

# *Dialysis Water and Dialysate Recommendations: A User Guide*



Glenda M. Payne



# *Dialysis Water and Dialysate Recommendations: A User Guide*

Glenda M. Payne

This publication is intended to be a helpful information resource,  
and reflects the expert advice and views of the editor.  
It is not to be construed as an interpretation of AAMI standards,  
nor does it constitute legal or regulatory advice.

*Published by*

Association for the Advancement of Medical Instrumentation  
4301 N. Fairfax Drive, Suite 301  
Arlington, VA 22203-1633  
[www.aami.org](http://www.aami.org)

© 2014 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at [www.aami.org](http://www.aami.org) or contact AAMI at 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: +1-703-525-4890; Fax: +1-703-525-1067.

Printed in the United States of America

ISBN 1-57020-518-3

# Table of Contents

|                                                                                                                                      | <i>Page</i> |
|--------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Foreword . . . . .                                                                                                                   | v           |
| Chapter 1. Introduction . . . . .                                                                                                    | 1           |
| Chapter 2. Index by Tag Number and Identifier . . . . .                                                                              | 7           |
| Chapter 3. Water and Dialysate Quality Crosswalk from the CMS Regulation<br>to the Applicable ANSI/AAMI ISO Recommendation . . . . . | 11          |
| Chapter 4. § 494.100 Condition: Care at Home . . . . .                                                                               | 149         |
| Chapter 5. Validation . . . . .                                                                                                      | 163         |
| Chapter 6. Terms and Definitions—Comparison Table . . . . .                                                                          | 169         |
| Chapter 7. Comparison of Tables and Figures . . . . .                                                                                | 189         |
| Table 1 from RD52:2004 with Tables 1 and 2 from ISO 23500 . . . . .                                                                  | 190         |
| Table 2 from RD52:2004 with Table B.1 from ISO 23500. . . . .                                                                        | 192         |
| Table 3 from RD52:2004 with Table B.2 from ISO 23500 . . . . .                                                                       | 194         |
| Table 4 from RD52:2004 with the table in Annex C.1 from ISO 23500. . . . .                                                           | 195         |
| Figure 1 from RD52:2004 . . . . .                                                                                                    | 201         |
| Figure 2 from RD52:2004. . . . .                                                                                                     | 202         |
| Tables 3, 4, and 5 from ISO 23500. . . . .                                                                                           | 203         |
| Table C.2 from ISO 23500 . . . . .                                                                                                   | 205         |
| Chapter 8. Table of Differences . . . . .                                                                                            | 209         |



# Foreword

It has long been known that potable water, suitable for drinking by the general population, can contain substances harmful to dialysis patients if that water is used directly to prepare dialysate. As early as the 1960s, the presence in dialysate of chemicals commonly found in drinking water was being linked to the development of a number of hemodialysis-associated comorbidities, including anemia, bone disease and neurological abnormalities. To help protect patients from injury, maximum allowable levels for a range of chemical contaminants, as well as for bacteria, were included in the first edition of the American National Standard for Hemodialysis Systems published by AAMI in 1981. An appendix to the standard provided guidance to dialysis professionals on how to treat drinking water to ensure compliance with the quality standard.

AAMI standards are not static documents; they are subject to regular review and revision as the related science and technology advance. Thus, the hemodialysis systems standard evolved over the years as our understanding of the risks posed to hemodialysis patients by contaminants in drinking water increased and water treatment practices changed. For example, introduction of the *Limulus* amebocyte lysate assay allowed a maximum limit for endotoxin to be added to the water quality standard in 2001 as we became more aware of the role microbiological contaminants play in dialysis-associated inflammation. Other changes were spurred by changes in water treatment practices, such as the replacement of free chlorine by monochloramine for microbial control in drinking water in response to the Environmental Protection Agency's introduction of an upper limit for trihalomethanes. These changes led to a series of revisions to the AAMI hemodialysis systems standard, culminating in the publication of separate standards for the treatment of water and the preparation of dialysate in 2001 and 2004, respectively. Finally, in 2011 those AAMI standards were replaced by adoption of a comprehensive suite of five standards developed by the International Organization for Standardization (ISO) that covered all aspects of fluid preparation for hemodialysis and related therapies and which was based on the existing AAMI standards. It is important to recognize that different parts of that suite of standards are directed at different audiences. Standards setting forth requirements for devices and commercially produced fluids, such as concentrates, are directed at manufacturers of those items, while standards setting forth the quality requirements of water and the dialysate prepared from that water, as well as guidance on achieving those quality requirements are primarily directed at the dialysis professionals responsible for delivering the actual dialysis treatments.

The Centers for Medicare and Medicaid Services (CMS) is the largest funder of dialysis therapy in the United States. As part of its oversight activities, CMS requires providers of dialysis to comply with certain performance criteria intended to promote improved outcomes and ensure the safety of dialysis patients. These requirements are set forth in the CMS Conditions for Coverage for End Stage Renal Disease Facilities (the CFC). Following publication of the original AAMI

hemodialysis standard in 1981, CMS—then known as the Health Care Financing Administration—made compliance with the water quality standard part of the CfC. That requirement was limited to complying with the maximum allowable contaminant levels and the guideline for monitoring water purity. Nevertheless, it is likely that inclusion of the AAMI water quality standard in the CfC promoted widespread acceptance of the standard and helped protect hemodialysis patients from harm during a time when patient numbers were increasing rapidly and significant changes were occurring in municipal water treatment practices.

The CfC is published as a Federal Regulation and changing it can be a long process involving publication of a proposed new regulation, a period of public comment on that proposal, publication of responses to the public comments, review by other governmental entities, such as the Office of Management and Budget, and publication of a final regulation. In 2008, 30 years after its initial publication, CMS published a major revision of the CfC. In that revision, the simple requirement that the water used for hemodialysis comply with the AAMI standard was replaced by incorporation of essentially all of the existing AAMI guideline for dialysate preparation (ANSI/AAMI RD52:2004), including fluid quality, water treatment equipment and monitoring guidelines. In addition, CMS published an Interpretive Guidance document intended to promote consistent application of the regulations contained in the CfC.

The AAMI standards have continued to evolve since the CMS CfC were published in 2008. That evolution has inevitably led to differences between the standards and the CfC, such that the CfC no longer mirrors exactly the recommendations contained in the current AAMI standards. Discrepancies involve both performance criteria, such as the maximum allowable levels for bacteria and endotoxin in water and dialysate, and recommended approaches to maintaining compliance with the fluid quality standards, with the current AAMI standards emphasizing compliance through the development and implementation of a facility-specific quality management program in contrast to the prescriptive approach included in ANSI/AAMI RD52:2004 and adopted in the CfC. As a consequence, we now have two diverging sets of documents that increasingly create problems for dialysis facilities, dialysis professionals, and the surveyors responsible for ensuring compliance with the CfC. A reader might ask why the CMS cannot deal with this problem by simply referencing the current edition of the AAMI standard in the CfC rather than including verbatim long sections of the standard. Alas, that action would have the effect of leaving AAMI in the position of writing Federal Regulation, since significant changes could be made to the standard without any Federal review or oversight; a clearly untenable position for a government agency.

This book, by an author with experience in writing both the CMS CfC and the AAMI standards, addresses the challenges posed by the existence of two sets of documents by systematically comparing the current AAMI standards with the CfC and the CMS Interpretive Guidance. The comprehensive tables clearly identify where differences occur between the documents and allow the reader to understand what is required by CMS, where the AAMI standards recommend more rigorous practices that would also be acceptable to CMS, and where the prescriptive approach generally favored by CMS makes it difficult to adopt more flexible practices recommended in the AAMI standards. Finally, the analysis undertaken in this book shows the reader the likely future direction of fluid preparation for hemodialysis and its related therapies. Altogether, this work makes an important contribution to reducing conflict between the surveyors and the surveyed and will help advance the cause of patient safety.

Richard A. Ward  
Past user co-chair, AAMI Renal Disease and Detoxification Committee

## CHAPTER 1

# Introduction

### Purpose and Intended Use of This Document

The purpose of this document is to provide a side-by-side comparison of the Centers for Medicare & Medicaid Services (CMS) regulations and interpretive guidance for the Condition of Water and Dialysate Quality and the section related to water and dialysate from the Condition of Care at Home with the suite of ANSI/AAMI/ISO Standards that have been adopted by AAMI as replacement for ANSI/AAMI RD52:2004. The suite of Standards includes the following:

- ANSI/AAMI/ISO 23500:2011, *Guidance for the preparation and quality management of fluids for hemodialysis and related therapies*;
- ANSI/AAMI/ISO 11663:2009, *Quality of dialysis fluid for hemodialysis and related therapies*;
- ANSI/AAMI/ISO 13958:2009, *Concentrates for hemodialysis and related therapies*;
- ANSI/AAMI/ISO 13959:2009, *Water for hemodialysis and related therapies*; and
- ANSI/AAMI/ISO 26722:2009, *Water treatment equipment for hemodialysis applications and related therapies*.

This document is provided as a tool for individuals who have responsibility for the oversight and operation of hemodialysis facilities to use in clarifying their understanding of the regulatory requirements and the current AAMI guidance. In those areas where the ANSI/AAMI/ISO Standards are more stringent, dialysis facility medical directors and technical supervisors may choose to follow the more stringent standard. In the few areas where the CMS regulation is more stringent, the regulation must be followed to maintain compliance.

### Background

In February 2005, CMS issued a Notice of Proposed Rule Making (NPRM) to completely revise the Conditions for Coverage (CfC) for End Stage Renal Disease (ESRD) outpatient dialysis facilities. The NPRM included a proposal that the Association for the Advancement of Medical Instrumentation (AAMI) publication, *Dialysate for Hemodialysis*, ANSI/AAMI RD52:2004 (RD52) be adopted as part of the ESRD regulations.

The renal community supported the proposed inclusion of RD52, and the AAMI Renal Disease and Detoxification Committee (RDD) collaborated with CMS to edit this document for clarity and to facilitate its use as regulation and interpretive guidance. CMS published the final rule defining the CfC for ESRD on April 15, 2008, with an implementation date of October 14, 2008.

The final rule language published in the Code of Federal Regulations (CFR) states the following:

**CFR §494.40 Condition: Water and dialysate quality**

The facility must be able to demonstrate the following:

- (a) *Standard: Water purity.* Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, “Dialysate for hemodialysis,” ANSI/AAMI RD52:2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html). Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 4301 N. Fairfax, Suite 301, Arlington, VA 22203-1633).

## Process of Development of the CMS Interpretive Guidance Document

To promote consistency in the application of this rule, as well as to allow dialysis facility staff to understand what to expect in the survey process for water and dialysate quality, CMS staff, including the editor of this comparative document, used the language from RD52 to create specific “V-tags,” identifiers used in survey computer software, to specify the “regulation” and corresponding “interpretive guidance.” This process resulted in the incorporation of the RD52 recommendations into the CMS document entitled, “ESRD Interpretive Guidance,” which is available electronically at [www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf).

As explained in the interpretive guidance column in this document at V175:

“This Condition incorporates by reference the Association for the Advancement of Medical Instrumentation’s (AAMI’s), “American National Standard for Dialysate for Hemodialysis,” 2004 (RD52:2004), and has the authority of regulation. This AAMI document references portions of the “American National Standard for Water Treatment Equipment for Hemodialysis Applications (RD62:2001) as the specifications for various water treatment components. The referenced portions of RD62:2001 are also incorporated by reference, and have the authority of regulation. When “should” or “recommend” are included in the AAMI language adopted as regulation (i.e., the language in the “Regulation” column), the referenced item or practice must be in use or in place.”

And at V176:

“Some explanatory language from ANSI/AAMI RD52:2004 and from the Annex to that document has been included . . . as guidance to surveyors. While the language in the “Regulation” column is taken exactly from the document, the AAMI language in the Surveyor Guidance area has been edited for clarity, brevity and to decrease redundancy. The order of the AAMI document has in some cases been altered, to organize requirements to more closely follow the survey process.”

The language in the “Regulation” column in the CMS document entitled, “Interpretive Guidance,” is taken directly from the Standard RD52 with rare insertions of a word or words for clarity indicated by the use of brackets, deletions of extraneous language, and transfer of explanatory detail to the column labeled “Interpretive Guidance.” Language in the “Interpretive Guidance” column in the CMS document comes from the transfer of explanatory detail from the RD52 standard, from the RD52 Annex, and includes “Additional Guidance” developed by CMS to clarify potential surveyor or provider questions. The order of the CMS Interpretive Guidance document follows the survey process, which required some alterations to the order of RD52.

In the Condition of Care at Home, CMS chose to incorporate language from AAMI RD52:2004/Annex C: Special Considerations for Home Dialysis into the Interpretive Guidance, while emphasizing that water treatment systems for home hemodialysis patients must produce water that meets the AAMI standards and the requirements specified in the Condition of Water and Dialysate Quality. As stated in the Interpretive Guidance at V595:

“The ANSI/AAMI RD52:2004, “Dialysate for Hemodialysis,” has been incorporated by reference into these regulations, as stated in § 494.40 Condition for Water and dialysate quality. CMS interprets this reference as inclusive of the “Amendment 1 to ANSI/AAMI RD52:2004: Annex C Special Considerations for Home Hemodialysis.” This document addresses concerns particular to the home hemodialysis setting. Be aware that many of the provisions of RD52:2004, as outlined in the Condition for Water and dialysate quality at § 494.40 pertain to the home hemodialysis setting when conventional water treatment equipment is used for water purification. The review of conventional water treatment equipment should reference the requirements listed in that Condition for the specific components in use in the home setting. Additional pertinent excerpts from ANSI/AAMI RD52:2004 Annex C, which clarify specific home hemodialysis issues, are [listed at V595].”

The AAMI RDD Committee was involved in the construction of the Water and Dialysate Quality portions of the Interpretive Guidance document and reviewed several versions in the development process. The editor of this comparative document was employed by CMS from 2002–2011 and coordinated the process of incorporation of the language from RD52 into the CMS Interpretive Guidance document.

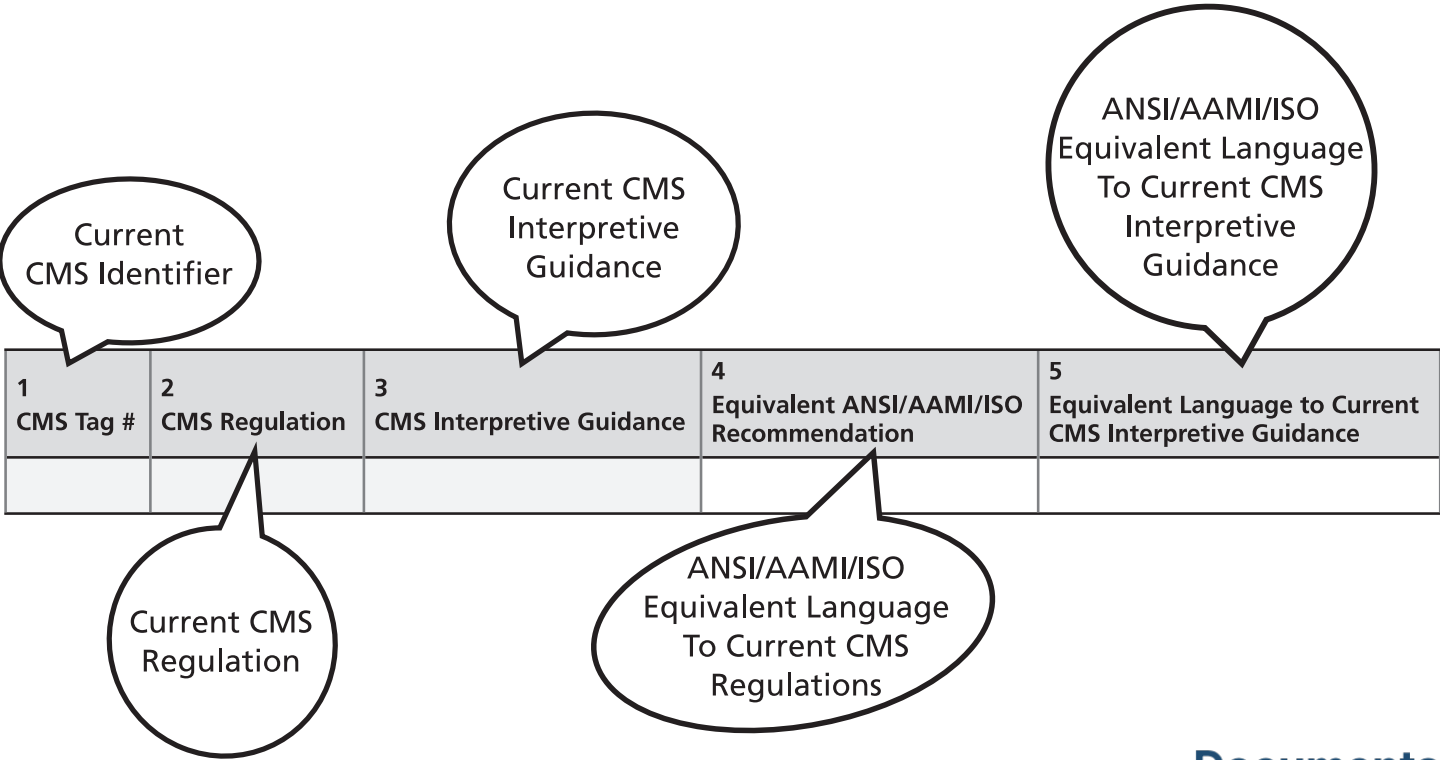
## Processes for Updating AAMI Documents Versus Updating CMS Regulations

Regulatory agencies typically adopt very specifically referenced documents. If CMS were to adopt “ANSI/AAMI RD52:2004 and subsequent revisions of this document,” CMS would be giving the referenced entity (in this case AAMI) regulatory authority: the power to create regulations. CMS adopted a specific AAMI document, ANSI/AAMI RD52:2004, as part of the ESRD regulations finalized in 2008. While AAMI honors a commitment to review each of their standards and recommended practice documents every 5 years and to make revisions as indicated, CMS must go through a formal rule-making process to change from one specific document adopted by reference to another. The current CMS ESRD regulations were published as a proposed rule in 2005 and included a proposal to adopt ANSI/AAMI RD52:2004 by reference. During the 38 months required to complete and publish the final rule, AAMI updated RD52 in order to harmonize with the ISO Standards. Because the updated AAMI document was not part of the proposed CMS rule, the older document (RD52:2004) was adopted as regulation in the final rule.

To change the regulatory requirement, CMS would have to publish a notice of proposed rule-making (NPRM), allow a 30–90 day comment period, review the comments, and develop and publish a final rule. This process typically takes at least 18 months, and as noted with the ESRD rule, can take longer than three years. At the time of publication of this comparative document, the NPRM process to update the CMS Condition for Water and Dialysate Quality to reflect AAMI’s adoption of the relevant ANSI/AAMI/ISO Standards as replacement for AAMI RD52 had not been initiated.

Development of this Document

AAMI considers RD52:2004 to be obsolete and that document is no longer available for purchase. Dialysis facility staff members are aware that AAMI has updated their guidance for dialysis water treatment and dialysate preparation and delivery and can be confused regarding what CMS currently requires in this area. While in most cases updates to AAMI guidance documents result in more stringent recommendations, the ISO Standards include some recommendations that could be considered less stringent than those detailed in RD52. This document was developed to allow a side-by-side comparison of RD52 as adopted by CMS as regulation with concomitant language from the ANSI/AAMI/ISO Standards. The construction of this document deliberately follows the same pattern as was used for constructing the CMS Interpretive Guidance document, with the original three column document (for V-tag, Regulation, and Interpretive Guidance) expanded to five columns. As illustrated below, the first three columns duplicate the CMS Interpretive Guidance document, with the only change being the movement of tables to a separate section due to the space limitations. Note that the columns including language from the CMS document are also shaded. The language in the fourth column is extracted from the relevant ANSI/AAMI/ISO Standards and addresses the same area as described by the CMS document in the second and third columns. Because some of the specific recommendations are not in the body of the ANSI/AAMI/ISO Standards but only in the Annexes of those Standards, it was sometimes necessary to include



language from the Annexes in the fourth column. When relevant language exists in the Standard, it is placed first in the fourth column. Language from the Annexes then follows the language from the Standard in that fourth column, when applicable. The fourth column can be viewed as specific and potentially usable as “regulation,” while the language in the fifth column, most of which is also extracted from the ANSI/AAMI/ISO Standards and their Annexes, should be viewed as broad and explanatory. “Additional Guidance,” when present in the third column, was edited for relevance to the ANSI/AAMI/ISO Recommendations and included in the fifth column.

In developing the section for comparison of the CMS requirements applicable to home hemodialysis, a slightly different format was used. Because the CMS Interpretative Guidance document did not place the language from AAMI’s RD52:2004 Annex C into the “Regulation” column, this portion of this comparative document does not include a “comparative” column for regulation. This four-column document matches recommendations from ANSI/AAMI/ISO 23500 Annex F Special Considerations for Home Hemodialysis with the equivalent requirements from AAMI’s RD52:2004 Annex C.

## Guidance for the Changes

A “Table of Differences between CMS (ANSI/AAMI RD52) and ANSI/AAMI/ISO Standards” has been provided to clearly define the differences between these documents. The table provides key information regarding how users should respond to gaps between the CMS regulation and ANSI/AAMI/ISO Standards. It is hoped that this table will facilitate interpretation of the cross-reference sections of the booklet.

## Next Steps: Validation of System Performance

Where the RD52:2004 document provided specific frequencies for monitoring the water treatment and dialysate preparation and delivery systems, the ANSI/AAMI/ISO Standards mandate the use of validation and revalidation to determine frequencies for monitoring as well as the limits for various systems. Section 6 of the ANSI/AAMI/ISO 23500 Standard describes Validation of System Performance, and Annex E: Validation provides information and guidance. These sections were not incorporated into the comparative document but are duplicated from ANSI/AAMI/ISO 23500 here for reference. As facilities choose to adopt the more stringent microbial and endotoxin standards detailed in the ANSI/AAMI/ISO Standards, it will be necessary for responsible staff members to develop competence in the validation steps described in these sections.



## CHAPTER 2

# Index by Tag Number and Identifier

| V Tag  | Identifier (From ANSI/AAMI RD52:2004)                             | Page |
|--------|-------------------------------------------------------------------|------|
| V175   | Condition for Coverage: Water and dialysate quality               | 12   |
| V176   | Water purity: ANSI/AAMI RD52:2004                                 | 14   |
| V177   | Maximum level of chemical contaminants in water/chemical analysis | 16   |
| V178   | Bacteriology of water-maximum and action limits                   | 22   |
| V179   | Bacteriology of water-medical director responsible                | 26   |
| V180   | Bacteriology of conventional dialysate-maximum and action levels  | 27   |
| V181   | Bacteriology of ultrapure dialysate                               | 30   |
| V182   | Equipment-general: back up plan                                   | 34   |
| No tag | Informational tag re water purification systems -general          | 36   |
| V184   | Environment: secure and restricted                                | 39   |
| V185   | Environment: access to ports/meters                               | 39   |
| V186   | Environment: alarms in treatment area                             | 40   |
| V187   | Environment: schematic diagrams/labels                            | 40   |
| V188   | Sediment filters: configuration and monitoring                    | 41   |
| V189   | Cartridge filters: configuration and monitoring                   | 44   |
| V190   | Softeners: automatically regenerated/timers/salt/salt level       | 45   |
| V191   | Softeners: testing hardness/log                                   | 48   |
| V192   | Carbon adsorption: two tanks/sample ports                         | 49   |
| V193   | Carbon adsorption: banks of tanks                                 | 51   |

| V Tag  | Identifier (From ANSI/AAMI RD52:2004)                                            | Page |
|--------|----------------------------------------------------------------------------------|------|
| V194   | Carbon adsorption: Iodine #900/replacement                                       | 52   |
| V195   | Carbon adsorption: 10 minutes Empty Bed Contact Time (EBCT)                      | 54   |
| V196   | Carbon adsorption: monitoring, testing frequency                                 | 54   |
| V197   | Carbon adsorption: action if first test positive                                 | 59   |
| V198   | Chemical injection systems                                                       | 60   |
| V199   | Reverse Osmosis (RO): meets AAMI/monitored, recorded on log                      | 64   |
| V200   | RO: monitor/alarm/prevent use of unsafe water                                    | 66   |
| V201   | RO: chemical analysis: frequency                                                 | 70   |
| V202   | Deionization (DI): continuous monitoring resistivity/logged 2 x day              | 71   |
| V203   | DI: alarms/divert to drain                                                       | 75   |
| V204   | DI: require carbon pre/ultrafiltration post                                      | 76   |
| V205   | DI: polish or back up                                                            | 77   |
| V206   | DI: chemical analysis: frequency                                                 | 77   |
| V207   | Ultrafiltration: effective/opaque housing/monitoring                             | 78   |
| V208   | Water storage and distribution: design                                           | 81   |
| V209   | Water storage tank: shape/vent/disinfected/filter post                           | 84   |
| V210   | Water storage: monitoring                                                        | 85   |
| V211   | Water distribution systems: continuous flow rates/no dead ends                   | 86   |
| V212   | Water distribution systems: no added burden                                      | 89   |
| V213   | Water distribution system: culture/LAL/sample sites/frequency(new)/log           | 89   |
| V214   | Bacterial control devices: ultraviolet irradiators: UV dose                      | 92   |
| V215   | Ultraviolet irradiators: filters post                                            | 94   |
| V216   | Ozone generators: system requirements/monitoring                                 | 94   |
| V217   | Hot water disinfection systems: temp/time/follow Directions for Use (DFU)/piping | 97   |
| V218   | Hot water disinfection systems: monitoring                                       | 98   |
| V219   | Strategies for bacterial control: disinfect monthly/disinfection dwell           | 99   |
| V220   | Strategies for bacterial control: machine supply line disinfected                | 103  |
| No tag | Informational tag re: concentrate preparation                                    | 104  |

| V Tag | Identifier (From ANSI/AAMI RD52:2004)                                                    | Page |
|-------|------------------------------------------------------------------------------------------|------|
| V222  | Acid bulk storage tanks: safety controls                                                 | 105  |
| V223  | Concentrate preparation: materials compatibility                                         | 106  |
| V224  | Mixing systems: water/drain/electric                                                     | 106  |
| V225  | Mixing systems: safe environment/Personal Protective Equipment (PPE)                     | 109  |
| V226  | Mixing systems: follow DFU/monitor/PM/log/sanitization                                   | 110  |
| V227  | Mixing systems: self designed                                                            | 111  |
| V228  | Mixing systems: labeling                                                                 | 111  |
| V229  | Mixing systems: permanent record/verification testing                                    | 113  |
| V230  | Mixing systems: cleaning                                                                 | 114  |
| V231  | Acid concentrate mixing systems: empty completely//prevent corrosion                     | 115  |
| V232  | Bicarbonate concentrate mixing systems: empty/disinfect/prevent corrosion                | 116  |
| V233  | Bicarbonate concentrate mixing systems: storage/use time limits/min combine              | 117  |
| V234  | Bicarbonate concentrate mixing systems: not overmixed                                    | 118  |
| V235  | Additives: mixing spikes                                                                 | 119  |
| V236  | Additives: labeling spiked jugs/labeling if for specific patient                         | 120  |
| V237  | Concentrate distribution: materials compatibility                                        | 121  |
| V238  | System configurations: elevated tanks                                                    | 122  |
| V239  | Bicarbonate concentrate distribution systems: weekly disinfect/dwell times/concentration | 123  |
| V240  | Bicarbonate concentrate distribution systems: use of Ultraviolet Irradiation (UV)        | 124  |
| V241  | Bicarbonate concentrate distribution systems: ozone disinfection                         | 125  |
| V242  | Concentrate distribution: Bicarbonate monitoring initially                               | 126  |
| V243  | Concentrate distribution: bicarbonate jugs rinsed daily/stored dry                       | 127  |
| V244  | Bicarbonate concentrate distribution systems: jug disinfection                           | 127  |
| V245  | Acid concentrate distribution systems: labeled & color-coded red                         | 128  |
| V246  | Bicarbonate concentrate distribution systems: color coded blue & sealed                  | 129  |
| V247  | Concentrate outlets: separate/labeled/connection safety                                  | 130  |
| V248  | Dialysate proportioning: match ratio: all concentrate/machine                            | 131  |

| <b>V Tag</b> | <b>Identifier (From ANSI/AAMI RD52:2004)</b>                                    | <b>Page</b> |
|--------------|---------------------------------------------------------------------------------|-------------|
| V249         | Dialysate proportioning: match machine configuration with ratio in use          | 133         |
| V250         | Dialysate proportioning: monitor pH/conductivity                                | 134         |
| No tag       | Informational tag; re monitoring water & dialysate systems                      | 136         |
| V252         | Microbial monitoring methods: monthly water samples/method                      | 137         |
| V253         | Microbial monitoring methods: monthly dialysate sample/collection/<br>frequency | 139         |
| V254         | Microbial monitoring methods: samples before disinfection                       | 141         |
| V255         | Microbial monitoring methods: repeat cultures                                   | 141         |
| V256         | Heterotrophic plate count: dip samplers require Quality Control                 | 142         |
| V257         | Heterotrophic plate count: refrigerate if delay > 2 hrs/no calibrated loop      | 143         |
| V258         | Bacterial endotoxin test: LAL testing in house: how to                          | 145         |
| V259         | Personnel: Policies & procedures                                                | 146         |
| V260         | Personnel: training program/periodic audits                                     | 147         |
| V277         | In-center preconfigured HD: meets AAMI RD52                                     | 148         |
| No tag       | Condition for Coverage: Care at home                                            | 149         |
| V593         | Monitor water/dialysate including on-site evaluation                            | 150         |
| V594         | Preconfigured HD system: testing water/dialysate follow DFU/FDA                 | 153         |
| V595         | Meet RD52:2004 testing and other requirements                                   | 154         |

CHAPTER 3

Water and Dialysate  
Quality Crosswalk from  
the CMS Regulation to the  
Applicable ANSI/AAMI/  
ISO Recommendation

The following table provides easy reference from the CMS water and dialysate quality regulations to the current ANSI/AAMI/ISO recommendations for dialysis water and fluid. The information has been organized in the order of the CMS regulations, and arranged to allow the reader to immediately refer to the equivalent ANSI/AAMI/ISO language.

In a few cases, there is new language in the ANSI/AAMI/ISO documents that was not included in the ANSI/AAMI documents adopted by CMS as regulation in 2008 (e.g., RD52 and portions of RD62). When this occurs, the first column includes the label “New ISO” rather than a V-tag identifier, and the comment under “CMS Regulation” of “no equivalent recommendation.”

| 1<br>CMS Tag # | 2<br>CMS Regulation                              | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V175           | § 494.40 Condition: Water and dialysate quality. | <p>This Condition incorporates by reference the Association for the Advancement of Medical Instrumentation's (AAMI's) "American National Standard for Dialysate for Hemodialysis," 2004 (RD52:2004) and has the authority of regulation. This AAMI document references portions of their "American National Standard for Water Treatment Equipment for Hemodialysis Applications (RD62:2001) as the specifications for various water treatment components. The referenced portions of RD62:2001 are also incorporated by reference, and have the authority of regulation. When "should" or "recommend" are included in the AAMI language adopted as regulation (i.e., the language in the "Regulation" column), the referenced item or practice must be in use or in place.</p> <p>Survey of this Condition requires inspection of the water treatment and dialysate preparation equipment and their distribution systems; interview of personnel responsible for day-to-day operation of those systems; and review of the records of operation and testing for those systems. Supervisory personnel may be interviewed to clarify issues or questions. Critical to ensuring patient safety is the expectation that every survey visit include</p> | <p>This document is provided to allow users to directly compare the Centers for Medicare &amp; Medicaid Services (CMS) requirements (i.e., ANSI/AAMI RD52:2004 adopted as regulation by reference) to the recommendations included in the multiple ANSI/AAMI/ISO documents adopted by AAMI as replacement for RD52 (e.g., ANSI/AAMI/ISO 23500, 11663, 13958, 13959, and 26722).</p> <p>Columns 1–3 are copied directly from the CMS Interpretive Guidance. The content in these columns includes the "V-tag" identifier (Column 1), the regulation (Column 2) and the Interpretive Guidance (Column 3).</p> <p>Column 4 includes the recommendation from one or more of the relevant ANSI/AAMI/ISO documents which most closely mirrors the CMS requirement.</p> <p>Column 5 includes recommendations from ANSI/AAMI/ISO 23500 and "Additional Guidance" developed by the author of this document to assist the user in understanding and meeting the recommendations.</p> <p>There is no equivalent language for this V-tag because the ANSI/AAMI/ISO replacement documents have not been adopted by CMS as regulation.</p> | <p><b>Additional Guidance:</b></p> <p>This document is not meant to replace the referenced ANSI/AAMI/ISO documents, which replaced ANSI/AAMI RD52:2004. For example, the content here does not include references for the evidence base of those recommendations. AAMI standards, to be fully understood, should be read in their entirety and anyone attempting to apply AAMI standards and recommended practices is encouraged to obtain the complete set of standards.</p> <p>It is important to note that the user may adopt a more stringent recommendation, but outpatient dialysis facilities must always meet the requirements of the CMS regulation, (refer to column 2) which are in all cases considered "minimum standards."</p> <p>The regulatory requirements in Column 2 are not subject to change without a Notice of Proposed Rule Making. This would be published in the <i>Federal Register</i> with a public comment period and subsequent publication of a Final Rule with an implementation date.</p> <p>Changes to the Interpretive Guidance (Column 3) can be made by CMS via a Survey &amp; Certification letter, which would be published on a public website. The content</p> |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |  | <p>direct observation of water testing for chlorine/chloramine.</p> <p>Noncompliance at the Condition level should be considered if identified deficient practices are pervasive throughout the Standards included in this Condition, serious in nature, or a potential risk to patient health and safety. Examples of potential Condition level non-compliance may include, but are not be limited to:</p> <ul style="list-style-type: none"> <li>• Demonstrated lack of knowledge or training of staff assigned responsibility for the operation or monitoring of the water treatment or dialysate preparation systems;</li> <li>• Failure to perform and document the test(s) for chlorine and chloramine accurately, including use of testing strips or reagents that are expired or not sensitive to the required levels;</li> <li>• Unsafe practices in the preparation, labeling or delivery of dialysate;</li> <li>• Failure to address out of range results for tests of water or dialysate (bacteria, endotoxin or chemical analysis).</li> </ul> | <p>Because the ANSI/AAMI/ISO replacement documents have not been adopted by reference as regulation, the reader is reminded of the intended meaning of the following verbs when they appear in Columns 4 &amp; 5:</p> <ul style="list-style-type: none"> <li>• “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;</li> <li>• “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;</li> <li>• “may” is used to describe a permissible way to achieve compliance with a requirement or test.</li> </ul> | <p>of Columns 1 &amp; 2 was current as of May 1, 2014.</p> <p>Should CMS choose to adopt the ANSI/AAMI/ISO replacement documents:</p> <ul style="list-style-type: none"> <li>• The Interpretive Guidance in Column 3 regarding the importance of each survey including review of the operation of the water and dialysate preparation systems would be applicable at this tag.</li> <li>• The examples of Condition level non-compliance listed in Column 3 would be applicable at this tag, with the following additional example:</li> <li>• Failure to develop and implement a Validation Program to assure safe operation of all water treatment and dialysate preparation equipment</li> </ul> |
|--|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| 1<br>CMS Tag # | 2<br>CMS Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V176           | <p>The facility must be able to demonstrate the following:</p> <p>(a) <i>Standard: Water purity.</i> Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, "Dialysate for hemodialysis," ANSI/AAMI RD52:2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C 552 (a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 75000 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <a href="http://www.archives.gov/federal-register/code_of_regulations/ibr_locations.html">http://www.archives.gov/federal-register/code_of_regulations/ibr_locations.html</a>. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795.</p> | <p>The practice guideline of the Association for the Advancement of Medical Instrumentation (AAMI) for "Dialysate for hemodialysis" (ANSI/AAMI RD52:2004) is incorporated by reference at 42 CFR 494.40 and is reflected in the tags and the interpretive guidelines at V176 to V278. AAMI is a professional organization in which boards composed of representatives of the industry, providers, and regulatory agencies develop voluntary guidelines for medical products and procedures.</p> <p>Some explanatory language from ANSI/AAMI RD52:2004 and from the Annex to that document has been included below as guidance to surveyors. While the language in the "Regulation" column is taken exactly from the document, the AAMI language in the Surveyor Guidance area has been edited for clarity, brevity and to decrease redundancy. The order of the AAMI document has in some cases been altered, to organize requirements to more closely follow the survey process.</p> <p>AAMI standards, to be fully understood, should be read in their entirety and anyone attempting to apply AAMI standards and recommended</p> | <p>No equivalent language because the ANSI/AAMI/ISO recommendations which replaced AAMI/ANSI RD52 have not been adopted by the Centers for Medicare &amp; Medicaid Services (CMS) as regulation.</p> <p>This document provides comparative recommendations from the ANSI/AAMI/ISO documents for the CMS regulations and interpretive guidelines for tags V176 to V278, which apply to in-center outpatient dialysis and for V593-595, which apply to home hemodialysis.</p> <p>All language taken directly from the ANSI/AAMI/ISO documents is referenced by document and identifying section numbers. This column includes language from those documents and additional explanatory guidance intended to clarify potential provider questions. Explanatory guidance within Column 5 will be labeled "Additional Guidance."</p> | <p><b>Additional Guidance:</b></p> <p>This guidance is provided to allow the user to directly compare the requirements from ANSI/AAMI RD52:2004, which were adopted by CMS in 2008 as regulation, with the recommendations included in ANSI/AAMI/ISO documents adopted by AAMI in replacement of ANSI/AAMI RD52:2004 (e.g., ANSI/AAMI/ISO 23500, 11663, 13958, 13959, and 26722).</p> <p>All language taken directly from the ANSI/AAMI/ISO document is referenced by document and identifying section numbers. This column includes language from those documents and additional explanatory guidance intended to clarify potential provider questions. Explanatory guidance within Column 5 will be labeled "Additional Guidance."</p> |



| 1<br>CMS Tag # | 2<br>CMS Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V177           | <p>ANSI/AAMI RD52:2004<br/>Requirements as Adopted by Reference 42 CFR 494.40 (a)</p> <p><b>4 Fluid quality</b></p> <p><b>4.1 Water</b></p> <p><b>4.1.1 Maximum level of chemical contaminants in water: <i>cem analysis</i></b></p> <p>Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall not contain chemical contaminants at concentrations in excess of those listed in ANSI/AAMI RD62, which is reproduced in Table 1 on page 190.</p> <p>The manufacturer or supplier of a complete water treatment system should recommend a system that is capable of meeting the requirements of this clause at the time of installation given the analysis of the feed water.</p> <p>The system design should reflect possible seasonal variations in feed water quality.</p> <p>Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the levels of chemical contaminants in the water and for complying with the requirements of this standard.</p> | <p>ANSI/AAMI RD52:2004</p> <p><b>4 Fluid quality</b></p> <p><b>4.1 Water</b></p> <p>The fluid quality requirements apply to the purified water as it enters the equipment used to prepare dialysate or concentrates from powder at a dialysis facility, and apply to the water treatment system as a whole and collectively, and not to each of the devices that make up the system.</p> <p><b>AAMI Rationale for the Development and Provision of This Recommended Practice</b></p> <p><b>A.4 Fluid quality</b></p> <p><b>A.4.1.1 Maximum level of chemical contaminants in water</b></p> <p>ANSI/AAMI RD62:2001 sets forth maximum levels of chemical contaminants in three categories: chemicals known to have particular toxicity for hemodialysis patients, chemicals included in the U.S. Environmental Protection Agency's Safe Drinking Water Act and physiological substances that can adversely affect the patient if present in the dialysate in excessive amounts.</p> <p>Several chemicals have been clearly shown to be toxic to dialysis patients at concentrations that are not necessarily toxic to the general population. Those chemicals</p> | <p>ANSI/AAMI/ISO 13959</p> <p><b>3 Dialysis water requirements</b></p> <p><b>3.1 Dialysis water verification and monitoring</b></p> <p>The quality of the dialysis water shall be verified upon installation of a water treatment system. Monitoring of the dialysis water quality shall be carried out thereafter.</p> <p><b>3.3 Chemical contaminants</b></p> <p>Dialysis water shall not contain chemicals at concentrations in excess of those listed in Tables 1 and 2 (see page 191), or as required by national legislation or regulations.</p> <p>Where the dialysis water is used for the reprocessing of hemodialyzers, (cleaning, testing and mixing of disinfectants) the user is cautioned that the dialysis water shall meet the requirements of this International Standard. The dialysis water should be measured at the input to the dialyzer reprocessing equipment.</p> <p><b>ANSI/AAMI/ISO 23500</b></p> <p><b>4 Dialysis water</b></p> <p><b>4.1.2 Chemical contaminants in dialysis water</b></p> <p>The manufacturer or supplier of a complete water treatment system should recommend a system that</p> | <p>ANSI/AAMI/ISO 23500</p> <p><b>4 Summary of quality requirements of ISO 13958, ISO 13959 and ISO 11663</b></p> <p><b>4.1 Dialysis water</b></p> <p><b>4.1.1 General</b></p> <p>The requirements contained in this clause apply to dialysis water at its point of use. As such, these requirements apply to the water treatment system as a whole and not to each of the devices that make up the system. However, collectively, the individual devices shall produce water that, at a minimum, meets the requirements of this clause.</p> <p>Tables 1 and 2 of this International Standard (see page 191) should not be taken as a definitive list of harmful substances, but as a partial listing of those that might reasonably be expected to be present and have clinical implications</p> <p><b>Additional Guidance:</b></p> <p>The reader should refer to ANSI/AAMI/ISO 13959, Annex A, A.2 for a historical review to better understand the considerations given to the chemical contamination of water used for dialysis treatments.</p> <p>The medical director is ultimately responsible for the safety and quality of the water used for patient treatments. Each product water</p> |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>include aluminum, copper, chloramines, fluoride, nitrate, sulfate, and zinc.</p> <p>Uptake of aluminum from the dialysate is associated with bone disease, anemia, and the dialysis encephalopathy syndrome, which is usually fatal. The suggested maximum aluminum level has been specified to prevent accumulation of this toxic metal in the patient. Aluminum is particularly likely to increase suddenly to high levels as a result of changing the method of water treatment to include aluminum-containing compounds.</p> <p>Chloramines damage red blood cells by oxidizing hemoglobin to methemoglobin and by inhibiting antioxidant pathways. Their toxicity in hemodialysis patients is undisputed. Although the role of free chlorine in oxidative blood damage is unclear, its high oxidation potential and its ability to form chloramines suggest that the use of highly chlorinated water in preparation of dialysate should be avoided.</p> <p>High levels (&gt; 20 ppm) of fluoride in the water used to prepare dialysate are clearly toxic to hemodialysis patients, and have resulted in patient deaths. Such high levels of fluoride have resulted from accidental over fluoridation of a municipal water supply, as well as from deionizer</p> | <p>is capable of meeting these requirements based on a feed-water analysis. The system design should reflect possible seasonal variations in feed-water quality. The manufacturer or supplier of a complete water treatment and distribution system should demonstrate that the complete water treatment, storage and distribution system is capable of meeting the requirements of ISO 13959 at the time of installation.</p> <p>Following installation of a water treatment, storage and distribution system, the user is responsible for regular monitoring of the levels of chemical contaminants in the water and for complying with the requirements of this International Standard.</p> | <p>chemical analysis must be within the parameters listed in Tables 1 &amp; 2, referenced at V177 and displayed on page 191. If any values are greater than those listed, facility staff must notify the medical director of the results, repeat testing, and take action to address any repeated high levels.</p> <p>The medical director must be knowledgeable of the water treatment system installed and assure that the system as installed will produce AAMI quality water. Ways to assure this result would include use of an analysis of the source water and consultation with experts in water treatment, as well as confirmation that the planned installation would be sufficient to produce AAMI quality water by the manufacturer or vendor of the water treatment equipment. For initial surveys, the facility should provide a copy of a chemical analysis with results within AAMI standards accomplished prior to starting any patient treatment in the new facility. For resurveys, there must be evidence of on-going monitoring of the chemical quality of the water, and actions taken when levels were outside the AAMI standards.</p> <p>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. An emergency "plan" that specifies</p> |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| 1<br>CMS Tag # | 2<br>CMS Regulation | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 4<br>Equivalent ANSI/AAMI/ISO Recommendation | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V177 (cont.)   |                     | <p>exhaustion. Toxicity of fluoride in dialysis patients is questionable at the levels usually associated with fluoridated water (1 ppm). However, in the absence of a consensus on its role in uremic bone disease, the AAMI Renal Disease and Detoxification (RDD) Committee thought it prudent to restrict the fluoride level of dialysate.</p> <p>Nitrates are a marker for bacterial contamination and fertilizer runoff and have caused methemoglobinemia. Nitrates should be permitted only at very low levels. Sulfate at levels above 200 mg/L has been related to nausea, vomiting, and metabolic acidosis. The symptoms disappear when the level remains below 100 mg/L. Both copper and zinc toxicity have been demonstrated when those substances are present in dialysate at levels below those permitted by the EPA standard. Hence, a lower level has been chosen.</p> <p>The second group of chemical contaminants included in ANSI/AAMI RD62:2001 is based on the U.S. Environmental Protection Agency's Safe Drinking Water Act (see 2.6). The standard specifies maximum allowable limits for most contaminants in this group</p> |                                              | <p>the facility will use tap water or dechlorinated tap water is not acceptable without evidence the source water has been found safe for such use (i.e., has levels below AAMI accepted limits of aluminum, copper, chloramines, fluoride, nitrate, sulfate, zinc and other contaminants known to be toxic to dialysis patients). The medical director is ultimately responsible for this decision; short term exposure limited to one treatment to contaminants, rather than not receiving dialysis may be the optimal choice. Refer to V182.</p> <p>If the water supply utility has notified the city that the source water is highly chlorinated due to a water main break, flooding, or bacterial contamination of the municipal system, the dialysis facility will need to do more frequent monitoring of chlorine/chloramines (standard practice would be every 30–60 minutes).</p> <p>For frequency of monitoring water for chemical contaminants, refer to V201 for Reverse Osmosis (RO) systems and to V206 for Deionization (DI) systems.</p> |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |
|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  |  | <p>at 1/10 of the EPA maximum allowable limit. The lower levels were chosen because the volume of water used for dialysis far exceeds that used for drinking water, because protein binding of these solutes may occur in the blood, and because there is reduced renal excretion of these substances. Selenium and chromium levels were set at the “no-transfer” level. The no-transfer level was chosen even though it is above the EPA limit for selenium and 28 % of the EPA limit for chromium, because there is no need for a restriction below the level at which there is no passage from the dialysate to the blood.</p> <p>The third group of substances included in ANSI/AAMI RD62:2001 consists of physiological substances that can adversely affect the patient if they are present in the dialysate in excessive amounts. Calcium, potassium, and sodium are examples of those substances.</p> <p>The chemical contaminants regulated by ANSI/AAMI RD62:2001 and reproduced in Table 1 should not be taken as a definitive list of harmful substances; they are only a partial listing of the contaminants that might reasonably be expected to be present and have clinical implications. Iron is not included because it does not enter the patient's blood in sufficient</p> |  |
|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

| 1<br>CMS Tag # | 2<br>CMS Regulation | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 4<br>Equivalent ANSI/AAMI/ISO Recommendation | 5<br>Equivalent Language to Current CMS Interpretive Guidance |
|----------------|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|---------------------------------------------------------------|
| V177 (cont.)   |                     | <p>quantities to cause toxicity. However, iron may cause fouling of water purification devices or dialysate proportioning systems. Furthermore, municipal water supplies are dynamic systems, which may change with the seasons or in response to new regulations from the EPA.</p> <p><b>Additional Guidance:</b></p> <p>Table 1 reflects the Standard adopted by CMS as regulation on April 15, 2008. Individual or groups of facilities may adopt newer requirements by policy.</p> <p>The medical director is ultimately responsible for the safety and quality of the water used for patient treatments. Each product water chemical analysis must be within the parameters listed in Table 1 at V177. If any values are greater than those listed, facility staff must notify the medical director of the results, repeat testing, and take action to address any repeated high levels.</p> <p>The medical director must be knowledgeable of the water treatment system installed and assure that the system as installed will produce AAMI quality water. Ways to assure this result would include use of an analysis of the source water and consultation with</p> |                                              |                                                               |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  |
|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  |  | <p>experts in water treatment, as well as confirmation that the planned installation would be sufficient to produce AAMI quality water by the manufacturer or vendor of the water treatment equipment. For initial surveys, the facility should provide a copy of a chemical analysis with results within AAMI standards accomplished prior to starting any patient treatment in the new facility. For resurveys, there must be evidence of ongoing monitoring of the chemical quality of the water, and actions taken when levels were outside the AAMI standards.</p> <p>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. An emergency “plan” that specifies the facility will use tap water or dechlorinated tap water is not acceptable without evidence the source water has been found safe for such use (i.e., has levels below AAMI accepted limits of aluminum, copper, chloramines, fluoride, nitrate, sulfate, zinc and other contaminants known to be toxic to dialysis patients). The medical director is ultimately responsible for this decision; short-term exposure limited to onetreatment to contaminants, rather than not receiving dialysis may be the optimal choice. Refer to V182.</p> |  |
|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|



| 1<br>CMS Tag # | 2<br>CMS Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V177 (cont.)   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <p>If the water supply utility has notified the city that the source water is highly chlorinated due to a water main break, flooding, or bacterial contamination of the municipal system, the dialysis facility will need to do more frequent monitoring of chlorine/chloramines (i.e., every 30–60 minutes).</p> <p>For frequency of monitoring water for chemical contaminants, refer to V201 for Reverse Osmosis (RO) systems and to V206 for Deionization (DI) systems.</p>                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| V178           | <p>ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a)</p> <p>4.1.2 Bacteriology of water: <i>max &amp; action levels</i></p> <p>Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL</p> <p>The action level for the total viable microbial count in the product water shall be 50 CFU/mL, and the action level for the endotoxin concentration shall be 1 EU/mL. If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels.</p> | <p><b>AAMI Rationale for the Development and Provision of This Recommended Practice</b></p> <p><b>A.4.1.2 Bacteriology of water</b></p> <p>When ANSI/AAMI RD5:1981 was initially developed, it was generally considered that the water used to prepare dialysate need not be sterile. Studies have demonstrated that the incidence of pyrogenic reactions is related directly to the number of bacteria in dialysate. It is also known that a dialysate delivery system can amplify the level of bacteria in the water used to supply the system. Those studies provided the rationale for setting a recommended maximum concentration of 200 bacteria per mL in the water used to prepare dialysate.</p> | <p><b>ANSI/AAMI/ISO 13959</b></p> <p><b>3 Dialysis water requirements</b></p> <p><b>3.2 Microbiological requirements</b></p> <p>Total viable microbial counts in dialysis water shall be less than 100 CFU/mL, or lower if required by national legislation or regulations. An action level shall be set based on knowledge of the microbial dynamics of the system. Typically, the action level will be 50 % of the maximum allowable level.</p> <p>Endotoxin content in dialysis water shall be less than 0.25 EU/mL, or lower if required by national legislation or regulations. An action level shall be set, typically at 50 % of the maximum allowable level.</p> | <p><b>ANSI/AAMI/ISO 13959</b></p> <p><b>Annex A: Rationale for the development and provisions of this International Standard</b></p> <p><b>A.1 Microbiology of dialysis water</b></p> <p>Originally, it was considered that the water used to prepare dialysis fluid need not be sterile. However, several studies had demonstrated that the attack rates of pyrogenic reactions were related directly to the number of bacteria in dialysis fluid.</p> <p>Several groups of investigators have shown convincingly that pyrogenic reactions are caused by lipopolysaccharides or endotoxins that are associated with gram-negative bacteria. ... Gram-negative water bacteria have been shown to be capable of multiplying rapidly in dialysis water prepared by</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Several groups of investigators have shown convincingly that pyrogenic reactions are caused by lipopolysaccharides or endotoxins associated with gram-negative bacteria. Gram-negative water bacteria are able to multiply rapidly in the chemically pure water used to supply hemodialysis systems. It has also been demonstrated clearly that endotoxins and endotoxin fragments can cross both low-flux and high-flux hemodialysis membranes.</p> <p>Because 48 hours can elapse between sampling water to determine microbial contamination and receiving results, and because bacterial proliferation can be rapid, action levels for microbial counts and endotoxin concentrations are included in these regulations. Those action levels allow the user to initiate corrective action before levels exceed the recommended maximum levels. Unlike cultures, endotoxin testing does not require extended incubation times. Endotoxin testing, if performed in the dialysis facility, can give results in about 1 hour, eliminating the long delay between sampling and obtaining a result.</p> <p>During the development of this recommended practice, the AAMI RDD Committee was asked to recommend levels of bacteria and endotoxin above which the water should not be used for dialysis</p> | <p><b>ANSI/AAMI/ISO 23500</b><br/><b>4.1.3 Microbiological contaminants in dialysis water</b></p> <p>If a total viable microbial count or endotoxin concentration at or above the action level is observed in the dialysis water, corrective measures should be taken promptly to reduce the level.</p> <p>distillation, deionization, reverse osmosis and softening. Dialysis fluid made with this water likewise provides a very good growth medium for these types of bacteria.</p> <p>Because 7 days can elapse between sampling water for the determination of microbial contamination and receiving results, and because bacterial proliferation can be rapid, action levels for microbial counts were introduced into this International Standard. These action levels allow the user to initiate corrective action before levels exceed the maximum levels established by this International Standard.</p> <p><b>Additional Guidance:</b></p> <p>Refer to the Annexes of ANSI/AAMI/ISO 13959 and 23500 for discussion of the historical references used in the development of the allowable levels.</p> <p>Note the reference to the extended incubation period (i.e., 7 days) required under this Standard. See Columns 4 &amp; 5 at V257 on pages 143–145 for more information on this requirement.</p> <p>If the facility reaches the “action” level, remedial action is required. Action could be to repeat a culture, particularly if only one in a set of cultures was above the action limit. Action could also be to disinfect the system and repeat cultures at several sites.</p> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| 1<br>CMS Tag # | 2<br>CMS Regulation | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 4<br>Equivalent ANSI/AAMI/ISO Recommendation | 5<br>Equivalent Language to Current CMS Interpretive Guidance |
|----------------|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|---------------------------------------------------------------|
| V178 (cont.)   |                     | <p>applications. In making the recommendations set forth in ANSI/AAMI RD52:2004 Section 4.1.2, the AAMI RDD Committee understood that dialysis would be continued at contaminant levels above the action level but below the recommended maximum level. Establishing a recommended maximum level of contamination at which dialysis should be stopped immediately is difficult, because the risk of adverse events, such as pyrogenic reactions, must be balanced against the risks of uremia if a patient is not dialyzed. The balance between those two risks will depend on the level of contamination and the time of exposure on the one hand, and the medical condition for the patient on the other hand. Because this balance will almost certainly vary from circumstance to circumstance, the AAMI RDD Committee felt that there was insufficient data on which to base levels of bacteria and endotoxins above which dialysis should not be performed. The final decision of whether to discontinue dialysis rests with the medical director of a facility. Whatever decision is made, the AAMI RDD Committee recommends that the water treatment and distribution system be disinfected promptly any time the levels of bacteria or</p> |                                              |                                                               |



| 1<br>CMS Tag # | 2<br>CMS Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V179           | <p>ANSI/AAMI RD52:2004<br/><b>Requirements as Adopted by Reference 42 CFR 494.40 (a)</b></p> <p><b>4.1.2 Bacteriology of water: <i>med dir resp</i></b></p> <p>The facility medical director is responsible to ensure the manufacturer or supplier of a complete water treatment and distribution system demonstrates that the complete water treatment, storage, and distribution system is capable of meeting these requirements at the time of installation.</p> <p>Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the water bacteriology of the system and for complying with the requirements of this standard, including those requirements related to action levels.</p> | <p><b>Additional Guidance:</b></p> <p>Existing facilities must monitor the AAMI water chemical analysis and microbial testing and take action if results are outside of the AAMI standards. In the event of culture results above the action levels, the facility may need to repeat cultures, or disinfect the system and repeat cultures (depending on the number of positive cultures, etc.) and continue treatment while awaiting results.</p> <p>If the water supply for the facility is from a private well, annual analysis of the product water may not be sufficient to ensure the feed water requirements of the water treatment system in use are continuously met. The quality of water from the well may change over time, and private wells are not routinely monitored. More frequent analysis may be needed if the well is subject to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks, or agricultural waste and chemicals. Such monitoring might not need to be the full AAMI analysis if only certain contaminants are known to be of concern.</p> | <p>ANSI/AAMI/ISO 13959</p> <p><b>3.1 Dialysis water verification and monitoring</b></p> <p>The quality of the dialysis water shall be verified upon installation of a water treatment system. Monitoring of the dialysis water quality shall be carried out thereafter.</p> <p><b>ANSI/AAMI/ISO 23500</b></p> <p><b>Annex A Rationale for the development and provisions of this International Standard</b></p> <p><b>A.1 Scope</b></p> <p>... the day-to-day responsibility for maintaining fluid quality lies with the healthcare professionals at each dialysis facility under the leadership of the facility's medical director.</p> | <p><b>Additional Guidance:</b></p> <p>The term "user" is defined as the physician or physician's representative responsible for the actual production and handling of dialysis fluid, and this International Standard is directed to the "user."</p> <p>Existing facilities must monitor the AAMI water chemical analysis and microbial testing and take action if results are outside of the AAMI standards. In the event of culture results above the action levels, the facility may need to repeat cultures, or disinfect the system and repeat cultures (depending on the number of positive cultures, etc.) and continue treatment while awaiting results.</p> <p>If the water supply for the facility is from a private well, annual analysis of the quality of the product water may not be sufficient to ensure the feed water requirements of the water treatment system in use are continuously met. The quality of water from the well may change over time, and private wells are not routinely monitored. More frequent analysis may be needed if the well is subject to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks, or agricultural waste and chemicals. Such monitoring might not need to be the full AAMI</p> |

|      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Frequency and methods for monitoring water bacteriology are addressed at V252 & V255.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Frequency and methods for monitoring water bacteriology are addressed at V252 & V255.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | analysis if only certain contaminants are known to be of concern.<br><br>Frequency and methods for monitoring water bacteriology are addressed at V252 & V255.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| V180 | <p><b>ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a)</b></p> <p><b>4.3.2.1 Bacteriology of conventional dialysate: max &amp; action limits</b></p> <p>Conventional dialysate should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration of lower than 2 EU/mL.</p> <p>The action level for the total viable microbial count in conventional dialysate should be 50 CFU/mL and the action level for the endotoxin concentration should be 1 EU/mL. If levels exceeding the action levels are observed in the dialysate, corrective measures, such as disinfection and retesting, should promptly be taken to reduce the levels.</p> | <p><b>ANSI/AAMI RD52:2004</b></p> <p><b>5.4.4.3 Bicarbonate concentrate mixing systems:</b></p> <p>The concentrate shall be shown to routinely produce dialysate meeting these regulations related to allowable bacterial and endotoxin levels.</p> <p><b>AAMI Rationale for the Development and Provision of This Recommended Practice</b></p> <p><b>A.4.3.2.1 Bacteriology of conventional dialysate:</b></p> <p>It is now clear that endotoxins, endotoxin fragments, or other bacterial products cross at least some dialysis membranes under some operating conditions.</p> <p>In addition to the risk of acute pyrogenic reactions, indirect evidence increasingly shows that chronic exposure to low amounts of endotoxin may play a role in some of the long-term complications of hemodialysis therapy. Patients treated with ultrafiltered dialysate have demonstrated a decrease in serum <math>\beta</math>2-microglobulin concentrations, a decrease in markers of inflammation, and an increased responsiveness to erythropoietin. In longer-term studies, use of</p> | <p><b>ANSI/AAMI/ISO 11663</b></p> <p><b>4 Requirements</b></p> <p><b>4.1 Microbiological contaminants in dialysis fluid</b></p> <p><b>4.1.2 Microbiological requirements for standard dialysis fluid</b></p> <p>Standard dialysis fluid shall contain a total viable microbial count of less than 100 CFU/mL (when tested in accordance with methods described at V253 on pages 139–140) and an endotoxin concentration of less than 0.5 EU/mL (when tested in accordance with methods described at V258 on page 145).</p> <p><b>NOTE 1</b> The action level for the total viable microbial count in dialysis fluid should be 50 CFU/mL.</p> <p><b>NOTE 2</b> If microbial counts exceeding the action levels are observed in the dialysis fluid, corrective measures, such as disinfection and retesting, should be taken promptly to reduce the levels.</p> | <p><b>ANSI/AAMI/ISO 23500</b></p> <p><b>4 Summary of quality requirements of ISO 13958, ISO 13959 and ISO 11663</b></p> <p><b>4.3 Requirements for dialysis fluid</b></p> <p><b>4.3.1 General</b></p> <p>The requirements contained in this clause apply to a sample of the dialysis fluid collected as close as practicable to the inlet to the dialyzer.</p> <p>ISO 11663 defines three levels of dialysis fluid: standard dialysis fluid; ultrapure dialysis fluid; and online-prepared substitution fluid. Standard dialysis fluid is considered the minimum acceptable quality for routine hemodialysis. Ultrapure dialysis fluid is recommended for routine hemodialysis.</p> <p><b>Additional Guidance:</b></p> <p>Note that the replacement ANSI/AAMI/ISO documents use the term “dialysis fluid” rather than “dialysate.”</p> <p>Note that the maximum and action levels of endotoxin counts for dialysis fluid are set higher than those for dialysis water. This was done in recognition that powder concentrates can contribute</p> |

| 1<br>CMS Tag # | 2<br>CMS Regulation | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 4<br>Equivalent ANSI/AAMI/ISO Recommendation | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V180 (cont.)   |                     | <p>microbiologically ultrapure dialysate has been associated with a decreased incidence of <math>\beta</math>2-microglobulin-associated amyloidosis, better preservation of residual renal function, and improved nutritional status.</p> <p>For those reasons, the AAMI RDD Committee reduced the recommended maximum microbial count in the dialysate to 200 CFU/mL and added a recommendation that the endotoxin concentration not exceed 2 EU/mL. The values are the same as those for water used to prepare the dialysate (ANSI/AAMI RD62:2001), implying that the dialysate proportioning system should not add significantly to the microbiological burden in the water. Although the AAMI RDD Committee did not review supporting data, it considered contemporary dialysate delivery systems to be fully capable of performing at this level provided that the user followed the manufacturer's instructions on cleaning and disinfecting the system, including disinfection of the line between the water distribution system and the concentrate mixing chambers of the dialysate proportioning system.</p> |                                              | <p>endotoxins, but not volume, to the final dialysis fluid.</p> <p>No such accommodation is made for bacteria since most bacteria will not survive in a viable form in powder concentrate.</p> <p>Refer to the Annexes of ANSI/AAMI/ISO 23500 and 11663 for the rationale for the development and provisions of this standard for microbiological contaminants in dialysis fluid.</p> <p>"Conventional dialysate" is a term referring to the dialysate generally used for hemodialysis in the U.S., as opposed to "Ultrapure dialysate." Recognize that the purity of dialysate is important, in that "reverse" ultrafiltration can occur, allowing dialysate to cross the dialyzer membrane and enter the patient's blood stream. This can occur with most dialyzers, especially high flux dialyzers at the distal end of the dialyzer and especially if the patient does not have much fluid weight to remove (allowing less ultrafiltration pressure to be used). A minimum ultrafiltration rate (UFR), as per the dialysis machine manufacturer's DFU should be maintained to reduce the potential for ultrafiltration.</p> |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |  | <p><b>Additional Guidance:</b></p> <p>“Conventional dialysate” is a term referring to the dialysate generally used for hemodialysis in the U.S., as opposed to “ultrapure dialysate.” Recognize that the purity of dialysate is important, in that “reverse” ultrafiltration can occur, allowing dialysate to cross the dialyzer membrane and enter the patient’s blood stream. This can occur with most dialyzers, especially high flux dialyzers at the distal end of the dialyzer and especially if the patient does not have much fluid weight to remove (allowing less ultrafiltration pressure to be used). A minimum ultrafiltration rate (UFR), as per the dialysis machine manufacturer’s DFU should be maintained to prevent reverse ultrafiltration.</p> <p>It is not expected that concentrates would be cultured or tested for endotoxin levels. Machine cultures (of dialysate) are the evidence used to determine if this requirement is met.</p> <p>“Promptly” would be met if action is taken within 48 hours of receiving the results of testing. Action might be repeating cultures, particularly in the case where one of several cultures are above the action level; or disinfecting the system and repeating cultures. Action would also include notifying the medical director of the results.</p> | <p>It is not expected that concentrates would be cultured or tested for endotoxin levels. Machine cultures (of dialysate) are the evidence used to determine if this requirement is met.</p> <p>“Promptly” would be met if action is taken within 48 hours of receiving the results of testing. Action might be repeating cultures, particularly in the case where one of several cultures are above the action level; or disinfecting the system and repeating cultures. Action would also include notifying the medical director of the results.</p> |
|--|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| 1<br>CMS Tag # | 2<br>CMS Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V181           | <p>ANSI/AAMI RD52:2004<br/>Requirements as Adopted by Reference 42 CFR 494.40 (a)</p> <p>4.3.2.2 Bacteriology of ultrapure dialysate: ultrapure</p> <p>Ultrapure dialysate should contain a total viable microbial count lower than 0.1 CFU/mL and an endotoxin concentration lower than 0.03 EU/mL. If those limits are exceeded in ultrapure dialysate, corrective measures should be taken to reduce the levels into an acceptable range. The user is responsible for monitoring the dialysate bacteriology of the system following installation. It is incumbent on the user to establish a regular monitoring routine.</p> | <p>AAMI Rationale for the Development and Provision of This Recommended Practice</p> <p>A.4.3.2.2 Bacteriology of ultrapure dialysate</p> <p>Ultrapure dialysate is defined as one having a bacterial content of less than 0.1 CFU/mL and an endotoxin content of less than 0.03 EU/mL using sensitive assays. This definition is now widely accepted, particularly in Europe, and use of ultrapure dialysate is considered a requirement for on-line convective therapies (see AAMI A.4.3.2.3). Ultrapure dialysate is prepared by sequential ultrafiltration of dialysate prepared from purified water meeting the requirements of AAMI 4.1 and concentrates. Dry powder cartridges are frequently used for on-line preparation of the bicarbonate concentrate to minimize the potential for the bicarbonate concentrate to contribute high levels of bacteria and endotoxin to the dialysate.</p> <p><b>Additional Guidance:</b></p> <p>At the time of publication of these regulations, most dialysis facilities in the U.S. were using conventional dialysate, rather than ultrapure. There is no requirement to use ultrapure dialysate, but if it is used, then this more stringent</p> | <p>ANSI/AAMI/ISO 11663</p> <p>4.1.3 Microbiological requirements for ultrapure dialysis fluid</p> <p>Ultrapure dialysis fluid shall contain a total viable microbial count of less than 0.1 CFU/ml (when tested in accordance with methods described at V253 on pages 139–140) and an endotoxin concentration less than 0.03 EU/ml (when tested in accordance with methods described at V258 on page 145).</p> <p>If those limits are exceeded in ultrapure dialysis fluid, corrective measures should be taken to reduce the levels to an acceptable range. The user is responsible for monitoring the dialysis fluid bacteriology of the system following installation. It is incumbent on the user to establish a regular monitoring routine.</p> | <p>ANSI/AAMI/ISO 11663</p> <p>Annex A Rationale for the development and provisions of this International Standard</p> <p>A.1 Microbiological contaminants in dialysis fluid</p> <p>In addition to the acute risk of pyrogenic reactions, there is increasing indirect evidence that chronic exposure to low amounts of endotoxin might play a role in some of the long-term complications of hemodialysis therapy. In developing this International Standard the desirability of using ultrapure dialysis fluid was recognized, but it was accepted that obtaining this level of purity on a routine basis might not yet be feasible in all dialysis settings.</p> <p><b>Additional Guidance:</b></p> <p>See the Annexes of ANSI/AAMI/ISO 11663 and 23500 for discussion and references.</p> <p>Note that the longer incubation period (7 days) requires prompt attention when action levels are detected.</p> <p>At the time of publication of this document, most dialysis facilities in the U.S. were using conventional dialysate, rather than ultrapure. There is no requirement to use ultrapure dialysate, but if it is</p> |

|         |                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                    |                                                                                                                                                                                                                                |
|---------|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NEW ISO | ANSI/AAMI RD52:2004<br>No equivalent recommendation | ANSI/AAMI RD52:2004                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | requirement must be followed.<br>The use of an extra filter in the water distribution path or dialysate flow pathway at the point of use does not constitute “adoption” of the ultrapure standard. | used, then this more stringent requirement must be followed. The use of an extra filter in the water distribution path or dialysate flow pathway at the point of use does not constitute “adoption” of the ultrapure standard. |
|         |                                                     | ANSI/AAMI/ISO 23500<br>7 Quality management<br>7.1 General<br>The clinic should establish communications with the feed-water supplier so that the feed-water supplier is aware that the feed water is used for the production of dialysis fluid [i.e. for life-saving treatment on end-stage renal disease (ESRD) patients] and request the establishment of formal procedures to provide the clinic with correct and timely information about any change in the supplied water quality (for example, change of source or type of raw water treatment) or delivery (i.e. water supply interruptions).<br>If such procedures cannot be established, additional monitoring of feed-water quality could be required. | Additional Guidance:<br>Each facility should communicate at least annually with their feed water supplier.                                                                                         |                                                                                                                                                                                                                                |

| 1<br>CMS Tag # | 2<br>CMS Regulation                                 | 3<br>CMS Interpretive Guidance | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------|-----------------------------------------------------|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| New ISO        | ANSI/AAMI RD52:2004<br>No equivalent recommendation | ANSI/AAMI RD52:2004            | <p>ANSI/AAMI/ISO 23500</p> <p>5 Critical aspects of system design</p> <p>5.1 Technical aspects</p> <p>... the system design should specifically address the following points:</p> <ul style="list-style-type: none"> <li>• compliance with mandatory local regulations;</li> <li>• provision for adequate process monitoring;</li> <li>• service and maintenance.</li> </ul> <p>If the entire fluid handling system is not obtained from a single supplier, then the user becomes responsible for ensuring that the separate parts of the system are compatible.</p> <p>The choice of the water treatment system should consider the following aspects concerning the feed-water supply:</p> <ul style="list-style-type: none"> <li>• full chemical analysis of the feed water and silt density index (SDI);</li> <li>• microbiological load, which could lead to the introduction of an additional chlorination step;</li> <li>• flow rates, pressure and temperature;</li> </ul> | <p>ANSI/AAMI/ISO 23500</p> <p>5 Critical aspects of system design</p> <p>The technical features of the water treatment component of that system should be based on the criteria listed in ANSI/AAMI/ISO 26722 [Error! Reference source not found.] with special regard to the aspects related to the water quality, the optimal use of resources (e.g. water and energy) and the operations of disinfection and maintenance.</p> <p><b>5.1 Technical aspects</b></p> <p>It is important that the pretreatment section of the water treatment system be designed to supply the main purification device (usually reverse osmosis) with feed water meeting the specifications for that device; i.e. pressure, temperature, flow and quality (for example, elimination of chemicals which cannot be effectively removed by the main purification device or that could damage it).</p> <p><b>8.2.1 Microbiological aspects of fluid system design</b></p> <p>Examples of good system design include:</p> <ul style="list-style-type: none"> <li>• use of a recirculation-type system,</li> <li>• avoidance of dead ends and dead space areas,</li> <li>• a high quality finish to joints and connections,</li> </ul> |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                |
|--|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |  | <ul style="list-style-type: none"> <li>the treatment techniques used by the provider of the feed water (for example, addition of chloramine, fluoride, aluminum sulfate, etc.). Because treatment techniques can change, ongoing communication with the provider of the feed water is recommended.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>use of materials compatible with the planned methods of disinfection, and</li> <li>avoidance of storage tanks. If a storage tank is necessary it should be designed and constructed in such a manner that it can be cleaned and disinfected.</li> </ul> |
|  |  | <p><b>ANSI/AAMI/ISO 23500</b></p> <p><b>5.2 Microbiological aspects</b></p> <p>The required microbiological quality of the dialysis water and dialysis fluid is achieved by paying adequate attention to the entire water treatment and dialysis fluid preparation cascade. ... the system should be designed to reduce, as much as possible, potential sources of contamination and to allow effective monitoring and disinfection of the critical parts.</p> <p>When applicable, equipment should be operated on a regular basis to reduce stagnation.</p> <p>The distribution system should be designed to maintain dialysis water or dialysis fluid quality and, ... should fulfill the following criteria:</p> <ul style="list-style-type: none"> <li>the distribution loop should be of the minimum length, and avoid multiple branches and dead ends;</li> <li>materials shall be compatible with the different operational conditions (i.e. supply, disinfection, cleaning);</li> </ul> |                                                                                                                                                                                                                                                                                                |

| 1<br>CMS Tag #  | 2<br>CMS Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| New ISO (cont.) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <ul style="list-style-type: none"> <li>there should be no release of chemicals and nutrients for microorganisms;</li> <li>temperature increases or exposure to sunlight should be minimized.</li> </ul> <p>Suitable sampling ports should be available at the start and the end of the distribution loop.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| V182            | <p>ANSI/AAMI RD52:2004<br/>Requirements as Adopted by Reference 42 CFR 494.40 (a)</p> <p>5 Equipment</p> <p>5.1 General: <i>back up plan</i></p> <p>A dialysis facility should develop contingency plans to cover the failure of its water purification and distribution system or a critical component of that system. Such contingency plans should describe how to deal with events that completely prevent dialysis from being performed, such as failure of the facility's municipal water supply or electrical service following a natural disaster or water main break. Other plans should address how to deal with sudden changes in municipal water quality, as well as with failure of a critical component and failure of the water purification and distribution system.</p> | <p>ANSI/AAMI RD52:2004</p> <p>5 Equipment</p> <p>5.1 General</p> <p>This section on equipment provides a brief description of the different components that may be included in a water purification and distribution system used for hemodialysis applications. Since feed water quality and product water requirements may vary from facility to facility, not all of the components described will be necessary in every purification and distribution system.</p> <p>Routine dialysis requires a well-functioning water purification and distribution system, since dialysis cannot be performed without an adequate supply of water. In addition, certain components of the water purification and distribution system are critical to its operation. An example of such a critical component is the circulating pump in an indirect feed system.</p> | <p>ANSI/AAMI/ISO 23500</p> <p>Annex B Equipment</p> <p>B.1 General</p> <p>— A dialysis facility should develop contingency plans to cover the failure of its water treatment and distribution system or a critical component of that system. Such contingency plans should describe how to deal with events that completely prevent dialysis from being performed, such as failure of the facility's municipal water supply or electrical service following a natural disaster or water main break. Other plans should address how to deal with sudden changes in municipal water quality, as well as with failure of a critical component of the water treatment and distribution system. Similar contingency plans should be developed to deal with the failure of concentrate preparation systems.</p> | <p>ANSI/AAMI/ISO 23500</p> <p>Annex B Equipment</p> <p>B.1 General</p> <p>This annex provides a brief description of the different components that may be included in systems to treat and distribute water and dialysis fluid and to prepare and distribute concentrates for hemodialysis applications.</p> <p>Since feed-water quality and product-water requirements can vary from facility to facility, not all of the components described in the following clauses will be necessary in every water treatment and distribution system. Also, not every dialysis facility will prepare concentrate at the dialysis facility.</p> <p>Routine dialysis requires a well-functioning water treatment and distribution system, since dialysis cannot be performed without an adequate supply of water. In addition, certain components of the</p> |

|         |                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|---------|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|         |                                                                       | <p><b>Additional Guidance:</b></p> <p>An emergency or contingency “plan” that specifies the facility will use tap water or dechlorinated tap water is not acceptable without evidence the water intended for use has been found safe for such use (i.e., has levels below AAMI accepted limits of aluminum, copper, chloramines, fluoride, nitrate, sulfate, zinc and other contaminants known to be toxic to dialysis patients). Refer also to the requirements for emergency policies and procedures found under the Condition for Physical Environment at V408.</p> |                                                                                                                                                                                                                                                                                                                                                                                                              | <p>water treatment and distribution system are critical to its operation. An example of such a critical component is the circulating pump in an indirect feed system.</p> <p><b>Additional Guidance:</b></p> <p>An emergency or contingency “plan” that specifies the facility will use tap water or dechlorinated tap water is not acceptable without evidence the water intended for use has been found safe for such use (i.e., has levels below AAMI accepted limits of aluminum, copper, chloramines, fluoride, nitrate, sulfate, zinc and other contaminants known to be toxic to dialysis patients). Refer also to the requirements for emergency policies and procedures found under the Condition for Physical Environment at V408.</p> |
| New ISO | <p><b>ANSI/AAMI RD52:2004</b></p> <p>No equivalent recommendation</p> | <p><b>ANSI/AAMI RD52:2004</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p><b>ANSI/AAMI/ISO 23500</b></p> <p><b>4.4 Record retention</b></p> <p>Records of installation, monitoring, maintenance and disinfection of water treatment, ... medical observation, and personnel education shall be kept according to national regulations. In the absence of national regulations, it is recommended that these records should be retained for the same period as clinical records.</p> | <p><b>Additional Guidance:</b></p> <p>The records of the installation, monitoring, maintenance and disinfection of the water treatment and dialysate preparation systems are considered medical records. CMS requires retention of medical records for a period of 6 years from the date of the patient’s discharge, transfer or death. Because the records of water treatment and dialysate preparation apply to all the patients treated in the outpatient dialysis facility, these records would need to be maintained permanently, or for 6 years after the facility was no longer treating patients.</p>                                                                                                                                    |

| 1<br>CMS Tag # | 2<br>CMS Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| No tag         | <p>ANSI/AAMI RD52:2004<br/>Requirements as Adopted by Reference 42 CFR 494.40 (a)</p> <p>5.2 Water purification systems</p> <p>5.2.1 General</p> <p>Water purification systems consist of three basic sections: a pretreatment section that conditions the water supplied to the primary purification device, which may be followed by other devices that polish final water quality. The pre-treatment section commonly includes a sediment filter, cartridge filters capable of retaining particles of various sizes, a softener, and carbon adsorption beds. The primary purification process most commonly used is reverse osmosis, which may be followed by deionization and ultrafiltration for polishing the product water from the reverse osmosis system. Whether a particular device is included in an individual water purification system will be dictated by local conditions.</p> | <p>AAMI Rationale for the Development and Provision of This Recommended Practice</p> <p>A.5 Equipment</p> <p>A.5.2 Water purification systems</p> <p>Devices marketed to purify water for hemodialysis are also subject to the U.S. Food and Drug Administration's 510(k) approval process. The FDA has published guidelines for water purification devices used in hemodialysis (Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis). Water purification devices marketed for use in hemodialysis applications must be approved by the FDA, and users should ensure that devices obtained from vendors have been approved by the FDA.</p> <p>Design and instrumentation of individual purification devices may vary from these general descriptions. For example, softeners may be configured as a single resin bed that is regenerated outside the normal operating hours of the dialysis unit, or they may have a dual-bed configuration that allows one bed to be regenerated while the other is used to provide water for normal dialysis operations.</p> | <p>ANSI/AAMI/ISO 23500</p> <p>Annex B Equipment</p> <p>B.2 Water treatment systems</p> <p>B.2.1 General</p> <p>Water treatment systems consist of three basic sections: a pretreatment section that conditions the water supplied to the primary purification device, which may be followed by other devices that increase final water quality. The pretreatment section commonly includes a sediment filter, cartridge filters capable of retaining particles of various sizes, a softener and carbon beds. The primary purification process most commonly used is reverse osmosis, which may be followed by deionization and ultrafiltration for polishing the product water from the reverse osmosis system. Whether a particular device is included in an individual water purification system will be dictated by local conditions.</p> | <p>ANSI/AAMI/ISO 23500</p> <p>Annex B Equipment</p> <p>B.2 Water treatment systems</p> <p>B.2.1 General</p> <p>Depending on the feed-water quality and product-water requirements, not every water treatment component might be required in a given facility. Likewise, additional components can be required in certain circumstances. For example, carbon might not provide adequate chloramine removal if the water contains substances, such as polyphosphates, that mask the reactive sites on the carbon particles. In those circumstances, other processes, such as infusion of sodium bisulfite, can be required to achieve product water that meets these requirements.</p> <p>Users are encouraged to obtain detailed descriptions of all water treatment components, together with operating manuals and maintenance procedures, from the manufacturer or the supplier of the water treatment and distribution system.</p> |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |  | <p>Depending on the feed water quality and product water requirements, not every component may be required in a given facility. Likewise, additional components may be required in certain circumstances. For example, carbon adsorption may not provide adequate chlorine removal if the water contains substances, such as polyphosphates, that mask the reactive sites on the carbon particles. In those circumstances, other processes, such as infusion of sodium metabisulfite, may be required to achieve product water that meets these requirements.</p> <p>Users are encouraged to obtain detailed descriptions of all purification processes, together with operating manuals and maintenance procedures, from the manufacturer or the vendor providing the water purification and distribution system.</p> <p><b>Additional Guidance:</b></p> <p>This is an informational tag; specific requirements for various water treatment components follow and deficient practices should be cited under the applicable component tags.</p> <p>Under FDA regulations at the time these regulations were published, all water treatment devices and systems installed after May 30, 1997 must meet review requirements under section 510(k) of the Food, Drug, and Cosmetic Act (21 USC sec. 360(k)) as described in Guidance for the Content of Premarket notifications for Water Purification Components and Systems for Hemodialysis. Equipment installed prior to that date is not required to have evidence of FDA 510(k) approval. Regardless of when a water purification system was installed, the system must yield water and dialysate that meets AAMI standards and must be monitored and maintained in accordance with the ANSI/AAMI RD52 guidelines, as incorporated by reference in these regulations.</p> <p>Each piece of water treatment equipment described below is not required for every system. The water treatment system must be designed to process the local source water into AAMI quality water. All facilities must have primary and secondary carbon tanks to remove chlorine/chloramines, and reverse</p> | <p><b>Additional Guidance:</b></p> <p>This is an informational tag; specific requirements for various water treatment components follow and deficient practices should be cited under the applicable component tags.</p> <p>Under FDA regulations at the time these regulations were published, all water treatment devices and systems installed after May 30, 1997 must meet review requirements under section 510(k)</p> | <p><b>Additional Guidance:</b></p> <p>This is an informational tag; specific requirements for various water treatment components follow and deficient practices should be cited under the applicable component tags.</p> <p>Under FDA regulations at the time these regulations were published, all water treatment devices and systems installed after May 30, 1997 must meet review requirements under section 510(k)</p> | <p><b>Additional Guidance:</b></p> <p>This is an informational tag; specific requirements for various water treatment components follow and deficient practices should be cited under the applicable component tags.</p> <p>Under FDA regulations at the time these regulations were published, all water treatment devices and systems installed after May 30, 1997 must meet review requirements under section 510(k)</p> |
|--|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| 1<br>CMS Tag # | 2<br>CMS Regulation | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 4<br>Equivalent ANSI/AAMI/ISO Recommendation | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                      |
|----------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| No tag (cont.) |                     | <p>of the Food, Drug, and Cosmetic Act (21 USC sec. 360(k)) as described in Guidance for the Content of Premarket notifications for Water Purification Components and Systems for Hemodialysis. Equipment installed prior to that date is not required to have evidence of FDA 510(k) approval. Regardless of when a water purification system was installed, the system must yield water and dialysate that meets AAMI standards and must be monitored and maintained in accordance with the ANSI/AAMI RD52 guidelines, as incorporated by reference in these regulations.</p> <p>Each piece of water treatment equipment described below is not required for every system. The water treatment system must be designed to process the local source water into AAMI quality water. All facilities must have primary and secondary carbon tanks to remove chlorine/chloramines, and reverse osmosis (RO) or deionization (DI) treatment systems. Any component in use must meet the requirements specified in these rules for that component.</p> |                                              | <p>osmosis (RO) or deionization (DI) treatment systems. Any component in use must meet the recommendations for that component.</p> |

|      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V184 | <p><b>ANSI/AAMI RD52:2004</b><br/><b>Requirements as Adopted by Reference 42 CFR 494.40 (a)</b></p> <p><b>8 Environment: <i>secure &amp; restricted</i></b><br/>The water purification and storage system should be located in a secure area that is readily accessible to authorized users. The location should be chosen with a view to minimizing the length and complexity of the distribution system. Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system.</p> | <p><b>Additional Guidance:</b><br/>Older systems (installed prior to the effective date of these regulations) may have been installed in a small space, with components added over the years to crowd the available space. To ensure access is restricted, the delivery doors/loading dock must not be left unlocked, open and unattended. Many water systems are in the same room as stored treatment supplies; staff members who are not responsible for the water system may come into that area to retrieve supplies.</p> <p>Hospital based chronic outpatient units may share the water room with an acute unit; staff from each unit would be expected to have access to the equipment.</p> | <p><b>ANSI/AAMI/ISO 23500</b><br/><b>9 Environment</b><br/>The water treatment and storage system should be located in a secure area that is readily accessible only to personnel authorized by the dialysis facility. The location should be chosen with a view to minimizing the length and complexity of the distribution system. Access to the treatment system should be restricted to those individuals responsible for monitoring and maintenance of the system.</p> | <p><b>Additional Guidance:</b><br/>To ensure access is restricted, the delivery doors/loading dock must not be left unlocked, open and unattended. Many water systems are in the same room as stored treatment supplies; staff members who are not responsible for the water system may come into that area to retrieve supplies.</p> <p>Hospital based chronic outpatient units may share the water room with an acute unit; staff from each unit would be expected to have access to the equipment.</p> |
| V185 | <p><b>ANSI/AAMI RD52:2004</b><br/><b>Requirements as Adopted by Reference 42 CFR 494.40 (a)</b></p> <p><b>8 Environment: <i>access to ports/meters</i></b><br/>The layout of the water purification system should provide easy access to all components of the system, including all meters, gauges, and sampling ports used for monitoring system performance.</p>                                                                                                                                                                                  | <p><b>ANSI/AAMI RD52:2004</b><br/><b>8 Environment</b><br/>An area for processing samples and performing on-site tests is also recommended.</p> <p><b>Additional Guidance:</b><br/>Older systems (installed prior to the effective date of these regulations) may not be as easy to access: provision must be made to allow staff to access all equipment, ports, etc. to operate and monitor the system. In all cases, the operator should be able to describe and identify the various pre-treatment components and the distribution system.</p>                                                                                                                                                | <p><b>ANSI/AAMI/ISO 23500</b><br/><b>9 Environment</b><br/>The layout of the water treatment system should provide easy access to all components of the system, including all meters, gauges and sampling ports used for monitoring system performance.</p>                                                                                                                                                                                                                 | <p><b>ANSI/AAMI/ISO 23500</b><br/><b>9 Environment</b><br/>An area for processing samples and performing onsite tests is also recommended.</p> <p><b>Additional Guidance:</b><br/>Provision must be made to allow staff to access all equipment, ports, etc. to operate and monitor the system. The operator should be able to describe and identify the various pre-treatment components and the distribution system.</p>                                                                                |

| 1<br>CMS Tag # | 2<br>CMS Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V186           | <p>ANSI/AAMI RD52:2004<br/><b>Requirements as Adopted by Reference 42 CFR 494.40 (a)</b></p> <p><b>8 Environment: <i>alarms in treatment area</i></b></p> <p>Critical alarms, such as those associated with deionizer exhaustion or low water levels in a storage tank, should be configured to sound in the patient treatment area, as well as in the water treatment room.</p>                                                                                                                                                                                                                                                                                                                         | <p><b>Additional Guidance:</b></p> <p>Responsible staff members must be able to test the alarms to validate they can be heard in the treatment area. If alarms normally sound during certain events documenting that these are heard in the treatment area will suffice for testing. The alarms in the patient treatment area and water treatment rooms must be loud enough to be heard while patients are on dialysis, and cannot be muted for more than 3 minutes (reference AAMI RD62:2001).</p>                                  | <p>ANSI/AAMI/ISO 23500</p> <p><b>9 Environment</b></p> <p>Critical alarms, such as those associated with deionizer exhaustion or low water levels in a storage tank, should be configured to notify staff in the patient treatment area, as well as in the water treatment room.</p>                                                                                                                                                                                                                                                                                                               | <p><b>Additional Guidance:</b></p> <p>Responsible staff members must be able to test the alarms to validate they can be heard in the treatment area. If alarms normally sound during certain events during the treatment day, documenting that these are heard in the treatment area will suffice for testing. The alarms in the patient treatment area and water treatment rooms must be loud enough to be heard while patients are on dialysis, and cannot be muted for more than 3 minutes (Reference ANSI/AAMI/ISO 26722).</p> |
| V187           | <p>ANSI/AAMI RD52:2004<br/><b>Requirements as Adopted by Reference 42 CFR 494.40 (a)</b></p> <p><b>8 Environment: <i>schematic diagrams/labels</i></b></p> <p>Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction.</p> <p>Additionally, piping should be labeled to indicate the contents of the pipe and direction of flow.</p> <p>If water system manufacturers have not done so, users should label major water system components in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range.</p> | <p><b>ANSI/AAMI RD52:2004</b></p> <p><b>8 Environment</b></p> <p>The use of text labels, such as “RO Water,” and color-coded “arrow tape” provide a convenient means of identifying pipe content and flow direction. Figure 2, an example of labeling for a generable softener is located on page 202.</p> <p><b>Additional Guidance:</b></p> <p>There must be a schematic diagram which allows the staff to follow the flow of the water through the components and each component and the piping must be labeled as described.</p> | <p>ANSI/AAMI/ISO 23500</p> <p><b>9 Environment</b></p> <p>Water systems should include schematic diagrams that identify components, valves, sample ports and flow direction.</p> <p>Additionally, piping should be labeled to indicate the contents of the pipe and direction of flow.</p> <p>If water system manufacturers have not done so, users should identify major water system components and describe their function. How performance is verified, and what actions to take in the event that performance is not within an acceptable range, should be readily available to the user.</p> | <p>ANSI/AAMI/ISO 23500</p> <p><b>9 Environment</b></p> <p>The use of text labels, such as “RO Water,” and color-coded “arrow tape” provides a convenient means of identifying the pipe content and flow direction.</p> <p><b>Additional Guidance:</b></p> <p>There must be a schematic diagram which allows the staff to follow the flow of the water through the components and each component and the piping should be labeled as described.</p>                                                                                 |

|      |                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V188 | <p>ANSI/AAMI RD52:2004<br/>Requirements as Adopted by Reference 42 CFR 494.40 (a)</p> <p>5.2.2 Sediment filters: <i>config and monitoring</i><br/>[Refer to RD62:2001, 4.3.8 Sediment filters:]</p> <p>Sediment filters shall have an opaque housing or other means to inhibit proliferation of algae.</p> <p>5.2.2 Sediment filters<br/>Bed filters should be fitted with gauges to measure the hydrostatic pressure at the filters' inlet and outlet.</p> | <p>ANSI/AAMI RD52:2004<br/>5.2.2 Sediment filters<br/>Permanent, backwashable sediment filters, also known as "bed filters," are frequently located at or near the beginning of hemodialysis water treatment systems and are intended to remove relatively coarse particulate materials from incoming water. Although single filtration medium may be used, bed filters known as multimedia filters are more commonly selected. These units contain multiple layers, each retaining progressively smaller particles. In this way, the bed is used to its fullest extent; the largest particles are removed in the first layer contacted by the water and the smallest in the final layer.</p> <p>As the bed accumulates particulate material, open passages begin to clog and resistance to the water flowing through the filter increases. Ultimately, the increased resistance lead to a reduction in water supply to downstream components. To prevent this situation from occurring, bed filters are cleaned by periodic backwashing, which is accomplished either manually or by using a timer-activated control valve.</p> | <p>ANSI/AAMI/ISO 26722<br/>4.2 Water treatment equipment requirements<br/>4.2.4 Sediment filters<br/>Sediment filters should have an opaque housing or other means to inhibit proliferation of algae. Filters should be fitted with pressure gauges on the inlet and outlet water lines to monitor the pressure drop, <math>\Delta P</math>, across the filter.</p> <p>ANSI/AAMI/ISO 23500<br/>7 Quality management<br/>7.3 Monitoring of water treatment equipment<br/>7.3.2 Monitoring of sediment filters<br/>... pressure drop (<math>\Delta P</math>) across the filter can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A backwash cycle is used as a preventive measure to remove particulate matter from the sediment filter and avoid the development of an excessive pressure drop. The frequency of backwashing should follow the manufacturer's</p> | <p>ANSI/AAMI/ISO 23500<br/>Annex B: Equipment<br/>B.2.2 Sediment filters<br/>Permanent, backwashable sediment filters, also known as "bed filters," are frequently located at or near the beginning of hemodialysis water treatment systems and are intended to remove relatively coarse particulate materials from incoming water. Although a single filtration medium may be used, bed filters known as multimedia filters are more commonly selected. These units contain multiple layers, each retaining progressively smaller particles. In this way, the bed is used to its fullest extent; the largest particles are removed in the first layer contacted by the water and the smallest in the final layer.</p> <p>As the bed accumulates particulate material, open passages begin to clog and resistance to the water flowing through the filter increases. Ultimately, the increased resistance to flow will lead to a reduction in water supply to downstream components. To prevent this situation from occurring, bed filters are cleaned by periodic backwashing, which is accomplished either manually or by using a timer-activated control valve.</p> |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| 1<br>CMS Tag # | 2<br>CMS Regulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 3<br>CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 4<br>Equivalent ANSI/AAMI/ISO Recommendation                                                                                                                                                                                                                           | 5<br>Equivalent Language to Current CMS Interpretive Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| V188 (cont.)   | <p><b>6.2.2 Sediment filters</b></p> <p>Sediment filters should be monitored on a periodic basis ... [for a] pressure drop (<math>\Delta P</math>) across the filter [that] can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A backwash cycle is used to remove particulate matter from the sediment filter. The frequency of backwashing should follow the manufacturer's recommendations. Sediment filter monitoring should include daily verification that the timer used to initiate backwashing cycles is set to the correct time of day. A log sheet should be developed to record the pressure drop measurements and timer verifications.</p> | <p>(Bed filter gauges) are used to determine the dynamic pressure drop across the filter (<math>\Delta P</math>), which serves as an index of resistance to flow and provides a basis for setting the frequency of backwashing of the filter.</p> <p>Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For sediment filter: monitor for pressure drop across the filter daily, looking for a pressure drop less than a number determined by facility policy. For sediment filter backwashing cycle: monitor the backwash cycle timer setting daily, at the beginning of the day, looking for backwash clock set to time determined by facility policy.</p> <p><b>Additional Guidance:</b></p> <p>This is the first of many references to language from ANSI/AAMI RD62, the AAMI "American National Standard for Water Treatment Equipment for Hemodialysis Applications" (RD62:2001) which is referenced in RD52:2004 for the specifications for various water treatment components. The referenced portions of RD62:2001 provided here are also incorporated by reference, and have the authority of regulation.</p> | <p>recommendations. Sediment filter monitoring should include verification that the timer used to initiate backwashing cycles is set to the correct time of day. A log sheet should be developed to record the pressure drop measurements and timer verifications.</p> | <p>Bed filters should be fitted with gauges to measure the hydrostatic pressure at the filters' inlet and outlet. These values can be used to determine the dynamic pressure drop across the filter (<math>\Delta P</math>), which serves as an index of resistance to flow and provides a basis, together with the manufacturer's recommendations, for setting the frequency of backwashing.</p> <p>Suggested monitoring guidelines from ANSI/AAMI/ISO 23500, Annex C, Table C.1: Sediment filter: Monitor pressure drop across the filter daily, looking for a pressure drop less than a number derived from manufacturer's instructions or measurements of system performance. If the sediment filter employs a backwash cycle, monitor the backwash cycle timer setting daily looking for backwash clock set to XX:XX, with the expected time being determined based on the setting of the timer (i.e., real time or off set).</p> <p><b>Additional Guidance:</b></p> <p>Sediment filters are not required in every facility: the source water should determine the water treatment components needed. If sediment filters are in use, the facility should follow these recommendations.</p> |