Monitoring Your Dialysis Water Treatment System

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Dedication

*Monitoring Your Dialysis Water Treatment System* was originally published in 2005 and has since been widely used in dialysis both nationally and internationally. The Northwest Renal Network has taken on the challenge of updating this valuable resource under the guidance of several of its original authors; reviewers have also included a member of the original reviewer group (see both, below). We would like to thank those who spent many hours reviewing this Manual, including Jim Curtis, Byron Roshto, Danilo Concepcion, John Pilmer, Jared Throop, MRB Chair Dr. John Stivelman, and the Medical Review Board.

It has been well documented that facility failure to implement excellent standards in maintaining the dialysis water treatment system has resulted in patient harm. This manual was designed to outline the methods used to both achieve and maintain quality standards. Authored and updated by some of the field’s experts in this area, it is our hope that it continues to be a ready resource to technicians, nurses and medical directors.

This publication remains dedicated to the patients we serve, who encourage and inspire us.

Stephanie Hutchinson
Executive Director

With respect to the information published in this Water Manual, HealthInsight, including the authors and reviewers, assume no legal liability or responsibility for the accuracy, completeness, or usefulness of any information provided by this Manual. Any questions regarding its content should be referred to the dialysis facility Medical Director. Copies of this document can be made for individual dialysis facility use only.
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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. We believe this manual will be useful to technical personnel in the dialysis facility responsible for the day-to-day monitoring of their water treatment system. In it, we have described the important monitoring parameters for each component in the system, from the incoming water to the drain system.

When this document was first introduced in 2005, it quickly became the most frequently downloaded document on the NW Renal Network website. In 2015, the Network decided that enough changes had occurred in dialysis water treatment systems to require a revision to this manual. This project was undertaken by two of the original authors, Jim Curtis and Byron Roshto, along with Jared Throop.

Monitoring the Temperature Blending Valve:

Often, water treatment systems will require that the feed water temperature be raised to a certain temperature range. 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 water 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°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: Blended water temperature
What to look for: Appropriate water temperature, minimal temperature fluctuation from day to day

Monitoring the Back Flow Prevention Device:

While the AAMI Standard does not discuss monitoring of these devices, building codes do require that dialysis water treatment equipment be connected to the feed water through a Backflow Prevention Device (also known as a Reduced Pressure 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. In our water main break scenario, 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 become obstructed thus restricting the water flow through it. Therefore, the RP device ideally should be monitored for fouling of the internal screen. However, many RP devices installed in dialysis facilities are not equipped with pressure gauges, so one can only monitor by assuring that the feed pressure is adequate. There is normally a significant reduction in pressure across an RP device, often as much as 20 pounds per square inch (PSI). After that, if the pressure difference between pre and post RP device increases by 10 PSI or more, the internal screen should be cleaned, or the RP device may need servicing by a certified individual.

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 (if gauges are present), annual testing performed
What to look for: A pressure drop change of 10 PSI from baseline; ascertaining that the annual testing was performed on schedule
NOTE: Water treatment systems vary greatly in their placement of components. Many systems will have an RP device placed on each of the cold and hot feed water lines, so that these devices would be inline before the temperature blending valve.

**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 is 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.

Bladder tanks are sometimes included as part of the booster pump system. These tanks have a flexible bladder, and compressed air allows for a reservoir of water to be used so that the water pressure is maintained when the pump is turned off. These systems will cycle the pump on and off at preset pressures.

Some systems use a variable speed pump that simply speeds up or slows down to maintain the desired water pressure. In this type of booster pump system you may see a small bladder tank that is used as a shock absorber so that rapid changes in the pump’s speed do not cause a “water hammer” (a vibration in the downstream piping).

**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). Additionally, 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 sediment filter 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 (left) and cartridge filters (right) 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. If more than one component are on timers, they should be set so that only one component is backflushing at a time.
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 primary use is to protect and prolong the life of the RO membrane. Excess calcium in the feed water can build up on the RO membranes and cause a significant decrease in the volume of water they produce. Water softeners remove calcium and magnesium from the water in exchange for sodium.

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

Total hardness post softener
- Hardness should be measured at the end of the day. This assures that you have the capacity to soften the water for all treatments. Testing in the morning does not assure this since the softener is regenerated overnight. Hardness is measured in either grains per gallon (GPG) or parts per million (PPM). The Association for the Advancement of Medical Instrumentation (AAMI) (ANSI/AAMI 23500:2014) recommends a limit based on the specifications from the manufacturer of the RO system (usually 1 GPG, which is equal to 17.1 PPM).

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.

Salt level in the brine tank
- The tank should always be at least half filled with salt pellets 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. This has not been an issue when salt pellets (preferred type of salt) are used rather than coarse rock salt.
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. Only one component should be regenerating (or backflushing) at a time.

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 manufacturer’s specification, 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 RO 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 creates a chemical reaction that converts it into chloride.

Carbon tanks are part of the pre-treatment section of a water treatment system and must be 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 (secondary tank) is called the “polisher.” Knowing the flow arrangement of your carbon tanks will help you understand how and why to test them.
The amount of carbon in your tanks must be adequate to allow the total chlorine to be adsorbed 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 6.69 cubic feet of carbon 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 total chlorine testing is to verify that all 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 treatments should be discontinued immediately (see below). If there is no breakthrough (i.e., the second tank—the polisher—is negative) the chlorine level should continue to be monitored after the second tank on a more frequent basis (based on facility policy; AAMI Standards state “The decision to increase frequency of monitoring should be based on past performance of the system and on whether changes in feed quality have occurred.”) until the primary tank is replaced, which must be within 72 hours. 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 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 for some period of time, 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 total chlorine 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 old limit for free chlorine is 0.5 PPM, and the limit for chloramine was 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

The newest AAMI standard requires testing just for total chlorine, and that the test is of appropriate sensitivity to assure that the result does not exceed 0.1 PPM total chlorine (the rationale being that if there is a zero reading for total chlorine then there is no chloramine present). As of the date of this publication, CMS has not adopted the newest AAMI standards, so either method is acceptable.

Most commonly, total chlorine 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, but it must be done at least every four hours. If any of your tests indicates the presence of chlorine you must immediately test after the polisher tank. Any time you have chlorine breakthrough you must promptly discontinue dialysis treatments, notify the nurse in charge, the Medical Director, and 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:** Total chlorine levels after the worker tank every four hours, 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 ($< 0.1$ ppm total chlorine), pressure drop change of 10 PSI or greater, backflush timer set to activate when
facility is not in operation, and no other components backflushing or in a regeneration cycle.

**Monitoring the Reverse Osmosis (RO) Device:**

The primary concerns in monitoring your RO for water 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 Operating 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.

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 AAMI standards for contaminant levels in feed water, though RO system manufacturers require that it meet EPA drinking water standards. The results of the feed water analysis can be used to approximate expected 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 AAMI Standards 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. Some states, such as Oregon, require testing at least semi-annually, so you should be aware of any such regulations in your state.

Samples for product water chemical analysis should be drawn from a sample port at the end of the distribution loop, near where it re-enters the RO or holding tank (this provides assurance that the system has not added anything to the water). 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 follows.).
### Table 1: AAMI Chemical Contaminant Standards

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

**NOTE:** The Medical Director has the ultimate responsibility for ensuring the quality of water used for dialysis and following the above standards.

**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 \( \{1 - \frac{\text{output conductivity}}{\text{input conductivity}}\} \times 100 \), 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 (feed water) conductivity is 100 PPM, and Output (permeate) conductivity is 8 PPM.

Enter into the formula: \( \{1 - \frac{8}{100}\} \times 100 \)

Equals \( 0.92 \times 100 \)

Therefore you have a 92% rejection of total dissolved solids.

Note: Conductivity of raw and RO water is actually measured in MicroSiemens. This measurement is converted to TDS, and is often stated as PPM on the RO water quality monitor. Some RO systems simply provide a direct conductivity reading in MicroSiemens (µS).

In a deionization system, water quality is monitored differently. Because the water from a DI is purer than RO water, the conductivity is too low to monitor accurately. For this reason we monitor resistance to the flow of electricity, resistivity, 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.

Both RO and DI monitors must give both a visual and audible alarm, and divert the water to drain in the event the alarm limit is exceeded.

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.
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 at a minimum, annually.
- 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.

Ultraviolet Light Monitoring

Some water treatment systems include an ultraviolet light for the purpose of reducing bacterial growth. UV light waves at 254 nanometers can kill, or at least disrupt bacteria so that they cannot multiply.

UV systems should be monitored by a radiant output monitor. However, many UV lights with monitors often do not provide a direct readout of the radiant energy. Those systems have a relative radiant energy monitor, in which you establish a baseline when the light is new and you then set the monitor at 100%. In this case you would replace the bulb when the monitor reading drops to 70% of its original energy level.

An alternative is to simply replace the bulb on an annual basis. Depending on the manufacturers recommendation you may need to replace the quartz sleeve at the same time. Care must be used when replacing the lamp and should not be touched without the use of gloves.

You are also indirectly monitoring the UV light whenever you draw microbiologic samples of your product water. Anytime you find bacterial growth that is higher than expected you should consider the possibility that the UV light is not performing as it should.
UV irradiation must be followed by a means of reducing endotoxin concentrations, such as an ultrafilter in the purified water distribution system or reverse osmosis in the pretreatment cascade. This ultrafilter should be monitored for fouling by calculating the pressure drop across the filter. If the pressure drop exceeds identified parameters, the filter should be cleaned or replaced.

**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, concentrate mixing and dialyzer reprocessing.

**Bacterial Standard for Water Used to Prepare Dialysis Fluid and Reprocess Hemodialyzers (see Table 2 below)**

The maximum level of bacteria in water used to prepare dialysis fluid and reprocess hemodialyzers must not exceed the AAMI standard of 100 colony forming units (CFU).

The AAMI action level is 50 CFU for bacteria in water used to prepare dialysis fluid. 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.
Table 2: AAMI Standards for Water Preparation for Dialysis

<table>
<thead>
<tr>
<th>Type of Fluid</th>
<th>Microbial Bioburden</th>
<th>Endotoxin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maximum Contaminant Level</td>
<td>Action Level</td>
</tr>
<tr>
<td>Water for all purposes</td>
<td>100 CFU/mL</td>
<td>50 CFU/mL</td>
</tr>
<tr>
<td>Conventional Dialysate</td>
<td>100 CFU/mL</td>
<td>50 CFU/mL</td>
</tr>
<tr>
<td>Ultrapure Dialysate</td>
<td>0.1 CFU/mL</td>
<td>NA</td>
</tr>
</tbody>
</table>

NA=not applicable
NOTE: These current AAMI water standards are more stringent than those adopted by CMS: 200 CFU Maximum, 50 CFU action level

Endotoxin Standard for Water Used to Prepare Dialysis Fluid and Reprocess Hemodialyzers (see Table 2 above, “Water for All Purposes”)

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.

Samples should be collected in a “worst case” scenario – just before a scheduled disinfection. It is inappropriate to test immediately following a disinfection, unless you are validating your disinfection procedure after a positive result.
Sample collection sites:

- **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 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.

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 23500; 2014) in dialysate is 100 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 three techniques for culturing samples:

- 48 hours at 35°C, using tryptic soy agar as the culture medium (TSA, also known as TGYE).
- 7 days at 17-23°C, using Tryptone glucose extract agar (TGEA)
- 7 days at 17-23°C, using Reasoner’s agar no. 2 (R2A)
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 should be taken within 48 hours and may include:

- Disinfection of RO machine membranes. Disinfection of the product water distribution system, including the entire loop.
- Resampling cultures and/or endotoxins.
- 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 inlet hose on the machine is being disinfected (This is often overlooked in facilities when the machines and RO loop are disinfected separately).
- Replacing components of the water treatment or distribution system. Increase the frequency of system disinfection.

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 0.125 EU/ml action level. A trend analysis should be done to determine if microbiological contamination is changing 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 for an indirect feed system, or 1.5 ft/second for a direct feed system, 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.

\[ V = \frac{Q}{A}, \]

where:

- \( V \) = flow velocity in feet/sec
- \( Q \) = flow rate in feet³/sec
- \( A \) = cross sectional area of distribution pipe in feet²

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 ft³/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 ft³/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 \( A = \pi r^2 \), where \( A = \) Area, \( \pi = 3.14 \), and \( r = \) radius (which is \( \frac{1}{2} \) 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 (\( r \)). \( r = \frac{1}{2}, r = 0.5 \) 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 \( \pi \). \( 0.00174 \times 3.14 = .00546 \)
Therefore, the Area of a 1-inch pipe is 0.00546 ft²

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Step three: Calculate the flow velocity: Once you know the area, the numbers can be plugged into the original formula, \( V = \frac{Q}{A} \).

\[
\text{Velocity} = \frac{Q (0.0145 \text{ ft}^3/\text{sec})}{A (0.00546 \text{ ft}^2)} = 2.656 \text{ feet/sec}
\]

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 \( \frac{3}{4} \) 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 your 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 3: Flow Velocity Chart**

<table>
<thead>
<tr>
<th>Pipe Size Inches (ID)</th>
<th>Flow Rate in GPM</th>
<th>Flow Velocity feet / sec</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>2.452</td>
</tr>
<tr>
<td>1</td>
<td>6.5</td>
<td>2.657</td>
</tr>
<tr>
<td>1</td>
<td>7</td>
<td>2.861</td>
</tr>
<tr>
<td>1</td>
<td>7.5</td>
<td>3.065</td>
</tr>
<tr>
<td>1</td>
<td>8</td>
<td>3.270</td>
</tr>
<tr>
<td>1</td>
<td>8.5</td>
<td>3.474</td>
</tr>
<tr>
<td>1</td>
<td>9</td>
<td>3.679</td>
</tr>
<tr>
<td>1</td>
<td>9.5</td>
<td>3.883</td>
</tr>
<tr>
<td>1</td>
<td>10</td>
<td>4.087</td>
</tr>
<tr>
<td>0.75</td>
<td>5</td>
<td>3.633</td>
</tr>
<tr>
<td>0.75</td>
<td>5.5</td>
<td>3.997</td>
</tr>
<tr>
<td>0.75</td>
<td>6</td>
<td>4.360</td>
</tr>
<tr>
<td>0.75</td>
<td>6.5</td>
<td>4.723</td>
</tr>
<tr>
<td>0.75</td>
<td>7</td>
<td>5.086</td>
</tr>
<tr>
<td>0.75</td>
<td>7.5</td>
<td>5.450</td>
</tr>
<tr>
<td>0.5</td>
<td>5.5</td>
<td>8.992</td>
</tr>
<tr>
<td>0.5</td>
<td>6</td>
<td>9.810</td>
</tr>
<tr>
<td>0.5</td>
<td>6.5</td>
<td>10.627</td>
</tr>
<tr>
<td>0.5</td>
<td>7</td>
<td>11.445</td>
</tr>
<tr>
<td>0.5</td>
<td>7.5</td>
<td>12.262</td>
</tr>
</tbody>
</table>
**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 of 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 results of this test must be properly documented.

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 4: Inappropriate Disinfectant Tests**

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

As an alternative to chemical disinfection, some water treatment systems are now using heat disinfection processes to minimize microbial growth. Heat can be used to disinfect the distribution loop and/or the RO membranes. These systems must utilize heat tolerant piping and membrane material.

There are many advantages to heat disinfection of water systems. Because the systems can perform this function automatically, they can disinfect much more frequently without adding labor costs. Another advantage is that there is no residual disinfectant to be concerned with. It is important to monitor the system (usually via a computer) to assure that the temperature reached the desired level for the desired amount of time.

**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. When initials are used, there must be a method, such as a signature page, to identify the name associated with the initials.

**Frequently Cited Water Treatment Standards:**

Below is a list of water treatment related standards (listed by quality tag numbers) most frequently cited during a survey by regulatory agencies, dating from 4/26/15-9/21/17, accompanied by examples of prevalent issues (courtesy, John Pilmer, RN):

V195 – Miscalculation of the EBCT

V196 – Not testing for chlorine every 4 hours or not performing the test correctly.

  Knowledge of the limits and what to do if they are exceeded

V199 – RO meets AAMI/monitored recorded on log

  Not addressing out of range parameters

  Missing checks for residual disinfection following disinfection and rinsing of the RO

V200 – RO monitor/alarm prevent unsafe H2O use
RO alarm set too high based on incoming water analysis and capabilities of the water system

RO alarm disabled or not functional

**V213 – Distribution system culture/LAL/sites/frequency/log**

No trending log with corresponding quality assurance analysis of water quality trends

**V229 – Bicarbonate that does not meet the test result requirements**

**V239 – Bicarbonate concentrate distribution—weekly disinfect/dwell/concentration**

Lack of weekly system disinfection

Missing documentation of test for residual disinfectant

Lack of staff knowledge regarding acceptable residual disinfectant test results

**V290 – Low salt level in the brine tank and no salt in the facility**

**V403 – Physical Environment – equipment maintenance – manufacturer’s directions for use**

Incorrect calibration solutions or electrode storage solutions

Not following manufacturer’s recommendations for preventive maintenance schedule

Meters used by the biomedical department are not calibrated annually as required by the manufacturer. Examples include, but are not limited to the electrical safety analyzer and 90XL temperature and conductivity modules.
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.nwrn.org. We would appreciate your contributions! If you have a monitoring log sheet 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.
## Water Treatment Monitoring Summary

<table>
<thead>
<tr>
<th>Component</th>
<th>What to monitor</th>
<th>What to look for</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP Device</td>
<td>Pressure drop across the device, if pressure gauges are present</td>
<td>A pressure drop change of 10 PSI from baseline</td>
</tr>
<tr>
<td>Blending Valve</td>
<td>Water temperature</td>
<td>Appropriate water temperature, minimal temperature fluctuation</td>
</tr>
<tr>
<td>Booster Pump</td>
<td>Water pressure within required specifications</td>
<td>Pump turning on and off at the appropriate pressures</td>
</tr>
<tr>
<td>Acid Feed Pump</td>
<td>pH post feed pump</td>
<td>pH should be between 7.0 and 8.0</td>
</tr>
<tr>
<td>Depth Filtration</td>
<td>Pressure drop across the device</td>
<td>Pressure drop of 10 PSI or more from normal operating pressures when fresh</td>
</tr>
<tr>
<td>Water Softener</td>
<td>Post softener hardness, amount of salt in the brine tank</td>
<td>Hardness not exceeding the RO system manufacturer’s specifications, adequate amount of salt with no salt bridge</td>
</tr>
<tr>
<td>Carbon Tank</td>
<td>Total chlorine levels after the worker tank every four hours</td>
<td>Total chlorine levels within AAMI standards (&lt;0.1 PPM total chlorine)</td>
</tr>
<tr>
<td>Reverse Osmosis Machine Operating Parameters</td>
<td>Water pressure and flow at various locations throughout the system</td>
<td>Changes from normal operating flows and pressures</td>
</tr>
<tr>
<td>DI Operating Parameters</td>
<td>Pressure before and after each tank</td>
<td>Pressure drop of 10 PSI or more from normal operating pressures when installed</td>
</tr>
<tr>
<td>RO Water Quality</td>
<td>Continuous product water conductivity and/or percent rejection; periodic water analysis</td>
<td>Percent rejection within calculated parameters, water analysis results within AAMI standards</td>
</tr>
<tr>
<td>DI Water Quality</td>
<td>Continuous product water resistivity, periodic water analysis</td>
<td>Resistivity greater than 1 Meg Ohm, water analysis results within AAMI standards</td>
</tr>
<tr>
<td>Bacteria and Endotoxin in RO, Holding Tank and Product Distribution Loop</td>
<td>Water cultures and LAL</td>
<td>Culture results less than the action level of 50 CFU’s/mL, LAL less than the action level of 0.125 EU/mL</td>
</tr>
<tr>
<td>Product Water Flow Velocity</td>
<td>Flow at the end of the loop</td>
<td>Flow rate adequate to maintain a velocity of greater than 3 ft/sec (indirect feed) or 1.5 ft/sec (direct feed)</td>
</tr>
</tbody>
</table>
Bibliography


