2012 NANT Symposium
V-tag Violations

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Common Technical Citations

- 1380 Surveys
- 319 Vtag cited
- 81 Technical
  - 25.4%
  - Reprocessing 27 >33.9%

V403 #3

- *Standard: Equipment maintenance.* The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

V196 #12

6.2.5 Carbon adsorption: *monitoring, testing frequency*

Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4hours

V250 #19

- Dialysate proportioning: *monitoring pH/conductivity*

  It is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method before starting the treatment of the next patient.

V175 #51

- 494.40 Condition: Water and dialysate quality

  This Condition incorporates by reference AAMI's RD52:2004 and has the authority of regulation. RD52 also references RD62:2001 as the specifications for various water treatment components and the referenced portion have the authority of regulation.

  (should and recommend)

V187 #54

- Environment: *schematic diagrams/labels*

  Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction.

  Additionally, piing should be labeled to indicate the contents of the pipe and direction of flow.

V229 #57

- Mixing systems: *perm record/verification testing*

  In addition to container labeling, there should be permanent records of batches produced. These records should include the concentrate formula produced, the volume of the batch, the lot numbers of powdered concentrate packages, the manufacturer of the powdered concentrate, the date and time of mixing, any test results, the person performing the mixing, the person verifying mixing and the test results, and the expiration date (if applicable)

V228 #59

- 5.4.4.1 Mixing systems: *labeling*

  Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single dialysis machine.

- Mixing tanks: Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. The labeling should remain on the mixing tank until the tank has been emptied.
- Bulk storage/dispensing tanks: These tanks should be permanently labeled to identify the chemical composition or formulation of their contents.

V191 #62

- Softeners: *Testing hardness/log*

  Users should ensure that test accuracy and sensitivity are sufficient to satisfy the total hardness monitoring requirements of the reerse osmosis machine manufacturer. Total hardness of the water exiting the water softener should be measured at the end of each treatment day.

V190

- 5.2.4 Softeners: *auto regn/timers/salts/salt level*
  - Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated.
  - The softener brine tank should be monitored daily to ensure that a saturated salt solution exists in the brine tank.

V184

- Environment: *secure and restricted*

The water purification and storage system should be located in a secure area that is readily accesible to authorized users.

Outline of Basic ESRD Survey Process

- Task 1 – Preparation Presurvey Offsite
- Task 2 – Activities at the Beginning of the Survey/Entrance Conference
- Task 3 – Tour and Ongoing Observations
- Task 4 – Survey of the Reuse Area
- Task 5 – Survey of the Water Treatment Area

Outline of Basic ESRD Survey Process

- Task 6 – Selection of Patient Sample for Interview and Record Review
- Task 7 – Interviews/Observations of Patients
- Task 8 – Personnel Interview
- Task 9 – Clinical Record Review
- Task 10 – QA/QI Review

Outline of Basic ESRD Survey Process

- Task 11 – Review of Operational Logs
- Task 12 – Review of Personnel Records
- Task 13 – Review of Affiliations
- Task 14 – Assessment of Special Situations
- Task 15 – Exit Conference

Task 3: Tour and Observations of HD Care

What surveyors are looking at/for:

- Patient treatment room
  - Condition of machines, chairs, equipment
  - NO DUMMY DRIP CHAMBERS!!!
  - Reprocessed dialyzers in use
  - Water room
  - Condition of room & components
  - Current chlorine/chloramine test & reagents

Task 3: Tour and Observations of HD Care

- Dialysate preparation area
  - Mixing ratios of acid , bicarb and machines match
  - Equipment condition
    - watch the build up of concentrates!
- Reuse room
  - Equipment condition
  - Appearance/condition of stored dialyzers
  - Dirty dialyzers: at room temp or refrigerated?
  - Germicide odors

Task 3: Tour and Observations of HD Care

- Machine maintenance area
  - Cleanliness
  - Machines being repaired clearly labeled
- Observation of HD patient care
  - Staff use of HD machines per DFU
  - Machine functions are intact
  - Dialysate pH/cond check w/independent method

Task 3: Avoiding citations

- Maintain ALL equipment
  - Clean, functional
  - Replace worn, broken parts/components
  - Don’t leave non-functional components in place
    - Ex: water treatment alarms, gauges
- Keep non-patient areas clean, organized
- Train ALL staff in use of equipment per DFU
  - Audit them periodically
- Verify that ALL supplies are appropriate
  - Ex: chl/chl reagents, concentrate proportioning ratios

Task 5: Water Treatment Area

- What surveyors are looking at/for: Water
  - Carbon system w/sample port b/t; 10 min EBCT
  - RO w/ quality monitor
    - If DI is present-automatic divert-to-drain required
  - Water quality alarms in treatment area working
  - All other components set up/ monitored per RD52
  - All components, valves and flow direction labeled
    - Schematic/valve chart posted and accurate

Task 5: Water Treatment & Dialysate Preparation

- What surveyors are looking at/for: Water
  - Will observe staff test for chlorine/chloramine
  - Will interview person responsible for daily monitoring of water treatment system
    - Assessing staff knowledge/competency (OK to read the component labels)
  - Will review water treatment logs
    - Daily system monitoring
    - Chlorine/chloramine testing
    - Microbial monitoring
    - Chemical analysis

Task 5: Water Treatment & Dialysate Preparation

- What surveyors are looking at/for: Dialysate
  - All proportioning ratios match machines
  - What mixing and distribution systems are in place
  - All equipment used per DFU
  - Central delivery outlets labeled
  - Will interview staff doing mixing/testing
  - May observe mixing/testing
  - Will review mixing & disinfection logs

Task 5: Avoiding Citations

- Get your water treatment and dialysate systems RIGHT and keep them that way
- Train, train, and re-train staff
  - Audit/monitor staff frequently
  - Download CMS interview guides (will ease anxiety)
- Review logs frequently
  - Address problems promptly
  - Encourage staff honesty in reporting by not “coming down” on them-use problem resolving solutions
  - NEVER create missing records-surveyors can spot this!

Task 10: Quality Assessment and Performance Improvement

You are an important part of the QAPI program

- Patient safety is the primary goal!
- Keep your logs/records organized

- Attend the QAPI meetings
- Report problems-opportunities for improvement
- Be actively involved in action plans & follow up

Task 10: Quality Assessment and Performance Improvement

- What are surveyors looking for/at:
  - Will review QAPI meeting minutes and materials
    - Participation of Biomed staff
    - Water analysis & water/dialysate cultures reported
    - Reuse QA audits completed
    - Equipment maintenance and repair discussed
    - All adverse occurrences & environmental issues discussed
  - Any areas of concern addressed w/action plans and follow up monitoring

Renal Technology Department Quality Management Report

St. Joseph Hospital Renal Center **Period Covered:**

Technology Aspect	Item	Expected Outcome	Jan/Feb/ Mar Results	Apr/May/ June Results	Jul/Aug/ Sep Results	Oct/Nov/ Dec Results
Medical Device and Equipment Safety (MDE)	1. Bicarb central delivery disinfected weekly.	100%				
	2. Acid concentrate/bicarb lot # documented at time of use	100%				
	3. Medical device problem or (trend not to exceed 3x in 3 mos.)	No Trend				
Equipment Maintenance (EM)	1. P.M. is current	100%				
Water System (WS)	1. Cultures within AAMI standard	100%				
	2. Endotoxin within AAMI standard	100%				
	3. Portable RO cultures/endotoxin used for diagnostic purpose. Critical value is based on paired dialysis machine results.	Trend with #4				
	4. Dialysis machine cultures paired with mobile RO	100%				
	5. Dialysis machine endotoxin paired with mobile RO	100%				
	6. Water analysis within AAMI standard	100%				
	7. R.O. System disinfect quarterly/PRN	100%				
	8. Monthly Distribution/Loop Disinfect	100%				
	9. Mobile R.O. Systems disinfect	100%				
	10. R.O. check performed daily	100%				
Dialyzer (D)	1. Blood leak incidents	No Trend				

Analysis/Evaluation:	**Action/Improvement Plan/Goal Date/ Individual Responsible:**

Miscellaneous:

Results documented in red indicate explanation required.

Reviewed by Medical Director: Date

Task 11: Machine Operation/Preventative Maintenance

- What are surveyors looking for/at:
  - HD machines & other equip maintained per DFU
  - Will interview Machine Tech- assess knowledge
  - Will review PM/repair logs of 25% HD machines
    - Tracking operating hours & calendar months b/t PMs
    - Repairs documented-trends addressed
  - Will review dialysate/machine cultures
    - Each machine at least annually (2 per month)
  - Will review ancillary equip maintenance logs
    - AED, scales, pH/cond meters, infusion pumps, eyewash stations, glucose meters, etc.

Task 11: Avoiding Citations

- Know the HD machine manufacturer DFU for PM and stick to it
- Have a master calendar for PM and cultures
- Keep good PM records-use manufacturer forms, if available
- Include ancillary equipment in program
- Train, train and re-train staff (no CMS interview guide yet, but look for one soon)

WHERE DO WE GO FROM HERE?

CURRENT WATER AND DIALYSATE QUALITY STANDARDS AND RECOMMENDATIONS

- **Pharmacopeia**
  - European Pharmacopeia – 5th Edition, 2005 (Water)
  - US Pharmacopeia – National Formulary, 2005 (Water)
- **National Standards and Regulations**
  - ANSI/AAMI RD62:2006 (Water)
  - CSA Z364.2.2-03 (Water)
- **International Standards**
  - ISO 13959:2009 (Water)
  - ISO 11663:2009 (Dialysate)
- **Practice Guidelines**
  - ERA-EDTA Best Practice Guidelines (Water and dialysate)
  - EDTNA Guideline (Water and dialysate)
  - ANSI/AAMI RD52:2004 (Dialysate)

CURRENT STANDARDS FOR CHEMICAL CONTAMINANTS

- **Include three classes of contaminants**
  - Substances with specific toxicity for hemodialysis patients
  - Substances normally included in dialysate
  - Substances with toxicity for the general population
- **General consensus for substances with specific toxicity for hemodialysis patients**
  - Aluminum, chloramine, copper, fluoride, lead, nitrate, sulfate, zinc
- **Some differences in other contaminants**
  - Selection of heavy metals
  - Allowable levels of magnesium, potassium and sodium

CURRENT STANDARDS FOR MICROBIOLOGICAL CONTAMINANTS IN STANDARD DIALYSATE

- **Small differences in maximum levels of bacteria**
  - 200 CFU/mL versus 100 CFU/mL
- **Significant differences in maximum levels for endotoxin**
  - 0.05 EU/mL – 2 EU/mL
- **Significant differences in culturing methodology**

DIFFERENCES IN CULTURING METHODOLOGY

- **CULTURE MEDIUM**
  - Tryptic Soy Agar (USA) versus Reasoner's 2A or Tryptone Glucose Extract Agar (Europe, ISO, Japan)
- **INCUBATION TEMPERATURE**
  - 35 – 37°C (USA) versus 17 – 23°C (Europe, ISO, Japan)
- **INCUBATION TIME**
  - 48 hours (USA) versus 168 hours (Europe, ISO, Japan)

ISO/IEC STANDARDS

ISO 13958	Concentrates for haemodialysis and related therapies	(AAMI RD61)
ISO 13959	Water for haemodialysis and related therapies	(AAMI RD62)
ISO 11663	Quality of dialysis fluid for haemodialysis and related therapies	(AAMI RD52)
ISO 26722	Water treatment equipment for haemodialysis applications and related therapies	(AAMI RD62)
ISO 23500	Guidance for the preparation and quality management of fluids for haemodialysis and related therapies	(AAMI RD52)
ISO 8637	Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators	(AAMI RD16)
ISO 8638	Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters	(AAMI RD17)
IEC 60601-2-16	Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	(AAMI RD5)

HARMONIZATION OF STANDARDS

Is it desirable?

Is it feasible?

What are the outstanding issues?

HOW ARE STANDARDS USED?

- **PRACTICE RECOMMENDATIONS**
  - Best Practice Guidelines
- **REGULATION WITHOUT ENFORCEMENT**
- **REGULATION WITH ENFORCEMENT**

MICROBIOLOGICAL CONTAMINANTS

- **Methodology for bacterial cultures**
  - Culturing method (membrane filtration, spread plate)
  - Culture medium (TSA, R2A, TGEA)
  - Incubation time and temperature (2 or 5 Days, 35°C or room temperature)
- **Should yeasts and fungi be monitored?**

WATER QUALITY

- **Ultrapure water and dialysate**
  - Are the clinical outcomes data sufficiently compelling to require their use?
  - Do we need a multicenter, prospective, randomized clinical trial?

AAMI STANDARDS FOR HEMODIALYSIS

- Will continue to evolve with our understanding of “adequate dialysis” and as new risks to patient safety are identified.
- Are likely to converge with other national and international standards.
- Will continue to be used by regulatory agencies