Evolution of AAMI/ANSI Standards: Harmonizing with ISO

What is AAMI?

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?

Primary resource in the USA for industry, the professions, and government… for national and international medical device standards.

- Standards program consists of over 100 technical committees and working groups
- Produces Standards, Recommended Practices, and Technical Information Reports for medical devices
- Renal Disease and Detoxification (RDD) Committee is the dialysis working group

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

What is ISO?

International Organization for Standardization

- Independent (non-governmental) international organization with a membership of 162 national standards bodies (AAMI represents the USA)
- Member / experts develop voluntary, consensus-based, market relevant international standards
- Founded in 1947. Based in Geneva, Switzerland

Standard vs. Recommended Practice

- STANDARD--recommendations to the manufacturer. Also 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
Association for the Advancement 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

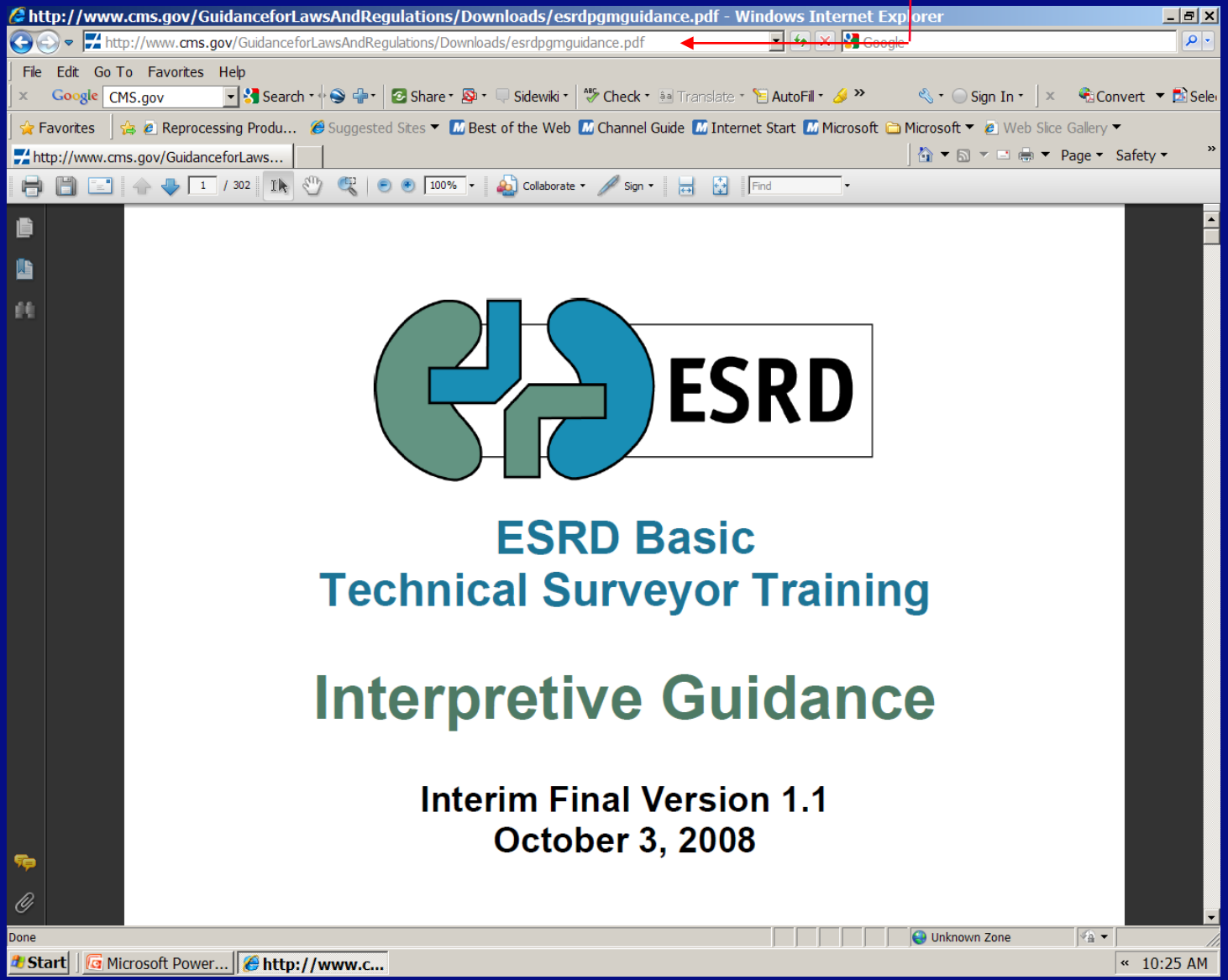
Application of AAMI Dialysis Standards

- 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



AAMI Dialysis Standards: ISO Harmonization Process

- 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 AAMI Standards	AAMI / ISO Standards
Water quality	ANSI/AAMI RD62 Water Treatment Equipment for Hemodialysis Applications (quality part)	ANSI/AAMI/ISO 13959:2014 Water for Hemodialysis and Related Therapies
Water treatment equipment	ANSI/AAMI RD62 Water Treatment Equipment for Hemodialysis Applications (equip. part)	ANSI/AAMI/ISO 26722:2014 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 13958:2014 Concentrates for Hemodialysis and Related Therapies

Table 1

Subject Matter	Prior AAMI Standards	AAMI / ISO Standards
Dialysate preparation and quality	ANSI/AAMI RD52 Dialysate for Hemodialysis (quality part)	ANSI/AAMI/ISO 11663:2014 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 23500:2014 Guidance for the Preparation and Quality Management of Fluids for Hemodialysis and Related Therapies

Table 2

Subject Matter	Prior AAMI Standards	AAMI / IEC / ISO Standards
Dialysis equipment requirements for manufacturers. Also helpful to users for evaluating equipment	ANSI/AAMI RD5 Hemodialysis Systems	ANSI/AAMI/IEC 60601-2-16:2012 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. Re-affirmed in April, 2013.

Table 3

How Do the 2014 AAMI / ISO Dialysis Standards Differ From Prior Versions?

- Much of what is in latest (2014) AAMI/ISO standards is same / similar to what is in prior AAMI standards

- Important current differences
  - Max. allowable free chlorine, chloramines in water combined into single contaminant (total chlorine)
  - Dialysate pH range of 6.9 to 8.0
  - Microbial quality of fluids

Subject Matter	Prior AAMI Standard	AAMI / ISO Standard
	ANSI/AAMI RD62	**ANSI/AAMI/ISO 13959:2014**
Maximum allowable level of **bacteria in dialysis water**	<200 CFU/mL	<100 CFU/mL
Maximum allowable level of **endotoxin in dialysis water**	<2 EU/mL	<0.25 EU/mL

Table 4

Subject Matter	Prior AAMI Standard	AAMI / ISO Standard
	ANSI/AAMI RD52:2004	**ANSI/AAMI/ISO 11663:2014**
Maximum allowable level of **bacteria in dialysate**	<200 CFU/mL Addresses “standard” dialysate only	<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 AAMI Standards	AAMI / ISO Standard
Bacteria culture conditions Medium	**ANSI/AAMI RD52:2004** Trypticase soy agar (TSA)	**ISO 11663:2014** Tryptone glucose extract agar or Reasoner's 2A. No dip samplers allowed. AAMI 11663:2014 (USA) deviation allows TSA.
Incubation temperature (°C)	35	17 – 23 35 (TSA)
Incubation time (h)	48	168 (7 days) 48h (TSA)

Table 6

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
- Seven (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 is not defined by ISO

This slide provided by J. Maltais, Ph.D., Maltais Consulting 2017

Proposed Changes to Next Revision ISO Hemodialysis 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 $\leq$0.5mg/L
- Consistency in use of "shall" and "should"

This slide provided by J. Maltais, Ph.D., Maltais Consulting 2017

Updated ISO Dialysis Standards To Be Released in 2018 How will they differ from 2014?

Documents will be renumbered to form a dialysis specific group (#23500) with sub numbers (1-5) to define each document within the group.

The document group title is:

Guidance for the preparation and quality management of fluids for hemodialysis and related therapies

Updated ISO Dialysis Standards To Be Released in 2018

Existing #	New #	Document Sub-Title
23500	23500-1	*Guidance for the preparation and quality management of fluids for hemodialysis and related therapies*
26722	23500-2	*Water treatment equipment for hemodialysis and related therapies*
13959	23500-3	*Water for hemodialysis and related therapies*
13958	23500-4	*Concentrates for hemodialysis and related therapies*
11663	23500-5	*Quality of dialysis fluid for hemodialysis and related therapies*

Updated ISO Dialysis Standards To Be Released in 2018 How will they differ from 2014?

- TSA 35° C, 48h will be included with TGEA and R2A 7 day as acceptable culture methods

- Max. allowable free chlorine (e.g. bleach) rinse level will no longer be specified in Standards
  - Manufacturers of dialysis machines or free chlorine tests to call out residual rinse level in their IFUs
  - Highly likely that manufacturers will continue with residual rinse level unchanged at 0.5 mg/l (ppm)

Updated ISO Dialysis Standards To Be Released in 2018 How will they differ from 2014?

- Handling bacterial culture samples for analysis after collection until ready to transport to lab
  - “stored at less than 10 degrees C w/o freezing”

- Use of syringes to collect samples
  – one syringe withdraw fluid, discard;
  second syringe for sample collection.

CMS View on the Latest AAMI / ISO Dialysis Standards

- At this time (March 2018), CMS will continue to enforce existing Interpretive Guidance requirements for the foreseeable future.
  - Sections of: RD52:2004, RD62:2001, RD47:2002

- CMS has been exploring adoption of some elements of the ISO Standards

CMS and Adoption of New AAMI / ISO Standards

- All new standards go through internal and external vetting process
  - Includes technical and public opinion reviews
  - Process takes a long time
- CMS does not discourage compliance with more stringent newer standards

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CMS ESRD Updates in Survey & Certification (as of 11/6/17)

- Finalizing Dialysis in Nursing Home survey process and guidance
- Revising State Operations Manual-Appendix H
- Updating guidance for recent S&C memos
  - Filling saline syringes at patient station (S&C 17-31)
  - Cleaning the patient station (S&C 17-32)
- Revising frequently asked questions document (FAQ's)
  - Removed from CMS website

AAMI RDD Committee Action Items
as of March 2018

- Finalize US position harmonizing AAMI Standards with the five 23500 series ISO Standards to be released in 2018
- Review of Standards
  - *Extracorporeal systems for blood purification, ISO 8637 (1-3)*
  - *Haemodialysis, haemo...equipment, IEC 60601 (2-16, 2-39)*
  - RD47 *Reprocessing of hemodialyzers, AAMI RD47, reaffirm*
- Technical Information Reports (TIR)
  - *Ultrapure dialysate for hemodialysis... (review/reaffirm)*
  - *Dialysis fluid chemical composition (in process)*
  - *Sorbent-Based Regenerative Hemo. Systems (in process)*
  - *Backflow prevention (in exploratory phase)*

Summary

- AAMI produces voluntary Standards, Recommended Practices, and TIRs for medical devices
- Prior versions of AAMI standards for dialysis fluids were adopted by CMS as regulatory requirements
- Current AAMI standards for dialysis fluids will be harmonized with ISO standards in 2018
- Latest standards compliance not yet required by CMS
- AAMI continues unending work of updating existing standards, while developing new standards & TIRs

Thank you for attending this session!

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