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PROVINCIAL STANDARDS & GUIDELINES

BCRenal
an agency of the Provincial Health Services Authority

Dialysis Water Treatment Equipment Monitoring

December 2017

Developed by the BCPRA Hemodialysis Committee

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IMPORTANT INFORMATION

This BCPRA guideline/resource was developed to support equitable, best practice care for patients with chronic kidney disease living in BC. The guideline/resource promotes standardized practices and is intended to assist renal programs in providing care that is reflected in quality patient outcome measurements. Based on the best information available at the time of publication, this guideline/resource relies on evidence and avoids opinion-based statements where possible; refer to www.bcrenalagency.ca for the most recent version.

For information about the use and referencing of BCPRA provincial guidelines/resources, refer to http://bit.ly/28SFr4n.

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1.0 Scope of Guideline

This guideline applies to in-centre and community dialysis units (CDUs) that provide hemodialysis (HD) and/or hemodialfiltration (HDF). It is applicable to both adult and pediatric units.

The purpose of this guideline is to support the implementation of common standards and processes for monitoring the equipment used to treat dialysis water within BC's HD units.

2.0 Summary of the Literature & Internet

Patients undergoing conventional hemodialysis three times per week are exposed to 300-600 litres of water per week, depending on their prescription (Coulliette, 2013). More than 90% of the dialysate delivered to the dialyzer is water (Layman-Amato, 2013).

The source of water used in HD consists basically of drinking water, purified by various techniques, whose composition and quality depend on its origin. Water treatment systems employ several physical and/or chemical processes either singly or in combination. These systems may be portable units or large facility systems.

The quality of the source water can change from season to season or even day to day (Layman-Amato, 2013). Monitoring of the quality of water used for dialysis is a vital aspect of hemodialysis treatment. Minerals in the water can be toxic to patients and harmful to equipment.

Refer to the Appendix for a visual of a dialysis water treatment system.

3.0 Definitions & Abbreviations

DI: Deionization

Dialysis water: Water that has been treated to meet the requirements of the CSA standard and is suitable for HD use in applications.

GPG: Water hardness unit; grains per gallon.

Hemodialysis (HD): Form of renal replacement therapy in which waste solutes are removed primarily by diffusion from blood flowing on one side of a membrane into dialysis fluid flowing on the other side.

MIs: Manufacturer's instructions

Percent rejection: Measurement of rejection of solutes by RO membrane and, thus, measurement of equipment performance.

Product water: Water produced by a water treatment system or individual component thereof.

PSI: Pressure unit; pounds per square inch

RO: Reverse osmosis. Water is pushed through a membrane with pores small enough to remove most contaminants, including ions.

Salt bridge: Where salt at the top of the tank solidifies, making it appear as though the tank is full when it is actually empty underneath.

TDS: Total dissolved solids

Water treatment system: Collection of water treatment devices and associated piping, pumps, valves, gauges, etc. that together produce treated

water for hemodialysis applications and deliver it to the point of use.

4.0 Recommendations

Recommendation #1: Conduct performance checks on dialysis water equipment as per Table 1.

Table 1 (see page 4) provides guidelines on monitoring systems used for preparing and distributing dialysis fluid. Not every item listed in the table will be required in all dialysis units and the frequency of monitoring may differ depending on the nature of the water supplied to the dialysis unit (e.g., whether the water supply is disinfected using chloramine). The water quality management program for a given centre will depend on the components used in that unit's water treatment system, the purpose for which the fluid is to be used, the results of validation procedures and any applicable local regulations (CSA/ISO 23500: 2011(E), page 50).

Recommendation #2: Document all checks on designated log sheet(s).

Log sheets may be site or manufacturer specific.

Recommendation #3: Develop mechanisms within each Health Authority for designated individuals to review the results and, if required, take action.

5.0 References

CSA Standards (CSA)

CAN/CSA-ISO 13959-11-Water for haemodialysis and related therapies (Adopted ISO 13959: 2009, 2nd edition, 2009-04-15), *Canadian Standards Association*, 2011.

CAN/CSA-ISO 26722-11–Water treatment equipment for hemodialysis applications and related therapies (Adopted ISO 26722:2009, First edition, 2009-04-15), *Canadian Standards Association*, 2011.

CAN/CSA-Z23500-12-Guidance for the preparation and quality management of fluids for haemodialysis and related therapies, *Canadian Standards Association*, March 2012.

Articles

Coulliette, A. and Arduino, M. (2013). Seminars in Dialysis, 26:4 (July-August), p.p., 427-438. http://onlinelibrary.wiley.com.ezproxy.library.ubc.ca/doi/10.1111/sdi.12113/epdf. Accessed Sept 10, 2015.

Layman-Amato, R, Curtis, J and Payne, G (2013). Nephrology Nursing Journal, 40:5 (September-October 2013), p. 383. https://tinyurl.com/ych9g9cs Accessed Sept 10, 2015.

6.0 Sponsors

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bcrenalagency.ca for the most recent version.
Developed by:

- a working group of biomedical/renal technicians from across BC (one per health authority)

Approved by:

- BCPRA Hemodialysis Committee
- BCPRA Medical Advisory Committee

For information about the use and referencing of BCPRA provincial guidelines/resources, refer to http://bit.ly/28SFr4n.

Table 1: Components, Values & Intervals for Monitoring Water Treatment Equipment

Component	What to Monitor	Typical Values	Frequency, CSA/ISO Guidelines	Frequency, BC Recommendation	Rationale for Variance from CSA-ISO Guideline
Feed water					
Backflow prevention valves	To check that water cannot reverse its flow	Not applicable	Not on CSA/ISO guidelines	Annually or as requested by the municipality.	
Temperature blending valve	Water temperature	Appropriate water temperature with minimal fluctuation.	Not on CSA/ISO guidelines	Daily	Some systems don't require the blending valve so monitoring would not be required.
Pre-treatment					
Sediment filter (multi media or NextSand) or cartridge filter	Pressure drop across the filter	Based on manufacturer's instructions (MIs) - typically a delta of 10 psi	Daily	Daily	If no history of sediment or cartridge filter clogging, may reduce monitoring.
Water softener	Product water softness	Based on MIs of RO equipment - typically <1 grain	Not specific in CSA/ISO guidelines.	Monthly	If feed water hardness is very low, a softener and, therefore monitoring, may not be required.
Carbon beds	Product-water total chlorine between the beds	<0.1 mg/l of total chlorine	Beginning of each treatment day.[1] For units that run 24/7, unit to determine time of day for sampling.	Daily	
Sediment/carbon control head	Backwash cycle timer setting	Based on MIs	Daily	Monthly & PRN (e.g., power outage; work done on system)	Not essential. No harm to patient if timer setting is incorrect.

[1] Testing for total chlorine should be performed at the beginning of each treatment day prior to the patient's initiating treatment. Where chloramine is used to disinfect the potable water supply at a level of 1 mg/l or more, testing should be repeated prior to the beginning of each patient shift; if there are no set patient shifts, testing should be performed approximately every 4 h during operation. More frequency monitoring could be appropriate during temporary operation with a single carbon bed, which can occur following breakthrough of the first bed. In such instances, testing is performed on water exiting the second carbon bed in a series-connected pair. The decision to change the frequency of monitoring should be based on the past performance of the system and on whether changes in feed-water quality have occurred. Samples should be drawn when the system has been operating for a least 15 min. The analysis should be performed onsite, since total chlorine levels will decrease if the sample is not assayed promptly. Results of monitoring should be recorded in a log sheet.

Component	What to Monitor	Typical Values	Frequency, CSA/ISO Guidelines	Frequency, BC Recommendation	Rationale for Variance from CSA-ISO Guideline
Water softener controller head	Regeneration cycle timer setting	Based on MIs	Daily	Monthly	Not essential. No harm to patient if timer setting is incorrect.
Water softener brine tank	Level of undissolved salt in tank	Based on MIs	Daily	Weekly	Effect of water softener lasts at least a week. No harm to patient if run out.
Pre endotoxin-retentive filters	Pressure drop across the filter at a fixed flow rate or product water flow rate at a fixed pressure drop	Based on MIs	Daily	Daily	Manual recording not needed if filter is monitored by the system or filters are self-cleaning.
Reverse osmosis (RO) system					
Reverse osmosis system	Product water conductivity Feed water conductivity Calculated % rejection Product flow rate	Depends on local feed water quality (action levels vary across BC HD units but are typically 5 - 10 uS). Depends on local feed water quality. >85% Sufficient to meet the needs of dialysis machine consumption.	Daily; preferable option is to set up audible alarm to sound if outside recommended limits.	Depends on local feed water quality. Depends on local feed water quality. Depends on local feed water quality. Depends on local feed water quality.	CSA recommends monitoring reject & calculated recovery rates; however, this does not provide useful information on a daily basis & may not be applicable to all systems.
Delivery system					
Deionizers (DI tanks or cannisters)	Product water resistivity or conductivity	Resistivity ≥1 MΩ cm Conductivity <1 uS/cm	Continuous monitoring	Set up audible alarm to sound if outside recommended limits. Sound is audible to end users.	Deionization can be set up as a dry back-up system and does not require continuous monitoring unless the system is put into operation.

Component	What to Monitor	Typical Values	Frequency, CSA/ISO Guidelines	Frequency, BC Recommendation	Rationale for Variance from CSA-ISO Guideline
Post endotoxin-retentive filters	Endotoxin levels (Eu/mL)	<0.25 EU/mL (action level: >0.125 EU/mL)	Monthly (CSA)	Monthly	These filters should not clog because they are post RO filters.
UV irradiators2	Energy output and/or the lamp lifespan	Based on MIs	Monthly	Daily: Check that light is on. Monthly: Check to see the energy output is sufficient. Annually: Replace lamp.	
Hot water disinfection systems	Temperature and time of exposure of the system to hot water	Based on MIs	During each disinfection	Monitored by the system. If out of range, system will alert. Check that each disinfection was successful.	
Chemical disinfection systems	Concentration of germicide in water and contact time	Based on MIs	During each disinfection	Automated chemical disinfection: Will be monitored by the system. If out of range, system will alert. Check that each disinfection was successful. Manual chemical disinfection: Verify the concentration during disinfection as per MIs. Check post-disinfection residual manually.	

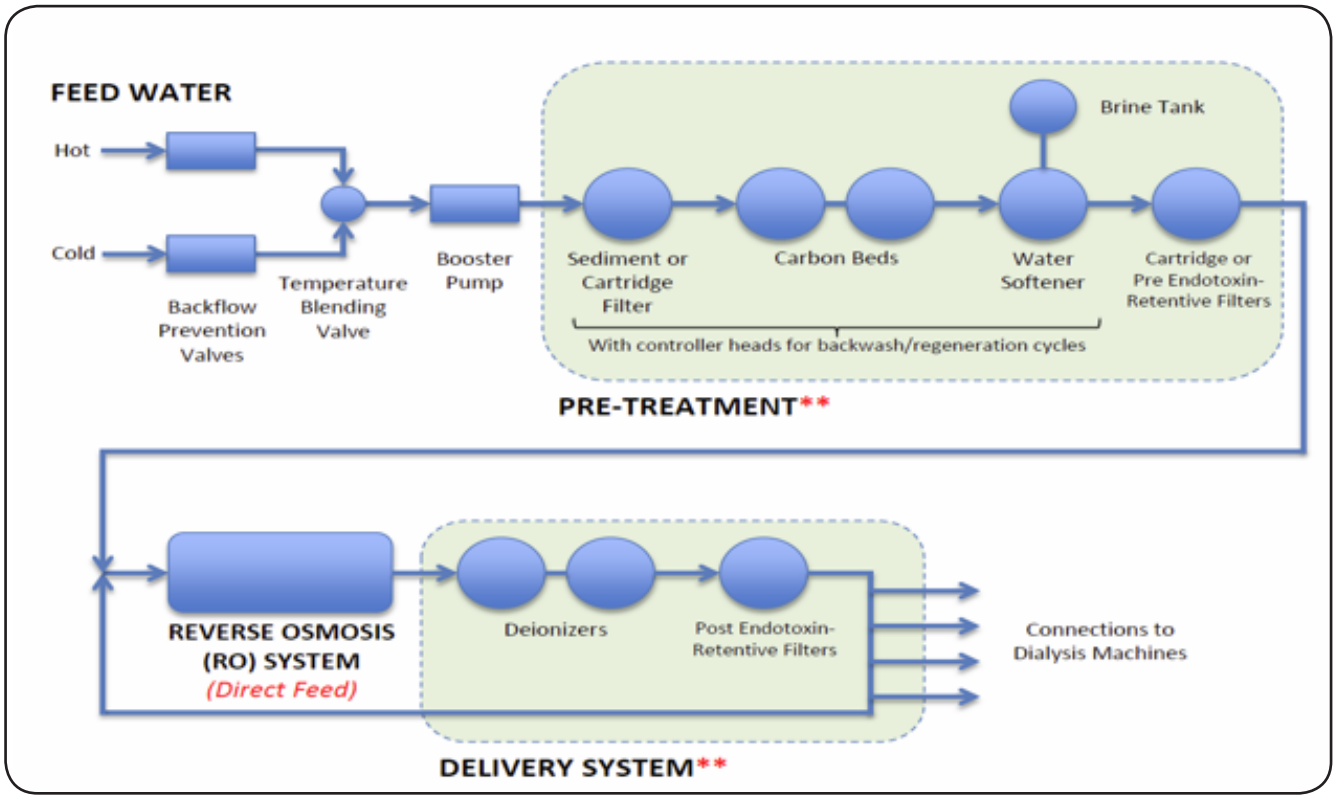
[2] Try and phase out.

Notes:

1. The list of "items to monitor" in Table 1 was extracted from ISO 23500:2011(E) Annex C Monitoring Guidelines for Water Treatment Equipment, Distribution Systems and Dialysis Fluid.
2. Six items from the ISO guideline were not included in Table 1 as they are addressed in separate BCPRA guidelines:
   - Sampling for water system chemical contaminants: BCPRA Chemical & Chlorine Sampling of Dialysis Water.
   - Sampling for dialysis water storage tanks and water distribution piping system: BCPRA Dialysis Water System Microbiology & Endotoxin Sampling.
   - Sampling of standard and ultrapure dialysis fluid: BCPRA Dialysate Microbiology & Endotoxin Sampling.

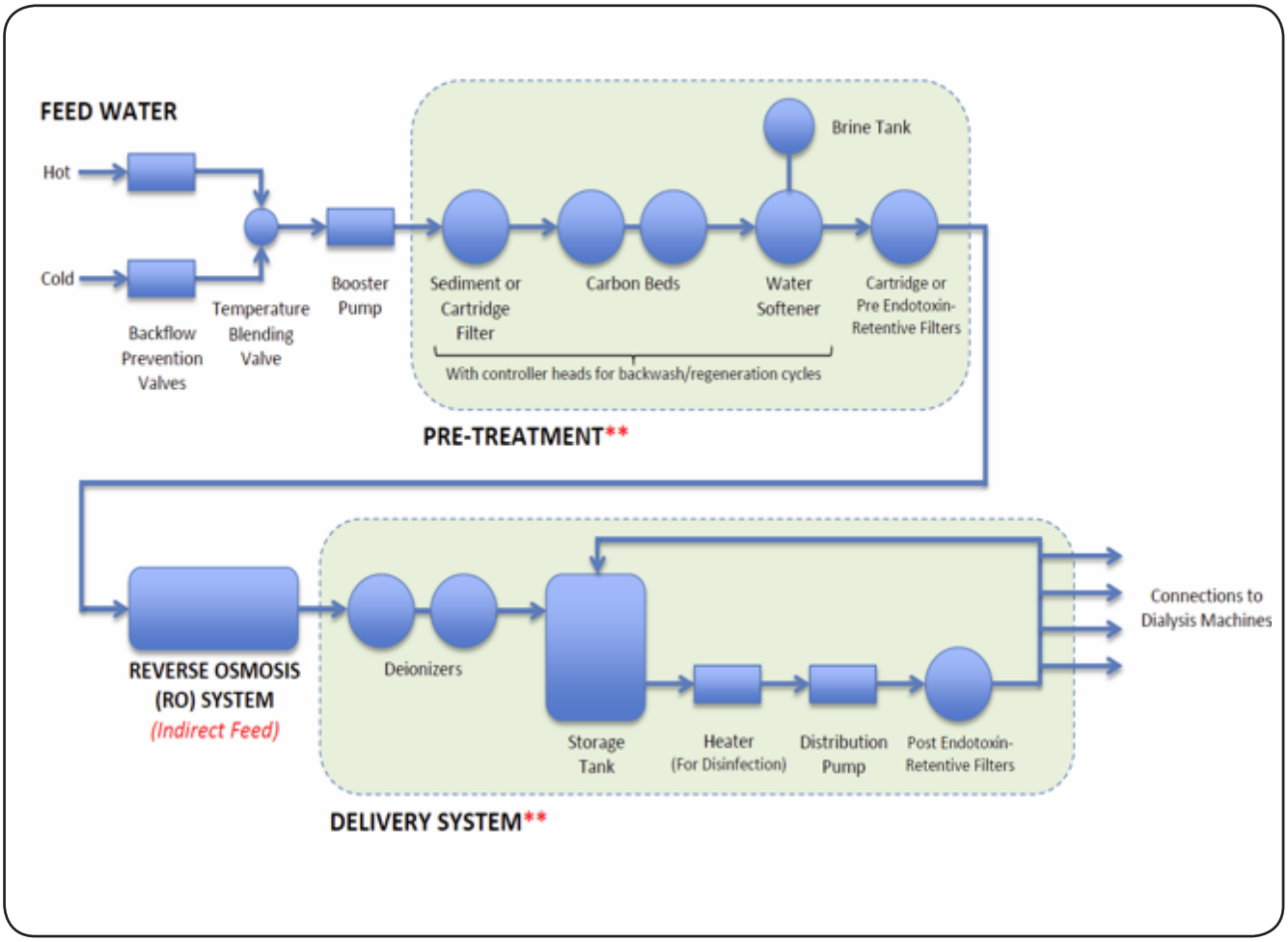
7.0 Appendix: Components of a Dialysis Water Treatment System

Direct Feed



** Actual components and configurations will vary - this is a guide only.

Indirect Feed



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