# Dialysis Water Purification and Conditions of Coverage

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Rich Benner, CWS III

# Overview

- Dialysis Water
- Key Contaminants
- Safe Levels
- Pre-treatment Equipment
- Water Distribution Equipment
- Maintenance & Monitoring

# What do we use water for in Dialysis?

- To make dialysate.
- To mix concentrates.
- To reprocess dialyzers.
- Clean equipment.

# Key Contaminants

The American Association for Medical Instrumentation (AAMI) has recognized 25 contaminants as needing restriction on the allowable level present in water used for dialysate or reprocessing.

# AAMI LEVELS

CALCIUM----------2 (0.1mEq/L)
MAGNESIUM---------4 (0.3mEq/L)
POTASSIUM----------8 (0.2mEq/L)
SODIUM----------70 (3.0mEq/L)
ANTIMONY----------0.006
ARSENIC----------0.005
BARIUM----------0.10
BERYLLIUM----------0.0004
CADMIUM----------0.001
CHROMIUM----------0.014
LEAD----------0.005
MERCURY----------0.0002

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SELENIUM----------0.09
SILVER----------0.005
ALUMINUM----------0.01
CHLORAMINES----------0.10
FREE CHLORINE----------0.50
COPPER----------0.10
FLUORIDE----------0.20
NITRATE----------2.00
SULFATE----------100.0
THALLIUM----------0.002
ZINC----------0.10

# Why are patients at risk from these contaminants?

- Hemodialysis patients are exposed to approximately 100 liters of water per treatment.
- Dialyzer membranes are non-selective, permitting exposure of water contaminants to patient's blood.
- Patient's ability to excrete such substances in their urine is impaired due to compromised renal function.

# How can we Minimize the Levels of Contaminants?

- Adopt proper policy and procedures, review regularly.
- Adequately train *technical and clinical* staff.
- Routine quality assurance reviews.
- Comply with governing standards for water treatment.
- Proper monitoring, and routine equipment maintenance.

# Water and Dialysate Quality

**Examples of potential Condition level non-compliance would include, but not be limited, to:**

- Demonstrated lack of knowledge or training of staff assigned responsibility for the operation or monitoring of the water treatment or dialysate preparation systems;
- Failure to perform and document the test(s) for chlorine and chloramine accurately, including use of testing strips or reagents that are expired or not sensitive to the required levels
- Unsafe practices in the preparation, labeling or delivery of dialysate
- Failure to address out of range results for tests of water or dialysate (bacteria, endotoxin or chemical analysis).

# Microbial Contaminants

**BACTERIA**

200 CFU/ml with an action level of 50 CFU/ml

**ENDOTOXIN**

2 EU/ml with an action level of 1 EU/ml

# Additional Guidance for Bacteriology of water

- If the facility reaches the “action” level, remedial action is expected within 48 hours.
- Action could be to repeat a culture, particularly if only one in a set of cultures was above the action limit.
- Action could also be to disinfect the system and repeat cultures at several sites.

# Bacteriology of Ultrapure Dialysate

- Ultrapure dialysate should contain a total viable microbial count lower than 0.1 CFU/mL
- Endotoxin concentration lower than 0.03 EU/mL
- If those limits are exceeded in ultrapure dialysate, corrective measures should be taken to reduce the levels into an acceptable range.
- The user is responsible for monitoring the dialysate bacteriology of the system following installation. It is incumbent on the user to establish a regular monitoring routine.

# Additional Guidance Ultrapure Dialysate

At the time of publication of these regulations, most dialysis facilities in the U.S. were using conventional dialysate, rather than ultrapure. The use of an extra filter in the water distribution path at the point of use does not constitute “adoption” of the ultrapure standard

# Water Room Environment

- The water purification and storage system should be located in a secure area that is readily accessible to authorized users.
- The location should be chosen with a view to minimizing the length and complexity of the distribution system.
- Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system.

# Additional Guidance
# Environment-Secure & Restricted

- Older systems (installed prior to the effective date of these regulations) may have been installed in a small space, with components added over the years to crowd the available space.
- In all cases, the operator should be able to describe and identify the various pre-treatment components and the distribution system.
- To ensure access is restricted, the delivery doors/ loading dock must not be left unlocked, open and unattended.
- Many water systems are in the same room as stored treatment supplies; staff members who are not responsible for the water system may come into that area to retrieve supplies.

# Additional Guidance
# Environment-Access to Ports/Meters

- Older systems (installed prior to the effective date of these regulations) may not be as easy to access: provision must be made to allow staff to access all equipment, ports, etc. to operate and monitor the system

# Additional Guidance Environment Alarms in Treatment Area

- Responsible staff members must be able to test the alarms to validate they can be heard in the treatment area.
- If alarms normally sound during certain events during the treatment day, documenting that these are heard in the treatment area will suffice for testing.
- The alarms in the treatment area must be loud enough to be heard while patients are on dialysis, and cannot be muted for more than 3 minutes (reference AAMI RD62:2001).

# Additional Guidance Environment Schematic Diagrams/Labels

- There must be a schematic diagram which allows the staff to follow the flow of the water through the components.

# Water Purification Equipment

- BACK FLOW PREVENTORS
- TEMPERATURE BLEND VALVE
- BOOSTER PUMPS
- SEDIMENT FILTER
- WATER SOFTENER
- CARBON TANKS
- REVERSE OSMOSIS
- DE IONIZATION
- DISTRIBUTION

# Four Questions...

... what does it do?

... how often is it monitored?

... how would failure effect the patient?

... what do I do if it fails?

# BACK FLOW PREVENTOR

Designed to prevent water in the purification system from being siphoned into the domestic water supply during low or no pressure conditions.

- ***How often is this equipment monitored?***
  - BFPs are typically checked for proper function on a semi-annual basis.
- ***How would failure effect the patient?***
  - Failure of BFPs will result in a siphon action while RO equipment is not running. This will ultimately result in failure of RO equipment operation, causing delay of treatment.
- ***What do I do if equipment fails?***
  - Immediate repair by certified plumber, check operation of all proceeding water purification equipment.

# TEMPERATURE BLEND VALVE

Mixes hot & cold domestic water to maintain optimal 77 degree F.

- ***How often is this equipment monitored?***
  - Feed water temperature is monitored constant during RO machine operation. Blend valve function is typically checked once daily.
- ***How would failure effect the patient?***
  - Delay of treatment due to RO equipment failure as a result of elevated or decreased feed water temperature.
  - Hemolysis.
- ***What do I do if equipment fails?***
  - Adjust manual hot and cold water valves for optimal temperature.
  - Increase frequency of temperature monitoring.
  - Repair temperature blend valve.

# BOOSTER PUMP

Used to maintain water pressure to water purification equipment.

- ***How often is this equipment monitored?***
  - Booster pump function is typically monitored on a daily basis.
- ***How would failure effect the patient?***
  - Failure of booster pump may or may not effect the patient or treatments based on incoming water pressures.
- ***What do I do if equipment fails?***
  - Normally, a second booster pump is installed as a back-up.
  - Failure of booster pump may not have any effect on equipment operation.
  - Have pump repaired or replaced A.S.A.P.

# SEDIMENT FILTER

Tank containing several layers of different media designed to filter sediment particles from city water supply.

- ***How often is this equipment monitored?***
  - The sediment filter is monitored on a daily basis.
  - It is regenerated or “backwashed” during hours of non-operation in order to clean the media and “fluff” the bed.
- ***How would failure effect the patient?***
  - Failure of this equipment may not effect operation at all, depending on the city feed water quality.
- ***What do I do if equipment fails?***
  - Depending on facility’s “Silt Density Index”, RO may handle short term bypass of this device.

# Additional Guidance
# Sediment Filters

- Sediment filters are not required in every facility: the source water should determine the water treatment components needed. If sediment filters are in use, the facility must follow these requirements.
- If a water treatment system includes multiple components that backwash, the “time” set on each timer may need to be staggered to allow sufficient water to be available for the backwashing.
- This may result in some timers being set an hour or two different from the correct time. If so, there should be a posted notice to that effect.
- Pressure readings must be taken while the equipment is running.

# WATER SOFTENER

The water softener removes hardness (calcium & magnesium) from feed water to prevent damage to the RO membranes due to scale deposits. This softening process is a result of an exchange with sodium ions.

- ***How often is equipment monitored?***
  - The softener tank is typically monitored daily for hardness breakthrough.
  - It is regenerated on a regular basis to “re-charge” the softener media.
- ***How would failure effect the patient?***
  - Prolonged failure of the water softener can cause failure of the RO membranes as well as patient complications.
- ***What do I do if it fails?***
  - Softeners may be temporarily bypassed. Running RO without a softener for a prolonged amount of time may cause permanent damage to RO membranes.

# Additional Guidance for Water Softeners

- Softeners are not required in every facility: the source water should determine the water treatment components needed. If softeners are in use, the facility must follow these requirements.
- The requirement to prevent water with a high concentration of sodium from entering the product water line is especially important when a facility offers nocturnal dialysis, as regeneration cycles for most components are set for nighttime.
- The timer box cover must have a clear window allowing the timers to be seen, or the cover must be removed when timers need to be viewed.
- Timers checked AM
- Hardness at end of day
- Nocturnal dialysis units must be particularly careful with high sodium concentrations  (when to monitor?) no guidelines.

# CARBON TANK

Tank filled with granular activated carbon (GAC) that adsorbs chlorine and chloramine. Two tanks are installed in series (worker & polisher).

- ***How often is this equipment monitored?***
  - GAC tanks are monitored for “breakthrough” several times daily.
  - GAC tanks are backwashed on a regular basis.
  - Empty bed contact time (EBCT) of 10 minutes.
- ***How would failure effect the patient?***
  - Failure of GAC tanks may result in an elevated level of chlorine and chloramine in the pre-treated water.
  - Chlorine and chloramine will cause permanent damage to most RO membranes.
  - Chlorine and chloramine in product water can lead to hemolysis or death.

# Carbon Tank continued

- ***What do I do if equipment fails?***
  - The total chloramine level after the primary “worker” tank should be checked before each daily patient shift. Once breakthrough is noted on this tank, the total chloramine level should immediately be checked after the secondary “polisher” tank.
  - If there is no breakthrough noted after the secondary tank, treatments can continue with an increased frequency of total chloramine monitoring.
  - If breakthrough **is** noted after the secondary GAC tank, **treatment must be stopped immediately**.
  - The “exhausted” GAC tank needs to be re-bed or replaced A.S.A.P.

# Additional Guidance
# Carbon Monitoring & Testing

- In choosing whether to use “quantitative” or “qualitative test methodology, it is important to recognize that the determination of low levels of chlorine (i.e., <0.1 ppm) requires the use of the quantitative method.

- If an on-line chlorine/chloramines monitor is in use which incorporates an automated alarm, particular testing times are not required. Facility policy and practice must follow manufacturer’s guidance regarding any required comparison testing and calibration of the monitor.

# REVERSE OSMOSIS (RO)

- Reverse osmosis is the device which purifies the water used for dialysate and reuse.
- Water is pumped through RO membranes where dissolved solids are rejected to waste.
- RO membrane performance is measured by calculating the percentage of dissolved solids that are being rejected.

# How Often is Equipment Monitored?

- Typically RO monitors are logged on a daily basis. Most RO machines today have real-time monitors that are active during machine operation. Should any values vary from the pre-set parameters, audible and visual alarms should occur.

- Routine audits of daily logs will aid in prevention of equipment failure.

- RO product water is monitored at least bi-annually to ensure that the permeate is within AAMI limitations.

- ***How would failure effect the patient?***
  - Spontaneous failure of RO equipment will delay treatments until repairs are made.
  - Failure to monitor membrane rejection and water quality on a regular basis could result in elevated contaminants in product water. These contaminants will present many different risks to the patient.
  - Effective monitoring of equipment and water quality is the best way to avoid risk to the patient.

- ***What do I do if it fails?***
  - De-ionization (DI) tanks are a common back-up to reverse osmosis.
  - DI is ultimately the medical director's decision.  Check with unit policies
  - RO membranes require routine cleaning to prevent membrane "fouling".  When membranes foul, cleaning with approved low and high pH solutions may help to regain acceptable permeate water quality.
  - Call your water vendor or repair service as soon as possible.

# RO Systems Additional Guidance Directions for Use

- The facility should have documentation of the RO manufacturer's Directions For Use, and facility procedures must reflect them.
- The RO parameters must be recorded and monitored each day the facility is operating.
- The medical director and chief technician must be able to describe how trends in the RO function are monitored to detect problems.

# De-Ionization

De-Ionization tanks are commonly used as a back-up to reverse osmosis in the event of failure. DI is sometimes used to “polish” reverse osmosis product water.

- Usually two tanks in series, each containing a “mixed bed” of cations and anions.
- As feed water passes through, contaminants are attracted to the ionic content of the media.
- Media exhausts once it has attracted all of the contaminants that it is capable of.

# De-Ionization

- Can release high bolus of contaminants back into the product water.
- Rate of exhaustion is measured through resistivity. (> 2 MegOhms)

# Additional Guidance
# DI Tanks

- Exhausted DI tanks (<1.0 megohm) present a serious risk to patients, and use of exhausted DI tanks have resulted in deaths.
- If the water system uses DI as primary purification or as a polish, the system must be closely monitored by knowledgeable staff.
- Pure water has a resistivity of 18.3 megohms. Documentation of a reading greater than 18.3 megohms would indicate some error.

# Water Distribution System

- ***How often is equipment monitored?***
  - A daily log of pressures and flows should be kept. Routine audits of these logs should be done to indicate the need for repair before treatment down time results.
- ***How would failure effect the patient?***
  - Failure of either type of distribution system would create a delay in patient treatments.
  - Routine maintenance and monitoring of this equipment is the best way to avoid treatment down-time.
- ***What do I do if it fails?***
  - Depending upon the distribution system, some repairs can be done “on the fly” to avoid down-time. Individual unit policies should be in place.

# Water Distribution System

- The water distribution system distributes the RO water to each ***point of use***.
  - There are two types of water distribution systems.

# Water Distribution System

**IN-DIRECT FEED**

- Permeate is pumped through the membranes into an ***RO storage tank***.
- ***Loop distribution pumps*** distribute the water from the storage tank through the RO water ***loop*** to each point of use***.***
- The loop end is returned to the storage tank.
- Float switches in the storage tank tell the RO machine when to make more water and when to stop.

# Water Distribution System

**DIRECT FEED**

- Permeate is pumped directly to the distribution loop from the membranes.

- Some direct feed loops return permeate to the RO machine for reprocessing

# Additional Guidance
# Water Storage

- If existing facilities with older storage tanks can demonstrate a history of water and dialysate cultures being below action levels, replacement of the existing tanks is not required.
- Bacterial control device(s) in use following the storage tank may include an ultrafilter or individual filters in the water supply line in each patient's dialysis machine
- The facility must follow the manufacturer's guidance for the disinfection of the water storage tank.

# Additional Guidance
# Water Storage

- Tanks which fill from the top and drain from the bottom may, in fact, drain several times a day.
- The goal is to not have stagnant water. A properly designed and functional storage tank replaces its total volume frequently as part of the normal operation and does not require manual or frequent draining of the tank.

# Additional Guidance
# Water Storage: Monitoring

- Suggested monitoring from ANSI/AAMI RD52, Table 4: To monitor the water storage tank, measure bacterial growth and pyrogens, weekly, until a pattern of consistent compliance can be demonstrated. Action levels for bacterial growth are 50 CFU/mL; for endotoxin 1 EU/m
- A “pattern of consistent compliance” could be demonstrated by showing results within these limits on weekly cultures for at least four weeks in a row

# ULTRAVIOLET LIGHT (UV)

UV is used to control bacterial proliferation in the water distribution system.

- ***How often is equipment monitored?***
  - UV is monitored on a daily basis on the daily RO log.
- ***How would failure effect the patient?***
  - Failure of the ultraviolet light should not effect the patient or his/her treatment provided the water treatment and distribution equipment is properly disinfected on a regular basis.
- ***What do I do if it fails?***
  - The UV can be by-passed until repaired.
  - Repair as soon as possible.

# Additional Guidance (UV)

- Monitoring may be accomplished by either of the following options: use of a meter to monitor intensity of the lamp, use of an on-line monitor that activates an alarm; or replacement on a predetermined schedule.

- The use of a UV irradiator in a bicarbonate distribution system may have a totally different role. If ozone is used to disinfect that system, the UV irradiator may be used to break down the ozone. If the UV irradiator is part of the bicarbonate distribution system, responsible staff must be able to describe the intended purpose of the UV in that application. Monitoring of the irradiator is still required, but there is no need to follow an irradiator used in the bicarbonate distribution system with an ultrafilter or other endotoxin-retentive device.

# ULTRAFILTER

This filter is capable of removing endotoxin from the water. Endotoxin is a bacterial by-product that is released during destruction of bacteria cells.

- ***How often is equipment monitored?***
  - Endotoxin filtration devices are monitored on a daily basis through feed and discharge pressures. Trend analysis and pressure drops indicate replacement of filter.
- ***How would failure effect the patient?***
  - Improper endotoxin filtration post UV could result in elevated endotoxin levels in the water.
- ***What do I do if equipment fails?***
  - Proper monitoring and routine maintenance (replacement or flushing) should be practiced in order to avoid failure.

# Equipment Maintenance

- Maintaining the RO membranes and pre-treatment equipment will help to keep chemical contaminants below the maximum allowable level.
- To prohibit extensive growth of microbial contaminants such as ***bacteria*** and ***endotoxins***, RO and distribution equipment must be routinely disinfected with an approved disinfecting agent.

# Additional Guidance
## Bacterial Control: Piping System

- In order to prevent or limit the development of biofilm, every dialysis facility must disinfect their water distribution system at least monthly.

- All surfaces in the water distribution system must have sufficient contact time with the disinfectant prior to its being rinsed from the system.

# Summary

- Uses for water in Hemodialysis.
- Key Contaminants.
- Pre-treatment.
- Reverse Osmosis.
- De-Ionization.
- Maintenance.

# Thank you