ACI NSW Agency for Clinical Innovation

GUIDE

Water for dialysis

A guide for in-centre, satellite and home haemodialysis in NSW

ACI Renal Network

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AGENCY FOR CLINICAL INNOVATION

Level 4, 67 Albert Avenue
Chatswood NSW 2067

PO Box 699 Chatswood NSW 2057
T +61 2 9464 4666 | F +61 2 9464 4728
E aci-info@health.nsw.gov.au | www.aci.health.nsw.gov.au

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Member	Role	LHD
Maureen Lonergan (Chair)	Renal Physician, Director – Illawarra-Shoalhaven Renal Service	ISLHD
John Landkauf	Senior Renal Technician, Wansey Dialysis Centre, John Hunter Hospital	HNELHD
Lucy Spencer	Dialysis Nurse Practitioner, Royal North Shore Hospital	NSLHD
Linda McCorriston	CNC, Southern NSW Renal Service	SNSWLHD
Sam O'Neill and Kellie Hardgrove	CNC, Hastings Renal Service, Port Macquarie	MNCLHD
Christopher Gibb	Nurse Manager, Western Renal Service	WSLHD and NBMLHD
Joanne Kemp	NUM, Central Coast Renal Service, Gosford	CCLHD
Dennis Walsh	Senior Renal Technician, Sydney Dialysis Centre, Royal North Shore Hospital	NSLHD
Ross Wenzel	Senior Hospital Scientist, Trace Elements Laboratory PaLMS, RNSH	NSLHD
Tracey Blow	Nurse Manager, St George Hospital	SESLHD
Patrick Wasielewski	Senior Renal Technician, Statewide Renal Services	SLHD
John Saunders	Renal Physician, Royal Prince Alfred Hospital	SLHD
Fidye Westgarth and Rama Machiraju	Renal Network Managers	ACI

This Guide is based on *Dialysis Water Pre-treatment for In-Centre and Satellite Haemodialysis Units in NSW: A Set of Guidelines* (2008) which was developed under the auspices of the NSW Greater Metropolitan Clinical Taskforce Renal Services Network. That work was largely produced from the efforts of:

- Kevin Pull, Engineer, Liverpool Hospital Sydney
- Mark Seward, Senior Electronics Technician, Hunter Area Dialysis Technical Services
- Michael Suranyi, Nephrologist, Liverpool Hospital Sydney

The completion of that document was overseen by the Water Guidelines Working Group of the Renal Services Network, and had considerable input from the NSW Senior Hæmodialysis Technicians Group.

Contents

Preface

The purpose of this document is to provide guidance for the provision of safe water for patients receiving haemodialysis therapy. This includes the design, operation and maintenance for water pre-treatment and reverse osmosis (RO) water plant/RO systems.

Part II contains guidance for water pre-treatment and RO systems for home haemodialysis.

Appropriate water quality is one of the most important aspects of ensuring the safe and effective delivery of haemodialysis. Haemodialysis may expose the patient to more than 300 litres of water per week across the semi-permeable membrane of a 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 (RO) 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.

For home haemodialysis therapy the water treatment is provided by the use of sediment filters, carbon filters and a portable reverse osmosis (RO) plant.

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

Table 1 Haemodialysis risks associated with water contamination

Symptoms	Possible water contaminants
Anaemia	Aluminium, chloramine, copper, zinc
Bone disease	Aluminium, fluoride
Haemolysis	Copper, nitrates, chloramine
Hypertension	Calcium, sodium
Hypotension	Bacteria, endotoxin, nitrates
Metabolic acidosis	Low pH, sulphates
Muscle weakness	Calcium, magnesium
Neurological deterioration	Aluminium
Nausea and vomiting	Bacteria, calcium, copper, endotoxin, low pH, magnesium, nitrates, sulphates, zinc, microcystin
Visual disturbances	Microcystin
Liver failure	Microcystin
Death	Aluminium, fluoride, endotoxin, bacteria, chloramine, microcystin

Ref – Layman-Amato R, Curtis J, Payne GM. Water treatment for hemodialysis: an update.Nephrol Nurs J 2013;40(5):384–404,465.

The standards quoted in this document are drawn from the International Standards Organisation (ISO), current at the time of release of the Guide. NSW Health is no longer using AAMI Standards.

PART I

Management of water quality - in-centre and satellite units

Executive summary: Part I

Informative

- For this guide:
  - **May** indicates an option
  - **Shall** indicates a statement that is mandatory, within this guide
  - **Should** indicates a recommendation.
- **Dialysis staff should have a fundamental understanding of water pre-treatment** for haemodialysis and participate in the rational design and safe running of haemodialysis water pre-treatment plants
- **Written policies, practices and procedures *shall* be in place** for the safe operation of dialysis water pre-treatment systems. Dialysis staff shall be trained and deemed to be competent in the safe operation of dialysis water pre-treatment systems.
- Dialysis-related practices ***shall*** be **regularly audited**.
- The ISO standards are the **accepted minimum standards** for water pre-treatment for haemodialysis.
- Haemodialysis should never take place without, at a minimum: **a multimedia filter, carbon filtration, a 1 micron filter and reverse osmosis (RO) water**. Further filtration may be used at the discretion of individual units to further extend the life of the equipment. However for emergency contingencies and absolute filter (0.22um) can be utlised to replace the RO plant supplying the distribution loop for one treatment per patient.
- Dialysis water quality ***shall*** be **regularly tested**, according to this guide.
- To ensure safe chlorine and chloramine (total chlorine) levels in pre-treated water, **water for haemodialysis *shall* be tested according to this guide**. This will occur after the start of each dialysis shift, once the water plant is fully running and when all machines are in operation without patients connected, using appropriate recommended techniques.
- All chlorine and/or chloramine (total chlorine) testing **results *shall* be recorded** in a suitable format.
- Written policies, practices and procedures ***shall*** be in place covering the protocol and methodology for chlorine and/or chloramine testing and the appropriate responses to results showing a high concentration of chlorine and/or chloramine.
- Dialysis staff *shall* be trained and deemed to be competent in water quality risk management. In-service education should be held on an annual basis.
- **All servicing, maintenance, interventions and changes** to the water pre-treatment plant, as a minimum, ***shall*** be recorded in an on-site log book. The log book should be kept in a convenient location, ideally near the equipment. An electronic equipment management database should be considered to allow trending and plan maintenance schedules.
- Water quality results and plant function performance ***shall*** be reviewed by a multidisciplinary committee made up at least of senior nursing, medical and technical staff and other appropriate stakeholders on a monthly basis and minutes kept.
- Minutes should be circulated **to appropriate health service authorities** to indicate safe running of the dialysis room and the dialysis water pre-treatment system and RO water plant/RO system.

Section 1

SCOPE and GENERAL for in-centre and satellite units

1.1 Scope

The recommendations in this document are based on the maximum level of known or suspected harmful contaminants that may be present in product water to be used for the preparation of dialysing fluids, as specified by ISO. 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 distribute this treated water. This document seeks to prevent the use of options that could be hazardous to dialysis patients.

Adherence to this document should provide a high level of patient safety in relation to exposure to dialysate.

The provision of haemodialysis occurs in many different settings. Primarily these are:

- In-centre dialysis unit
- Satellite dialysis unit
- Intensive care unit (ICU)
- Home.

This document is designed primarily for dialysis units and home haemodialysis. 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. When less rigorous product water quality standards are allowed, the onus is on the dialysis staff to ensure appropriate product water quality is maintained through increased monitoring and maintenance of the water pre-treatment system and RO water plant.

1.2 Application

Part I of this document applies to dialysis water pre-treatment systems used in purpose-built haemodialysis facilities. This document is directed towards patient facilities and manufacturers of water pre-treatment systems and RO water plants 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.

1.4 Exclusion

Nil

1.5 Referenced documents

ISO 11663: 2009 Quality of dialysis fluid for haemodialysis and related therapies

ISO 13958: 2009 Concentrates for haemodialysis and related therapies

ISO 13959: 2014 Water for haemodialysis and related therapies

ISO 26722: 2014 Water treatment equipment for haemodialysis applications and related therapies

ISO 23500: 2011 Guidance for preparation and quality management of fluids for haemodialysis and related therapies

Clinical Practice Guideline by the UK Renal Association and Association of Renal Technologists

NHMRC, NRMMC (2011) Australian Drinking Water Guidelines Paper 6 National Water Quality Management Strategy. Version 3.0. Updated December 2014. National Health and Medical Research Council, National Resource Management Ministerial Council, Commonwealth of Australia, Canberra.

Previously referenced documents

- International Organization for Standardization, ISO 13959: 2002 Water for haemodialysis and related therapies, International Organization for Standardization, Geneva.
- Amato RL. Water treatment for hemodialysis, including the latest AAMI standards. Nephrol Nurs J 2001;28(6):619-29.
- American National Standards Institute, ANSI/AAMI RD5; 2003 Hemodialysis systems, Association for the Advancement of Medical Instrumentation, Arlington, Virginia.
- American National Standards Institute, ANSI/AAMI RD52; 2004, Dialysate for hemodialysis, Association for the Advancement of Medical Instrumentation, Arlington, Virginia.
- American National Standards Institute, ANSI/AAMI RD62; 2001 Water treatment equipment for hemodialysis applications, Association for the Advancement of Medical Instrumentation, Arlington, Virginia.
- European Best Practice Guidelines. Section IV. Dialysis fluid purity. Nephrol Dial Transplant 2002;17 (Suppl 7):45-62.
- ISO 13959: 2009 Water for haemodialysis and related therapies
- ISO 26722: 2009 Water treatment equipment for haemodialysis applications and related therapies
- Kerr P, Perkovic V, Petrie J, et al. The CARI guidelines. Dialysis adequacy (HD) guidelines, Nephrology 2005;10(Suppl 4):S61–S80.
- NSW Department of Health, Health Facility Guideline: Renal Dialysis Unit, NSW Department of Health, North Sydney, NSW. 2006. Available at: http://healthdesign.com.au/nsw.hfg/hfg_content/guidelines/hfg_b_renal_dialysis_unit_460_484.pdf
- Water Quality for Haemodialysis, Dialysis Adequacy (HD) Guidelines, Nephrology 2005; 10: S61-S80

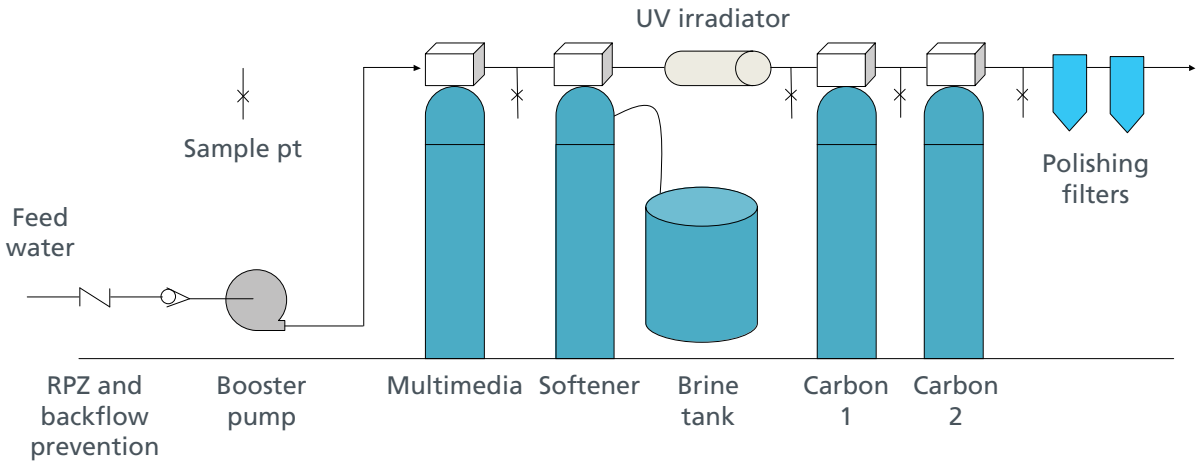
1.6 Definitions

AAMI	Association for the Advancement of Medical Instrumentation.
ANSI	American National Standards Institute, Arlington, Virginia.
Back-wash	A process where the fluid flow in a vessel is reversed using special controls and valves with the express intent of removing collected unwanted particles from a filter system. Back-wash occurs on multimedia, softener and carbon filters.
Bacteria	Specifically referring to microscopic organisms.
Biofilm	A protective slime coating that bacteria secrete. Possible to form inside distribution loops causing bacterial contamination.
Brine tank	Vessel used to house a solution of salt and water that is used by the softener to condition 'hard' water. Dry salt is added, when required.
Central water plant (CWP)	Plant that produces reverse osmosis (RO) water. The equipment generally has process control devices that measure, monitor and control.
Chloramine	A combined chlorine that cannot combine with other chemicals that has become the major disinfectant of drinking water.
Chlorine, combined	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.
Chlorine, free	Dissolved molecular chlorine.
Chlorine, total	Chlorine plus chloramine.
Component	An individual part of a water purification unit, such as a softener, carbon tank, or reverse osmosis (RO) unit.
Conductivity	A measure of the ability of an aqueous solution to conduct electricity. This is directly related to the concentration of dissolved salts/ions in the water, and therefore water purity. The premise being that pure water is a poor conductor, hence its low conductivity reading, expressed in microSiemens per cm (µS/cm). Testing is required to monitor the performance of components.
Device	An individual water purification unit, such as a softener, carbon tanks, reverse osmosis (RO) unit.
Dialysate	A mixture of treated water and specifically formulated fluid. Used to create a fluid environment to assist in the migration of solutes across a dialyser.
Dialysis facility	Building where patients attend dialysis treatment.
Dialysis staff	Any medical, nursing, allied health and technical staff who are involved in providing the dialysis service.
Differential pressure (ΔP)	The measure of a pressure gradient. Usually a measure across a membrane or vessel, where it is used as an indication of level of performance restriction.
Disinfection	The destruction of pathogenic and other kinds of micro-organisms by thermal or chemical means. Disinfection is a less lethal process than sterilisation, since it destroys most recognised pathogenic micro-organisms, but not necessarily all microbial forms. This definition of disinfection is equivalent to low-level disinfection in the Spalding classification.
Disinfection, chemical	The destruction of pathogenic and other kinds of micro-organisms by chemical means. The most common chemicals are chlorine and peracetic acid, which attack cell structure preventing the cell from multiplying.
Disinfection, heat	The destruction of pathogenic and other kinds of micro-organisms by thermal means. Typically, heating the fluid levels to approximately 90 degrees Celsius for a fixed time period will destroy most micro-organisms.
Drain	A generic term for unwanted fluids. The path used for water not conditioned by water treatment systems. Can also refer to the fluid waste product from dialysis machines. In reference to RO water plant, drains must be of a sufficient material and size to cope with copious amounts of water.

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 is calculated from the equation: EBCT = volume/flow, where EBCT is in minutes (min), volume is in litres (L) and flow is in litres per minute (L/min). The volume of particles needed to achieve a specified EBCT can be calculated from the equation: Volume (L) = time (min) x flow (L/min). The calculation needs to take into account the maximum expected water flow rate.
Endotoxins	Substances that are a major component of the outer cell wall of gram-negative bacteria that produce an inflammatory host response. 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 characterised 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.
Filter, carbon	Inert vessel containing granular activated or catalytic carbon appropriately sized to remove chlorines or chloramines by adsorption from the feed water supply. Will also remove microcystins, some organic matter, taste and odour.
Filter, multimedia	Inert vessel containing granular gravels appropriately sized to remove sediment from the feed water supply.
Filter, submicron	Specially designed filter with small pore size able to reduce the level of bacteria in a fluid system.
Filter, ultra	Specially designed filter with small pore size able to remove bacteria and endotoxin in a fluid system.
GAC	Granular activated carbon (carbon media).
Germicide	Agent that kills microorganisms.
Hardness, test	Usually a two-part solution used to test for the presence of calcium carbonate in feed water systems. Testing is required to monitor the performance of components.
ISO	International Organization for Standardization, Geneva
Microbial	General reference to microscopic organisms, such as bacteria and fungi.
Microcystins	Toxic peptides, produced in large quantities during cyanobacterial blooms, often called blue-green algal blooms, can cause damage to liver, visual disturbance and death. Dialysis patients and the immunosuppressed are at risk.
Osmosis	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.
Osmosis, reverse (RO)	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.
Osmosis, reverse dual-pass, twin-pass, two-stage	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. Some devices utilise a system whereby the permeate from the first-stage membrane is passed through a second membrane, thus producing purer water.
Patient area	Zone or room where dialysis treatment is carried out.
Permeate	Water that has been processed completely through a water pre-treatment system and distributed to haemodialysis equipment. Also known as product water.
Reduced pressure zone (RPZ)	A device that controls pressure in the feed water system. Subject to regulation by AS2845.3 NSW Code of Practice for Plumbing and Drainage and AS3500.

Salt bridge	A condition that can occur in the brine tank of a softener system where the salt will form a surface crust that is not in contact with any solution, hence not mixing into a brine solution.
Softener	Inert vessel containing resin beads that will react to remove calcium and magnesium by ion exchange.
Thermostatic mixing valve (TMV)	A device that controls the temperature of the water. Subject to regulation by AS2845.3 NSW Code of Practice for Plumbing and Drainage and AS3500.
Thin film (TF) membranes	Currently the most popular type of membrane used in RO units are thin film, spiral wound membranes that are constructed of polyamide.
Total dissolved solids (TDS)	The sum of all ions in a solution. Approximated by electrical conductivity or resistivity measurements. Expressed in terms of $CaCO_3$ or NaCl (parts per million [ppm]). Used to assess performance of reverse osmosis (RO) units.
Trending	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 10 test results. The trending result will show if there is any slight change of test results over time.
UV irradiator	A disinfection device that uses radiant energy to destroy bacteria.
Water, dialysis	Water that has been treated to meet the requirements of ISO13959 and that is suitable for use in haemodialysis applications.
Water, feed	Water supplied to a water pre-treatment system. Usually will be pressure-controlled, may be temperature-controlled.
Water, hard	High levels of calcium and magnesium in the feed water cause the water to be termed 'hard'. Hardness is measured in grains per gallon (gpg; 'grain' literally taken from the precipitate left from evaporated water being the size of a grain of wheat) or mg/L and is generally expressed in terms of $CaCO_3$ (calcium carbonate) for uniformity purposes.
Water, product	Water that has been processed completely through a water pre-treatment system and distributed to haemodialysis equipment. Also known as permeate.
Water, reject	Considered to be filtered water that has passed through the CWP/RO system, but not through the RO membrane. Many options exist for the re-use of this water, such as use in flushing, irrigation or cleaning.
Water, source	Water entering a dialysis facility from an external supplier, such as a municipal water supply.
Water, pre-treatment system	A collection of water purification devices and associated piping, pumps, valves, gauges, etc., including the reverse osmosis (RO) plant, that together produce water for haemodialysis applications and deliver it to point of use.

Diagram 1: Pre-treatment filters



Note: The UV irradiator can also be located after the polishing filters.

Diagram 2: Water plant and distribution

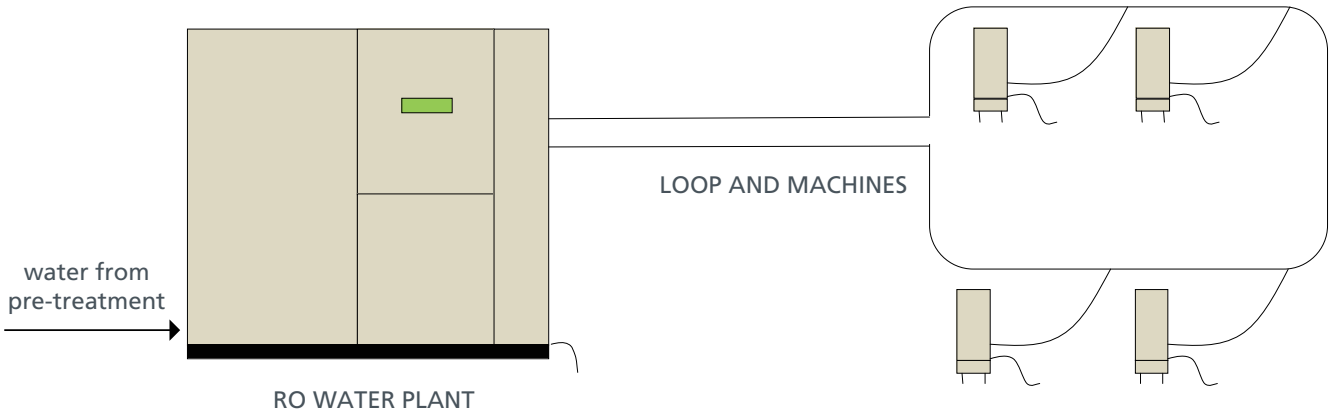
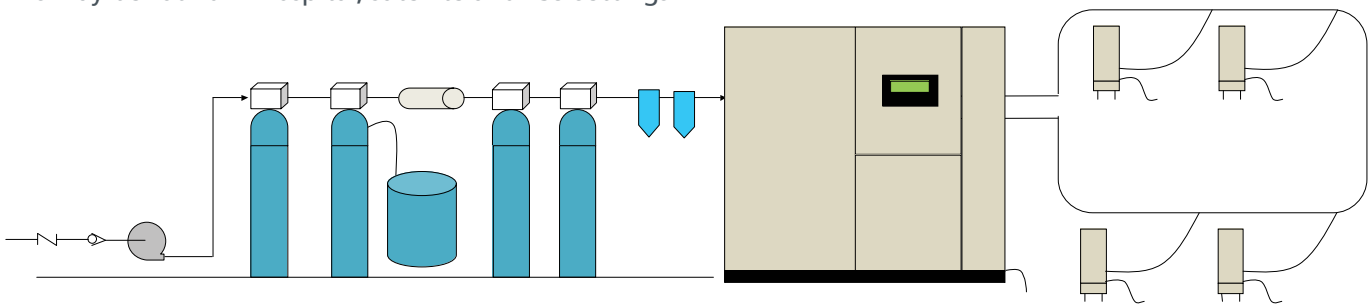


Diagram 3: Typical central RO configuration

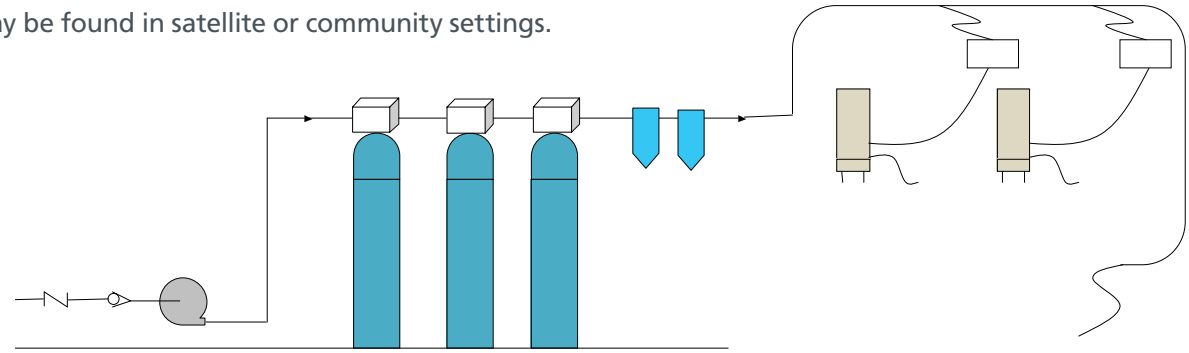
As may be found in hospital, satellite and ICU settings.



PRE-TREATMENT FILTERS | RO WATER PLANT | LOOP AND MACHINES

Diagram 4: Multiple single portable RO configuration

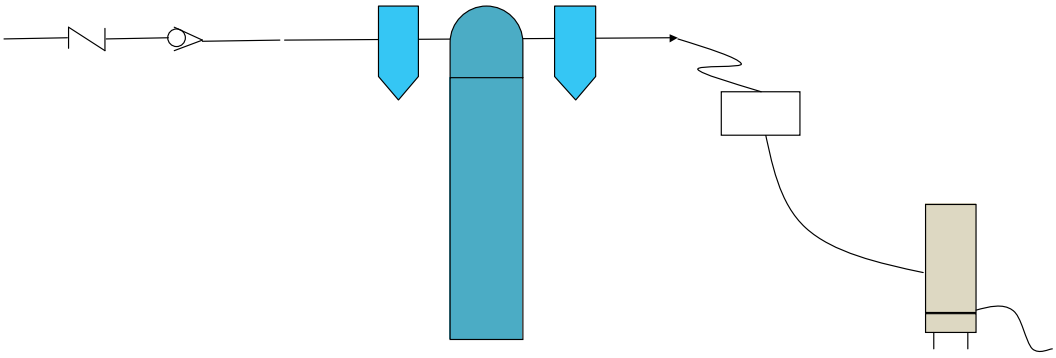
As may be found in satellite or community settings.



PRE-TREATMENT FILTERS | PORTABLE ROs AND MACHINES

Diagram 5: Single portable RO configuration

Typical for home HD installation, single treatment hospital and ICU settings.



CARBON FILTER | PORTABLE ROs AND MACHINES

Section 2

Planning

2.1 General

Nephrologists and renal nursing staff shall have a fundamental understanding of the water pre-treatment required for haemodialysis. Nephrologists should participate in the rational planning, design, operation and maintenance of water pre-treatment systems. Planning the design, operation and maintenance of water pre-treatment system shall be done very early in the setting up of a Renal Dialysis Unit. From October 2007 water pre-treatment systems shall be listed, registered or included on the Australian Register of Therapeutic Goods (ARTG) in order to be supplied for that purpose.

Responsibility for the safe and effective design and running of water pre-treatment systems is shared between ALL dialysis staff, including dialysis water consultants.

2.2 Considerations

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

1. The microbiology quality of the feed water. The basis for deciding on components, e.g. use of UV irradiators.
2. The chemical quality of the feed water.
3. The maximum temperature of the feed water. To allow determination of any requirement for a heat exchanger or chiller design.
4. The source of the feed water, e.g. from storage tanks, dam, artesian etc.
5. The pressure of the feed water.
6. The maximum water flow, including expected future growth in the number of patients to be treated.
7. Average water flow per day, also including expected future growth.
8. Space required to safely install, maintain and operate the water pre-treatment plant.
9. Drainage required.
10. The weight of the operational water pre-treatment plant and the ability of the floor to safely support that weight.
11. Water quality monitoring systems.
12. The capacity of the power supply for the water pre-treatment plant.
13. Facilities to safely service and maintain the water pre-treatment plant.

Planning consideration for the design and installation of a **reverse osmosis (RO) water plant/reverse osmosis (RO) system** shall include, but not necessarily be limited to, the following:

1. Choice of equipment for power and water efficiency/conservation.
2. Consideration of installation designs that utilise water conservation, e.g. dual-pass reverse osmosis (RO) systems or the use of reject water in sterilising departments or storage tanks for irrigation or sanitation flushing.
3. The maximum water flow, including expected future growth in the number of patients to be treated. Consider the maximum disinfection water flow.
4. Average water flow per day also including expected future growth.
5. Space required to safely install maintain and operate the RO water plant.
6. Drainage required.
7. The weight of the operational RO water plant and the ability of the floor to safely support that weight.
8. Water quality monitoring systems.
9. The capacity of the power supply for the RO water plant. Consider the disinfection mode requirement.
10. Facilities to safely service and maintain the central water plant (CWP).
11. RO water distribution loop path, material, length and insulation requirements.
12. RO water distribution loop outlet types, number of, consideration of spare and testing outlets.

The above information should be gathered by a competent dialysis water contractor or provider. With this information the contractor or provider will be able to determine the type, size, volume, weight and location for the safe operation of the pre-treatment and RO water plant.

While it is true for all measurements on a water pre-treatment system, it is especially important to include the expected parameters for water quality on the log and record sheets. Trend analysis is also vital for documenting water pre-treatment systems. It allows the dialysis facility to be more proactive, seeing a problem arising, rather than being reactive.

2.3 Components

Many of these components are designed to protect the RO water plant membranes, which are the primary barrier used for patient safety in relation to purified water.

2.3.1 Feed water temperature control

In areas where high feed water temperatures are experienced 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.

Subject to regulation by AS2845.3 NSW Code of Practice for Plumbing and Drainage and AS3500.

2.3.2 Backflow preventer

A backflow prevention device is used on water pre-treatment pathways to stop the water in the water pre-treatment system from flowing back into the source water supply system. This can be achieved with the use of a reduced pressure zone device (RPZD) or a break tank with an air gap. Subject to regulation by AS2845.3 NSW Code of Practice for Plumbing and Drainage and AS3500.

2.3.3 Multimedia depth filter

Turbidity occurs in feed water due to the presence of particles, such as sand, clay, silt and suspended matter occurring as colloids. These particles are removed by a multimedia filter, sometimes referred to as a depth bed filter.

Large particulates in feed water potentially adversely affect water filtration systems by blocking both carbon filters and water softening systems and damaging the RO membrane and machinery. RO membrane manufacturers recommend that feed water provided to an RO unit has a silt density index (SDI) below 5.0 as the higher the SDI, the faster the water will clog the various pre-treatment filters within the system.

Feed water initially passes through multimedia filters which consist of a number of layers that gradually trap the suspended particles as water filters from the top layer through to the bottom layer. The tiers are constructed from different sized elements so that the particulates are removed throughout the filter and not just collected in the top layer, thus ensuring longevity and efficiency of the filter.

Multimedia filters are usually set to back-wash at regular intervals when the RO unit is not being used. This process flushes water from the bottom of the filter to the top of the filter (back-washing), releasing the collected particulate matter from the layers where it has been trapped, and flushing it out of the top of the filter to the drain.

The frequency of back-washing the multimedia filter depends on the amount of particulates in the feed water. Back-washing can be programmed by a time clock on the filter tank or a signal from the central reverse osmosis (RO) unit. If a time clock on the tank is used, the time on the clock should be read and recorded daily. Compare the time on the tank head to real time and adjust, as necessary.

Power failures and time adjustments related to daylight saving can result in back-washing occurring during dialysis treatments. If this did occur, there would be minimal risk to the patient, as the reverse osmosis (RO) unit would have no water flow and a low water alarm would be generated. Pressure gauges on the inlet and outlet of the tank should be fitted to monitor pressure drop (differential pressure [ΔP]).

The size of the multimedia filter shall be determined by a competent dialysis water pre-treatment plant contractor or provider.

2.3.4 Water softener

Required in areas where there is 'hard' feed water. Hard water will eventually foul the RO water plant membranes.

Softeners work on an ion exchange basis, where calcium and magnesium are replaced with sodium. The resin beads within the tank have a high affinity for the cations calcium and magnesium (both divalent) present in the feed water and release two sodium ions (monovalent) for each calcium or magnesium ion captured. High levels of calcium and magnesium in the feed water cause the water to be 'hard'. Hardness is measured in grains per gallon (gpg; 'grain' literally taken from the precipitate left from evaporated water being the size of a grain of wheat) or mg/L and is generally expressed in terms of calcium carbonate ($CaCO_3$) for uniformity purposes. To a lesser degree, softeners will remove other polyvalent cations, such as iron.

Calcium carbonate	Classification
0–60 mg/L	Soft
61–120 mg/L	Moderately hard
121–180 mg/L	Hard
Greater than 180 mg/L	Very hard

Over time, calcium carbonate scale deposits that form on the RO membrane will foul the membrane. An indication of mineral deposits forming on the membrane will be high readings of total dissolved solids (TDS), percent rejection and conductivity (or low resistivity). This will lead to a decline in product water quality. Potentially, if the deposits are not removed, this scale will reduce RO membrane life expectancy. In feed water classified as being very hard, damage to the RO membrane may occur extremely rapidly, even within hours, with irreversible membrane damage transpiring in that time. However, sodium chloride does not deposit scale on the RO membrane, so the softener is placed before the reverse osmosis (RO) unit to protect the RO membrane.

Analysis of the level of calcium carbonate ($CaCO_3$) in the feed water is important for determining the size of the softener. A formula can be used to calculate how long the softener will last before needing regeneration:

$$\text{Ion exchange capacity} = \frac{\text{Resin volume x Resin rating (g/L) x 1000}}{\text{Water hardness (mg/L)}}$$

Softeners are usually 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.

Water softeners also require regular back-washing and regeneration of the resin within the filter. The initial process is similar to that which occurs in multimedia filters, with the flow of water redirected so flow occurs from the bottom to the top of the filter, to loosen the resin beads in the softener and clean any particulates from the tank. Then, salt is drawn into the softener and forces calcium and magnesium from the resin beads in the system.

The process needs to be undertaken frequently – generally systems will be set up for regeneration to be done on a daily basis and on an automatic cycle. Any softener system set up to automatically regenerate should also ensure patient safety by ensuring there is an automatic lock out device to prevent patient exposure to water containing high levels of calcium, magnesium and sodium.

Regeneration can be programmed by a time clock on the softener tank or a signal from the central reverse osmosis (RO) unit. If a time clock on the tank is used the time on the clock should be read and recorded daily. Compare the time on the tank head to real time and adjust, as necessary. Situations, such as power failures, can reset the regeneration time to occur during patient treatment. Pressure gauges on the inlet and outlet of the tank should be fitted to monitor differential pressure (ΔP).

If a portable exchange softener is used, there must be a regular replacement program in place. This type of device is sometimes used to simplify the equipment needed and to enable exchange of the equipment in a timely fashion rather than undertaking complicated regeneration regimes.

Water hardness of both feed and product water should be less than 35 mg/L (2 gpg) and may be tested and recorded monthly so trends can be monitored and corrective action taken, as necessary. Should a decision be taken not to test monthly, then water hardness should be tested 6-monthly or after a carbon tank is changed, whichever occurs first. Record and trend the water hardness test results.

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 performed on 'fresh' water, not water that has sat in the tank for extended periods. Therefore, ensure water has been running through the pre-treatment system for 15–30 minutes prior to sampling. When results indicate a high level of water hardness (>35 mg/L), consider implementing a system regeneration followed by retesting of levels. RO water plant/RO systems may have an inbuilt continuous water hardness meter.

2.3.5 Brine tank

A supersaturated salt solution is created by combining water with sodium chloride in the form of salt pellets. Other forms of salts (e.g. rock salt) may contain too many impurities, such as soil.

The salt level in the brine tank should be inspected daily and maintained, as needed. As long as there is undissolved salt present, the solution is considered supersaturated. Record the level of the water in the brine tank and the amount of salt used daily[1].

One of the problems the brine tank can encounter is the formation of a 'salt bridge', that is a hard crust not in contact with the solution. If a salt bridge has formed, the softener will not function to the standard expected. To clear the salt bridge, gently tap on the side of the tank or physically break the bridge with a clean wooden rod.

1 Info: Imperial: 15 lbs of salt is required to regenerate 1 ft 3 of resin (30,000 grain capacity).
Metric: Approx. 3 kg of salt is required to regenerate 0.03 m^3 of resin.

2.3.6 Ultraviolet irradiator (optional)

Ultraviolet (UV) light is produced by a low-pressure mercury vapour lamp enclosed in a quartz sleeve that is required to emit a germicidal 254 nm wavelength and provide a dose of radiant energy of 30 milliwatt-sec/cm^2 in order to kill bacteria.

UV irradiation causes cellular death or cellular malfunction by interrupting cellular reproduction. However, some bacteria have developed resistance to the effects of UV irradiation.

The device shall be sized for the maximum anticipated flow rate according to the manufacturer's instructions. Installation position will be determined by the nature of the problem and the manufacturer's recommendations.

Note 1: UV does not destroy endotoxins. Instead, the UV irradiation process may increase endotoxin contamination due to the effects of cellular destruction with subsequent contamination of dialysis water with cell fragments. Therefore, if used, UV should be followed, at some point, by ultrafiltration.

Note 2: Biofilm is a sticky, protective coating that is produced by bacteria when cells adhere to a surface, such as in the water pre-treatment system. The efficacy of UV irradiation is reduced in the presence of biofilm.

Regular maintenance of the UV irradiation device includes continuous monitoring of radiant energy output that activates an audible and visual alarm, routine cleaning of the quartz sleeve and replacing the lamp at least annually, or sooner, as recommended by the manufacturer. Most installations contain a control box with an hour-run meter to assist with maintenance scheduling.

2.3.7 Carbon filters (tanks)

Carbon filters (tanks) are required to remove chlorine and chloramine additives from the feed water. Chlorine and chloramine are added to water supplies for disinfection purposes and have been shown to provide long-lasting protection in providing safe drinking water. However, chlorine can combine with natural organic matter to form potentially carcinogenic by-products, such as trihalomethane. Therefore, many water authorities are now using chloramines as the water disinfectant of choice. Most commonly, chlorine is combined with ammonia to form chloramine, which is then used to treat drinking water. Chloramine is safe in drinking water because it is neutralised in the digestive system before it enters the bloodstream. However, if there is direct contact of chloramines with blood, oxidation can occur, leading to haemolysis of red blood cells. Therefore, carbon filtration is used to remove chlorine and chloramines from water used for dialysis.

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.

Beside the deleterious effects in patients, both chlorine and chloramine will damage the reverse osmosis (RO) membrane if they are not removed by the pre-treatment system. Therefore, they shall be removed before the reverse osmosis (RO) system.

There are two main types of carbon media to consider for use: catalytic carbon or granular activated carbon.

1. 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 granular activated carbon (GAC). The use of CC, which is more expensive than GAC, can add an additional degree of safety because of its more rapid and extensive removal of chlorine and chloramine.
2. Carbon media, often referred to as GAC, will remove chlorine and chloramine that is present in the feed water through a physical process and a chemical process termed adsorption, where the chlorine and chloramine molecules in the water become attached to the structure of the carbon within the filter. As a side benefit, along with chlorine and chloramine, many other low molecular

weight organic chemicals, such as herbicides, pesticides and industrial solvents will also be adsorbed.

GAC is manufactured from a number of different materials with high carbon content, most commonly wood, coal, lignite, nut shells or peat. 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.

Note: Steam-activated carbon should not be used as it can leach detritus ('fines'), which clog filters and RO membranes. Steam-activated carbon can also leach heavy metals, which, when removed by the RO membrane, cause damage to the reverse osmosis (RO) unit.

The effectiveness of activated carbon is described in terms of the amount of a specified test chemical that it can adsorb, with iodine commonly used to measure the quality of a particular GAC used for water filtration. The higher the number, the more adsorptive the carbon. An iodine number of 900 or higher indicates a good quality of carbon and is recommended for use in the removal of chlorine and chloramine for dialysis.

Peroxide number is another rating system that is closely associated with the activated 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.

It is recommended to use 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.

Note: Regenerated carbon shall not be used.

CALCULATION EXPLANATION

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 and is expressed as empty bed contact time (EBCT).

A minimum of 10 minutes EBCT is recommended for the removal of both chlorine and chloramine.

Two equal-sized tanks, in an in-series configuration, with the first tank feeding into the second tank, shall be the standard set-up, one as the worker (lead tank) and one for back-up (polisher, lag tank), with each tank having at least 5 minutes EBCT.

The two carbon tanks are connected in series to allow water to be tested for chlorine content as it passes between the two tanks. By using this two carbon tank configuration failure of the lead (first) carbon tank, indicated by a high level of chlorine in the water between the two tanks, will be detected early. By passing the water subsequently through the lag (second) carbon tank prevents high levels of chlorine or chloramine from reaching the patient, while prompt action is taken to replace the failed carbon.

Using the 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 (L), F = water flow (L/min), and EBCT = carbon bed contact time (min).
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 (L) and
V_C = carbon volume (L).

Example

A tank volume calculation can be done using the above formula, with a water flow rate (F). With a F rate of 40 L/min (F) and a EBCT of 10 minutes, according to V_C = F x EBCT, V_C= 40 x 10 = 400 L.

Therefore carbon volume is 400 L, and according to $V_T = 2V_C$, total tank volume = 800 L.

In this example each carbon tank needs to have a capacity of 400 L and contain 200 L of carbon. A 400 L tank could be about 1800 mm high with a diameter of 750 mm.

(Area of a circle = πr^2. Volume of tank = area x height).

(Diameter of tank (m)= (2 x $\sqrt{}$volume (m^3)) / π / height(m)).

In NSW, a Health Department edict has directed that any carbon tank for home or individual machine use shall not be smaller than 21 L capacity, and shall only use GAC. See Home Therapies Section.

MAINTENANCE

GAC has the ability to become saturated with chlorine and/or chloramine to a point where any further adsorption 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.

The safest technique to minimise the possibility of high levels of chlorine being present in the water is to rotate the carbon tanks out on a routine basis, for example every six months. The lead (first) tank is taken out of service and the lag (second) carbon tank is relocated to the lead (first) position. The carbon in the removed tank is replaced and this tank is then returned to the lag (second) carbon tank position. This will ensure that the lag (second) carbon tank is filled with new carbon every six months. Also the maximum time any carbon tank is without exposure to chlorinated water is no more than six months, which in turn will minimise the level of bacteria that may form in a carbon tank.

Pressure gauges on the inlet and outlet of the tank should be fitted to monitor differential pressure (ΔP).

As an added precaution, individual renal units may decide to replace all carbon after six months of use.

Note: As a minimum, carbon shall be replaced on a 12-monthly basis, or earlier, if high chlorine concentrations are experienced.

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 reverse osmosis (RO) membrane. A back-wash of at least eight hours is suggested.

Carbon tanks should be back-washed at frequent intervals (at least weekly) to reduce the impact of channel formation, to remove debris and expose unreacted carbon surface. Biological fouling is an inherent problem with GAC because it is an organic medium, and with the chlorine and chloramine removed from the water, bacteria grow. Channelling, accumulation of debris and bacteria all cause the carbon surface area to be underused. Therefore, carbon tanks are back-washed on a routine basis to 'fluff' the bed, clean the debris out, and expose unused surfaces of the carbon particles.

Note: Back-washing does not 'regenerate' the carbon when it is exhausted. It simply exposes unused sides of the carbon. If the carbon tank cannot be back-washed, the carbon media should be changed on a more frequent basis.

During back-washing the water pre-treatment plant cannot be used.

Back-washing can be programmed by a time clock on the filter tank or a signal from the RO water plant. If a time clock on the tank is used the time on the clock should be read and recorded daily. Compare the time on the tank head to real time and adjust, as necessary.

Alert: *Situations such as power failures can reset the back-wash time to occur during patient treatment.* This could expose patients to high levels of chlorine or chloramine.

Note: Bypass valves placed on the piping to carbon tanks that allow the feed water to completely bypass the carbon tanks are unsafe and shall not be used. Bypassing a single carbon tank for urgent repairs is acceptable, but monitoring chlorine levels is critical during this event.

2.3.8 Polishing filter

Polishing filters are particulate filters positioned after the pre-treatment system and immediately before the RO water plant, which contains the RO membranes. Generally, the pore size for these filters is either 1 µm or 5 µm. These filters are used to protect the RO membrane and RO pump from damage by particles, such as resin beads from the softener or carbon fines from the carbon filters.

Polishing filters are an inexpensive insurance against damaging more expensive items downstream in the system. Therefore, a monthly replacement schedule should be considered. Monitoring via differential pressure (ΔP can determine filtering efficiency).

MAINTENANCE

Gauges can be used to monitor the inlet versus outlet pressures across the filter. An eight-fold increase in the differential pressure (ΔP) across filters indicates that the filter is obstructed and should be changed. Inspect the used filter's centre tube for soiling. If foreign material is present, the filter was overburdened and should be replaced sooner next time.

All filter changes shall be recorded in the logbook.

2.3.9 Reverse osmosis systems/ reverse osmosis water plant

Depending on the size of the dialysis facility, there are some considerations for how to supply dialysis water.

The outcome of the reverse osmosis (RO) water plant is to provide purified water to the dialysis facility.

Reverse osmosis (RO) systems may be a single, central reverse osmosis (RO) water plant or individual RO units attached to each dialysis machine.

Many dialysis units will require a reverse osmosis (RO) water plant, as well as several individual portable reverse osmosis (RO) devices for mobile dialysis machines to provide dialysis, e.g. in ICU/CCU/private rooms etc. The portable reverse osmosis (RO) units will require a filtered feed water supply.

A central reverse osmosis (RO) water plant is recommended for dialysis facilities with six chairs or more to reduce costs associated with maintenance and repair of individual reverse osmosis (RO) units.

Individual (single) reverse osmosis (RO) devices give more flexibility and mobility, but require more maintenance and repair.

2.3.10 Reverse osmosis pump and motor

The reverse osmosis (RO) pump and motor is typically an internal component of the reverse osmosis (RO) water plant.

The reverse osmosis (RO) pump increases water pressure across the reverse osmosis (RO) membrane to increase both product water flow and rejection characteristics of the reverse osmosis (RO) membrane. Reverse osmosis (RO) systems typically operate between 1400–1700 kPa (200–250 psi). It is important that reverse osmosis (RO) pumps are made of high-grade stainless steel, inert plastics, and carbon graphite-wetted parts.

Alert: Operating an reverse osmosis (RO) pump without water will damage the mechanism and is to be avoided.

Note: Brass, aluminium, and mixed metal pumps will leach contaminants into the water and are not compatible with peracetic acid type disinfectants. Therefore, brass, aluminium, and mixed metal pumps shall not be used.

2.3.11 Reverse osmosis membranes

These are typically an internal component of the reverse osmosis (RO) water plant with the reverse osmosis (RO) membrane being the most critical part of the water treatment system. It produces the purified water through reverse osmosis – a process that is the opposite of osmosis.

Osmosis is the movement of water across a semipermeable membrane from an area of lower solute concentration to an area of higher solute concentration. A reverse osmosis unit works by using high pressure, to force water molecules across a semipermeable membrane. The pores in the membrane are small enough to restrict the passage of undesirable dissolved solids. The dissolved solids remain behind and are removed as a reject product from the system. The water produced by the reverse osmosis (RO) unit is used for preparation of dialysate. Some reverse osmosis (RO) units will be constructed with two separate banks of membranes to improve the quality of the water produced, also providing some operational redundancy if required in an emergency.

Reverse osmosis (RO) membranes reject up to 95–99% of dissolved inorganic elements, such as ions of metals and salts, chemicals and organic compounds greater than a molecular weight of 200 daltons (Da), as well as bacteria, endotoxins and viruses.

CONSTRUCTION

Currently, the most popular type of membrane used in reverse osmosis (RO) units are thin film (TF), spiral wound membranes, which are constructed of polyamide. This construction provides for a large surface area while minimising the size of the device.

MAINTENANCE

There are a number of chemicals that damage RO membranes. Carbon tanks are used to protect the membrane from chemical exposure by chlorine and chloramines. These chemicals cause oxidative damage. Membranes exposed to peracetic acid products of greater than 1% dilution, which are used for system disinfection, also cause oxidative damage. Membrane exposure to iron deposits will also result in damage.

Membrane performance is influenced by adequate water pre-treatment, pH control, and cleanliness of the RO membrane surface. Additionally, the colder the incoming water, the more resistant it is to crossing the RO membrane, thereby decreasing purified water production. Thin film membrane performance is optimised at a water pH of 5.0–8.5. However, TF membranes are able to perform adequately within a pH range of 2–11. A high pH can precipitate scale formation by calcium and magnesium on the membrane. Organics and dirt do accumulate and routine cleaning and disinfection will ensure proper functioning and extend the life of the reverse osmosis (RO) membrane, and also reduce bacterial growth in the system.

Reverse osmosis (RO) membrane performance is measured by percent (%) rejection, and final product water quality can be measured by either conductivity in micro-siemens/cm (µS/cm) or TDS displayed as mg/L or parts per million (ppm).

It is recommended to use both percent rejection and water quality monitors. They should have adjustable set points, be continuously displayed with visual and audible alarms that can be heard in the patient area.

2.3.12 Submicron and ultrafiltration

Submicron filters remove bacteria, but do not remove endotoxins. Ultrafilters remove both bacteria and endotoxins. These filters are rated to a nominal or an absolute rating with a pore size of 0.22 micron (µm).

Submicron filters are typically fitted to portable ICU RO trolleys and can also be used as an emergency measure for bypass when a RO water plant/RO system is faulted. Submicron filter housings should be opaque to inhibit algae growth. Since ultrafilters have tighter pores, they inherently have low flows and high differential pressure (ΔP across the membrane). They will decrease flow velocity in the loop, if not designed and staged properly i.e. as RO water enters the haemodialysis machine.

Ultrafiltration offers an added benefit and extra patient protection when placed at the point of use and ultrafilters are now commonly fitted to haemodialysis machines to provide optimal water quality and improve patient safety. Ultrafilter performance is usually rated in 'log reduction values' for bacteria and endotoxin.

$$\text{*LRV=Log reduction value (LRV)} = \log_{10} \frac{\text{Number of organisms in challenge suspension}}{\text{Number of organisms in filtrate}}$$

Even though submicron and ultrafilters remove microbes, if not routinely disinfected or replaced, submicron and ultrafilters are targets for bacterial infestation.

Note: All submicron and ultrafilters shall be changed on a scheduled period basis.

Alert: Check that submicron and ultrafilters are validated for medical use. If filters are not validated for medical use, they may contain chemicals that require rinsing with over 2000 L of water for effective removal.

Maintenance: Inspect the used filter's centre tube for soiling. If dirt is present, the filter was over-burdened and should be replaced sooner next time.

All filter changes shall be recorded in the logbook.

2.3.13 Distribution system

Also referred to as the RO water loop, RO distribution systems can be grouped into two categories: direct feed and indirect feed.

1. A direct feed system 'directly' delivers the product water from the RO water plant to the loop for distribution. Unused product water can be recirculated back to the input of the RO unit for conservation reasons.
   Direct feed systems are closed-loop systems preventing the ingress of contaminants, thus are deemed more robust than other systems in restricting bacterial growth.
2. An indirect feed system stores the product water in a storage tank prior to distribution through the loop. Water that is not used within the distribution system is returned to the storage tank. The RO unit is driven by the level of water within the tank and switches on and off as product water is needed to maintain water levels in the tank.
   Storage tanks should be made of inert materials that do not contaminate the purified water, and the bottoms should be conical shaped for complete emptying. The size of the tank should be in proportion to meet the peak demands of the dialysis facility to eliminate the risk of stagnation. The design should incorporate tight fitting lids and hydrophobic submicron vent filters to inhibit airborne microbes from entering the tank.

The recommendation is to design and choose a direct-feed system for delivery of RO water to dialysis machines.

Highly purified water is very aggressive and will leach metals and chemicals it comes into contact with. Polyvinyl chloride (PVC) is the most common piping material to use as it is low cost and has a relatively inert nature. Other substances that may be used include, but are not limited to, high-grade stainless steel (SS), polypropylene (PP), cross-linked polyethylene (PEX), polyvinylidene fluoride (PVDF), and glass.

Presently the preferred material for the distribution loop is PEX, which has proven to be resistant to the growth of bacteria. If a heat disinfectable system is utilised, then this loop must be insulated to ensure a constant temperature gradient for disinfection efficacy. Specialised designers/installers will ensure an effective loop length with minimal bends for an efficient delivery system.

To reduce the risk of the development of biofilm within the distribution loop, all surfaces and any joins should be as smooth as possible. Chamfered connections are recommended and machine and drain outlet connections should be as short, and as simple, as possible. There should be regular evaluation of water flow velocity and a visual inspection made of the distribution loop to ensure that there have been no unauthorised or inappropriate repairs or alterations to the system. Following any break in the distribution loop, adequate disinfection of the fluid pathway must always be undertaken. Weekly monitoring for bacteria and endotoxin should be conducted for one month to verify that levels are within the allowable limits.

Specialised keyed fittings should be considered for the connection points between the distribution loop and the dialysis machine. Utilising keyed fittings will ensure that cross connections between machine supply and machine drain cannot occur.

Though there continue to be some water treatment systems that have non-returning lines that go to a drain, a continuous loop design is recommended. Dead-ends or multiple branches shall not exist in the distribution system, as these are places for bacterial biofilm to grow.

Note: No copper, brass, aluminium, or other toxic substances shall be used in the piping.

2.3.14 Disinfection of the distribution piping systems

Disinfection of the distribution piping system shall happen on a regular basis. The frequency can be determined on compliance results from microbiology testing. The type of distribution piping system and the disinfection method to be used will influence how often disinfection is carried out. There are two types of disinfection methods.

1. **Chemical disinfection**
   When the manufacturer recommends chemical disinfectants, means shall be provided to restore the equipment and the system in which it is installed to a safe condition relative to residual disinfectant prior to the product water being used for dialysis applications. **When recommending chemical disinfectants, the chemical manufacturer shall also recommend methods for testing for residual levels of the disinfectants.**

2. **Hot water disinfection**
   When used to control bacterial proliferation in water treatment, storage, and distribution systems, the water heater of a hot water disinfection system shall be capable of delivering hot water at the **temperature** and for the **exposure time** specified by the manufacturer (minimum distribution loop temp 60 °C).
   Heat disinfection will not remove established biofilms, but is convenient, requires little rinse time and can thus be used more often to prevent biofilm formation. An occasional chemical disinfection might still be necessary.
   Moving to heat, rather than chemical, disinfection of storage and distribution pipework should be considered in all new installations.
   Note: PVC piping shall not be used with heat disinfection. However, high-grade stainless steel (SS), polypropylene (PP), cross-linked polyethylene (PEX), polyvinylidene fluoride (PVDF), and glass can be used with heat disinfection.

2.3.15 Disinfection protection

Disinfection protection, as by definition, ensuring water is returned to a safe condition after disinfection.

When disinfection is accomplished automatically by chemical disinfectant, including ozone, 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. This may require process and procedures that use manual or automated monitoring/testing to validate for safe use after the disinfection cycle.

2.3.16 Deionisers

Deionisers produce water of high ionic quality, but do not remove bacteria and endotoxins. In fact, bacteria and endotoxin levels may increase the frequency to replace ultrafilters, UV systems, etc. to ensure bacteria/endotoxins are removed.

The risk of operating deionisers to exhaustion may cause ions previously removed to be re-released back into the water. An accurate sensitive conductivity monitor is required to ensure appropriate warning of this. Deionisers may also cause wide pH shifts to occur.

Note: Deionisers were previously commonly used, but should not now be used as part of a haemodialysis water pre-treatment system.

2.3.17 Drains

In reference to RO water plants, drains must be of a sufficient material and size to cope with copious amounts of water. RO water and body waste components are aggressively corrosive. Design considerations for volume and type of fluids involved is critical. An appropriate drain material is high-density polyethylene (HDPE), which has high strength properties and is corrosion resistant.

Drainage is required for RO water plant reject water, pre-treatment filter back-wash water, machine waste (typically via a tundish) and for dialysis facility treatment areas in the event of pipework failure.

Drains require a ‘freefall’ component in their design, ensuring that waste cannot be returned back to the system via siphoning effects.

Section 3

Performance requirements

3.1 General

Source water can contain many contaminants. The following table is a list of contaminants that could cause concern for haemodialysis patients. Aluminium, chlorines, copper, nitrates, sulphates and zinc are known to have particular toxicity for haemodialysis patients – dementia, osteomalacia, haemolytic anaemia, nausea, vomiting, and acidosis among some of the symptoms.

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 source/feed water quality shall be periodically monitored thereafter to assure continued appropriate water pre-treatment.

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 in the dialysis water pre-treatment system

Contaminant	Maximum concentration for dialysis source/feed water (mg/L = ppm)	Maximum concentration for product water (mg/L = ppm)
Aluminium (Al)	0.01	0.01
Antimony (Sb)	0.003	0.006
Arsenic (As)	0.01	0.005
Chlorine (Free Cl)	*Refer to total chlorine*	*Refer to total chlorine*
Chlorine (Total Cl)	5	0.1
Chloramines (NH_xCl_y)	3	*Refer to total chlorine*
Copper (Cu)	2	0.1
Fluoride (F)	1.5	0.2
Lead (Pb)	0.01	0.005
Nitrate (as NO_3)	50	2.0
Nitrite (as NO_2)	3	2.0
Sulphate (SO_4)	250	100
Zinc (Zn)	3	0.1
Electrolytes that contribute to dialysate concentration		
Calcium (Ca)	Not listed	2.0
Magnesium (Mg)	Not listed	4.0
Potassium (K)	Not listed	8.0
Sodium (Na)	180	70
Trace elements		
Barium (Ba)	2	0.1
Beryllium (Be)	0.06	0.0004
Cadmium (Cd)	0.002	0.001
Chromium (Cr)	0.05	0.014
Chloride (Cl)	250	50
Mercury (Hg)	0.001	0.0002
Selenium (Se)	0.01	0.09
Silver (Ag)	0.1	0.005
Thallium (Tl)	Not Listed	0.002

Reference: Australian Drinking Water Guidelines ISO13959:2014

The quality of the **product water**, as specified 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. This will provide an analytical dataset allowing potential problems to be resolved early.

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	**Sand filter**	**Softener**	**Carbon tank**	**RO unit**	**UV irradiation**
Aluminium				X	
Arsenic				X	
Barium				X	
Cadmium				X	
Calcium		X		X	
Chloramines			X		X
Chlorine			X		
Chromium				X	
Copper				X	
Fluoride				X	
Lead				X	
Magnesium		X		X	
Mercury				X	
Microcystins				X	
Nitrate				X	
Potassium				X	
Selenium				X	
Silver				X	
Sodium				X	
Sulphate				X	
Zinc				X	
Viruses				X	
Organic contaminants				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 for in-centre and satellite units unless all 'Essential' components are functional and on-line.

Table 3.3 Components, functions and requirements of dialysis water pre-treatment systems

Component	Function	Requirement
Multimedia depth filter	Particle removal	**Essential**
Softener	Hardness correction with brine tank (Ca/Mg – Na)	Where required
Carbon tank	Removes chlorine and chloramine	**Essential**
Polishing filter	Filters particles larger than 1 micron (µm)	**Essential**
UV irradiation	Kills bacteria	Where required
RO unit	Removes ions, bacteria, heavy metals, endotoxins, microcystin	**Essential**

3.2 Water testing

Water testing routines are based on system performance recommendations, including historical and trending data.

Table 3.4 Summary of recommended water testing frequency for dialysis water pre-treatment systems

Water test	Frequency
Water hardness, pre- and post-softener	During design and commissioning. Maximum interval: six-monthly, or after carbon change.
Chlorine	During commissioning. At least once per dialysis shift.
Bacteria	During commissioning, then monthly for period of validation. Progressing to three-monthly.
Endotoxin	During commissioning. Maximum interval: six-monthly.
Chemical contaminant and heavy metal levels	During commissioning. Maximum interval: six-monthly, or after carbon or reverse osmosis (RO) unit change.

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 source water factors.

TEST FREQUENCY AND METHOD

Water hardness (source and product water) may be tested and recorded monthly so trends can be monitored and corrective action taken, as necessary. Should a decision be taken not to test monthly, then six-monthly tests or tests after a carbon tank is changed, whichever occurs first, shall be carried out. The results shall be recorded and trended. As a minimum use a titration hardness test kit. The reagent tests for calcium carbonate, $CaCO_3$ typically less than 25 mg/L.

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.

ACCEPTABLE LEVELS OF HARDNESS

Hardness tests for product water shall 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.

Recommendation: 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. RO water systems may contain an in-built continuous water hardness meter.

3.2.2 Chlorine and chloramine (total chlorine)

GENERAL

DIALYSIS TREATMENT SHALL NOT PROCEED if a total chlorine test result of 0.1 mg/L or greater is identified.

After a high reading and subsequent investigation, should the test results be acceptable, continue patient treatment and carry out further tests in one hour. If a high test result is produced during dialysis treatment, then **treatment shall be terminated.**

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.

Chlorine and chloramine are removed from water by passing the water through a bed of carbon (activated charcoal). Contact time is a critical factor in determining the efficiency of the carbon to adsorb any chlorine or chloramine. The longer the contact time, the less chlorine and chloramine there will be in the water post-carbon.

As a minimum, all dialysis units shall have a process to measure total chlorine, which is the easiest and more meaningful measure.

TEST FREQUENCY AND METHOD

Tests for chlorine and/or chloramine shall be done and recorded at least once per dialysis shift, **prior to any patient being connected**. **The chlorine/chloramine testing shall, as a minimum, be done using a hand-held colorimeter photo spectrometry method. The use of an in-line total chlorine meter regularly referenced to a colorimeter is also recommended.**

Reagent test strips do not constitute an adequate test in a hospital or satellite dialysis unit, but may be appropriate for home dialysis purposes.

Any testing needs to be sufficiently reliable and repeatable to ensure that total **chlorine** levels are not unacceptably elevated.

Note: If any chlorine breakthrough is detected in permeate/product water then dialysis treatment is NOT to be commenced.

WHEN WATER SHOULD BE TESTED

1. **Dialysis units that have individual RO units per patient.**
   The best time to test for total chlorine is after there has been maximum water flowing through the carbon tanks during a dialysis shift. This will give the highest chlorine and/or chloramine concentration as the water will be in contact with the carbon for the minimum time. The delay in 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) to allow water that has been in the carbon tanks for some time to be flushed through the pre-filtration system. At least 30 minutes after a dialysis shift has commenced, maximum water is usually flowing and is a true representation of the water being used for dialysis.
2. **Dialysis units that use a central RO water plant.**
   The best time to test for total chlorine is after there has been maximum water flowing through the carbon tanks during a dialysis shift.
   Automated RO water plants usually have maximum water flowing for some time prior to dialysis shift commencement, dialysis machines will have performed automated disinfections and this will have allowed water that has been in the carbon tanks for some time to be flushed through. This will give the highest chlorine and/or chloramine concentration as the water will be in contact with the carbon for the minimum time.

WHAT WATER SHOULD BE TESTED

In a system where the two carbon tanks are connected in a series configuration, with the first (lead carbon tank feeding water into the second (lag, polisher) carbon tank, the water flowing between the two carbon tanks shall be tested, at least every dialysis shift. If the water sample point is some distance from the carbon tanks the sample water shall flow for at least a few minutes before it is tested. This minimal time is to ensure that any water in the sample pipe has been flushed out prior to the sample being taken.
If there is any doubt about water quality, the product water post-RO shall be tested, as the absolute indicator of patient safety.

ADDITIONAL WATER TESTS

To check the efficacy of the carbon, additional water testing is recommended. Water should be sampled for total chlorine prior to the first (lead carbon tank and after second the lag, polisher) carbon tank. These tests should be done at least once a week. Test results shall be recorded and trended.

HOW WATER SHOULD BE TESTED

There are a number of methods that can be used for chlorine measurement:

1. Photo spectrometry – typically a hand held **colorimeter**
2. In-line chlorine meter – typically a fixed unit using electrodes or cells via amperometric or automatic photometer
3. Titration – typically laboratory but reagent kits are available.

There is no test that can be used for directly testing the concentration of chloramines in water. The concentration of chloramines in water can only be derived from the equation:

Chloramines = Total chlorine – Free chlorine

The manual process photometer method can measure total and free chlorine and is the minimum accepted standard method.

Note: In-line chlorine meters can be programmed to measure total chlorine or free chlorine by the automatic process photometer method.

Only in-line chlorine meters set up to measure total chlorine shall be used.

1. **Manual process photometer method (colorimeter)**

   A standard test for chlorine in water is the manual process photometer method. This method uses a photometer and relies on chlorine reacting with diethyl-p-phenylene diamine (DPD) in a buffered solution to produce a pink colour. A capable, reliable method of detecting dangerously high levels of chlorine and/or chloramine.
   This test method has an acceptable level of reliability, sensitivity, accuracy and repeatability, and constitutes the lowest acceptable level of testing appropriate for a dialysis unit.
   The manual test method for chlorine shall be done at least once per dialysis shift. Results shall be recorded and trended.

The advantage of using the manual test method is that it is portable and economical and mainly repeatable and reliable.

The disadvantages of using a manual photometer are:

- When attempting to measure a total chlorine concentration of 0.5 mg/L the accuracy is ± 10%.
- When attempting to measure a total chlorine concentration of 0.1 mg/L the accuracy is ± 50%.
- The water sample can be contaminated by the container or stirring stick.
- The volume of water may not be consistent.
- DPD tablets or powder have an expiry date.
- The crushing time and the dissolving of the DPD tablet in the water is not consistent.
- The sample water may contain bubbles.
- The time to complete the total test may vary from test to test.

2. Typically in-line chlorine meter amperometric

In-line chlorine meters can be configured to continuously measure the total chlorine concentration in the sample water. Placement will require technical discussion as to where the most appropriate sampling point will be between the two carbon tanks.

When total chlorine tests are used as a single analysis, the maximum level for both chlorine and chloramine shall not exceed 0.1 mg/L. Since there is no distinction between chlorine and chloramine, this safely assumes that all chlorine present is chloramine.

Currently two types of in-line chlorine meters are readily available:

a) Amperometric method with electrodes

The advantages of using an amperometric in-line chlorine meter are:

- An in-line chlorine meter can be set up to continuously monitor total chlorine.
- A remote audible and visual remote alarm can be connected to the in-line chlorine meter.

The disadvantages of using an amperometric in-line chlorine meter are:

- Lacks sensitivity and specificity uncertain.
- Threshold is 0.1 mg/L.
- Requires regular and frequent calibration using titration technology (i.e. shall be performed by a company technician).
- Low chlorine concentration levels cause the probe membrane to clog after a short period of operation, which could be within weeks of operation.
- Probe needs to be protected from 'fines' by separate filter.
- Probe needs to be replaced every six months.

b) Automatic process photometer method

This method is based on the colorimetric measurement principle. Total chlorine is determined using the DPD method. Typically, the total chlorine measurement accuracy is ± 0.01 mg/L in the measuring range 0.00–1.00 mg/L. The measuring time is two minutes.

The advantages of using this method of in-line chlorine meter are:

- Absolute measurement, no calibration necessary
- Extended long-term stability
- Reliable method for measuring total chlorine
- Low maintenance.

The disadvantage of using this method is:

- The need for reagents.

3. Titration

The titration method uses colour formation with reagents through titration.

The advantage of titration is:

- Absolute measurement depending on the sample provided.

The disadvantages of titration are:

- Mainly laboratory bench mounting
- Very expensive
- Requires operator input for every measurement
- Accuracy is dependent on a true sample being provided without contamination.

ACCEPTABLE LEVELS OF CHLORINE AND CHLORAMINE

ISO13959:2014 has recommended that the maximum level of total chlorine be the same as for chloramine, which is 0.1 mg/L.

If using an in-line chlorine meter the acceptable maximum level for total chlorine is 0.1 mg/L.

When trending of test results indicates an increase in the level of chlorine, then the carbon shall be replaced earlier than a 12-monthly routine maintenance schedule.

Should an in-line chlorine meter produce a high test result at any time, carry out a manual process photometer test (colorimeter) as a check on the high test result. Tests should be sampled at the following three locations:

1. between the two carbon tanks
2. post-lag (second) carbon tank
3. post RO.

Note: Testing post-RO is mandatory as the absolute indicator of patient safety. For practical purposes, sampling from the loop is acceptable.

If the manual test shows a high result post-lag (second) carbon tank or post-RO, indicating a true high concentration of chlorine and/or chloramine reaching the patients, then implement the Dialysis Unit Policy on High Chlorine Readings (i.e. dialysis shall not proceed).

3.2.3 Bacteria (CFU) and endotoxin (EU) testing

Bacterial levels should be tested during commissioning, then monthly for a period of validation progressing to a maximum interval of three months.

Sample at the points where all haemodialysis equipment connects to the distribution piping system (post-RO, post-water loop).

Bacteria levels shall not exceed 100 colony forming units/mL (CFU/mL) – with an action trigger level of 50 CFU/mL.

For guidance refer to the Decision Flow Chart (See Section 6: pages 43–46)

Samples shall be assayed within 30 minutes of collection, or be immediately stored at a temperature between 1–5 °C and assayed within 24 hours of collection on a regular schedule. 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.

Note: The calibrated loop technique is not accepted.

Culture media shall be tryptic soy agar or equivalent.

Note: Blood culture media are not appropriate.

Colonies shall be counted after 48 hours incubation at 35–37 °C. Recheck at 72 hours. If negative after the initial 48 hours, recheck after a further 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 500–1000 mL of water and culturing on low-nutrient medium, such as R2A agar and incubating for 5 days or longer at 28–32 °C is preferable and more appropriate. This technique is rational and also acceptable. Total viable microbial counts in product water shall not exceed 100 CFU/mL.

Endotoxins should be measured six-monthly. The endotoxin content in product water shall not exceed 0.25 endotoxin units (EU)/mL. These measurements apply to sampling at the point of delivery to haemodialysis equipment (post-RO, post-water loop).

Note: It is important to monitor haemodialysis equipment that rotates among sites to assure that each device is tested within the test cycle.

The presence of endotoxins can be tested using the limulus amoebocyte lysate (LAL) assay.

These are the recommended levels for Australian dialysis units.

Table 3.5 Levels of contaminants in product water

MICROORGANISMS	ISO 13959:2014
CFU/mL maximum	100
CFU/mL action level	50
ENDOTOXINS	
EU/mL maximum	0.25
EU/mL action level	0.12

Table 3.6 Maximum contaminant concentration levels in the dialysis permeate/product water

Contaminant	Maximum concentration for dialysis product water (mg/L = ppm) ISO13959:2014
Bacteria	100 CFU/ml (Action level : 50 CFU/mL)
Endotoxin	0.25 EU/mL (Action level: 0.12 EU/mL)

Table 3.7 Maximum contaminant concentration levels in dialysate

Contaminant	Maximum concentration for dialysate (mg/L = ppm) ISO13959:2014
Bacteria	100 CFU/mL (Action level: 50 CFU/mL)
Endotoxin	0.25 EU/mL (Action level 0.12 EU/mL)

Table 3.8 Maximum contaminant concentration levels in ultra-pure fluid

Contaminant	Maximum concentration for ultra-pure fluid (mg/L = ppm) ISO13959:2014
Bacteria	0.1 CFU/mL (Action level: n/a)
Endotoxin	0.03 EU/mL (Action level: n/a)

On-line substitution fluid is now produced by a number of haemodialysis machines and is used for both priming the extracorporeal circuit and replacing convective losses in haemodiafiltration (HDF) and haemofiltration (HF). Fluid produced for this purpose must be sterile and free of pyrogens. While standards for microbiological quality and dialysate are out of scope of this document, it should be noted that dialysate quality is largely dependent on the quality of water used in its preparation. A regular surveillance program and validation of substitution fluid quality is required.

3.2.4 Chemical contaminant and heavy metal levels testing

Table 3.9 Test methods for chemical contaminants (Please refer to ISO 13959:2014, Table 3)

Contaminant	Test name
Aluminium	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)
Antimony	Inductively coupled plasma mass spectrometry or atomic absorption (platform)
Arsenic	Inductively coupled plasma mass spectrometry or atomic absorption (gaseous hydride)
Barium	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)
Beryllium	Inductively coupled plasma mass spectrometry or atomic absorption (platform)
Cadmium	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)
Calcium	Inductively coupled plasma mass spectrometry, EDTA titrimetric method, atomic absorption (direct aspiration) or ion-specific electrode
Chlorine and chloramines	DPD ferrous titrimetric method or DPD colorimetric method. TMK/MTK colorimetric method
Chromium	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)
Copper	Inductively coupled plasma mass spectrometry, atomic absorption (direct aspiration) or neocuproine method
Fluoride	Ion chromatography, or ion-selective electrode method or SPADNS method
Lead	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)
Magnesium	Inductively coupled plasma mass spectrometry, atomic absorption (direct aspiration) or ion chromatography
Mercury	Flameless cold vapour technique (atomic absorption)
Nitrate (as nitrogen)	Ion chromatography, spectrophotometric method using sulphosalicylic acid or cadmium reduction method
Potassium	Inductively coupled plasma mass spectrometry, atomic absorption (direct aspiration) flame photometric method or ion chromatography
Selenium	Inductively coupled plasma mass spectrometry, atomic absorption (gaseous hydride) or atomic absorption (electrothermal)
Silver	Inductively coupled plasma mass spectrometry or atomic absorption (electrothermal)
Sodium	Inductively coupled plasma mass spectrometry or atomic absorption (direct aspiration), flame photometric method or ion-specific electrode
Sulphate	Ion chromatography or turbidimetric method
Thallium	Inductively coupled plasma mass spectrometry or atomic absorption (platform)
Total heavy metals	Colorimetric
Zinc	Inductively coupled plasma mass spectrometry atomic absorption (direct aspiration) or dithizone method

For the purpose of testing of chemical contaminants and heavy metal levels, it may be sufficient to collect sample(s) at a point chosen so that the effects of the water pre-treatment system and the piping are completely included (e.g. post-RO, post-water loop). Chemical contaminant and heavy metal testing shall be done as part of the commissioning procedure for any new water pre-treatment system.

Once the water pre-treatment system is in operation, **testing shall be done six-monthly or at the time of carbon/RO change, whichever is earlier. Results shall be recorded and trended.**

Table 3.9 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.

***Historical** – New procedures added to 'Test name'. Tin is now removed from contaminant list.*

3.2.5 Conductivity testing

Permeate conductivity readings can be a useful indicator for the performance of the water plant. Typically readings of less than 25 µS/cm indicate adequate levels for permeate/product water. An automated plant will also display rejection rate. A reading of >95% rejection is adequate.

3.2.6 Residual testing

Test to determine that no residual of any chemical cleaning/disinfection agent is present.

1. Water plant – Adverse or abnormal readings may indicate that the condition of the RO membrane requires interventional maintenance. The maintenance must adhere to the manufactures recommendations and may require chemical cleaning. Therefore, it is imperative that residual testing is undertaken at the completion of the maintenance.
2. Dialysis machine – After performing a cleaning/disinfect program on a dialysis machine with sodium hypochlorite (bleach), the machine shall be tested to ensure no disinfectant remains in the machine. Test strips with a minimum indication of 0.1 ppm are adequate for this task. If other hazardous chemicals are used, appropriate testing as per the manufacturer's recommendations shall be used.

Section 4

Quality control

4.1 General

Every haemodialysis unit shall have **written policies and procedures for the safe operation of the water pre-treatment systems and RO water plant**, including, but not limited to:

- Procedures for collection of water sampling/ frequency and type of testing
  i.e. chemical, heavy metal, bacteria or endotoxin
- Procedures for device and component operation and maintenance
- Procedures to cover routine servicing, including the changing of filters and of media
- Policies for education in operation of water plant, testing of samples, recording and trending results, identifying trends in results, guidelines for actions to be taken when high test results are obtained and Work Health and Safety principles
- Medical, nursing and technical staff working in dialysis units **share responsibility for the safe operation of the water pre-treatment plant and shall participate together in regular committee meetings to review the safe operation of the water pre-treatment plant and RO water plant.** Dialysis nurses should participate in audits and ongoing training, continuing education and accreditation.

4.2 Policies and procedures

4.2.1 Education

Medical, nursing and technical staff working in dialysis units shall be educated and approved for clinical competency in the operation and maintenance of the water pre-treatment systems. All other persons involved in the water pre-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.

4.2.2 Operation of the water pre-treatment systems and reverse osmosis water plant

The operation of the water pre-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 and RO water plant shall be maintained within the dialysis unit.

4.2.3 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 the water sample is collected in and how the sample is maintained up to the time it is tested.

4.2.4 Testing of samples

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

4.2.5 Recording and trending results

All water test results shall be recorded and trended over time. Trending may be done on a graph (e.g. with the results being obtained by averaging the last 10 test results). The trending result will show if there is any slight changes of test results over time. The test results and trending graphs should be maintained near the water pre-treatment system.
[See Template for recording chlorine and chloramine levels in Appendix II]

4.2.6 Identifying trends in results

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

4.2.7 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 high. It is essential that any high results are promptly communicated to responsible senior staff.

4.2.8 Work Health and Safety principles

Every dialysis unit shall have safe work method statements for every procedure to be undertaken on the water pre-treatment system. Safe work method statements shall be developed while carrying out a risk management procedure. These safe work method statements shall be followed by all persons working on any part of the water pre-treatment system. There shall also be safe work method statements for persons collecting and testing water samples.

All contractors shall complete a site induction and a written risk management procedure before commencing any work on the water pre-treatment system in accordance with individual institutional policies.

Records of all risk management procedures, safe work method statements, contractor inductions, etc. shall be maintained within the dialysis unit.
[See Examples in Appendices III, IV and V, to assist managing Work Health and Safety requirements]

4.2.9 Committee meetings

Water quality and the safe functioning of the water pre-treatment system shall be reported on a regular basis to a multidisciplinary committee, made up of clinical staff, technical staff and other appropriate stakeholders. Local conditions are such that some institutions may not have representatives from all disciplines, but the intention is that there is adequate monitoring of water quality. These minutes should be circulated to appropriate health service authorities, to indicate safe running of the dialysis room and the dialysis water pre-treatment plant.

Note: Smaller units may have to exercise flexibility in achieving a working party.

4.2.10 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 committee.

4.2.11 Third party involvement

The use of third parties to provide services shall be audited to ensure that the third party is licenced or accredited and that there is an understanding of the responsibility and reporting structure required by the Health Service.

Section 5

Servicing and maintenance

5.1 General

Water pre-treatment systems and RO water plant require regular supervision, maintenance and servicing. Each water pre-treatment system shall have a log book with careful written records documenting every intervention, repair, servicing or maintenance procedure.

The use of an electronic medium, such as an equipment management system, is encouraged as the software features allow powerful analytical tools to be utilised.

All servicing, maintenance, interventions and changes to the water pre-treatment system and RO water plant shall be locally recorded in water pre-treatment and RO water plant room records.
[See example Maintenance Log in Appendix VII]

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) at three metres from the nurses' station, and it shall not be possible to silence these alarms for more than five minutes.
- All treated water outlets should have special fittings that match dialysis machine connections. The intention is to eliminate connection to untreated water. In addition, consideration may be given to labelling untreated water outlets.

5.2.2 Labelling and 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.

5.2.3 Device markings

The following information shall accompany each water treatment device or system. Items one through four shall be directly affixed to the device or system or, in the case of disposable elements, to the immediate packaging, whereas items five and six may be provided in accompanying product literature.

1. Name and address of manufacturer.
2. Trade name and type of device.
3. Model and serial number.
4. A warning that product literature should be read before use, if appropriate.
5. Prominent warnings about substances (e.g. germicides) that shall be removed from the device before using the product water for dialysis.
6. Identification of fitting type or specification when necessary to prevent improper connections.

5.2.4 Product literature

The manufacturer shall provide literature to each patient facility that contains, but is not necessarily limited to, the following information:

- A description of the device or system, including a list of monitors, alarms and component devices provided as standard equipment.
- A schematic diagram of the device or system showing the location of any valves, in-line monitors or sampling ports.
- Operating specifications, such as maximum and minimum input water temperature, pressure and flow rate, limits on input water quality, pressure of product water at various flow rates, and maximum output of product water.
- Detailed instructions for use including initial start-up, testing and calibration, operation and meaning of alarms, operational adjustments to monitors, alarms and controls and connections to other equipment.
- An explicit statement of the relationship between feed water quality and product water quality for the chemical contaminants listed in Table 3.1.
- The minimum quality of feed water required for the system to produce product water meeting the chemical requirements of Table 3.1.
- A warning that although a water pre-treatment system and RO water plant may produce water of sufficient quality to meet the requirements of Table 3.1, distribution of the water may degrade its quality to the point where it no longer meets the requirements of Table 3.1, if the distribution system is not maintained appropriately.
- In the case of systems whose product water is proportionally related to feed water quality, warnings that feed water quality shall be monitored. Since changes in product water may exceed acceptable limits if feed water deteriorates significantly, the patient facility shall be responsible for monitoring the feed water quality.
- For automatically regenerated water treatment devices, identification of the mechanism (e.g. lockout valves) that prevents excessive levels of contaminants entering the product water during regeneration.
- In the case of ultraviolet (UV) irradiators, a requirement that the manufacturer disclose the effectiveness of the device in killing specific bacteria under specified operating conditions, and a recommendation that UV irradiators be followed by an ultrafilter or other bacteria-reducing and endotoxin-reducing device.
- In the case of hot water disinfection systems, a requirement that the manufacturer disclose the effectiveness of the system in killing specific bacteria under specified operating conditions.
- Typical life expectancy, capacity or indication of the end of life of components that are non-durable or require periodic regeneration or reconstitution and a statement that additional information on component life expectancy or capacity relative to the patient facilities typical feed water is available, upon request.

5.2.5 Maintenance literature

The dialysis facility, or the dialysis technical service should retain copies of maintenance and service instructions, including recommended preventive maintenance procedures and schedules, recommended monitoring schedules, troubleshooting guidelines intended for the patient facility, service information, a recommended spare parts list and a warning of the consequences if maintenance instructions are not followed.

The literature should contain information about germicides and cleaning agents as well as recommendations from the manufacturer regarding compatibility with materials used in the device, as well as information about chemicals with which materials used in the device are incompatible.

It is important that Safety Data Sheets are kept as part of the literature.

5.2.6 Water pre-treatment system changes

A warning that if, after installation and subsequent use, any component of the water pre-treatment system or RO water plant is changed or replaced, the patient facility should conduct appropriate tests to ensure that the revised system meets the initial design criteria.

5.2.7 Maintenance and service procedures

Any maintenance, repair or service to the dialysis equipment must be performed in accordance with the manufacturer's recommendations and carried out by qualified and accredited personnel. Safe Work Practices and Job Safety Analysis for the tasks should be available for these personnel.

All replacement parts or media are to be of the approved type and suitable for the intended purpose.

Failed parts should be inspected for cause of failure with a view to quality improvement performance.

Service reports should indicate work performed, duration for the task and list any recommendations for further maintenance.

Records must be maintained in accordance with:

- At state level, the *States Records Act 1998*
- At local level, the Local Health District records management policy.

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 hospitals and dialysis units when an interruption to water supply occurs, or is planned, to avoid or minimise any adverse impact on patients. Even though this may be part of the Disaster Management Team brief, more direct communication is essential.

Protocols or procedures should exist to provide a dialysis treatment alternative in the event of a water supply failure. Business Continuity Plans (BCPs) should encompass the hospital or satellite setting, but consideration should be taken into account for home haemodialysis patients.

Hospitals and dialysis units should inform their local water utility when a patient undergoes dialysis treatment at home, and when treatment ceases.

INFORMATIVE

Hospitals and dialysis 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.

Hospitals and dialysis 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 healthcare facilities should define the criteria for notification of interruption to water supply with their local water utility.

Please refer to Appendix IX.

Section 6

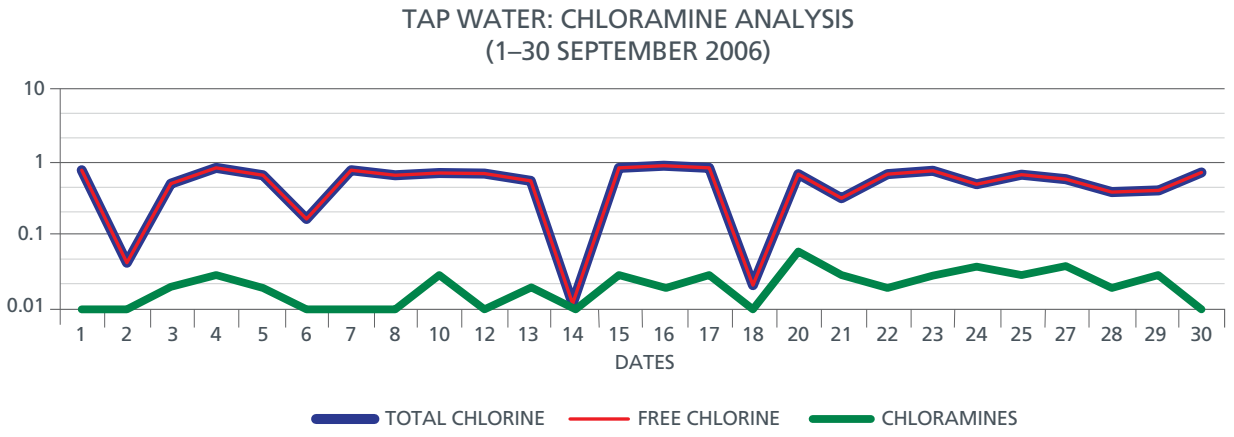
Recordings

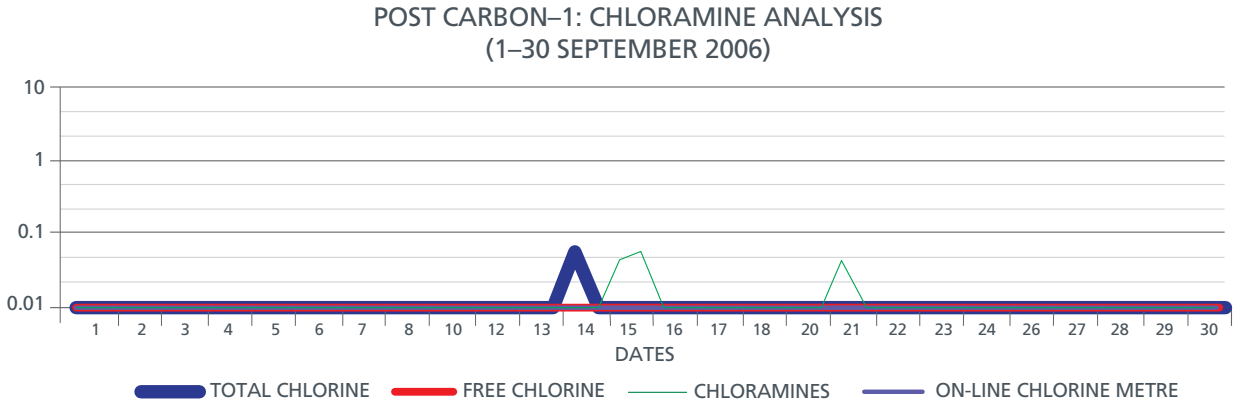
6.1 A model data recording system for chlorine/chloramine measurements

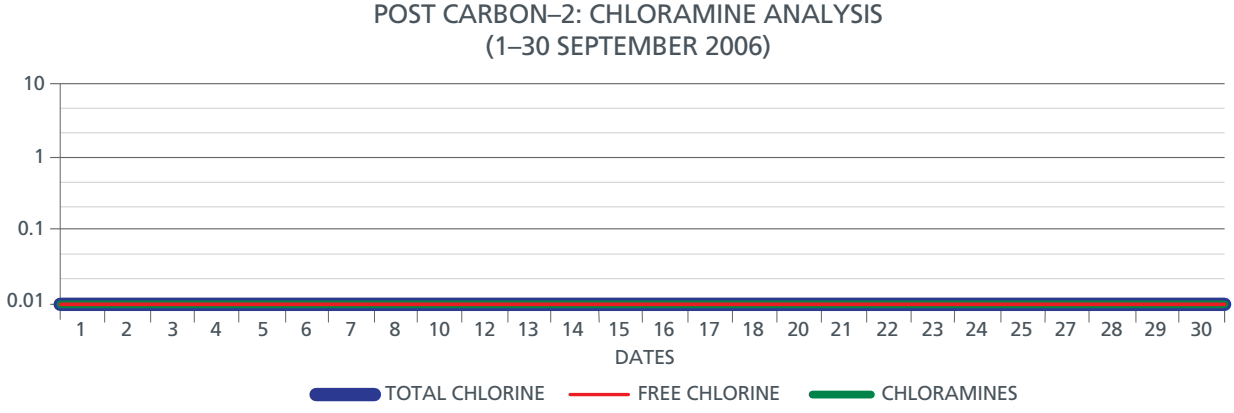
A Microsoft Excel spreadsheet is a suitable data recording and trending document [see Appendix II].

Note: As the scale below is logarithmic, no zero results can be recorded, and any result less than 0.001 mg/l shall be recorded as 0.001 mg/l.

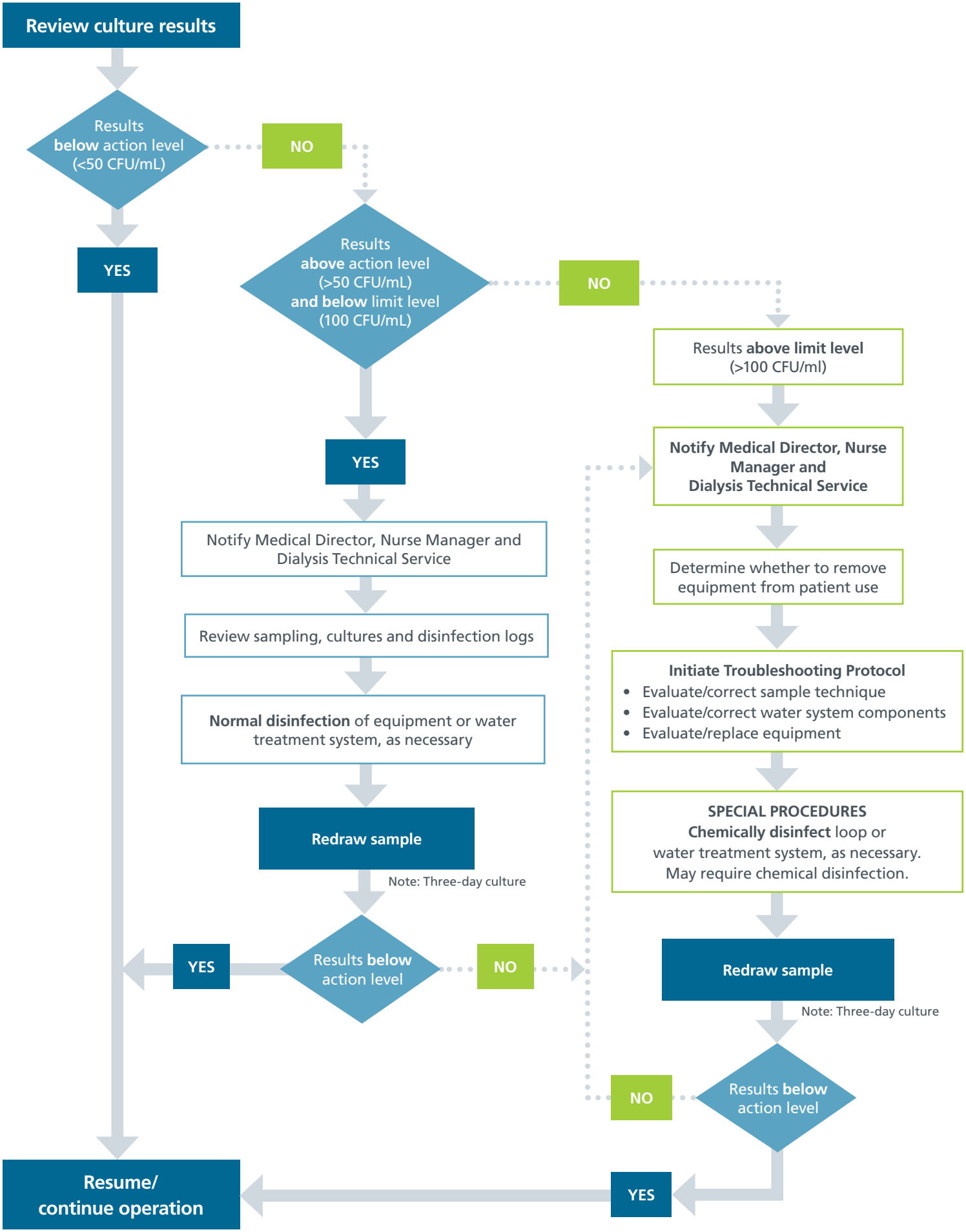
Figure 1 Example of chlorine/chloramine measurement trends recorded in a Microsoft Excel spreadsheet



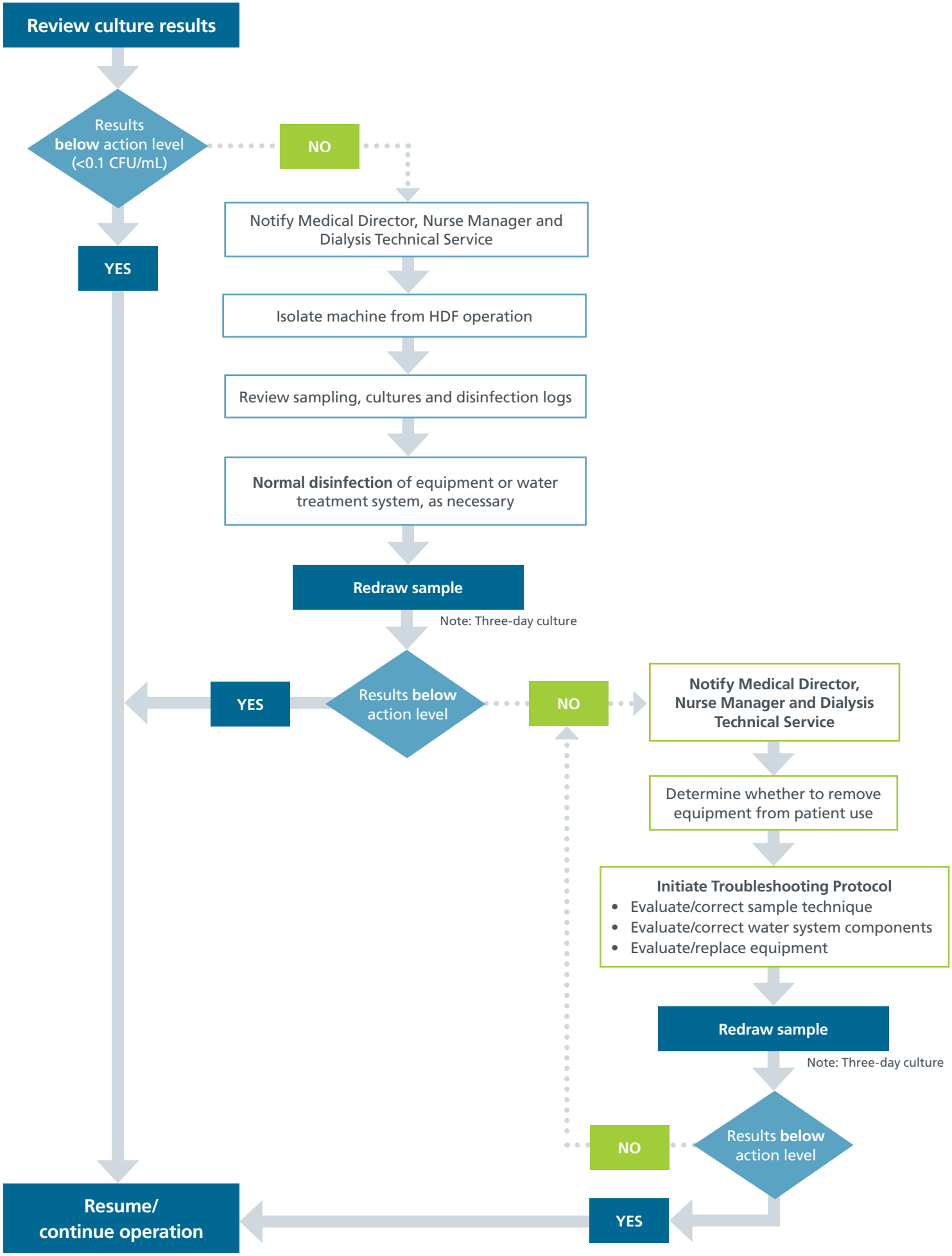




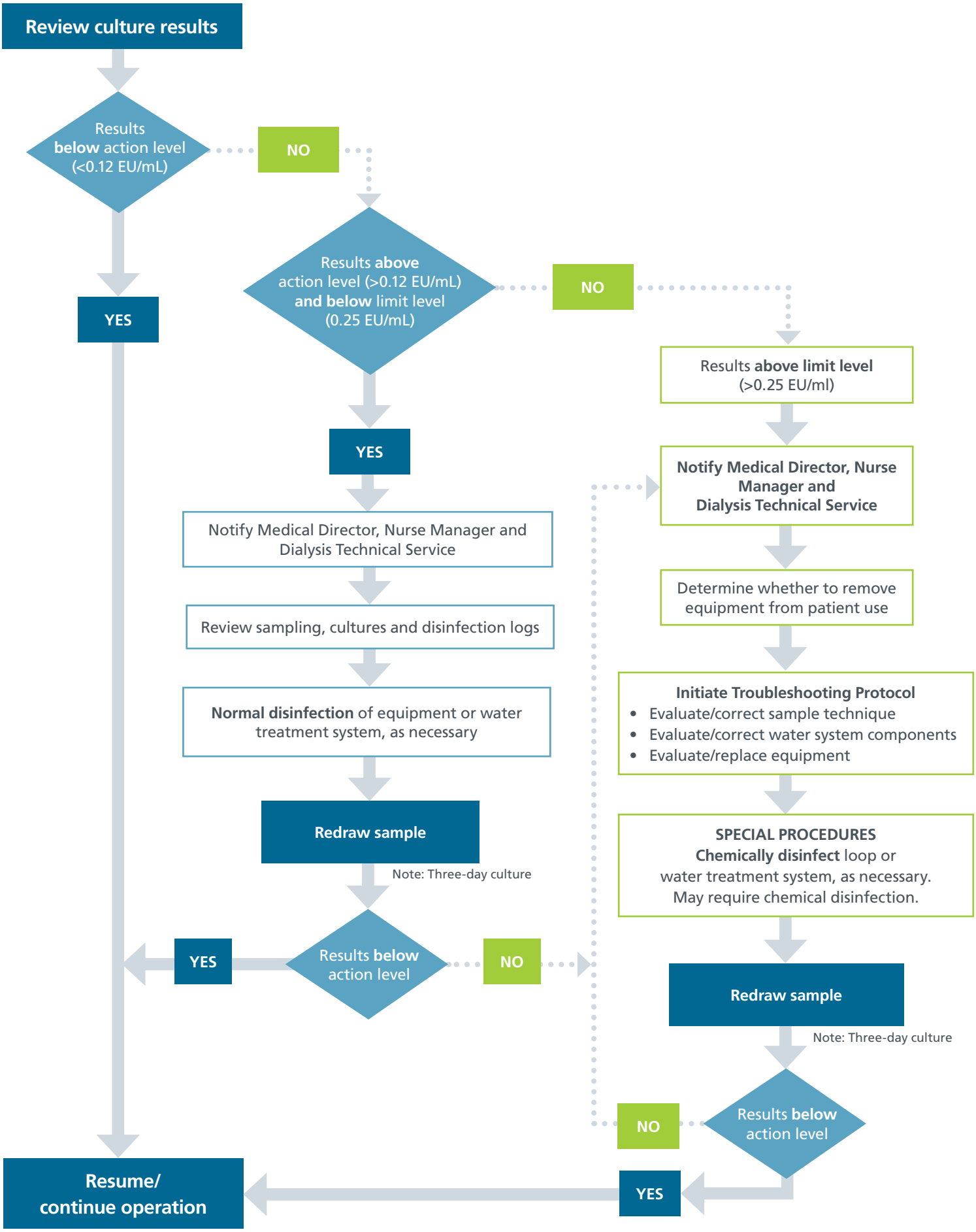
6.2 Decision flow chart for bacterial contamination (CFU) Haemodialysis (HD) machines, distribution loop



6.3 Decision flow chart for bacterial contamination (CFU) Haemodiafiltration (HDF) machines



6.4 Decision flow chart for endotoxin contamination (EU) Haemodialysis (HD) machines, distribution loop



PART II

Management of water quality – home haemodialysis

FOR USE IN CONJUNCTION WITH PART I OF THIS GUIDE

Executive summary: Part II

- 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 haemodialysis.
- The ISO standards are the accepted **minimum** standards for water pre-treatment for home haemodialysis.
- The quality of dialysis water ***shall*** be regularly tested, according to this Guide.
- Home haemodialysis-related practices ***shall*** be regularly audited.
- Home haemodialysis ***shall*** never take place without, at a minimum, a sediment filter, carbon filtration and reverse osmosis (RO) plant for water treatment.
- All servicing, maintenance, interventions and changes to the water pre-treatment plant ***shall*** be recorded.

Section 7

SCOPE and GENERAL for home haemodialysis

7.1 Scope

The recommendations in this document are based on the maximum level of known or suspected harmful contaminants that may be present in product water to be used for the preparation of dialysing fluids, as specified by ISO. 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 that 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.

7.2 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.

7.3 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.

7.4 Referenced documents

ISO 11663: 2009 Quality of dialysis fluid for haemodialysis and related therapies

ISO 13958: 2009 Concentrates for haemodialysis and related therapies

ISO 13959: 2014 Water for haemodialysis and related therapies

ISO 26722: 2014 Water treatment equipment for haemodialysis applications and related therapies

ISO 23500: 2011 Guidance for preparation and quality management of fluids for haemodialysis and related therapies

Clinical Practice Guideline by the UK Renal Association and Association of Renal Technologists

NHMRC, NRMMC (2011) *Australian Drinking Water Guidelines Paper 6 National Water Quality Management Strategy.* Version 3.0. Updated December 2014. National Health and Medical Research Council, National Resource Management Ministerial Council, Commonwealth of Australia, Canberra.

Previously referenced documents

- Amato, Rebecca L. (2001) *Water Treatment for Hemodialysis.* Nephrology Nursing Journal, Dec 2001.
- Amato RL. Water treatment for hemodialysis, including the latest AAMI standards. *Nephrol Nurs* J 2001;28(6):619–29.
- American National Standards Institute, ANSI/AAMI RD5; 2003 *Hemodialysis systems,* Association for the Advancement of Medical Instrumentation, Arlington, Virginia.
- American National Standards Institute, ANSI/AAMI RD52; 2004, *Dialysate for hemodialysis*, Association for the Advancement of Medical Instrumentation, Arlington, Virginia.
- American National Standards Institute, ANSI/AAMI RD62; 2001 *Water treatment equipment for hemodialysis applications,* Association for the Advancement of Medical Instrumentation, Arlington, Virginia.
- ANSI/AAMI 2006
- ANSI/AAMI RD5:2003, *Hemodialysis systems,* 3ed
- ANSI/AAMI RD52:2004, *Dialysate for hemodialysis*, 1ed.
- ANSI/AAMI RD62:2001, *Water treatment equipment for Hemodialysis applications,* 1ed.
- CARI Guidelines (Caring for Australasians with Renal Impairment)
- Water Guidelines Working Group of the Renal Services Network, GMCT. *Dialysis water pre-treatment for in-centre and satellite haemodialysis units in NSW: A set of guidelines*, June 2008.
- EBPG (European Best Practice Guidelines. Section IV. Dialysis Water Purity. *Nephrol Dial Transplant 2002;* 17 [Supp17]: 45-62)
- European Best Practice Guidelines. Section IV. Dialysis fluid purity. *Nephrol Dial Transplant 2002;*17(Suppl 7):45–62.
- International Organization for Standardization, ISO 13959: 2002 *Water for haemodialysis and related therapies,* International Organization for Standardization, Geneva.
- ISO 13959, Water for Haemodialysis and related therapies.
- ISO 13959: 2009 *Water for haemodialysis and related therapies*
- ISO 26722: 2009 *Water treatment equipment for haemodialysis applications and related therapies*
- Kerr P, Perkovic V, Petrie J, et al. The CARI guidelines. Dialysis adequacy (HD) guidelines, *Nephrology* 2005;10(Suppl 4):S61–S80.
- Water Quality for Haemodialysis, Dialysis Adequacy (HD) Guidelines, *Nephrology* 2005; 10: S61-S80
- NSW Department of Health, Health Facility Guideline: Renal Dialysis Unit, NSW Department of Health, North Sydney, NSW. 2006. Available at: *http://healthdesign.com.au/nsw.hfg/hfg_content/guidelines/hfg_b_renal_dialysis_unit_460_484.pdf*.

Section 8

Planning for home haemodialysis

8.1 General

Home haemodialysis (HHD) patients should have access to the same quality of dialysis as 'in-centre' patients.

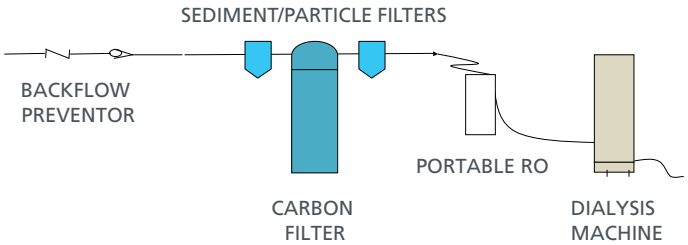
8.2 Considerations

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 microbiology quality of the feed water.
2. The chemical quality of the feed water.
3. The source of the feed water, e.g. from storage tanks, dam, artesian etc.
4. The pressure of the feed water.
5. Drainage requirements, e.g. sewer systems or transpiration septic or biocycle systems.
6. Space required to safely install, maintain and operate dialysis equipment.
7. Power supply considerations.

8.3 Components

Diagram 6: Typical home haemodialysis arrangement



8.3.1 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.

8.3.2 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.

8.3.3 Particle filtration

Also known as sediment filters, particle filters remove large particulates of 10 µm or greater that cause the feed water to be turbid, such as dirt, silt and colloidal matter (suspended matter). Large particulates can clog the carbon and softener tanks, destroy the RO pump, and foul the RO membrane.

Typically, home haemodialysis installations use sediment filters before and after the carbon filter. An installation that incorporates the sediment filters and carbon filter as one unit will alleviate physical space constraints in a home treatment setting.

8.3.4 Water softener

Typically, most metropolitan water supplies are of sufficient quality as to not require softeners. However, rural communities may require the addition of a small water softening system for treating the source water at a home haemodialysis installation.

Commercial units are available for home dialysis settings either utilising solid salt blocks or brine mixtures. Typically, a regeneration cycle is required prior to or after each dialysis treatment.

Use of water softeners is optional and dependent on the source water chemical characteristics. Both water softeners and RO units remove calcium from the water being treated. Calcium bonds to resin beads contained in water softener resin tanks and is removed from these resin beads during regeneration.

RATIONALE

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.

Note: New technology is available, but as yet it has not been tested for dialysis treatment. The use of polymer spheres as a media that transforms dissolved $CaCO_3$ calcium carbonate to crystalline forms is referred to as template-assisted crystallisation (TAC). The technology is based on container replacement rather than regeneration.

For detailed information refer to Part I of this Guide.

8.3.5 Carbon filter (tank)

The purpose of the carbon filter is to remove chlorine or chloramine from the source water making the water suitable for haemodialysis. The process is called adsorption.

In the home haemodialysis installation a requirement is for an EBCT of 10 minutes. Typically, a 22 L carbon filter will be sufficient for this task.

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 filter. Depending on quality of the water supply it may be prudent to routinely to change the carbon filter.

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 back-wash is recommended. The carbon tank shall be tested for conductivity and chlorine removal prior to use.

For detailed information refer to Part I of this Guide.

8.3.6 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 (RO) unit is the semipermeable membrane, i.e. a membrane that allows the passage of water, but retains most of the dissolved salts, particles, bacteria, microcystins and pyrogens.

The typical home haemodialysis installation consists of a portable reverse osmosis (RO) unit. This unit requires a conditioned source water and a suitable power supply.

Power supply requirements will depend on the mode of disinfection the device uses. There are two modes of disinfection: heat or chemical.

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 RO internal tank.

8.3.7 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 chemically 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.

The health service should decide on the most appropriate mode of disinfection based on, but not limited to, the following factors:

- Location of technical service
- Location of installation
- Policy and procedure based on risk management of devices, possibly the use of a 50% duty cycle, where devices are serviced twice a year rather than annually.

Informative: This is also referred to as a 100% safety factor management strategy.

Disinfection protection, by definition, involves ensuring water is returned to a safe condition after disinfection.

8.3.8 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 ultrafilters, ISO recommends they are validated for medical use. In the industry, there are 'nominal' and 'absolute' ratings for ultrafilters 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 L of water to rinse thoroughly.

It is recommended that all home haemodialysis machines be fitted with ultrafilters. Policy and procedure must be in place to manage the changing of ultrafilters in line with the manufacturer's recommendations.

8.3.9 Haemodiafiltration (HDF) at home

Haemodiafiltration requires the machine to produce ultrapure fluid that is added to the patient's blood circuit. As this fluid is in direct contact with the patient's blood it is vital to ensure purity for patient safety.

A suggestion is that the home installation comprises the standard filtration, but coupled with a heat disinfectable portable reverse osmosis (RO) unit.

Section 9

Performance requirements – home haemodialysis

9.1 General

9.1.1 Source water/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 at home. At a minimum a pre-dialysis survey of the water is required for bacteria, endotoxin and chemical (heavy metal) components. This will allow for the design of the water pre-treatment system to establish required components, e.g. the addition of a softener in high-calcium locations.

The feed water shall meet the Australian drinking water guidelines. 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 annually. Tank, creek or bore water should be tested more frequently.

9.1.2 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 9.1.

9.1.3 Water for use in haemodiafiltration (HDF)

Haemodiafiltration requires the machine to produce ultrapure fluid that is added to the patient's blood circuit. As this fluid is in direct contact with the patient's blood it is vital to ensure purity for patient safety.

A suggestion is to test for microbiological activity (CFU) every month for the first three months after installation at home, with regular surveillance thereafter (e.g. every 3–4 months).

Currently, the best practice is to incorporate integrated heat disinfection, where machine, feed water lines and RO unit heat at the same time ensuring all water components are disinfected at the one time.

Table 9.1 Maximum contaminant concentration levels in the dialysis water pre-treatment system

Contaminant	Maximum concentration for dialysate (mg/L = ppm) ISO13959:2014
Aluminium (Al)	0.01
Antimony (Sb)	0.006
Arsenic (As)	0.005
Barium (Ba)	0.1
Beryllium (Be)	0.0004
Cadmium (Cd)	0.001
Calcium (Ca)	2.0
Chloride (Cl)	50
Chlorine (free Cl)	Refer total chlorine
Chlorine (total Cl)	0.1
Chloramines (NH_xCl_y)	Refer total chlorine
Chromium (Cr)	0.014
Copper (Cu)	0.1
Fluoride (F)	0.2
Lead (Pb)	0.005
Magnesium (Mg)	2.0
Mercury (Hg)	0.0002
Nitrate (as Nitrogen)	–
Nitrate (as NO_3)	2.0
Potassium (K)	2.0
Selenium (Se)	0.09
Silver (Ag)	0.005
Sodium (Na)	70
Sulphate (SO_4)	100
Thallium (Tl)	0.002
Tin (Sn)	–
Zinc (Zn)	0.1
Bacteria	100 cfu/ml (action level 50 CFUu/mL)
Endotoxin	0.25 EU/mL (action level 0.12 EU/mL)
HDF bacteria	<0.1 CFU/mL
HDF endotoxin	0.03 EU/mL

Table 9.2 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 attached and working.

Table 9.2 Components of a home dialysis water pre-treatment system

Component	Function	Requirement
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 (µm) filter	Filters particles larger than 1 micron (µm)	**Essential**
RO Unit	Removes ions, bacteria, heavy metals, endotoxins, microcystins	**Essential**

9.2 Water testing

Table 9.3 Summary of recommended water testing frequency for home dialysis water

Water test	Frequency
Water hardness, pre- and post-softener (where installed)	During design and commissioning, and at each service.
Chlorine	Each service or by the operator of the machine before each treatment.
Bacteria and endotoxin, Haemofiltration (HF)	During commissioning. Further home testing is not recommended, as sampling is difficult to do correctly and produces a high rate of false positive results.
Haemodiafiltration (HDF)	During commissioning. Bi-monthly after filter replacements. By request of treating clinician.
Chemical contaminant and heavy metal levels	During commissioning. By request of treating clinician.

9.2.1 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. 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. A minimum 15-minute flush is recommended to rid the system of stagnant water.

9.2.2 Chlorine and chloramine

GENERAL INFORMATION

Chlorine and chloramine are removed from water by passing the water through a bed of carbon (activated charcoal). 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 adsorb the chlorine and chloramine. The longer the contact time the less chlorine and chloramine there will be in the water post-carbon.

A 2002 Department of Health recommendation stated that 20 L carbon filters should be used for all home dialysis patients. This has since become a minimum standard for all home patient installations in order to provide at least a 100% safety margin, as home patients are not able to monitor chlorine or chloramine levels with the same degree of accuracy as institution-based dialysis units.

- 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 filters are changed well within the recommended time frame. Usually 12-monthly.
- The responsibility for ensuring that the filters 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 filters 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 filters are to be of sufficient capacity to handle chlorine and chloramine levels with at least a 100% safety margin for the worst case scenario.
3. The quantity of water is low in relation to the size of the filter to be provided.

Note: At the time of publication, trials are underway comprising of a system of 2 x 11 L carbon filters.

Rationale: Two filters may give added protection against chlorine breakthrough, and in relation to safe work practice, the use of smaller vessels may alleviate physical injuries.

Potential limitations: May require changing more often due to physical size and the possibility of sedimentation effects. As this is a new innovation, monitoring and validation may dictate maintenance practices.

Acceptable levels of chlorine and chloramine:
The maximum level for chlorine and for chloramine is 0.1 mg/L, in line with ISO13959:2014 recommendations.

9.2.3 Bacteria and endotoxin testing

Bacteria and endotoxin testing should be performed on source water prior to a home haemodialysis installation to establish suitability and a baseline reference. Bacterial levels shall be tested at the point where the dialysis machine connects to the distribution piping system (post-RO).

Bacteria levels shall not exceed 100 colony forming units/ml (CFU/mL), with an action level of 50 CFU/mL. Endotoxin levels shall not exceed 0.25 endotoxin units/ml (EU/mL), with an action level of 0.12 EU/mL.

The frequency of testing should be based on the quality of the source water, hence the frequency of testing may be dependent upon location or at a clinician's request.

Home HDF machine water testing should be attended regularly: Usually performed after a filter change and disinfection routine to validate the water purity.

Bacteria levels shall not exceed 0.1 colony forming units/ml (CFU/mL.
Endotoxin levels shall not exceed 0.03 endotoxin units/ml (CFU/ml)EU/mL.

For guidance refer to the **Decision flow chart** (See Section 6: pages 44-46)

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 waterborne organisms using a membrane filtration technique, filtering 500–1000 mL of water and culturing on low-nutrient medium, such as R2A agar, and incubating for 5 days or longer at 28–32 °C is preferable and more appropriate. This technique is rational and also acceptable. Total viable microbial counts in product water shall not exceed 100 CFU/mL.

Testing for endotoxins: According to ISO, the endotoxin content in product water shall not exceed 0.25 EU/mL, or as required by national legislation or similar.

The presence of endotoxins can be tested using the Limulus Amoebocyte Lysate (LAL) assay.

These are the recommended levels for Australian dialysis units.

Table 9.4 Testing for bacteria and endotoxins

Microorganisms	ISO 13959:2014
CFU/mL Maximum	100
CFU/mL Action level	50
Endotoxins	
EU/mL Maximum	0.25
EU/mL Action level	0.12

The following table provides the maximum levels for home HDF.

Table 9.5 Maximum contaminant concentration levels in ultrapure fluid

Contaminant	Maximum concentration for ultrapure fluid (mg/L = ppm)
	ISO13959:2014
Bacteria	0.1 CFU/mL (action level: n/a)
Endotoxin	0.03 EU/mL (action level: n/a)

9.2.4 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.

Please refer to Table 9.1 Maximum contaminant concentration levels in the dialysis water pre-treatment system post-RO and submicron and ultrafilters.

For a complete summary of contaminant testing procedures please refer to Part I of this Guide.

Section 10

Quality control – home haemodialysis

10.1 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 Work 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 systems and shall participate together in regular committee meetings to review the safe operation of the water pre-treatment plant.**

10.2 Policies and procedures

10.2.1 Operation of water pre-treatment systems

The operation of a water pre-treatment system shall only be carried out by persons who have been trained and accredited. 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.

10.2.2 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 and dialysis technical service. These policies and procedures shall include information on how to collect the water sample, where the sample is collected from, and what the water sample is collected in and how the sample is maintained up to the time it is tested.

10.2.3 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 and/or dialysis technical service.

10.2.4 Recording results

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

For guidance, please refer to the Decision flow chart in Section 6.

10.2.5 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.

For guidance, please refer to the Decision flow chart in Section 6.

10.2.6 Committee meetings

On a regular basis (at least 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.

For guidance, please refer to the Decision flow chart in Section 6.

10.2.7 Work 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 and/or dialysis technical service.

10.2.8 Audits, training and continuing education

The operation of the water pre-treatment systems and the on-going 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.

10.2.9 Third party involvement

The use of third parties to provide services shall be audited to ensure that the third party is licenced or accredited and that there is an understanding of the responsibility and reporting structure required by the Health Service.

Section 11

Servicing and maintenance – home haemodialysis

11.1 General

Recommendation that a 50% duty cycle/loading for dialysis equipment is utilised to manage risks, i.e. change at half the validated maintenance frequency. For example, if device validated for 12 months then adopt policy to change at 6 months.

Water pre-treatment systems require regular supervision, maintenance and servicing. It is highly recommended that servicing is performed in a dialysis-appropriate workshop, where possible. All servicing, maintenance, interventions and changes to the water pre-treatment system shall be recorded.

[See recommended structure of Maintenance Logbook/ Folder in Appendix VII.]

11.2 Technical considerations

11.2.1 Safety requirements

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

- Comply with electrical safety standards
- Have the ability to be manoeuvred easily
- 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 minutes.

11.2.2 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.

11.2.3 Machine logbooks

All machines should have a readily available log book that should contain information as to the servicing and testing of that machine. It is recommended that machine faults be recorded in these books to assist with analysing trends in either use or operation.

11.2.4 Training manuals

Home haemodialysis patients should be provided with a training manual that contains information on the identity and purpose of the components, as well as detailed instructions for machine disinfection and cleaning.

11.3 Water utility communications

NSW Health recommends that **dialysis home training 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 home training units and home dialysis patients when an interruption to water supply occurs, or is planned, to avoid or minimise any adverse impact on patients. Even though this may be part of the Disaster Management Team brief, more direct communication is essential.

Home-training Units should consult with their local water utility and provide details of a contact person to ensure notification of interruptions to water quality. These healthcare 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.

Protocols or procedures should exist to provide a dialysis treatment alternative in the event of a water supply failure. Business Continuity Plans (BCP) should encompass the hospital or satellite setting, but consideration should be taken into account for home haemodialysis patients.

Hospitals and dialysis units should inform their local water utility when a patient undergoes dialysis treatment at home and when treatment ceases.

INFORMATIVE

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. (For other NSW locations, see Appendix IX.)

11.4 Maintenance

General maintenance should encompass machine and water testing.

Any maintenance, repair or service to the dialysis equipment must be performed in accordance with the manufacturer's recommendations and carried out by qualified and accredited personnel. Safe Work Practices and Job Safety Analysis for the tasks should be available for these personnel.

All replacement parts or media are to be of the approved type and suitable for the intended purpose.

Failed parts should be inspected for cause of failure with a view to quality improvement performance.

Service reports should indicate work performed, duration of the task and list any recommendations for further maintenance.

Records must be maintained in accordance with:

- at state Level, the *States Records Act 1998*
- at local level, the Local Health District records management policy.

Water testing is to be performed in accordance with manufacturer's recommended procedures and frequency. Source water, pre-treated water, product water and machine fluids should be tested.

11.4.1 Feed/source water

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.

11.4.2 Sediment or particle filters

Recommended filters are changed on a monthly basis. These items are consumables, relatively inexpensive and by frequent renewal will minimise problems associated with silts. Filters should be changed monthly by the patient, or earlier if a pressure differential (ΔP) is noted between inlet and outlet filters. If this is not practicable, arrangements will need to be made with the technical service department regarding filter changes.

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

11.4.3 Carbon

Granulated activated carbon (GAC) has the ability to become saturated with chlorine and/or chloramine to a point where any further adsorption 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 filters. Carbon filters for the home haemodialysis setting should have a minimum volume of 22 L. These carbon filters should be changed at a frequency directly related to the source water supply. Filters should be changed annually for town water and more frequent for tank, creek or bore water.

11.4.4 Machine ultrafilter

Is a point-of-use filter to remove bacteria and endotoxin. The ultrafilter should be maintained and replaced in accordance with the manufacturer's recommendations.

Appendix I

List of important contact details for water quality issues

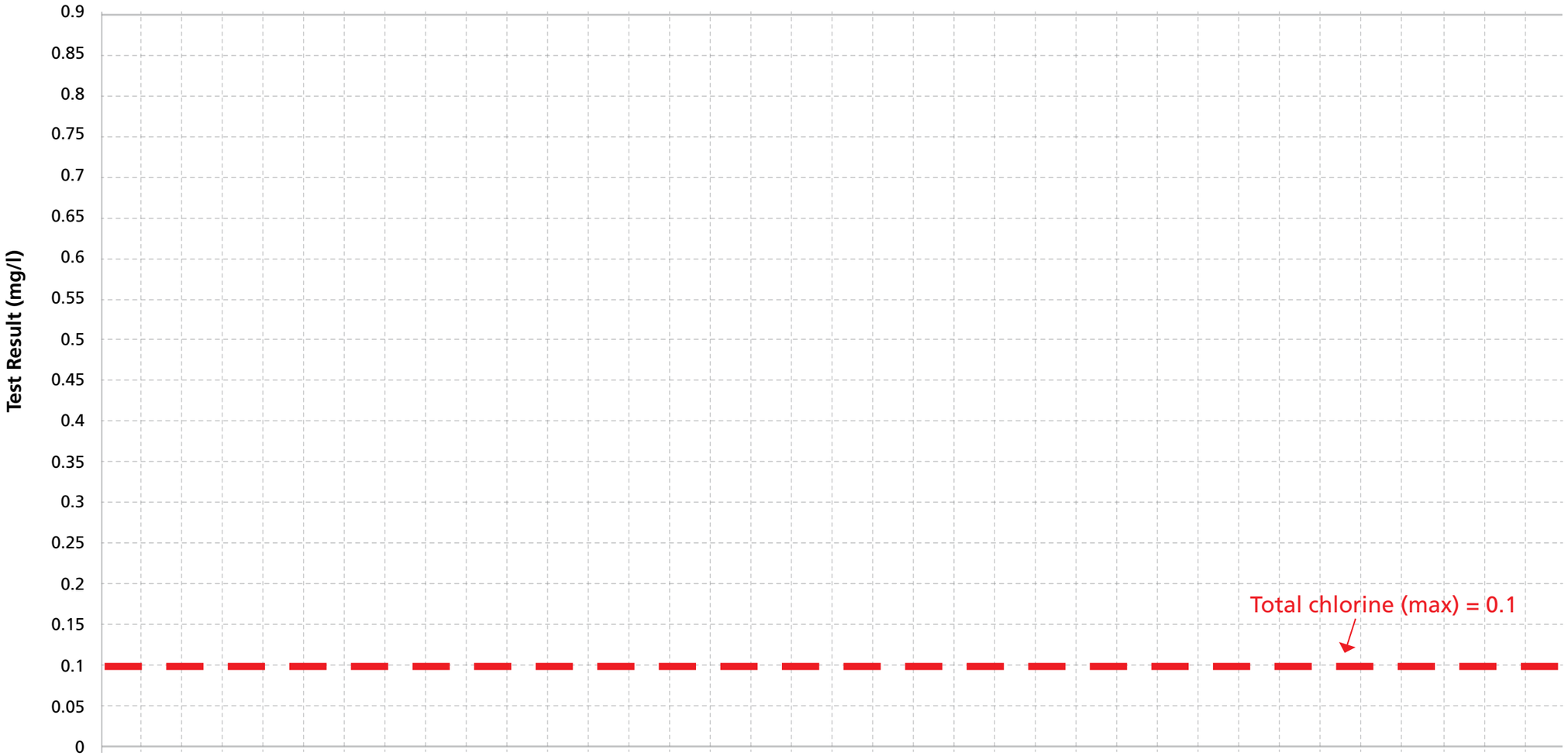
Place	Contact details	Phone no.
Local water authority		
Satellite units – addresses and contact details		

Appendix II

Water testing – Chart for monitoring test results

RO Water – Test results for measurement of total chlorine (mg/litre)

Start date _____ / _____ / _____ Finish Date _____ / _____ / _____



Date																															
Total chlorine																															

Appendix III

Occupational health and safety examples – safe work practices

Safe work practices:	**(Name of) _____ Dialysis Unit**
TASK:	Water treatment plant (In-centre)
Hazard ID No:	
HAZARDS:	Electrical, infection control, manual handling, ergonomics
Original date issued:	

SAFETY RULES

1. Run plant according to manufacturer's instructions.
2. Be aware of hazards, protruding pipes etc. within plant area.
3. Report any changes in gauges immediately to maintenance dept.
4. Attend all water checks and test according to manufacturer's instructions.
5. Wear appropriate footwear when dealing with large amounts of water within plant area.

SAFE WORK PROCEDURE

1. Operate according to manufacturer's instructions.
2. Read operator's manual prior to using equipment.
3. Follow policies relating to water tests and checks in centre manual.
4. Report any faults or malfunctions to maintenance dept.
5. Report any leakage from any part of the plant to maintenance department.
6. Use safe manual handling principles when moving equipment. Obtain assistance when required.
7. Ensure maintenance service is attended as per contractual agreement.
8. Always move slowly within the plant area.
9. Be aware of confined areas between filters.

Reviewed by:	1. [Name of person responsible for developing this document]
	2. [Name of other person responsible for safety of staff]
Signature:	
Designation:	
Date:	

Safe work practices:	(Name of) _____ Dialysis Unit
TASK:	Use of pocket portable chlorine meter
Hazard ID No:	
HAZARDS:	Manual handling
Original date issued:	

SAFETY RULES

1. Use equipment as per manufacturer's instructions.
2. Ensure equipment is not broken or damaged prior to use.
3. Store equipment in designated container, when not in use.
4. Report faulty equipment to Nurse Unit Manager (NUM).

SAFE WORK PROCEDURE

1. Use equipment in a well-lit area.
2. Do not use if any parts of the equipment is damaged.
3. Use equipment as per manufacturer's instructions, and as per policy statement in centre policy manual.
4. Clean and dry the bottles after use.

Reviewed by:	1. [Name of person responsible for developing this document]
	2. [Name of other person responsible for safety of staff]
Signature:	
Designation:	
Date:	

Appendix IV

Occupational health and safety examples – risk analysis

Task	Central water plant
Department:	Nursing
Analysis conducted by:	
Date:	
Location of task:	Renal Unit
Personal protective equipment used:	(please circle) Yes No N/A
Risk rating score:	1 2 3 4 5 6
Requirements of TASK:	1. Plug in power outlet at all times – connected to back-up generator 2. Maintenance staff attend filter changes regularly and record changes 3. Maintenance staff disinfect water plant weekly/bi-weekly and record/test 4. Nursing staff access remote panels in renal units – auto-heat function 5. Maintenance record book kept in water plant room and instruction books.
Potential hazards or risks:	1. Electrical shock/fault 2. Possible explosion or fire 3. Flood 4. Malfunction.
Risk management:	1. Check maintenance book regularly 2. Do not use if any faults – contact dialysis technician 3. Check for water leakages 4. Check maintenance record book – ensure water plant has been disinfected and filters changed regularly 5. Regular maintenance.

Log of ACTION items and timeline:

Action required	By person	Copy to Manager	Results reviewed	Manager initial and date	Further action: Yes / No

Appendix V

Policy and procedure examples – dialysis water testing

The Guideline and Procedure information in Appendix V are provided by HNELHD Dialysis Service.

Renal: Water for dialysis – Central water plant total chlorine testing

Sites where Guideline and Procedure applies	All HNE facilities where a patient undergoes haemodialysis.
This Guideline and Procedure applies to:	
1. Adults	Yes
2. Children up to 16 years	No
3. Neonates – less than 29 days	No
Target audience	Nephrology clinical and technical staff who provide care to all patients requiring haemodialysis.
Description	This document comprises part of the clinical information package for care for treatment of dialysis water.

Click here for procedure details

Keywords	Central water, chlorine, chloramine, dialysis, renal
Document registration number	TBA
Replaces existing document?	Yes
Registration number and dates of superseded documents	HNE GranP10_34

Related legislation, Australian Standard, NSW Ministry of Health Policy Directive or Guideline, National Safety and Quality Health Service Standard (NSQHSS) and/or other, HNE Health Document, Professional Guideline, Code of Practice or Ethics:

- Relevant Accreditation Criterion e.g. NSQHS Standards/EQuIP Criterion and/or other:
- NSW Ministry of Health Policy Directive 2007_079. Correct patient, correct procedure, correct site. http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_079.pdf
- NSW Ministry of Health Policy PD 2005_406. Consent to medical treatment. http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_406.pdf
- NSW Ministry of Health Policy Directive PD 2007_036. Infection control policy. http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_036.pdf

Prerequisites (if required)	This procedure should be attended by nephrology clinical and technical staff who are trained and deemed competent in the use of Fresenius 4008S and 5008 haemodialysis machines.
Guideline and Procedure note	This document reflects what is currently regarded as safe and appropriate practice. The guideline section does not replace the need for the application of clinical judgment in respect to each individual patient, but the procedure/s **require mandatory compliance**. If staff believe that the procedure/s should not apply in a particular clinical situation they must seek advice from their unit manager/delegate and document the variance in the patients health record. If this document needs to be utilised in a non-renal area please liaise with the Renal Service to ensure the appropriateness of the information contained within the Guideline and Procedure.
Position responsible for the Guideline and Procedure and authorised by	HNELHD Renal Clinical Stream Leadership Group
Contact person	John Landkauf (Senior Technician) & Kelly Adams, Renal Stream Coordinator
Contact details	02 4904-8800
Date authorised	

This document contains advice on therapeutics	No
Issue date	
Review date	Up to 3 years
TRIM number	

RISK STATEMENT

Appropriate water quality is one of the most important aspects of ensuring safe and effective delivery of haemodialysis. Failure to ensure adequate water quality may have dire consequences to patient safety and welfare (NSW Health).
Risk Category*:* Clinical care and patient safety

GLOSSARY

Acronym or term	Definition
ISO	International Organization for Standardization
CARI	Caring for Australians with Renal Impairment
RO	Reverse osmosis
DPD	N,n-Diethyl-P-Phenylene-Diamine
ppm	Parts Per Million

GUIDELINE

This Guideline does not replace the need for the application of clinical judgment in respect to each individual patient.

- It is the responsibility of the Nephrology Clinical Nurse to ensure that the total chlorine level each shift is safe, so that water can be used for haemodialysis prior to patients commencing treatment.
- The standards used in determining this guide are based on the ISO Standards, and the following procedure for total chlorine level testing is per the manufacturer's instructions.

PROCEDURE

This procedure requires mandatory compliance.

Staff preparation

It is mandatory for staff to follow relevant: 'Five moments of hand hygiene', infection control, moving safely/safe manual handling and documentation practices.

Alert: The RO unit must run for a minimum of 15 minutes before the water sample for total chlorine testing can be obtained. This is to minimise the risk of false results.

Alert: In systems where twin carbon tanks are in series the water must be obtained and tested from distribution loop at least each dialysis shift.

Equipment requirements

- Alcohol-based hand rub
- Colorimeter
- Water sample container
- 2 x Glass sample cells
- DPD sachet
- Total chlorine testing record sheet

Procedure steps

1. Collect equipment, wash/gel hands
2. Obtain water sample from distribution loop at the beginning of each shift
3. Fill the glass sample cell to the 10 mL line. Make sure the external surface of the sample cell is dry, wipe if necessary.
4. Remove instrument cap. Place the cell into cell holder (diamond mark facing you) and cover the sample with the instrument cap.
5. Press 'Zero' - The instrument will turn on and the display will show --- followed by 0.00.
6. Remove instrument cap and cell cap and add contents of one DPD total chlorine powder pillow to the measurement cell. Re-Cap and gently invert until contents are dissolved. Ensure there are no bubbles in the cell (bubbles in the cell may affect measurement).

Alert: *If the sample temporarily turns pink you have a high level of residual chlorine.*

7. Allow time lapse of three minutes. The instrument may automatically shut off after one minute, but stores the last reading in memory.
8. Press read after time lapse. The instrument will turn on and the display will show, followed by the result in mg/L (= ppm).
9. After measurement is complete, rinse the sample cell with RO water (DO NOT USE TAP WATER – IT CONTAINS CHLORINE) and dry inside of sample cells with paper towel.
10. Record the result on the total chlorine testing record sheet
11. If the reading is 0.1 mg/L or greater repeat the test.
12. If the reading remains greater the 0.1 mg/L contact Dialysis Technical Services immediately and do not commence haemodialysis treatment.

COMPLIANCE

Compliance with this the procedural part of this document is mandatory.

IMPLEMENTATION

The guideline and procedure **Water for dialysis – Central water plant total chlorine testing** will be made available on the intranet Policy, Procedure and Guidelines page. The Managers will be responsible for ensuring staff have adequate equipment and training to enable them to comply with this Guideline and Procedure.

MONITORING

Staff compliance will be monitored through the Incident Information Monitoring System (IIMS) and acted on accordingly. Evidence-based practice will continue to influence the content of this guideline and procedure and will be reflected in the review process.

APPENDICES

- Diagram One: Clinical audit tool
- Chlorine test (total) using Hach Pocket Colorimeter

REFERENCES

Hand Hygiene Australia.

CARI Guidelines, 2005, Water quality for Haemodialysis located at:

http://www.cari.org.au/DIALYSIS_adequacy_published/water_quality_for_hemodialysis_jul_2005.pdf

NephroCare Procedures. 2009. Section 4: Water sampling.

ACI Renal Services Network. 2015. *Water for dialysis: A set of guidelines for in-centre and satellite haemodialysis units in NSW and for home haemodialysis.*

FEEDBACK

Any feedback on this document should be sent to the Contact Officer listed on the front.

Clinical audit tool

(**National Standard 1:** 1.7.2 The use of agreed clinical guidelines by the clinical workforce is monitored)

Criterion no.	Criterion	Exceptions	Definition of terms and/or general guidance	Data source	Frequency	Position responsible
1.	Audit of data collection and compliance with water testing pathway.	None	The aim is to ensure that staff are aware of the correct procedure for water testing and recording/acting on results.	Chlorine testing logbook	Prior to morning and afternoon haemodialysis shift.	Unit Managers

Reference: *Electronic audit tool – National Institute for Health and Clinical Excellence (NICE):* *www.nice.org.uk/nicemedia/live/10996/56372/56372.xls*

Policy & Procedure Example – provided by HNELHD, 2015

Renal: Water sample collection for microbiological testing
of dialysate on Fresenius 4008S and 5008 dialysis machines

Sites where Guideline and Procedure applies	All HNE facilities where a patient undergoes haemodialysis
This Guideline and Procedure applies to:	
1. Adults	Yes
2. Children up to 16 years	No
3. Neonates – less than 29 days	No
Target audience	Nephrology clinical and technical staff who provide care to all patients requiring haemodialysis
Description	This document comprises part of the clinical information package for care for treatment of dialysis water

Hyperlink to procedure below

Keywords:	Water test, microbiology sample, renal, dialysate, fresenius
Document registration number	TBA
Replaces existing document?	Yes
Registration number and dates of superseded documents	HNE GranP10_35

Related legislation, Australian Standard, NSW Ministry of Health Policy Directive or Guideline, National Safety and Quality Health Service Standard (NSQHSS) and/or other, HNE Health Document, Professional Guideline, Code of Practice or Ethics:

- NSW Health Policy Directive 2007_079. Correct patient, correct procedure, correct site. http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_079.pdf
- NSW Health Policy PD 2005_406. Consent to medical treatment. http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_406.pdf
- NSW Health Policy Directive PD 2007_036. Infection control policy. http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_036.pdf
- Caring for Australians with Renal Impairment (CARI) guidelines 2005 - *Water Quality for Haemodialysis* http://www.cari.org.au/dialysisadequacypublished/waterqualityforhemodialysisjul2005.pdf
- HNE Renal Stream Guideline and Procedure. Changing Diasafe filters on Fresenius 4008 and 5008 haemodialysis machines. *Water for Dialysis: a set of guidelines for In-centre and Satellite Haemodialysis Units in NSW and for home haemodialysis* .

Prerequisites (if required)	This procedure should be attended by nephrology clinical and technical Staff who are trained and deemed competent in the use of Fresenius 4008S and 5008 haemodialysis machines.
Guideline and Procedure note	This document reflects what is currently regarded as safe and appropriate practice. The Guideline section does not replace the need for the application of clinical judgment in respect to each individual patient, but the procedure/s **require mandatory compliance**. If staff believe that the procedure/s should not apply in a particular clinical situation they must seek advice from their Unit Manager/Delegate and document the variance in the patient's health record. If this document needs to be utilised in a non-renal area please liaise with the Renal Service to ensure the appropriateness of the information

	contained within the Guideline and Procedure.
Position responsible for the Guideline and Procedure and authorised by	HNELHD Renal Clinical Stream Leadership Group
Contact person	John Landkauf (Senior Technician) & Kelly Adams, Renal Stream Coordinator
Contact details	02 4904-8800
Date authorised	
This document contains advice on therapeutics	No
Issue date	
Review date	Up to 3 years
TRIM number	

RISK STATEMENT

Appropriate water quality is one of the most important aspects of ensuring safe and effective delivery of haemodialysis. Failure to ensure adequate water quality may have dire consequences to patient safety and welfare (NSW Health).
Risk Category*:* Clinical care and patient safety

GLOSSARY

Acronym or term	Definition
ISO	International Organisation for Standardisation
CARI	Caring for Australians with Renal Impairment
CFU	Colony Forming Unit
°C	Degrees Celsius

GUIDELINE

This Guideline does not replace the need for the application of clinical judgment in respect to each individual patient.

- It is the responsibility of the Nephrology Clinical Nurse to ensure that the total chlorine level each shift is safe, so that water can be used for haemodialysis prior to patients commencing treatment.
- The standards used in determining this guide are based on the ISO Standards, and the following procedure for total chlorine level testing is per the manufacturer's instructions.

PROCEDURE

This procedure requires mandatory compliance.

Staff preparation

It is mandatory for staff to follow relevant 'Five moments of hand hygiene', infection control, moving safely/safe manual handling and documentation practices.

Equipment requirements

- Fresenius 4008S or 5008 haemodialysis machine
- Personal protective equipment, including an apron, mask and non-sterile gloves
- Alcohol hand gel
- Isopropyl alcohol spray
- Sterile sample container
- Pathology specimen bag
- Pathology form for microbiological sampling
- Machine maintenance record sheet and black pen to record sample collection.

Procedure steps

1. Ensure machine has had a heat disinfection program post filter change
2. Connect concentrate bottle and bibag and initiate T1 test
3. Wait for T1 test to be completed
4. Collect equipment required to carry out procedure
5. Don mask
6. Wash hands or gel
7. Clean sample port on the dialysate line thoroughly by spraying short bursts of isopropyl alcohol spray (do not touch nozzle to port)
8. Connect 30 mL syringe to luer lock of the sampling valve/port
9. Press the lever on the sample port and keep it pressed whilst withdrawing fluid
10. Withdraw 20 mL of dialysate from sample port with first syringe

Troubleshooting: If unable to withdraw fluid inject 5 cc of air into the sampling valve to release airlock in order to withdraw fluid.

11. Apply alcohol hand gel
12. Discard both syringe and dialysate
13. Connect second 30 mL syringe to luer lock of the sampling valve/port
14. Press the lever on the sample port and keep it pressed whilst withdrawing fluid
15. Withdraw 20 mL sample with second syringe and disconnect from sampling port maintaining sterility
16. Open lid of sample jar
17. Slowly inject dialysate into sample jar without contaminating the tip of the syringe or sample jar
18. Securely close lid onto sample jar
19. Label sample jar 'Dialysate sample' and include date, time and machine information
20. Store dialysate specimen appropriately until able to transfer to pathology or testing facility
21. Record date dialysate testing carried out on machine maintenance log as per unit policy
22. Note and file results of testing in the machine maintenance log book as per unit policy
23. Inform technicians of abnormal results and retest as required.

Sample storage and testing

Samples must be either assayed within 30 minutes of collection or stored immediately at a temperature of between 1–5 ºC.

Sample incubation temperature to be between 35–37 °C and CFU counts to be attended after 72 hours.

Total CFU counts should be <1 for HDF or high-flux dialysis and <100 for low-flux dialysis.

APPENDICES

Diagram 1: Decision flow chart for bacterial contamination

REFERENCES

Caring for Australians with Renal Impairment (CARI) guidelines 2005 - Water Quality for Haemodialysis http://www.cari.org.au/dialysisadequacypublished/waterqualityforhemodialysisjul2005.pdf

Fresenius 5008 Machine Procedures document, 2006

Fresenius Medical Care 4008S. Haemodialysis machine operating instructions. Software version: 4.5. Edition: 18/09.08.

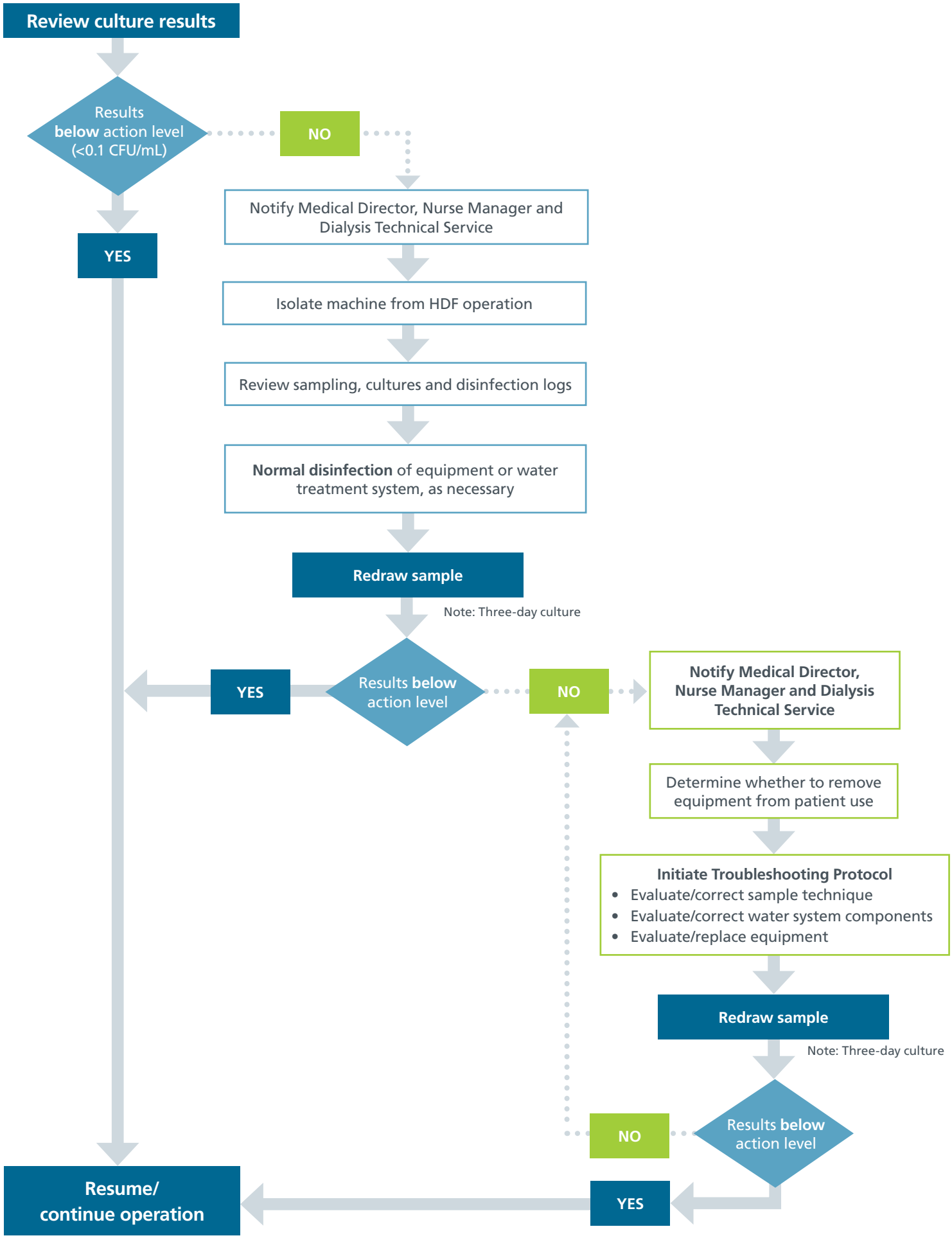
Fresenius Medical Care 5008. Haemodialysis system operating instructions. Software version: 3.96. Edition: 8/10.08.

NephroCare Procedures 2009, Section 4, Water Sampling

Ward, R.A. 2004 Ultrapure Dialysate, *Seminars in Dialysis*, Nov- Dec: 17, 489-497

ACI Renal Services Network, 2015, *Water for Dialysis: A set of guidelines for In-centre and Satellite Haemodialysis Units in NSW and for Home Haemodialysis*

Diagram 1


Review culture results
Results **below** action level (<0.1 CFU/mL)
NO
YES
Notify Medical Director, Nurse Manager and Dialysis Technical Service
Isolate machine from HDF operation
Review sampling, cultures and disinfection logs
Normal disinfection of equipment or water treatment system, as necessary
Redraw sample
Note: Three-day culture
Results **below** action level
YES
NO
Notify Medical Director, Nurse Manager and Dialysis Technical Service
Determine whether to remove equipment from patient use
Initiate Troubleshooting Protocol
• Evaluate/correct sample technique
• Evaluate/correct water system components
• Evaluate/replace equipment
Redraw sample
Note: Three-day culture
Results **below** action level
NO
YES
Resume/ continue operation

Appendix VI

Maintenance log examples

Maintenance record log book/folder

for management of water quality for haemodialysis

Name of Renal Unit

SECTION 1: Copies of monthly reports to Haemodialysis Management Committee

SECTION 2: Copies of incident reports and periodic trend analysis

SECTION 3: Copies of chlorine and chloramine monitoring

SECTION 4: Permanent record of filter changes (pre-filters)

SECTION 5: Permanent record of carbon filter rotation

SECTION 6: Heavy metal testing schedule and record of actions

Appendix VII

Recommended schedule of testing

Haemodialysis machines and 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	Technicians	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 Sample 2: dialysis machine at venous port	Laboratory results to Home Haemodialysis Unit	If post-RO CFU count >200 mL 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	Endotoxin–positive. High-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 and 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	Technicians	By technician on service sheet	Pre- and post-carbon tank	Reported by technician to Manager, NUM 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

Appendix VIII

Recommended schedule of maintenance for reverse osmosis units

Procedure	Frequency	Performed by	Record of procedure	Instructions	Response to problems	Alert
Backflushing of carbon tanks and sand filters	Daily	Automated	Not recorded		Reported to Manager, Technical Services, NUM Nursing and Site Maintenance Supervisor	Unit Managers
Disinfection of loop MANUAL	Six-monthly	Technicians and maintenance staff	Staff to record disinfection process and test result for residual disinfectant in RO log	Test for residual with approved method	Reported to Manager, Technical Services, NUM and Site Maintenance Supervisor	Test for residual must be safe before staff leave
Disinfection of loop AUTOMATED	Daily	Automated	Machine log	Interrogate error log regularly	Reported to Manager, Technical Services, NUM and Site Maintenance Supervisor	Machine error log
Reverse osmosis membrane treatment	Monthly	Technicians	Staff to record disinfection process and test result for residual disinfectant in RO log	Test for residual with approved method	Reported to Manager, Technical Services, NUM and Site Maintenance Supervisor	Test for residual must be safe before staff leave
Replacement of carbon filters	Annually, or as determined by chloramines test results	Maintenance	By technician on service sheet and RO log book		Reported to Manager, Technical Services, NUM and Site Maintenance Supervisor	Chlorine saturation of both carbon filters will result in Dialysis Unit being closed until problem solved

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

Appendix IX

Australian Drinking Water Guidelines

Aluminium (endorsed 2001)

Guideline

Based on aesthetic problems caused by post-flocculation, the concentration of acid-soluble aluminium in drinking water should not exceed 0.2 mg/L. Water authorities are strongly encouraged to keep acid-soluble aluminium concentrations as low as possible, preferably below 0.1 mg/L.
No health-based guideline is set for aluminium at this time but this issue will be kept under review.

Health considerations

It has been estimated that for Australian adults, the intake of aluminium from food and beverages is approximately 5–7 mg/day. Drinking water contributes less than 2% of the total daily intake, and only 0.3–0.4% of the aluminium in water is absorbed by the body. Recent studies have shown that the bioavailability (i.e. uptake into the bloodstream) of aluminium in drinking water is similar to that of food (Stauber *et al.* 1999).

The metabolism of aluminium in humans is poorly understood. Studies indicate that less than 1% of dietary aluminium is absorbed by the gastrointestinal tract, with the remainder excreted in faeces. The small amount absorbed passes into the blood stream. Some aluminium accumulates in bone, liver and brain tissue but most is removed from the blood stream by the kidneys and excreted. In healthy adults, the total accumulated body load of aluminium has been estimated at about 35 mg. Whether this remains constant with age has not been determined.

There is considerable evidence that aluminium is neurotoxic. Kidney dialysis patients, in whom the gut barrier is bypassed, can accumulate aluminium in their blood resulting in an encephalopathy known as dialysis dementia. Investigations have established a correlation between the concentration of aluminium in water used to prepare dialysis fluid and the incidence of dialysis dementia. If this condition is not too far advanced it responds to chelation therapy. It appears that dialysis patients are much more susceptible to aluminium in dialysis fluid than from other sources such as food and antacids. Aluminium has also been linked to other conditions associated with the use of dialysis units including osteomalacia (a softening of the bones) and anaemia. Reverse osmosis or deionisation units are now used to treat dialysis water before use, and aluminium concentrations are kept below 0.01 mg/L.

Arsenic (endorsed 2001)

Guideline

Based on human health considerations, the concentration of arsenic in drinking water should not exceed 0.01 mg/L.

Health considerations

The health considerations apply mainly to inorganic arsenic compounds, as they are more likely than the organic compounds to be present in drinking water supplies.

Soluble arsenic salts are readily absorbed by the gastrointestinal tract. After absorption, inorganic arsenic binds to haemoglobin, and is deposited in the liver, kidney, lungs, spleen, and skin. Inorganic arsenic does not appear to cross the blood-brain barrier but can cross the placenta. Very little ingested arsenic is excreted in faeces, but approximately 45-85% appears in the urine within 1 to 3 days.

Extensive reviews and summaries of the human and animal toxicity data for arsenic are available (IPCS 2001, WHO 2003, IARC 2004, Health Canada 2006, ATSDR 2007). Consumption of elevated levels of arsenic through drinking-water is causally related to the development of cancer at several sites, particularly skin, bladder kidney and lung. Cancer is considered to be the most sensitive toxicity endpoint for setting a drinking water guideline for arsenic, however the mechanisms or modes of action by which arsenic causes cancer are yet to be definitively elucidated (WHO 2003).

Barium (endorsed 2001)

Guideline

Based on health considerations, the concentration of barium in drinking water should not exceed 2 mg/L.

Health considerations

Reviews of the human and animal toxicity data for barium are available (IPCS 2001, OEHHA 2003, WHO 2004a, USEPA 2005, ATSDR 2007).

Barium toxicity is caused by the free cation, and highly soluble barium compounds are more toxic than insoluble compounds. In rodents, kidney toxicity appears to be the most sensitive effect, whereas in humans, cardiovascular (hypertension) effects have been of prime concern.

Chronic toxicity studies of barium chloride in drinking water of rats and mice caused kidney effects at the higher doses used. Relevant NOAELs in these studies were 45 mg/kg bw/day for female rats and 75 mg/kg bw/day in male mice (NTP 1994).

There is no evidence from chronic rodent studies that barium causes cancer. The weight of evidence indicates barium is not mutagenic in tests with bacteria and does not damage DNA.

Cadmium (endorsed 1996)

Guideline

Based on health considerations, the concentration of cadmium in drinking water should not exceed 0.002 mg/L.

Health considerations

Absorption of cadmium in the gastrointestinal tract depends on a number of factors including the solubility of the compounds ingested, but a healthy person typically absorbs 3–7% of ingested cadmium.

This figure may be higher in people with iron, calcium and protein deficiency. Cadmium accumulates in the kidney and is only released very slowly, with a biological half-life in humans of 10 to 15 years.

An extensive review and summary of the human and animal toxicity data for cadmium is available (IPCS 1992).

In humans, long-term exposure can cause kidney dysfunction leading to the excretion of protein in the urine. This may occur, in a certain proportion of people, if the amount of cadmium exceeds 200 mg/kg renal cortex tissue; about 10% of the population is estimated to possess this sensitivity. Other effects can include osteomalacia (softening of the bones). Cases of Itai-Itai disease have been reported in Japan among elderly women exposed to highly contaminated food and water. Symptoms are similar to osteomalacia accompanied by kidney dysfunction characteristic of cadmium poisoning.

Carbon, granulated activated (endorsed 2005)

Guideline

Granular activated carbon is used in drinking water treatment to adsorb or biologically degrade dissolved organic matter, pesticides, algal toxins and compounds causing taste or odour problems. Use of activated carbon used before disinfection reduces the formation of disinfection by-products, by reducing the amount and reactivity of organic precursors of these by-products.

General description

Granular activated carbon (GAC) is a black, solid, extremely porous material that can adsorb impurities and contaminants from air and water. It has a complex, porous internal structure, with internal surface areas averaging about 900 m^2/g and a bulk density of 250–600 kg/m^3. Activated carbon is insoluble in water and organic solvents.

The properties of activated carbon depend on its degree of activation and the raw material from which it is produced. Coal, wood and coconut-based activated carbons each have different pore structures and different characteristics.

GAC may act as a biological carrier by housing bacteria in its internal honeycomb structure. When GAC filters are used in an enhanced biological mode, they are referred to as biological activated carbon (BAC) filters. BAC filters work through two mechanisms: biodegradation of contaminants (e.g. taste and odour compounds, and organics) and biological regeneration of the carbon's adsorption sites.

Dry activated carbon can be stored in cast iron or steel silos. Wet activated carbon can be stored in Plastic, rubber or silicon-lined containers, or in stainless steel (type 316), monel or bronze.

Status

Activated carbon was endorsed by the NHMRC for use as a drinking water treatment chemical in 1983. The revision undertaken in 2003 did not change the status of this chemical for the treatment of drinking water.

Contaminants

The purity of chemicals used in Australia for the treatment of drinking water varies, depending on the manufacturing process. The following chemical contaminants may be present in the ash that may be found in activated carbon:

- aluminium
- manganese
- arsenic
- mercury
- chromium
- phosphorus
- iron
- silver
- lead
- zinc.

Residual and by-product formation in drinking water

When employed in drinking water treatment, activated carbon should be used in such a way that any contaminant or by-product formed by the use of the chemical does not exceed guideline values in the Australian Drinking Water Guidelines.

Chlorine (endorsed 2005)

Guideline

Based on health considerations, the guideline value for total chlorine in drinking water is 5 mg/L, except for chloraminated systems, where a guideline value of 4.1 mg/L applies.

Contaminants

The purity of chemicals used in Australia for the treatment of drinking water varies, depending on the manufacturing process. The following chemical contaminants may be present in chlorine (NRC 1982, JECFA):

- arsenic
- manganese
- carbon tetrachloride
- mercury
- lead
- trihalomethanes.

Residual and by-product formation in drinking water

When employed in drinking water treatment, chlorine should be used in such a way that any contaminant or by-product formed by the use of the chemical does not exceed guideline values in the *Australian Drinking Water Guidelines.*

The use of a disinfectant such as chlorine results in the formation of free chlorine and combined chlorine residuals and disinfection by-products, including trihalomethanes (THMs), haloacetic acids (HAAs), haloacetonitriles (HANs), haloketones, chloral hydrate and chloropicrine. Although many specific chlorine disinfection by-products have been identified, several of the total organic halogens have yet to be identified.

Factors affecting the distribution of disinfection by-product species include pH, temperature and the levels of total organic carbon (TOC), bromide and chlorine. THMs (e.g. chloroform, bromodichloromethane, dibromochloromethane and bromoform) are the best known chlorination by-products. Chlorinated THM, HAA and HAN species generally dominate over brominated species. However, brominated species predominate in high-bromide waters.

Chromium (endorsed 1996)

Guideline

Based on health considerations, the concentration of hexavalent chromium (Cr(VI)) in drinking water should not exceed 0.05 mg/L. If the concentration of total chromium exceeds this value then a separate analysis for hexavalent chromium should be undertaken.

Health considerations

The absorption of chromium after ingestion is low and depends on the valence state.

An extensive review and summary of the human and animal toxicity data for chromium is available (IPCS 1988).

Epidemiological studies have found an association between inhalation of hexavalent chromium compounds and lung cancer, especially in humans occupationally exposed during chromate production.

There is no evidence that organs other than the lung are affected or that ingestion of hexavalent chromium compounds can cause cancer.

Copper (endorsed 2001)

Guideline

Based on health considerations, the concentration of copper in drinking water should not exceed 2 mg/L.
Based on aesthetic considerations, the concentration of copper in drinking water should not exceed 1 mg/L.

Health considerations

Copper is an essential trace element for humans. It is estimated that adult requirements are about 2–3 mg per person per day. High doses of copper (above 50 mg/kg bodyweight) can be lethal.

The absorption of copper by the gastrointestinal tract is in the range of 25–60%, depending on a number of factors, including copper speciation and copper dietary status (Olivares *et al* 1998). Copper is stored in the liver, brain and muscle tissue. High concentrations can also be found in the kidneys, heart and hair.

Copper is eliminated from the body mainly in the bile.

Fluoride (endorsed 1996)

Guideline

Based on health considerations, the concentration of fluoride in drinking water should not exceed 1.5 mg/L.

Health considerations

Because fluoride is widely dispersed in the environment, all living organisms are exposed to it and all tolerate modest amounts. It has been claimed that fluoride is an essential trace element for humans, but this is difficult to establish conclusively, and no data are available on the minimum amount needed.

Fluoride is absorbed quickly following ingestion. It is not metabolised, but diffuses passively into all body compartments. About 40% is excreted in urine within 9 hours, and about 50% over 24 hours. Fluoride has an affinity for mineralising tissues of the body: in young people, bone and teeth; in older people, bone.

Thus excretion is somewhat greater in adults because they have proportionately less mineralising tissue than children.

People with kidney impairment have a lower margin of safety for fluoride intake. Limited data indicate that their fluoride retention may be up to three times normal.

Lead (endorsed 1996)

Guideline

Based on health considerations, the concentration of lead in drinking water should not exceed 0.01 mg/L.

Health considerations

Lead can be absorbed by the body through inhalation, ingestion or placental transfer. In adults, approximately 10% of ingested lead is absorbed but in children this figure can be 4 to 5 times higher.

After absorption, the lead is distributed in soft tissue such as the kidney, liver, and bone marrow where it has a biological half-life in adults of less than 40 days, and in skeletal bone where it can persist for 20 to 30 years.

Other adverse effects associated with exposure to high amounts of lead include kidney damage, interference with the production of red blood cells, and interference with the metabolism of calcium needed for bone formation.

Epidemiological studies have found no association between lead and tumour incidence. Kidney tumours, however, have been reported in rats, mice and hamsters fed lead salts in their diet, but only at doses above 27 mg/kg body weight per day. Gliomas (brain tumours) have also been reported in rats. In addition, lead salts given orally to rats have increased the carcinogenic activity of known carcinogens.

Mercury (endorsed 1996)

Guideline

Based on health considerations, the concentration of total mercury in drinking water should not exceed 0.001 mg/L.

Health considerations

Inorganic mercury

Less than 15% of inorganic mercury in drinking water is absorbed by the gastrointestinal tract. Inorganic mercury compounds accumulate in the kidney and have a long biological half-life, probably many years.

An extensive review and summary of the human and animal toxicity data for inorganic mercury is available (IPCS 1991).

Many studies have looked at groups of workers occupationally exposed to mercury, and have reported health effects including tremors, mental disturbances and gingivitis (inflammation of the mucous membrane surrounding the teeth). The main toxic effects are to the kidney, leading to kidney failure.

Nitrate and nitrite (endorsed 2011)

Guideline

Nitrate: Based on health considerations, the guideline value of 50 mg-NO_3/L (as nitrate) has been set to protect bottle-fed infants under 3 months of age. Up to 100 mg-NO_3/L can be safely consumed by adults and children over 3 months of age.

Where a water supply has between 50 and 100 mg-NO_3/L nitrate, active measures are required to ensure that those caring for infants are aware of the need to use alternative water sources in making up bottle feeds for babies under 3 months of age. Water may be used for bottle-fed infants if the nitrate concentration is between 50 and 100 mg/L, but medical authorities need to be increasingly vigilant and the water must also be known to be microbiologically safe.

Nitrite: Based on health considerations, the concentration of nitrite in drinking water should not exceed 3 mg-NO_2/L (as nitrite).

Health considerations

The toxicity of nitrate to humans is thought to be solely due to its reduction to nitrite. The major biological effect of nitrite in humans is its involvement in the oxidation of normal haemoglobin to methaemoglobin, which is unable to transport oxygen to the tissues. This condition is called methaemoglobinaemia. Young infants are more susceptible to methaemoglobin formation than older children and adults. Other susceptible groups include pregnant women and people with a deficiency of glucose-6-phosphate dehydrogenase or methaemoglobin reductase.

Selenium (endorsed 1996)

Guideline

Based on health considerations, the concentration of selenium in drinking water should not exceed 0.01 mg/L.

Health considerations

Selenium is an essential element for many species, including humans. Signs of selenium deficiency in humans are not well established but may include a chronic disorder of the heart muscle, other heart diseases and cancer.

Silver (endorsed 1996)

Guideline

Based on health considerations, the concentration of silver in drinking water should not exceed 0.1 mg/L.

Health considerations

Although silver can be found in many biological substances, it is not considered an essential trace element for mammals.

It has been estimated that less than 10% of dietary silver is absorbed by the gastrointestinal tract. Silver is stored mainly in the liver and skin and is capable of binding to amino acids and proteins.

The best-known clinical condition of silver intoxication is argyria, which results in a bluish-grey metallic discolouration of the skin, hair, mucous membranes, mouth and eye. Most cases have been associated with self-administration of silver preparations, or occupational exposure to silver and silver compounds.

Experiments with laboratory rats and mice have reported similar results. Very high concentrations of silver in drinking water (over 600 mg/L) for a lifetime caused discolouration in the thyroid and adrenal glands, the choroids of the brain and eye, and the liver and kidney. Some hypoactive behaviour was also reported.

No data are available on the carcinogenicity of silver. Silver salts are not mutagenic in tests with bacteria, but can induce damage in mammalian DNA.

Sodium (endorsed 1996)

Guideline

Based on aesthetic considerations (taste), the concentration of sodium in drinking water should not exceed 180 mg/L.

No health-based guideline value is proposed for sodium. Medical practitioners treating people with severe hypertension or congestive heart failure should be aware if the sodium concentration in the patient's drinking water exceeds 20 mg/L.

Health considerations

Whether water is consumed directly or with food or beverages, virtually all of the sodium in it will be absorbed. Sodium is present in all body tissues and fluids and its concentration is maintained by the kidney; increases in the sodium concentration in plasma give rise to the sensation of thirst.

Sodium is essential to human life but there is no agreement on the minimum daily amount needed to maintain health. It has been estimated that a total daily intake of less than 200 mg/person is required to meet the needs of growing infants and children.

Excessive sodium intake, usually via diet, can severely aggravate chronic congestive heart failure. While it is clear that reduced sodium intake can reduce the blood pressure of some individuals with hypertension, it is equally clear that this type of therapy is not effective in all cases. Health authorities are of the opinion, however, that reduced sodium intake is beneficial.

Sulfate (endorsed 1996)

Guideline

Based on aesthetic considerations (taste), the concentration of sulfate in drinking water should not exceed 250 mg/L. Purgative effects may occur if the concentration exceeds 500 mg/L.

Health considerations

Sulfate is rapidly absorbed by the gastrointestinal tract but a number of factors, such as the accompanying cation, can influence the rate of absorption. Low doses are probably absorbed more effectively than high doses. Sulfate is found in all body tissue but is highest in the metabolically active areas of bone and tooth formation, and may be important in regulating bone development. Sulfate is one of the least toxic anions. Ingestion of high doses can result in catharsis (loosening of the bowels) with dehydration as a possible side effect.

No harmful effects have been reported in studies with animals.

Sulfate can interfere with disinfection efficiency by scavenging residual chlorine. It can also increase corrosion of mild steel pipes.

Zinc (endorsed 1996)

Guideline

Based on aesthetic considerations (taste), the concentration of zinc in drinking water should be less than 3 mg/L. No health-based guideline value is proposed for zinc.

Health considerations

Zinc is an essential element for humans. The recommended intake for adults is 12 mg per day. Nutritional zinc deficiency results in retarded growth, anorexia, mental lethargy, skin changes and night blindness.

Approximately 20–30% of dietary zinc is absorbed by the gastrointestinal tract. Highest concentrations are found in the liver, kidney, bone, retina, prostate and muscle. In humans, consumption of very high amounts of zinc can result in nausea, vomiting, diarrhoea and abdominal cramps. The major effects of long-term exposure to zinc are copper deficiency, anaemia and gastric erosion.

In animal studies, zinc has been reported to reduce the toxic effects of nickel and cadmium. High doses over long periods may, however, be toxic to nerve cells of mammals.

There is no evidence that occupational exposure to zinc increases the risk of cancer.

Zinc has been shown to induce chromosomal aberrations in mammalian cells, but is inactive in bacterial mutation tests.

Total dissolved solids (endorsed 2011)

Guideline

No specific health guideline value is provided for total dissolved solids (TDS), as there are no health effects directly attributable to TDS. However for good palatability total dissolved solids in drinking water should not exceed 600 mg/L.

General description

Total dissolved solids (TDS) consist of inorganic salts and small amounts of organic matter that are dissolved in water. Clay particles, colloidal iron and manganese oxides and silica, fine enough to pass through a 0.45 micron filter membrane can also contribute to total dissolved solids.

Total dissolved solids comprise: sodium, potassium, calcium, magnesium, chloride, sulfate, bicarbonate, carbonate, silica, organic matter, fluoride, iron, manganese, nitrate, nitrite and phosphates.

The palatability of drinking water can be rated according to TDS concentrations and a breakdown is provided below, based on World Health Organization guidelines (WHO 2004):

TDS (mg/L) palatability
0 – 600 good
600 – 900 fair
900 – 1200 poor
> 1200 unacceptable (unpalatable)

High TDS values may be associated with excessive scaling in pipes, fittings and household appliances.

Water with very high or very low TDS may also be corrosive.

Typical values in Australian drinking water

In major Australian cities, TDS values can range from below 100 mg/L to more than 750 mg/L; regional supplies can have TDS values up to 1000 mg/L and some rural and remote communities may have TDS in excess of 1000 mg/L, owing mainly to groundwater characteristics.

Health considerations

No health effects have been associated specifically with high TDS concentrations. The health effects of individual components of TDS are discussed separately in the discussions on inorganic chemicals (Section 6.3.1 and relevant Fact Sheets). Indirectly, high TDS water, being less palatable than that with a low TDS, might discourage consumers from drinking tap water, leading to use of potentially less healthy water (from alternative sources, natural or manufactured) and/or other less healthy drinks.

Appendix X

Communicating with water utilities in regional locations

Information sheet for water utilities: chlorine, chloramines and dialysis

Appendix E: (Provided by NSW Health – reviewed 2014)

Drinking water must be specially treated before it is used for renal dialysis (or haemodialysis).

Oxidising disinfectants such as chloramine and chlorine can damage or destroy red blood cells in patients undergoing dialysis. Dialysis treatment units include activated carbon filtration to remove chlorine and chloramines, and dissolved organic substances. Activated carbon filters are not designed to remove high concentrations of disinfectants for extended periods of time.

'Breakthrough' of chloramines into dialysis filters is thought to present a more serious risk than 'breakthrough' of free chlorine. In cases of inadequate carbon filtration, chloramines may cause serious reactions in dialysis patients including nausea, vomiting, low blood pressure, anaemia, shortness of breath, heart palpitations, lethargy or even death.

Renal technicians or other staff monitor the performance of dialysis treatment units. Generally, dialysis treatment units are installed and operated to suit local water treatment conditions. Home dialysis units typically include a carbon filter and a reverse osmosis filter. There may be dangers for patients if the carbon filters are near their replacement time and are challenged with a high chlorine concentration.

All water utilities should have readily available the telephone contact number for the renal dialysis coordinator/s responsible for their area of operations. The renal dialysis coordinators will be able to issue warnings to patients or hospitals where appropriate.

Below is a suggestion for determining the conditions under which renal dialysis coordinators are notified:

- Any planned work involving superchlorination.
- Any planned increase in typical maximum chlorine/chloramine concentration by 25% or more above the long term 95th percentile.
- Any test result that shows an unplanned increase in chlorine/chloramine concentrations greater than 15% above the long term 95th percentile.
- A chlorine concentration above 1.7 mg/L.*

Notifications should be made as soon as possible after elevated chlorine is detected.

*Where a water utility typically doses above 1.7 mg/L to maintain effective disinfection, a locally appropriate target could be negotiated.

The long-term 95th percentiles of free and total chlorine concentrations in the distribution system can be determined from the NSW Drinking Water Database. 95th percentile is one of the summary statistics generated as part of a Results Report or Results Report Quick.

For further information and to discuss appropriate notification arrangements water utilities should contact their local Public Health Unit. Contact details for Public Health Units can be found at:
http://www.health.nsw.gov.au/Infectious/Pages/phus.aspx