Clinical Practice Standards and Procedures for Dialysis Water Quality:
3: Chemical Analyses of Dialysis Water

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The most current version is located on the BCPRA Website (www.bcrenalagency.ca)

1.0 PRACTICE STANDARD

1.1. Purpose

The Biomedical Technologist or Renal Dialysis Technician who is trained and has demonstrated competency in dialysis water practices will use the procedure outlined in this document to collect dialysis water samples for chemical analyses, and to perform the necessary actions should test results for any of the chemical contaminants exceed its acceptable limits.

1.2. Standards (based on CSA-ISO)

Dialysis water must not contain chemical contaminants at concentrations in excess of those listed in the following table:

<table>
<thead>
<tr>
<th>Contaminant</th>
<th>Max. Concentration (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contaminants with documented toxicity to haemodialysis</td>
<td></td>
</tr>
<tr>
<td>Aluminum</td>
<td>0.01</td>
</tr>
<tr>
<td>Total chlorine</td>
<td>0.1</td>
</tr>
<tr>
<td>Copper</td>
<td>0.1</td>
</tr>
<tr>
<td>Fluoride</td>
<td>0.2</td>
</tr>
<tr>
<td>Lead</td>
<td>0.005</td>
</tr>
<tr>
<td>Nitrate (as N)</td>
<td>2</td>
</tr>
<tr>
<td>Sulfate</td>
<td>100</td>
</tr>
<tr>
<td>Zinc</td>
<td>0.1</td>
</tr>
<tr>
<td>Electrolytes normally included in dialysis fluid</td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>2 (0.05 mmol/L)</td>
</tr>
<tr>
<td>Magnesium</td>
<td>4 (0.15 mmol/L)</td>
</tr>
<tr>
<td>Potassium</td>
<td>8 (0.2 mmol/L)</td>
</tr>
<tr>
<td>Sodium</td>
<td>70 (3.0 mmol/L)</td>
</tr>
<tr>
<td>Trace elements</td>
<td></td>
</tr>
<tr>
<td>Antimony</td>
<td>0.006</td>
</tr>
<tr>
<td>Arsenic</td>
<td>0.005</td>
</tr>
<tr>
<td>Barium</td>
<td>0.1</td>
</tr>
<tr>
<td>Beryllium</td>
<td>0.0004</td>
</tr>
<tr>
<td>Cadmium</td>
<td>0.001</td>
</tr>
<tr>
<td>Chromium</td>
<td>0.014</td>
</tr>
<tr>
<td>Mercury</td>
<td>0.0002</td>
</tr>
<tr>
<td>Selenium</td>
<td>0.09</td>
</tr>
<tr>
<td>Silver</td>
<td>0.005</td>
</tr>
<tr>
<td>Thallium</td>
<td>0.002</td>
</tr>
</tbody>
</table>

The quality of the dialysis water must be verified to meet these standards at the time of installation of the water treatment system. Chemical analyses on feed water must be performed to determine the compatibility of the system (or portable RO) with the feed water and the suitability of the RO for providing dialysis water that meets the above standards. Monitoring and testing the chemical concentration levels
source water suggest worsening water quality, and at no less than annual intervals in in-centre units, community clinics, and for portable ROs.

2.0 DEFINITIONS AND ABBREVIATIONS

**Chlorine, combined** Chlorine that is chemically combined, such as chloramine compounds.

**Chlorine, free** Dissolved molecular chlorine.

**Chlorine, total** Sum of combined chlorine and free chlorine.

**Dialysis water** Water that has been treated to meet the requirements of the CSA/ISO standards and which is suitable for use in haemodialysis applications, including the preparation of dialysis fluid.

**Feed water** Water supplied to a water treatment system or an individual component of a water treatment system.

**Haemodialysis** 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.

**RO** Reverse osmosis.

Disclaimer: The procedure steps may not depict actual sequence of events. Site-specific considerations may be made when applying the following procedures and protocols.

3.0 EQUIPMENT

- Sampling units (provided by third party testing laboratory; see Special Considerations for a list of approved laboratories in BC)
- Gloves

4.0 PROCEDURE

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
</table>
| 4.1 | Collect water samples.  
*Note 1:* Samples should be collected as instructed by the third party testing laboratory.  
*Note 2:* Samples should always be collected before cleaning/disinfection.  |
| 4.1.1 | Feed water samples must be collected from source water, prior to the first water treatment filter.  |
| 4.1.2 | Dialysis water samples must be collected from a point in the distal segment of the loop, immediately prior to where water returns to the RO, or immediately prior to where the water re-enters the storage tank, if one is present.  
For portable ROs, collect the sample from the outlet of the portable RO.  |
| 4.2 | Send the samples to the third party laboratory for testing and log all incoming results.  |
| 4.3 | Review the test results.  
*4.3.1* If none of the chemical contaminants exceed the acceptable concentration limits, resume routine testing  
Otherwise, take corrective measures (go to step 4.5).  |
| 4.4 | Perform corrective action (refer to Process Flowchart below).  
*4.4.1* If this is the 1st round of samples, retest immediately (repeat steps 4.1.2 to 4.4.1).  
*4.4.2* If this is the 2nd (or more) round of samples:  |
4.4.2.1 Notify the Area Renal Manager, Biomed Risk & Quality, the Biomed Lead Tech, and the Nephrologist.

4.4.2.2 Assess the RO membranes.

4.4.2.3 If necessary, shut down the RO, complete a PSLS report, and replace the membranes.

4.4.2.4 Initiate troubleshooting protocol:
   - Collect and test samples from other parts of the distribution loop (applicable to RO systems only).
   - Evaluate/correct sample collection technique.
   - Evaluate/correct compliance with disinfection procedures.
   - Evaluate/correct water system components. (Verify that everything checks out as per the Dialysis Water Equipment Monitoring clinical standard.)

4.4.2.5 Retest the system or portable RO (repeat steps 4.1 to 4.4.1).

5.0 DOCUMENTATION CONSIDERATIONS

All chemical analyses test results for feed and dialysis water received from the third party testing laboratory must be documented. These results must be reviewed by the Area Renal Manager, and reviewed and signed off by the Nephrologist annually.

6.0 SPECIAL CONSIDERATIONS

- While taking samples, it is important that no contact is made with the inside of the sampling unit.
- The procedure should be done when the system is operating under stable conditions representing normal operation.
- The procedure should not be done within a 2-hour period following a heat clean procedure as the sample may be too warm.
- List of laboratories currently approved by the BC Provincial Health Officer for water testing (alphabetical order):
  - Agrichem Analytical
  - ALS Laboratory Group – Environmental Division – Calgary
  - ALS Laboratory Group – Environmental Division – Vancouver
  - BCCDC PHMRL Environmental Microbiology Laboratory
  - C R D Water Services Laboratory
  - ECO Tech Laboratory Ltd.
  - Exova Canada Inc.
  - IG Micromed Environmental Inc.
  - MB Laboratories Ltd.
  - Metro Vancouver Water Laboratory
  - North Island Laboratories
  - Northern Laboratories (2010) Ltd.

7.0 REFERENCES

- Dialysate for hemodialysis (ANSI/AAMI RD52:2004/(R)2010), Association for the Advancement for Medical Instrumentation, Arlington (VA), 2009.
- Laboratories Approved by BC Provincial Health Officer for Drinking Water Microbiology Testing, Enhanced Water Quality Assurance, BC Centre for Disease Control, Dec. 2010. [Available online:
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NHA Renal Biomedical Technologists and Renal Program Technicians and Managers
FHA Renal Biomedical Technologists and Renal Managers
VIHA Renal Biomedical Technologists and Renal Managers
PHC Renal Biomedical Technologists and Renal Managers

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12.0 PROCESS FLOWCHART
Chemical Analyses of Dialysis Water Process Flowchart

START: Designated tester* takes feed water samples and dialysis water samples at the end of the water distribution loop.

Send samples to third party laboratory for testing

Scan and file lab results on Renal Water Quality SharePoint site

Result exceeds max. limit

YES

First samples?

YES

Retest immediately; retake samples

NO

Result not exceeded

NO

Resend samples

YES

Membranes need replacement?

NO

Assess the RO membranes

YES

Shut down RO

Complete PSLS report

Replace the RO membranes

Notify:
- Area Renal Manager
- Biomed Lead Tech and Risk & Quality
- Nephrologist

Results are reviewed by the Area Renal Manager

Results are reviewed and signed off by the Nephrologist

Resume routine chemical contaminants testing annually or semi-annually, accordingly

*Note: Designated tester may be a Biomedical Technologist or Renal Dialysis Technician, depending on the particular renal site.