CMS
Water Treatment Standards
Summary Guide

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THE NEW CHANGES

The CMS provisions defined in 42 CFR Part 494 (which took effect October 14, 2008) establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.

This condition adopts the Association for the Advancement of Medical Instrumentation's (AAMI's) "American National Standards for Dialysate for Hemodialysis," 2004 (RD52:2004) and referenced portions of AAMI's "American National Standards for Water Treatment for Hemodialysis Applications" (RD62:2001) as regulation. The interpretive guidance for 42 CFR Part 494 establishes that when the words "should" or "recommend" are included in the adopted AAMI standards language, the referenced item must be put into use in the dialysis facility. For the most part, the CMS conditions have adopted the AAMI standards without adaptation.

This document summarizes the CMS points of emphasis that will require close attention to ensure the water purification system is in compliance with the CMS conditions of coverage.

CENTRAL WATER TREATMENT SYSTEMS

ANSI/AAMI RD52:2004, Amendment 3-Annex E: Special Considerations for Acute Hemodialysis, states that any water system supplying 3 or more stations are considered central water treatment systems and must meet the general requirements of ANSI/AAMI RD52 and ANSI/AAMI RD62.

WHEN IS FDA 510K REQUIRED?

All water treatment devices and systems installed after May 30, 1997 must be cleared for market by FDA through the 510(k) process. Regardless of installation date, the system must meet the requirements described in the CMS Conditions for Coverage.

LOCATION OF WATER PURIFICATION SYSTEM

The water purification system should be located in a secure area where access is restricted to individuals responsible for monitoring and maintenance of the system. The layout of the system should provide easy access to all components, including meters, gauges, and sample ports used for monitoring. For older systems, provisions should be made to allow staff to access all equipment and components to operate, monitor, and maintain the system. The location selected should minimize the length and complexity of the distribution system.

TRAINING AND STAFF RESPONSIBILITY

Training is a critical element of the CMS conditions. Dialysis facility staff must be trained on the proper operation and monitoring of the water treatment system. Training must be conducted by the manufacturer of the equipment, or the training must be done from materials provided by the manufacturer. The facility must define the frequency of audits to evaluate the staff's compliance. Audits must be conducted at least annually, more often if problems are identified, and must include actual observation of water sampling and testing.

The CMS conditions emphasize that the medical director is ultimately responsible for the safety and quality of the water used for patient treatments. The medical director must be knowledgeable of the

water treatment system and assure that the system as installed will produce AAMI quality water. If any monitored parameter is found to be out of specification, facility staff must notify the medical director of the results.

EMERGENCY CONTINGENCY PLAN

The dialysis facility must develop contingency plans and emergency policies and procedures to cover the failure of its water purification and distribution system or a critical component of that system. The plans should describe how to deal with catastrophic failures that completely prevent dialysis from being performed, as well as how to deal with other failures such as sudden changes in water quality or the failure of a critical component. Responsible staff members must have a means to test alarms in order to verify that they can be heard in the patient treatment area. Documenting that alarms that sound normally during the treatment day are heard in the treatment area satisfies this condition.

IDENTIFICATION OF WATER SYSTEMS

Water systems must include schematic diagrams that identify components, valves, sample ports, and flow direction. The diagram must allow staff to follow the flow of the water through the components and each component and the piping must be labeled as described. Major water system components must be labeled in a manner that not only identifies the device but also describes its function, how performance is verified, and what actions to take in the event that the device operates out of specification. The use of text labels, such as “RO Water,” and color-coded “arrow tape” are acceptable methods for identifying pipe contents and flow direction.

MONITORING & EQUIPMENT REQUIREMENTS

Timer Controlled Pretreatment Devices

Timers on backwashing filters (multimedia, carbon) and softeners are required to be checked at the beginning of each day to determine the timers are set to the correct time. The face of the timers must be visible to the user and the timer box must have a clear window allowing the timers to be seen, or the cover must be removed when timers need to be viewed. In the event that the “time” set on each timer needs to be staggered to prevent multiple components from backwashing at the same time, there must be a posted notice to that effect. The timer checks should be documented on a log to show evidence that the verification occurred.

Sediment Filters

Sediment filters (Multimedia Filters) must be monitored daily for pressure drop across the filter, looking for a pressure drop less than a number determined by facility protocol. Pressure drop measurements and timer verification must be recorded on a log sheet.

Cartridge Filters

Cartridge filters must be monitored for pressure drop across the filter daily. The pressure drop must be less than a number determined by facility policy. Results of monitoring must be recorded on a log sheet.

Softener

Softener product water must be monitored at the end of each treatment day for hardness as calcium carbonate (≤ 1 grain/gal) using an ethylenediaminetetracetic acid (EDTA) titration test with "dip and read" test strips, or a similar method. Water hardness measurements and timer verification must be recorded on a log sheet. Softeners must be interlocked with the RO system so that the RO is stopped during the softener regeneration cycle.

Softener Brine Tank

The softener brine tank should be monitored daily to verify that salt pellets fill at least half of the tank. The results of monitoring activities must be documented on a log sheet.

Carbon Adsorption Filters

Carbon adsorption filters must be tested for free chlorine, chloramines, or total chlorine *prior to* each patient shift or approximately every 4 hours. Samples should be drawn from the water exiting the first carbon bed in a series after the system has been operating for at least 15 minutes. Analysis should be conducted onsite using appropriate test kits or test strips sensitive enough to detect levels as low as 0.1 ppm. For parallel connected tanks/beds, testing must be conducted on each set of tanks/beds each time testing is performed. When samples from the first sampling port are positive for chlorine or chloramines, operation may be continued for up to 72 hours until a replacement bed is installed providing that samples from the second sampling port remain negative. When a facility operates with one exhausted carbon bed, the log of testing must include the actual times testing was done rather than indicating the shift.

Granular activated carbon must have a minimum iodine number of 900, and acid-washed carbon is recommended. The empty bed contact time (EBCT) of the granulated activated carbon (GAC) should be calculated periodically for the maximum water flow through the carbon tanks to verify a 10-minute total EBCT. Empty bed contact time is calculated by multiplying the RO feed flow by 10 and dividing the product by 7.48 resulting in the total cubic feet of carbon required for 10-minute EBCT. The RO feed flow is the sum of the RO product water flow and the RO reject water flow.

Supplemental Strategies for Chlorine Removal

Supplemental strategies for chlorine removal may only be used in addition to the use of at least two carbon beds.

Replacement Carbon Beds

The replacement bed should be placed in the second position, and the existing second bed should be moved to the first position to replace the exhausted bed. If it is not possible to rotate the position of the beds, both beds must be replaced.

Chemical Injection Systems

Chemical injection systems that inject acid to lower pH must include a monitor with audible alarm in the treatment area. An alarm is not needed if a flocculent is being injected. When acid is being injected to control pH, mineral acids should be used and organic acids should be avoided as they

may act as a nutrient and allow bacteria to proliferate. The level of chemical in the reservoir, injector function, and value of the controlling parameter (i.e. pH) should be monitored daily.

Reverse Osmosis (RO)

All results of measurements of RO performance should be recorded daily in an operating log that permits trending and historical review. The facility should have documentation of the RO manufacturer's directions for use and facility procedures must reflect them. The medical director, nurse manager, and chief technician must be able to describe how trends in the RO function are monitored to detect problems. Reverse osmosis devices must be equipped with on-line monitors that allow determination of rejection rates and product water conductivity. To calculate the rejection rate for RO systems that do not include a percent rejection display, subtract the product water conductivity from the feed water conductivity and divide the difference by the feed water conductivity. Multiply the result by 100 for the rejection percentage.

[(Feed conductivity – Product conductivity) / Feed Conductivity] x 100 = % Rejection

The product water conductivity monitor should activate audible and visual alarms when the product water conductivity exceeds the preset alarm limit. The audible alarm should be audible in the patient care area when the RO is the last chemical purification process in the water treatment system.

RO systems should be monitored daily for product water conductivity, product and reject stream flow rates, and various internal pressures as permitted by the RO instrumentation. The medical director and the chief technician must be able to discuss how the product water conductivity limit set point was determined. Chemical analysis (AAMI) should be done at installation, when the membranes are replaces, and at least yearly.

The reverse osmosis system should include a means to prevent unsafe water from reaching the patient, such as divert to drain, in the event of a product water conductivity alarm. If the RO does not include a divert to drain feature, the facility staff must demonstrate the process to manually stop water flow to the dialysis machines and other equipment should the conductivity alarm sound.

Deionization (DI)

Deionization (DI) systems must be monitored continuously, using temperature-compensated resistivity monitors, to produce water of one megohm/cm or greater specific resistivity. The resistivity monitor must include audible and visual alarms and have a minimum sensitivity of 1.0 megohm-cm. Resistivity monitor readings should be recorded on a log sheet twice each treatment day. Except for home patients, there must be an automatic divert-to-drain system for any DI system in use. In all instances, an ultrafilter or other bacteria- and endotoxin-reducing device (validated endotoxin-retentive filter) must follow DI. When DI is used as the primary method of purification (reverse osmosis is not employed), or is used to polish RO water, chemical analysis to ensure that the requirements of AAMI 4.1.1 (Table 1) are met should be performed when the system is installed and at annual intervals thereafter.

Upon exhaustion of the first DI bed, operation may be continued for up to 72 hours on the second bed until a replacement bed is installed providing that the resistivity of the water exiting the second bed remains above 1 megohm-cm. Under no circumstances shall DI be used when the product water of the final bed has a resistivity below 1 megohm-cm.

When Deionization tanks are available for back-up use, actions must be taken to counter the tendency of DI to contribute bacterial contamination. The tanks may either be stored dry, placed on line post-RO to allow a low flow of water through them, or flushed daily. DI tanks should not be stored “wet” (filled with stagnant water). The date of DI tank exchange should be posted on the tank(s) and recorded in a log (all DI exchanges must be documented on the log).

Endotoxin-Retentive Filter

A validated endotoxin-retentive filter must follow DI and storage tanks. The endotoxin-retentive filters should have an opaque housing, and should be included in routine disinfection procedures. The filters should be monitored daily for pressure drops across the filter. In addition, test results should be drawn pre and post filter to show evidence that concentration of bacteria and endotoxin are reduced as stated by the manufacturer. This testing should be conducted whenever an endotoxin-retentive filter is originally installed, and whenever the specific type of endotoxin-retentive filter is changed. Results of pressure measurements and bacteria and endotoxin levels should be recorded in a log.

Direct Feed Water Distribution Systems

Direct feed water distribution systems typically include a means to return unused product water (product recovery) to the inlet or feed water side of the reverse osmosis system. In this type of application, dual check valves must be used to prevent retrograde flow of nonpurified water into the distribution loop. Additionally, the pressure at the end of the distribution loop must be monitored.

Water Storage Tank and Water Distribution Piping System

Water distribution systems should be configured as a continuous loop and designed to minimize bacterial proliferation and biofilm formation. Dead-end pipes and unused branches and taps should be eliminated. There should always be flow of water in the piping system at a minimum velocity of 3 ft/sec in a storage tank system and a minimum of 1.5 ft/sec in a direct feed system when the system is operating at peak demand. Responsible staff should be able to describe how the system is monitored to assure at least minimum flow during operation. A bacterial control device such as a validated endotoxin-retentive filter must always be installed following storage tanks.

Monitoring the water storage tank and water distribution piping system is accomplished by measuring bacterial growth and pyrogens, weekly, until a pattern of consistent compliance can be demonstrated. A “pattern of consistent compliance” is demonstrated by showing results within AAMI limits on weekly cultures for at least four weeks in a row. When a pattern of consistent compliance is demonstrated, the frequency of testing may be reduced to monthly. While the frequency of disinfection may vary with system design, disinfection must be performed at least monthly and should include the line between the outlet from the water distribution system and the back of the dialysis machine. Samples for water storage tank testing should be obtained at the first outlet to the distribution loop. Monitoring of the water distribution piping system should be accomplished by taking samples from the first and last outlets of the water distribution loop and the outlets supplying reuse equipment and bicarbonate concentrate mixing tanks. Changes to an existing system (i.e. changes to the RO membranes or installation of a new storage tank) would require weekly testing of the water distribution system until a pattern of consistent compliance can be demonstrated. It is also required that a chemical analysis of the reverse osmosis product water be conducted following membrane replacement to verify that the product water meets AAMI requirements for chemical contaminants. All bacteria and endotoxin results should be recorded on a log sheet. The log could be graphic reports or documents generated by the laboratory, or created by staff from laboratory data.

In the event a facility is using piping material in a water distribution system that is not indicated in the AAMI standards as compatible with the disinfectant in use, responsible staff must provide evidence that the disinfectant has been verified by the manufacturer of the disinfectant or the 510(k) licensed disinfection device as compatible with their distribution piping. Every dialysis facility must disinfect their water distribution system (including machine supply lines – the hose connecting the dialysis machine to the water loop) at least monthly.

Ultraviolet Irradiators

When used to control bacterial proliferation in water storage and distribution systems, ultraviolet irradiators (UV) shall be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm. The UV should be fitted with a calibrated ultraviolet intensity meter that is filtered to restrict its sensitivity to the disinfection spectrum and is installed in the disinfection chamber at point of greatest water depth from the lamp. The minimum dose of radiant energy for UV systems fitted with an ultraviolet intensity meter is 16 milliwatt-sec/cm^2. In the event that the UV system does not include a calibrated ultraviolet intensity meter, the minimum dose of radiant energy required is 30 milliwatt-sec/cm^2. UV shall be followed by a means of reducing endotoxin concentrations, such as a validated endotoxin-retentive filter in the purified water distribution system or reverse osmosis in the pretreatment cascade.

The UV system should be monitored by use of a meter to monitor intensity of the lamp, use of an on-line monitor that activates an alarm, or replacement of the lamp on a predetermined schedule. Lamps typically require replacement annually. Periodic cleaning of the quartz sleeve may also be required. A log sheet should be used to indicate that monitoring has been performed.

Ozone Generators

Ozone may be used for bacterial control in systems constructed from ozone-resistant materials. Ozone generators should be monitored for ozone output (ozone concentration in the water) at a level specified by the manufacturer. The ozone concentration should be measured by a test based on indigo trisulfonate chemistry or equivalent each time disinfection is performed. In addition, an ozone-in-ambient-air test should be conducted at an interval determined by facility policy to ensure compliance with the OSHA permissible exposure limit of 0.1 ppm. Results of monitoring should be recorded on a log sheet.

Bulk Acid Concentrate Storage and Distribution

Bulk acid concentrate storage tanks and associated plumbing should form an integral system to prevent contamination of the acid concentrate. The inlet and outlet connections should be secure and clearly labeled. There must be safety controls in place to prevent inadvertent mix-ups, tampering, or contamination of acid concentrates. Acid concentrate delivery piping should be labeled and color-coded red at the point of use. If more than one acid concentrate is centrally distributed to treatment stations, outlets must be clearly labeled with the acid type. Bicarbonate concentrate delivery piping should be color-coded blue at the point of use. Facilities should check daily to ensure that the appropriate acid and bicarbonate concentrate is connected to the corresponding concentrate delivery line.

Bicarbonate Mixing Systems

Bicarbonate mixing systems must include a system to prevent over mixing of bicarbonate. This may be accomplished by the use of a timer integrated into the mixing system for automatic cut-off, or by a policy requiring staff to monitor the mixing and cut it off immediately when the mix time is completed. *Dialysate* produced by new bicarbonate distribution systems should be monitored weekly for at least four consecutive weekly reports of acceptable levels. The frequency of monitoring may then be reduced to at least monthly. Facilities that use dip samplers for microbial monitoring must send duplicate samples to a laboratory at least annually to evaluate the accuracy of the testing done with the dip samplers.

There must be a log or other method of recording the preparation of concentrates, to include the number of bags or weight of the powder and the amount of purified water used. The log must include the concentrate formula produced, the volume of the batch, the lot numbers of powdered concentrate packages, the manufacturer of the powdered concentrate, the date and time of mixing, any test results, the person performing the mixing, the person verifying mixing and test results, and the expiration date. The use of pH as an indicator of proper dissolution is inappropriate for both acid and bicarbonate concentrates. Verifying mixing and test results means the staff member checks the results against the expected ranges for the test and does not release mixtures for use that test outside those ranges. Facility policy must stipulate the expected ranges for the test(s) used to verify correct mixing.

Facilities must have records of the manufacturer's instructions for the disinfection, maintenance and monitoring of the mixing system. Staff assigned responsibility for mixing concentrates and for maintenance and monitoring of these systems must be competent in following the manufacturer's directions for use. Facility policy must ensure the mixing tank is completely emptied between mixing batches of concentrate. The medical director and applicable staff must be able to describe safeguards in place to prevent mismatching dialysate components/machines when multiple dialysate proportioning ratios are in use. Label made by the facility are acceptable provided the required information is included. Furthermore, labels should be used to alert staff when disinfectant is in the mixing or distribution tank during disinfection. Central delivery systems must be cleared of bicarbonate solution at some point during the treatment day and rinsed clear. This is typically done at the end of the treatment day. The interval between disinfections should not exceed 1 week. Cleaning with a 1:34 solution of 5% acetic acid (i.e. distilled white vinegar) or 5% citric acid solution (if the manufacturer allows) is acceptable for removing precipitation or salt build-up from the piping systems.

CONCLUSION

In summary, the CMS conditions have adopted the AAMI RD52:2004 and RD62:2001 standards as regulation for water treatment equipment and dialysate standards for hemodialysis. This document is not meant to be a complete listing of the conditions for coverage, but rather a summary of key requirements that require close attention to assure compliance. Water purification equipment manufacturers, installers, and service people, as well as dialysis facilities must be in compliance with all requirements listed in the AAMI RD52:2004 and RD62:2001 standards.

REFERENCES

Association for the Advancement of Medical Instrumentation. Dialysate for Hemdialysis (ANSI / AAMI RD52:2004)

Association for the Advancement of Medical Instrumentation. Water Treatment Equipment for Hemodialysis Application (ANSI / AAMI RD62:2001).

Centers for Medicare and Medicaid Services (CMS), HHS. US Department of health and Human Services. Conditions for coverage for end stage renal disease facilities (42CFR, Part 494) Final Rule 2008.

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