

## ➡ **Water Treatment and Dialysate Review:** ▲

Purpose - To verify that systems in use and facility oversight of water and dialysate quality are able to protect patients from harm

**Review critical water treatment components** with staff responsible for the activity and daily monitoring of the component:

- **Observe total chlorine test and interview** about maximum allowable level of 0.1mg/L total chlorine, chlorine “breakthrough” procedures and the amount of carbon in the system (empty bed contact time-EBCT). If the facility is using a continuous on-line chlorine monitor, **ask** about periodic (usually daily) validation testing with an alternate method.
- **Observe reverse osmosis (RO) unit, water quality monitor and alarm and interview** about monitoring RO function by % rejection, and product water quality by total dissolved solids (TDS) or conductivity.
- **Observe deionization(DI) and resistivity monitor and alarm**, if present. **Interview** about the DI system, and determine if there is a plan to use DI as back-up. If DI is present or included in a back-up plan, **ask** about the presence of an automatic divert-to-drain or automatic cut-off valve to stop water flow to the dialysis stations, ultrafilter (UF) post DI, how monitoring is conducted, what the minimum allowable resistivity level is, and what actions are taken when resistivity falls <1 megohm (i.e., STOP dialysis).

**Interview the person responsible for microbiological monitoring** of water and dialysate regarding system disinfection, sample sites, collection methodology, sample timing (before disinfection) and how often dialysate cultures are done for each HD machine.

**Interview the person responsible for bicarbonate and acid dialysate concentrate mixing** regarding verification of proper mixing, testing of acid concentrate, bicarbonate concentrate time frame for use (24 hours or per manufacturer's DFU) and “spiking” (inserting additives) into individual dialysate containers.

**Review facility oversight of water & dialysate systems in the following areas:**

- **Chemical and microbiological monitoring**
  - Total chlorine testing-2 months
  - RO monitoring by % rejection and product water quality by TDS or conductivity, **NOT** all gauge and component readings-2 months
  - If DI present or has been used in past 12 months: 2 months of resistivity readings at least twice per treatment day
  - Product water chemical analysis-12 months
  - Microbiological monitoring of water, including in the reuse room, and dialysate; both colony forming units (CFU) and endotoxin units (EU)-6 months
- **Practice audits of the operators' compliance with procedures** - Look at 12 months of facility documentation of observations of staff conducting water testing, dialysate mixing, pH/conductivity testing, etc. (V260)

### **Triggers for citation or more investigation of concerns:**

- Chlorine removal/carbon system
  - 2 or more carbon tanks with sample port between **not** present (V192)
  - Insufficient carbon empty bed contact time (<10 minutes total EBCT)-verify this by interview and/or record review-surveyors are **not** expected to calculate EBCT (V195)

- Observed total chlorine test result greater than maximum allowable level; test done incorrectly or with incorrect reagents/equipment (V196)
- Staff assigned total chlorine testing has inadequate knowledge of maximum allowable level of 0.1mg/L total chlorine and/or breakthrough procedures (V260)

**Extending** may include an additional observation of another staff member conducting the chlorine test, or additional staff interviews. **Note** that the absence of 2 carbon tanks with a sample port between in an outpatient water treatment system is citable on identification and should be considered an immediate jeopardy situation.

- RO
  - RO % rejection and product water conductivity or TDS not monitored daily or alarm non-functional, not audible in patient treatment area (V200)

**Extending** should include an interview with technical administrative staff. **Note** that the absence of functional methods for monitoring RO function and warning staff of problems is citable on identification. If the water treatment components appear in obvious disrepair, consider reviewing the pre-treatment and water distribution components for compliance with the applicable V-tags (V188-191, V198-215).

- DI, if present (if part of a back-up plan, each trigger below should be included in the plan)
  - Resistivity monitor or alarm non-functional; alarm not audible **and** visible in patient treatment area; resistivity not monitored and recorded at least twice per treatment day (V202, 203)
  - Automatic divert-to-drain or automatic cut-off valve to stop water flow to the dialysis machines not present or non-functional (V203)
  - Staff unaware of accurate monitoring, minimum allowable resistivity of 1.0 megohm or actions for DI tank exhaustion (i.e., stop dialysis) (V260)
  - No ultrafilter in-line post DI (V204)

**All of the above DI triggers are citable on identification, due to the serious safety hazard poorly managed and monitored DI systems present to patients.**

- Interviews
  - Water/dialysate samples not drawn before disinfection (V254)
  - Water distribution system not disinfected at least monthly (V219)
  - Each HD machine not cultured at least annually (V253)
  - Staff unaware of correct dialysate concentrate mixing, acid concentrate batch testing, etc. (V260)

**Extending** may include additional interviews with staff responsible for applicable water & dialysate activities, observations of dialysate mixing and acid concentrate batch testing (V229, V232), and review of dialysate mixing and bicarbonate system disinfection logs (V230,239).

- Log reviews
  - Total chlorine results exceeding 0.1mg/L without documentation of appropriate actions taken (V197)
  - Chemical analysis of product water not done at least annually (V201)
  - Irregularities, trends of omitted tests (V178, 196, 199, 213, 252, 253)
  - Microbiological results of water or dialysate exceeding action or maximum levels without documentation of appropriate actions taken (V178, 180)
  - Practice audits of staff conducted less than annually (V260)

**Extending** should include technical administrative staff interview and review of an equal number of additional logs, e.g., 2 more months of total chlorine logs or RO logs, 12 more months of chemical analysis, etc.