NSW HEALTH

Water Pre-treatment Standards for Home Haemodialysis

Supplement

For use in conjunction with

Dialysis Water Pre-treatment for Haemodialysis Units in New South Wales: A Set of Guidelines

DISCLAIMER:
The guidelines in this document are based on the AAMI standards, as the minimum acceptable standard for the pre-treatment of water for haemodialysis.
Use of more rigorous standards is acceptable for systems in NSW - and is strongly recommended.

NSW RENAL SERVICES NETWORK

gmct

This document is an initiative of the GMCT Renal Services Network Dialysis Working Group

Members of the Water Guidelines Working Party:

Mark	**Seward** (Lead)	Senior Electronics Technician, Hunter Area Dialysis Technical Services, HNEAHS
Patrick	**Wasielewski**	Senior Electronic Technician, Dame Eadith Walker Dialysis Centre, SSWAHS
Paul	**Kelly**	Senior Electronic Technician, Sydney Dialysis Centre, NSCCAHS
Ian	**Mackie**	Senior Electronic Technician, NCAHS
Rodney	**Brown**	Senior Electronic Technician, HNEAHS - Tamworth
Frank	**Zentrich**	Senior Electronic Technician, Illawarra Health Service, Wollongong
Stephen	**Rabin**	Dept Clinical Engineering, Prince of Wales Hospital, Randwick
Umesh	**Panchal**	Dept Clinical Engineering, Prince of Wales Hospital, Randwick
Dr Paul	**Snelling**	Nephrologist, Royal Prince Alfred Hospital
Fidye	**Westgarth**	Network Manager, GMCT Renal Services Network

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Preface

The purpose of this document is to provide guidelines for safe water pre-treatment for patients receiving hæmodialysis therapy. This includes the design, operation and maintenance for water pre-treatment systems.

Appropriate water quality is one of the most important aspects of ensuring safe and effective delivery of haemodialysis. Haemodialysis may expose the patient to more than 300 litres of water per week across the semipermeable membrane of the haemodialyser. Healthy individuals seldom have a weekly oral intake of water above 12 litres. The near 30 times increase in water exposure to dialysis patients requires control and monitoring of water quality to avoid excesses of known or suspected harmful elements being carried in the water and transmitted to the patient.

The water to be used for the preparation of haemodialysis fluids needs treatment to achieve the appropriate quality. The water treatment is provided by a water pre-treatment system which may include various components such as sediment filters, water softeners, carbon tanks, micro-filters, ultraviolet disinfection units, reverse osmosis units, ultrafilters and storage tanks. The components of the system will be determined by the quality of feed water and the ability of the overall system to produce and maintain appropriate water quality.

Failure to ensure adequate water quality may have dire consequences to patient safety and welfare. Patients undergoing haemodialysis may show signs and symptoms caused by water contamination, which can lead to patient injury or death. Some of the important possible signs and symptoms due to water contamination are listed below in **Table 1.**

TABLE 1: Hæmodialysis Risks associated with Water Contamination[1]

Symptoms	Possible Water Contaminants
Anaemia	Aluminium, chloramine, copper, zinc
Bone Disease	Aluminium, fluoride
Hæmolysis	Copper, nitrates, chloramine
Hypertension	Calcium, sodium
Hypotension	Bacteria, endotoxin, nitrates
Metabolic acidosis	Low pH, sulfates
Muscle weakness	Calcium, magnesium
Neurological deterioration	Aluminium
Nausea and vomiting	Bacteria, calcium, copper, endotoxin, low pH, magnesium, nitrates, sulfates, zinc
Death	Aluminium, fluoride, endotoxin, bacteria, chloramine

The guidelines in this document are based on the AAMI standards, as the minimum acceptable standard for the pre-treatment of water for haemodialysis. Use of more rigorous standards is acceptable for systems in NSW - and is strongly recommended.

[1] NOTE: Revised from Food and Drug Administration (FDA). (1989). *A manual on water treatment for hemodialysis.*

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Executive Summary

Supplement: For use in conjunction with
Dialysis Water Pre-treatment for Haemodialysis Units in New South Wales: A Set of Guidelines

- Written policies, practices and procedures shall be in place in the technical workshop of the Haemodialysis Home-Training Unit, for the safe operation of the dialysis water pre-treatment system for Home Dialysis.
- The AAMI standards are the accepted minimum standards for water pre-treatment for home haemodialysis.
- The quality of dialysis water shall be regularly tested, according to these guidelines.
- Home Dialysis-related practices shall be regularly audited.
- Home haemodialysis shall never take place without, at a minimum, a 1 micron filter, carbon filtration and reverse osmosis.
- All servicing, maintenance, interventions and changes to the water pre-treatment plant shall be recorded.

Section1 SCOPE and GENERAL INFORMATION

1.1 Scope

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 dialysing fluids as specified by AAMI. The document details the water pre-treatment systems and practices needed to achieve and maintain these levels.

This document contains information on the items to be used to treat water for the preparation of concentrates and dialysate, and the devices used to store and distribute this treated water. This document seeks to prevent the use of options that could be hazardous to dialysis patients. For example, when this document is followed, it should prevent patient poisoning caused by formulation of dialysate with water containing high levels of harmful contaminants.

This document is for dialysis which is performed in situations involving a single patient, specifically home haemodialysis. Also, single patients may be treated in an acute hospital setting where dialysis equipment is taken to the patient's bedside. Although a common standard for chemical and microbiological quality of product water should apply in all settings, there is recognition that the need for portability may necessitate relaxation of some of the product water quality standards in a mobile acute dialysis setting.

1.2 Application

This document applies to dialysis water pre-treatment systems used for home haemodialysis. This document is directed towards home patient facilities and manufacturers of water pre-treatment systems for such haemodialysis facilities.

1.3 Innovation

It is not intended that this document impose unnecessary restrictions on the use of new or unusual materials or methods, providing that all the performance requirements of this document are maintained.

1.5 Referenced Documents

- CARI Guidelines (requires full citation)
- ISO 13959, *Water for Haemodialysis and related therapies*.
- ANSI/AAMI RD62:2001, Water treatment equipment for Hemodialysis applications, 1ed.
- ANSI/AAMI RD5:2003, Hemodialysis systems, 3ed
- ANSI/AAMI RD52:2004, Dialysate for hemodialysis, 1ed.
- ANSI/AAMI 2006 -- What should be written here?
- HEALTH FACILITY GUIDELINE: RENAL DIALYSIS UNIT from the NSW Dept of Health
- *Dialysis Water Pre-treatment for In-Centre and Satellite Haemodialysis Units in NSW: A Set of Guidelines*
- Amato, Rebecca L. (2001) *Water Treatment for Hemodialysis*. Nephrology Nursing Journal, Dec 2001.
- EBPG (European Best Practice Guidelines. Section IV. Dialysis Water Purity. Nephrol Dial Transplant 2002; 17 [Supp17] : 45-62)

1.6 Definitions

- **AAMI** - Association for the Advancement of Medical Instrumentation.
- **Chlorine:**
  Free chlorine Dissolved molecular chlorine.
  Combined chlorine 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 a combined chlorine.
  Total Chlorine All chlorine, whether free or present in chemical compounds.
- **Device** - An individual water purification unit, such as a softener, carbon tanks, reverse osmosis unit.
- **Disinfection** - The destruction of pathogenic and other kinds of micro organisms by thermal or chemical means. Disinfection is a less lethal process than sterilization, since it destroys most recognized pathogenic micro organisms, but not necessarily all microbial forms. This definition of disinfection is equivalent to low-level disinfection in the Spalding classification
- **Empty bed contact time (EBCT)** – A measure of how much contact time there is between particles, such as activated carbon, and water as the water flows through a bed of the particles.
  EBCT (minutes) is calculated from the following equation:- EBCT = Volume/Flow
  where EBCT is in minutes (min), Volume is in litres (lt) and flow is in litres per minute (lt/min)
  The volume of particles needed to achieve a specified EBCT can be calculated form the following equation:- Volume (lt) = Time (min) x Flow (lt/min). The calculation needs to take into account the maximum expected water flow rate.
- **Endotoxin** - Endotoxins are the major component of the outer cell wall of gram-negative bacteria. Endotoxins are lipopolysaccharides, consisting of a polysaccharide chain covalently bound to lipid A. Endotoxins can acutely activate both humoral and cellular host defences, 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. However, the mechanisms of this process remain incompletely understood.
- **Feed water** – water supplied to a water pre-treatment system.
- **May** - Indicates an option.
- **Product water** - water which has been processed completely through a water pre-treatment system and distributed to haemodialysis equipment.
- **RO** – Reverse Osmosis unit.
- **Shall** – indicates a statement that is mandatory.
- **Should** – indicates a recommendation.
- **Trending** - 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 real change of test results over time.
- **Pre-Filter** - Pre-filters are particulate filters positioned after all the pre-treatment and immediately before the RO unit.
- **Dialysate** – Aqueous fluid containing electrolytes and usually dextrose, which is intended to exchange solutes with blood during haemo-dialysis.

Section 2 PLANNING

2.1 General

Home dialysis patients should have access to the same quality of dialysis as “in-centre” patients.

2.2 Considerations

Planning consideration for the design and installation of the water pre-treatment system shall include, but not necessarily be limited to, the following:-

1. The quality of the feed water, including the source and availability of the water.
2. The pressure of the feed water.
3. Space required to safely install and operate the water pre-treatment plant.
4. Drainage required.
5. Water quality monitoring systems
6. Non-public reticulated water source (eg Tank water)

2.3 Components

2.3.1 Feed water temperature control.

In areas where they experience high feed water temperatures it may be necessary to use a heat exchanger to cool the feed water. Where the feed water is cold it can be heated by mixing hot and cold water with a thermostatic mixing valve.

2.3.2 Back flow preventer.

All water pre-treatment systems require a form of back flow prevention device. This device prevents the water in the water pre treatment system from flowing back into the source water supply system

2.3.3 Particle Filtration.

Large particulates of 10 microns or greater that cause the feed water to be turbid - such as dirt, silt, colloidal matter (suspended matter) - are removed by particle filters. Large particulates can clog the carbon and softener tanks, destroy the RO pump, and foul the RO membrane.

Many feed waters, in spite of their apparent clarity, carry a large amount of suspended particulate matter that can adversely affect pre-treatment and RO performance. A silt density index (SDI) test measures and evaluates how rapidly a screen becomes clogged on a particular water source. Most RO membrane manufacturers recommend that feed water SDI not exceed a value of 5.0.

Particle filters located before the carbon filter should be bled free of air prior to use. Many carbon filters, currently available, do not self bleed. Failure to remove this air before water pressure is applied will result in air being trapped inside the carbon cylinder – effectively reducing the carbon cylinder volume and thus its performance.

2.3.4 Water softener.

Use of water softeners is optional. Both water softeners and RO units remove calcium from the water being treated. Calcium will bond with resin beads contained in water softener resin tanks, and is removed from these resin beads during regeneration. In a RO unit calcium will adhere to the RO membrane and slowly decrease the RO performance by allowing calcium layers to physically block the membrane pores. Both pieces of equipment are effective in calcium removal however water softeners are considered to be the more cost effective device for calcium removal.

Softeners are sized in grains of capacity; 1 cubic foot (cu. ft.) of resin equals 30,000 grains of hardness exchange capability. A feed water analysis that states the level of $CaCO_3$ is important in determining the size of the softener. A formula can be used to calculate how long the softener will last before needing regeneration.

Softeners are normally placed before the carbon tank, on the chlorinated/chloraminated water side, in order to impede microbial growth, decreasing the bacterial bio-burden to the RO membrane. Decreased softener resin life may occur if exposed to detrimental levels of chlorine or chloramine in the incoming water. Therefore, the softener may be placed after the carbon tank if the incoming chlorine and/or chloramine levels dictate.

The softener needs regenerating on a routine basis with concentrated sodium chloride solution (brine) before the resin capacity is used up. Also, like multimedia filters, during normal operation, the water flows downward through the resin and tightly packs the resin beads. Before the regeneration process, the resin is backwashed to loosen the media and clean any particulates from the tank. After the back-washing step, the brine solution is drawn into the tank to regenerate the resin. The calcium and magnesium are forced off the resin beads even though they possess a stronger bond than sodium because they are overwhelmed by the amount of sodium ions. Next, the excess salt solution is rinsed out of the tank.

When water hardness tests are done, it is best to test the softened water twice, once in the morning to determine that the softener did regenerate and once at the end of the day to prove that the softener performed adequately all day. Hardness tests should be less than 35 mg/L (2 grains per gallon (gpg)) hardness and performed on “fresh” water, not water that has sat in the tank for extended periods. Start the water pre-treatment system approximately 15 to 30 minutes (shorter interval for portable systems) prior to drawing the sample. If the hardness test reads above 35 mg/L, the softener may need regenerating before use. Central RO systems may have an inbuilt continuous water hardness meter.

2.3.6 Carbon tanks.

Chlorine and chloramine are added to the city water supply for disinfection purposes. In drinking water, these additives allow us to drink the water with minimal risk of becoming ill from a parasite or pathogenic bacteria. However, there are some drawbacks to the disinfectants themselves. For instance, chlorine can combine with other organic chemicals to form trihalomethanes, a carcinogenic. For this reason, chloramine, a “combined chlorine” that cannot combine with other chemicals, has become the major disinfectant of drinking water in recent years. But, as compared to chlorine, it takes a longer contact time with (activated charcoal) carbon for the chloramine to be adsorbed by the carbon. Since the initiation of chloramine use, there have been more reported incidents of haemolysis and related symptoms in patients due to chloramine exposure than compared with chlorine, though chlorine is harmful also.

Even if chloramine is not normally present in the feed water, chloramine can form naturally from chlorine combining with ammonia from decomposing vegetation. Chloramine may also be added unexpectedly to the feed water, especially in those municipal suppliers using surface water. **Therefore, always test for total chlorine and never just free chlorine alone**.

In addition to the deleterious effects in patients, neither chlorine nor chloramine are removed by RO and they actually damage the thin film-type RO membranes. Therefore they shall be removed before the RO system.

Carbon media will remove chlorine and chloramine that are almost always present in the feed water through a chemical process termed adsorption. As the input water flows downward through the carbon media, solutes diffuse from the fluid into the pores of the carbon and become adsorbed or attached to the structure. As a side benefit, along with chlorine and chloramine, many other low molecular weight organic chemicals such as herbicides, pesticides, and industrial solvents will be adsorbed.

Granular activated carbon (GAC) is the preferred medium, as other types can cause damage to the RO. GAC can be made from different organic material such as bituminous coal, coconut shells, peach pits, wood, bone, and lignite that have been exposed to excessive temperatures (pyrolysis). It is then acid washed to remove the ash and to etch the carbon to increase the porosity and therefore the absorbency of the GAC. All carbon used for dialysis should be acid washed, especially carbon derived from bone, wood, or coal, as these tend to leach metals such as aluminium when they are not acid washed and exposed to water. Steam activated carbon should not be used as it can leach detritus (‘fines’) which clog filters and RO. Steam activated carbon can also leach heavy metals which, when removed by the RO, cause damage to the RO. Catalytic Carbon (CC) which has a high porosity may be used in carbon tanks. The volume of CC should be the same as calculated for GAC. The use of CC, which is more expensive, can add an additional degree of safety by its more rapid and extensive removal of chlorine and chloramine.

GAC is rated in terms of an “iodine number,” which measures the ability of the GAC to adsorb low molecular weight, small organic substances like iodine and subsequently, chlorine and chloramine. The higher the iodine number, the more chlorine and chloramine will be adsorbed. An iodine number of 900 or greater is recommended for the removal of chlorine and chloramine. Peroxide number is another rating system that is closely associated with the carbon’s ability to adsorb chlorine and chloramine. When other forms of carbon are used, the manufacturer shall provide performance data to demonstrate that each adsorption bed has the capacity to reduce the chloramine concentration in the feed water to less than 0.1 mg/L when operating at the maximum anticipated flow rate for the maximum time interval between scheduled testing of the product water for chloramines.

Another rating system that is pertinent to dialysis is the abrasion number, which reflects the ability of activated carbon to withstand degradation - the higher the number, the more resistant to breakdown. Since there is frequent back-washing associated with carbon used for dialysis, a durable carbon such as acid washed bituminous coal should be considered.

AAMI recommends the use of virgin carbon and not carbon that has been reburned by the manufacturer. Carbon is used in many, more toxic applications than dialysis and can be recycled and reburned by vendors. Reburnt or reprocessed carbon can retain impurities that may be toxic to patients. **Regenerated carbon shall not be used**.

An appropriate exposure time of the water flow through the carbon tank is imperative in order for the chlorine and chloramine to be adsorbed adequately. **A minimum of 10 minutes EBCT is recommended by AAMI for the removal of both chlorine and chloramine**

Using the Imperial System the contact time can be measured using the input flow rate (Q) in gallons per minute (gpm) and the amount of the carbon media in cu. ft. (V) and is expressed as empty bed contact time (EBCT).

$$EBCT = \frac{V \times 7.48}{Q}$$

Metric System carbon tank volume calculations can be carried out as follows:-

1. The initial calculation for carbon volume is done by first knowing the maximum water flow requirement with all dialysis and RO machines within the Dialysis Unit operating at the same time.
2. The volume of carbon is calculated by $V_C = F \times EBCT$.

   Where, V_C = carbon volume in litres,
   F = water flow in litres per minute,
   EBCT = carbon bed contact time in minutes.

3. With the volume of carbon known the volume of the total carbon tanks can be calculated. Carbon tanks should contain no more than 50% carbon by volume. The total carbon tanks volume is calculated by $V_T = 2V_C$.

   Where, V_T = total tank volume in litres,
   V_C = carbon volume in litres.

In NSW, a Health Department edict has directed that no carbon tank for home or individual machine use shall be smaller than 21 Litres capacity. However, there should be at least 10 minutes EBCT, no matter what size tank is used.

GAC has the ability to become saturated with chlorine and/or chloramine to a point where any further absorption is not possible. This saturation usually occurs over time, but may occur suddenly, and shows up as increasing levels of chlorine and/or chloramine in the water leaving the carbon tanks.

As a minimum, carbon shall be replaced on a 12 monthly basis or earlier if high chlorine concentrations are experienced. This is normally done by exchanging the carbon tank.

When new carbon is installed in a tank it shall be back-washed thoroughly to remove the ash and carbon fines (small pieces of carbon) that will damage the RO membrane. At least an eight hour backwash is recommended. The carbon cylinders shall be tested for conductivity and chlorine removal, prior to use.

2.3.7 Pre-filter.

Pre-filters should be changed monthly by the patient, or earlier if a pressure differential is noted. If this is not practicable, arrangements will need to be made with the technical service department regarding filter changes. [Note: SDC supply larger filter housings for their home patients, and thus change the filters every four months.]

Pre-filters are particulate filters positioned after all the pre-treatment and immediately before the RO unit. Carbon fines, resin beads, and other debris exiting the pre-treatment destroy the pump and foul the RO membrane. Typically, pre-filters range in pore size from 1 to 5 microns. Pre-filters are inexpensive insurance against damaging more expensive items downstream in the system. Particle filters should be installed in an approved opaque housing. The concern with the pre-filter is the build-up of bacterial contamination. *Paul should check the wording of the whole of this paragraph – seems to be some duplication.

Reverse Osmosis

2.3.8 Reverse Osmosis Process

Reverse Osmosis is a membrane filtration process and is the most widely used technique for the purification of water for dialysis. The critical part of a reverse osmosis unit is the semipermeable membrane, i.e. a membrane which allows the passage of water but retains most of the dissolved salts, particles, bacteria and pyrogens.

A high-pressure pump feeds the pre-treated water into the RO module. The pressure forces part of the water through the membrane where most of the contaminants are retained. The product water (permeate) then leaves the module through the product water outlet. The rest of the water containing the retained contaminants (reject) leaves the module through the reject outlet and is then diverted to drain or back to the tank.

2.3.9 RO membranes.

The reverse osmosis (RO) membrane is the heart of the system. It produces the purified water through RO. RO is the opposite of osmosis. Osmosis is a naturally occurring phenomenon involving the flow of water from a less concentrated compartment (e.g., non-salty side) to the more concentrated compartment (e.g., salty side) across a semi-permeable membrane to equilibrate the two solutions. In reverse osmosis, concentrated water is forced to flow in the opposite or unnatural direction across a semipermeable membrane by means of high pressure. Natural osmotic flow is overcome and pure water passes through the membrane leaving the dissolved solids (salts, metals, etc.) and other constituents behind on the concentrated side. Dependent upon how much product water is needed, the RO system will have one or more RO membranes.

RO membranes reject dissolved inorganic elements such as ions of metals, salts, and chemicals and organics including bacteria, endotoxins and viruses. Rejection of charged ionic particles ranges from 95-99°/o, whereas contaminants such as organics that have no charge are rejected at a greater than 200 molecular weight cut-off. Ionic contaminants are highly rejected compared to neutrally-charged particles, and polyvalent ions are more readily rejected than monovalent ions.

Thin film (TF) RO membranes made of polyamide (PA) are the most common type used in HD. These RO membranes are made with a thin, dense, semipermeable membrane over a thick porous substructure for strength and spiral wound around a permeate collecting tube. The spiral design allows for a large surface area in a small space.

TF RO membrane will degrade when exposed to oxidants such as chlorine and/or chloramine and, therefore, shall be preceded by carbon tanks. Care shall be taken with the use of peracetic acid products used for disinfection, as they will oxidize the RO membrane if used above a 1% dilution or if iron deposits reside on the RO membrane

The colder the incoming water, the more resistant it is to cross the RO membrane, thereby decreasing purified water production. Adequate water pre-treatment, pH control, and cleanliness of the RO membrane surface also influence performance of the membrane. TF membranes have a wide pH tolerance of 2-11; however, the optimum pH range for membrane performance is between 5.0-8.5. High alkalinity also enhances scaling of the RO membrane surface.

Scale deposits such as calcium and magnesium salts and silt composed of colloidal matter, metals such as iron, and organics and dirt will accumulate on and eventually foul the RO membrane. Routine cleaning and disinfection will insure proper functioning and will extend the life of the RO membrane and reduce bacterial growth in the system, which can harm patients.

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 recommends both percent rejection and water quality monitors be used. They should be continuously displayed with audible and visual alarms with set points that can be heard by the patient. *Paul - Include something here about monitoring.

2.3.10 Disinfection protection

When disinfection is accomplished automatically by chemical disinfectant or by high temperature procedures, activation of the disinfection system shall result in activation of a warning system and measures to prevent patient exposure to an unsafe condition.

Patients should not disinfect their own water treatment systems using chemicals. It is therefore recommended, when purchasing new equipment, to specify for heat disinfection capabilities so that patients can disinfect their own ROs.

2.3.11 Submicron and ultrafiltration.

A submicron filter reduces the level of bacteria in the final product water, whereas an ultrafilter removes both bacteria and endotoxin. Both are membrane filters that can be cross flow types with a feed stream and reject stream or a dead-ended design with one stream. The housing should be opaque to inhibit algae growth.

When using submicron and ultra filters, AAMI recommends they are validated for medical use. In the industry, there are “nominal” and “absolute” ratings for ultra filters and submicron filters. Absolute ratings are more appropriate for dialysis applications. Also, filters that are not for medical use may contain preservatives that require up to 2000 litres of water to rinse thoroughly.

Section 3 PERFORMANCE REQUIREMENTS

3.1 General

3.1.1 Feed Water

The quality of feed water and its variation shall be determined in order to design an appropriate water pre-treatment system to meet the needs of patients undergoing dialysis. The feed water shall meet the Australian drinking water guidelines. See Appendix I for water utilities communications. The feed water quality shall be periodically monitored thereafter to assure continued appropriate water pre-treatment. Non-reticulated water (tank or bore water) should be tested once per year.

3.1.2 Product Water

The quality of the product water, as specified below, shall be **verified upon installation** of a water pre-treatment system. **Regular testing** of product water quality and monitoring of any trend in the results shall be carried out. These tests measure contaminant concentration in the water pre-treatment system. The results of the tests are compared with the concentration levels detailed below in the Table 3.1.

Table 3.1 Maximum contaminant concentration levels[2] in the dialysis water pre-treatment system, post RO and submicron and ultrafilters.

Contaminant	Maximum (mg/L)
Calcium	2
Magnesium	4
Potassium	8
Sodium	70
Antimony	0.006
Arsenic	0.05
Barium	0.1
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Lead	0.005
Mercury	0.0002
Selenium	0.09

Contaminant	Maximum (mg/L)	
Silver	0.005	
Aluminium	0.01	
Chloramines	0.1	
Chlorine	0.5	
Copper	0.1	
Fluoride	0.2	
Nitrate (as Nitrogen)	2.0	
Sulphate	100	
Tin	0.1	
Zinc	0.1	
Bacteria	200 cfu/ml	*(Action level = 50 cfu/ml)*
Endotoxin	2EU/ml	*(Action level = 1EU/ml)*

[2] AAMI maximum concentration for dialysis water (mg/L)

There are components within the dialysis water pre-treatment system that are able to remove or lower the concentration of the listed contaminants. The "X" in Table 3.2 indicates which contaminant is removed by each component of the dialysis water pre-treatment system.

Table 3.2: Contaminant removed by each component of the dialysis water pre-treatment system

	Component of water pre-treatment system				
Contaminant	**Particle Filter**	**Softener**	**Carbon Tank**	**RO Unit**	**UV light**
Aluminium				X	
Arsenic				X	
Barium				X	
Cadmium				X	
Calcium		X		X	
Chloramines			X		
Chlorine			X		
Chromium				X	
Copper				X	
Fluoride				X	
Lead				X	
Magnesium		X		X	
Mercury				X	
Nitrate				X	
Potassium				X	
Selenium				X	
Silver				X	
Sodium				X	
Sulphate				X	
Zinc				X	
Viruses			X	X	
Organic contaminants			X	X	
Endotoxins				X	
Bacteria				X	X
Particles	X			X	

Table 3.3 details in general terms, the component, function and requirements of dialysis water pre-treatment systems. Haemodialysis shall never be performed **unless all 'Essential' components are on line**.

Table 3.3 – Components of a dialysis water pre-treatment system.

COMPONENT	FUNCTION	REQUIREMENT
5 Micron Particle Filter	Particle removal	**Essential**
Softener	Hardness correction with brine tank (Ca/Mg – Na)	Where required
Carbon tank	Removes chlorine and chloramine	**Essential**
1 Micron filter	Filters particles larger than 1 micron.	**Essential**
RO Unit	Removes ions, bacteria, heavy metals, endotoxins	**Essential**

3.2 Water Testing

Table 3.4 – Summary of recommended water testing frequency for dialysis water pre-treatment system.

Water Test	Frequency
Water hardness, pre and post softener	During design and commissioning, and at each service.
Chlorine	Each service
Bacteria and Endotoxin	During commissioning. Further testing is not recommended, as sampling is difficult to do correctly and produces a high rate of false positive results.
Chemical contaminant and heavy metal levels	During commissioning. By request of treating clinician.

3.2.1 Water hardness.

The first test that is done for any dialysis water pre-treatment system is feed water hardness. Hardness shall be tested early to assist in the design of the water pre-treatment system, including whether a softener is required, and the volume of the vessel if it is required. Once the softener has been installed and in operation the product water hardness shall be tested and recorded to verify the operation of the softener. Water hardness does not greatly vary thereafter, as it depends on catchment area soil constituents and town water factors.

Acceptable levels of hardness:
Hardness tests for post-softener water should be less than 35 mg/L (2 grains per gallon (gpg)) hardness and performed on “fresh” water, not water that has been in the tank for extended periods. Start the water treatment system approximately 15 minutes (shorter interval for portable systems) prior to drawing the sample. If the hardness test reads above 35 mg/L, the softener may need regenerating before use.

3.2.2 Chlorine and Chloramine

General Information
Chlorine and chloramine are removed from water by passing the water through a bed of (activated charcoal) carbon. The water needs to be in contact with the carbon for this to occur. The contact time is a critical factor in determining the efficiency of the carbon to absorb the chlorine and chloramine. The longer the contact time the less chlorine and chloramine there will be in the water post carbon.

NSW Health policy states that all home dialysis patient machines are to be fitted with a 21 litre or greater carbon cylinder which will have at least 100% safety margin.

- Water for each machine is to be tested and recorded by the technicians on each visit to the patient’s home regardless of the reason for the visit.
- The home training centre is to ensure that the carbon cylinders are changed well within the recommended time frame. Usually 12 monthly.
- The responsibility for ensuring that the cylinders are changed appropriately lies with the Director of the unit, the Unit Manager, and the Technical Manager and appropriate records must be kept.

- If the technical services are subcontracted to a dialysis supplier the responsibility for ensuring the cylinders are changed remains as above.

Rationale:

1. Home patients are not required to test for chlorine and chloramines as many are unlikely to carry out the test. When not carried out appropriately tests may be inaccurate.
2. The carbon cylinders are to be of sufficient capacity to handle chlorine and chloramines levels at least 100% safety margin for the worst case scenario ie 20 litres.
3. The quantity of water is low in relation to the size of the cylinder to be provided.

Acceptable levels of chlorine and chloramine.
The AAMI maximum level for chlorine is 0.5 mg/L and for chloramine is 0.1 mg/L

3.2.3 Bacteria and endotoxin testing.

Regular testing for bacteria and endotoxin is **only undertaken where requested** by the clinician. If testing is required, the following methodology for sampling and testing shall be followed:

Bacterial levels shall be tested at the points where all haemodialysis equipment connects to the distribution piping system (post RO, post water loop). **Bacteria levels shall not exceed 200 colony forming units/ml (CFU/ml) - with an action level of 50 CFU/ml.**

Samples shall be assayed within 30 minutes of collection, or be immediately stored at a temperature between 1°C and 5°C and assayed within 24 hours of collection. Total viable counts (standard plate counts) shall be obtained using conventional microbiological assay procedures (pour plate, spread plate membrane filter techniques, commercial samplers including dip test devices etc.). Discussions should occur with the local microbiological laboratory on actual technique.

The calibrated loop technique is not accepted. Culture media shall be tryptic soy agar or equivalent. Blood culture media are not appropriate. Colonies shall be counted after 48 hours incubation at 35°C to 37°C. Recheck at 72 hours if negative after 48 hours. The above method has proved effective in assuring safety for many years, and is the standard practice. Other authorities believe that a different method designed to detect water-borne organisms using a membrane filtration technique, filtering 500ml to 1000ml of water and culturing on low-nutrient medium such as R2A agar and incubating for 5 days or longer at 28°C to 32°C is preferable and more appropriate. This technique is rational and also acceptable. Total viable microbial counts in product water shall not exceed 200 CFU/ml.

Testing for Endotoxins: According to AAMI the endotoxin content in product water shall not exceed 2 IU/ml, or as required by national legislation or similar. These measurements apply to sampling at the point of delivery to haemodialysis equipment (post RO, post water loop). At the outlet of water treatment (post RO), no more than 1IU/ml is the requirement. When monitoring haemodialysis equipment, rotation among sites should assure that each is tested with a cycle of several months. The presence of endotoxins can be tested using the Limulus Amoebocyte Lysate (LAL) assay.

The European Best Practice Guidelines have somewhat more stringent criteria than AAMI. The comparison is provided below, in Table 3.5. Many Australian dialysis units now seek to conform to the more stringent standards.

Table 3.5 Testing for Bacteria and Endotoxins

MICROORGANISMS	**AAMI:RD52**	**EDTNA/ERCA based on EP**
CFU/ml Max	200	100
CFU/ml Action	50	25 (typ)
ENDOTOXINS		
EU/ml or IU/ml Max	2	0.25
EU/ml or IU/ml Action	1	0.125 (typ)

3.2.4 Chemical contaminant and heavy metal levels testing.

Testing is not usually done on reticulated city water due to the constant monitoring by water authorities, but can be performed if requested. For non-reticulated domestic water, testing should be done prior to installation of dialysis equipment.

For the purpose of testing of chemical contaminants and heavy metal levels, testing should be done pre- and post RO and post water loop.

Refer to Table 3.1, in §3.1.2 – Maximum contaminant concentration levels in the dialysis water pre-treatment system post RO and submicron and ultrafilters.

Table 3.6 (next page) details the type of test to be used to measure the concentration of each contaminant. Other test methods may be used provided they have been shown to be of comparable precision and reproducibility. Appropriate containers and pH adjustments shall be used to ensure accurate determinations.

Table 3.6 – Test Methods for Contaminants

Contaminant	Test name
Aluminium	LeGendre and Alfrey (1976)
Arsenic	Atomic absorption (gaseous hydride)
Barium	Atomic absorption (gaseous furnace)
Cadmium	Atomic absorption (gaseous furnace)
Calcium	EDTA titrimetric method or atomic absorption (direct aspiration) or ion-specific electrode
Chlorine and chloramines	DPD ferrious titrimetric DPD calorimetric methods
Chromium	Atomic absorption (gaseous furnace)
Copper	Atomic absorption (direct aspiration) Neocuprocine method
Fluoride	Electrode method SPADNS method
Lead	Atomic absorption (graphite furnace)
Magnesium	Atomic absorption (direct aspiration)
Mercury	Flameless cold vapour technique (atomic absorption)
Nitrate (N)	Brucine method or cadmium reduction method
Potassium	Atomic absorption (direct aspiration) or flame photometric method or ion-specific electrode
Selenium	Atomic absorption (gaseous hydride) or atomic absorption (graphite furnace)
Silver	Atomic absorption (graphite furnace)
Sodium	Atomic absorption (direct aspiration or flame photometric method or ion-specific method)
Sulfate	Turbidimetric method
Tin	Atomic absorption (graphite furnace)
Zinc	Atomic absorption (direct aspiration) dithizone method

Section 4. QUALITY CONTROL

4.1 General

Every Haemodialysis Home-Training Unit shall have **written policies and procedures for the safe operation of the water pre-treatment systems**, including:- education policies, obtaining suitable water samples, testing of samples, recording and trending results, identifying trends in results, action to be taken when high test results are obtained and Occupational Health and Safety principles. Medical, nursing and technical staff working in Haemodialysis Home-Training Units **share responsibility for the safe operation of the water pre-treatment sytems and shall participate together in regular committee meetings to review the safe operation of the water pre-treatment plant.**

4.2 Policies and Procedures

4.2.1 Operation of the water pre-treatment systems.

The operation of the water pre-treatment system shall only be carried out by persons (staff and patients) who have been trained. Records of those responsible for the operation of all or part of the water pre-treatment system shall be maintained within the Home-Training Unit.

4.2.2 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 Home-Training Unit. These policies and procedures shall include information on how to collect the water sample, where the sample is collected from, what the water sample is collected in and how the sample is maintained up to the time it is tested.

4.2.3 Testing of samples.

Testing of water samples shall be carried out by trained and accredited persons or accredited laboratories. The Haemodialysis Home-Training Unit shall maintain records of persons who have been trained and accredited and full details of accredited laboratories. The records shall be maintained within the Home-Training Unit.

4.2.4 Recording results.

All water test results shall be recorded and abnormal results shall be actioned as appropriate. *[See Sample Template for Monitoring, at Appendix II]*

4.2.5 Action when high test results are obtained.

Every Haemodialysis Home-Training Unit shall have written policies and procedures in place to detail what action is required when any test result is high. It is essential that any high results are promptly communicated to responsible senior staff.

4.2.6 Committee meetings.

On a regular basis (at minimum twice per year), **water quality and the safe functioning of the water pre-treatment system shall be reported** to a multidisciplinary committee of the Home Training Unit which includes senior nursing, medical and technical staff and other appropriate stakeholders, any issues resolved and the minutes kept. Requirements for action shall be reported to the head of the Renal Department, to ensure correct governance of patient safety.

4.2.7 Occupational Health and Safety principles.

Every Haemodialysis Home-Training Unit shall have safe work method statements for every procedure to be undertaken on a water pre-treatment system. Safe work method statements shall be developed for carrying out tasks involving risk to staff or patients. These safe work method statements shall be followed by all staff working on any part of the water pre-treatment systems. There shall also be safe work method statements for persons collecting and testing water samples. Records of all risk management procedures, safe work method statements, etc shall be maintained within the Haemodialysis Home-Training Unit.

4.2.8 Audits, training and continuing education.

The operation of the water pre-treatment systems and the ongoing training of persons involved in the operation of the system shall be audited on a 12 monthly basis. Audit reports and recommendations shall be reviewed and managed by the Home-Training Unit management committee.

Section 5 SERVICING AND MAINTENANCE

5.1 General

Water pre-treatment systems require regular supervision, maintenance and servicing. Servicing and maintenance is carried out in the workshop (Refer to *Dialysis Water Pre-treatment for In-Centre and Satellite Haemodialysis Units in NSW: A Set of Guidelines*). All servicing, maintenance, interventions and changes to the water pre-treatment system shall be recorded. *[See recommended structure of Maintenance Log Book/Folder, at Appendix III]*

5.2 Technical Considerations

5.2.1 Safety requirements

Each water treatment device shall exhibit the following minimum safety requirements:-

- Monitors shall be designed so that the monitor cannot be disabled while a patient is at risk, except for brief, necessary periods of manual control with the operator in constant attention.
- The sound emitted by audible alarms shall be at least 65 db(A). It shall not be possible to silence these alarms for more than five (5) minutes.

5.2.2 Documentation requirements

NOTE—The term "labelling," as used in this document, includes any written material accompanying any water treatment device or system, such as instructions for use and operator's manuals, or any instructions or control feature markings attached to the device or system.

5.3 Water Utility Communications

NSW Health recommends 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.

NSW Health recommends that water utilities communicate with Haemodialysis Home-Training Units and patients when an interruption to water supply occurs or is planned, to avoid or minimise any adverse impact on patients.

Home-Training Units provided with water services by Sydney Water are notified of changes to water quality when chlorine or chloramine concentrations exceed the agreed maximum chlorine or chloramine concentration.

Home-Training Units outside Sydney Water's area of operations should consult with their local water utility and provide details of a contact person to ensure notification of interruptions to water quality. These health care facilities should define the criteria for notification of interruption to water supply with their local water utility.

Procedures shall be in place for Home-Training Units to inform local water utility providers when dialysis machines are installed and removed. Specific plans should be in place to provide alternative dialysis for any patient whose pre-treatment system suddenly becomes ineffective.

APPENDICES

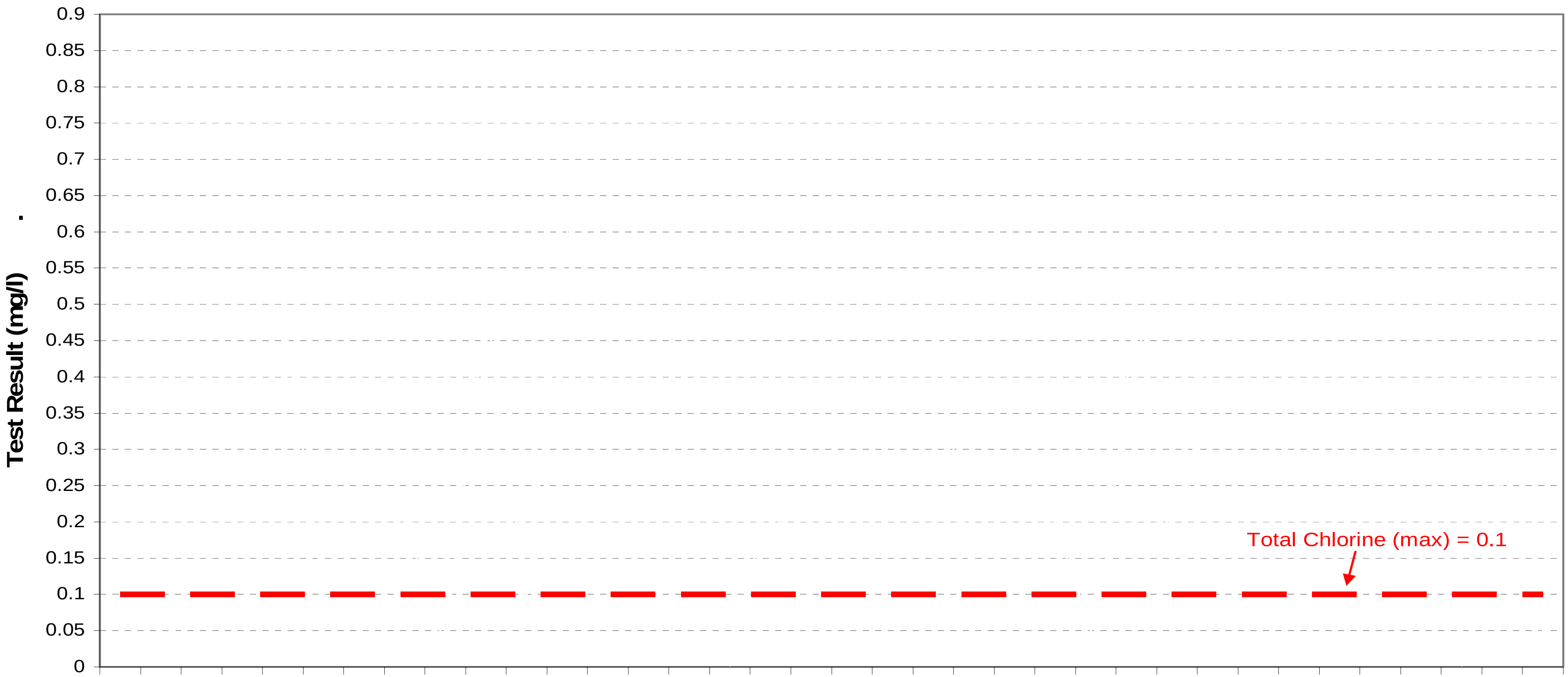
Appendix I: List of important contact details for home-based units

Place	Name	Phone No.

Appendix II: Water Testing – Chart for Trending Results

RO Water - Test Results for Measurement of Total Chlorine (mg/litre)

START Date: ....../....../........ FINISH Date: ....../....../.......



Date																																				
Total Chlorine:																																				

Appendix III: *Log Sheet for managing Maintenance*

Recommended Schedule of Testing: **Haemodialysis Machines & Home Haemodialysis Reverse Osmosis Units**

Six monthly results to be tabled as part of Quality Report to the Area Renal Services Committee

Test	Frequency	Collected By	Results or Procedure Recorded	Sample Sites And Instructions	Reported to	Response To Problems	Audited By
Chloramines	Each technical visit	By technician	Recorded in home dialysis record sheet	Pre and Post carbon tank	Reviewed by home haemodialysis training unit staff on home visits.	Technicians	Nursing staff of Home Haemodialysis Training Unit.
Microbiology*	Not practical for all home installations due to geographical locations	Technicians	In-patient records in Home Training Unit	Sample 1) Post portable RO unit. 2) Dialysis machine at venous port	Laboratory results to Home Haemodialysis Unit	If post RO CFU count > than 200 mls machine to be replaced or disinfected and re-sampled for CFUs.	Nursing staff of Home Haemodialysis Training Unit
Endotoxins*	Not practical for all home installations due to geographical locations	Technicians	In-patient records in Home Training Unit	Dialysis machine at venous port	Laboratory results to Home Haemodialysis Unit	If endotoxins positive Hi-flux dialysis to cease – return to standard dialyser. Technician to change U8000 filter and chemical disinfect machines.	Nursing staff of Home Haemodialysis Training Unit
Heavy metals & trace elements	Annually	Technicians	By home haemodialysis training unit staff in patient records	2 samples – Inlet supply and post RO unit	Results to go from laboratory to home haemodialysis training unit	Haemodialysis Training Unit. Nursing staff to inform technician and Clinical Director of Nephrology.	Technicians and Nursing staff of Home Haemodialysis Training Unit
Replacement of carbon filters	Annually or as determined by chloramines test results	N/A	By technician on service sheet	N/A	Reported by technician to Manager, Biomedical Services and nursing staff from Home Haemodialysis Training Unit. Nursing staff to inform Clinical Director of Nephrology.	Nursing staff of Home Haemodialysis Training Unit	Technicians and Nursing staff of Home Haemodialysis Training Unit

Example of Maintenance Log – provided by Ian Mackie, NCAHS , 2008 – modified by the Working Group, 2008