Role and Evolution of AAMI/ANSI Standards for Dialysis Fluids
What is AAMI?

The Association for the Advancement of Medical Instrumentation

- Nonprofit organization founded in 1967
- Diverse community of nearly 7,000 healthcare technology professionals
- Supports development, management, and use of safe and effective medical technology.
What is AAMI?

AAMI is the primary resource for industry, the professions, and government for national and international standards.

• Standards program consists of over 100 technical committees and working groups

What is ANSI?

American National Standards Institute

- Coordinates U.S. voluntary consensus standards
- Serves as a watchdog for standards development
- Accredits qualified organizations to develop standards
  - Does not itself develop standards
Standard vs. Recommended Practice

- STANDARD--recommendations to the manufacturer. May also be helpful to purchaser or user for understanding safe/effective device use in clinical environment.

- RECOMMENDED PRACTICE—guidelines mainly directed to the healthcare professional, for safe, effective use, care and/or processing of a medical device.
Adoption

• AAMI Recommended Practice accepted by ANSI = “Standard” Recommended Practice.

• ANSI/AAMI Standards and AAMI Recommended Practice documents are meant to be “Voluntary”.

• Often adopted by government agencies or procurement authorities as “Regulation”--enforceable requirements.
Technical Information Report (TIR)

- Addresses particular aspect of medical technology
- Not subject to same formal approval process as a standard
- Produced and approved for distribution by RDD Committee and AAMI
- Permits the inclusion of differing viewpoints on technical issues
Hemodialysis Fluids: Why Do We Need Standards?

- Patients are at risk of injury from contaminants in water and in final dialysate
  - E.g. aluminum, chloramines, fluoride, microbial contaminants
- Contaminants associated with morbidities
  - E.g. anemia, bone disease, dialysis dementia, clinical complications such as pyrogenic reactions, septicemia, and inflammatory state associated with loss of kidney function
Hemodialysis Fluids: A Need For Standards

- Acknowledgement of patient risks associated with dialysis fluids led to development of standards
- ANSI/AAMI RD5 Hemodialysis Systems
  - First dialysis standard
  - Published in United States in 1981
  - Intended for dialysis equipment manufacturers. Included dialysis machines, water treatment systems, concentrate, etc.
Development and Progression of AAMI Dialysis Standards

- RD5 was revised to divide it into three parts (separate standards)
  - RD61 addressed hemodialysis concentrates (2000)
  - RD62 addressed water and water treatment equipment for hemodialysis (2001)
  - RD5 was changed to address only hemodialysis equipment (2003)
American National Standard

Water treatment equipment for hemodialysis applications

ANSI/AAMI RD62:2001

American National Standard

Hemodialysis systems

ANSI/AAMI RD5:2003
Development and Progression of AAMI Dialysis Standards

- In addition, RD47 – a separate standard for Reuse of Hemodialyzers - was updated (2002)

- AAMI RDD committee began work on a standard (RD52) to address dialysate for hemodialysis
  - Patients are treated with dialysate. Quality standard for water alone...not enough to fully protect patient.
  - Released in 2004
American National Standard

ANSI/AAMI RD47:2002

Reuse of hemodialyzers

American National Standard

ANSI/AAMI RD52:2004

Dialysate for hemodialysis

AAMI Association for the Advancement of Medical Instrumentation
Application of AAMI Dialysis Standards

- Intended by AAMI to be voluntary
- Increase safety & effectiveness of technology
- Support/encourage new technology development
- Provide manufacturers with basic safety and performance criteria
- Provide end users with guidelines for safe & effective device use
CMS Adoption of AAMI Dialysis Standards

• Outpatient hemodialysis regulated by CMS

• In 2008 CMS integrated AAMI Standards within dialysis regulations (Conditions for Coverage)
  - Incorporated selected parts of these standards within CMS “Interpretive Guidance” (IG) ESRD surveyor training document (Oct. 2008)
The Joint Commission (TJC)

• Does not regulate inpatient dialysis in same way outpatient dialysis is regulated by CMS

• Expects accredited organizations to follow applicable industry guidelines such as those provided through AAMI Standards and Recommended Practices.
New ISO Harmonized AAMI Dialysis Standards

- AAMI dialysis standards and International Organization for Standardization (ISO) dialysis fluid standards reviewed in 2009-2010.
- After this major review and significant input to ISO, AAMI adopted a set of five dialysis fluid standards developed by ISO.
- ISO standards now serve as replacements for the previous AAMI standards.
<table>
<thead>
<tr>
<th>Subject Matter</th>
<th>Prior Standard</th>
<th>New Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production of concentrates used to make up dialysate</td>
<td>ANSI/AAMI RD61, Concentrates for Hemodialysis</td>
<td>ANSI/AAMI/ISO 13958:2009 Concentrates for Hemodialysis and Related Therapies</td>
</tr>
<tr>
<td>Subject Matter</td>
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<td>New Standard</td>
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<td>--------------------------------------------------</td>
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**Table 2**
<table>
<thead>
<tr>
<th>Subject Matter</th>
<th>Prior Standard</th>
<th>New Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysis equipment requirements for manufacturers. Also helpful to users for</td>
<td>ANSI/AAMI RD5 Hemodialysis Systems</td>
<td>ANSI/AAMI/IEC 60601-2-16:2008 Medical Electrical Equipment, Part 2-16</td>
</tr>
<tr>
<td>evaluating equipment</td>
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How Do New AAMI/ISO Dialysis Standards Differ From Prior Versions?

• Most of what is in new standards is the same or similar to what is in prior AAMI standards.

• Important differences
  – Free chlorine, chloramines combined into single contaminant (total chlorine)
  – Microbiological quality of fluids
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<tr>
<th>Subject Matter</th>
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<th>New Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum allowable level of <strong>bacteria in dialysis water</strong></td>
<td>ANSI/AAMI RD62 &lt;200 CFU/mL</td>
<td>ANSI/AAMI/ISO 13959:2009 &lt;100 CFU/mL</td>
</tr>
<tr>
<td>Maximum allowable level of <strong>endotoxin in dialysis water</strong></td>
<td>&lt;2 EU/mL</td>
<td>&lt;0.25 EU/mL</td>
</tr>
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</table>

*Table 4*
<table>
<thead>
<tr>
<th>Subject Matter</th>
<th>Prior Standard</th>
<th>New Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum allowable level of <strong>bacteria in dialysate</strong></td>
<td><strong>ANSI/AAMI RD52:2004</strong>&lt;200 CFU/mL Addresses “standard” dialysate only</td>
<td><strong>ANSI/AAMI/ISO 11663:2009</strong>&lt;100 CFU/mL Standard &lt;0.1 CFU/mL Ultrapure Sterile – Substitution Fluid</td>
</tr>
<tr>
<td>Maximum allowable level of <strong>endotoxin in dialysate</strong></td>
<td><strong>&lt;2 EU/mL</strong></td>
<td><strong>&lt;0.5 EU/mL Standard</strong>&lt;0.03 EU/mL Ultrapure Non-pyrogenic – Substitution Fluid</td>
</tr>
<tr>
<td>Subject Matter</td>
<td>Prior Standard</td>
<td>New Standard</td>
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<td>--------------------------------</td>
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</tr>
<tr>
<td>Medium</td>
<td>Trypticase soy agar</td>
<td>Tryptone glucose extract agar or Reasoner’s 2A agar</td>
</tr>
<tr>
<td>Incubation temperature (°C)</td>
<td>35</td>
<td>17 - 23</td>
</tr>
<tr>
<td>Incubation time (h)</td>
<td>48</td>
<td>168 (7 days)</td>
</tr>
</tbody>
</table>

*Table 6*
Does CMS Require Compliance with New AAMI/ISO Dialysis Standards?

- Dialysis clinical & technical managers have been asking this question from the day the new standards were released.

- CMS will continue to enforce existing IG requirements for the foreseeable future.
When Will CMS Require Compliance with New AAMI/ISO Standards?

• Quality Assurance Efficiency & Effectiveness Initiative is current focus for CMS

• From this date (Q1/2013) forward, it’s likely to be at least a year; perhaps 2 or more years

• CMS does not discourage compliance with more stringent newer standards
CMS Quality Assurance Efficiency and Effectiveness Initiative

• New “ESRD Core Survey” is initiative #1
  – Utilizes survey resources most efficiently by focusing on elements of dialysis care and technical operations that most impact patient safety and quality care.
  – Developed, piloted, and refined in 2012
    • included consultation with AAMI RDD Committee
  – Being rolled out nationally during 2013
Increased focus on ESRD survey findings which link to mortality, hospitalization, and infections evidenced by available and prospective data.

Goal is to improve patient outcomes and efficiency of survey process

1. Develop more focused core survey process
2. Surveyor education
3. Implementation of a change management strategy

New CMS ESRD Core Survey
AAMI RDD Committee Action Items in process as of February 2013

• Development of US position to revise five ISO dialysis fluid standards to bring into harmony regarding requirements and terminology

• Technical Information Reports (TIR)
  — Water testing methodologies
  — Electrolytes in concentrates
  — Sorbent based systems
  — Risk management

• Discussion on potential change to maximum allowable residual level - ozone in dialysis water
Summary

• AAMI produces voluntary Standards, Recommended Practices, and TIRs for medical devices

• Prior versions of AAMI standards for dialysis fluids adopted by CMS as regulatory requirements

• Current AAMI standards for dialysis fluids are harmonized with ISO standards

• New standards compliance not yet required by CMS

• AAMI continues unending work of updating existing standards, while developing new standards & TIRs
AAMI Webinars on CD

ANSI/AAMI/ISO 11663 & 23500, Quality Requirements and Monitoring of Water Treatment and Dialysis Fluid for Hemodialysis and Related Therapies

The website address is:

http://www.aami.org/meetings/webinars/webinar.cds/051512_hemodialysis_water.html
"AAMI Dialysis Water and Dialysate Recommendations: A User Guide"

- Intended to help users understand similarities & differences in RD52 - currently in use by CMS - vs. AAMI ISO documents adopted as replacements.
- Will provide a crosswalk from familiar requirements to the new guidance.
- Will define changes in practice necessary to meet the new guidance.
- Projected release date is in first half of 2013
Thank you for attending this session!

To download this and other educational presentations visit the technical support section of the RPC website.

The website address is:

www.rpc-rabrenco.com