Name of Policy:	**Hemodialysis Reverse Osmosis (RO) Water Quality**	
Policy Number:	3364-118-18	
Department:	End Stage Renal Disease Program/ Hemodialysis (Nursing Service)	
Approving Officer:	Chief Nursing Officer &Clinical Director, End Stage Renal Disease Program	
Responsible Agent:	Clinical Director, End Stage Renal Disease Program	Effective Date: 6/1/2022
Scope:	The University of Toledo Medical Center	Initial Effective Date: November, 1984

_____ New policy proposal	_____ Minor/technical revision of existing policy
_____ Major revision of existing policy	**X** Reaffirmation of existing policy

(A) Policy Statement

The quality of water used for hemodialysis will be routinely monitored.

(B) Purpose of Policy

To ensure that the water treatment system meets or exceeds the minimum standards as published under the American Association for Medical Instrumentation (AAMI) guidelines and the guidelines of the State of Ohio.

(C) Procedure

1. Reverse Osmosis (RO) water sample will be cultured on a rotating basis with all patient care outlets sampled at least once yearly.
    a. Collect sample at the venous hanson sample port.
    b. Cleanse the sample port with a chlorhexidine swab. Draw off 30 ml and discard. Draw off 10ml for specimen. Fill appropriate container, label, and send sample to Spectra Lab immediately after collection. If unable to send immediately, refrigerate specimen until able to ship.
    c. Total bacterial count should not exceed 200 cfu's/ml. Any equipment that exceeds this level will be taken out of service, re-disinfected and re-cultured. Equipment may not return to service unless total bacterial count is less than 200 cfu's.
2. Dialysate fluid (RO water mixed with dialysate concentrate) sample from dialysis machine for culture and Litmulus Amoebocyte Lysate (LAL) endotoxin will be obtained on a rotating basis. All dialysis machines will be sampled at least once yearly.
    a. Individual machines will be cultured and have LAL specimen collection on a rotational basis per schedule in Water Log Book.
    b. Collect sample at the venous hanson sample port.
    c. Cleanse the sample port with a chlorhexidine swab. Draw off 30 ml and discard. Draw off 10 ml for specimen. Fill appropriate container, label and send sample to Spectra Lab immediately after collection. If unable to send immediately, refrigerate specimen until able to ship.
    d. Total bacterial count should not exceed 200 cfu's/ml. LAL level should not exceed >2.0 EU. Any equipment that exceeds these levels will be taken out of service, re-disinfected and re-cultured. Equipment may not return to service unless total bacterial count is less than 200 cfu's for cultures and <2.0 EU for LAL specimens.

3. Preliminary reports are followed for action or out of service levels of bacteria or LAL content and will be re-cultured or re-disinfected and re-cultured as needed.
4. Final reports are reviewed by the Medical Director who will sign and date and make recommendations as necessary to address any problems or issues.
5. Culture Action Levels are any result >50 CFU/ml. This level will require re-culturing
   If second specimen is also >50 CFU/ml, unit will be disinfected and re-cultured.
6. LAL Action Level is >1.0 EU. If specimen result> 1.0 UE, take unit out of service and repeat LAL test.
7. Any specimen result above Action Level will initiate a collaborative investigation between Biomed and Hemodialysis to include observation of compliance with disinfection and sampling procedures and an evaluation of microbiological data for the previous 3 months to look for trends. This information will be evaluated, and results shared with the Medical Director.
8. If any patient experiences a pyrogenic reaction during dialysis or septicemia is suspected, samples of the dialysate fluid from that machine will be immediately collected for culture and evaluated for cause. Medical Director will be informed and participate in identification and correction of cause.
9. A reverse osmosis water sample will be analyzed for chemical contaminants.
    a. Weekdays: RO system will be monitored by the Biomed technician or hemodialysis staff and entered in the Daily Log Book; if hardness increases to more than 1.0 grain/gallon or if the total chlorine test exceeds 0.1 ppm, the Biomed Department, Hemodialysis Unit, and Medical Director will be notified. The Water Treatment Vendor may be notified for technical assistance.
    b. Daily Chloramine testing will be done by the Biomed Department or Hemodialysis Staff and recorded in log. If test >0.1 ppm, the RO water cannot be used for dialysis. Biomed, Hemodialysis unit, and Medical Director will be notified. Water treatment vendor may be notified for technical assistance.

All test results will be recorded in the appropriate logs and will be reviewed by the Medical Director as part of the Quality Improvement program.

10. Failure in the piping of the RO system.
    a. Upon completion of repairs to the piping, the RO system shall be flushed, sanitized, flushed and tested.
    b. The chloramine test shall not exceed 0.1 ppm. The system shall be flushed until this is achieved.
    c. A water sample will be cultured. The total bacterial count should not exceed 200 cfu's/ml.
    d. Upon achieving desired results, the system can be returned to service.
    e. Medical Director is to be notified when system is back in service.

Approved by:		**Review/Revision Date:**
/s/ Kurt Kless, MSN, MBA, RN, NE-BC Chief Nursing Officer	Date	1985 7/05 1986 11/06 1987 1/23/2008 1988 8/2011 1990 8/2014 9/91 5/8/2015 1/93 6/2015 3/93 6/1/2018 4/94 6/2022 3/95 4/96 9/97 10/98 2/00 7/02 7/03
/s/ Deepak Malhotra, MD, PhD Clinical Director, End Stage Renal Disease Program	Date	
Review: Policy & Standard Committee, 8/11, 814, 6 /15, 6/2022 *Revision Completed By: Trish Carter, DNP, RN 5/2018*		**Next Review Date: 6/2025**
Policies Superseded by This Policy:		

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.