INTRODUCTION TO

WATER TREATMENT

FOR HEMODIALYSIS

WHY DOES WATER USED FOR DIALYSIS NEED TO BE TREATED?

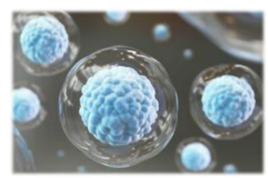
The average person is exposed to approximately ***14*** liters of water each week from food and beverages. Contaminants in this water are excreted from the kidneys and GI system usually without incident.

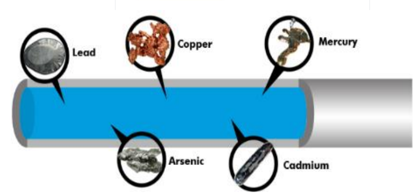
Conversely, the average dialysis patient's bloodstream is exposed to approximately ***432*** liters of water each week. If contaminants are in this water, the only barrier between the patient's bloodstream and the water is the dialyzer. Unfortunately, many contaminants are small enough to pass through the dialyzer membrane and into the patient. One of the greatest potential risks a dialysis patient can face is being dialyzed with water that is not safe:

- Because a patient's bloodstream is exposed to very large amounts of water during each dialysis treatment.
- An entire shift of patients can be harmed or even die if the water used for dialysis is unsafe.

WHAT TYPE OF CONTAMINANTS MAKE WATER UNSAFE FOR DIALYSIS?

Contaminants in the city water supply that must be removed or reduced to a safe level before water can be used for dialysis are:



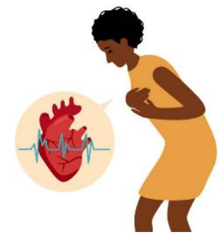


- Microorganisms – viruses, bacteria, and endotoxins. Endotoxins are part of the outer membrane of the cell wall of Gram-negative bacteria - Examples of Gram-negative bacteria that contain these endotoxins are E-coli and Salmonella.
- Organics – such as pesticides, herbicides, chlorine, and chloramines (chlorine combined with ammonia)
- In-organics – such as salts, metals, aluminum, fluoride, arsenic, and lead.

The city water supply is governed by several bodies to ensure that our water is safe to drink. In many instances, additives such as chlorine and aluminum are added to the water for safety and treatment reasons. However, the allowable limits for contaminants and additives in drinking water exceed the limits that are safe for dialysis. As stated earlier, if patients are dialyzed on water that contains contaminants that exceed safe dialysis limits, the results can be detrimental.

WHAT ARE SOME SYMPTOMS OF INADEQUATELY TREATED WATER?

If water used for dialysis contains contaminants that exceed safe levels, patients can exhibit a range of symptoms depending on the specific contaminant. Exposure to any contaminant can lead to death if not caught in time. Some examples of symptoms based on contaminant are:



- Chlorine/chloramines exposure – can cause the red blood cells to rupture - chest pain, arrhythmias, S.O.B., nausea and vomiting.

- Aluminum exposure – neurological deterioration, tremors, and speech abnormalities.

- Fluoride exposure – S.O.B., chest pain, nausea, vomiting, diarrhea, hypotension, headache, weakness, numbness, and severe itching.

- Endotoxin exposure – usually occurs from 1 hour to halfway into the treatment – uncontrollable shaking, chills, temperature spikes, nausea, vomiting, muscle pain and hypotension.

Since many of the contaminants may cause similar symptoms, it may be difficult to initially pinpoint specific exposure. The important thing to remember is that these symptoms, especially if occurring in more than one patient at the same time, may indicate unsafe water. If unsafe water is ever suspected, dialysis should be discontinued immediately to minimize harm/prevent death.

WHO REGULATES DIALYIS FACILITIES TO KEEP THE WATER SAFE?

Every dialysis facility in the U.S. is regulated by the federal government, specifically CMS – Centers for Medicare & Medicaid Services. CMS issues specific requirements for all areas of dialysis (called Conditions for Coverage), including water treatment. These requirements or conditions must be adhered to for any facility to operate. CMS utilizes other governing bodies, such as AAMI – Association for the Advancement of Medical Instrumentation – to help them determine how water treatment for dialysis is regulated and what requirements are necessary.

Some of the many requirements that are listed in the Conditions for Coverage regarding water treatment for dialysis are:

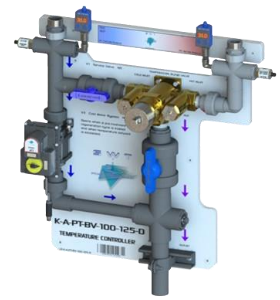
- How often disinfection of the patient loop piping/RO storage tank must take place.
- How often, what sites and acceptable results for bacteriological and endotoxin testing.
- How often and where chlorine/chloramines and water hardness testing must take place.
- How much carbon must be used to effectively remove chlorine/chloramines.
- How often and what data is captured regarding the water treatment systems.
- How RO rooms are labeled and what must be identified in diagrams and schematics.
- How audible and visual alarms must sound and where they are located.

HOW IS WATER TREATED TO MAKE IT SAFE FOR DIALYSIS?

There are many components that make up the water treatment systems that are used at the Northwest Kidney Centers. Regardless of system or unit, the basics are the same: the water is sent through several pre-treatment components and then a reverse osmosis system.

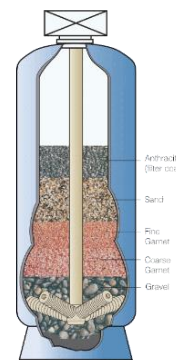
NKC pre-treatments systems utilize a variety of equipment when the city water enters the facility. In order of flow from one to the next each facility may include:

- **Water Temperature Blending Valve** – A temperature blending valve is used to increase the temperature of the incoming water. Warmer water helps make acid mixing more efficient, allows RO membranes to produce more product water, and keeps a stable water temperature in the piping system to help prevent damage from temperature fluctuations.

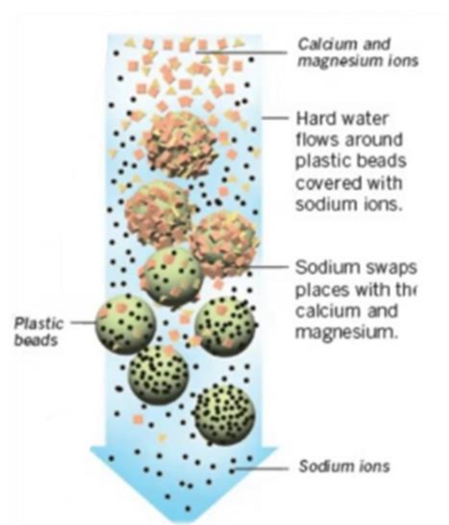


- **Booster Pump** – Most NKC systems utilize a booster pump before the first tank or filters on the pretreatment system. Booster pumps are used to increase the flow rate through the pretreatment system as needed during times of increased demand.

  Multi-media/Dual Gradient Depth Filters – NKC uses one of two different filters at the beginning of the pretreatment to filter out large particles. A multimedia tank contains various sized rocks/sand that remove particles 10 microns in size or larger; this helps the other components downstream stay cleaner and functioning correctly; the multi-media filter tank is flushed to drain on a regular schedule to remove the captured particles. The "Big Blue" dual gradient filters are dual sized filters with a larger pore on the outside (usually 25 micron) than on the inside (usually 5 micron) which remove particles 5 microns in size or larger.

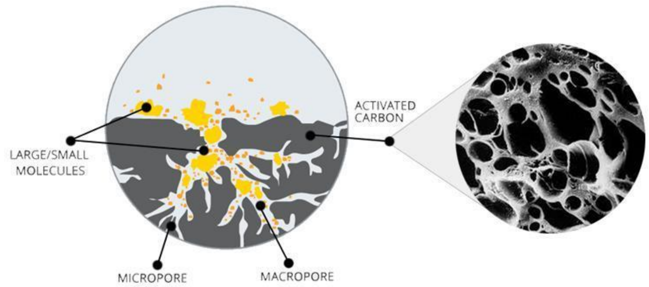


- **Water Softener Tank(s)** – contains a resin media that will remove calcium and magnesium via ion exchange with sodium or salt. Calcium and magnesium make the water "hard." When the water enters the softener tank(s), the calcium and magnesium ions trade places with the sodium ions. The sodium that is released from the softener tank(s) during this exchange will be removed by the RO that is downstream. The calcium and magnesium ions captured in the softener tank(s) will be flushed to drain on a regular schedule. The salt used for the ion exchange is stored in a tank (called a



brine tank) that sits next to the softener tank(s). The softener tank(s) refill themselves with salt from the brine tank on a regular schedule. High levels of calcium and magnesium can be unsafe for patients and can ruin the RO membranes.

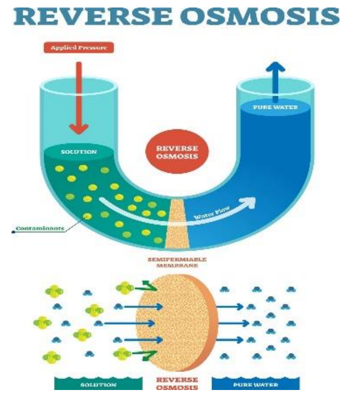
- **Carbon Tanks** – contain carbon media that removes chlorine/chloramines via adsorption; adsorption is when a gas, liquid or solid adheres to the surface of a solid but does not penetrate it. Carbon is very porous and has an enormous amount of surface area for the chlorine/chloramines to adhere to. However, the amount of surface area on the carbon is finite. When the carbon has no more surface area for adsorption to take place, the chlorine/chloramines will pass through the tanks.



When water flows through the carbon tanks, it must remain in contact with the carbon media for a certain amount of time for the chlorine/chloramines to be removed. This time requirement is called Empty Bed Contact Time (EBCT). Per CMS, the EBCT must be at least 10 minutes to effectively remove chlorine/chloramines. Factors such as the number of patient stations and how much water the RO can produce help determine how much carbon media is necessary to meet the EBCT.

Carbon tanks are set up so that water flows through one tank called a "worker" tank and then a second tank called a "polisher" tank. The worker and polisher tanks together are referred to as a "carbon bed." NKC units have one carbon bed. When chlorine/chloramines pass through the worker carbon tank because the carbon has no more surface area for adsorption to take place, the carbon media in every single tank in the facility is changed out for new.
Carbon tanks are rinsed out on a regular schedule to remove particulate matter and bacterial growth and to expose new surfaces of the carbon media for adsorption. Chlorine/chloramines are removed because they can rupture red blood cells. Chlorine/chloramines can also burn holes in the RO membranes allowing contaminants to pass through.

Following the pre-treatment section, the water flows to a Reverse Osmosis Unit. Reverse osmosis is the process of using high pressure (via a pump) to force water through a semi-permeable membrane while leaving the contaminants behind.

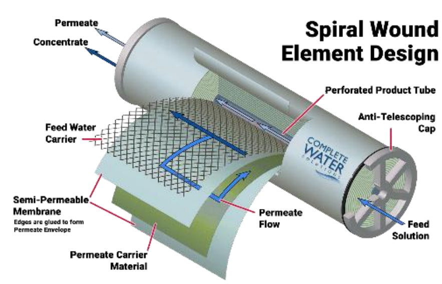


Reverse Osmosis Unit - a medically approved device when used for dialysis is made up of the following main components:

- **Pre-filters** – the pre-filters are located on the RO unit and are used to capture carbon particles and other particulate matter that may be released from the carbon tanks. The carbon particles can damage the RO pump that is downstream. The RO pre- filters are changed on a regular schedule so water flow to the RO is not obstructed.

- **Pump** – the pump is located on the RO unit and is what creates the high pressure for reverse osmosis to occur. The pump also sends the water out to the next stage of the water treatment system.

- **Reverse osmosis membranes** – the semi-permeable membranes that filter out the contaminants from the water. Even though the water produced is not 100% pure, it meets the very strict standards that are set forth by the Conditions for Coverage. The amount of water necessary to run a facility at its maximum load determines the number of membranes an RO contains. RO membranes are cleaned or changed as needed to ensure dialysis quality water is always being produced.
    - The water that is forced through the RO membranes and used for patient care is called product or permeate water.
    - The water that contains the contaminants and is flushed to drain is called concentrate water.



At NKC facilities, once the permeate water leaves the RO it is pumped directly out to the patient stations and other sites (acid mixers, PM lab, rinse stations etc.) through a piping system. The water that is not used returns to the RO and is processed again. This type of system is called a direct feed system. Direct feed RO systems are turned “Off” or put into a “Standby” mode when patient care is not taking place.

RO water has little to no organic and inorganic materials, such as metals, minerals, salts, and ions. Because of the absence of these things, water as a universal solvent will begin to slowly dissolve inappropriate loop piping materials causing a “leaching” effect that may contribute harmful chemicals to the permeate water after it has been treated. Distribution loop piping is never constructed of aluminum, copper or lead because of this potential “leaching”. PEX is the preferred material for distribution loops due to its inert leaching potential.

NKC uses “eco-friendly” RO systems that have a heat-sterilization system rather than chemical disinfection. These systems use less water, cost less to maintain, and the heat-on-demand disinfection of the distribution ring (loop piping) and the RO system increases safety for patients and staff while limiting potential exposure to harmful chemicals. We have used 38 percent less water and 10 percent less electricity per month in some of our facilities because of these systems.

The following components are disinfected routinely per the Conditions for Coverage: the distributions loop piping as well as the incoming water line to every available dialysis machine are disinfected monthly, and the RO membranes must be disinfected at least quarterly. Heat disinfections can be automatically set to disinfect the loop and RO membranes. NKC chooses to disinfect the loop weekly and the RO membranes monthly. This is an additional safety feature for our patients.

The disinfection procedure takes place when the facility is closed. To ensure the disinfections are effective, the Conditions for Coverage require monthly testing of sites on the loop, so that all test sites are tested at least annually. Test results should indicate that bacterial and endotoxin levels do not exceed maximum limits. If the test results exceed maximum limits, patient care cannot take place until the situation is resolved.

THE IMPORTANCE OF CHLORINE & CHLORAMINE TESTING

Chlorine and potential chloramine levels are closely monitored in accordance with AAMI standards and the Conditions for Coverage because chlorine and chloramine exposure can be fatal to patients because it causes hemolysis.

Carbon tanks are the principal means of removing both free chlorine and chloramine. Removal of free chlorine to a maximum level of 0.5 mg/L and chloramine to a maximum level of <0.10 mg/L is necessary to protect hemodialysis patients from red cell hemolysis. In addition, free chlorine may also degrade some reverse osmosis membranes.

NKC tests for total chlorine (the sum of free chlorine and chloramine), allowing a maximum level of <0.1 mg/L of total chlorine, rather than analyzing for free chlorine and chloramine separately. Total chlorine minus free chlorine equals the chloramine level. At NKC the Hach CM 130 in-line chlorine meter is used to measure the total chlorine level automatically while staff perform verification checks with total chlorine test strips.

The Conditions for Coverage require a chlorine check approximately every 4 hours. The Hach CM 130 checks the chlorine level approximately every 5 minutes. NKC requires a verification chlorine test strip at the beginning of the day before patient treatments start and at the start of the evening charge nurse shift. If the verification strip is not done, NKC requires a SAS. If the Hach meter is out of order, NKC requires the chlorine test strips be done every 3 hours.

If the worker carbon tank test result is positive – equal to or greater than 0.10 mg/L – the corresponding polisher tank must be tested. If the result from the polisher tank is <0.10 mg/L, operations may be continued for up to 72 hours. Total chlorine testing increases to approximately every 2 hours. Once the 72 hours have elapsed, operations must be discontinued, even if the test result from the polisher carbon tank is <0.10 mg/L.

If the test result from the polisher carbon tank is equal to or greater than 0.10 mg/L, dialysis must be discontinued immediately. DO NOT go into backup. Put the dialysis machines into bypass and determine if the patients can be rinsed back safely; rinse the patients back ONLY if the chlorine test result from the RO permeate sample port is <0.10 mg/L.

WHAT HAPPENS IF THE WATER TREATMENT SYSTEM IS DOWN?

NKC facilities can still provide dialysis even when the main water treatment system is not functioning. This is done by utilizing dual stage RO systems, meaning that each RO is two RO's in series. A dual RO system not only produces higher quality water than a conventional single pass RO system, but also provides backup redundancy. By using a dual RO system, we can isolate the RO that needs repair while still running our patients on RO water. This redundancy of having a built in "backup" RO provides additional safety for our patients while minimizing downtime.

HOW ARE RO SYSTEMS MONITORED?

The Conditions for Coverage require that all water treatment systems be monitored each day the facility is providing patient care. Monitoring is performed by the clinical staff and includes recording data on pressures, flows, and water quality readings. Monitoring also includes daily testing of water hardness levels post softener tanks (performed at the end of day) and chlorine/chloramines testing every three hours at a minimum. This data will be used to determine if the components are functioning correctly and helps to determine such things as:

- Do the filters need to be changed?
- Do the RO membranes need to be cleaned or changed?
- Do the carbon tanks need to be cleaned? Do the carbon tanks need to be changed?

One of the most important readings obtained on a water treatment system is the water quality reading. This reading lets us know that we are providing safe AAMI quality water to our patients. A good indicator of the quality of water is to determine how well it conducts electricity. Treated or pure water is not a good conductor of electricity because there are very few ions (contaminants) to carry the current along.

RO units measure the conduction capabilities of the permeate water via a conductivity meter. The conductivity meter reading indicates how well the water conducts electricity. A low reading indicates that the water is not a good conductor of electricity and is therefore pure of most contaminants. Every NKC facility has a specific limit on how high the permeate conductivity reading can be before it may reach a dangerous level. The type and number of contaminants in the city water entering the facility determines the unit specific alarm limit. If the permeate conductivity reading exceeds the unit specific limit, patients may be dialyzing on water that does not meet AAMI quality standards.

The Conditions for Coverage state that clinical staff must know how to keep the water from reaching the patients if the RO alarms for "permeate conductivity high." To prevent patient exposure during any water related emergencies the dialysis machines should be placed into bypass until the situation has been resolved.

WHAT CAN I DO TO HELP ENSURE PATIENT SAFETY?

If you are directly responsible for learning about and monitoring the water treatment systems, please take this very seriously. You will be trained in the following:

- How to record RO room daily data.
- Troubleshooting alarms – some of the alarms you may see include *permeate conductivity high* which indicates poor water quality, *Leakage* alarms which indicate a loss of pressure in the distribution loop or a tank low alarm indicating there may not be enough water going into the RO.
- How to perform hardness and chlorine testing.
- How to convert to the backup water system should the main system malfunction.

If you are not directly responsible for learning about the water treatment systems, please assist in any way possible during a water emergency. You may be asked to:

- Place phone calls.
- Keep patients calm.
- Answer machine alarms.
- Rinse patients back or discontinue dialysis.

Keeping patients safe during dialysis is a team effort. You can help ensure the proper functioning of the water treatment systems and safe quality water by:

- Recording data accurately and completely.
- Knowing the water policies and procedures for which you have been trained.
- Responding to water alarms immediately.
- Knowing where to find the FSS on-call schedule (K-Net under the Work Order Tab)
- Communicating any concerns or questions to your FSS.

Full Name: ____

Completion Date: _______________________________

Score: ____

Reviewed by: _________________________________

INTRODUCTION TO WATER TREATMENT FOR HEMODIALYSIS TEST

1. One of the greatest risks a dialysis patient can face is being dialyzed with ____________________ that is not safe.
2. T or F – A dialysis patient's bloodstream is exposed to more water in one week than an average healthy person consumes.
3. The three types of contaminants that must be removed to a safe level before water can be used for dialysis are __________________, __________________, and _________________.
4. Salt, metals, and fluoride are examples of ____________________ (contaminants).
5. Viruses, bacteria, and endotoxins are examples of ____________________ (contaminants).
6. Pesticides, herbicides, and chlorine are examples of ____________________ (contaminants).
7. The red blood cells can be ruptured, causing chest pain and S.O.B. during exposure to ____________________.
8. A patient can experience hypotension and severe itching when exposed to ________________.
9. T or F – If patients are exposed to contaminants in water that exceed safe levels, death may occur.
10. What specific government agency regulates and monitors dialysis facilities? ____.

11. The specific requirements that are issued for all areas of dialysis, including water treatment are called ____.

12. List three requirements that are government regulated regarding water treatment for dialysis:

    a) ____

    b) ____

    c) ____

13. What are three components of the pre-treatment systems that are used at NKC?

    ____________________, ____________________ and ____________________.

14. A multi-media filter tank removes ____ while a dual gradient filter removes ____.

15. Softener tanks use the process of ____________________ to remove ____________________ and ____________________ in exchange for ____________________ ions.

16. Carbon tanks remove ____________________ via ____________________.

17. Per the Conditions for Coverage, what is the time requirement for how long the water must remain in contact with the carbon media to effectively remove chlorine/chloramines is called?

    ____.

18. The EBCT must be at least ____________________ per the Conditions for Coverage.

19. Chlorine/chloramines are removed by the carbon tanks because they can

    ____________________________________ and ____________________________________.

20. Reverse osmosis is the process of using ________________________ to force water through a ____________________________________ while leaving the ____________________ behind.

21. A reverse osmosis unit is made up of the following three components:

____________________; ____________________; ____________________

22. T or F – Even though an RO cannot produce water that is 100% pure, it can meet the very strict quality standards that are set forth by the Conditions for Coverage.

23. The water that is produced by the RO and used for patient care is called ____________________ or ____________________ water.

24. In a ____________________feed system, the water is pumped directly out to the patient stations after leaving the RO.

25. Since dialysis water is very pure, it is a great place for ____________________ to grow.

26. NKC uses direct feed systems that use less ____________________, cost less to ____________________, and reduces potential exposure to ____________________.

27. Since loop piping cannot be constructed of materials that would contribute chemicals to the water, it should never be made from ______________, ______________ or ______________.

28. T or F – Monthly disinfections of the loop piping are required by the Conditions for Coverage.

29. The ____________________ to every available dialysis machine must be disinfected at least monthly.

30. NKC uses a heat disinfection process and the NKC policy is that the RO distribution loop will be disinfected ________________ and the RO membranes will be disinfected ________________.

31. To ensure the disinfections are effective, the Conditions for Coverage require ______________ testing of sites on the loop, so that ____________ sites are tested at least _______________.

32. The Conditions for Coverage require monthly testing, the test results should indicate that

____________________ and ____________________ levels do not exceed maximum limits.

33. The Conditions for Coverage require that all water treatment systems be monitored

____.

34. Monitoring is performed by the ____________________.

35. The Conditions for Coverage require a chlorine check approximately ____________________.

36. One of the most important readings obtained on a water treatment system is the water

____________________ reading.

37. A good indicator of the quality of water is how well it conducts _________________.

38. Treated or pure water is not a good conductor of electricity because there are very few

____________________ to carry the current along.

39. The Conditions for Coverage require that staff know how to prevent water from reaching the

patients in the event of a water ________________ alarm such as "permeate conductivity high.

40. RO's measure water quality via a ____________________ meter.

41. Keeping patients safe during dialysis is a ____________________ effort.

42. The FSS on-call schedule is located on the _______________ under the _______________ tab.

43. What is the maximum allowable level for free chlorine?

a. 0.1 mg/l c. 0.5 mg/l

b. 0. 025 mg/l d. 1.0 mg/l

44. What is the maximum allowable level for chloramine?

a. 1.0 mg/l c. 0.25 mg/l

b. 0.5 mg/L d. 0.10 mg/l

45. If sampling for total chlorine only, the maximum allowable level is ________mg/L.

46. Why do we remove chlorine/chloramines? ____

47. How often does the Hach CM130 perform a chlorine test?

a. every 3 hours
c. once a day at any time
b. once per 8-hour shift
d. every 5 minutes

48. If you miss a verification strip test does NKC require a SAS? Circle - Yes or No

49. If the Hach meter is out of order, how often do you perform chlorine testing?

a. every 3 hours
b. once per 8-hour shift
c. once a day at any time
d. every other day

50. What do you do if the test result from the worker carbon tank is positive? ________________________

____

51. How long can a facility run on polisher carbon tanks regardless of test results at the end of this time?

a. 24 hours
b. 8 hours
c. 72 hours
d. 7 days

52. Do you increase chlorine testing when running on polisher carbon tanks? (Circle the correct answer)

Yes, go to approximately every 2 hours.

No test at approximately every 4 hours

53. What do you do if the polisher carbon tank tests equal to or greater than 0.10 mg/L? ________________

____