CMS, FDA and AAMI Requirements for Bicarbonate Systems Made Simple

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by AmeriWater Incorporated

Background on the Standards

FDA , 21 CFR Sec. 876.5820(a) states that hemodialysis systems and accessories are Class II medical devices used for the treatment of patients with renal failure or toxemic conditions. Bicarbonate concentrate mixing and distribution systems (Bicarb Systems) are included in this category and must be cleared for market through the FDA 510K process. In addition to FDA requirements, ANSI/AAMI RD52 and ANSI/AAMI/ISO 23500:2011 and ANSI/AAMI/ISO 11663:2009 (a voluntary industry standard) defines several requirements for bicarb systems.

The ANSI/AAMI standards for hemodialysis have been adopted by the Centers for Medicare and Medicaid Services (CMS) as their conditions for coverage. 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. The latest CMS provisions, defined in 42 CFR Part 494, became effective October 14, 2008. These provisions establish the conditions for coverage of service under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility’s services may be covered. There are several requirements for bicarbonate concentrate mixing and distribution systems within these provisions.

This document summarizes the CMS requirements that will require close attention to ensure that Bicarbonate concentrate mixing and distribution systems are in compliance with the CMS Conditions for Coverage and FDA regulations.

Materials Compatibility

The components used in bicarbonate concentrate mixing and distribution systems (including mixing and storage tanks, pumps, valves, and piping) must be fabricated from materials that do not interact chemically or physically with the concentrate so as to affect its purity. Furthermore, the materials must be compatible with the chemicals or processes used to disinfect the equipment. Some examples of acceptable materials include plastic and appropriate stainless steel. It is strictly prohibited to use materials known to cause toxicity in hemodialysis, such as copper, brass, galvanized material and aluminum.

Design Requirements

Bicarbonate concentrate mixing and distribution systems require a purified water source, a suitable drain, and a ground fault protected electrical outlet. The mixing tank must be designed to drain completely, for example, a tank with a sloping bottom and a drain at the lowest point. The tank must also have a tight fitting lid, and must be designed to allow all internal surfaces to be disinfected and rinsed. Because of the highly corrosive nature of the concentrate solutions, the system must be designed and maintained to prevent corrosion. The mixing tank must also include a system to prevent over-mixing, such as a timer integrated into the mixing system for automatic cut-off.

High and low level alarms are not required on the mixing tank, but may be incorporated to help prevent overfilling or to signal low tank conditions. Translucent tanks are recommended to allow users to see the liquid level. Sight tubes should not be used because of the potential for bacteria, algae, and fungi growth.

Distribution tanks must be equipped with a conical or bowl shaped bottom, tight fitting lids, a spray mechanism, high and low level alarms and 0.2 micron hydrophobic vent filters. There are two common configurations for distribution. Those are gravity feed and pressurized systems. Gravity feed systems require an elevated tank and pressurized systems use a pump and motor and do not require an elevated tank. Bicarbonate concentrate delivery piping must be color-coded blue at the point of use, and all joints must be sealed to prevent leakage of concentrate.

Monitoring & Maintenance Requirements

Bicarbonate concentrate mixing and distribution systems must be monitored according to the manufacturer's recommendations. The mixing system must be completely emptied, cleaned and disinfected at least weekly. Bicarb distribution systems must be disinfected at least weekly. The distribution systems must be purged of bicarbonate concentrate before disinfection. Furthermore, the distribution system must be cleared of bicarbonate solution at some point during the treatment day and rinsed clear. This is generally done at the end of the treatment day.

Bacteria and endotoxin testing must be performed weekly until a pattern of consistent compliance can be demonstrated (four consecutive compliant results). The frequency of monitoring may then be reduced, but must be performed at least monthly. If elevated levels of bacteria or endotoxin are found, the system must be evaluated, appropriate action taken (including disinfection), and the frequency of monitoring must be increased until a pattern of consistent compliance can be demonstrated.

References:

Association for the Advancement of Medical Instrumentation. Concentrates for Hemodialysis and Related Therapies (ANSI / AAMI / ISO 13958:2009).

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

Association for the Advancement of Medical Instrumentation. Guidance for the Preparation and Quality Management of Fluids for Hemodialysis and Related Therapies (ANSI / AAMI / ISO 23500:2011).

Association for the Advancement of Medical Instrumentation. Water for Hemodialysis and Related Therapies (ANSI / AAMI / ISO 13959:2009).

Association for the Advancement of Medical Instrumentation. Water Treatment Equipment for Hemodialysis Applications (ANSI / AAMI RD62:2006).

Association for the Advancement of Medical Instrumentation. Water Treatment Equipment for Hemodialysis Applications and Related Therapies (ANSI / AAMI / ISO 26722:2009).

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

US Food and Drug Administration (FDA). US Department of Health and Human Services. Hemodialysis system and accessories (21 CFR 876.5820) April 1, 2009.

Compliance Checklist

This checklist has been compiled by AmeriWater to help you quickly determine if your Bicarbonate system meets the latest standards.

Yes	No	**Bicarbonate Concentrate System**
☐	☐	Materials compatible with concentrates & disinfectants. (No copper, brass, galvanized material or aluminum)
☐	☐	Bicarb system has purified water source, suitable drain, and GFI receptacle.
☐	☐	Translucent tanks (no sight tubes).

Yes	No	**Mix System**
☐	☐	Designed to drain completely (cone bottom tank with drain at lowest point)
☐	☐	Tank has a tight fitting lid (no opening for paddle type mixer).
☐	☐	All internal surfaces can be disinfected & rinsed (spray ball).
☐	☐	Includes a system to prevent over-mixing (such as a mix timer).

Yes	No	**Distribution System**
☐	☐	Tank with a conical or bowl shaped bottom (drain at lowest point).
☐	☐	Tank has a tight fitting lid.
☐	☐	All internal surfaces can be disinfected & rinsed (spray ball).
☐	☐	Tank includes high and low level alarms.
☐	☐	Includes 0.2 micron hydrophobic vent filters.
☐	☐	Bicarbonate delivery piping color-coded blue at the point of use.

Yes	No	**Monitoring & Maintenance**
☐	☐	Mixing system completely emptied and disinfected at least weekly.
☐	☐	Distribution system purged of bicarb solution & disinfected at least weekly.
☐	☐	Distribution system cleared of bicarb solution & rinsed clear daily.
☐	☐	Bacteria and endotoxin testing completed at least monthly.

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