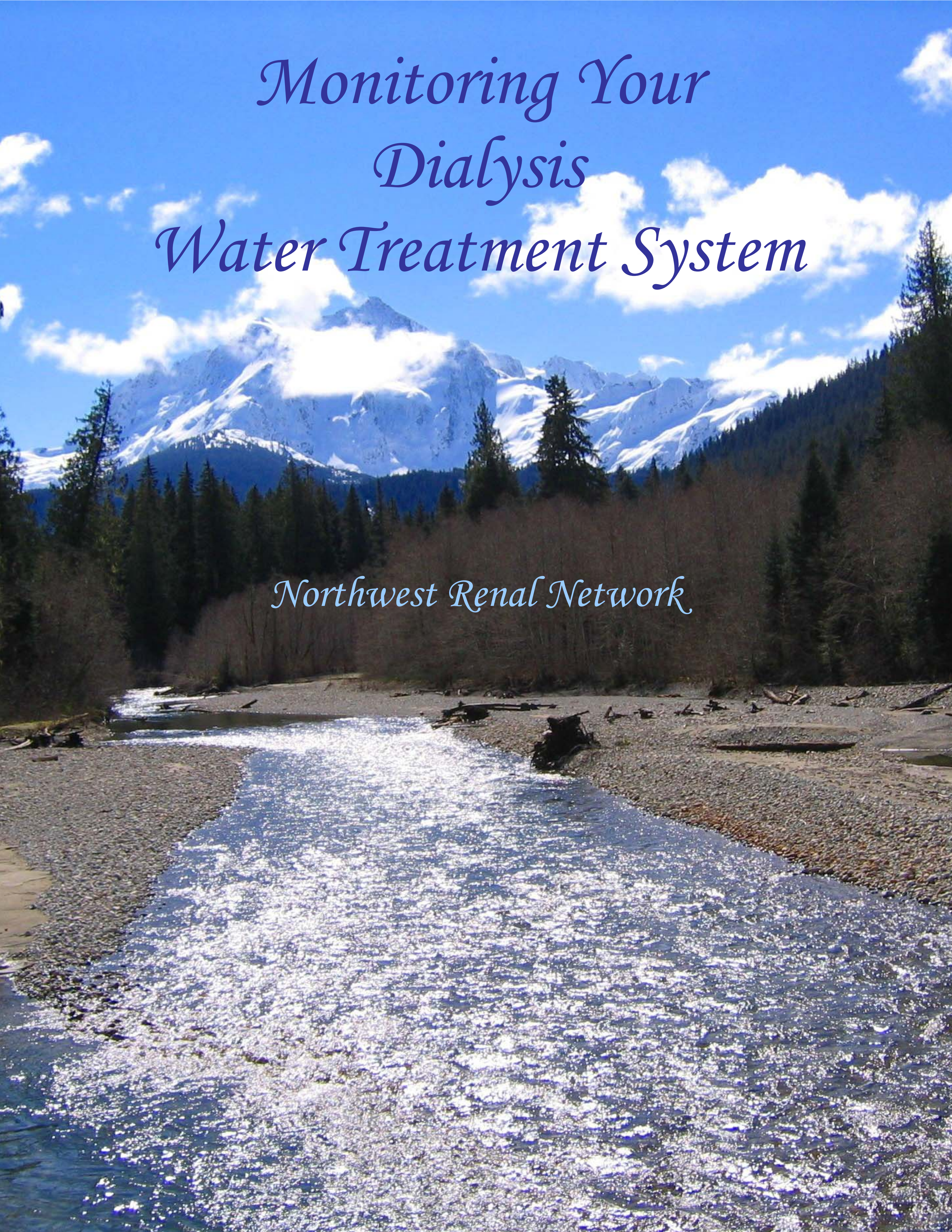
Monitoring Your Dialysis Water Treatment System

Northwest Renal Network



NORTHWEST RENAL NETWORK
— Serving Network Area #16 —

Monitoring Your Dialysis Water Treatment System

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Cover Photograph: Mt. Shuksan by Lorabeth Lawson

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Dedication

Monitoring Your Dialysis Water Treatment System is dedicated to Michael Lee Matson, an eloquent advocate for kidney patients.

Michael cared passionately about patient safety, and felt that the best outcomes for patients could be achieved when all members of the team, including patients, were informed and responsible.

An outstanding grass roots organizer, Michael articulated the concerns of kidney patients as an active member of our Medical Review Board, served on the Board of the National Kidney Foundation of Oregon and Washington, and on the Consumer Advocacy Group at Olympic View Dialysis Center. His testimony to a Washington State Task Force on the Certification of Dialysis Technicians was key to developing the guidelines in place today.

We miss Michael's humor and the special wisdom he gained from over thirty years on dialysis. He brought many deliberations of our Medical Review Board back into focus on the "person" rather than the "patient", and challenged his fellow consumers to be informed participants in their care and encouraged them to view their physicians, nurses and dialysis technicians as consultants. He was particularly vigilant about the technical process of dialysis, and thus, we honor his memory with this document.

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Executive Director

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Northwest Renal Network's Mission:

To promote optimal dialysis and transplant care for kidney patients in Alaska, Idaho, Montana, Oregon and Washington.

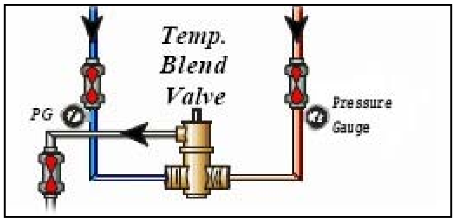
Monitoring Your
Dialysis Water Treatment System

Water treatment systems used in dialysis are a critical factor in the overall care received by dialysis patients; they also provide one of the greatest hazards to the patients if they are not functioning properly.

Monitoring of water treatment systems has been an identified area of concern, and an opportunity for quality improvement nationally. To respond to this need, the Northwest Renal Network developed this comprehensive review of water treatment monitoring. This document was created by the Network Water Treatment Monitoring committee: Jim Curtis, Network Quality Improvement Consultant; Byron Roshto, Director of Operations for Renal Care Group Northwest; Blu Roshto, Area Education Coordinator, Fresenius Medical Services; and Larry Byers, Director of Technical Services for Puget Sound Kidney Centers. Key reviewers were Lynda Ball, Quality Improvement Coordinator for Northwest Renal Network; Suhail Ahmad, Medical Director of Scribner Kidney Center; and John Pilmer, Client Care Surveyor at Oregon State Health Division. The graphics in both the document and accompanying poster were created by Byron Roshto.

We believe that it will be very useful to technical personnel in the facility who are responsible for the day-to-day monitoring of their water treatment system. We have described the important monitoring parameters for each component in the system, from the incoming water to the drain system.

Monitoring the Temperature Blending Valve:



Often, water treatment systems will require that the feed water temperature be raised to a certain degree. For example, reverse osmosis systems operate most efficiently (produce the largest volume of dialysis-quality water for the number and type of membranes) - at a feed water temperature of 77°F. This is accomplished through the use of a heater in conjunction with a temperature blending valve. A common problem comes from the water heater not being large enough to keep up with the facility’s needs.

The temperature blending valve is a device that can be set to mix hot and cold water to achieve a specific water temperature. There are various designs for this important piece of equipment, but some are more appropriate for use in a dialysis setting – specifically ones with an incorporated temperature indicator or thermometer. A common type seen today uses a spring-loaded thermostat. This is important because these tend to fail hot—meaning that when they go out, the output water temperature rises, and rises quickly. For this reason, it is necessary to monitor and record the output temperature at least daily.

When working properly, with an appropriately sized water heater, the blending valve output temperature will rarely vary more than plus or minus 2 to 3 degrees F. If, during your daily recording, you note a temperature fluctuation out of this acceptable range, immediately bring it to the attention of the facility's maintenance person or your supervisor.

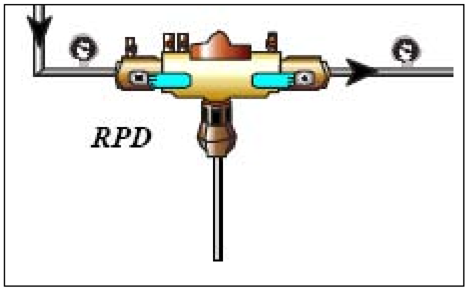
A defective blending valve will not necessarily endanger your patients (dialysis machines have a bypass mechanism for overheated water/dialysate), but it can damage the heart of your dialysis clinic, your water treatment equipment.

Blending Valve Summary

What to monitor: Water temperature

What to look for: Appropriate water temperature, minimal temperature fluxuation

Monitoring the Back Flow Prevention Device:



It is required by building codes that dialysis water treatment equipment be connected to the source water through a Backflow Prevention Device (also known as a Reverse Flow Prevention Device), or RP. The purpose of this is to prevent water from the water treatment equipment being pulled backward through the building's water supply piping. As an example, if a water main broke at the bottom of a hill, gravity would cause the water in the pipe feeding the dialysis unit to drain down. The RP device would prevent the draining back of water from the treatment system. If there were not backflow prevention, this suction would pull water out of the treatment system. The Backflow Prevention Device also prevents the backflow of chemicals into the building water main during the process of chemical disinfection of the water treatment system, thus eliminating the risk of chemical exposure to the other parts of the building. If the system was being disinfected, the chemical would be pulled into the water main as well. Once the break was fixed, water that had been in the RO machine, and is now in the water main could be diverted to any other uses on the main water line.

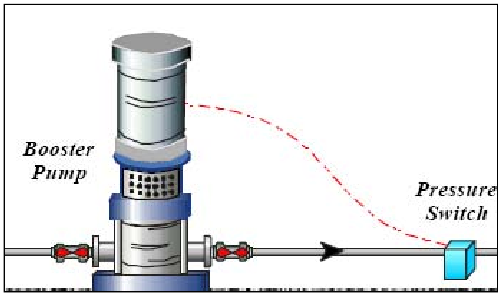
The screen on the RP device can get plugged up thus reducing the water flow through it. Therefore, the RP device needs to be monitored for fouling of the internal screen. This is done by monitoring the pressure going into and out of the device. There is normally a significant reduction in pressure across an RP device, often as much as 20 Pounds Per Square Inch (PSI). It is important to have a baseline pressure drop established which would be the normal pressures for the device. After that, if the pressure difference between pre and post RP device increases by 10 PSI, the internal screen should be cleaned, or the RP device may need servicing.

RP devices must also be checked for proper function at least annually by someone who has been properly trained and certified. Most facilities use a plumber for this, though you can get certified by taking a class specifically for this purpose.

RP Device Summary

What to monitor: Pressure drop across the device, annual testing
What to look for: A pressure drop change of 10 PSI from baseline

Monitoring the Booster Pump:

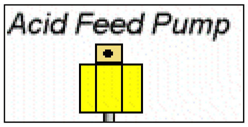


In order to maintain the necessary minimum pressure and flow to the treatment system, booster pumps are often used on the feed water line. The on/off cycle of booster pumps are controlled by either a pressure switch or flow switch, which turns the pump on when the pressure drops below a specific set point, and turns it off once the pressure recovers to the baseline (above the set point). These set points vary depending on the needs of an individual dialysis facility. Once the proper set points are established, the pump should be monitored periodically to ensure its proper functioning and that the booster pump cycles on and off as needed.

Booster Pump Summary

What to monitor: Water pressure
What to look for: Pump turning on and off at the appropriate pressures or flow rates

Monitoring the Acid Feed Pump:



Though this is not needed in all water treatment systems, adding an acidic solution to the raw water is indicated in areas where the pH of incoming feed water is high. Some municipalities add a base such as sodium hydroxide into the water system to increase the pH of the water. This minimizes leaching of metals from the pipes. Carbon filtration and Reverse Osmosis devices will not work as effectively at a pH of >8.5. In these municipalities, adding an inorganic acid to lower the feed water pH may be required for the proper functioning of water treatment system. Organic acids are discouraged because they encourage bacterial growth.

To assure that the acid is fed in at the appropriate rate, pH must be monitored from a sample port just downstream from the acid feed pump. This monitoring should be performed with a pH meter or pH strip that is designed for the level anticipated.

The expected range for pH should be between 7.0 and 8.0. Some important points to consider:

1. Place the acid feed system before the multi-media since the lower pH can cause aluminum to precipitate.
2. Online monitoring of pH is required with both audible and visual alarms in place
3. An independent test of pH is required daily

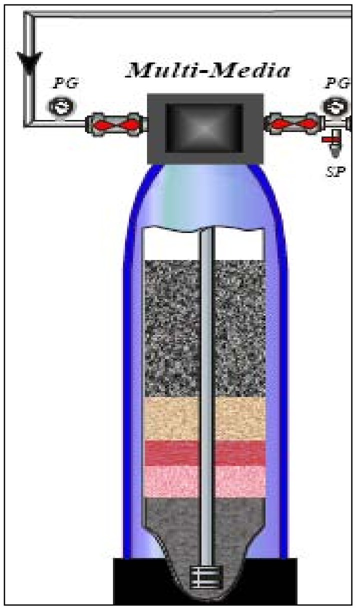
Note: Sometimes as an alternative pretreatment, weak acid cation tanks are used to lower pH by adding hydrogen ions.

Acid Feed Pump Summary

What to monitor: pH post acid feed pump

What to look for: pH should be between 7.0 and 8.0

Monitoring Depth Filtration Devices:



Depth filters are used to remove particulate matter from the water. They range from large multi-media filters and cartridge filters which remove dirt from the incoming water to ultrafilters that remove bacteria from product water.

Monitoring of depth filters is the same, regardless of their size or configuration. The pressure should be measured both pre and post filter, and a baseline pressure drop established when they are fresh. From this point, there should not be more than a 10 PSI pressure drop from this baseline. If the pressure drop change is greater than 10 PSI, the filter should be replaced or backflushed to restore unrestricted flow of water.

The backflush timer (if present) should be set to perform the backflush operation after facility operation hours.

Depth Filtration Summary

What to monitor: Pressure drop across the device, backflush timer

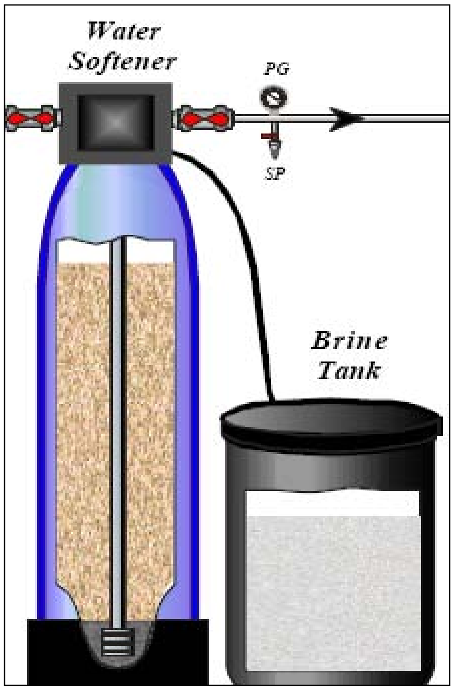
What to look for: Pressure drop of 10 PSI or more from baseline operating pressures, timer set correctly

Monitoring the Water Softener:

Water softeners are an important part of most water treatment systems. Their use, however, is primarily in protecting and prolonging the life of the RO membrane. Water softeners are used primarily to remove calcium and magnesium from the water, which an RO will do easily as well. (Softeners remove Ca^{++} and Mg^{++} by exchanging these for

Na$^+$.) The problem resolved by softening is that the calcium would otherwise build up on the RO membrane and cause a significant decrease in water quality as well as RO membrane life.

To assure that your softener will perform appropriately, you need to monitor:



1. **Total hardness post softener**

   Measured in either Grains per Gallon (GPG) or Parts per Million (PPM). The Association for the Advancement of Medical Instrumentation (AAMI) RD52 recommends a limit of 1GPG, which is equal to 17.2 PPM. PPM can be converted to GPG by multiplying by 0.058. GPG can be converted to PPM by dividing by 0.058.

2. **Pressure Drop**

   The pressure should be monitored before and after the softener. Softeners vary in how much pressure is lost across them, and you need to establish a baseline when it is working properly. The device may require back flushing if the pressure drop changes by more than 10 PSI. A breakdown of the resin can occur (from chlorine) which can also cause increased pressure drops.

3. **Salt level in the brine tank**

   There should always be an adequate amount of salt in the tank to allow the resin beads to be regenerated by the softener.

   Monitor the brine tank for a “Salt Bridge”- where salt at the top of the tank solidifies, making it appear as though the tank is full when it is actually empty underneath.

4. **Regeneration Timer**

   The system should be set to regenerate the resin beads often enough to provide exchange ions for the calcium and magnesium.

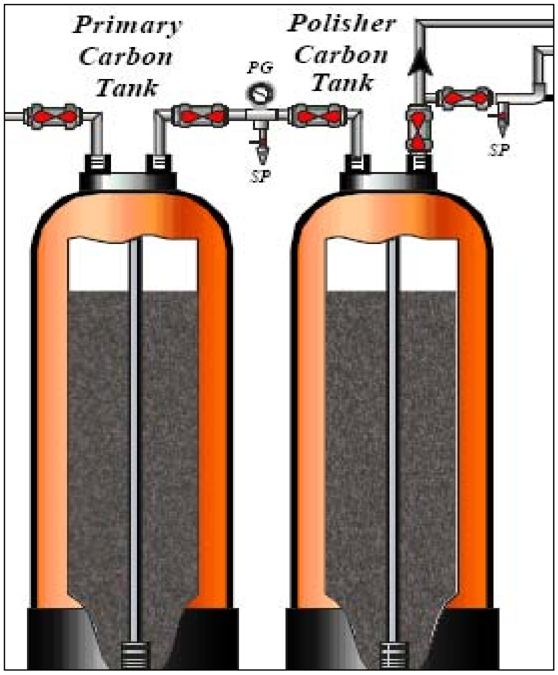
   The timer should be set to activate when the facility is not operating, and monitored daily to make sure it will not go into a regeneration cycle during a patient treatment. The timer should always be visible.

Water Softener Summary

What to monitor: Post softener hardness at the end of the day, amount of salt in the brine tank, “salt bridge” in the brine tank, pressure drop across the device, settings on regeneration timer.

What to look for: Hardness not exceeding 1 GPG (17.24 PPM), adequate amount of salt with no salt bridge, pressure drop change from baseline of 10 PSI or more, timer set to activate when facility is not in operation.

Monitoring the Carbon Tanks:



One of the most critical tasks regarding patient safety in the day of a dialysis technician is checking the water treatment system for chlorine and chloramines. Chlorine and its combined form, chloramine, are high-level oxidative chemicals. They are added to municipal water systems to kill bacteria—but they also destroy red blood cells. For this reason they must be removed from water to be used for dialysis. Unfortunately the R/O system is not very effective at removing chlorine and chloramines. In fact, many membranes are destroyed by them. Chlorine is removed from the incoming water by running it through tanks filled with Granulated Activated Charcoal (GAC, or carbon), which absorbs it.

Carbon tanks are part of the pre-treatment section of a water treatment system and normally are arranged where water will flow first through one tank and then directly into another. This is called a “series” configuration. The first tank in the series (Primary Carbon Tank) is referred to as the “worker” tank and second is called the “polisher.” Knowing the flow arrangement of your carbon tanks will help you understand how and where to test them.

The amount of carbon in your tanks must be adequate to allow the chlorine to be absorbed in the amount of time the water is flowing through it. The water must be exposed to the carbon for 5 minutes in each tank, for a total of 10 minutes for both the worker and polisher. This residence time is known as Empty Bed Contact Time, or EBCT. It is calculated using the formula EBCT=V/Q, where V= the Volume of Carbon (in cubic feet) and Q= the water flow rate, in cubic feet per minute. To calculate the volume of carbon needed, use the formula V= (Q * EBCT) / 7.48 (this is the number of gallons in one cubic foot of water).

For example, if you know that you have a flow rate of 10 Gallons per Minute (GPM), and you want an EBCT of 5 minutes, your calculation would be:

$V = (Q * EBCT) / 7.48$

$V = (10 * 5) / 7.48$

$V = 6.69$

You need a 6.69 cubic foot carbon tank for each working and polishing tank

To calculate your EBCT from a known carbon tank volume and flow rate (assume a 6 cubic foot tank and a 12 GPM flow rate), your calculation would be:

EBCT = V/Q
EBCT = 6 / (12/7.48)
EBCT = 6 / 1.6
EBCT = 3.75 minutes per 6 cubic foot tank

The objective of your chlorine/chloramine testing is to verify that chlorine has been removed from the water entering the RO. Your sample should be taken at the point where the water leaves the first tank (worker) and before entering the second (polisher). If the results show any chlorine leaving the first tank, a second sample should be taken immediately after the water leaves the second tank. *If there is chlorine leaving the second tank, dialysis should be discontinued in the facility.* If there is no breakthrough, the chlorine level should continue to be monitored after the second tank on an hourly basis until the primary tank is replaced. This is because you no longer have redundant protection.

It is very important that the water system be in full operation for *at least 15 to 20 minutes* before you take your first test. If you take your sample as soon as you start up the system, you will be testing water that has been sitting in the tank overnight, and it will not give you a representative sample of the carbon tank's capability at normal flow rates.

There are various ways to test water for chlorine/chloramine but the most widely used are colorimeters, color comparators, and test strips. Because the results of this test (and others) are determined by comparing colors, it is important that the person performing them has passed a color blindness test.

The limit for chlorine is 0.5 PPM, and the limit for chloramine is 0.1 PPM. There is no method to test directly for chloramine, so you must perform two separate tests: one for Total Chlorine, and one for Free Chlorine. The chloramine level is the difference between the two tests.

Example:

Your Measured Total Chlorine is 1.2 PPM
Your Measured Free Chlorine is 0.8 PPM
1.2 - 0.8 = 0.4 PPM
Therefore your Chloramine Level is 0.4 PPM

It is acceptable, according to the AAMI, to just test for total chlorine so long as the test is of appropriate sensitivity and the result *does not exceed* 0.1 PPM. The rationale being if you have a zero reading for total chlorine then there is no chloramine present.

Most commonly, chlorine/chloramine testing is done before each patient shift. In most clinics, it would be difficult to find times during the day when there are no patients on the dialysis machine, so one strategy is to test before the first patient treatment at the beginning of the day, again at 9:00 am or 10:00 am, followed by a third and last test between 2:00 pm and 5:00 pm depending on your patient schedule. You will probably find that the best plan would specify exact times rather than a time frame, approximately every four hours. *If any of your tests indicates the presence of chlorine/chloramine, you must immediately notify the person responsible for maintaining the water treatment system.*

Pre and post pressures must also be monitored on the carbon tanks to assure consistent flow of water. If the carbon is fouled by particulate matter, the pressure drop will increase, indicating a need to backflush the tank to remove the particulates.

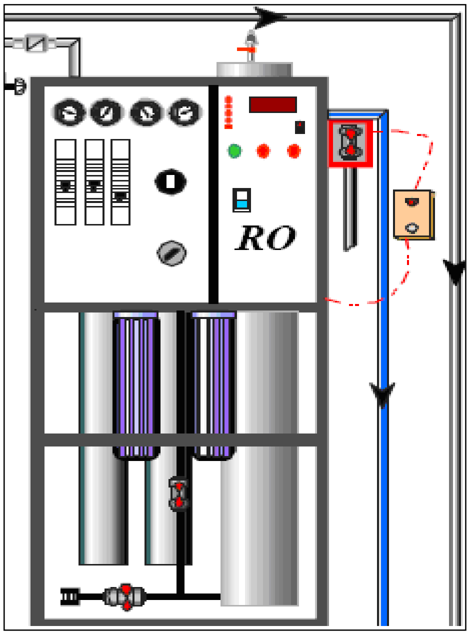
On larger tanks in particular, it is important to periodically backflush the tank to prevent channeling, which causes the water to flow quickly through established channels reducing the expected EBCT.

Carbon Tank Summary

What to monitor: Chlorine and chloramine levels after the worker tank before each patient shift, pressure drop across each tank, backflush timer. EBCT calculated and at the minimum 10 minutes for both tanks.

What to look for: Chlorine levels within AAMI standards (0.5 PPM chlorine, 0.1 PPM chloramine), pressure drop change of 10 PSI or greater, backflush timer set to activate when facility is not in operation.

Monitoring the Reverse Osmosis (RO) Device:



The primary concerns in monitoring your RO for quality are discussed below in their own sections on Chemical Contamination and Microbiological Monitoring. However, it is important to monitor the operation of the RO system to maintain its efficiency. Every RO will have its own specific parameters that indicate whether it is operating correctly.

Water pressure is measured in several places. Incoming water pressure needs to be adequate to maintain flow through the RO, generally 30-40 PSI. Pre and post pressure should be monitored on any incorporated depth filter as well. There is usually a safety switch that shuts down the RO if the pressure is too low to prevent damage to the RO pump. The pump pressure is monitored, as this pressure is what pushes water through the membrane, and is generally 200-250 PSI. The reject pressure is usually 50-75 PSI less than the pump pressure. The pressure of the product water is also monitored, and it will vary greatly depending on whether it is a direct or indirect (holding tank) system.

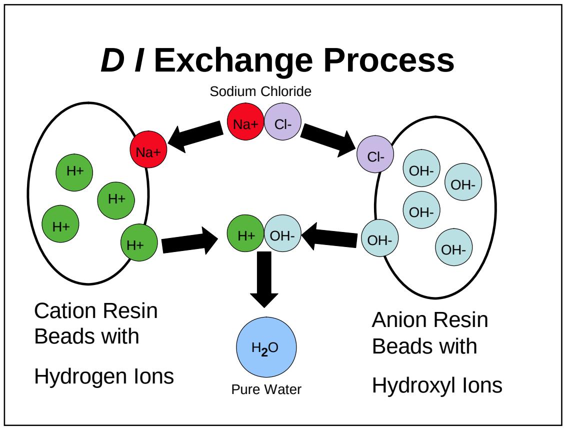
Water flow is also measured in several places using flow meters. Product flow indicates the amount of purified water that is getting through the membrane. Waste flow indicates the amount of concentrated water being flushed down the drain. Direct systems often measure the amount of product water recirculated through the system, and being blended with the incoming water.

The amount of dissolved solids is monitored in the incoming and product water, and is discussed in detail in the Monitoring Chemical Contamination section.

Reverse Osmosis Summary

> **What to monitor:** Water pressure and flow at various locations throughout the system.
>
> **What to look for:** Pressure and flow in an RO system are inter-related. For example, if you reduce the RO pump pressure, you will have a decrease in product water flow, and an increase in waste water flow. If the product water flow drops without a change in pump pressure, the RO membrane may be getting plugged up. A change in the delta pressure between the pump and reject pressures can indicate fouled membranes. It is therefore very important to establish appropriate baseline values for all pressures and flows, and then investigate any deviations. Use a trend analysis so that even minor changes can be seen over time.

Monitoring the De-Ionization (DI) System:



The primary concerns in monitoring your DI for quality are discussed below in the sections on Chemical Contamination and Microbiological Monitoring. However, it is important to monitor the pressures of the DI system to maintain its efficiency.

Water pressure should be monitored before and after each DI tank you are using. Baseline pressure drops should be established when the system is operating correctly. Changes of 10 PSI or greater indicate that the tanks are becoming plugged with particulate matter, or potentially the resin is breaking down, and restricting the flow of water.

Flow rates in DI systems are determined by product water usage. They do not generate a waste stream like an RO. If a holding tank is used, the flow velocity in the distribution loop should be a minimum of 3 ft/sec.

DI System Summary

> **What to monitor**: Pressure before and after each tank.
>
> **What to look for:** A change in pressure of 10 PSI or more from baseline.

Chemical Contamination

Monitoring the Feed Water:

A chemical analysis of your feed water should be performed periodically so that you are aware of the chemical composition, and assure that the water treatment system is designed to be able to reduce those contaminants to levels identified by AAMI. The list of contaminants and the appropriate methodology for analysis is listed below in Table 1.

The feed water analysis should be taken from the water before it enters any part of the water treatment system. It can be taken from a sink near the water treatment room so long as it has not been treated in any way.

If your back-up water plan is to use softened, dechlorinated water, or DI water in the event of an RO failure, you must also test this water. Testing should be performed for pH, endotoxin and bacteria on water from this back up plan as well.

The samples should be sent to a qualified lab that has the capability of analyzing them by the correct methodology and to the levels specified by AAMI. It is strongly suggested that the feed water be analyzed at least four times a year so that you know any seasonal variations, which are often present. There are no standards for contaminant levels in feed water. The results of the feed water analysis can be used to predict product water contamination by simply multiplying the individual results by the RO's percent rejection. A trend analysis should be performed to show trends over time.

It is very important that you maintain communication with the municipality that supplies water to your facility. Let them know who you are, and how important water quality is to your patients' health. They will inform you of any changes that occur, whether they are planned or accidental.

Monitoring the Product Water:

Your product water should be analyzed periodically to confirm that the water you are using for dialysis meets AAMI standards for chemical contamination. The sample should be sent to a qualified lab that has the capability of analyzing them by the correct methodology and to the levels specified by AAMI. Though the regulations state water is to be tested every 12 months, you are required to meet the AAMI Standards at all times. It is therefore strongly recommended that you test your product water at least quarterly.

Samples for product water chemical analysis should be drawn from a sample port immediately after the RO or DI system. When reviewing the results you should do two things. First, make sure that there are no contaminant levels that exceed AAMI standards. Then you should compare the results with past testing results and do a trend analysis to determine if any levels are increasing. This will give you advance knowledge about a potential degradation of your water treatment system, or changes in the supply water.

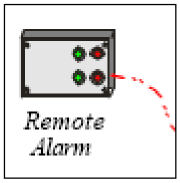
Table 1: AAMI Chemical Contaminant Standards

Contaminant	**Maximum Concentration mg/L** (Unless otherwise noted)	**Test Methodology**
Calcium	2 (0.1 mEq/L)	EDTA Titrimetric Method, or Atomic Absorption (direct aspiration), or Ion Specific Electrode
Magnesium	4 (0.3 mEq/L)	Atomic Absorption (direct aspiration)
Potassium	8 (0.2 mEq/L)	Atomic Absorption (direct aspiration), or Flame Photometric Method, or Ion Specific Electrode
Sodium	70 (3.0 mEq/L)	Atomic Absorption (direct aspiration), or Flame Photometric Method, or Ion Specific Electrode
Antimony	0.006	Atomic Absorption (platform)
Arsenic	0.005	Atomic Absorption (gaseous hydride)
Barium	0.10	Atomic Absorption (electrothermal)
Beryllium	0.0004	Atomic Absorption (platform)
Cadmium	0.001	Atomic Absorption (electrothermal)
Chromium	0.014	Atomic Absorption (electrothermal)
Lead	0.005	Atomic Absorption (electrothermal)
Mercury	0.0002	Flameless Cold Vapor Technique (Atomic Absorption)
Selenium	0.09	Atomic Absorption (gaseous hydride), or Atomic Absorption (electrothermal)
Silver	0.005	Atomic Absorption (electrothermal)
Aluminum	0.01	Atomic Absorption (electrothermal)
Chloramines	0.10	DPD Ferrous Titrimetric Method, or DPD Colorimetric Method
Total chlorine	0.50	DPD Ferrous Titrimetric Method, or DPD Colorimetric Method
Copper	0.10	Atomic Absorption (direct aspiration), or Neocuproine Method
Fluoride	0.20	Ion Selective Electrode Method, or SPADNS Method
Nitrate (as N)	2.00	Cadmium Reduction Method
Sulfate	100.00	Turbidimetric Method
Thallium	0.002	Atomic Absorption (platform)
Zinc	0.10	Atomic Absorption (direct aspiration), or Dithizone Method

NOTE: The physician has the ultimate responsibility for ensuring the quality of water used for dialysis.

Additional Note: *The above note in the AAMI Standards has been interpreted by some facilities to mean that the physician, or more specifically the Medical Director, has the leeway to deviate from these standards. Please understand that from the perspective of AAMI and regulatory agencies, this note indicates that the Medical Director is responsible for assuring that these standards are met, as stated, at all times. If the standards are not met, it is this person who will be cited as the negligent party.*

Continuous Monitoring of Chemical Contamination:



An indirect method must be employed to continuously monitor the chemical quality of the water. This is achieved by monitoring conductivity in RO systems and resistivity in DI systems.

In an RO system, conductivity is generally measured before (input) and after (output) the water passes through the RO membrane. Conductivity indicates the level of Total Dissolved Solids (TDS) in the water in terms of Parts per Million (PPM). By using the “percent rejection” formula {1-(output conductivity / input conductivity)}* 100, you can determine the percentage of a given solute that is removed by the RO membrane. The conductivity monitor should be temperature compensated to give a consistent conductivity reading.

Example: Input conductivity is 100 PPM, and Output conductivity is 8 PPM.
Enter into the formula: {1-(8/100)}*100
Equals (1-0.08)*100
Equals 0.92*100
Therefore you have a 92% rejection of total dissolved solids.

> Note: Conductivity of raw and RO water is actually measured in Micro Siemens. This measurement is equivalent to PPM, and is usually stated as PPM on the RO water quality monitor.

In a Deionization System, water quality is monitored differently. Because the water from a DI is more pure than RO water, the conductivity is too low to monitor accurately. For this reason, we monitor resistance to the flow of electricity, which is the inverse of conductivity. Percent rejection is not monitored, just the final product water. The acceptable limit of resistivity is greater than 1 megohm/cm resistance. It is very important that you understand the monitor on your particular DI system, as they can be variable. Usually, the indicators are simply LED’s that indicate water quality.

There was an incident in Chicago several years ago where a DI system was installed during a remodel. The DI monitor had a single indicator light that burned amber when the water was OK (greater than 1 megohm/cm), and went out if the water quality dropped. When this DI tank exhausted, a new one was put in that had a dual light indicator. It burned green when the water was OK, and turned amber when the quality dropped. A technician returned from vacation after the tank exchange, and had no idea that there was a different monitoring system. He checked the monitor, and when it was amber, assumed that all was well. This resulted in several patient deaths due to fluoride contamination.

A secondary method of monitoring DI is pH. Often when a DI tank is exhausted, the pH will drop. This is not always the case depending on the contaminants in the raw water, so pH can never be used as the primary means of monitoring a DI system, and resistivity monitoring must be used.

Chemical Contamination Summary:

What to monitor:

Analysis of raw and treated water for chemical contaminants outlined in the AAMI table. The standards state that these should be tested annually, but the Network's Committee recommends that they be done quarterly.

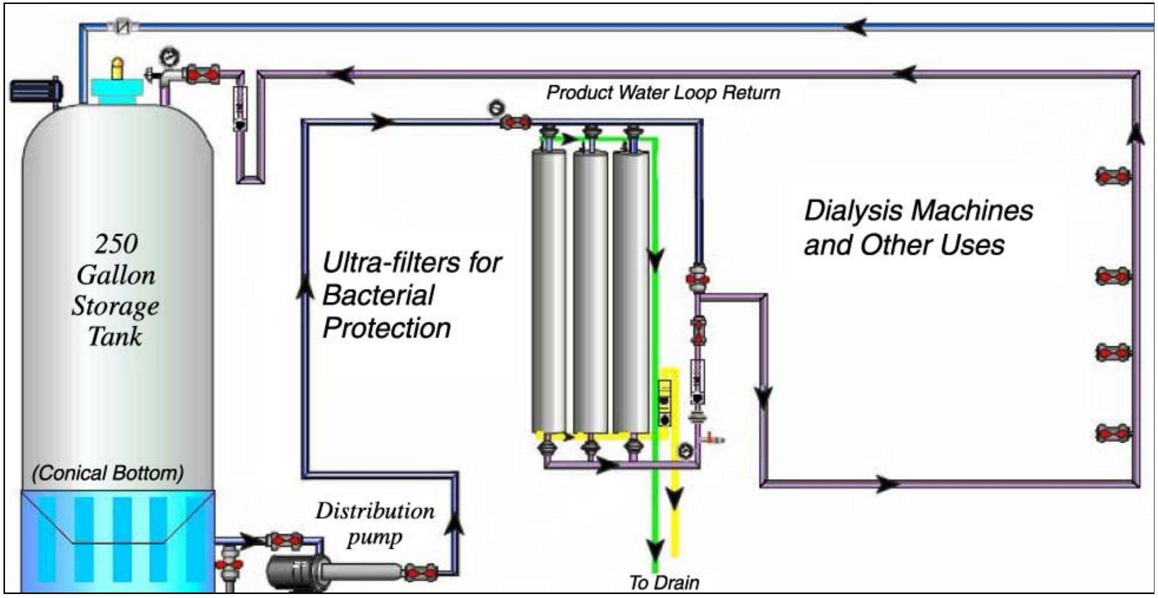
Product water must be indirectly monitored continuously using either conductivity for RO water, or resistivity for DI water. These monitors must have an alarm in the treatment room that alerts you if the water quality degrades.

What to look for:

Any contaminant results that exceed AAMI standards. A trend analysis should be done to see if any contaminant levels are increasing.

Any changes in your indirect, continuous monitor that would indicate product water quality were below AAMI standards. The percent rejection alarm on an RO depends on your incoming water analysis. For DI the alarm point is 1 Meg Ohm of resistance.

Monitoring Microbiological Contamination:



Microbiological contamination of water is a serious health concern for patients on dialysis. High levels of bacteria and/or endotoxin can harm patients by causing pyrogenic reactions or even systemic infections if a dialyzer membrane ruptures. If the bacterial contamination is severe enough, there can be a release of toxins that can adversely affect dialysis patients. It is essential that dialysis facilities monitor both bacteria and endotoxin levels in the water used for dialysis and dialyzer reprocessing.

Bacterial Standard for Water Used to Prepare Dialysis Fluid and Reprocess Hemodialyzers

The maximum level of bacteria in water used to prepare dialysis fluid and reprocess hemodialyzers must not exceed the AAMI standard of 200 colony forming units (CFU).

The AAMI action level is 50 CFU for bacteria in water used to prepare dialysis fluid. The Network Water Treatment Monitoring Committee recommends an action level of 25 CFU for monitoring RO machine membrane effectiveness as a bacteria barrier, because if you have that much bacteria passing through your RO membrane, it is likely to proliferate rapidly in your system.

An action level is defined as a point when measures must be taken to correct the potential source to remain in compliance with AAMI standards.

Endotoxin Standard for Water Used to Prepare Dialysis Fluid and Reprocess Hemodialyzers

The maximum level of endotoxin in water used to prepare dialysis fluid and reprocess hemodialyzers must not exceed the AAMI standards of 2 Endotoxin Units per Milliliter (EU/ml).

The action level of endotoxin in water used to prepare dialysis fluid is 1 EU/ml.

Frequency of Testing for Bacteria and Endotoxin levels

Testing should be performed monthly. If standards are exceeded, testing should be performed weekly until the problem is resolved.

Sample Collection:

The sample ports used to collect the samples must be rinsed for at least one minute at normal pressure and flow rate before drawing the samples. Samples should be collected using a “clean catch” technique to minimize potential contamination of the sample, leading to false positive results. Sample ports should not be disinfected. If a facility insists on disinfecting the ports, alcohol should be used and allowed to completely dry before the sample is drawn. Bleach or other disinfectants should not be used.

Sample collection sites:

The sample should be taken from the product water distribution piping at the following locations:

Site 1: At the point where the water leaves the RO machine, before it enters the holding tank (Indirect System), or before it goes to the treatment room to provide water for dialysis machines (Direct System).

Site 2: If an RO water holding tank is present, a sample should be taken at the point where the water leaves the tank.

Site 3: At the end of the return line of the RO water distribution loop, whether it is returning to the RO or a water holding tank. If a bacteria filter is installed anywhere in the system, a sample is to be drawn from a sample port both pre and post filter.

Site 4: At the point where water enters into the dialyzer reprocessing system, whether it is a manual or automated system**.** (Note: If a sample port is not present one should be installed.)

Site 5: At a point where water enters equipment used to prepare bicarbonate and acid concentrate. (Note: If a sample port is not present one should be installed.)

Site 6: At the point where the dialysis machine is hooked up to the product water loop. If a dialysis machine is consistently attached to that location, you may culture the machine instead of the water outlet.

Site 7: If your facility uses softened, dechlorinated water as a backup water plan, it is necessary to perform cultures and a Limulus Amebocyte Lysate (LAL) test on this water, because the RO is the primary source of bacterial protection for the patients.

Note: Though this document deals with water treatment, it is very important to culture your dialysis machines as well. The new limit for bacteria (ANSI/AAMI RD52 2004) in dialysate is 200 CFU's/ml. Two of your machines should be cultured monthly, or enough that all of them are cultured at least annually. The water line into the machine should be suspected if you ever get positive results, as this line is often overlooked in disinfection procedures.

Important: If a DI system is being used to prepare dialysis fluid, the samples are to be drawn at a point between the DI outlet and the bacteria filter **and** from the water valve at the furthest point on the distribution water line from the DI system.

Testing Methodology

Samples for bacteriological testing should be processed within 1-2 hours or refrigerated and processed within 24 hours. The AAMI standard recommends culturing samples of 0.5 to 1.0 cc for 48 hours at 35 C, using tryptic soy agar as the culture medium. Filter membrane devices such as the Millipore paddles are acceptable, but require a solid QA program that includes sending duplicate samples to a lab annually. Techniques that should absolutely be avoided are the calibrated loop, and blood or chocolate agar. This is because calibrated loops have too small a sample size (either 0.01 or 0.001 cc), and the blood and chocolate agars are too nutrient rich for water borne bacteria, which would cause them to die rather than multiply. The testing of endotoxin is performed by the LAL test.

When Test Results Exceed the Action Level:
In the event test results are above the action level, there should be a review of the following procedures as the first step to isolate the potential problem:

- Level of bacteria exiting the RO machine.
- Product water distribution system disinfection procedures.
- Examination of the distribution piping system for dead spots that may contribute to bacterial contamination including possible contamination of bacteria filters if they are installed in the distribution system.

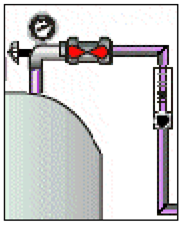
Corrective action should be undertaken in the area of the suspected cause for exceeding the action level. Corrective action may include:

- Cleaning and disinfection of RO machine membranes.
- Disinfection of the product water distribution system, including the entire loop.
- The installation of an endotoxin filter system in the RO water distribution system and/or increasing the frequency of disinfection of existing bacteria filter(s).
- Make sure that the water hose on the machine is being disinfected (This is often overlooked in facilities when the machines and RO loop are disinfected separately).

Microbiological Monitoring Summary

- **What to monitor:** Bacterial cultures and LAL tests from a representative portion of your product water delivery system.
- **What to look for:** Bacterial culture results that exceed the action level of 50 CFU's/ml. LAL results that exceed the 1 EU/ml action level. A trend analysis should be done to determine if microbiological contamination is increasing from previous testing results.

Monitoring Product Water Flow Rates:



Under certain conditions, bacteria in water systems can attach themselves to the walls of the pipe, and form a layer of biofilm. This hazard can be minimized by the friction of rapidly moving the water through the pipes. A flow velocity of 3 ft/second is the minimum recommendation in order to reduce bacteriological problems. The rate of flow and the size of the pipes in use will determine the flow velocity. A flow meter should be placed on the return loop after the last point of use and before the storage tank.

The following formula can be used to calculate flow velocity in the water system loop when the return flow from the loop is known. It can also be used to calculate the flow rate required, based on the diameter of pipe in use.
$V = Q/A$, where:

V = flow velocity in feet/sec
Q = flow rate in feet^3/sec
A = cross sectional area of distribution pipe in feet^2

In order to use the formula, the flow rate must be converted to cubic feet per second. This is done by dividing the Gallons per Minute (GPM) by 60 and then dividing that number by 7.48, which is the number of gallons of water contained in one cubic foot. (The same result can be achieved by multiplying the gallons per second by 0.1337)

Example: What is the flow velocity of the return flow through a 1-inch pipe at 6.5 GPM rate?

Step one: Convert GPM to ft^3/sec

Formula: GPM/60 (seconds in a minute) / 7.48 (gallons of water in one cubic foot)

First: 6.5 GPM / 60sec = .10833 gallons per second

Then: 0.10833 / 7.48 = 0.0145

Therefore, 6.5 gallons / min = 0.0145 ft^3/sec

The next step is to calculate the cross sectional area of the pipe. Essentially, this means we need to calculate the area of a flat circle the size of the internal diameter of the piping. The area of a circle is calculated using the formula $A = pi \times r^2$, where A = Area, pi = 3.14, and r = radius (which is ½ of the diameter).

We will assume a 1-inch diameter pipe is being used. To convert diameter in inches to radius in feet: Divide the diameter by 2 to get the radius in inches, and then divide this number by 12 to convert into feet.

Step two: Calculate the cross sectional area of the pipe.

Formula: Area = $pi(r^2)$

First: Find the Radius (r). r =1/2, r = 0.5 inch

Second: Convert the r from inches to feet. 0.5 / 12 = 0.0417

Third: Square the Radius. $r^2 = 0.0417^2 = .00174$

Fourth: Multiply by pi. 0.00174 X 3.14 = .00546

Therefore, the Area of a 1-inch pipe is 0.00546 ft^2

Step three: Calculate the flow velocity: Once you know the area, the numbers can be plugged into the original formula, V = Q / A.

Velocity = Q (0.0174 ft^3/sec) / A (0.00546 ft^2) = 2.657 feet/sec

In this case the flow velocity is less than 3 feet per second, and doesn’t meet AAMI Standards. If this pipe were to have an internal diameter of ¾ inch, this calculation would result in a flow rate of 4.72 feet per second.

Please be aware that internal diameter of pipes is often slightly smaller than stated. For example, the actual internal diameter of a 1-inch pipe is about 0.95 inches.

Flow rate monitoring summary

What to monitor: Flow rate at the end of your distribution loop, whether it is returning to a tank or the RO system.

What to look for: You need to perform the calculations on you specific system to determine the flow velocity of your pipes. After determining the minimum flow rate needed to maintain a 3 ft/sec flow velocity, assure that your end of loop flow always meets the required amount.

Table 2: Flow Velocity Chart

Pipe Size Inches (ID)	Flow Rate in GPM	Flow Velocity feet / sec
1	6	2.452
1	6.5	2.657
1	7	2.861
1	7.5	3.065
1	8	3.270
1	8.5	3.474
1	9	3.679
1	9.5	3.883
1	10	4.087
0.75	5	3.633
0.75	5.5	3.997
0.75	6	4.360
0.75	6.5	4.723
0.75	7	5.086
0.75	7.5	5.450
0.5	5.5	8.992
0.5	6	9.810
0.5	6.5	10.627
0.5	7	11.445
0.5	7.5	12.262

Monitoring the Drain System:

There are some important things to consider in maintaining the drain lines in the dialysis facilities.

The first is the requirement for a minimum 1-inch air gap between the equipment drain line and the building drain pipes. This air gap prevents the possibility of sewage being drawn into the machine, or direct contact with the drain line, in the event the sewer gets backed up.

Second, dialysis drains can attract fruit flies, which create infection control issues within the unit. If this occurs, some have reported that periodically pouring or straight household bleach or a commercial gel product down the drains will resolve the problem.

Drain system summary:

What to monitor: Periodically monitor your drain line placement. Monitor for fruit flies in the unit

What to look for: A minimum 1-inch air gap at all connections to the drain piping, absence of fruit flies

Monitoring of Disinfectants:

Water treatment systems and dialysis machines need to be disinfected periodically. Chemicals such as bleach (chlorine), peracetic acid/hydrogen peroxide mixtures, and formaldehyde are commonly used for this purpose. Whenever you use these or other chemicals in the dialysis facility to disinfect your equipment, it is necessary to test the concentrations. You should test the concentration of the solution you are using for potency, to assure that you have an adequate concentration to achieve disinfection of the system. After the disinfection procedure is complete and the system is rinsed, you must test for the absence of that chemical in the system.

The test you use must be appropriate for the chemical you are using. Below is a list of tests that are sometimes used in dialysis facilities that are not of the appropriate sensitivity to assure that you meet AAMI standards.

Table 3: Inappropriate Disinfectant Tests

Test Method (Chemical)	**Sensitivity**	**AAMI Standard**
Starch Iodide Paper (Chlorine)	8-10 PPM	0.5 PPM
Starch Iodide Paper (Residual Peroxide)	25 PPM	3.0 PPM
Starch Iodide Paper (Peracetic acid potency)	Tests strongly positive at 100 PPM	Should be negative if below 500 PPM
Clinitest Tablets® (Formaldehyde)	80-160 PPM	5 PPM (3 PPM in California)
Clinitest Strips® (Formaldehyde)	Does not react at all	5 PPM (3 PPM in California)
Hema-Stix® (Chlorine)	3-5 PPM	0.5 PPM

Documentation:

As the old saying goes, “If it isn’t documented, it wasn’t done.” This holds as true for water treatment documentation as it does for clinical documentation. Log sheets should be used to document each parameter of the treatment system. You must also document the time, date and results of each quality test that you perform, such as chlorine testing, hardness, etc. Every entry should be signed or initialed so that the person performing the testing is known. There should be no blank spaces on the logsheet.

Frequently Cited water Treatment Standards:

Below is a list of water treatment related standards that are most frequently cited during a survey by regulatory agencies:

Water system disinfection: “The dates of disinfection and the dates and results of tests for residual disinfectant should be recorded in the equipment maintenance record accompanied by the signature or other unique means of identification of the person performing the procedure."

> Though this condition comes from the reuse section of the regulations, it is required that equipment disinfection be performed and appropriately documented when it is needed in all facilities.

Physical Environment: “Water used for dialysis purposes must be analyzed periodically and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques.”

> The most frequent circumstance cited under this regulation is the lack of documentation that a facility responded appropriately to action levels of bacteria.

Maximum level of Chemical Contaminants: “The water used to prepare dialysate shall not contain chemical contaminants at concentrations in excess of those in Table 2” (of the AAMI standards).

> The most common citation is regarding chlorine/chloramine testing. Common errors include lack of documentation that it was tested at the specified frequency, drawing the sample from the wrong place, and occasionally use of inappropriate testing methodology.
>
> Another issue that is sometimes cited is the backup water plan. The water for the backup plan must meet AAMI standards and must be tested quarterly to ensure compliance. This must include chemical contaminants, cultures and endotoxins. Aluminum, copper, and/or fluoride are often high in softened, dechlorinated water.

The Medical Director is responsible for “assuring adequate monitoring of the patient and the dialysis process…”

> The Medical Director is responsible for the quality of the water. There needs to be documentation that the Medical Director is involved in monitoring the water quality. This can be done through Continuous Quality Improvement (CQI) meeting minutes, which indicate that s/he was in attendance. Many facilities have the Medical Director initial the testing results to indicate that they have reviewed

> them. Any time the water treatment system is out of compliance, the Medical Director can be cited for not assuring that it was in compliance.

Documentation: "Technical logs will meet the same documentation standards as the medical records, including proper correction of errors."

> All spaces on log sheets should be filled in. If initials are put on logs to identify the staff person, a signature list should be readily available to identify the users of initials. Errors must be corrected by crossing out with a single line and the staff initials written near the correction. The original entry should be decipherable.

Closing Thoughts

Thank you for taking the time to read this document. The Network believes that we have provided some valuable information that will help you keep your patients safe. In virtually every instance in which patients have come to harm from water treatment systems in dialysis, there has been a lapse in effective monitoring. This document has provided you with some tools, but it is up to each facility and each technician to use them.

A good training program is very important. Technicians involved in monitoring the water treatment system should have a good understanding of each component and how it works. They should understand why each part of the system is important. They need to know what parameters to document, and what the appropriate range is for each of them. They need to know how to respond if there is ever a reading that is out of range.

It is also important to develop and follow good Continuous Quality Improvement principles to "monitor your monitoring." This assures that your monitoring program is being adhered to by all staff in a consistent manner, and keeps the physicians and administration informed of water treatment issues. It should also be designed to help ensure regulatory compliance.

The last page of this document is a summary table that can serve as a quick reference guide to the recommendations in this document. Please feel free to copy and distribute it as you please. The Northwest Renal Network will post additional useful information on our website, www.nwrenalnetwork.org. We would appreciate your contributions! If you have a monitoring logsheet that you would like to share with other facilities, or any other suggestions that you think would help patients in the Northwest, please let us know.

Northwest Renal Network's Mission:
To promote optimal dialysis and transplant care for kidney patients in Alaska, Idaho, Montana, Oregon and Washington.

NORTHWEST RENAL NETWORK
— Serving Network Area #16 —

Water Treatment Monitoring Summary

Component	**What to monitor**	**What to look for**
RP Device	Pressure drop across the device	A pressure drop change of 10 PSI from baseline
Blending Valve	Water temperature	Appropriate water temperature, minimal temperature fluxuation
Booster Pump	Water pressure	Pump turning on and off at the appropriate pressures
Acid Feed Pump	pH post feed pump	pH should be between 7.0 and 8.0
Depth Filtration	Pressure drop across the device.	Pressure drop of 10 PSI or more from normal operating pressures when fresh.
Water Softener	Post softener hardness, amount of salt in the brine tank.	Hardness not exceeding 1 GPG (17.24 PPM), adequate amount of salt with no salt bridge.
Carbon Tank	Chlorine and chloramine levels after the worker tank before each patient shift	Chlorine levels within AAMI standards (0.5 PPM chlorine, 0.1 PPM chloramine).
Reverse Osmosis Machine Operating Parameters	Water pressure and flow at various locations throughout the system.	Changes from normal operating flows and pressures
DI Operating Parameters	Pressure before and after each tank	Pressure drop of 10 PSI or more from normal operating pressures when installed.
RO Water Quality	Product water conductivity, percent rejection, periodic water analysis	Percent rejection greater than 80%, water analysis results within AAMI standards
DI Water Quality	Product water resistivity, periodic water analysis	Resistivity greater than 1 Meg Ohm, water analysis within AAMI standards
Bacteria and Endotoxin in RO, Holding Tank and Product Distribution Loop	Water Cultures and LAL	Culture results less than the action level of 50 CFU’s/ml, LAL less than the action level of 1 EU/ml
Product Water Flow Velocity	Flow at the end of the loop	Flow rate adequate to maintain a velocity of greater than 3 ft/sec

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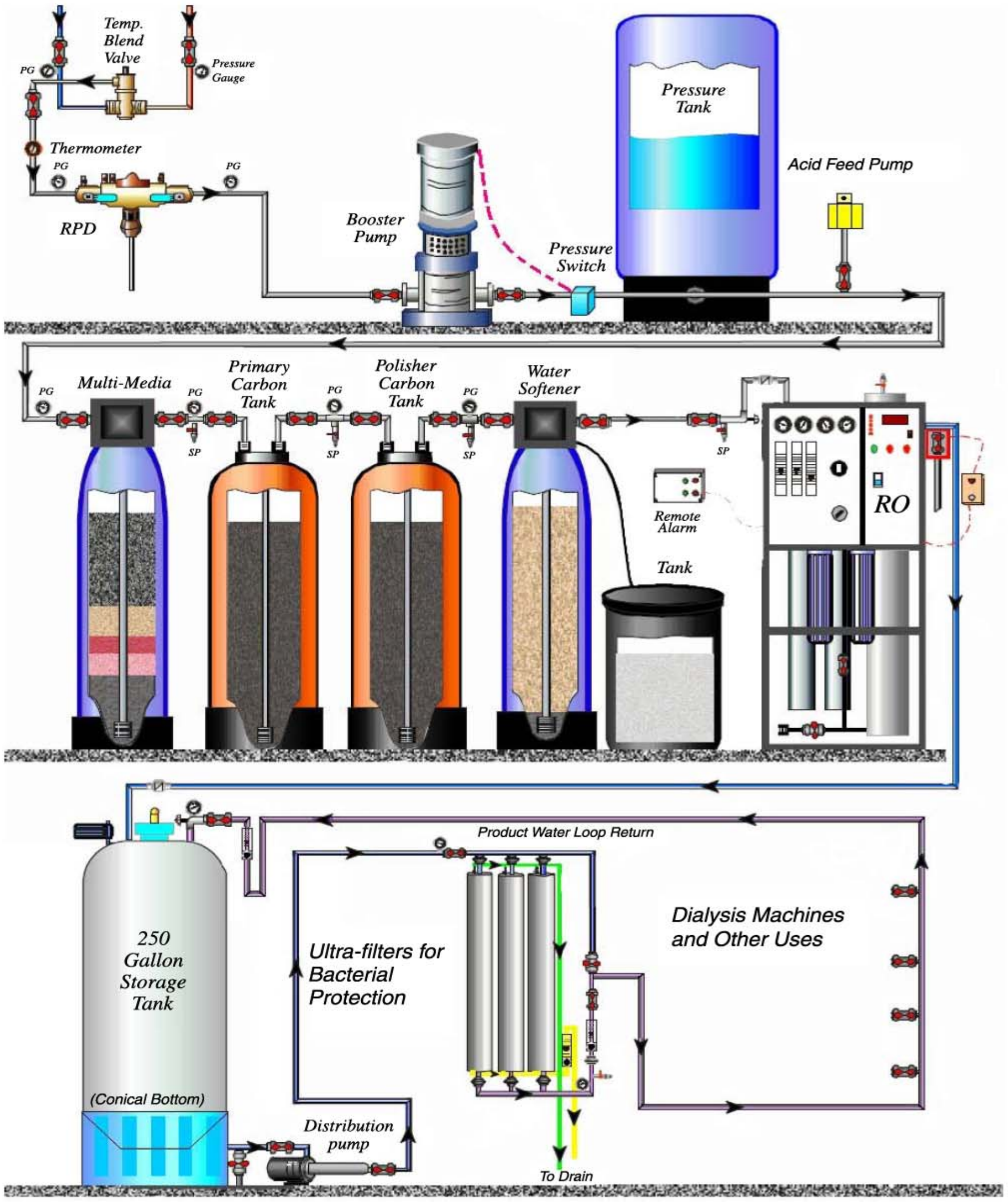
NORTHWEST RENAL NETWORK

— Serving Network Area #16 —

Monitoring Your Water Treatment System



Art Work Courtesy of Byron Roshto and Renal Care Group Northwest