



Rancho Los Amigos National Rehabilitation Center

DEPARTMENT OF NURSING ADMINISTRATIVE POLICY AND PROCEDURE

SUBJECT: Hemodialysis: Reverse Osmosis Monitoring

Policy: A190.7

Effective Date: July 3, 2023

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PURPOSE: To ensure that the quality of water is safe to use for hemodialysis.

POLICY STATEMENTS:

The quality of water produced by Reverse Osmosis (RO) membranes vary according to the quality of the city water supply. RO membranes can only reject a percentage of the incoming impurities, not a fixed value. This is determined by the quality of the city water, pre-treatment, and care of the membranes. The Total Dissolved Solids value will be based on the Association for the Advancement of Medical Instrumentation (AAMI) Water Standards.

Total complete water analysis is performed twice a year regardless of the Total Dissolved Solids value. This will ensure that no individual element exceeds its safety limit.

If the Total Dissolved Solids value is out of established parameters from the AAMI Water Standard Guidelines notify Nurse Manager, Infection Control, Medical Safety Officer who will determine if that level is acceptable to continue dialysis. If the quality is not satisfactory, the RO membranes will be replaced.

PROCEDURE: To be performed by Dialysis Equipment Technician

1. Replace the carbon filter of the portable Reverse Osmosis system quarterly or more frequently as necessary
2. Check endotoxin with Limulus Amebocyte Lysate (LAL) and bacterial cultures of dialysate from each dialysis machine once a month
3. Send dialysate specimen to the lab for chemistry analysis (Spectra)
4. Check lab results against minimum and maximum allowable limits noted on the log sheets
5. Log results and comments in the HD machine culture book. Report any problem to the Nurse Manager immediately. **If the results are out of established parameters**, the Dialysis Equipment Technician must notify the Dialysis nurse or Nurse Manager immediately.
6. The dialysis nurse or Nurse Manager will request immediate Corrective Action Measures (See below action plan):
 - Identify and tag the affected machine "Out of Service - Do not use" and take the machine out of service
 - Communicate and provide a copy of the out-of-range result to the Medical Safety Officer, Clinical Nurse Director, and Infection Prevention
 - Clean and disinfect machine and portable RO system per manufacturers' recommendations
 - Review the water culture collection procedure with Dialysis Team
 - Re-culture the affected machine as soon as possible. This machine will remain "Out-of-Service - Do not use" until all results revert to "within normal limits"
 - Provide a copy of re-culture results to the Medical Safety Officer, Clinical Nurse Director, and Infection Prevention Department
 - Monthly testing results are reported to Infection Control

Bacteriologic and Endotoxin Monitoring and Action Plan

Bacteria standard for water to prepare for Dialysis fluid

1. The maximum level of bacteria in the water to prepare dialysis fluid must not exceed the AAMI standard
2. The total viable microbial count should be less than 200 CFU/mL. When the microbial count is above 50CFU/MI, corrective measures shall promptly be taken to reduce the levels

3. The recommendation of corrective measures by Infection Prevention and Control is:
 - a. Isolate the machine and label it with the sign "DO NOT USE"
 - b. Clean & disinfect the RO machine as indicated in the P&P and manufacturer's operational manual
 - c. Machine should be cultured and only be used once the microbiological result is within limits

Endotoxin Standard for water used to prepare for dialysis fluid

1. The maximum level of endotoxin in water used to prepare dialysis fluid must not exceed the AAMI standard
2. Endotoxin concentration should be less than 2EU/mL. When the endotoxin level is above 1EU/mL, the machine is disinfected and cultured as same as the bacteriologic monitoring standard

Sample Collection Procedure

The bacterial and endotoxin levels are evaluated monthly to ensure the water used for dialysis fluid does not exceed AAMI standards for bacterial contamination and endotoxin

1. Perform hand hygiene and don PPE
2. Remove any hose or tubing connected to the sampling port
3. Flush the sampling port for a minimum of 2 minutes
4. Collect the sample midstream in samples sterile container sample. It should be collected using a "clean catch" technique to minimize potential contamination of the sample model, leading to false positive results
5. Disinfect sample ports only with alcohol and allow to dry before sample is drawn
6. Change gloves between each collection
7. Label the sample with the name of the machine and serial number, dialysate or water source, date, and time
8. Place the sample in the microbiology lab and send to contract laboratory

Corrective Action When Test Exceeds the Action Level

It is the users' responsibility to monitor the system's water bacteriology to determine ongoing compliance with the standard. Infection Control will review the microbiology and endotoxin results. The laboratory personnel should report any result exceeding the standard to Dialysis Equipment Technician. The Dialysis Technician will notify to Nurse Manager.

1. If the test results are above the action level, isolate the dialysis machine and only be used until it is within the normal range
2. Disinfect Dialysis Machine, obtained a second culture sample and send to the contract laboratory

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Rancho Los Amigos Infection Prevention and Control Policy number IC100

Rancho Los Amigos Policy C109- *Transfusion of Blood Products and Colloid Solution*

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