OLIVE VIEW-UCLA MEDICAL CENTER
DEPARTMENT OF NEPHROLOGY
POLICY & PROCEDURE

NUMBER: 11747
VERSION: 1

SUBJECT/TITLE: DIALYSIS: CHLORAMINE REMOVAL FROM RENAL DIALYSIS WATER

POLICY:

1. The chemical purity of dialysis solution is important if patient injury is to be avoided. Dialysis solution is prepared from purified water. The purity of the water used to prepare dialysis solution is the responsibility of the dialysis service.

2. The maximum chloramine concentration in the hemodialysis system product water will not exceed 0.1mg/L.

3. The following minimum equipment requirements for chloramine removal will be followed:
   - Two carbon block filters installed in series.
   - The placement of the two carbon block filters will be upstream of the reverse osmosis (R.O.) membrane.
   - The R.O. membrane will be protected from carbon blocks with 1 micron pre-filters.

4. The operating polices for the carbon block filters treatment system includes:
   - Testing of the water for chloramine as it exits the first carbon block filter shall be performed prior to every treatment. In the event that more than 0.1mg/L of chloramine is detected, there shall be an immediate test for chloramine levels in the product water.
   - If breakthrough occurs, chloramine in the filter effluent exceeds 0.1 mg/L, dialysis treatments may not be started until the carbon block filter(s) have been replaced and testing verifies that it is safe to proceed with further treatment(s).
   - The Carbon Block Filters should be replaced whenever chlorine and/or chloramine breakthrough (levels higher than 0.1 mg/L) has occurred or when a 15 PSI differential drop or higher as occurred on the Filtration System.
   - It is recommended that the worker carbon block cartridge be replaced every three (3) months by rotating out the polisher, or more often if chlorine breakthrough occurs to help prevent bacterial overgrowth and subsequent bacterial seeding of downstream equipment.

5. Chloramine testing frequency and methodology:
    - Test the Carbon Block Filtration to verify the absence of total chlorine. Follow the instructions in the test kit. Always confirm the absence of total chlorine in the Carbon Block Filtration System before operating the RO unit. If the total chlorine test is ≥ 0.1 mg/L, the carbon block cartridge(s) need(s) to be replaced.
    - Take a water sample from the Chlorine Sample-Worker port to verify the absence of total chlorine. If this is acceptable, the Carbon Block Filtration System is ready for operation.
    - If the Chlorine Sample-Worker port is positive: 1) Do NOT start any dialysis treatment, 2) tag machine (out of service) and 3) notify Biomed for machine maintenance and nurse manager.
    - Chloramine testing is performed with the Reagent Strip (Serim Research Corp.) for HiSense Ultra 0.1 for total chlorine / chloramines:
    - The test is performed on water outflow from the first carbon tank.
    - If the reagent strip test is performed by the dialysis equipment technician, the test strip is to be shown to the charge nurse or senior nurse on duty after completion of the test. Test results are recorded.
    - Testing will occur prior to starting of each patient treatment.
    - Storage conditions and maximum shelf life for the chemicals used in the total chlorine residual test shall conform to the manufacturers' recommendations. The expiration date on the test strip bottle or the powder pillow is to be observed.

6. The Director, Hemodialysis Service, will certify in writing that those personnel responsible for testing for chloramine using the reagent strip test have been trained and are qualified (Appendix A).

7. All employees working in the dialysis service, and performing dialysis related services will receive orientation and have access to the policy and procedures for chloramine removal from renal dialysis water supplies.

8. Additional testing of the water and dialysate occurs as follows:
    - Testing for bacterial growth and endotoxin levels in the water and in the dialysate shall occur once per month.
    - Product water must meet the AAMI and CSA Standards for both bacteria (AAMI 100 CFU max level (or lower if required by national legislation or regulations)) / 50 CFU action level (typically the limit will be 50% of the maximum allowable level) and endotoxin levels (AAMI and CSA 0.25 EU max (or lower if required by national legislation or regulations)) / 0.125 EU action level (typically at 50% of the maximum allowable level).

- **ANSI/AAMI RD52:200 Requirements as Adopted by Reference 42 CFR 494.40 (a) 4.1.2 Bacteriology of water:** ***max & action levels:***
- The action level for the total viable microbial count in the product water shall be 50 CFU/ml, and the action level for the endotoxin concentration shall be 1 EU/mL. If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels. Conventional dialysate should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration of lower than 2 EU/mL.
- Action levels for endotoxins and microbial counts in water and dialysate are 1.0 IU/mL and 50 CFU/mL. If these levels are reached, additional disinfection is performed and tests are repeated.
- The water and dialysate will be tested for electrolytes once per month.
- Twice per year water samples will be sent to Spectra Diagnostic Laboratory for analysis for trace elements.
- All of the above tests are performed in the dialysis water.

Reporting of all unusual incidents and occurrences such as epidemic outbreak, poisoning, fire, major accident, or disaster which threaten the welfare, safety or health of patients, personnel or visitors shall be reported to the Licensing and Certification Division, Department of Health Services, State of California (714-558-4001), within 24 hours.

9. Monthly results of bacterial growth and chemical dialysate samples will be reviewed every month as part of the quality assurance data collection.

PURPOSE:

To establish the hospital's policy for removal of chloramine from renal dialysis water.

Federal standards require that "Water used for dialysis purposes is analyzed periodically and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques."[1]

The California Administrative Code, Section 5-1011 (g) states: "Dialysis water is the water used for dialysis treatment and which meets the standards established by the American Association of Medical Instrumentation (AAMI) 1981, or the Recommended Interim Products Water Standards for Hemodialysis as established by the U.S. Food and Drug Administration, 1980."[2]

DEPARTMENTS: **ALL**

DEFINITIONS: Chloramine is added to water to prevent bacterial proliferation. Chloramine causes hemolytic anemia.

PROCEDURE:

1. Product Water Culture Procedure:
   - The sample should be assayed within 4 hours of collection or be immediately refrigerated and assayed within 24 hours on a regular schedule.
   - Obtain the samples while wearing long sleeves and a mask to prevent contamination of samples; use a “mid-stream,” “clean catch,” type procedure.
   - Using alcohol, wipe the sample port and allow to air dry. Using aseptic technique, insert the male luer end of the first sterile/pyrogen free syringe into the port, withdraw the syringe plunger to the maximum sample volume. Remove and discard the syringe.
   - Using the second sterile/pyrogen free syringe, draw a sample by inserting the male luer end into the port and withdraw the appropriate sample as required for your laboratory. Aseptically transfer the sample to the lab supplied container, cap the specimen container immediately.
   - Label the specimen appropriately with:
     - Test to be performed - "culture/colony count"
     - Sample source - product water/RO, machine serial number
     - Time and date sample obtained
     - Person who obtained specimen
     - Any other pertinent information or procedures your facility or lab requires

2. Endotoxin Testing Procedure**:**
   - The samples should be assayed within 4 hours of collection or refrigerated immediately and assayed within a 24-hour period.
   - Turn on the RO. Allow the RO to run for 10-15 minutes.
   - Using alcohol, wipe the sample port and allow to air dry. Using aseptic technique, insert the male luer end of the first sterile/pyrogen free syringe into the port, withdraw the syringe plunger to the maximum sample volume. Remove and discard the syringe.
   - Using the second sterile/pyrogen free syringe, draw a sample by inserting the male luer end into the port and withdraw the

appropriate sample as required for your laboratory. Aseptically transfer the sample to the lab supplied container, cap the specimen container immediately.

- Label the specimen appropriately with:
  - Test to be performed - "culture/colony count"
  - Sample source - product water/RO, machine serial number
  - Time and date sample obtained
  - Person who obtained specimen

References:

[1]*Federal Register* Vol 41 No 108; June 3, 1976 405.2140 (a) (5).
[2]California Administrative Code, Title 24, Section 5-1011 (g).

Approved by: Bonnie Bilitch (Chief Nursing Officer), Judith Maass (Chief Executive Officer), Rima Matevosian (Chief Medical Officer)	Date: 07/03/2019
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