



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
- Produce Standards, Recommended Practices, and Technical Information Reports for medical devices.



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**

ANSI/AAMI RD62:2001

**Water treatment equipment for
hemodialysis applications**

AAMI
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of Medical Instrumentation

**American
National
Standard**

ANSI/AAMI RD5:2003

Hemodialysis systems

AAMI Association for the
Advancement of Medical
Instrumentation



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
& RD47:2002/A1:2003

Reuse of hemodialyzers

AAMI Association for the
Advancement of Medical
Instrumentation

**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)
 - Entire RD52:2004, RD47:2002. Sections RD62:2001
 - Incorporated selected parts of these standards within CMS “Interpretive Guidance” (IG) ESRD surveyor training document (Oct. 2008)

www.cms.gov/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf

The screenshot shows a Windows Internet Explorer browser window. The address bar contains the URL: <http://www.cms.gov/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf>. The browser's menu bar includes File, Edit, Go To, Favorites, and Help. The toolbar contains various icons for search, share, and navigation. The main content area displays the title page of a document. At the top center is the ESRD logo, which consists of two stylized kidneys in green and blue, with the letters 'ESRD' in bold black text to the right. Below the logo, the title 'ESRD Basic Technical Surveyor Training Interpretive Guidance' is written in large, bold, blue and green text. Underneath the title, it says 'Interim Final Version 1.1' and 'October 3, 2008'. The browser's status bar at the bottom shows 'Done', 'Unknown Zone', and the system clock '10:25 AM'.

ESRD

**ESRD Basic
Technical Surveyor Training
Interpretive Guidance**

**Interim Final Version 1.1
October 3, 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.

Subject Matter	Prior Standard	New Standard
Water quality	ANSI/AAMI RD62 Water Treatment Equipment for Hemodialysis Applications (quality part)	ANSI/AAMI/ISO 13959:2009 Water for Hemodialysis and Related Therapies
Water treatment equipment	ANSI/AAMI RD62 Water Treatment Equipment for Hemodialysis Applications (equip. part)	ANSI/AAMI/ISO 26722:2009 Water Treatment Equipment for Hemodialysis and Related Therapies
Production of concentrates used to make up dialysate	ANSI/AAMI RD61, Concentrates for Hemodialysis	ANSI/AAMI/ISO 13958:2009 Concentrates for Hemodialysis and Related Therapies

Table 1

Subject Matter	Prior Standard	New Standard
Dialysate preparation and quality	ANSI/AAMI RD52 Dialysate for Hemodialysis (quality part)	ANSI/AAMI/ISO 11663:2009 Quality of Dialysis Fluid for Hemodialysis and Related Therapies
User guidance on how to comply with fluid quality standards	ANSI/AAMI RD52, Dialysate for Hemodialysis (guidance part)	ANSI/AAMI/ISO 23500:2011 Guidance for the Preparation and Quality Management of Fluids for Hemodialysis and Related Therapies

Table 2

Subject Matter	Prior Standard	New Standard
Dialysis equipment requirements for manufacturers. Also helpful to users for evaluating equipment	ANSI/AAMI RD5 Hemodialysis Systems	ANSI/AAMI/IEC 60601-2-16:2008 Medical Electrical Equipment, Part 2-16
User guidance and recommendations for an optimal dialyzer reuse program	ANSI/AAMI RD47, Reuse of Hemodialyzers	No ISO version. Latest version is AAMI/ANSI RD47:2008.

Table 3



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



Subject Matter	Prior Standard	New Standard
Maximum allowable level of bacteria in dialysis water	ANSI/AAMI RD62 <200 CFU/mL	ANSI/AAMI/ISO 13959:2009 <100 CFU/mL
Maximum allowable level of endotoxin in dialysis water	<2 EU/mL	<0.25 EU/mL

Table 4

Subject Matter	Prior Standard	New Standard
Maximum allowable level of bacteria in dialysate	ANSI/AAMI RD52:2004 <200 CFU/mL Addresses “standard” dialysate only	ANSI/AAMI/ISO 11663:2009 <100 CFU/mL Standard <0.1 CFU/mL Ultrapure Sterile – Substitution Fluid
Maximum allowable level of endotoxin in dialysate	<2 EU/mL	<0.5 EU/mL Standard <0.03 EU/mL Ultrapure Non-pyrogenic – Substitution Fluid

Table 5

Subject Matter	Prior Standard	New Standard
Bacteria culture conditions	ANSI/AAMI RD52:2004	ANSI/AAMI/ISO 11663:2009
Medium	Trypticase soy agar	Tryptone glucose extract agar or Reasoner's 2A agar
Incubation temperature (°C)	35	17 - 23
Incubation time (h)	48	168 (7 days)

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.
 - Sections of: RD52:2004, RD62:2001, RD47:2002



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



New CMS ESRD Core Survey

- 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



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](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!**

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The website address is:

www.rpc-rabrenco.com