Water and Dialysate Safety: Your Role in Maintaining Quality

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Objectives

- Describe basic water and dialysate safety and quality expectations
- Identify key actions technicians must take to maintain water and dialysate quality and safety
Water: Quality & Safety

• Goal—prevent patient harm

• Measures are based on patient outcomes
  • Does the quality of the water meet the minimum standards for dialysis?
  • Is the water safe for use for dialysis?
  • Is the dialysate safe to use for dialysis?
Safe Water & Dialysate

- Are chemicals harmful to patients removed from the water or reduced to safe levels?
- Are the water and dialysate systems protected from microbiological contamination?
Stay Safe: “Copy” Survey Techniques

- **Observe:**
  - The physical environment: is equipment maintained clean and functional?
  - Any testing procedures
  - Mixing bicarbonate & acid

- **Ask:**
  - Interview responsible staff members

- **Review:**
  - Logs for completeness
  - Action taken and documented if logs have gaps or parameters are not met
Removal of Chemicals
Critical Components

- **Pre-treatment:**
  - Carbon removal system

- **Treatment component:**
  - Reverse Osmosis
  - Deionization
Carbon Removal System
Observe and Ask

- Are there 2 carbon tanks or banks of tanks with a sample port between?
- What is the empty bed contact time (EBCT) of the carbon tanks?
- What test is done for total chlorine? When is the test done? What is the maximum allowable result?
- If 0.1 mg/L total chlorine is exceeded, what action is taken?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
Observe Testing for Total Chlorine

- Is the test performed correctly?
- Are the correct reagents used for the correct sample size?
- Are reagents within expiration dates?
- Are reagents sufficiently sensitive to detect 0.1 mg/L total chlorine?
- If digital meter is used, is it zeroed prior to testing?
- If strips are used, is the quantitative method of testing used?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
What Are “Triggers?”

- Findings that require additional action be taken and documented
  - May require
    - Change in practice
    - Additional education
    - More frequent audits of practice
- May be cited if identified by a surveyor
Carbon System “Triggers”

- Absence of 2 carbon tanks
- No sample port between primary & secondary carbon tanks
- Insufficient EBCT
- Observed chlorine test result above allowable level; testing errors
- Staff knowledge level is not adequate for patient safety

Source: CMS ESRD Core Survey Water & Dialysate Review, Version 1.3
Treatment Component
Ask: Reverse Osmosis (RO)

- Is there a continuous water quality monitor?
- Is there an audible alarm to notify staff in the patient treatment area of poor water quality?
- How is the water quality monitored?
  - What is the set point for the water quality alarm?
  - How was this determined?
  - What actions are taken if the percent rejection falls below 90% or the water quality falls below the set point?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
Ask: Deionization (DI)

- Is there a DI system in use or planned to back-up the RO?
- Is there a functional, continuous resistivity monitor for the DI system, with an audible and visual alarm in the patient treatment area?
- Is there an automatic divert-to-drain component or other mechanism to prevent use of low quality water?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
Ask: Deionization Systems

- Is there an ultrafilter after the DI system?
- How often is the DI system monitored?
- What resistivity level would cause the alarm to sound?
- What actions are taken if a DI tank exhausts and water resistivity drops to <1 megohm?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
Review: Monitoring Operations

- Are chlorine logs complete?
- If the level exceeded 0.1mg/L total chlorine, were appropriate actions taken?
- Is the water quality recorded daily?
- Is the percent rejection monitored?
- Is a chemical analysis done and reviewed at least annually or more often if required by policy or state law?
Review: DI Monitoring

If DI is present or has been used:

- Is resistivity reading recorded at least 2 times each day?
- If resistivity fell below 1 megohm, was dialysis stopped and actions taken to resolve the problem?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
RO or DI System Triggers

- RO water quality not monitored daily
- RO alarm non-functional or inaudible in patient treatment area
- DI resistivity alarm non-functional; not visible and audible in patient treatment area
- DI resistivity not monitored & recorded at least twice per treatment day
- Staff unaware of minimum allowable resistivity or actions for DI tank exhaustion
- No ultrafilter in-line post DI

Source: CMS ESRD Core Survey, Water Treatment and Dialysate Review, Version 1.3
Protection from Microbiological Contamination
Ask: Microbiological Monitoring

- How often is the water distribution system disinfected?
- When are water cultures and endotoxin levels obtained in relation to disinfection?
- From what sites are cultures and endotoxin levels obtained?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
Ask: Microbiological Monitoring

- How often are dialysate cultures taken from each hemodialysis machine?
- How many machines are cultured each month?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
Ask: Sample Collection and Testing

- How are samples of water and dialysate collected?
- How are cultures and endotoxin testing performed, e.g., in-house “dip” samplers, in-house LALs, outside lab?
- What are the action and maximum allowable microbiological levels for product water and dialysate?
- What actions are taken when those levels are exceeded?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
Microbiological Contamination Triggers

- Water/dialysate samples not drawn before disinfection
- Water distribution system not disinfected at least monthly
- Each HD machine not cultured at least annually

Source: CMS ESRD Core Survey, Water Treatment and Dialysate Review, Version 1.3
Review: Logs and Reports

- Are monthly cultures and endotoxin levels tested from identified sites in the water treatment and distribution system?

- Are dialysate cultures and endotoxins tested from at least 2 machines/month, and each machine tested at least annually?

- If results exceed action or maximum allowable levels, are appropriate actions taken?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
Documentation Triggers

- Total chlorine equal or >0.1 mg/L without documentation of appropriate action
- Less than annual chemical analysis
- Trends of omitted tests
- Microbiological results outside of action/maximum levels without evidence of appropriate action
Dialysate Quality & Safety
Dialysate Preparation and Delivery

- Observe: Are the dialysate mixing system maintained?
- Observe: Are batches of bicarbonate and/or acid concentrates mixed on site?
- Ask: What verification testing is done for batches of acid concentrate?
- Ask: How long is mixed bicarbonate kept?
- Ask: Are acid concentrates ever “spiked” with additional electrolytes? If yes, who does this and are jugs clearly labeled?

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
Dialysate Safety Triggers

- Staff unaware of correct dialysate concentrate mixing, acid concentrate batch testing, etc.

Source: CMS ESRD Core Survey, Water Treatment and Dialysate Review, Version 1.3
Maintaining Quality
Review: Technical Audits

- Water and dialysate testing
- Dialysate mixing
- Dialysate pH and conductivity testing at the point of use (i.e., at the hemodialysis machine)

Each staff member assigned these tasks is expected to be audited at least annually

Source: CMS ESRD Core Survey Worksheet Water & Dialysate Review, Version 1.2
Audit Trigger

- Practice audits of staff conducted less than annually

Source: CMS ESRD Core Survey, Water Treatment and Dialysate Review, Version 1.3
Let’s Review:

• Describe basic water and dialysate safety expectations

• Identify key actions technicians must take to maintain water and dialysate quality and safety
Resources

- CMS ESRD Core Survey Field Manual available at