Water Treatment for Hemodialysis: An Update

CNE Continuing Nursing Education

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While nurses may not routinely service the water treatment system or mix the dialysate, they are responsible for understanding all of the clinical ramifications of water treatment and dialysate preparation for hemodialysis as a part of the entire dialysis treatment picture. Although the water treatment system has historically been in the technicians' domain, knowing the technical aspects is important for the entire team to work together to ensure patient safety and well-being. This article describes the composition of water treatment systems for hemodialysis, as well as the monitoring and testing necessary to assure that both water and dialysate are safe for patient use.

Key Words: **Hemodialysis, water treatment system, dialysate preparation, patient safety.**

Goal

Discuss the technical components of the water treatment system used for dialysis.

Objectives

1. List the components of the water system at your dialysis clinic.
2. Describe the required monitoring of the water treatment system.
3. Discuss clinical manifestations patients may experience due to exposure to improperly treated water.

In hemodialysis (HD), more than 90% of the dialysate delivered to the dialyzer is water. The more pure the water, the more accurate the dialysate prescription that is delivered, as long as the water is properly mixed with the correct concentrates and in the correct proportions. Water contamination can lead to anemia, alterations in blood pressure and acid-base balance, neurological issues, bone disease, and more, and patients may suffer acute or chronic problems from exposure to substandard dialysate. The potential clinical symptoms of using inadequately purified water or contaminated dialysate are shown in Table 1. It is estimated that many reactions to inadequately purified water of go unreported because the chronic symptoms of kidney disease mineral bone disorder or chronic inflammation, can be insidious and attributed to problems secondary to end stage renal disease (ESRD) unless a patient exhibits an acute or sub-acute reaction.

The Food and Drug Administration (FDA) regulates dialysis water purification systems and classifies water systems, along with dialysis machines, as Class II medical devices (FDA, 2011). Class II devices require diligent tracking of critical components and a complaint investigation system in place. Class I devices include loosely regulated items, such as tongue depressors and Band-Aids®, while Class III devices, such as high-flux hemodialyzers and implantable pace makers, are stringently regulated devices and require tracking of all parts (even nuts and bolts) (FDA, 2009).

Water Supply

The first step to understanding water treatment is to understand water sources. There are two sources of water that municipal water suppliers use: ground water and surface water. Ground water comes from underground chambers, such as wells and springs, and is generally lower in organic materials but higher in inorganic ions, such as iron, calcium, magnesium, and sulfate. Surface water comes from lakes, ponds, rivers, and other surface type reservoirs. Surface water is generally more contaminated with organisms and microbes, industrial wastes, fertilizers, pesticides, and sewage. Some municipalities rely pri-

Note: Authors' biographical information can be found on the following page.

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All other authors reported no actual or potential conflict of interest in relation to this continuing nursing education activity.

Note: Additional statements of disclosure and instructions for CNE evaluation can be found on page 405.

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Table 1
Signs and Symptoms and Possible Water Contaminant-Related Causes

Symptom	Possible Water Contaminants
Anemia	Aluminum, chloramine, copper, zinc
Bone disease	Aluminum, fluoride
Hemolysis	Copper, nitrates, chloramine
Hypertension	Calcium, sodium
Hypotension	Bacteria, endotoxin, nitrates
Metabolic acidosis	low pH, sulfates
Neurological deterioration	Aluminum
Nausea and vomiting	Bacteria, calcium, copper, endotoxin, low pH, magnesium, nitrates, sulfates, zinc, Microcystins (from blue-green algae)
Death	Aluminum, fluoride, endotoxin, bacteria, chloramine, microcyctins
Visual disturbances	Microcystins
Liver failure	Microcystins

Note: Revised from FDA (1989).

marily on surface water most of the year, and then blend in well water when the supply of surface water falls. Dialysis facilities must be constantly vigilant and cognizant of their water source if the source varies over time.

Municipalities or public water suppliers process both types of water, and depending on the quality of the supply water, they may add chemicals. The Environmental Protection Agency (EPA) regulates all public water systems that serve 500 or more households, and those laws require strict adherence to the Safe Drinking Water Act (EPA, 2012). This law sets the maximum allowable level of contaminants in drinking water (potable water).

Municipal water suppliers may process waste water from sewage and industry for drinking water. For example, waste from the manufacturing process may be metered into the waste water drain in compliance with EPA and other regulations. The waste water is distributed to a waste water plant where it runs into large settling ponds and is treated with chemicals and flocculants (agents that cause sediment to "clump" and settle to the bottom of the pond) to remove the contaminants. The top layer of water is then fed into a river or reservoir that feeds the municipal potable water facility. At that facility, the water is further treated with flocculants, such as aluminum sulfate (alum), to remove non-filterable suspended particles (colloidal matter); depth filtration to remove filterable solids; chlorination/chloramination for disinfection; and fluoridation (which is elective) to prevent dental cavities. Ironically, most chemical additives have unenforceable contaminant level goals; in other words, no citations are given when a desired level is violated. Some, like aluminum, are even considered nuisance chemicals and have only a secondary standard. The maximum allowable levels of contaminants in water as set by the Association for the Advancement of Medical Instrumentation (AAMI) (for dialysis water) and the EPA (for drinking water) are shown in Table 2.

The EPA requires municipal water supply companies to monitor and test the water on a periodic basis. The quality of the water can change from season to season and even day to day. Though our drinking water is generally safe, it has been reported that between 2004 and 2009, 252 million Americans were exposed to tap water contaminants that are above health guidelines (Environmental

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Note: *This article is an update of Ms. Amato's article, "Water Treatment for Hemodialysis, Updated to Include the Latest AAMI Standards for Dialysate (RD52:2004)," which was first published in the March-April 2005 issue of the* Nephrology Nursing Journal *(Volume 32, Number 6, 151-167).*

Note: *The reader may notice that many of the references for this article are older than normally would be used. These are classic articles that reported the results of discovery, rather than research.*

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Table 2
AAMI and EPA Maximum Allowable Levels of Contaminants in Water

Contaminant	EPA Maximum for Drinking Water (mg/L) (Condensed List) July 2002	AAMI Maximum Concentration for Hemodialysis Water (mg/L Unless Otherwise Noted)	Concentration Associated with Hemodialysis Toxicity (mg/L)
Calcium	Not regulated	2 (0.1 mEq/L)	88.00
Magnesium	Not regulated	4 (0.3 mEq/L)	
Potassium	Not regulated	8 (0.2 mEq/L)	
Sodium	Not regulated	70 (3.0 mEq/L)	300.00
Antimony	0.006	0.0060	
Arsenic	0.005	0.0500	
Barium	2.000	0.1000	
Beryllium	0.004	0.0004	
Cadmium	0.005	0.0010	
Chromium	0.100	0.0140	
Lead	0.015**	0.0050	
Mercury	0.002	0.0002	
Selenium	0.050	0.0900	
Silver	0.100	0.0050	
Aluminum	0.05 to 0.2*	0.0100	0.06
Chloramines	4.000*	0.1000	0.25
Free Chlorine	4.000*	0.5000	
Copper	1.300**	0.1000	0.49
Fluoride	2.0* to 4.0	0.2000	1.00
Nitrate (as Nitrogen)	10.000	2.0000	21.00
Sulfate	250.000*	100.0000	200.00
Thallium	0.002	0.0020	
Zinc	5.000*	0.1000	0.20

*Unenforceable maximum contaminant level goal (secondary standard).
**Action level at 90th percentile.

Working Group, 2009). This places an extra burden on nephrology professionals working to deliver the purest water feasible to persons on HD.

Acute dialysis programs should ascertain whether the medical center where dialysis occurs adds further chemicals to the water for hospital use. Some hospitals have mini water treatment plants and may add disinfectants, such as chlorine dioxide or descalers, to the water. The hospital should give advance warning of any chemical process affecting the water supply to the dialysis professionals.

Why Water Purity Is Important During Hemodialysis

By the time water arrives at our faucets, it is deemed acceptable to drink by the municipality and EPA; however, drinking water is not acceptable for use in HD treatments. The average person consumes approximately two liters of water a day in different forms (juice, coffee, etc.), whereas a patient on HD is exposed to 90 to 192 liters of water per treatment. In healthy individuals, the contaminants in water are mainly excreted through the kidneys and gastrointestinal (GI) system. Patients on HD do not have functioning kidneys to excrete the waste products. They rely on HD to remove the wastes and normalize the electrolytes, and to not potentially add a life-threatening contaminant from the massive water (as dialysate) exposure. While people typically filter everything through their kidneys and liver, those on HD have dialysate exposure filtered via the dialyzer's semi-permeable membrane. That membrane is only selective with respect to molecular size and is not contaminant-specific. Contaminants in the water can diffuse from the dialysate into the blood, dependent upon the level within the blood and the thresholds for that contaminant.

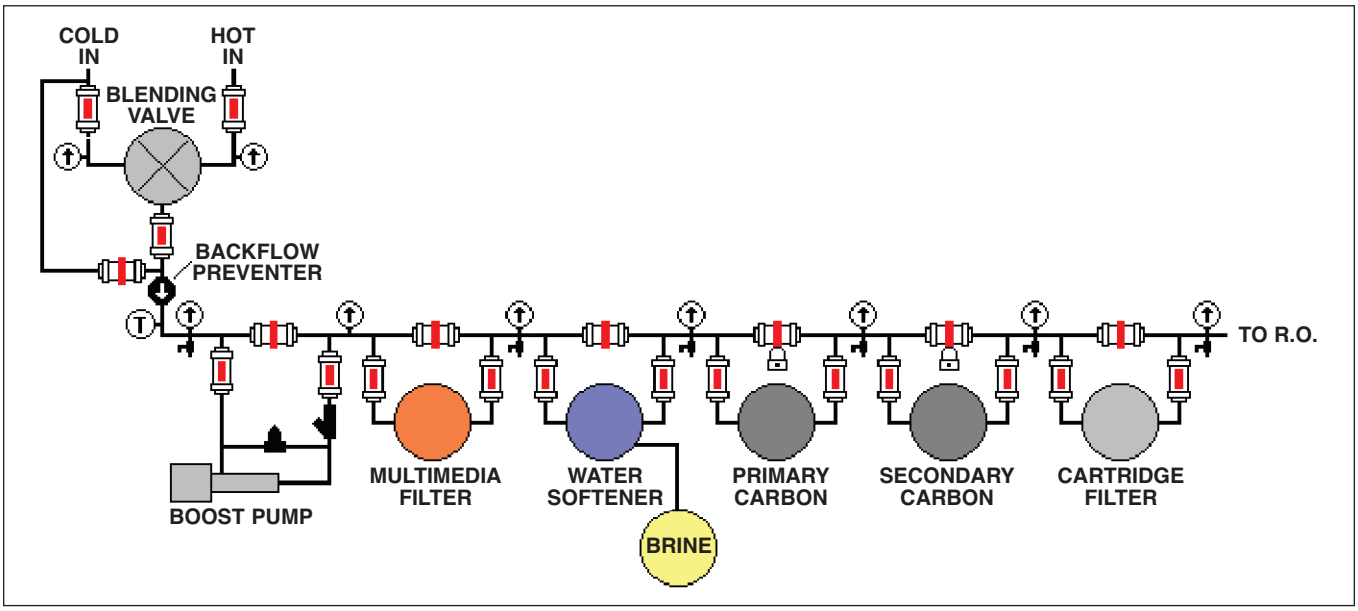
This article reviews technical information on feed water components, pretreatment components, reverse osmosis (RO) systems, posttreatment components, distribution systems, alternative disinfection methods, bacteria and endotoxins, and bacteriology of dialysate. Typically, not all components mentioned are part of a water treatment system for HD. Components will vary from facility to facility depending upon the incoming water quality and philosophy of the staff or organization.

Organizing the System

The AAMI standards provide recommendations that the FDA and Centers for Medicare & Medicaid Services (CMS) have embraced. They require that the labels for all water treatment devices must include: (AAMI, 2009a; CMS, 2008b).

- The type of device, how it functions, and what to monitor.
- The manufacturer name and address with phone number.
- Model and serial number.
- Appropriate warnings for use.
- Identification of methods to prevent improper connections.

Figure 1
Typical Pretreatment System



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- Prominent warnings if the component contains germicides.

Flow schematics and diagrams should be displayed in the water treatment room and updated as necessary. Having directional arrows on the piping and clearly labeling valves will help keep things organized. CMS requires the operator to know the parameters of the different components. Listing these on the water treatment log sheet will facilitate this process and serve as a ready reference. Some parameters vary from facility to facility, and should be set based on the facility's unique situation and upon manufacturers' recommendations. Parameters that may vary in different systems include items such as pressure readings, flow readings, and conductivity measurements in various locations of the system.

Contingency Plan

A dialysis facility must develop a contingency plan as to what to do if the electrical or water supply to the facility is lost or if there is a failure of a critical component of the system (e.g., carbon tank, RO system, or circulation pump). The plan should also address sudden changes in incoming water quality (AAMI, 2011; CMS, 2008b).

Water Treatment System

The components of a water treatment system are discussed in the order that they are most likely to be placed in a dialysis water treatment system (see Figure 1). (***Note:*** When the word "shall" appears, it is taken from the AAMI standards in which "shall" means "must."

Feed Water Components

Back-flow preventer. All water treatment systems, including water systems for acute dialysis, require a form of back-flow prevention. A back-flow preventer prevents the water in the water treatment components from flowing back into the municipality's potable water lines. This protects drinking water from contamination with disinfectants and cleaners that are used in dialysis water treatment systems. Many other devices connected to the drinking water supply, such as large air conditioning units, require back-flow prevention to inhibit back-siphoning of potential contaminates, such as antifreeze and other toxins, into the potable water system.

Local codes dictate the type of back-flow preventer that can be used, and these vary from area to area. Some areas may require a break tank for water treatment systems used for acute dialysis. These use an air gap to separate the water supply from the system. Back-flow prevention devices should never be placed on the purified water loop piping because they can potentially contaminate the product water with bacteria, disinfectants, and metals. Back-flow prevention is only necessary at the very beginning of the system to prevent contamination of the city water by breaking the connection to the dialysis water system.

Discharge of spent water and dialysate in the acute care setting should be into an appropriate floor drain or standpipe connection. If these are not available, a sink may be used as long as there is an air gap to

prevent contaminated effluent from back-flowing into the dialysis machine, and the sink is not used for any other purpose during the treatment.

Monitoring of back flow preventers is accomplished by inspection after installation, and an annual inspection thereafter. Backflow preventers must be installed by a licensed plumber and inspected by a qualified inspector.

Temperature blending valve (Tempering Valve). The temperature blending valve mixes hot and cold water to achieve an RO membrane industry-standard temperature of around 77° F (25° C). These valves are widely used on large central RO systems in geographical areas that tend to have cold incoming water. The colder the source water, the lower volume of purified water the RO membranes will produce. For each 1° F temperature drop, the RO membrane produces 1.5% less purified water (each 1° C drop equals a 3% decrease in product water volume). For instance, an incoming temperature of 50° F would result in an approximate loss of 40% product water flow rate compared to the flow rate achieved with 77° F water.

An alternative plan when temperature blending is not practical, as in single patient portable RO machines, is to use larger or more RO membranes. The larger membrane surface area produces more permeate (product water). If blending hot and cold water together from a sink faucet for an acute dialysis treatment, a temperature gauge must be in place with an audible alarm because high temperatures can damage the RO membranes (though heat-tolerant RO membranes exist, most are sensitive to over-heating) and possibly harm the patient if the dialysis machine temperature alarm fails to place the dialysate flow in bypass.

Temperature blending valves shall be sized to accommodate the anticipated range of flow and shall be fitted with a means to prevent backflow into the hot or cold water lines. A temperature gauge is normally in place after the temperature blending valve and the reading is recorded daily.

Monitoring of tempering valves is accomplished by observing the blended water temperature. This temperature should be documented on the daily RO log sheet, and trends should be monitored. A temperature that fluctuates from day to day could indicate an eminent failure of the temperature blending valve, which could be replaced proactively.

Booster pump. The entire RO system requires a constant supply of water flow and pressure to operate successfully. Dialysis facilities experience fluctuating or decreased incoming water pressure and flow, especially since back-flow preventers and temperature blending valves substantially lower the pressure of the feed water. In order to compensate, a booster pump may be placed after these devices. Booster pumps should be preceded and followed by pressure gauges that are read daily and the readings recorded.

Monitoring the booster pump is accomplished by observing the water pressure. In many systems, the (low) pressure should be recorded when the pump turns on, and the (higher) pressure when the pump turns off.

Pretreatment Components

Chemical injection systems. In order for the RO to operate properly and for the carbon tanks to remove chlorine/chloramine effectively, the ideal incoming water pH should be 5.0 to 8.5. In many areas of the country, the pH is higher than 8.5, so a chemical injection system to lower the pH may be incorporated into the design of the pretreatment system, especially in the presence of chloramine. A pH higher than 8.5 with chloramines present will cause the carbon to be less *adsorptive* (a chemical process) and the RO membrane performance to degrade, resulting in poor water quality (Leuhmann, Keshaviah, Ward, Klein, & Thomas, 1989). To reduce the pH, chemical injection systems meter a small amount of a strong mineral acid, such as muriatic acid, also known as hydrochloric acid (HCl), or sulfuric acid into the feed water system. The use of organic acids, such as acetic acid, is not recommended because they are nutrient rich and can encourage the growth of bacteria in the pretreatment and RO system.

Chemical injection systems may also be used to reduce chloramines in the incoming water when the usually sufficient carbon tanks alone are not adequate to do the job. Sodium bisulfite and ascorbic acid are two chemicals that may be injected into the water treatment system to aid in the reduction of chloramines (AAMI, 2009a).

All chemicals shall be shown to be compatible with all components of the water treatment system and in all operation modes. For instance, if the system were to go into emergency back-up and use deionization for its primary filtration, the additives should not create a toxic chemical when combined with the deionization resin. A means to verify that the reduction of the chemical additive and its byproducts are decreased to a safe level before the product water is used for patients shall also be employed, or there should be evidence that the chemicals in use do not cross into the bloodstream during dialysis (i.e., they are not dialyzable).

Chemical injection systems dispensing acid should be placed before the sediment filter because the lower pH will cause dissolved metals, such as aluminum, and some salts in the feed water to precipitate. The sediment filter can then filter out most of the solidified particles.

Chemical injection devices consist of a reservoir that contains the chemical to be injected, a metering pump, and a mixing chamber. These devices are located in the incoming water line. The device should be able to tightly control the addition of chemicals and have a control system that allows chemical to be injected in proportion to the water flow through the pretreatment tanks, or a pH monitor that automatically adjusts the injection of chemicals.

Monitoring of the chemical injection pump is accomplished by moni-

toring the pH of the water. If an automated injection system is used, the pH should be continuously monitored (AAMI, 2011). All material safety data sheets (MSDS) and Occupational Safety and Health Administration (OSHA) requirements must be followed for the safe handling of chemicals used.

Sediment filters. Large particulates of 10 microns or greater that cause the supply water to be turbid – such as dirt, silt, and colloidal matter (suspended particles) – may be removed by sediment filtration. Such foulants can clog the carbon and softener tanks, destroy the RO pump, and foul the RO membranes. Unfortunately, not all suspended materials are removed by sediment filters, and these materials can coat the surfaces of the softener and carbon media, rendering these components useless.

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

Sediment filters are typically placed at the beginning of the pretreatment cascade (series of components) and can be cartridge type filters, single media filters, or multimedia filters. Multimedia filters contain layers of various-sized media ranging from gravel to sand that physically trap the large particles as the water is filtered downward through the tank. Each tier is composed of a different-sized media so that not all the particulates are collected at the top, but rather, distributed through the media bed. By using a stratified bed, increasingly smaller particles are captured, the entire bed is used, and the filter is not rapidly clogged.

An automatic multimedia filter is backwashed on a preset time schedule (when the system is not in use) so that the media is cleansed and redistributed regularly. By redirecting the water flow from the bottom of the tank upward (backwashing), the tightly packed bed is lifted so that the lighter material floats to the top and out to drain. The media, chosen for its size and density, then resettles in its ordered layers when the process is complete. Multimedia filters should be backwashed routinely – how often depends on the amount of particulates in the supply water and the pressure drop through the tank.

Monitoring of the sediment filters is accomplished by measuring the water pressure. Pressure gauges on the inlet and outlet of the tank monitor pressure changes (delta pressure) and are read and recorded at least daily to monitor clogging of the filter bed. When the readings of the gauges before the filter display a difference of a predetermined value (e.g., 10 PSI or greater) from the reading of the gauge after the filter, it is time to backwash (multimedia type) or replace the filter (cartridge type). Multimedia filters tend to work better when they are a little dirty. Further, the timer on the head of the multi-media tank should be visible and the time of day reading recorded daily. When comparing the time on the display with the actual time, they should be the same unless there is a posted notice that the time is off-set to allow sequential backwashing of multiple components. Situations such as power failures can result in backwashing occurring during patient treatment. No patient harm would occur, but the patients' treatments would be delayed because backwashing would prevent water flow to the RO.

Water softener. Hard water containing calcium and magnesium forms scale or mineral deposits on the

Figure 2
Water Softener

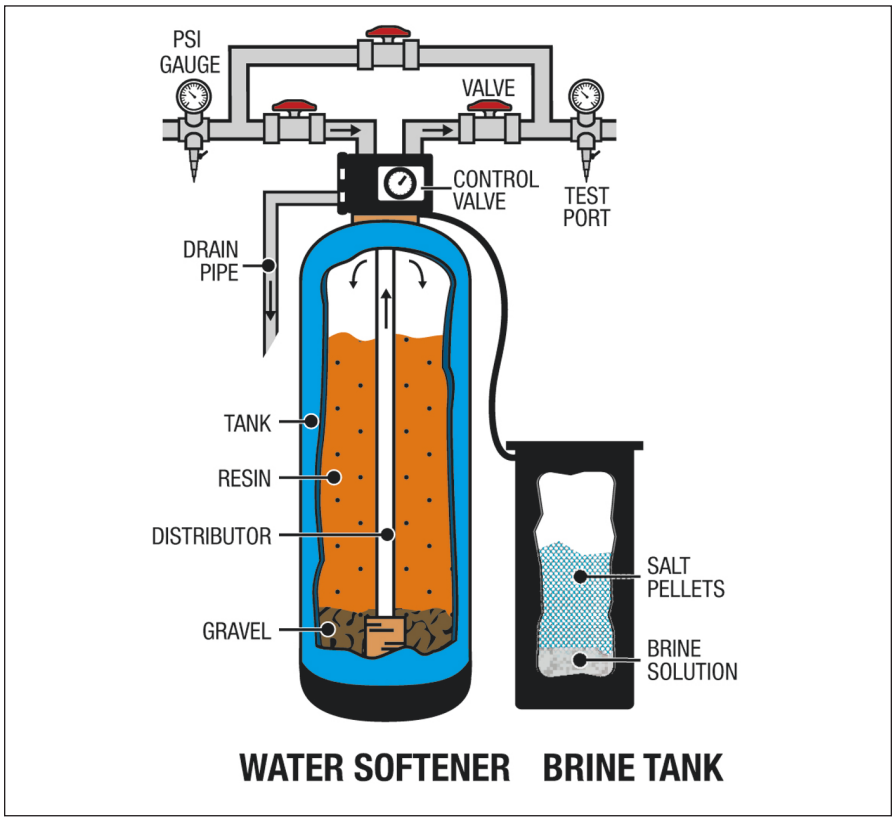

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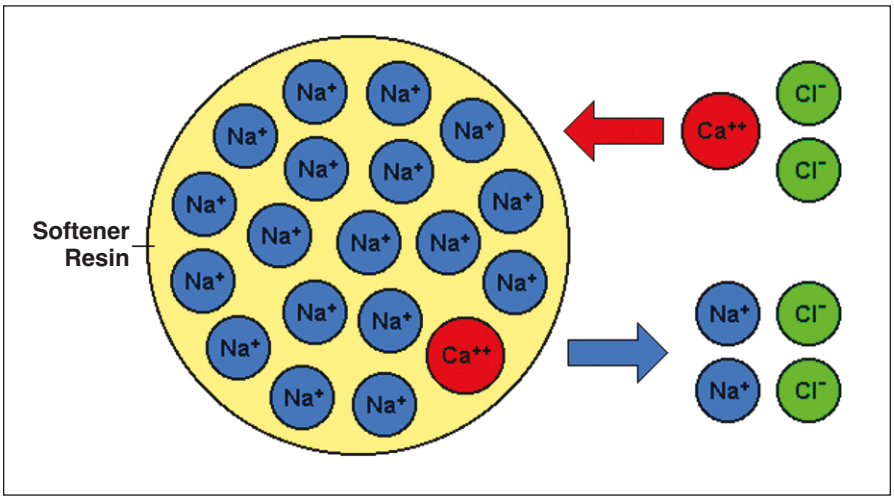
Figure 3
Softener Ion Exchange



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RO membranes and eventually fouls the membranes. Once mineral deposits form on the RO membrane surface, the membrane performance and product water quality will decline. Mineral scale can become permanent and decrease the life expectancy of the RO membranes if not cleaned. Some source waters can foul RO membranes within hours if a softener is not used, turning the membranes literally to stone. A softener is placed before the RO unit to protect the RO membrane life and before deionization (DI) in order to extend the life of the DI (see Figure 2).

Softeners turn hard water into "soft" water by removing the hardness and exchanging it for sodium (see Figure 3). The resin beads within the tank have a high affinity for the cations calcium and magnesium (both divalent bonds) that are present in the source water. The resin beads release two sodium ions (monovalent bond) for every one calcium or magnesium captured. Sodium chloride does not deposit scale on the RO membranes and is rejected by the RO quite readily to the drain.

Hardness is measured in grains per gallon (grain literally meaning that the white precipitate left from evaporated water is the size of a grain of wheat) or mg/L. To a lesser degree, softeners will also remove other polyvalent cations, such as iron and manganese.

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

The softener can be placed before or after the carbon tanks. If the softener is placed before the carbon tanks, decreased softener resin life may occur if the resin is exposed to detrimental levels of chlorine or chloramines in the incoming water. If the softener is placed after the carbon tanks, the water processed by the softener will not contain chlorine/chloramines, which can allow microbial growth within the softener, increasing the bacterial bioburden within the softener and downstream to the RO membrane. Even in the harsh environment of a softener, halophyllic (salt-loving) bacteria can thrive.

The softener needs regenerating on a routine basis with concentrated sodium chloride solution (brine) before the resin capacity is exhausted. Further, similar to multimedia filters during normal operation, the water flows downward through the resin and can tightly pack the resin. Before the regeneration process, the resin is backwashed to loosen the media and rinse away any particulates. After the backwashing step, the brine solution is drawn into the tank to regenerate the resin. The calcium and magnesium are forced off the resin bead sites, even though they possess a stronger bond than sodium, because they are overwhelmed by the amount of sodium ions. Next, the excess salt solution is rinsed out of the tank.

Regeneration is usually performed every day or every other day that the softener is used at a time when the water treatment system is not in use. Since high water flow and pressure are required for backwashing, generally one pretreatment tank is backwashed at a time. Most dialysis facilities use a permanent softener that incorporates a brine tank and control head to execute the automatic regeneration cycle. Automatically regenerated softeners shall be fitted with a regeneration lock-out device to prevent the regeneration process from occurring during patient treatments, averting the possibility of highly concentrated sodium levels being transported to the patients (AAMI, 2011).

Portable exchange softeners (softeners that are regenerated off-site) are sometimes used in areas that regulate the amount of sodium chloride discharged to drain. In this case, the softener tank will be replaced on a routine basis and will not have a control head or brine tank. This type may also be used on single-patient portable RO systems in acute dialysis settings for quick turn-around and ease. If portable exchange softeners are used, the water treatment vendor is expected to ensure that the tank shall be disinfected and rinsed before it is filled with the regenerated resin, and care shall be taken to keep nonpotable water resins and potable or medical resins separated during processing (AAMI, 2009a).

Monitoring of water softeners is accomplished by testing water hardness post-softener. A hardness test using an ethylenediaminetetracetic acid (EDTA) titration test, or dip and read test strips on the effluent softened water, should be done at least once at the end of the day and recorded (AAMI, 2011). Testing at the end of the day demonstrates that the softener performed adequately all day in removing hardness. While doing an additional test at the beginning of the day is optional, this test would determine whether the softener was regenerated adequately during the night. Hardness test results should be less than 1 grain per gallon (gpg) hardness (less than 17.5 mg/L) and performed on water just processed, not water that has been in the tank all night. Start the water treatment system approximately 15 minutes prior to drawing the sample. A shorter interval is acceptable for the smaller portable systems. If the hardness test reads above 1 gpg, the softener may need regenerating before use. Check the timer in the control head to see that it displays the correct time, and read and record the pressure from the gauges pre- and post-softener daily to assure the softener is not clogged. It is required that the face of the timer be visible to the user (CMS, 2008b).

Brine tank. The brine tank contains the salt pellets and water to create the super-saturated salt solution (brine) used for softener regeneration. Fifteen pounds of salt are required to regenerate 1 cubic foot of resin (30,000 grain capacity). Only refined pellet-shaped salt should be used. Salt designated as rock salt may contain too many impurities, such as dirt, that may damage or clog the brine tank and softener control head (AAMI, 2011).

Monitoring of the brine tank is accomplished by visual inspection. The salt level in the brine tank should be inspected daily, and the tank should be at least half-full with salt. Ascertain that a "salt bridge" has not formed by tapping on the top of the salt in the tank. If a salt bridge has formed, the salt will not dissolve into solution, and when tapped, it will break and fall into the tank. When a salt bridge forms, the softener will not regenerate to full capacity and would not function for the expected duration of time. Record the level of salt in the tank daily.

Anion exchange resin tanks or organic scavenger tanks remove organic material from the source water that would mask the adsorption sites of the carbon media. Organic scavenger tanks can increase the life of the carbon tank when placed before the carbon tanks. A test on the supply water for high levels of tannins (a plant chemical from decomposing leaves), lignines (a complex polymer in plant cell walls and wood), and total organic or oxidizable carbon (TOC) will determine whether an organic scavenger is necessary in a system. Seasonal changes will affect levels of TOC, lignines, and tannin in the source water.

Anion exchange tanks work on a similar basis as softeners, but instead of exchanging sodium, a cation, they swap chloride, an anion, for organic matter. Once an anion exchange tank is exhausted, it needs to be regenerated. An inline TOC monitor can detect when organic chemicals are breaking through, or a water sample can be sent to a laboratory for analysis. The most cost-effective plan is to regenerate the tank routinely according to the manufacturer's recommended schedule and based on your source water because AAMI does not have a standard for these organic compounds. Be mindful that if the tank does exhaust, the trapped organics will be released and could mask the carbon resin, causing it not to work. If the tank is equipped with a backwashing mechanism, it should be equipped with a visible timer and in and out pressure gauges that should be read and recorded daily. The back-flushing cycle will remove sediment, but it will not regenerate the anion exchange media.

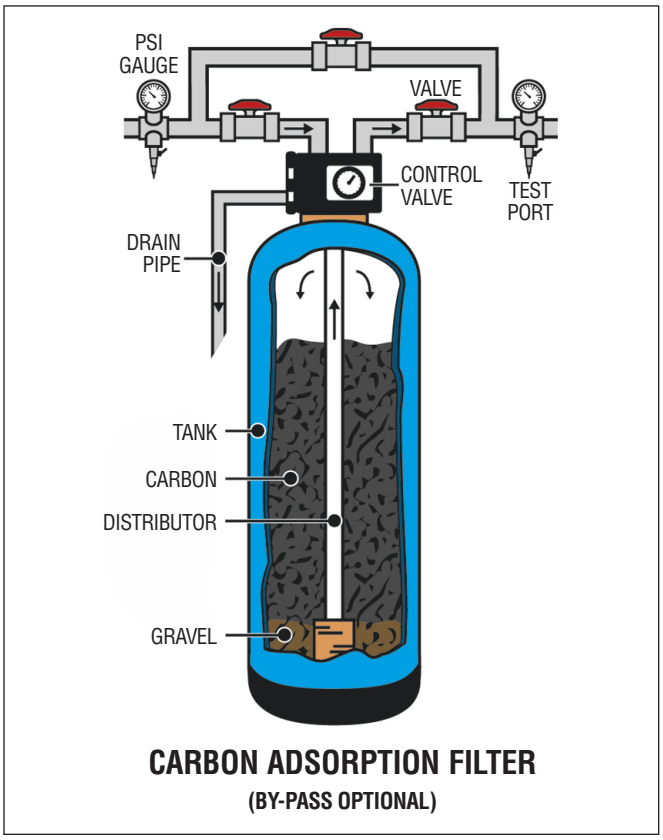
If portable anion exchange tanks are used, the same requirements apply as were mentioned for exchange tanks for softeners: the tanks shall be disinfected and rinsed before refilling, and a separate process for resins used for bio-medical purposes must be demonstrated at the facility (AAMI, 2009a).

Carbon adsorption. Chlorine and chloramines are added to the city water supply to disinfect the potable water and reduce the risk of bacterial contamination in the city water distribution system. A third chemical, chlorine dioxide, is gaining popularity as a pre-disinfectant for raw water and is removed before the post-disinfection process at the municipality. Some municipal water treatment plants also use ozonation systems for disinfection purposes. Chlorine dioxide and ozonation do not eliminate the use of disinfectants in the water distributed to customers, but they aid in reducing the amount of disinfectant needed. You should be aware of what additives and techniques your water supplier employs.

These additives allow us to drink water with minimal risk of becoming ill from a parasite or pathogenic bacteria. However, there are some drawbacks to the disinfectants themselves. For instance, chlorine can combine with other organic chemicals to form trihalomethanes, a known carcinogen. For this reason, chloramines, a combined chlorine that cannot combine with other chemicals, has become a major disinfectant of drinking water. But as compared to chlorine, a longer contact time is required for chloramine to be adsorbed. Since the initiation of chloramine use, there have been more reported incidents of hemolysis and related symptoms in patients on HD due to chloramine exposure when compared to similar reported instances with chlorine, though chlorine is also harmful to patients on HD (Ackerman, 1988; FDA, 1988; Leuhmann et al., 1989).

In addition to the serious risks exposure to chlorine or chloramines present to patients, neither chlorine nor chloramines are effectively removed by RO and actually damage the thin film-type RO membranes. Therefore, chlorine and chloramines must be removed from the water before the water enters the RO system. Further, chloramines must be

Figure 4
Carbon Filters



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removed before DI because there is a possibility that carcinogenic nitrosamines may develop if non-carbon filtered water enters the DI bed (Kirkwood, Dunn, Thomasson, & Simenhoff, 1981).

Carbon filtration will remove chlorine and chloramines that are almost always present in the source water by means of adsorption. As the input water flows down through the granular activated carbon (GAC), solutes diffuse from the water into the pores of the carbon and become attached to the structure (see Figure 4). In addition, a wide variety of naturally occurring and synthetic organic compounds, such as herbicides, pesticides, and industrial solvents, will be adsorbed as well (Leuhmann et al., 1989).

GAC is a type of carbon that is appropriate for HD and can be made of many different organic materials, such as bituminous coal, coconut shells, peach pits, wood, bone, and lignite, that have been exposed to excessive temperatures without oxygen to keep it from burning. GAC is then acid washed to remove the ash and etch the carbon to increase the porosity and thereby the adsorbency of the GAC. GAC used for dialysis should be acid washed, especially carbon derived from bone, wood, or coal because these types tend to leach metals, such as aluminum, when they are not acid washed and are then exposed to water. Non-acid washed carbon may be used but should be rinsed thoroughly (AAMI, 2011).

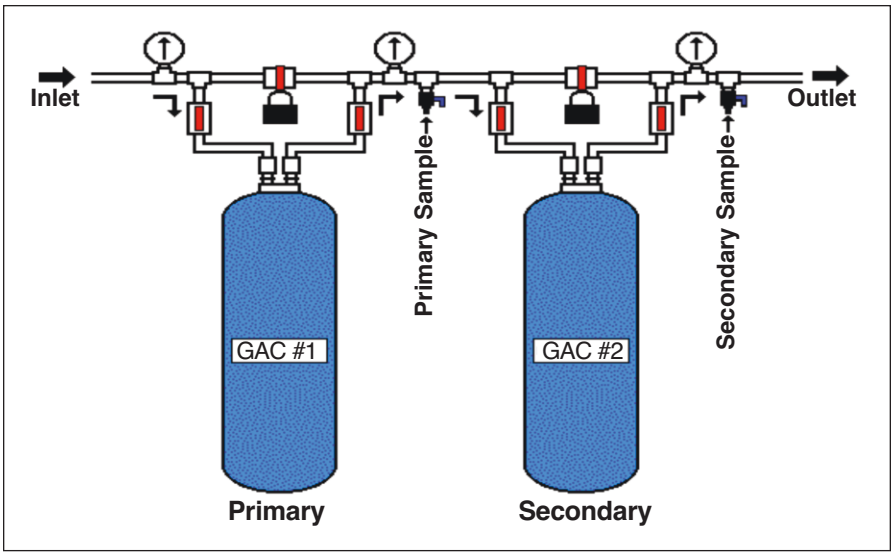
GAC is rated in terms of an "iodine number," which measures the ability of the GAC to adsorb low molecular weight, small organic substances, such as iodine and subsequently, chlorine and chloramines. The higher the iodine number, the more chlorine and chloramines will be adsorbed. It would be ideal to have a total chlorine number rating for carbon, but it is not the practice. An iodine number of 900 or greater is considered optimal for chlorine and chloramines removal (AAMI, 2009a).

Though not a regulation, another rating to consider with GAC is the abrasion number. The higher the abrasion number is, the more durable the carbon is. This is important because frequent backwashing associated with carbon tanks can be wearing on the carbon.

Regenerated carbon that is reburnt and reused by the manufacturer shall not be used for dialysis; only virgin carbon may be used (AAMI, 2009a). Carbon adsorption is used in many more toxic applications than dialysis, and when regenerated, the carbon can retain impurities that may be toxic to patients. It is recommended that GAC has a mesh size of 12 x 40 or *smaller* to provide a large surface area, but not too small, or the smaller particles will compact and flow will be impeded through the bed (Leuhmann et al., 1989). New carbon must be rinsed by flushing water thoroughly through the tank to remove the ash and carbon fines (small pieces of carbon), or these will damage the RO pump and membrane.

At least two carbon beds shall be used in a series configuration (where the effluent of the first tank feeds the next tank) and shall have a sample port after the first tank, and preferably, one after the second tank. Sometimes tanks are arranged as a series-connected pair (the water stream is split and feeds into two or more parallel sets of carbon tanks) so that the tanks are not so large (see Figure 5). In either set-up, each tank or group of tanks shall provide 5 minutes empty bed contact time (EBCT) for a total of 10 minutes EBCT at the maximum anticipated flow rate, and the water flow through the tanks should be equal. A 5-minute exposure time of the water through each

Figure 5
Paired Carbon Filters



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tank or set of the carbon tanks is required for the total chlorine in the water leaving the tank to be reduced to less than 0.1 mg/L (AAMI, 2009b), with the second tank (or set of tanks) providing an equal level of redundancy. The contact time can be calculated using the input flow rate (Q) in gallons per minute (gpm) and the volume of carbon media in cu. ft. (V). Use the following formula to calculate EBCT (AAMI, 2011):

$$EBCT = (V/Q) \times 7.48$$

where V = volume of carbon and Q = flow rate in gallons per minute

Portable single-patient systems in the acute or home care setting can meet the requirement to reduce the chlorine level to below 0.1 mg/L with less than a 10-minute EBCT. This is most often accomplished by incorporating the use of carbon block technology. Solid block activated carbon (SBAC) is a densely compacted block of GAC powder that has a large surface area in a compact size. A system may incorporate a GAC tank and a carbon block as the polisher, or may use two SBACs in a series. The manufacturer is required to show the block carbon technology is capable of achieving the required chlorine reduction.

GAC has a finite capacity, and there is a point at which its adsorption capacity is exhausted. The ability for the carbon to remove chlorine and chloramines may be reduced when other substances mask the reactive sites or when the pH of the water increases or the temperature decreases. Due to all these variables, it is impossible to predict when the carbon may exhaust, so frequent testing is mandatory. The chlorine/chloramines level should be checked before every patient shift. If there is not a definite patient shift, the chlorine/chloramines test should be done every 4 hours (CMS, 2008b).

Carbon tank monitoring is accomplished by testing the chlorine level as it leaves the first or "worker" tank. The N, N-diethyl-p-phenylenediamine (DPD)-based test kits (e.g., Hach™ digital tester) or equivalent (dip and read test strips) are recommended. Alternatively, an on-line monitor may be used for automated testing. Proper quality control procedures, such as testing meters or strips against known standards, is important with any method chosen.

In the 2001 AAMI RD62 standard, the maximum allowable contamination levels for chlorine were 0.5 mg/L for free chlorine and 0.1 mg/L for chloramines (AAMI, 2001). In the new standard, the maximum level is simply 0.1 mg/L for total chlorine. Use of this lower level assures that the chloramines level is within the limit (AAMI, 2011). This level is readily achievable with most dialysis facility water systems, and many facilities have already implemented the use of a single test because it is simpler and was an acceptable alternative in AAMI RD62.

If the total chlorine level after the first tank (or group of tanks) rises to 0.1 mg/L or above (a positive test result), total chlorine must be checked after the second tank (or tanks). As long as the test is negative after the second tank, dialysis treatments may resume as long as arrangements have been made to change out the first tank(s) within a 72-hour period, and more frequent total chlorine testing is initiated (e.g., test every half hour to 1 hour) (CMS, 2008b). If the test result after the second carbon tank or set of tanks becomes positive, all treatments must promptly cease to protect patients from harm.

When replacing the carbon, whenever practical, the used second carbon tank may be placed in the first position, and the new tank put in the second spot. If it is not possible to switch the position of the tanks, both tanks should be replaced. Bypass valves placed on the piping to the carbon tanks that allow the feed water to completely bypass all the carbon tanks are unsafe and not recommended. If there are any bypass valves present, they should be labeled with warnings and locked in the open position (e.g., via zip or cinch plastic tie) so they cannot be accidentally repositioned.

Inherent problems with carbon tanks are channeling (when water follows the same path through the tank because water tends to flow in the path of least resistance), compaction forming smaller carbon fines, and biological fouling because carbon is an organic medium. These phenomena cause

the carbon surface area to be underutilized. Therefore, carbon tanks are backwashed on a routine basis to "fluff" the bed, clean the debris out, and expose unused binding sites of the carbon. Backwashing does ***not*** regenerate the carbon. When the carbon adsorption sites are exhausted, the carbon must be replaced. Cartridge or exchange carbon tanks may be used. These are not back-washable and need to be replaced on a more frequent basis. In all cases, the emptied tank shall be disinfected and rinsed before repacking with new GAC.

Monitoring the carbon tanks also includes documenting pre- and post-tank pressures, and checking the clock on the backwash timer for the correct time so the timer does not begin a backwash cycle while treatments are occurring. Document when the carbon tanks have been exchanged or re-bedded, and include the grade of carbon used and the length of time the new carbon is rinsed before use (if not rinsed thoroughly, the residue will harm the RO membranes).

Reverse Osmosis Systems

Cartridge prefilter. Prefilters are positioned after all the pre-treatment components and immediately before the RO pump and membranes to capture particulates. Carbon fines, resin beads, and other debris exiting the pretreatment components can destroy the pump and foul the RO membranes. Typically, prefilters range in pore size from 1 to 5 microns. Gauges monitor the filter inlet and outlet pressures. If the delta pressure increases by approximately 8 or greater over the *new* filter pressure differential, the filter is clogged and needs replacement. Prefilters are inexpensive insurance against damaging more expensive items downstream in the system. Therefore, changing them on a routine basis before the delta pressure indicates the need for such change is a good practice. When removing the old filter, inspect the filter's center tube for soiling. If dirt is present, the filter was overburdened and should have been replaced sooner. The housing of the prefilter shall be opaque to deter algae growth (AAMI, 2009a). Read and record pre- and post-filter pressures and the delta pressure daily.

Figure 6
Basic Reverse Osmosis Element

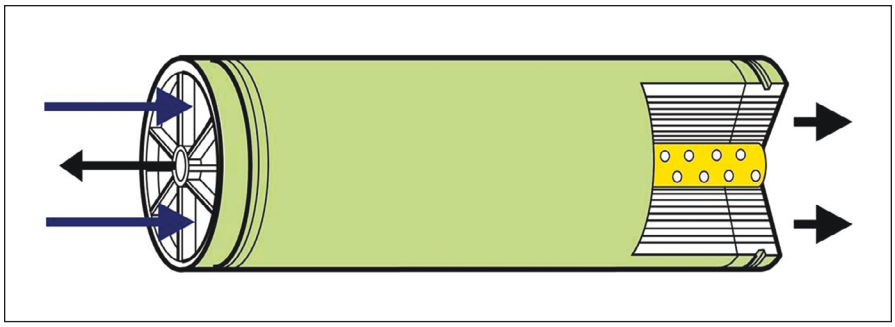

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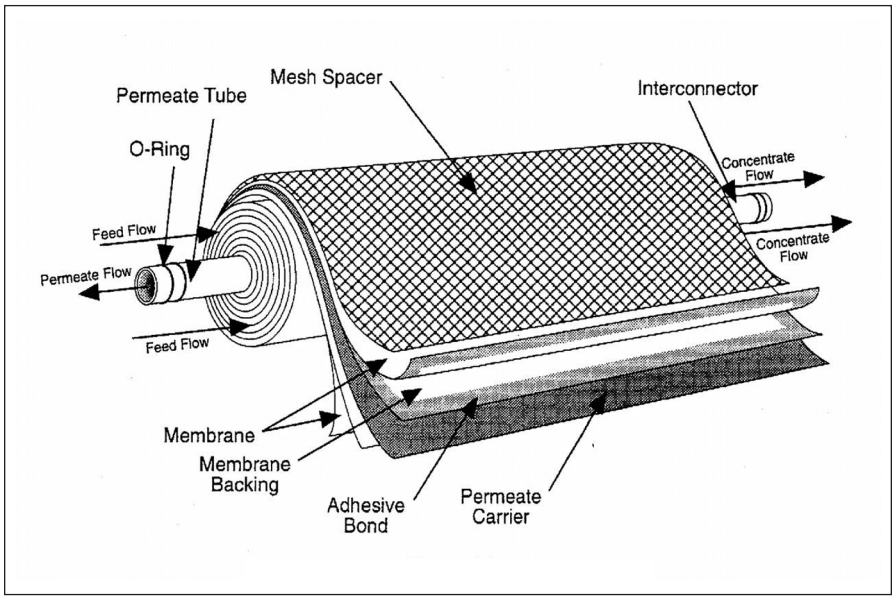
Figure 7
Reverse Osmosis Membrane



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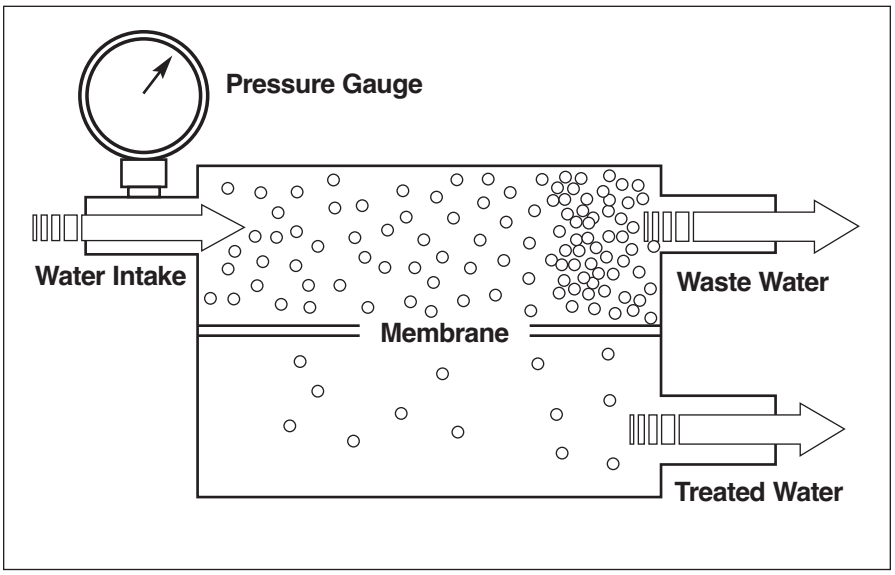
RO pump and motor assembly. The RO pump (the noisy thing you hear in the RO room) increases water pressure across the RO membranes to make pure water. RO systems typically operate between 200 to 250 PSI (pounds per square inch).

It is imperative that RO pumps are made of high-grade stainless steel, inert plastics, or carbon graphite-wetted parts. Brass, aluminum, copper, and other metals will leach contaminants into the water and are not compatible with peracetic acid-type disinfectants. Operating RO pumps dry will cause irreparable damage. Monitor the inlet and discharge pressures continuously and record daily.

RO membranes. The RO membrane is the heart of the system. These membranes produce the purified water through RO (see Figures 6 and 7). RO is just that, the opposite of osmosis. Osmosis is a naturally occur-

Figure 8
Reverse Osmosis



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ring phenomenon involving the flow of water from a less-concentrated compartment (e.g., non-salty side) to the more concentrated compartment (e.g., salty side) through a semi-permeable membrane until solute equilibrium is obtained. In reverse osmosis, water (feed or supply water) is forced to flow in the opposite or unnatural direction across a semi-permeable membrane to the compartment with less concentration of solutes by means of high hydraulic pressure (see Figure 8). Natural osmotic flow is reversed, and pure water passes through the membrane, leaving the dissolved solids (salts, metals, etc.) and other solutes behind on the concentrated (or waste) side. In an RO system, hydraulic pressure overpowers the osmotic pressure. Dependent upon how much product water is needed, the RO system will have one or more membranes.

RO membranes are the tightest membrane used in dialysis – they have pores that are much smaller than those in a dialyzer membrane. RO membranes reject dissolved inorganic elements to the drain, such as ions of metals, salts, chemicals, and organics, including bacteria, endotoxin, and viruses. Rejection of charged ionic particles ranges from approximately 95% to 99%, whereas contaminants, such as organics that have no charge, are sieved out if they are larger than 200 molecular weight. Ionic contaminants are highly rejected compared to neutrally charged particles, and polyvalent ions are more readily rejected than monovalent ions. pH of the incoming water and damage to the membranes will change the function of the RO and its rejection characteristics.

Thin film (TF) RO membranes made of polyamide (PA) are the most common type used in HD. These membranes are made with a thin, dense, semi-permeable membrane over a thick porous substructure for strength and are spiral-wound around a permeate collecting tube. The spiral design allows a large surface area to be created in a small space. The incoming water stream will split into two streams – one of purified water that crosses the membrane and the other a waste stream used to carry rejected solutes to the drain. This is known as cross flow filtration.

TF RO membranes will degrade when exposed to oxidants such as chlorine/chloramines, and therefore, must be preceded by carbon adsorption. Bleach cannot be used to sanitize TF RO membranes. Care must be taken with the use of peracetic acid products for disinfection because they will oxidize the RO membrane if used above a 1% dilution, if left in contact with the membrane longer than 11 hours, or if iron deposits and other metals are present on (or within) the RO membrane. Other factors that can influence RO membrane performance and water quality include incoming water temperature and pH, adequate pretreatment, and cleanliness of the RO membrane surface.

TF membranes have a wide pH tolerance of 2 to 11; however, the optimum pH range for membrane functioning is 5.0 to 8.5. High alkalinity also enhances scaling of the RO membrane surface (deposition of substances on the membrane), which reduces the available surface area.

RO membrane performance is measured by percent rejection. Final product water quality is measured by conductivity and displayed as either micro-Siemens/cm or total dissolved solids (TDS). TDS is sometimes displayed as mg/L and sometimes as parts per million (PPM), which are equivalent terms because there are 1 million milligrams in a liter. TDS monitors are actually just conductivity monitors with a conversion factor built-in – most often TDS is equal to micro-Siemens/cm multiplied by ~0.65 (different meters use different conversion factors). Either percent rejection or permeate water quality monitors shall be used and continuously displayed, and should have audible and visual alarms when quality set points are exceeded. When an RO is the final treatment component, the audible alarm shall be heard in the patient care area. To prevent potential patient harm, if a predetermined set point is violated, the water for use should divert to drain. Small portable RO systems are exempt from the divert-to-drain standard because one-to-one monitoring usual-

ly exists. If the quality of water produced by a portable system falls below the set quality limit, the treatment should be discontinued and the physician notified (AAMI, 2011).

Percent rejection alone only measures membrane performance. For example, if the source water is relatively pure, containing 100 PPM dissolved solids (metals, salts, etc.), and the percent of those dissolved solids that are rejected to waste equals 95%, the final water quality would display 5 TDS mg/L or PPM. However, if the source water had as much as 1000 PPM, and the percent rejection continued to be 95%, the final water quality would then be 50 PPM. In each scenario, the percent rejection is the same 95%, but the final water quality is significantly different. An AAMI chemical analysis is the only direct way to measure the quality of the water because the rejection rate and TDS do not specify which contaminants are left. If the water quality falls below the preset quality limits, the medical director shall be notified to determine whether to continue treatments (CMS 2008a). However, "the use of water outside of AAMI standards should be extremely rare, considered only when no other option is available to provide desperately needed dialysis, and limited to one treatment per patient" (CMS, 2008b).

AAMI has determined the maximum allowable levels of contaminants that can safely be in the water for HD without causing harm (see Table 2). Usually, RO systems can produce water that meets the AAMI standards if the source water is drinking water that meets EPA guidelines. A double-pass or two-stage RO, in which product water from one RO is fed into a second RO, is sometimes used for extra purification. Deionization may also be used to polish RO water when the product water from the RO does not meet the quality standard.

RO systems, pumps, dialysis machines, and other equipment each require a minimum flow rate and pressure to operate properly without damage. RO system pressure gauges typically measure the inlet water supply, pump, reject water (or waste), and product water pressures, which are displayed as pounds per square inch (PSI) or in actual gallons per minute (GPM) using flow monitors. Percent recovery (not to be confused with percent rejection) of a large RO system is generally set between 50% to 75%, meaning that if the RO has a GPM flow of 8 and a 50% recovery, half (or 4 gallons) of the incoming water will be made into product water, and the other half (or 4 gallons) will go to drain or be recycled back into the feed water line. With 75% recovery, 75% of the water entering the RO would be made into product water, and 25% would go to drain or recycle. Many RO systems will recycle some of the reject stream to increase the flow into the RO and to conserve water (waste recycle). Most RO distribution systems will return the unused purified product water back to the system to decrease water wastage.

Scale deposits, such as calcium and magnesium salts, silt, metals, organics, and dirt, will accumulate on and eventually foul the exterior surface of the RO membrane. Routine cleaning, usually quarterly, will strip off the scale and silt build-up. High pH cleaners will remove the silt and dirt slime layer, and low pH cleaners strip the mineral scale and metal build-up.

Disinfection regimens vary widely, but at least once a month is required for the system (AAMI, 2011). It is also important to disinfect the often-forgotten incoming water line to the dialysis machine (Amato, 1995; Bland & Favero, 1989). Weekly disinfection of the storage tank and distribution loop is a good idea with storage tank systems. For portable RO systems, weekly disinfection should be performed, or whenever there is more than 48 hours of downtime (Amato, 1995). A method to prevent disinfectant from being delivered to the patients (e.g., disinfection lock-out) shall be provided by the manufacturer (AAMI, 2009a).

All gauges and flow meters should be maintained within manufacturer's specifications, and readings should be recorded daily. Water quality (conductivity or TDS) should be within the limits defined for the facility, checked against an independent device routinely, and recorded at least daily. Percent rejection should be above 90% and documented daily. While it is true for all measurements on a water treatment system, it is especially important to include the expected parameters for water quality on the log sheet. Trend analysis is vital for monitoring water treatment systems. Monitoring trends allows the user to be more proactive and to see a problem arising, rather than "putting out fires."

Post-Treatment Components

Deionization. DI is sometimes required to polish the water when RO alone cannot reduce the contaminants to levels within AAMI standards. Facilities may use DI as an emergency back-up to the RO and have the tanks off-line or in a "dry" stage ready for deployment as needed. As an alternative, there may be a contingency plan with a DI vendor to deliver the tanks quickly in case of an emergency. There is also an individual home HD treatment system with a disposable water treatment system that uses DI as the primary water treatment component (NxStage Medical, Inc., 2006).

DI tanks contain resin beads that remove both cations and anions from the water in exchange for hydroxyl (OH^-) and hydrogen (H^+) ions. The ions released combine to form pure water (H_2O) (see Figure 9). Particles without an electrical charge are not removed by DI as they are with RO, so non-ionized substances, such as bacteria and endotoxin, will not be removed. In fact, the DI resin provides a conducive environment for microbial growth. Because of the potential for bacterial contamination, DI shall be followed by an ultrafilter (UF) so that the downstream components are not contaminated and patient safety is not compromised (AAMI, 2009a).

DI resins retain all the ions accumulated until the resins reach an exhaustion point. Before this occurs, the DI tank must be exchanged for a

Figure 9

Figure 9a
Deionization (DI) Ion Exchange Process

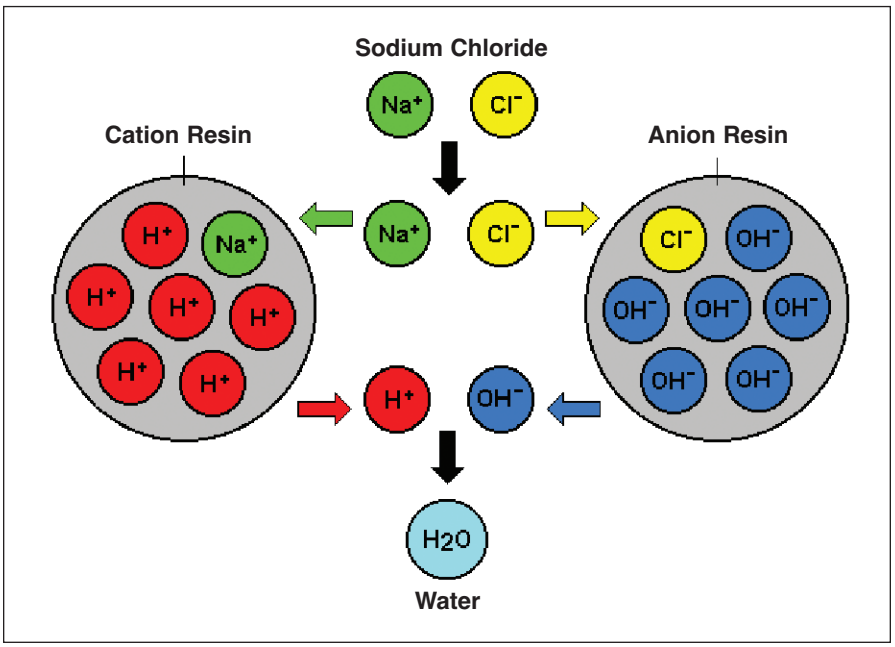

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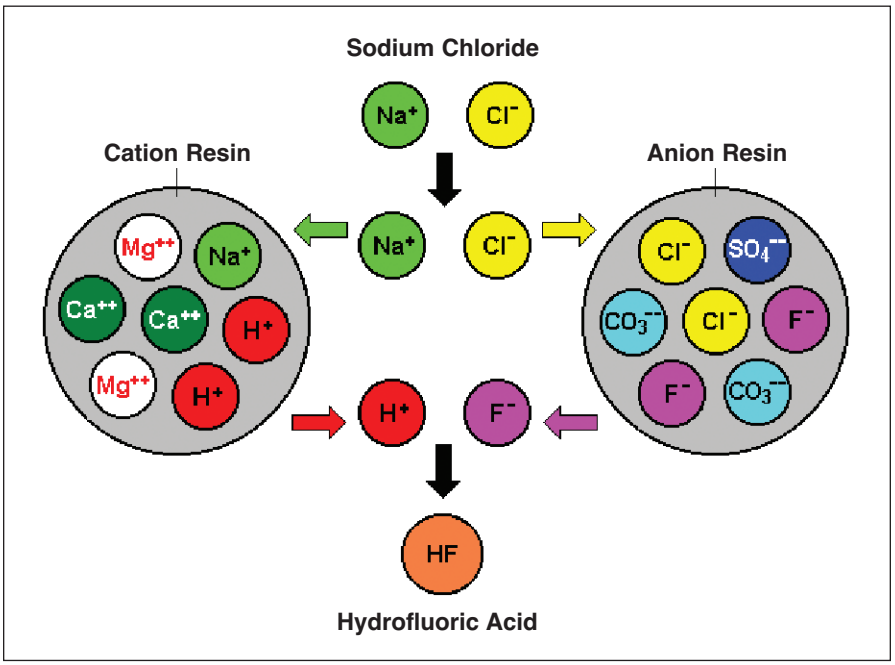
Figure 9b
Deionization (DI) Ion Exchange – DI Exhausted



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new one. If a DI is used past its point of exhaustion (measured by less than 1 meg-ohm/cm resistivity, equal to a conductivity less than 1 microsiemen), the resins will release mass quantities of the more weakly attracted ions to accommodate ions with higher attraction. Weakly attracted ions, such as aluminum and fluoride, would be among the first "dumped." Patient injuries and deaths have been reported when DI is used past the point of exhaustion (Leuhmann et al., 1989).

DI tanks can be either dual-bed or mixed-bed varieties. The dual-bed types are tanks that contain either all cation- or all anion-attracting resin beads and require at least two tanks, one cation and one anion, in series to remove the unwanted ions from the water. Mixed-bed deionizers contain both cation- and anion-attracting resin beads in one tank, and produce a higher quality of water than dual beds. Dual beds may be used as long as they are followed by at least one mixed-bed DI tank. It is recommended that when DI is in place, two mixed beds are used in a series configuration so if the first tank exhausts, it can be taken off-line and the second one used for a short time, with constant monitoring, until the first DI is replaced (AAMI, 2009a).

DI has a finite capacity: 1 cu.ft. of DI resin equals 8,000 grains of exchange capability. When the bed is exhausted, the resin must be replaced with medical (or potable water) designated resins (AAMI, 2001; FDA, 1996; Leuhmann et al., 1989). DI is used for many industrial applications, such as in chrome plating factories, which can leave the resin full of toxins and heavy metals. These industrial resins could harm patients and should be regenerated separately from resins used for dialysis. Further, the emptied tanks should be disinfected at the time of regenerating to prevent pyrogenic episodes in patients.

Carbon filtration shall precede DI; otherwise, carcinogenic nitrosamines can develop when water that is not carbon filtered contacts the resin beads (AAMI, 2009a; Kirkwood et al., 1981; Leuhmann et al., 1989).

DI shall be monitored continuously with a temperature compensated audible and visual resistivity alarm that is able to be heard and seen in the patient care area. DI shall also have an automated divert-to-drain mechanism to prevent patient exposure to unsafe water (AAMI, 2009a). Since DI can exhaust and dump its retained ions, DI is not recommended for primary filtration (without RO) for the treatment of water for use with multiple patients. DI coupled with UF is unable to remove low molecular weight bacterial by-products, such as microcystins (toxins from blue-green algae), that can be deadly to patients. Whenever DI is used, two tanks need to be set up in a series configuration, one as the worker, one as the back-up.

Resistivity, which is the inverse of conductivity, must be monitored continuously and should read above 1 meg-ohm/cm and be recorded twice daily (AAMI, 2009a). Pre- and post-DI tank pressure readings should be read and recorded daily. DI tanks should be exchanged on a regular basis even if the resin is not exhausted due to the microbiological fouling potential. Bacteria and endotoxin levels post-DI and ultrafilter should be routinely monitored.

Ultraviolet (UV) irradiator. UV is a low-pressure mercury vapor lamp enclosed in a transparent quartz sleeve that emits a germicidal 254 nm wavelength, delivering a dose of radiant energy to control bacteria proliferation. The UV is able to penetrate the cell wall of the bacterium and alter the DNA to either kill it or render it unable to replicate.

It is possible for some species of bacteria to become resistant to the UV irradiation, which is more of an issue if bacteria are exposed to sublethal doses. Therefore, the irradiator shall be equipped with a calibrated ultraviolet intensity meter that delivers a minimum dose of radiant energy at 16 milliwatt-sec/cm^2 and activates a visual alarm that indicates the lamp needs to be replaced. If the UV is not equipped with an intensity meter, the dose of radiant energy delivered shall be at least 30 milliwatt-sec/cm^2. As the UV kills the bacteria, it may increase the level of endotoxin in the water as a result of the destruction of the gram-negative bacteria (endotoxin producing) cell wall where endotoxins harbor. To trap the endotoxin, UV should be followed by ultrafiltration (AAMI, 2009a).

UV irradiation may also be placed on the feed side of the water treatment system, after all of the pretreatment components (e.g., post-carbon tank) and before the RO. This will diminish the bacteria exiting from the tanks and reduce the bioburden to the RO membranes. An appropriately sized UV for the expected water flow and an easy-to-clean quartz sleeve would increase the effectiveness of the UV in this position.

Regular maintenance of the UV device includes replacing the lamp when the radiant output indicates, or at least annually (or every 8000 hours operation). Biofilm, a protective slime coating that bacteria secrete when they attach themselves to a surface, will decrease the effectiveness of UV. Routine cleaning of the quartz sleeve will remove the biofilm. Record the output of the radiant monitor daily, as well as the readings of any pressure gauges associated with the UV.

Endotoxin retentive, submicron, and ultrafilters (UF). A submicron filter reduces the level of bacteria in the final product water, whereas an ultrafilter or endotoxin retentive filter removes both bacteria and endotoxin (see Figure 10). Each is a membrane filter that can be a cross flow type with a feed stream, product stream, and reject stream (like RO membranes), or a dead-ended design with one stream.

It is recommended that any submicron, endotoxin retentive filters, and ultrafilters used in water treatment systems be validated for med-

Figure 10
Endotoxin Filter

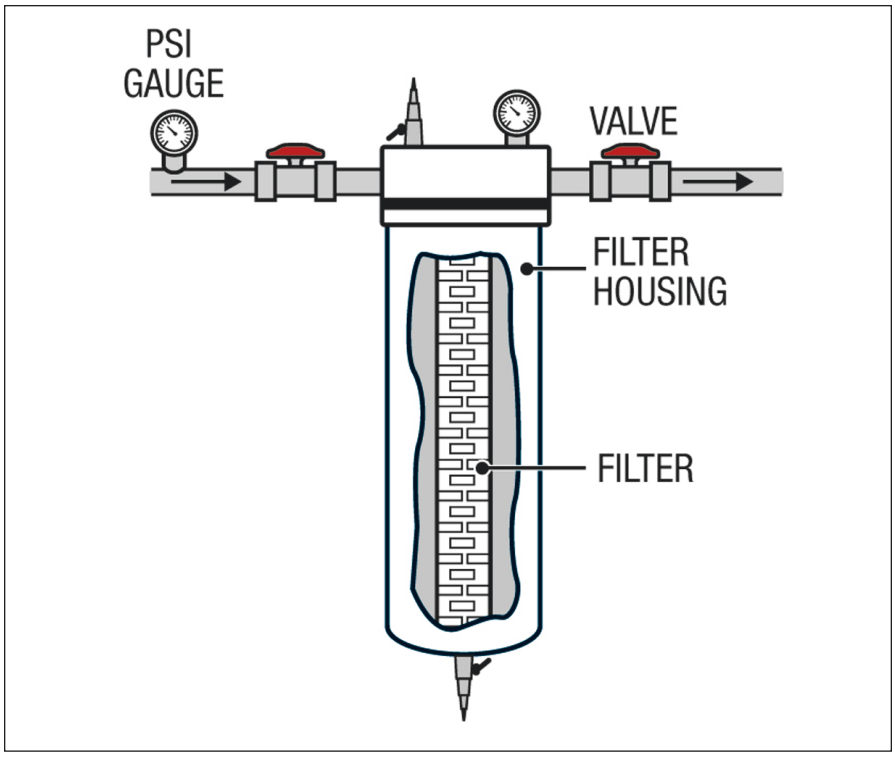

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Figure 11
Indirect Feed Design

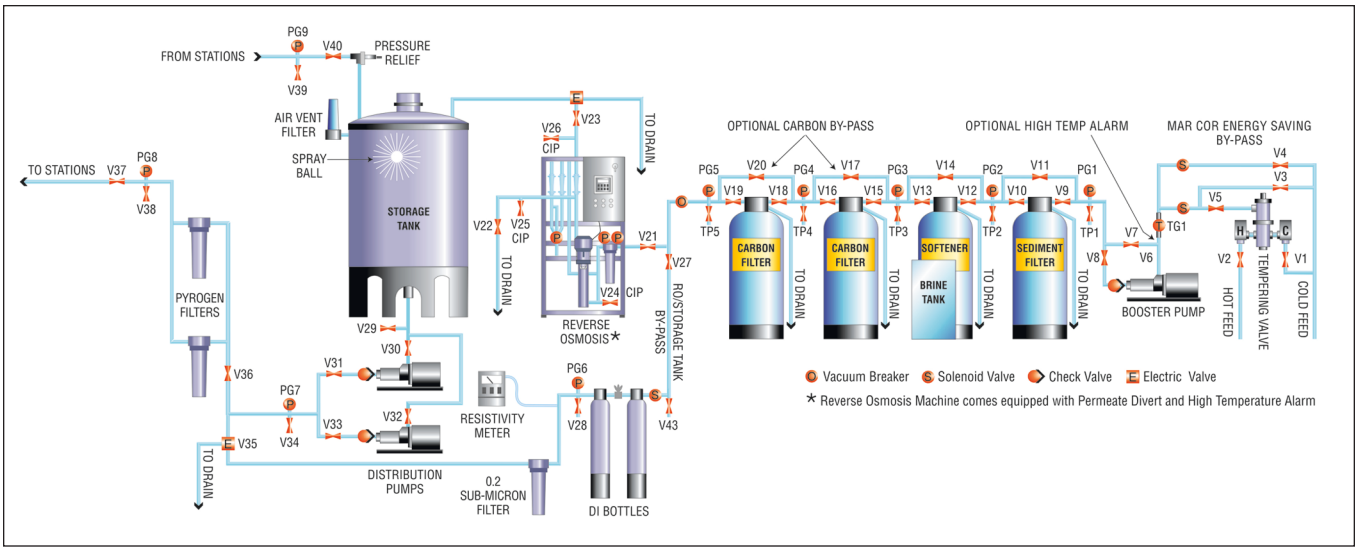

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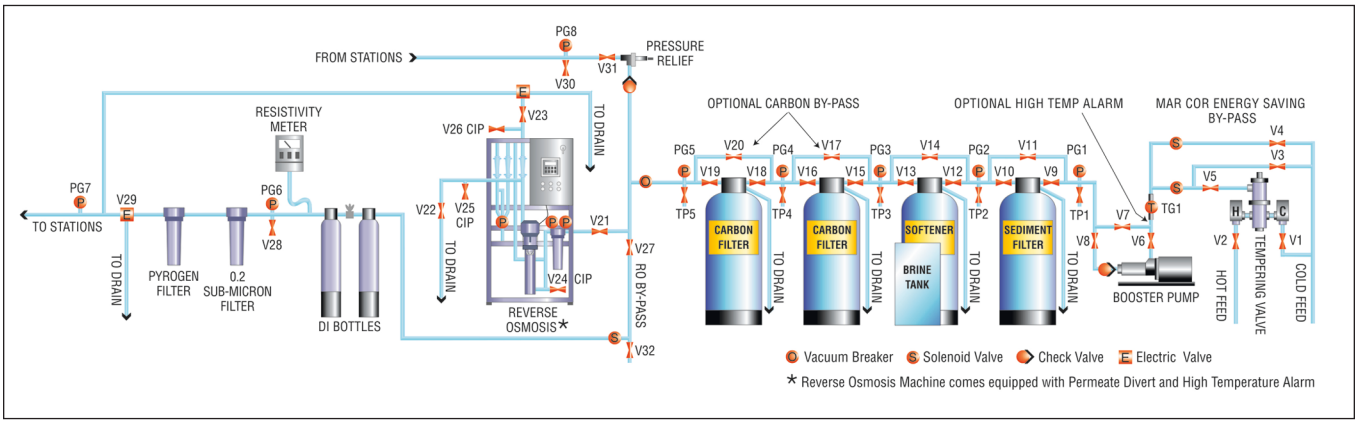
Figure 12
Direct Feed Design



Source: Courtesy of Mar Cor Purification, Inc. Used with permission.

ical use. There are "nominal" and "absolute" ratings for UF and submicron filters in the industry. "Nominal" generally means "as stated on the label." Absolute ratings are more appropriate for dialysis applications because they are derived from a validation process. Filters that are not for medical use may contain preservatives that require 500 to 1000 gallons of water to thoroughly rinse. One incident occurred in New York in 1989 that was caused by the use of a commercially available, non-medical filter. Sodium azide, a desiccant and preservative, was inadequately rinsed from the filter, and this exposure caused nine patients to experience life-threatening hypotension, blurred vision, abdominal pain, headache, and loss of consciousness shortly after treatments began (FDA, 1989).

Though there are some ultrafilters and endotoxin retentive filters on the market that have better flow designs, these filters in general have tighter pores, and thus, lower flows and higher delta pressures across the membrane. These filters will decrease flow velocity in the product water loop if not designed and staged properly. Whenever DI or UV is used, UF shall follow these devices. UF gives added benefit when placed at points of use, such as at the source for reuse water, bicarbonate fill station, and in

the dialysate flow path of each dialysis machine (Cappelli, 1991).

Submicron, endotoxin retentive filters and ultrafilters, even though they eliminate microbes, are targets for bacteria infestation if not routinely cleaned and disinfected or replaced. Membranes can become fouled with bacteria, which actually grow through the membrane, contaminating the product water. Routine bacteria and endotoxin testing is recommended. The pressure differentials pre- and post-filter should be monitored continuously and documented at least daily. There should be some difference between the inlet and outlet pressures. If these pressures are the same, it is possible that the water is flowing around the filter and not through the membrane at all. On the other hand, too great a difference between the inlet and outlet pressures ("delta") indicates that the membrane is clogged. Filters operated in the cross flow design should be fitted with a flow meter to monitor the waste stream.

Distribution System

Water storage. RO distribution systems can be grouped into two categories, direct feed and indirect feed. A direct feed system "directly" delivers the product water from the RO unit to the product water loop for distribution (see Figure 11). Unused product water is usually re-circulated back into the RO unit for conservation reasons.

An indirect feed system involves a storage tank that accumulates the product water and delivers it to the distribution loop (see Figure 12). Unused portions of the product water are typically sent back into the storage tank. The RO unit will stop and start filling the tank by receiving signals from the high and low level switches on the storage tank.

Water storage and distribution systems contain large amounts of water that no longer include chlorine/chloramine to prevent microbial growth. The larger volume and surface area increases the potential for biofilm formation. The tank should be designed to minimize the growth of bacteria by having a conical or bowl-shaped bottom to allow for complete emptying, and have a tight-fitting lid that is vented to air through a hydrophobic 0.45 m air filter to prevent microbes from entering the tank. The tank should be designed for easy, frequent disinfection and rinsed with an internal spray mechanism. Storage tanks shall be made of inert materials that do not leach contaminants into the purified water, and the size of the tank should be in proportion to meet the facility's peak demands, no larger (AAMI, 2009a; FDA, 1996; Leuhmann et al., 1989).

In the 2001 version of the AAMI standards (AAMI, 2001), there was a recommendation that the flow velocity in the distribution system be maintained at 1.5 ft/sec for direct feed systems, and 3.0 ft/sec in indirect feed systems. The 2009 AAMI standard (AAMI, 2009a) does not specify a recommended flow velocity because there was no evidence that a certain velocity would prevent biofilm formation.

Storage tanks require a recirculation pump made of inert, non-leaching materials that can meet the challenge of the higher velocities of flow needed to supply water to a group of dialysis machines. An aggressive and frequent disinfection program should be employed. Many facilities disinfect the distribution system on a weekly basis. Monitoring bacteria and endotoxin is recommended after the storage tank; the air vent filter should be replaced routinely. Pre- and post-pump pressures should be recorded daily.

Water distribution piping systems. A continuous loop design where the water returns to the storage tank or to the RO unit will conserve water and is the recommended design. No dead-ends or multiple branches should exist in the distribution system (e.g., a branch sending purified water to the hospital laboratory) because these are places water can stagnate and allow bacteria and biofilm to grow.

Highly purified water is very aggressive and will leach metals and chemicals from materials with which it comes in contact. Polyvinyl chloride (PVC) is the most common piping material used in the United States for dialysis because of its low cost and relatively inert nature. Other substances that may be used include, but are not limited to, chlorinated PVC (CPVC), polyvinylidene fluoride (PVDF), polyethylene (PE), cross-linked polyethylene (PEX) polypropylene (PP), and stainless steel (SS). Though these materials may be more inert than PVC, they tend to be more expensive. Extreme attention to detail in installing the distribution system is imperative: if the system is plumbed improperly, many problems can result, wasting time and money and potentially placing patients at risk of harm. No copper, brass, aluminum, lead, zinc, or other toxic substances shall be used in the piping; nor shall the piping contribute bacterial contamination. The inner surfaces of the joint connections should be as smooth as possible to avoid microbiological adhesion; smooth beveled edges should be used in connections (rather than hacksawn edges), and simple wall outlets with the shortest possible fluid path and minimum pipe fittings are recommended (Leuhmann et al., 1989).

The distribution system should be evaluated routinely (e.g. quarterly) and the loop visually inspected (when possible) for incompatible materials that may have been inadvertently added. Loop repairs should be performed by trained personnel or reputable plumbers, and all materials used should be inspected for compatibility. Disinfection should always follow any invasive repair to the system. Bacteria and endotoxin testing should be done routinely on the loop (AAMI, 2011; FDA, 1996; Leuhmann et al., 1989).

Alternative Disinfection Of Water Systems

Biofilms are communities of microorganisms attached to surfaces. Once bacteria and other microorganisms attach to a surface, they excrete an extracellular polymer or glycocalyx that will both protect them from chemicals and supply nutrients to maintain life (Meltzer, 1997). Anywhere nonsterile water flows, biofilm will form.

Biofilms offer bacteria and other microbes an endless supply of food and protection against most disinfectants. Even with routine chemical disinfection, biofilm can form. Biofilms form faster in slow-moving water and have a more difficult time attaching themselves in fast-moving water, but eventually they will take hold.

Bleach and ozone are the most effective means for reducing or removing biofilms (AAMI, 2011). Once a biofilm has firmly established itself, it is nearly impossible to eradicate. Many times entire water treatment systems and distribution piping have had to be replaced to eliminate a biofilm problem.

Ozone disinfection. Ozone is a very powerful oxidizing agent that is in the form of a gas, O_3, that is formed from oxygen being put through an electrical generator placed onsite. The ozone generated is then injected into the water. With sufficient exposure time, ozone can sometimes eradicate existing biofilms.

Ozone has a very short half-life of about 25 minutes at 20° C in highly purified water. In the presence of organic and inorganic impurities, ozone will degrade more rapidly. Exposure to UV irradiation will quickly remove ozone. Ozone must always be rinsed out of the system, and its absence verified prior to the water being used for patient treatment.

The by-products of ozone in the presence of impurities (e.g., biofilm) are safe and include carbon dioxide, carboxylic acids, filterable solids, and neutralized organics (such as inactivated endotoxin). Ozone has been classified by the FDA as generally recognized as safe (GRAS). The OSHA maximum exposure level for ambient ozone is 0.1 ppm over a time weighted average of eight hours in a five-day period (shorter exposure time to higher levels [e.g., 0.3 for 15 minutes] is acceptable). To prevent ozone from getting into the air, it is recommended that the storage tank system and piping remain closed when ozone is in use.

Ozone is not recommended for RO disinfection because the powerful oxidant will destroy the membranes. The facility must continue to use chemical disinfection for the RO unit. Because ozone is easy to make (using air and an ozone generator) and does not require a lengthy rinse time, it is convenient to use on the storage tank system and distribution piping.

Because all distribution piping systems are different, each system would have to be evaluated for compatibility with ozone. Ozone, for example, is listed as being incompatible with PVC, the material used in most distribution pipes. However, at the low levels used for disinfection purposes, between 0.3 to 0.7 ppm, the PVC is hardly affected. Bleach is also not compatible with many materials, but at low concentrations, is considered acceptable. Ozone can be aggressive with UF filters made of polysulfone, so ultrafilter and endotoxin retentive filter materials would have to be considered when deciding to use ozone (Amato & Curtis, 2002; Meltzer, 1997; Murphy, 1998).

A test based on indigo trisulfonate or an equivalent (e.g., DPD with a conversion factor) will indicate the absence of ozone in the water. An ambient air ozone test should be performed routinely to comply with the OSHA-permissible exposure limits (AAMI, 2011).

Hot water disinfection systems. The use of hot water disinfection is well known in the HD industry because many dialysis machines use this method for routine disinfection. However, hot water disinfection has not commonly been used in the U.S. for water treatment system disinfection because heat is not compatible with PVC piping. Some manufacturers supply an RO system that is compatible with heat disinfection that includes RO membranes, which can withstand high temperatures, but most existing RO systems are not heat-tolerant. If the RO is not heat-tolerant, hot water could still be used to sanitize the storage tank and distribution system. Piping materials, such as PVDF, SS, PEX, and PP, are compatible with hot water disinfection.

Hot water disinfection will not remove established biofilms. It is, however, a convenient disinfection process that requires little to no rinse time, so it could be used more often, thus preventing the formation of biofilm. An occasional chemical disinfection may be necessary.

Generally, a minimum of 80° C for a 10-minute exposure time will perform a more than adequate disinfection of an RO system and distribution loop. The temperature and contact time need to be established and validated by the manufacturer of the system. It is recommended that the temperature be monitored and recorded at a point most distal from the water heater. Demonstration of reaching the correct temperature for the right amount of time is considered a successful disinfection (AAMI, 2011).

Bacteria and Endotoxins

The major change in the 2011 update of the AAMI standards was the adoption of a set of five International Standard Organization (ISO) documents, listed in Table 6, that include recommendations of lower bacterial and endotoxin levels and different culturing methods (see Table 3) as replacement documents for the 2004 AAMI RD52 document. (***Note:*** Four of these documents were approved by AAMI in 2009 and are referenced here with their 2009 dates). It must be noted that CMS adopted the 2004 AAMI RD52 document as regulation and has not yet proposed adopting the updated documents. While the 2004 AAMI RD52 standard and CMS allow higher levels of bacteria and endotoxins, users would be in compliance with CMS regulations should the user choose to follow the newer recommendations for lower bacterial and endotoxin levels because these would be considered more stringent than the minimum CMS requirements.

Bacteria testing of product water. The 2009 AAMI standards require that the bacteria levels in water used for HD shall not exceed 100 colony forming units/ml (CFU/mL) with an action level set based on knowledge of the microbial dynamics of the system. Typically, the action level will be 50% of the maximum

Table 3
Comparison of Maximum Allowable Levels of Bacteria and Endotoxin in HD Water According to ANSI/AAMI RD52:2004 and ANSI/AAMI/ISO 13959:2009

	Bacteria Limit/Action Level (CFU/mL)	Endotoxin Limit/Action Level (EU/mL)
ANSI/AAMI RD52:2004	< 200/50	< 2/1
ANSI/AAMI/ISO 13959:2009	< 100/50	< 0.25/0.125

Source: Ward, 2011. Reprinted with permission.

Table 4
Comparison of Bacterial Culture Conditions According to AAMI/ANSI RD52:2004 and ANSI/AAMI/ISO 11663:2009

	ANSI/AAMI RD52:2004	ANSI/AAMI/ISO 11663:2009
Medium	Trypticase soy agar	Tryptone glucose extract agar or Reasoner's 2A agar
Incubation Temperature (C)	35	17 to 23
Incubation Time (h)	48	168

Source: Ward, 2011. Reprinted with permission.

allowable level (AAMI, 2009b). If the action level is violated, the facility must show it is taking some action (e.g., disinfection, re-assaying) to address the potential problem. At a minimum, bacterial levels should be tested monthly. Weekly bacteria assays are recommended for new systems until a pattern of compliance with the allowable level is established (e.g., 1 to 2 months) (AAMI, 2011).

At a minimum, water samples should be collected from the first and last outlets of the water distribution loop, water entering the reprocessing equipment, water used to prepare concentrates, and water exiting the DI, UF, UV, and storage tank systems. The outlet should be allowed to flow for 60 seconds before obtaining the sample. Sample ports should *not* be disinfected with bleach or betadine because the residual disinfectant will kill any potential bacteria in the sample. Alcohol may be used on the outside of the ports if allowed to dry completely before samples are taken (AAMI, 2011).

Bacteria assaying technique. Samples that cannot be assayed within four hours can be refrigerated for up to 24 hours after collection. Total viable counts shall be obtained using the membrane filter technique (where a known volume of water is filtered through a membrane, and the membrane is then aseptically transferred to an agar plate) or the spread plate technique (an inoculum of at least 0.1 to 0.3 mL of sample is spread over the agar). Use of a calibrated loop to apply the sample is prohibited; this method is not sensitive enough for HD bacteria testing because the sample used is too minuscule. Culture media should be tryptone glucose extract agar (TGEA), Reasoners 2A (R2A), or other media that can be demonstrated to provide equivalent results. Blood and chocolate agar are too nutrient rich and will kill the bacteria being tested and should not be used. Samples shall be incubated at 17° to 23° C for 168 hours (seven days) (see Table 4). Colonies should be counted using a magnifying device (AAMI, 2011). Note that the culture parameters described by this new standard are different than the shorter incubation time and higher temperatures required by the 2004 AAMI RD52 standards adopted by CMS as regulation. These more current standards may be adopted by facility policy; following these more stringent standards in both culture parameters and action and maximum levels would be in compliance with the minimum CMS requirements.

Endotoxin testing of product water. Note that the newer standards require a lower endotoxin level than the 2004 ANSI/AAMI RD52 standards. As referenced by the 2011 ANSI/AAMI/ISO 23500 standards, endotoxins in the water used for HD purposes shall not exceed 0.25 EU/mL (endotoxin units/mL), and action must be taken when the level exceeds 0.125 EU/mL. Endotoxin testing is done with the *Limulus* Amebocyte Lysate (LAL) assay using either a kinetic assay or a gel-clot assay. The kinetic assay is more reliable and sensitive than the gel-clot method because it uses computer-driven spectrophotometry that calculates the amount of endotoxin. The gel-clot assay only renders a negative or positive result at a given concentration. At a minimum, two tubes should be run each time the gel-clot method is used, one for control and one for testing the sample. When drawing the water samples for endotoxin, the same techniques apply as for bacteria sampling, as long as these follow the recommendations of the test manufacturer or the laboratory, and endotoxin-free sample collection tubes are used (AAMI, 2011).

Bacteriology of Dialysate

The aforementioned assaying techniques will work for dialysate samples. Routine sampling of bicarbonate *concentrate* for bacteria is unnecessary unless it is believed to be the source of a problem. If testing of bicarbonate is needed, the concentrated sample will need to be diluted to be tested (AAMI, 2004). AAMI

Table 5
Comparison of Maximum Allowable Levels of Bacteria and Endotoxin in Dialysate According to AAMI/ANSI RD52:2004 and ANSI/AAMI/ISO 11663:2009

		Bacteria Limit/Action Level (CFU/mL)	Endotoxin Limit/Action Level (EU/mL)
ANSI/AAMI RD52:2004	Standard	< 200/50	< 2/1
ANSI/AAMI/ISO 11663:2009	Standard	< 100/50	< 0.5/0.25
	Ultrapure	< 0.1	< 0.03
	Substitution Fluid	Sterile	Non-pyrogenic

Sources: AAMI, 2009d; Ward, 2011. Reprinted with permission.

has broken up the dialysate purity into three different categories – conventional dialysate, ultra-pure dialysate, and dialysate for infusion (see Table 5).

Conventional Dialysate

Conventional dialysate should contain a viable *microbial* level less than 100 CFU/mL, with an action level of 50 CFU/ml. The endotoxin level should be less than 0.5 EU/mL, with an action level of 0.25 EU/mL. While the bacterial standard is the same for product water, the allowable level of endotoxins in conventional dialysate is higher than the allowable level in dialysis water in recognition that the components used to constitute concentrates may contribute endotoxins (AAMI, 2009b). If the action levels are violated, steps should be taken to address the issue, such as disinfection of the dialysis machine and/or resampling.

AAMI and CMS regulations require that dialysate samples should be collected from at least two machines per month, making sure all machines are tested within a year (CMS 2008a). Some states may require all machines to be sampled within a quarterly period. The machines tested are to be viewed as a sample of all machines; a pattern of positive test results should result in action taken to address all machines. Dialysate samples shall be drawn where the fluid enters the dialyzer from the Hansen connector or a port in the dialysate line for this purpose (AAMI, 2011).

Assays should be repeated if the bacteria or endotoxin levels in the dialysate violate the action level. For new systems, weekly testing should be performed until the bacteria and endotoxin in the dialysate demonstrate a pattern of compliance with the limits. If a patient exhibits an endotoxin reaction or septicemia, dialysate and water sampling should be done as close in time to the event as possible, along with blood cultures and other tests that the medical director may dictate. If the endotoxin reaction arose due to endotoxin build-up in the reprocessed dialyzer, it may be difficult to confirm because LAL testing may be negative in this instance (a protein carrier, like blood, is necessary to draw-out the endotoxin from the dialyzer). In facilities that practice reuse of hemodialyzers, close attention must be paid to water used for reprocessing, and these practices should be evaluated with any patient reactions potentially related to exposure to endotoxin.

Ultrapure Dialysate

Though fluid and solutes mainly flow from the blood side of the dialyzer into the dialysate and down the drain, dialyzers with highly permeable membranes, such as high-flux dialyzers, can have back-filtration and back-diffusion occurring due to their large pore size. This allows water and solutes to flow from the dialysate into the blood side of the dialyzer (Leypoldt, Schmidt, & Gurland, 1991). This results in a concern that endotoxins and endotoxin fragments, which are small enough to cross the high-flux porous membrane, may cause acute and/or long-term symptoms in patients.

Quite a number of research papers conclude that the long-term effects of exposure of patients on dialysis to endotoxin and other cell fragments from gram-negative bacteria results in a chronic inflammatory response. AAMI has therefore taken a step toward more strict standards in dialysate. Chronic endotoxin exposure from dialysate, at a level lower than that which causes an acute pyrogenic reaction (e.g., temperature spike, chills, rigors, hypotension) can stimulate pro- and anti-inflammatory activities, resulting in decreased transferrin, increased beta-2 microglobulin, and amyloidosis, leading to carpal tunnel syndrome and accelerated atherosclerosis (Canaud, Bosc, Leray, Morena, & Stec, 2000). Elevated C-reactive protein (CRP) levels from the acute phase inflammatory response can predict mortality and morbidity in patients on HD and have been linked to malnutrition, resistance to erythropoietin, and when combined with cholesterol and triglyceride levels, increased cardiovascular risk (Panichi et al., 2000).

Ultrapure dialysate should have a viable *microbial* count less than 0.1 CFU/mL and an endotoxin level lower than 0.03 EU/mL. If the levels are violated, action must be taken to correct the situation. The user is responsible for developing a monitoring plan, including testing frequency, that would keep the microbial and endotoxin levels within the standard. Dry powder bicarbonate cartridges are frequently used to achieve the low microbial standard because bulk bicarbonate is more easily contami-

Table 6
Relationship Between Previous AAMI Standards for Hemodialysis Fluids and Newly Adopted ISO Standards

New Standard	Content	Previous Standard
ANSI/AAMI/ISO 13958:2009, Concentrates for Hemodialysis and Related Therapies	Production of dialysate concentrates	ANSI/AAMI RD61, Concentrates for Hemodialysis
ANSI/AAMI/ISO 13959:2009, Water for Hemodialysis and Related Therapies	Water quality standard	ANSI/AAMI RD62, Water Treatment Equipment for Hemodialysis Applications (part)
ANSI/AAMI/ISO 11663:2009, Quality of Dialysis Fluid for Hemodialysis and Related therapies	Dialysate quality standard	ANSI/AAMI RD52, Dialysate for Hemodialysis (part)
ANSI/AAMI/ISO 26722:2009, Water Treatment Equipment for Hemodialysis and Related Therapies	Water treatment equipment	ANSI/AAMI RD62, Water Treatment Equipment for Hemodialysis Applications (part)
ANSI/AAMI/ISO 23500:2011, Guidance for the Preparation and Quality Management of Fluids for Hemodialysis and Related Therapies	User guidance on achieving compliance with fluid quality standards	ANSI/AAMI RD52, Dialysate for Hemodialysis (part)

Sources: AAMI, 2009c; Ward, 2011. Reprinted with permission.

nated with microbes and endotoxin (AAMI, 2004). The use of in-line ultrafiltration on the dialysate may also be necessary to achieve the low microbial/endotoxin standard.

Dialysate for Infusion

In the United States, convective therapies, where a large volume of an electrolyte solution (20 to 70 L) is infused into the patient's blood for replacement, is not commonplace. Hemodiafiltration and hemofiltration therapies require sterile replacement fluids. In Europe, machines are commercially available that will produce the sterile solution online from conventional dialysate by sequential ultrafiltration through the use of UF membranes. Dialysate for infusion should be sterile and non-pyrogenic (AAMI, 2009b). The manufacturer of the equipment must validate the ability of the equipment to consistently produce water that meets these requirements. The user should follow the manufacturer's guidelines for use, monitoring, and maintenance so the equipment used will continue to meet the specifications through an established process (AAMI, 2009b).

The Philadelphia Incident

Even though there have been many more recent incidences with chloramine poisoning of patients, the most noted example remains the "Philadelphia Incident" of 1987 because it was multifaceted. Initially, a nurse in the facility noticed an unusually large number of hematocrit values that were lower than normal. Patients also complained of headaches and malaise, and were hypotensive. After two to three days of symptoms, it became apparent that chloramine was the culprit causing hemolysis. Forty-four patients out of 107 required transfusions, and 10 were sent to the emergency department for additional treatment. Fortunately, thanks to careful clinical monitoring, no patients died during this event (Ackerman, 1988; FDA, 1988).

Upon further investigation, it was discovered that the water requirements for the facility had increased, and a water vendor added more RO membranes without increasing the size of the pretreatment carbon beds to accommodate the higher flow rate. The staff person monitoring the system recorded the chloramine levels accurately as they climbed to toxic levels (AAMI maximum level is 0.1 mg/L), but the staff member was not aware that this was a dangerous situation and did not report it to a supervisor. Further, no written policy was in place regarding the testing of total chlorine levels, and double checks with signatures were not standard procedure. Finally, the staff erroneously believed that backwashing the carbon would regenerate the tank (Ackerman, 1988; FDA, 1988).

This incident illustrates the need for staff education, choosing reputable water vendors, having proper policies and procedures in place, and re-evaluating the entire water treatment system if any component is changed.

New Hemodialysis Fluid Standards

During the years 2009 to 2011, AAMI participated in the development of international standards for the purity of water and dialysate used in dialysis. These International Standards Organization (ISO) standards have been adopted by AAMI as the United States standards. A comparison between these five new standards and the previous AAMI standards that they replaced is shown in Table 6. While the level of chemical contaminates remains the same (except for the change to the use of a lower level for total chlorine to allow a single test to be used), there are significant differences in microbiological contamination and culture methods.

It is important to remember that while AAMI has adopted new standards, the 2008 revision of the CMS Conditions for Coverage incorporated the entire 2004 AAMI RD52 document and the sections of the 2001 AAMI RD62 document referenced by RD 52 into the regulations for dialysis facilities. Until CMS revises the Conditions for Coverage, surveyors will use the older standards as the minimum requirement that facilities must meet. This time should be used by facilities to develop methods to assure that the new standards can be met to improve the quality of care for patients and to be prepared when CMS adopts the new standards. Because the newer standards are more stringent than the older standards, a facility that choses to adopt the newer standards and follows those requirements would be considered in compliance with CMS requirements.

It is important to understand that monitoring of microbiological contamination in dialysis water systems should focus on establishing a routine that prevents the development of growth in the system. A protocol that uses monitoring to retroactively decide when to disinfect a system will inevitably result in exceeding the bacterial purity standards.

Summary

By understanding water treatment system operation, dialysate purity issues, and the nuances of patient reactions, and by working closely with technicians, nephrology nurses can protect patients from unsafe water and dialysate and contribute immensely to long-term positive outcomes for patients.

References

Ackerman, R.A. (1988). The Philadelphia incident. *Contemporary Dialysis and Nephrology, 9,* 27-28, 33.

Amato, R.L. (1995). Disinfection of an RO: Clearing the issues. *Dialysis and Transplantation, 24*(5), 244-249, 258.

Amato, R.L. (2005). Water treatment for hemodialysis, Updated to include the latest AAMI Standards for Dialysate (RD52:2004). *Nephrology Nursing Journal, 32*(6), 151-167.

Amato, R.L., & Curtis, J., (2002). The practical application of ozone in dialysis. *Nephrology News and Issues, 16*(10), 27-30.

Association for the Advancement of Medical Instrumentation (AAMI). (2001). *Volume 3: Hemodialysis Systems* ANSI/AAMI RD62-2001. Arlington, VA: Author.

Association for the Advancement of Medical Instrumentation (AAMI). (2004). *Volume 3: Hemodialysis Systems* ANSI/AAMI RD52-2004. Arlington, VA: Author.

Association for the Advancement of Medical Instrumentation (AAMI). (2009a). ANSI/AAMI/ISO 26722: 2009 *Water treatment equipment of hemodialysis applications and related therapies.* Arlington, VA: Author.

Association for the Advancement of Medical Instrumentation (AAMI). (2009b). ANSI/AAMI/ISO 13959: 2009 *Water for hemodialysis related therapies.* Arlington, VA: Author.

Association for the Advancement of Medical Instrumentation (AAMI). (2009c). ANSI/AAMI/ISO 13958: 2009 *Concentrates for hemodialysis related therapies.* Arlington, VA: Author.

Association for the Advancement of Medical Instrumentation (AAMI). (2009d). ANSI/AAMI/ISO 11663: 2009 *Quality of dialysis fluid for hemodialysis and related therapies.* Arlington, VA: Author.

Association for the Advancement of Medical Instrumentation (AAMI). (2011). ANSI/AAMI/ISO 23500: 2011 *Guidance for the preparation and quality management of fluids for hemodialysis and related therapies.* Arlington, VA: Author.

Bland, L.A., & Favero, M.S. (1989). Microbial control strategies for hemodialysis systems. *Plant Technology & Safety Management Series, 3,* 30-36.

Canaud, B., Bosc, J.Y., Leray, H., Morena, M., & Stec, F. (2000). Microbiologic purity of dialysate: Rationale and technical aspects. *Blood Purification, 18*(3), 200-213.

Cappelli, G. (1991). Dialysate contribution to bio-incompatibility in hemodialysis: The effect of microbial contamination. *Contemporary Dialysis & Nephrology, 12,* 20-22.

Centers for Medicare & Medicaid Services (CMS). (2008a). Medicare and Medicaid programs: Conditions for coverage for end stage renal disease facilities 42 CFR Parts 405, 410. 413, 414, 488, and 494. *Federal Register, 73*(73), 20370-20484. Retrieved from http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/ESRDfinalrule0415.pdf

Centers for Medicare and Medicaid Services (CMS). (2008b). *ESRD basic technical surveyor training interpretive guidance. Interim final version 1.1.* Retrieved from http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/downloads/esrdpgmguidance.pdf

Environmental Protection Agency (EPA). (2012). *Drinking water standards and risk management.* Washington, DC: Author. Retrieved from http://water.epa.gov/drink/standardsriskmanagement.cfm

Environmental Working Group (2009). *National Drinking Water Database: Executive summary.* Washington, DC: Author. Retrieved from http://www.ewg.org/tap-water/executive-summary

Food and Drug Administration (FDA). (1988). *FDA safety Alert: Chloramine contamination of hemodialysis water supplies.* Rockville, MD: Author.

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Food and Drug Administration (FDA). (1989). *FDA safety alert: Sodium Azide contamination of hemodialysis water supplies*. Rockville, MD: Author.

Food and Drug Administration (FDA). (1996). *FDA premarket approval guidelines for hemodialysis water treatment systems*. Rockville, MD: Author.

Food and Drug Administration (FDA). (2009). *Device classification*. Retrieved from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm

Food and Drug Administration (FDA). (2011). *Code of Federal Regulations (CFR) – Water purification system for hemodialysis* [Title 21, volume 8, 876.5665]. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=876.5665

Kirkwood, R.G., Dunn, S., Thomasson, L., & Simenhoff, M.L. (1981) Generation of the precarcinogen dimethylnitrosamine (DMNA) in dialysate water. *Transactions of the American Society for Artificial Internal Organs, 27*, 168-171.

Leypoldt, J.K., Schmidt, B., & Gurland H.J. (1991). Measurement of backfiltration rates during hemodialysis with highly permeable membranes. *Blood Purification, 9*, 74-84.

Leuhmann, D., Keshaviah, P., Ward, R., Klein, E., & Thomas, A. (1989). *A manual on water treatment for hemodialysis*. Rockville, MD: Food and Drug Administration.

Meltzer, T.H. (1997). Ozone and its applications. In T.H. Meltzer (Ed.), *Pharmaceutical water systems* (pp. 125-164). Littleton, CO: Tall Oaks Publishing, Inc.

Murphy, J.C. (1998). Materials compatibility for ozone. *Water Conditioning and Purification*, *40*(5).

NxStage Medical, Inc. (2006). *PureFlow SL user's guide. NC1460 Rev C*. Lawrence, MA: Author.

Panichi, V., Migliori, M., De Pietro, S., Taccola, D., Bianchi, A.M., Norpoth, M., … Tetta, C. (2000). C-reactive protein as a marker of chronic inflammation in uremic patients. *Blood Purification*, *18*(3), 183-190.

Ward, RA (2011). New AAMI Standards for Dialysis Fluid. *Nephrology News and Issues*, 25(13), 33-36.