Clinical Guideline

South Australian Haemodialysis Guidelines: Routine Water Testing and Reverse Osmosis Monitoring

Policy developed by: Statewide Renal Clinical Network
Approved SA Health Safety & Quality Strategic Governance Committee on: 18 August 2015
Next review due: 3 Years

Summary
This Guideline and instructions are for haemodialysis machines and water from Reverse Osmosis Units that are used in the haemodialysis machines and processes.

Keywords
Haemodialysis, Guidelines, South Australian, SA, Reverse Osmosis Unit, Water Quality, Reverse Osmosis Monitoring, Routine Water Testing, Bacteria and Endotoxin Testing.

Policy history
Is this a new policy? N
Does this policy amend or update an existing policy? Y
Does this policy replace an existing policy? Y
If so, which policies?
South Australian Haemodialysis Guidelines; Routine Water Testing and Reverse Osmosis Monitoring, Jan 2013

Applies to
CALHN, SALHN, NALHN, CHSALHN, WCHN, Public Renal Dialysis Units in South Australia.

Staff impact
SA Health Biomedical Engineering Staff
Renal Unit, Medical, Nursing, Allied Health, Pathology staff.

PDS reference
CG225

Version control and change history

<table>
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<tr>
<th>Version</th>
<th>Date from</th>
<th>Date to</th>
<th>Amendment</th>
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<tr>
<td>1.0</td>
<td>Jan 2013</td>
<td>June 2015</td>
<td>Original version</td>
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<tr>
<td>2.0</td>
<td>June 2015</td>
<td>June 2018</td>
<td>Revised version</td>
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South Australian Haemodialysis Guidelines

- Routine Water Testing
- Reverse Osmosis Monitoring

June 2015
Background

The Water Quality Working Group has drafted this guideline. The Working Group reports to the Renal Clinical Network Steering Committee

The Working Group’s membership consists of:

Tiffany Whittington (Chair)  Clinical Practice Improvement CPC CNARTS
Fiona Donnelly  Clinical Services Coordinator Haemodialysis, CNARTS
Dr. George Passaris  Nephrologist, Flinders Medical Centre
Michael Connors  Technician, SA Health, Statewide Biomedical Engineering
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Acknowledgements

The working group acknowledges the NSW Renal Clinical Network document Water Pre-Treatment for Dialysis in NSW – A set of guidelines and standards.

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### Glossary of Terms

<table>
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<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AAMI</strong></td>
<td>Association for the Advancement of Medical Instrumentation</td>
</tr>
<tr>
<td><strong>Combined chlorine</strong></td>
<td>Chlorine that is chemically combined, such as in chloramine compounds. No direct test exists for measuring combined chlorine, but it can be measured indirectly by measuring both total and free chlorine and calculating the difference. Chloramine is combined chlorine.</td>
</tr>
<tr>
<td><strong>Disinfection</strong></td>
<td>The destruction of pathogenic and other kinds of microorganisms by thermal or chemical means. Disinfection is a less lethal process than sterilization, since it destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms. This definition of disinfection is equivalent to low-level disinfection in the Spalding classification.</td>
</tr>
<tr>
<td><strong>Dialysis staff</strong></td>
<td>Any medical, nursing, allied health and technical staff who are involved in providing the dialysis service.</td>
</tr>
<tr>
<td><strong>Endotoxins</strong></td>
<td>Endotoxins are lipopolysaccharides, consisting of a polysaccharide chain covalently bound to lipid A and which form the major component of the outer cell wall of gram-negative bacteria. Endotoxins can acutely activate both humoral and cellular host defenses, leading to a syndrome characterized by fever, shaking chills, hypotension, multiple organ failure, and even death if allowed to enter the circulation in a sufficient dose. Long-term exposure to low levels of endotoxin has been implicated in a chronic inflammatory response, which may contribute to some of the long-term complications seen in haemodialysis.</td>
</tr>
<tr>
<td><strong>Feed water</strong></td>
<td>Water supplied to a water pre-treatment system.</td>
</tr>
<tr>
<td><strong>Free chlorine</strong></td>
<td>Dissolved molecular chlorine</td>
</tr>
<tr>
<td><strong>Product Water</strong></td>
<td>Water which has been processed completely through a water pre-treatment system and distributed to haemodialysis equipment.</td>
</tr>
<tr>
<td><strong>Reverse Osmosis (RO)</strong></td>
<td>The process of forcing water from one side of a semi-permeable membrane to the other, producing purified water by leaving behind the dissolved solids and organic particles. The equipment that performs this process is frequently referred to as the RO. (See Section 2.3)</td>
</tr>
<tr>
<td><strong>Trending</strong></td>
<td>Reviewing results to identify a general direction or tendency. Trending may be done on a graph with the results being obtained by averaging the last ten test results. The trending result will show if there is any slight change of test results overtime.</td>
</tr>
<tr>
<td><strong>Water pre-treatment</strong></td>
<td>A collection of water purification devices and associated piping, pumps, valves, gauges, etc. that together produce water for haemodialysis applications and deliver it to point of use</td>
</tr>
</tbody>
</table>
Introduction

Executive Summary

- A Governance structure should exist at Local Health Network (LHN) level to ensure these guidelines are followed and a review mechanism is in place to assess the outcomes of water quality for haemodialysis.

- Dialysis staff should have a fundamental understanding of water treatment for haemodialysis and participate in the design and safe running of haemodialysis water treatment plants.

- Written procedures and instructions shall be in place outlining where to test, how to test and frequency of testing at each site. Dialysis staff shall be trained and deemed to be competent to perform testing and recognise unacceptable water quality levels.

- Dialysis related water practices shall be regularly audited.

- The ANSI/AAMI 13959:2014 and 26722:2014 standards are the accepted minimum standards for water treatment for haemodialysis.

- Dialysis water quality shall be regularly tested in accordance with these guidelines.

- All servicing, maintenance, interventions and changes to the water pre-treatment plant shall be recorded in water pre-treatment logbook, available in a convenient location.
Scope

The scope of this document is restricted to water quality testing for public Haemodialysis units in South Australia. Design of water treatment systems is out of scope of this document and reference for commissioning and design of water treatment systems for haemodialysis should be sought from ANSI/AAMI 26722:2014 Water treatment equipment for hemodialysis applications and related therapies.

The recommendations in this document are based on the maximum level of known or suspected harmful contaminants which may be present in product water to be used for the preparation of dialysis fluids as specified by ANSI/AAMI 13959:2014 Water for hemodialysis and related therapies.

The provision of haemodialysis occurs in many different settings. This document is designed primarily for metropolitan incentre, satellite and country units. Home hemodialysis water standards should be addressed in a separate document.

As South Australian units use high flux dialysis and a growing emphasis is now placed on offering convective therapies such as Haemodialfiltration (HDF) a stringent approach to water quality management needs to be employed

General

Nephrologists shall have a fundamental understanding of the water quality required for haemodialysis. Nephrologists should participate in the planning, design, operation and maintenance of water treatment systems. Planning the design, operation and maintenance of water pre-treatment system shall be done very early in the commissioning of a dialysis unit.

Responsibility for the safe and effective design and running of water pre-treatment systems is shared between ALL dialysis staff, including medical staff, nursing staff and technicians.
Water Testing

Responsibility for water quality testing and evaluation should be allocated at local level and clear documentation and instructions should exist at each site.

Flow charts/decision making trees should exist at each site to determine the appropriate action to be taken if testing is out of range.

Testing Frequency, Location and Method

Water hardness

<table>
<thead>
<tr>
<th>Post Water Softener</th>
<th>Test</th>
<th>Sample</th>
<th>Frequency</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring</td>
<td>Salt level in brine tank</td>
<td>Visual inspection</td>
<td>Check for level in brine tank</td>
<td>Weekly</td>
</tr>
<tr>
<td>Water Hardness</td>
<td>Hardness test kit</td>
<td>Water from softener</td>
<td>Weekly</td>
<td>If &gt; 20ppm, inform technician</td>
</tr>
</tbody>
</table>

Hardness tests for product water shall be less than 20 ppm hardness and performed on “fresh” water, not water that has been in the tank for extended periods. Ideally a hardness test should be taken 'worse case' scenario - prior to softener regeneration and results trended. If the hardness test is greater than 20ppm, the softener my require regeneration prior to commencing dialysis.

Chlorine and Chloramines

<table>
<thead>
<tr>
<th>Post Carbon 1</th>
<th>Test</th>
<th>Sample</th>
<th>Frequency</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring</td>
<td>Total Chlorine</td>
<td>Post carbon 1</td>
<td>Each patient shift</td>
<td>&lt;0.1mg/L</td>
</tr>
<tr>
<td>Test</td>
<td>Chlorine Test Kit</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As a minimum, all dialysis units shall have a facility to measure total chlorine. In-line Total Chlorine Meters may be considered for existing dialysis units and should be installed in new dialysis units.

Tests for total chlorine shall be done and recorded at least once per dialysis shift. The total chlorine test shall, as a minimum, be done using the manual process photometer although a digital photometer is preferred due it repeatability and accuracy. In addition an In-line Total Chlorine Meter is highly recommended.
Test strips do not constitute an adequate or reliable test and as such must not be used.

Ideally testing should occur when there has been maximum water flowing through the carbon tanks. This testing should be no less than 15 minutes and may be as long as 30 minutes after the start of the dialysis shift (and all dialysis machines are on) and is to allow water that has been in the carbon tanks for some time to be flushed through the pre-filtration system. Should there be a concern about the total chlorine levels before starting a dialysis shift refer to the concentration results from previous shifts to determine if it’s acceptable to commence the dialysis shift.

Should there be any doubt about the total chlorine levels, the product water post RO must be tested and is the absolute indicator of patient safety.

Additional water tests that may be required
To check the operation of the carbon and for problem solving, two additional water tests may be carried out. The water can be tested at the feed water to the lead (first) carbon tank and the product water post lag (second) carbon tank. Test results shall be recorded and trended.

Acceptable levels of chlorine and chloramine.
The AAMI/ISO maximum level for chlorine is 0.5 mg/L and for chloramine is 0.1 mg/L. As testing of total chlorine is usually performed and chloramine levels are no greater than 0.1 mg/L then the limit for total chlorine should be 0.1mg/L.

As a minimum, carbon shall be replaced on a 12 monthly basis or earlier if trending of test results indicates an increasing level of total chlorine concentrations are experienced.

Each unit must have a policy and decision making tree/ flow chart that outline the strategy for management of total chlorine levels that exceed 0.1mg/L
Reverse Osmosis units

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>Test</th>
<th>Sample</th>
<th>Frequency</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permeate Conductivity</td>
<td>Visual Inspection</td>
<td>Displayed Permeate conductivity</td>
<td>Daily before first dialysis treatment commenced</td>
<td>If conductivity greater than 25uS/cm or rejection rate &lt;90% inform technical services</td>
</tr>
<tr>
<td>Rejection Rate</td>
<td>Visual Inspection</td>
<td>Displayed rejection rate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RO membrane performance is measured by percent rejection and final product water quality can be measured by either conductivity in micro-siemens / cm or total dissolved solids (TDS) displayed as mg/L or parts per million (PPM). AAMI/ISO recommends both percentage rejection and water quality monitors be used. They should be continuously displayed with set points and audible and visual alarms that can be heard in the patient care area. Units that do not currently have these monitors should consider installation and new units should install as described.

<table>
<thead>
<tr>
<th>Permeate Monitoring</th>
<th>Test</th>
<th>Sample</th>
<th>Frequency</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contaminants with documented toxicity in HD</td>
<td>Aluminum</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>0.01 mg/L</td>
</tr>
<tr>
<td>Copper</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>0.1 mg/L</td>
<td></td>
</tr>
<tr>
<td>Fluoride</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>0.2 mg/L</td>
<td></td>
</tr>
<tr>
<td>Lead</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>0.005 mg/L</td>
<td></td>
</tr>
<tr>
<td>Nitrate (as Nitrogen)</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>2.0 mg/L</td>
<td></td>
</tr>
<tr>
<td>Sulphate</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>50 mg/L</td>
<td></td>
</tr>
<tr>
<td>Zinc</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>0.1 mg/L</td>
<td></td>
</tr>
<tr>
<td>Monitoring</td>
<td>Test</td>
<td>Sample</td>
<td>Frequency</td>
<td>Limit mg/L</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>----------</td>
<td>-------------</td>
<td>-----------</td>
<td>------------</td>
</tr>
<tr>
<td>Electrolytes</td>
<td>Calcium</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>2 mg/L</td>
</tr>
<tr>
<td></td>
<td>Magnesium</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>2 mg/L</td>
</tr>
<tr>
<td></td>
<td>Potassium</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>2 mg/L</td>
</tr>
<tr>
<td></td>
<td>Sodium</td>
<td>Post RO Permeate</td>
<td>Monthly</td>
<td>50 mg/L</td>
</tr>
<tr>
<td>Maximum allowable levels of trace elements in permeate</td>
<td>Antimony</td>
<td>Post RO Permeate</td>
<td>Annually</td>
<td>0.006 mg/L</td>
</tr>
<tr>
<td></td>
<td>Arsenic</td>
<td>Post RO Permeate</td>
<td>Annually</td>
<td>0.005 mg/L</td>
</tr>
<tr>
<td></td>
<td>Barium</td>
<td>Post RO Permeate</td>
<td>Annually</td>
<td>0.1 mg/L</td>
</tr>
<tr>
<td></td>
<td>Beryllium</td>
<td>Post RO Permeate</td>
<td>Annually</td>
<td>0.0004 mg/L</td>
</tr>
<tr>
<td></td>
<td>Cadmium</td>
<td>Post RO Permeate</td>
<td>Annually</td>
<td>0.001 mg/L</td>
</tr>
<tr>
<td></td>
<td>Chromium</td>
<td>Post RO Permeate</td>
<td>Annually</td>
<td>0.014 mg/L</td>
</tr>
<tr>
<td></td>
<td>Mercury</td>
<td>Post RO Permeate</td>
<td>Annually</td>
<td>0.0002 mg/L</td>
</tr>
<tr>
<td></td>
<td>Selenium</td>
<td>Post RO Permeate</td>
<td>Annually</td>
<td>0.09 mg/L</td>
</tr>
<tr>
<td></td>
<td>Silver</td>
<td>Post RO Permeate</td>
<td>Annually</td>
<td>0.005 mg/L</td>
</tr>
<tr>
<td></td>
<td>Thallium</td>
<td>Post RO Permeate</td>
<td>Annually</td>
<td>0.002 mg/L</td>
</tr>
</tbody>
</table>
Compliance with the requirements listed for trace elements can be shown in three ways

Where testing is available, the individual trace contaminants can be determined using chemical analysis methods

Where testing for the individual trace elements is not available and the source water can be demonstrated to meet the standards for potable water defined by WHO or local regulations, an analysis for total heavy metals can be used with a maximum allowable level of 0.1mg/L

If neither of these options are available compliance can be met by using water that can be demonstrated to meet potable water requirements of the WHO or local regulations and a reverse osmosis system with a rejection of >90% based on conductivity.

Commissioning of new dialysis machines and reverse osmosis units

All newly commissioned dialysis machines and reverse osmosis units must be tested against standards outlined in this document to ensure they comply with safe practice, prior to use in a patient care area.

The frequency of testing will be determined against the outcome of initial testing and testing continued until trended data validates safe use.

Where maintenance and upgrading of the reverse osmosis unit involves disruption to the loop, then revalidation of the system should be performed. Frequency and type of testing will be determined by nature of the work performed and by the outcome of the tests and continue until trended data indicates a reduction in monitoring is warranted.
### Bacteria and endotoxin testing

#### Permeate

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>Action Level</th>
<th>Limit level</th>
<th>Frequency</th>
<th>Recommended Testing Method</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viable counts</td>
<td>50CFU/ml</td>
<td>100CFU/ml</td>
<td>monthly</td>
<td>As per standard laboratory testing methods</td>
<td>Ideally for maximum microbial recovery, incubation temperatures 17°C to 23°C for 168Hrs with TGEA or R2A Plate</td>
</tr>
</tbody>
</table>

#### Haemodialysis Machine not equipped with ultrafilter

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>Action Level</th>
<th>Limit level</th>
<th>Frequency</th>
<th>Recommended Testing Method</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viable counts</td>
<td>50CFU/ml</td>
<td>100CFU/ml</td>
<td>3 monthly</td>
<td>As per standard laboratory testing methods</td>
<td>Ideally for maximum microbial recovery, incubation to 17°C to 23°C for 168Hrs with TGEA or R2A Plate</td>
</tr>
</tbody>
</table>

#### Haemodialysis Machine equipped with ultrafilter – Testing of ultra pure Dialysate

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>Limit Level</th>
<th>Frequency</th>
<th>Recommended Testing Method</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viable counts</td>
<td>0.1 CFU/ml</td>
<td>3 monthly</td>
<td>As per standard laboratory testing methods</td>
<td>Ideally for maximum microbial recovery, incubation to 17°C to 23°C for 168Hrs with TGEA or R2A Plate</td>
</tr>
<tr>
<td>Endotoxins</td>
<td>0.03 EU/ml</td>
<td>3 monthly</td>
<td>Limulus Amebocyte Lysate (LAL)</td>
<td></td>
</tr>
</tbody>
</table>

Endotoxin samples should be collected and tested as soon as practically possible. Should there be a delay in sampling then samples should be stored between 2 and 8 degrees within 24 hours of collection and frozen for periods greater than 24 hrs.
QUALITY CONTROL

General

Every haemodialysis unit shall have written procedures and a process to support this document, including water quality education, obtaining suitable water samples, testing of samples, recording and trending results, identifying trends in results and action to be taken when abnormal test results are obtained. Medical, nursing and technical staff working in dialysis units share responsibility for the safe operation of the water treatment plant and shall participate together in regular committee meetings to review the safe operation of the water treatment plant. Dialysis nurses should participate in audits, ongoing training, continuing education and accreditation.

Policies and Procedures

Education

Dialysis nursing staff shall be educated in the operation and performance of the water treatment systems. All other persons involved in the water treatment system shall be educated in the operation of their area of responsibility. All education shall be recorded and the records maintained within the dialysis unit.

Operation of the water treatment systems

The operation of the water treatment system shall only be carried out by persons who have been trained and accredited. Records of who is responsible for the operation of all or part of the water pre-treatment system shall be maintained within the dialysis unit.

Obtaining suitable water samples

Water samples for testing shall be obtained from the appropriate location as detailed in the operational policies and procedures for the dialysis unit. These policies and procedures shall include information on how to collect the water sample, where the sample is collected from, what water sample is collected and how the sample is maintained up to the time it is tested.


**Testing of samples**

Testing of water samples shall be carried out by trained and accredited persons or accredited laboratories. The records shall be maintained within the dialysis unit.

The Women’s and Children’s Hospital (WCH) Pharmacy Quality Control lab currently performs all LAL testing for the state. Any decision to source alternative testing should be first discussed with the Directors of Dialysis to assess impact of the decision on the rest of the state.

**Recording and trending results**

All water test results should be recorded and trended over time.

**Identifying trends in results**

The trended water test results shall be reviewed by an approved staff member on a regular basis. Regular review of results should show any trend that may require intervention to prevent contaminated product water reaching the haemodialysis equipment or patients.

**Action when high test results are obtained**

Every dialysis unit shall have written policies and procedures in place to detail what action is required when any test result is out of acceptable range. It is essential that any abnormal results are promptly communicated to responsible senior staff.
Water Quality Governance

Water quality governance should exist at each site and at Local Health Network level. (See Appendix A)

Each organisation and Local Health Network (LHN) should have an established mechanism for review of water quality practices and results. Audits, reports and minutes of each meeting should be kept. Frequency of meetings shall be determined by each LHN.

Servicing and Maintenance

General

Water treatment systems require regular supervision, maintenance and servicing. Each water treatment system shall have a log book with careful written records documenting every intervention, repair, servicing and maintenance procedure. All servicing, maintenance, interventions and changes to the water treatment system shall be locally recorded in water treatment records.

Maintenance

Other maintenance and service instructions, including recommended preventive maintenance procedures and schedules, recommended monitoring schedules and troubleshooting guidelines should be in place.
Water Utility Communications

It is recommended that hospitals and dialysis units provide contact details to their local water utility to avoid or minimise any adverse impact on patients if the water supply is interrupted or there is a significant change in chlorine or chloramine concentration.

It is recommended that water utilities communicate with hospitals and dialysis units when an interruption to water supply occurs or is planned to avoid or minimise any adverse impact on patients.
REFERENCED DOCUMENTS

• American National Standards Institute, Water treatment equipment for hemodialysis applications and related therapies, ANSI/AAMI 26722; 2014, Association for the Advancement of Medical Instrumentation, Arlington, Virginia.


• Amato, RL 'Water treatment for hemodialysis, , including the latest AAMI standards', Nephrology Nursing Journal, 2001: vol. 28, no. 6, pp. 619-29.


Document history

<table>
<thead>
<tr>
<th>Date</th>
<th>Author</th>
<th>Version</th>
<th>Change reference</th>
</tr>
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<tbody>
<tr>
<td>Jan 2013</td>
<td>Water Working Group, Renal Clinical Network</td>
<td>V. 1</td>
<td>Chair: Tiffany Whittington</td>
</tr>
<tr>
<td>June 2015</td>
<td>Water Working Group, Renal Clinical Network</td>
<td>V. 2</td>
<td>Chair: Tiffany Whittington</td>
</tr>
</tbody>
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Endorsements

<table>
<thead>
<tr>
<th>Date</th>
<th>Endorsed by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan 2013</td>
<td>Renal Clinical Network Steering Committee</td>
</tr>
<tr>
<td>Jan 2013</td>
<td>SA Health Quality and Safety Strategic Committee</td>
</tr>
<tr>
<td>July 2015</td>
<td>Renal Clinical Network Steering Committee</td>
</tr>
<tr>
<td>Aug 2015</td>
<td>SA Health Quality and Safety Strategic Committee</td>
</tr>
</tbody>
</table>
Appendix A

Governance Reporting Structure

Governance for Haemodialysis Routine Water Testing & Reverse Osmosis Monitoring Is at the Local Health Network (LHN) level.

CALHN & CNARTS LHN Governance

Private centres Governance

Southern LHN Governance

Country LHN Governance

WCH LHN Governance

RAH

PDC

FMC

Berri

Children’s unit

TQEH

Modbury

NHS

Ceduna

LMH

Hartley

Clare

Hampstead

Home HD

Maitland

Mt Gambier

Murray Bridge

Pt Augusta

Pt Lincoln

Pt Pirie

Victor Harbour

Whyalla