodialysis Applications”
- October 19th — RD47: “Reprocessing of Hemodialyzers”
- October 26th — RD61:2006 “Concentrates for Hemodialysis”
To submit a question anytime during today’s event, please type your question in the “Chat (Q&A)” box on the left side of your screen and press Enter.

Water Treatment
AAMI

Jo-Ann B. Maltais, Ph.D.
- Independent Consultant
- Over 18 yrs experience in kidney dialysis on both the product & provider side
- Expertise in H₂O treatment, microbial monitoring & control, biofilm, disinfection, concentrate & dialysate preparation
- Member of AAMI RDD Committee
Objectives

- Describe the role of AAMI in the development of guidance documents and standards
- Discuss how the standards are viewed/adopted as regulation
- Identify critical sections and aspects of RD52
- Clear up some of the ambiguities within RD52
- Relate RD52 sections to CMS requirements
- Identify most frequent CMS citations
- Develop strategies to avoid CMS citations
Overview of AAMI RD52

RECOMMENDED PRACTICE-AAMI

STANDARD--ANSI

REGULATION--CMS

What Does RD52 Cover?

Dialysate & Concentrates
  • Preparation
  • Distribution
  • Monitoring
  • Risks & Hazards of Improper Preparation
  • Incorporates AAMI RD62 (Water Treatment)
  • By Reference
    • Operation of equipment
    • Distribution of product water
What is RD52 Trying to Accomplish?

- Minimize risk to the dialysis patient & staff
- Provide useful information to achieve quality water and dialysate
- Not to replace professional judgment
- Use as one of many sources of information
- Harmonize where possible with other standards
- Emphasize the ultimate responsibility of the medical director for compliance & quality

How RD52 Is Typically Used

➢ By the Manufacturer
  - How their products are used in a clinical environment
  - Impact of products on patient care & safety

➢ By the Dialysis Clinics
  - Establish & monitor water Tx system & product water
  - Production & use of dialysate concentrates
  - Ensure patient safety
  - Comply with CMS requirements

➢ Expert source: chemical & microbiology limits
Important Terminology
AAMI 52:2004

• **Shall**—Required
  - Recommendations & Procedures

• **Should**—Goal
  - Not a requirement except if by CMS

• **Must**—used only to describe areas where there are no options, including those mandated by government regulation

RD52, RD62 & CMS Related

• RD52 adopted by CMS as regulation
• RD62 adopted by CMS as regulation by reference
• Effective date: 10/14/2008
Presenter

**Glenda Payne, MS, RN, CNN**
- ESRD Technical Advisor, CMS, Dallas & Atlanta
- Over 20 years experience as a state/Federal surveyor
- Over 30 years experience in nephrology nursing
- Member of the AAMI RDD Committee since 2003

Notice:

- The opinions and assertions in Glenda Payne’s presentation are the private views of the author and are not to be construed as official or reflecting the views of the Centers for Medicare & Medicaid Services.
Objective: How Standards Become Regulation

- Government agencies may choose to use recognized standards as a basis for regulation
- Use work already done, by recognized experts
- Examples: CMS adoption of RD47, adoption of CDC documents
- Portions of RD5 were included in the previous ESRD regulations:
  - Chemical and bacteriological quality of water
  - Bacteriological quality of dialysate

Why Adopt RD52?

Previous limited regulations were no longer sufficient to protect patient safety:
- Increased complexity of systems
- Greater variability in staff qualifications
- More facilities mixing concentrates from powder
- Multiple instances of patient harm from errors in water treatment or dialysate management
Regulatory Process

- First full revision of ESRD regulations was published as proposed in February 2005
- Included proposal to adopt RD52, 2004 as regulation
- Comments supported this adoption
- ESRD updated regulations published as final April 15, 2008, effective date: October 14, 2008
- RD 52, 2004 included as regulation

Specifically RD52, 2004

- AAMI Committees do not “make” regulations
- In order to adopt an update of RD52, CMS would have to follow the regulatory process:
  - Publish proposed rule for comments
  - Review comments for incorporation
  - Publish as final, including a preamble which would discuss the comments and reasons for accepting or rejecting the comment(s)
# Converting from Standard to Regulation

- CMS staff worked directly with AAMI RD Committee
- Separated requirements from explanations
- Requirements went into regulation column, explanations and annex went into Interpretive Guidance column
- Reordered to more closely match the survey process “flow”

---

# Definition of Terms

“When “should” or “recommend” are included in the AAMI language adopted as regulation (i.e., the language in the “Regulation” column of the Interpretive Guidance), the referenced item or practice must be in use or in place.”

If “should” or “recommend” are used in the “Regulation” column, these should be considered as required.
Condition vs. Standard

- Sixteen ESRD Conditions for Coverage (CfC)
- Condition for Water and Dialysate Quality
  - Includes 92 individual “tags” (standards or elements)
- Condition-level findings cited if there are:
  - Pervasive deficient practices
  - Deficient practices that place patients at risk of harm

Examples of Condition-Level Findings

- Lack of knowledge of responsible staff
- Failure to accurately perform tests (e.g., using test strips are expired or which are not sufficiently sensitive)
- Unsafe practices in preparing, labeling or delivery of dialysate
- Failure to correct situations where monitoring finds out-of-range results (bacteria, endotoxin, chemical testing)
Examples of Standard-Level Findings

- Dialysate ports not labeled at point of use
- Time of start-up of the system not indicated to demonstrate system is operating at least 10-15 minutes before first test for total chlorine
- Casual access is allowed to the water treatment room (e.g., open, unattended loading door)
- Out-of-date Standards for calibration of meters used for conductivity or pH

Survey Data

- 1286 surveys completed* from October 1, 2009, to September 12, 2010
- Water and Dialysate Quality = Third most frequently cited Condition (64 X)
- 89 of 92 tags have been cited at least once
- “Top Ten” most frequently cited deficiencies DO NOT include any in the Condition for Water and Dialysate Quality…

*Completed = uploaded to National database
### “Top Ten” Deficiencies

<table>
<thead>
<tr>
<th>Tag</th>
<th>Description</th>
<th># X cited</th>
<th>% surveys</th>
</tr>
</thead>
<tbody>
<tr>
<td>V113</td>
<td>IC-Wear gloves/hand hygiene</td>
<td>349</td>
<td>27.1%</td>
</tr>
<tr>
<td>V122</td>
<td>IC-Clean, disinfect surfaces &amp; equipment</td>
<td>303</td>
<td>23.6%</td>
</tr>
<tr>
<td>V403</td>
<td>PE-Equipment maintenance-manufacturer’s DFU</td>
<td>272</td>
<td>21.2%</td>
</tr>
<tr>
<td>V715</td>
<td>MD Resp-Ensure all adhere to P&amp;P</td>
<td>235</td>
<td>18.3%</td>
</tr>
<tr>
<td>V541</td>
<td>POC-Goals-Community-based Standards</td>
<td>205</td>
<td>15.9%</td>
</tr>
</tbody>
</table>

Source: 1286 surveys, 10/1/09 – 9/12/10

---

### “Top Ten” Deficiencies

<table>
<thead>
<tr>
<th>Tag</th>
<th>Description</th>
<th># X cited</th>
<th>% surveys</th>
</tr>
</thead>
<tbody>
<tr>
<td>V401</td>
<td>PE-Safe, functional, comfortable environment</td>
<td>179</td>
<td>13.9%</td>
</tr>
<tr>
<td>V115</td>
<td>IC-Wear gowns, shields/masks, staff not eat/drink in treatment area</td>
<td>164</td>
<td>12.8%</td>
</tr>
<tr>
<td>V402</td>
<td>PE-Building-constructed/maintained to ensure safety</td>
<td>159</td>
<td>12.4%</td>
</tr>
<tr>
<td>V117</td>
<td>IC-Clean/dirty areas, med prep area, no common med carts</td>
<td>157</td>
<td>12.2%</td>
</tr>
<tr>
<td>V116</td>
<td>IC-Items taken to station disposed/dedicated or disinfected</td>
<td>153</td>
<td>11.9%</td>
</tr>
</tbody>
</table>

Source: 1286 surveys, 10/1/09 – 9/12/10
Water Treatment

Presenter
Jo-Ann B. Maltais, Ph.D.

Water Treatment

- Importance of Water Quality in Dialysate
  - Dialysate Mostly Water
  - Chemical Quality
  - Microbiological Quality
  - Risk to Patients
Importance of Water Quality

- **Volume Exposure**
  - Normal person—14 liters/week
  - Dialysis patient—360 liters/week

- **Toxic chemical contaminants**
  - Aluminum—bone disease, dementia
  - Chloramines—RBC damage—hemolysis, anemia
  - Nitrates—methemoglobinemia, cyanosis, hypotension
  - Sulfates—nausea, vomiting, metabolic acidosis

- **Bacterial & endotoxin contaminants**
  - Pyrogenic reactions directly related to number of bacteria in dialysate (Dawids & Vejlsgaard, 1976; Favero, 1974)
<table>
<thead>
<tr>
<th>Contaminant</th>
<th>Maximum Concentration (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contaminants with documented toxicity in hemodialysis</strong></td>
<td></td>
</tr>
<tr>
<td>Aluminum</td>
<td>0.01</td>
</tr>
<tr>
<td>Chloramines</td>
<td>0.1</td>
</tr>
<tr>
<td>Free chlorine</td>
<td>0.5</td>
</tr>
<tr>
<td>Copper</td>
<td>0.1</td>
</tr>
<tr>
<td>Fluoride</td>
<td>0.2</td>
</tr>
<tr>
<td>Lead</td>
<td>0.005</td>
</tr>
<tr>
<td>Nitrate (as N)</td>
<td>2</td>
</tr>
<tr>
<td>Sulfate</td>
<td>100</td>
</tr>
<tr>
<td>Zinc</td>
<td>0.1</td>
</tr>
<tr>
<td><strong>Contaminants normally included in dialysate</strong></td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>2 (0.1 mEq/L)</td>
</tr>
<tr>
<td>Magnesium</td>
<td>4 (0.3 mEq/L)</td>
</tr>
<tr>
<td>Potassium</td>
<td>8 (0.2 mEq/L)</td>
</tr>
<tr>
<td>Sodium</td>
<td>70 (3.0 mEq/L)</td>
</tr>
<tr>
<td><strong>Other contaminants</strong></td>
<td></td>
</tr>
<tr>
<td>Antimony</td>
<td>0.008</td>
</tr>
<tr>
<td>Arsenic</td>
<td>0.005</td>
</tr>
<tr>
<td>Barium</td>
<td>0.1</td>
</tr>
<tr>
<td>Beryllium</td>
<td>0.0004</td>
</tr>
<tr>
<td>Cadmium</td>
<td>0.001</td>
</tr>
<tr>
<td>Chromium</td>
<td>0.014</td>
</tr>
<tr>
<td>Mercury</td>
<td>0.0002</td>
</tr>
<tr>
<td>Selenium</td>
<td>0.09</td>
</tr>
<tr>
<td>Silver</td>
<td>0.005</td>
</tr>
<tr>
<td>Thallium</td>
<td>0.002</td>
</tr>
</tbody>
</table>

*The physician has the ultimate responsibility for ensuring the quality of water used for dialysis.*

*Unless otherwise noted.*
### Microbiological Limits

<table>
<thead>
<tr>
<th></th>
<th>Water</th>
<th>Standard Dialysate</th>
<th>Ultrapure Dialysate</th>
<th>Dialysate for Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacterial Limit</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Action Level</td>
<td>&lt;200 CFU/mL</td>
<td>&lt;200 CFU/mL</td>
<td>&lt;0.1 CFU/mL</td>
<td>&lt;1 CFU/1000 L</td>
</tr>
<tr>
<td></td>
<td>50 CFU/mL</td>
<td>50 CFU/mL</td>
<td>Not established</td>
<td>Not established</td>
</tr>
<tr>
<td><strong>Endotoxin Limit</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Action Level</td>
<td>&lt;2 EU/mL</td>
<td>&lt;2 EU/mL</td>
<td>&lt;0.03 EU/mL</td>
<td>&lt;0.03 EU/mL</td>
</tr>
<tr>
<td></td>
<td>1 EU/mL</td>
<td>1 EU/mL</td>
<td>Not established</td>
<td>Not established</td>
</tr>
</tbody>
</table>

### How to Achieve AAMI Quality Water

- Analysis of source water—Check at least annually
- Work with local water supplier
- Choose water treatment system company wisely
  - Supplying 510(k) systems
  - Following GMP/QS regulations
  - Experienced with dialysis water treatment requirements
  - System compatible with your choice of disinfectant
  - System easy to disinfect and monitor
  - Systems available can meet your capacity needs
  - Service provided

Monitor, trend & respond to data
Water Treatment System

Water System Flow Diagram
Location 2411
AAMI Requirements

• Up-to-date schematic with all components identified
• Labels on devices to match schematic
• ID tags on important valves, gauges, sample port locations
• Alarms in treatment area

Typical Water Treatment System Components

• Multi-media filter
• Carbon
• Water softener
• RO pre-filter
• Reverse Osmosis (RO) Membrane
• DI polish, backup or primary
• Endotoxin retentive filter
• Distribution loop +/- storage tank +/- UV
Choosing the Components

Multi-Media Filter
- First component
- Removes large particles
- Protects against clogging carbon bed & RO membrane
- Backwashable or cartridge type
- Monitor ΔP

Carbon Filters
- Remove chlorine & chloramines
  - Harmful to patients & RO
- Chloramine more difficult to remove
- Types
  - Backwashable
  - Exchange Tanks
- Pre or Post Softener?
- Typically 2 in series
- Test between beds for total chlorine
Softener

- Prevents RO fouling
- Removes Ca\(^{++}\) & Mg\(^{++}\)
- Replaced with Na\(^{++}\) & Cl\(^{-}\)
- Salt regeneration of resin
- Test for hardness at end of day
- Check \(\Delta P\)

RO Pre-filter

- Removes carbon fines
- Removes water softener resin particles
- Protects the RO membrane
- Monitor \(\Delta P\) daily
- Clean & disinfect housing periodically
Reverse Osmosis

- Heart of water treatment system
- Needed to achieve AAMI quality water
- Pressure pushes water molecules thru
- Concentrates impurities in reject water
- Daily monitoring
  - Conductivity
  - Inlet psi
  - Flow rates (product & reject)
  - $\Delta P$ across RO membrane
  - Monthly bacteria & endotoxin monitoring
  - Monthly disinfection
  - Quarterly cleaning
  - Annual AAMI chemical analysis

Endotoxin Retentive Filter

- Removes particles down to 1000 Daltons in size
  - Bacteria
  - Endotoxin
- Locations
  - In water distribution system
  - Post DI
Distribution Loop

- Greatest source for recontamination of treated water
- Design to minimize bacterial growth, biofilm and endotoxin production
- No dead legs
- Continuous recirculation
- 3-7 ft/sec velocity
- Disinfect at least monthly

Protecting Your Water Treatment System

- Identify critical components of water treatment system
- Provide redundancy
  OR
- Develop contingency plan in case of failure
  • For example, a redundant circulation pump
Table 4—Monitoring guidelines for water purification equipment and distribution systems and dialysate

<table>
<thead>
<tr>
<th>Item to monitor</th>
<th>What to monitor</th>
<th>Special interval</th>
<th>Normal interval</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sediment filter</td>
<td>Pressure drop across the filter</td>
<td>NA</td>
<td>Daily</td>
<td>Pressure drop less than XXX</td>
</tr>
<tr>
<td>Sediment filter backwashing cycle</td>
<td>Backwash cycle timer setting</td>
<td>NA</td>
<td>Daily—beginning of the day</td>
<td>Backwash clock set to XX:XX</td>
</tr>
<tr>
<td>Cartridge filter</td>
<td>Pressure drop across the filter</td>
<td>NA</td>
<td>Daily</td>
<td>Pressure drop less than XXX</td>
</tr>
<tr>
<td>Water softener</td>
<td>Product water softness</td>
<td>NA</td>
<td>Daily—end of the day</td>
<td>Hardness as calcium carbonate less than 1 grain/gal, unless otherwise specified by the manufacturer of the reverse osmosis equipment</td>
</tr>
<tr>
<td>Water softener brine tank</td>
<td>Level of undissolved salt in tank</td>
<td>NA</td>
<td>Daily—end of the day</td>
<td>Salt level at XXX</td>
</tr>
<tr>
<td>Water softener regeneration cycle</td>
<td>Regeneration cycle timer setting</td>
<td>NA</td>
<td>Daily—beginning of the day</td>
<td>Softener timer set to XX:XX</td>
</tr>
<tr>
<td>Carbon adsorption beds</td>
<td>Product water free chlorine and/or total chlorine between the beds</td>
<td>NA</td>
<td>Prior to beginning each patient shift</td>
<td>≤ 0.1 mg/l. of total chlorine</td>
</tr>
<tr>
<td>Chemical injection system</td>
<td>Level of chemical in the reservoir, injector function, value of the controlling parameter (e.g., pH)</td>
<td>NA</td>
<td>Daily</td>
<td>Chemical level in reservoir ≥ XXX; controlling parameter in range XX-XX</td>
</tr>
<tr>
<td>Reverse osmosis</td>
<td>Product water conductivity, total dissolved solids (TDS), or resistivity and calculated rejection</td>
<td>NA</td>
<td>According to the manufacturer's recommendations (continuous monitors)</td>
<td>Rejection ≥ XX%</td>
</tr>
</tbody>
</table>

NOTE—Refer to footnote for an explanation of the use of X’s in the Specification column.

Monitoring Guidelines - Table 4

- Guidelines for Monitoring
  - Water purification equipment
  - Distribution system
  - Dialysate
- Column Headings:
  - Item to monitor
  - What to monitor
  - Interval
  - Special
  - Normal
  - Specification
- Logs demonstrate practice
Ambiguous Areas of AAMI RD52 Clarification Needed

- Maximum allowable chloramine level
  - ≤ 0.1ppm
- Continuous flow water distribution loops to prevent biofilm formation
  - Recommended in current AAMI RD52
    3 ft/sec distal portion of direct feed system
    1.5 ft/sec distal portion of indirect feed system
  - Challenged by current published studies
    5-17 ft/sec inadequate in preventing attachment of bacteria to piping walls

Water Treatment & Distribution CMS

Presenter
Glenda Payne, RN, MS, CNN
Survey of Water & Dialysate

- Observations and inspection of the water treatment and dialysate preparation and delivery systems
- Observation of practice (testing, mixing, etc.)
- Interview of responsible staff members
- Review of logs
- Review of laboratory reports
- Review of QAPI related to water & dialysate

Water Treatment: CMS Focus

- Knowledge of the operator: the person doing the work, day to day
- Components selected based on source water
- Up-to-date schematic of components, including valve “legend”
- All components labeled, including direction of flow
- Up-to-date, legible logs
- Evidence of thoughtful monitoring of the system
Most Common Citations in Water Treatment

- V196: issues with testing for chlorine and/or chloramine (#17, 134 times, 10.4%)
- V187: schematic diagrams/labels (#33, 88 times, 6.8%)
- V191: Softeners/testing hardness/log (#65, 58 times, 4.5%)
- V190: Softeners: timers/salt/salt level (#79, 49 times, 3.8%)

Dialysate & Concentrates

Presenter
Jo-Ann B. Maltais, Ph.D.
Dialysate

- Types of Dialysate
  - Bicarbonate based (Standard)
  - Lactate based (NxStage)
  - Acetate (No longer used)
- Levels of Quality
  - Conventional/standard dialysate
  - Ultrapure dialysate
  - Dialysate for infusion/substitution fluid

AAMI RD52 Dialysate Definitions

- Dialysate
  Aqueous fluid with electrolytes and dextrose
  Exchanges solutes with blood during hemodialysis
- Ultrapure Dialysate
  Highly purified
  Can be used in place of conventional dialysate
  Can be further processed for injection directly into blood
- Dialysate for Infusion
  Used in convective therapies
  Produced by sequential ultrafiltration
Dialysate Bacterial & Endotoxin Limits/Action Levels

<table>
<thead>
<tr>
<th></th>
<th>Standard Dialysate</th>
<th>Ultrapure Dialysate</th>
<th>Dialysate for Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacterial Limit</strong></td>
<td>&lt;200CFU/mL</td>
<td>&lt;0.1CFU/mL</td>
<td>&lt;1CFU/1000 L</td>
</tr>
<tr>
<td><strong>Action Level</strong></td>
<td>50 CFU/mL</td>
<td>Not established</td>
<td>Not established</td>
</tr>
<tr>
<td><strong>Endotoxin Limit</strong></td>
<td>&lt;2 EU/mL</td>
<td>&lt;0.03 EU/mL</td>
<td>&lt;0.03 EU/mL</td>
</tr>
<tr>
<td><strong>Action Level</strong></td>
<td>1 EU/mL</td>
<td>Not established</td>
<td>Not established</td>
</tr>
</tbody>
</table>

Dialysate Preparation

Prepared from two concentrates plus water:

- **Bicarbonate Concentrate** (Sodium bicarbonate +/- Sodium chloride)
  
  Mixed from powder
  
  Powder cartridges
  
  Gallon containers (liquid)

- **Acid Concentrate** (Ions, acetic acid, +/- glucose)
  
  Mixed from powder
  
  55 gallon drums or 1 gallon containers

- Proportioned by the hemodialysis machine
  
  Based on patient prescription
Concentrates

• Manufacturer’s Responsibilities
  • Concentrates supplied meet labeling claims/content requirements
    55 gallon drums and 1 gallon containers

Concentrates

• User Responsibilities
  • Acid concentrate
    Pumped into bulk storage: Maintain in original state
    Prepared onsite from powder & water
    Procedures/systems to prevent mixing of formulas: Correct formula, used according to patient prescription
    Storage tanks, connections secure & labeled
Concentrate Mixing Systems

• Concentrate from powder
  • Manufacturer’s system
    Monitor as per manufacturer’s instructions
  • Dialysis clinic designed system
    • Procedures for proper mixing
    • Establish acceptable concentration limits
    • Test each batch—conductivity or hydrometer
      • DO NOT USE pH
      • Record data, sign—dedicated log
    • Verification by independent laboratory
      • Batches prepared over 3-day period

Additives

• Follow mixing procedures from additive manufacturer
• Meet same concentrate proportioning ratio requirements
• Container Labeling
  • Patient’s name
  • Final concentration of added electrolyte
  • Date made
  • Name of person who mixed the additive
Dialysate Proportioning

- Monitored as per manufacturer’s instructions
- Maintain record of critical parameters
  - Conductivity
  - Approximate pH

Concentrate Ratios & Labeling

Table 3—Symbols and color coding for different concentrate proportioning ratios

<table>
<thead>
<tr>
<th>Concentrate type</th>
<th>Acid proportioning ratio (Red color coding)</th>
<th>Geometric symbol</th>
<th>Bicarbonate concentrate (Blue color coding)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>35X</td>
<td>1:34</td>
<td>Square</td>
<td>Dry, liquid, or cartridge</td>
<td></td>
</tr>
<tr>
<td>36.83X</td>
<td>1:35.83</td>
<td>Circle</td>
<td>Dry or liquid</td>
<td></td>
</tr>
<tr>
<td>45X</td>
<td>1:44</td>
<td>Triangle</td>
<td>Dry, liquid, or cartridge</td>
<td></td>
</tr>
<tr>
<td>36.1X</td>
<td>1:35.1</td>
<td>Hexagon</td>
<td>Cartridge</td>
<td>Powder cartridges may be used for other proportioning ratios, except for 36.83X, in which the bicarbonate concentrate also contains NaCl.</td>
</tr>
</tbody>
</table>

NOTE 1—The acid proportioning ratio refers to acid concentrate:water + bicarbonate concentrate.

NOTE 2—Acetate-containing concentrate is color-coded white.
Dialysate Monitoring

- pH—6.9-7.6
- Conductivity— +/-5% nominal machine value
- Frequency—Before each treatment

Effect of Biofilm Presence on Dialysate Quality

- Biofilm is a source of contaminants that can be transferred to patients during dialysis thru dialysate
  - Bacteria
  - Debris:

<table>
<thead>
<tr>
<th>Endotoxin</th>
<th>Exotoxin</th>
<th>Peptidoglycan</th>
</tr>
</thead>
<tbody>
<tr>
<td>LPS, Lipid A</td>
<td>DNA &amp; RNA fragments</td>
<td>Carbohydrate slime layer</td>
</tr>
<tr>
<td>Matrix Proteins</td>
<td>Cytokine inducing substances</td>
<td>Low molecular weight by-products of bacterial metabolism</td>
</tr>
</tbody>
</table>

- Most undetectable with current testing methods
Dialysate & Concentrates

CMS

Presenter
Glenda Payne, RN, MS, CNN

Dialysate: CMS Focus

• Knowledge of the operator: the person doing the work, day to day
• Safe practices: mixing concentrates, labeling, delivery systems
• Follow manufacturer’s DFU
• Having correct range of Standards, in date
• Safe practices at chair side
Most Common Citations in Dialysate

V250 Dialysate proportioning-monitor pH/conductivity (#18, 125 times, 9.7%)
- Can be chair side issue
- Really important to understand the purpose of the test and the acceptable variability
- Can be Standard in use issue

Most Common Citations in Dialysate

• V228: Mixing systems—labeling (#78, 49 times, 3.8%)
• V233: Bicarb mixing systems—storage/use time limits/minimize combining (21 times, 1.6%)
• V236: Additives—labeling spiked jugs/labeling if for specific patient (16 times, 1.2%)
• V243: Bicarb jugs rinsed daily/stored dry (tie)
Strategies for Bacterial & Endotoxin Control

Presenter
Jo-Ann B. Maltais, Ph.D.

- Proper water treatment system design
- Proper operation of systems & equipment
- No oversized piping
- Routine disinfection
  - Water treatment & distribution systems
  - Storage tank
  - Hemodialysis machines
  - Line between distribution system & dialysis machine
- Routine monitoring and trending
Biofilm: In Standard Dialysis & Ultrapure Water

**Standard Dialysis Quality Water**

**Ultrapure Water**

**Purpose of Monitoring**

Demonstrate effectiveness of disinfection program

Not When to Disinfect
Monitoring Schedule
Bacteria & Endotoxin

- Water Treatment System – Monthly
- (Weekly for New Systems Until Pattern Established)
  - Sample Sites
  - Post RO
  - First & last outlet of distribution system
  - Feed to reprocessing station
  - Feed to bicarbonate concentrate mixing system
  - Outlet of storage tank
  - Outlet of Ultrafilters
- Dialysate—Monthly
  At least 2 machines per month
  Every machine sampled at least once/year

Bicarbonate Concentrate Distribution System Monitoring

- Daily check for correct connection to concentrate delivery line
- Monthly monitoring for bacteria & endotoxin
- New systems
  - Monitor dialysate weekly until consistent compliance demonstrated, then reduce frequency
Acid Concentrate Distribution System

- Acid concentrate does not support bacterial growth
- No requirement for bacterial or endotoxin testing

IMPORTANT

SAMPLE BEFORE DISINFECTION
NOT AFTER
Where to Sample

- Sampling ports
  - Installed pre & post water treatment system components
  - In dialysate line of hemodialysis machines

How to Sample Correctly

- Disinfect port with alcohol
- Let dry completely
- Do not use other disinfectants
- Flush for 1-2 minutes or withdraw fluid with 30cc syringe & discard
- Take sample with new syringe
- Collect or transfer into sterile, endotoxin-free, leak-proof container
- Label with location, date, time, initials
Sample Handling

- To prevent secondary contamination
  - Cover skin as much as possible
  - Wear gloves while collecting samples
    - Change gloves or alcohol wipe if gloves become soiled, contaminated with sample or wet
  - Prepare sample collection supplies
    - Open only while wearing gloves
  - Do not handle extraneous materials while sampling

Sample Storage & Transport

- Refrigerate samples not analyzed within 4 hrs of collection
- Ship on ice packs
- Lab analysis within 24 hours of collection
Response to Data

- Bacteria and/or Endotoxin results >action level
  
  OR

- Trending indicates problems developing
  - Notify medical director
  - Re-disinfect
  - Repeat sampling (bacteria & endotoxin)
  - Weekly sampling thereafter
    - Until acceptable results achieved
Decision Tree
Evaluate Culture Results & Start Corrective Action

1. Review dialysate culture results
   - Results ≤ 50 CFU/mL
     - Yes: Repeat this site in next regular monthly sample collection
     - No: Results < 50 CFU/mL
2. Results 50–100 CFU/mL
   - Notify Facility Manager & Biomedical Technician
   - Review culture & disinfection logs
   - Disinfect equipment or water system if necessary
   - Redraw sample
3. Results > 200 CFU/mL
   - Notify Medical Director, Facility Manager & Biomedical Technician
   - Review culture & disinfection logs
   - Disinfect equipment or water system if necessary
   - Redraw sample
4. Results > 500 CFU/mL
   - Notify Medical Director, Facility Manager & Biomedical Manager
   - Initiate troubleshooting protocol
   - Evaluate/correct sample collection technique
   - Evaluate/correct bicarbonate preparation/distribution technique
   - Evaluate/correct water system components
   - Evaluate/modify equipment salvage
   - Evaluate/Implement biofilm removal protocols
   - Redraw sample

Figure 1—Example of decision tree that can be used to evaluate culture results and initiate corrective action, if necessary
Disinfection

Water System Disinfection

• What should be disinfected?
  • Water Treatment & Distribution Systems
  • Hemodialysis machines
  • Line between water distribution system & dialysis machines
  • Water storage tank

• When?
  • Based on bacterial & endotoxin test results (>action level)
  • At least monthly
  • After maintenance or replacement of components
  • Indications of biofilm
Bicarbonate Concentrate Disinfection

- What should be disinfected?
  - Bicarb jugs
  - Concentrate Mixing Systems
  - Piped bicarbonate concentrate distribution systems

Bicarbonate Concentrate Disinfection

- When to disinfect?
  - Bicarb jugs—**Weekly**
  - Concentrate mixing & distribution systems
    - **Weekly** or as per manufacturer's instructions
    - Facility-designed system—cleaned & disinfected by validated procedure
    - Routinely meets AAMI RD52: 2004, Section 4.3.2.1
  - Record data per disinfection cycle in dedicated log
Factors to Consider in Choosing a Disinfectant

- Materials compatibility (Table 2)
- Hazards
- Training
- Design of system
- Problem to solve or routine disinfection
- Effectiveness
- Frequency
- Cost

Disinfectants

- Bleach
- Peracetic Acid
- Formaldehyde
- Glutaraldehyde
- Heat
- Ozone
Bacteria & Endotoxin Control

CMS

Presenter
Glenda Payne, RN, MS, CNN

Microbiological Control: CMS
Focus

• Knowledge of the persons responsible for maintaining and monitoring the system
• Ensuring a safe system is maintained
• Oversight of the system by the medical director
• Reports of monitoring reviewed in QAPI
### Most Common Citations in Microbiological Control

- **V213** Distribution system: culture/LAL/sample sites/frequency (new)/log (#74, 50 times, 3.9%)
- **V180** Bacteriology of conventional dialysate—max and action levels (38 times, 3%)
- **V178** Bacteriology of water: max/action levels (36 times, 2.8%)

---

<table>
<thead>
<tr>
<th>Number</th>
<th>Citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>V219</td>
<td>Bacterial control—disinfect monthly/disinfection dwell (33 times, 2.6%)</td>
</tr>
<tr>
<td>V254</td>
<td>Microbial monitoring—sample before disinfect (28 times, 2.2%)</td>
</tr>
</tbody>
</table>
Why Do These Deficient Practices Occur?

Lack of knowledge
- Of the regulations
- Of facility policy & procedure
- Of the reasons for the requirement

Why Do These Deficient Practices Occur?

- Lack of training
- Lack of understanding of the impact each person’s performance has on outcomes
- Failure to recognize limits of practice
- Not enough staff
- Lack of oversight
Objective: Develop Strategies to Avoid Citations

“You can’t use knowledge you don’t have”

Orientation and on-going education are CRITICAL

Be Sure All Understand the “WHY”

- Understanding “why” promotes consistent practice
- Understanding “why” decreases the likelihood of staff taking shortcuts or altering practice
- Understanding “why” empowers staff to do the right thing
Training of Staff

- Each staff member responsible for any task related to water or dialysate must have training and demonstrate competency for the task(s) assigned
- Level of knowledge should = the sort of tasks assigned
- V260 REQUIRES audits of practice

Staff Training Requirements

- V260 Personnel—training program/periodic audits (#45, 71 times, 5.5%)
- V696 Water treatment system techs training (25 times, 1.9%)

Staff who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and governing body.
Quality Assessment Performance Improvement (QAPI)
CMS

Presenter
Glenda Payne, RN, MS, CNN

- Technical staff participation is expected
- Reports should include water and dialysate culture reports, chemical analysis, any deviations from parameters on daily monitoring logs, any repairs
- Adverse event reporting: comply with FDA requirements for any death, illness or serious injury related to water or dialysate systems
Patient Outcomes Potentially Related to Water or Dialysate

- Pyrogenic reactions
- Bacterial infections
- Allergic reactions
- Bone disease
- Anemia
- Hemolysis
- Hypertension
- Hypotension
- Metabolic acidosis
- Muscle weakness
- Nausea
- Vomiting
- Neurological deterioration and encephalopathy

How to Avoid Patient Harm

- Take responsibility for these areas seriously
- Be sure the medical director is involved in decision making
- Educate, educate, educate
- Audit, audit, audit
- Pay close attention to any high-risk areas
High-Risk Area: Water Treatment

Ask yourself:
• Who is responsible?
• Are they competent?
• Who is responsible on Saturday or holidays?

Reduce your risk:
• Walk through the start-up procedures
• “Show me the testing”
• Spot check routinely
• Include log review in QAPI

High-Risk Area: Testing for Chlorine/Chloramine

Ask yourself:
• What test are you using?
• Is it sensitive enough?
• Where are samples taken?
• When are samples taken?
• Who does the testing?
• Does anyone verify the testing?

Reduce your risk: Routinely audit testing
High-Risk Area: “Manufacturing”
Dialysate: Bicarbonate or Acid

What are your policies and practices related to:

> Mixing > Storing
> Cultures > Testing
> Cleaning > Disinfecting

Reduce your risk:
- Carefully review logs
- Routinely audit practice

6 Rights for Mixing Concentrates

1. Right mixing ratio: machine, bicarb, acid, additives “match”
2. Right PPE
3. Right directions (DFU)
4. Right amount of water, added as directed
5. Right mixing time
6. Right data recorded
QAPI: Make It Work for You

Reduce your risks:
- Know what's happening in the back room
- Include water treatment and dialysate in routine monitoring
- Don’t just include the logs: review them!
- Expect problems to be reported: don’t punish reporting—work together to correct the underlying causes

Experience Less Anxiety When the State Walks In

- Include survey expectations in orientation and annual updates for all employees
- Never make anything up
- If you are unsure of an answer, ask to get more information before responding
- It’s okay to read the labels on components!
- Be sure all information requested is provided
Surviving a Survey: Experience
Less Anxiety

- Never make anything up
- Immediately correct any deficient practices as they are identified; might still be cited, but at less severity
- Follow the Golden Rule with surveyors too.

Another source for answers to questions:
esrdsurvey@cms.hhs.gov

Where Are We Headed?
AAMI

Presenter
Jo-Ann B. Maltais, Ph.D.
Where are We Headed?

AAMI

• Harmonization with ISO 23500
  • Lower limits for Bacteria and Endotoxin
    <100 CFU/mL; Action level 50 CFU/mL
    <0.25 EU/mL; Action level 0.125 EU/mL
  • Ultrapure Dialysate
    <0.1 CFU/mL
    <0.03 EU/mL
• Timeframe for Adoption by ANSI/AAMI

Where Are We Headed?

CMS

Presenter
Glenda Payne, RN, MS, CNN

ANSI/AAMI RD52:2004 - Dialysate for Hemodialysis
Where Are We Headed?

CMS

- Continue to educate surveyors to better understand the water and dialysate requirements
- Continue to survey most facilities every 3-4 years
- Consider an update to this portion of the regulation in the not-too-distant future!

Questions?

To submit a question anytime during today’s event, please type your question in the “Chat (Q&A)” box on the left side of your screen and press Enter.
Presenters

Jo-Ann B. Maltais, Ph.D.
Glenda M. Payne, MS, RN, CNN

j.maltais@comcast.net
glenda.payne@cms.hhs.gov

Closing Reminders

Visit the AAMI Webinar Home Page to learn about future webinar events. Upcoming programs include:

- Physical aspects of ethylene oxide sterilization - AAMI TIR15:2009
- Labeling and Labeling Controls
- Ethylene Oxide Residuals