Preparing for the New Medical Director Responsibilities

Disclosure

- I would like to disclose that I am president of AmeriWater and receive an annual salary and bonus from AmeriWater, Inc. My presentation does not endorse any commercial interest, product or services.
- This presentation will not advocate for the off-label use of medications.

OUTLINE

- Water & Water for Dialysis
- Standards and Regulations
- Water Treatment Systems
  - Central Chronic
  - Portable Acute
  - Home Dialysis
- Monitoring & Testing
Introduction

To

Water

& Water for Dialysis

Water

The

Universal

Solvent

Hydrologic Cycle
Water Spot

Patient Water Exposure

- Normal person
  - 10 Liters/week
- Dialysis Patient
  - 350 Liters/week

Dialysis
Water Usage

Importance of Ultra Pure Water
- The Trend is Toward Ultra Pure USP Type Water.
- The Water System Will Need to be Microbiologically Controlled.

AAMI Water Quality
- Four Groups of Contaminants Based on Their Effects on Patients
Group 1-Toxicity

<table>
<thead>
<tr>
<th>TOXIC CONTAMINANTS</th>
<th>LOWEST TOXICITY CONCENTRATION (MG/L)</th>
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<tbody>
<tr>
<td>Aluminum</td>
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<tr>
<td>Chloramines</td>
<td>0.25</td>
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<tr>
<td>Fluoride</td>
<td>1.0</td>
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<tr>
<td>Copper</td>
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<tr>
<td>Zinc</td>
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<tr>
<td>Nitrate</td>
<td>21 (as N)</td>
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<tr>
<td>Sulfate</td>
<td>200</td>
</tr>
<tr>
<td>Calcium/Magnesium</td>
<td>85 (Ca++)</td>
</tr>
<tr>
<td>Sodium</td>
<td>300</td>
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<tr>
<td>Microbial</td>
<td>-</td>
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Group 2-Drinking Water Standard

- Barium
- Chromium
- Silver
- Mercury
- Selenium
- Lead
- Cadmium
- Arsenic
- Antimony
- Beryllium
- Thallium

AAMI is 10% of Drinking Water Standard

Group 3-Physiological

- Calcium
- Sodium
- Potassium
Group 4 - Microbiological

- Bacteria
- Endotoxin

Bacteria/Endotoxin

The Goal
Biofilm

- Bacteria creates biofilm.
- We need to disinfect enough to control biofilm.
- Requires at least monthly:
  - Disinfection
  - Monitoring (cultures & LALs)

Dialysate & Water Standards

- Bacteria = 200 CFU, action level 50 CFU
- Endotoxin = 2 EU/ml, action level 1 EU/ml
- MONTHLY, MONTHLY, MONTHLY

Dialysis Standards

- AAMI
- CMS
- FDA
- JCAHO
- ISO
“Voluntary” industry water standards that are accredited through ANSI. However CMS has made them requirements for coverage so they are mandatory for payment.

ANSI/AAMI RD62:2006

- Water Treatment Equipment for Hemodialysis Operations
- The water treatment equipment manufactures standard. Revised from the 2001 standard...
Microbiological:
- Bacteria: 200 CFU/mL Max., 50 CFU/mL Action
- Endotoxin: 2 EU/mL Max., 1 EU/mL Action

Chemical:
- Addition of Antimony, Beryllium, and Thallium

Chemical Contaminants:
AAMI Analysis

1. Contaminants that are toxic
2. Contaminants that are physiological
3. Contaminants from the USEPA Safe Drinking Water Act

New Additions to the RD 62 Standard
- The face of any timer controlling a regeneration or backwash cycle shall be visible.
- Cartridge filters shall be fitted with pressure gauges on the inlet and outlet.
- Carbon Beds:
  - Iodine number less than 900 in high organic waters, validated.
  - Arrangements of multiple beds in worker/polisher configurations approved.
  - RO lockout when backwashing.
- Addition of UV chlorine/chloramine reduction.
Anion resin systems as organic scavenger and pH remediation.

Chemical injection systems for sodium bisulfite and acid injection with special control requirements.

Storage tanks that have overflow shall be fitted with means of preventing contamination.

Endotoxin Filters: change ultrafilters to endotoxin retentive filters.

Hot water disinfection systems should be equipped with a temperature monitor at the end of the loop.

Ozone disinfection systems shall produce 0.5 ppm ozone for at least 10 minutes. Residual ozone should be less than 0.1 ppm before use.

Direct feed flow in loop should be at least 1.5 feet per second.

Total chlorine “dip and read” test strips may be used.
AAMI RD52:2004
“Dialysate for Hemodialysis”

- This is your water system operation standard
- Same water quality as RD62:2006
- Monthly samples from water system and at least from two dialysis machines per month with all machines sampled per year.

Important Note: New systems or Bad results

When new water systems are installed or if results don’t meet standards, weekly sampling should be performed until it is clear that the system is under control.

RD 52 Recommends

- Written policies and procedures
- Periodic audits of operators compliance
- Contingency plans
- Monthly Disinfection
- Monthly Cultures and LALs
Water System Key Points

- MultiMedia measure differential pressure.
- Cartridge filters measure differential pressure.
- Water softeners test hardness at end of day.
- Carbon Adsorption:
  - test total chlorine less than 0.1 mg/L (ppm)
  - high pH water may interfere with carbon performance
  - replace carbon within 72 hours on worker breakthrough
  - test total chloramine before every shift or at least every four hours

Reverse Osmosis:
- use conductivity (or TDS) to monitor RO, not % rejection
- monitor RO flows and pressures
- AAMI chemical analysis when new membranes are installed

Deionization:
- stop flow if quality drops below 1 megohm/cm
- follow with bacteria/endotoxin retentive filter
- replace worker tank(s) within 72 hours upon exhaustion

Storage Tank:
- internal spray mechanism to wash down the top and facilitate disinfection

Concentrate Preparation:
- Label mixing tank with date and chemical composition until emptied.
- Jugs labeled with contents.
- Permanent records:
  - concentrate formula
  - volume of batch
  - lot numbers of powered concentrate
  - the manufacturer of the powder
- date and time of mixing
- test results, not pH but conductivity or specific gravity
- the person performing the mixing
- the person verifying the mixing and their test results
- Acid concentrate additives
  - make sure the “spike” is completely mixed
  - label container with final concentration, the date and time mixed, and the person mixing
  - log of mix in permanent record

- Distribution systems;
  - color code piping, point of use and machine connection
    - Bicarb = Blue
    - Acid = Red
  - Remove bicarb from systems and jugs before disinfection

- You should have a copy of RD 52 at your facility.
  - Order from [www.aami.org](http://www.aami.org) / marketplace / dialysis equipment

RD 52

- Brings the water system requirements of AAMI together with the FDA.
- “Devices used to purify water for hemodialysis are also subject to the FDA 510(k) approval process…they must be approved by the FDA and users should ensure that devices obtained from vendors have been approved by the FDA.”
It’s Coming....

- CMS Conditions for Coverage of Suppliers of ESRD Services.
- Final Rule January 2009
- Incorporates AAMI RD52:2004
- Certified PCT required (18 months)
- Water Treatment Training
- Interpretive Guidelines for Inspectors

Water Treatment Systems

Central Chronic Water System
Water Heater

- Sizing
- 50-50 flow
- Cold vs. Hot weather

Blend Valve Assembly
AAMI & FDA Features

- Sized to application
- Check Valve on hot and cold
- Monitor outlet temperature (LOG)

Backflow Preventer

Break Tank
Backflow Preventer
- Protects potable water system
- Causes pressure loss
- Double check and dump type
- Required by the Plumbing Code

Booster Pumps
- Good practice
- Proper sizing needed to prevent over pressure
- Inlet pressure regulator option
- By-pass for service
- Runs off of flow, pressure switch, off a signal from the RO or pressure transducer/pump speed control.

Booster Pump(s)
System Filter

- Multi-Media type
- Cartridge type
- Or both

Multi-Media

- Layers of media
- Backwashes
- 10-20 micron removal
- Depth filtration
- Exposed timer & RO lockout
- By-pass for service
- Monitor pressure loss from inlet to outlet \((\Delta P)/(\log)\)
Multi Cartridge Filter

Cartridge Filter

- Smaller micron removal
- Replaceable cartridges
- By-pass for service
- Surface filtration
- Polish multi-media for smaller particles

Carbon Filters
Purpose of Carbon

To Remove Chloramines and Chlorine

Inside the Carbon Granule

AAMI-Carbon Adsorption

- At least two (2) beds in series
- Sample ports after each bed
- Replace with new media within 72 hours
- Exposed timer & RO lockout
- Minimum iodine number of 900
- 12x40 mesh acid washed
- 10 minute EBCT
- Home and portables have new separate standards.
  (0.1 mg/L verified before each treatment at least every 4 hours)
EBCT
• Empty Bed Contact Time
• RO feed flow x 10 ÷ 7.48 = total cubic feet of carbon

Supplementing Carbon
Additions to carbon to improve performance
1. pH adjustment using mineral acid.
2. Sodium bisulfite feed.
3. Dealkalizer pre-treatment
4. UV toc reduction light

Backwashing Carbon
Exchange Carbon

- Worker/polisher arrangement
- Sample ports
- PSI gauges (to measure $\Delta P$)
- Replacement protocol (less than 6 months)
- Easier to expand
- Easier to change
- 510K service company is best

Inside Exchange Carbon
Water Softener

Two Ways to Protect the RO Membrane from Scale
- Salt regenerated water softener
- Antiscalant chemical feed system

AAMI-Water Softener
- Sized properly
- Timers visible to the user
- Test for hardness at end of day
- Prevent high brine concentration from entering the RO (lockout)
- Brine tank at least 1/2 full
Water Softener Control - Fleck

Softener Maintenance
- Monitor hardness with test strips at the end of the day. Should be less than 1 grain per gallon (LOG).
- Use 99% pure salt such as solar, cubes, or pellets.
- Check salt level daily. Should be at least 2/3 full (LOG).
- Check time of day daily (LOG).
- Monitor ΔP (LOG).
- Replace resin periodically, usually between five and ten years.
- Sanitize the brine tank every three to four months.

RO Pre-filter
Cartridge Filter Efficiency Rating

AAMI-Sediment Filters
- Opaque housing
- Monitor the differential pressure
- Follow the manufacturers instructions for replacement

RO Pre-filter Maintenance
- Monitor dynamic pressure loss from inlet to outlet ($\Delta P$)(LOG)
- Inspect for carbon fines at replacement
- One micron may be better than five micron cartridge
Reverse Osmosis
The Heart of Most
Water Systems
Pre-treat – RO – Post-treat
RO Membrane

AAMI Reverse Osmosis

- In-line temperature compensated monitor of product conductivity.
- Conductivity monitor activates audible and visual alarm in patient care area on high conductivity.
- Divert product water to drain on alarm.
- Monitor flow meters and gauges.

RO Schematic
Good Operation Practices

- Do not oversize
- Good pre-filter (one micron)
- Monitor conductivity for quality
- Monitor Pre and post membrane PSI (ΔP)
- Operate at pH of six to eight
- Do not exceed flux rate (4” x 40” membrane = product flow of 1.0 to 1.3 GPM)

RO Maintenance (log)

Daily Monitor:
- Conductivity, uS
- Inlet pressure, psi
- Product flow, gpm
- Reject flow, gpm
- Recirculation flow, gpm
- Membrane Δ P, membrane psi - reject psi

Monthly:
- Disinfect
- Test for bacteria and endotoxin, culture & LAL

Quarterly:
- Clean in place, CIP

Annually:
- AAMI chemical contaminants test

RO Cleaning

Cleaning should be performed with warm water at high flow rate under low pressure
**RO Disinfection**

- Peracetic Acid (PAA) Injection
- Soak at least one hour
- Rinse and flush to remove endotoxin
- Verify residual at 1 ppm or less

**Storage Tank or Direct Feed**

- Direct Feed = RO Product directly to the loop feeding dialysis machines.
- Indirect Feed = RO Product to Storage Tank then pumped to the loop & dialysis machines.
- Which one should you use?

**Direct Feed**

- Program flush when not in use
- Disinfect Monthly (RO and loop)
- Use smallest diameter pipe for loop
- Return product (loop flow) to RO feed, use pressure regulator on feed from the pretreatment
- Plan for bulk (peak) uses
Storage Tank

AAMI Storage Tank
- Small as practical
- Cone bottom
- No overflow drain
- 0.2μ vent filter (hydrophobic)
- Tight lid, sealed tank
- “Spray ball” wash down mechanism for disinfection

Distribution Pumps and Controls

Single
Or
Dual?
Single Distribution Pump

Dual Pumps

Distribution Pump Specifications

- Sizing of 12 GPM at 80 psi for 1” loop (dynamic pressure)
- Loop return PSI 20 to 40
- Justification for dual pumps or spare single pump (alternate every 4 to 6 hours)
- High quality stainless steel pump
- Low-level shut down on storage tank
Deionization

- Polish RO
- RO back-up
- Acute treatment
- 1 meg divert or shut-off (portable and home use does not)
- Must be replaced when used in “off-line” mode every three to six months
- Usually installed as worker/polisher
- 510K service vendor

Deionizer Tanks On-line

Deionizer tanks off-line
AAMI Deionization
- One (1) megohm/cm minimum resistivity
- Audible and visual alarm in patient area
- Prevent less than one megohm/cm flow to patients (home and portable use exempt)
- Pretreated with carbon
- Post DI endotoxin-retentive filter
- Replace worker within 72 hours upon exhaustion

Portable RO & DI for Acute and Home
- Have Special Needs
- Micro Control is Essential
- Operate Under Different Regulations from Central Systems

Portable RO and DI
- Designed to be attended (supervised)
- No divert to drain of product flow needed
- Test for TOTAL chlorine before each treatment (use strips)
- They have special microbiological needs
Down Time = Bugs

- Bacteria and endotoxin proliferation (caused by carbon and lack of use)
- Flush (carbon) before and after use
- “Pack” with bacteriostat
- Disinfect at least monthly

The Differences, RO vs. DI

**RO**
- Grows bacteria
- Continuous process
- Removes microbes
- Percent rejection
  - Pre-carbon filter

**DI**
- Won’t grow bacteria
- Limited output
- Post endotoxin filter
- Removes all ions
  - Pre-carbon filter

Portable RO Maintenance

- Membrane life is one to three years
- Test bacteria and endotoxin before disinfection (after periodically)
- Plan to maintain the RO
- Log all operation, testing, & disinfection
- Follow manufacturers instructions
Portable DI Maintenance

- Use worker/polisher configuration
- Disinfect all filter housings & tubing monthly
- Exchange DI tanks every 3 months at least
- Test bacteria & endotoxin before disinfect
- Log all replacements and disinfections
- Follow manufacturers instructions

Alarm Systems

- Monitors cannot be disabled without notice
- Remote in patient care area
- Audible alarm at 65 decibels at 3 meters
- Silence for only 180 seconds (3 minutes)
- Temperature compensated resistivity and conductivity meters
- Include all important alarms

AAMI - Safety
Some Common Alarms

- RO
- Low (mid) level tank
- DI
- Bicarb
- Loop conductivity
- UV

Endotoxin Retentive Loop Filters

Now required (sub-micron non endotoxin validated are not recommended)

Disinfectant compatibility is critical

Good design and maintenance practices are very important

Cross flow vs. dead end design debate!

Endotoxin Retentive Filter
Two Endotoxin Filtration System Designs

- Cartridge (dead end with charged surface - validated)
- Cross-flow membrane (validation is a problem)

Cross-Flow UF Membrane

Cross-Flow Disinfection

- PAA (Peracidin/Minncare) only
Cartridge Endotoxin Filter

Cartridge endotoxin filters have a charged surface that hold the endotoxin fragments.

AAMI Endotoxin Retentive Filter

- After storage tank, DI or UV
- Cross-flow mode or dead end design—both need to be validated for endotoxin removal
- Opaque housing to discourage algae and bacteria growth
Piping
Recommendations

- No dead legs
- Flow velocity (recirculation)
- Ability to isolate use points (valves)
- Good installation practices should be followed

Labeling

AAMI Labeling

- P&ID (schematic system drawing)
- Tags on important devices and action points
- By-pass process clearly displayed
- Identified water treatment components
  - Descriptions and actions on label
- 510K certificate or letter
- Complete manual
**Accessories**

- Wall Boxes
- Bicarbonate Concentrate systems
- Acid Concentrate systems

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**DISINFECTION**

Prevent Biofilm

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**Microbial Levels**

The lower the bacteria and endotoxin level, the healthier the patient.

This is especially true of endotoxin, even at low levels.
Disinfectants

- Need to destroy bacteria and endotoxin
- Requires high dosages of the disinfectant to “burn out” the endotoxin

Disinfectants

- Chlorine (bleach)
- PAA (Peracidin/MinnCare)
- Ozone
- Heat

What to Disinfect

- Reverse Osmosis
- Storage Tank
- Distribution Loop
- Bicarb Mixing
- Bicarb Distribution & Loop
- Dialysis Machine
- Reuse Machine & Rinse Station
Portable Systems Maintenance

- Disinfect at least Monthly
- Flush before treatment - Flush or replace carbon after use
- "Pack" with bacteriostatic solution
- Replace carbon regularly

Water Testing
And
Monitoring

AAMI Chemical Contaminants

- Chemical contaminants
- At least yearly
- Both the RO and the Loop
- Consider on tap water and product water
Endotoxin and Bacteria Sample Points

- End of recirculation loop
- Reuse area
- Bicarb mix water
- Treatment station(s)
- Reverse Osmosis
- Dialysate

Proper Sampling

Flush for 1 to 2 minutes

Clean Catch

Monitoring-How Often?

- Each facility needs to decide and write up a procedure for where, when, and how often they will test and sample.
- AAMI - At least monthly.
Chloramine

- Total chlorine test
  - Test each patient shift or
  - At least every 4 hours

The Log

- The daily log is a very important record of performance and testing

The Log

- The Log

- The Log
Summary

- The quality of water is important for dialysis.
- Current and Future regulations.
- Water systems and components.
- Testing, Monitoring & Logs.

DID WE ANSWER YOUR QUESTIONS?

Thank You!