



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-44-ESRD

DATE: June 26, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Use of Portable Reverse Osmosis (RO) Units and Block Carbon

Memorandum Summary

- Portable Reverse Osmosis Units that meet Association for the Advancement of Medical Instrumentation (AAMI) water quality standards, as incorporated by reference in the End Stage Renal Disease (ESRD) Condition for Coverage (CfC) at 42 CFR Section 494.40, may be used in outpatient dialysis facilities.
- ESRD Surveyors should follow the ESRD Core Survey process in conjunction with this guidance for use of portable RO units and block carbon in outpatient dialysis facilities.

Portable Reverse Osmosis (RO):

A central water treatment and delivery system remains the traditional method for water purification for multiple hemodialysis machines in a dialysis facility. However, improvements in the manufacturing of small portable water treatment devices (i.e. portable reverse osmosis units) have created changes in options for water treatment in small chronic dialysis facilities. Consultation by the Centers for Medicare & Medicaid Services (CMS) with members of AAMI has revealed that the use of portable RO units in small chronic dialysis facilities is an alternative method of delivering AAMI quality water to the point of use (hemodialysis machine), if the portable ROs are appropriately constructed, monitored, and maintained. The portable RO unit must produce the water quality defined in American National Standard Institute (ANSI)/AAMI RD52:2004 as incorporated by reference in 42 CFR Section 494.40 Condition: Water and dialysate quality. The portable RO must be operated in accordance with manufacturer's directions for use.

Block Carbon:

The water provided to a portable RO unit must be dechlorinated by means of a redundant carbon system (primary and secondary carbon tanks with a sample port between) that meets the AAMI requirement (as incorporated by reference in the ESRD CfC) of 10 minutes empty bed contact time (EBCT) or equivalent. This is vital to patient safety.

Some portable RO units currently available are marketed with a separate dual block carbon system (condensed carbon rather than granular activated carbon) for chlorine removal. According to the AAMI members consulted, if block carbon is used to supply dechlorinated water to a portable RO unit, there must be evidence from the manufacturer that the system attains equivalency to the 10 minute EBCT requirement, based on performance data of the block carbon. In addition, there must be one dual block carbon system per portable RO and each portable RO must supply one hemodialysis machine, per manufacturer's directions. These requirements are supported by the following excerpts from ANSI/AAMI RD52 (incorporated by reference into the CfC) and the International Standards Organization (ISO), which AAMI currently supports.

ANSI/AAMI RD52:2004 Annex E Section E.3.4

“...Where practical, portable water treatment systems should include two carbon adsorption beds in series, which together provide a minimum of 10 minutes Empty Bed Contact Time (EBCT). Initially, the requirement for two carbon beds in series was waived for portable dialysis systems because of the impracticality of providing these features while retaining the portability of the system. However, alternative technologies are now available that allow portability while retaining the redundancy associated with two carbon beds in series. Some portable reverse osmosis systems employ one granular activated carbon (GAC) tank followed by a dense carbon block as a polisher. Alternatively, two carbon block filters in series could be used. These configurations should provide the equivalent of a 10-minute EBCT based on the performance of the dense carbon block as stated by the manufacturer as long as only one dialysis machine is attached to the portable water treatment system. Block carbon filters used in this application should not compromise the feed water requirements specified by the manufacturer of the reverse osmosis system. Testing to demonstrate that the level of chloramine or total chlorine is less than 0.1 mg/L should be performed before each treatment using a sample obtained from a port located between the two beds or filters. The equipment should be allowed to operate for at least 15 minutes before the test sample is drawn.”

ANSI/AAMI/ISO 26722 Section 4.2.8

“...When other forms of carbon or granular activated carbon with an iodine number of less than 900 are used, the manufacturer shall provide performance data to demonstrate that each adsorption bed has the capacity to reduce the total chlorine concentration in the feed water to less than 0.1 mg/l when operating at the maximum anticipated flowrate for the maximum time interval between scheduled testing of the product water for total chlorine.”

When using the portable ROs and accompanying carbon systems, the facility must be in compliance with 42 CFR Section 494.40 Condition: Water and dialysate quality.

Monitoring of each portable RO unit must include testing for total chlorine before each treatment, monthly microbiological monitoring of cultures and endotoxins, and at least annual testing of chemical quality of the product water. Monitoring must also include daily function monitoring and recording of the portable RO unit for percent rejection and the water quality produced by conductivity or total dissolved solids (TDS).

Surveyors should continue to follow the guidance of the ESRD Core Survey process and tools, expanding their review for the above-mentioned specific requirements, when reviewing a facility using portable ROs. During an initial certification survey, the Surveyor should confirm that the facility's policies address all of these special requirements.

Contact: Please email any questions to the ESRD mailbox: ESRDQuestions@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management