

American National Standard

ANSI/AAMI RD52:2004/(R)2010
and
ANSI/AAMI RD52:2004/A1:2007/(R)2010,
A2:2007/(R)2010, A3:2009, & A4:2009
(Consolidated Text)

Dialysate for hemodialysis



Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

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All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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American National Standard

ANSI/AAMI RD52:2004/(R)2010 and
ANSI/AAMI RD52:2004/A1:2007/(R)2010, A2:2007/(R)2010,
ANSI/AAMI RD52:2004/A3:2009 and A4:2009
(Consolidated Text)

Changes to ANSI/AAMI RD52:2004, as a result of Amendments 1 – 4, are noted as follows:

Highlight for new info
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Dialysate for hemodialysis

Developed by
Association for the Advancement of Medical Instrumentation

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American National Standards Institute, Inc.

Abstract: This recommended practice covers the appropriate preparation of dialysate, handling of concentrates, operation of water treatment equipment and handling of its product water, monitoring of systems and the dialysate produced, and risks and hazards of dialysate preparation failure. This document also includes normative annexes (added by amendment) on special considerations for home hemodialysis, self-assessment of compliance with recommendations for dialysate preparation, and special considerations for acute hemodialysis.

Keywords: dialysate, dialyzing fluid

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2009	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical

International designation	U.S. designation	Equivalency
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Renal Disease and Detoxification Committee

This recommended practice was developed by the AAMI Renal Disease and Detoxification Committee. Committee approval of this recommended practice does not necessarily imply that all committee members voted for its approval.

At the time the consolidated text of this document and amendments 1 through 4 were published, the **AAMI Renal Disease and Detoxification Committee** had the following members:

<i>Cochairs:</i>	Conor Curtin Richard A. Ward, PhD
<i>Members:</i>	G Steven Acres, MD, Carolina Regional Nephrology Associates Larry Alexander, Florian Services Matthew J. Arduino, DrPH, U.S. Centers for Disease Control and Prevention James Weldon Baker, AmeriWater Robert Berube, Church & Dwight Co Inc. Arnold Boehnlein, Baxter Healthcare Corporation Wayne Carlson, Minntech Corporation Danilo B. Concepcion, CHT CCHT, St. Joseph Hospital Renal Center Conor Curtin, Fresenius Medical Care Renal Therapies Group R. Barry Deeter, RN, MSN, University of Utah Dialysis Program Robert Dudek, Siemens Water Technologies Corporation Martin S Favero, PhD, Johnson & Johnson Gema Gonzalez, U.S. Food and Drug Administration/Center for Devices and Radiological Health Elizabeth Howard, Davita Total Renal Care Inc. Bertrand L. Jaber, MD, Caritas St. Elizabeth's Medical Center Byron L. Jacobs, CBET, Sanford USD Medical Center David C. Katz, El Camino Hospital Fei M. Law, CaridianBCT Sterilization Services Inc. Nathan W. Levin, MD, Renal Research Institute LLC Bruce H. Merriman, Central Florida Kidney Centers Glenda Payne, RN, MS, CNN, U.S. Centers for Medicare & Medicaid Services Mark Rolston, Nashville, TN James D. Stewardson, Brighton, CO Denny Treu, BSME, NxStage Medical Inc. Richard A. Ward, PhD, University of Louisville Michael John Zang, Renal Solutions Inc.
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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

Acknowledgment

The AAMI Renal Disease and Detoxification Committee dedicates this recommended practice to LeRoy J. Fischbach of Minntech Corporation, and the late Scott N. Walker of Fresenius USA for their outstanding contributions to AAMI dialysis standards work.

Foreword

This recommended practice was developed by the AAMI Renal Disease and Detoxification Committee. The committee's objective is to provide rational guidelines for handling water and concentrates and for the production and monitoring of dialysate used for hemodialysis. The need for such guidelines is based on the critical role of dialysate quality in providing safe and effective hemodialysis, and the recognition that day-to-day dialysate quality is under the control of the health care professionals who deliver dialysis therapy.

This recommended practice reflects the conscientious efforts of health care professionals, patients, medical device manufacturers, and representatives of federal agencies to develop recommendations for handling water and concentrates and for the production and monitoring of dialysate for hemodialysis. The document is intended as a guide for physicians, particularly the directors of dialysis facilities. The recommendations contained in this document may not be applicable in all circumstances and they are not intended for regulatory application. The term "should" as used in this document reflects the committee's intent to define goals, not requirements. The term "shall" as used here denotes quality recommendations and procedures that are required by applicable standards. The term "must" is used only to describe unavoidable situations, including those mandated by government regulation.

The concepts incorporated in this recommended practice should not be considered inflexible or static. The recommendations presented here should be reviewed periodically in order to assimilate increased understanding of the role of dialysate purity in patient outcomes and technological developments.

Suggestions for improving this recommended practice are invited and should be sent to: AAMI, Attn: Standards Department, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of the American National Standard ANSI/AAMI RD52:2004, *Dialysate for hemodialysis*.

Introduction: Need for this AAMI recommended practice

The American National Standard *Hemodialysis systems* was first approved in May 1982 and was published under the designation ANSI/AAMI RD5:1981. In 1996, during the five-year review of RD5, the AAMI Renal Disease and Detoxification Committee determined that the hemodialysis community would be better served by this standard if it were divided into three parts: (1) hemodialysis concentrates, (2) water treatment equipment for hemodialysis, and (3) hemodialysis equipment. This decision resulted in the publication of ANSI/AAMI RD61:2000, *Concentrates for hemodialysis*; ANSI/AAMI RD62:2001, *Water treatment equipment for hemodialysis applications*; and ANSI/AAMI RD5:2003, *Hemodialysis systems*. These standards are addressed primarily to the manufacturers of equipment, although they also provide users with a basis for understanding the products and processes covered therein. The critical product resulting from the joint application of the devices addressed by the three standards is the dialysate, the fluid against which the patients' blood is balanced. Control of the dialysate characteristics is necessary in order to have safe and effective hemodialysis. Although hemodialysis machines are used to proportion concentrates and water to produce dialysate, the actual production and handling of dialysate is under the control of professional clinicians who care for the patients. Clinicians involved in providing hemodialysis may not be exposed to the technical aspects of water treatment for hemodialysis applications during their training. Therefore, the AAMI Renal Disease and Detoxification Committee undertook the development of this recommended practice to provide guidance to health care professionals.

NOTE—This introduction does not contain provisions of the American National Standard ANSI/AAMI RD52:2004, *Dialysate for hemodialysis*.

Changes to ANSI/AAMI RD52:2004, as a result of Amendments 1 – 4, are noted as follows:

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Annexes C, D, and E were added by amendments 1, 2, and 3. For readability, these annexes are not highlighted. Amendment 4 made one change to annex C, which is noted as indicated above.

Dialysate for hemodialysis

1 Scope

1.1 General

The intent of this recommended practice is to provide dialysis practitioners with guidance on the preparation of dialysate for hemodialysis and related therapies, from the point at which municipal water enters their dialysis facility to the point at which the final dialysate enters the dialyzer. Included in the scope of the recommended practice are: (1) use, maintenance, and monitoring of equipment used to purify and distribute water used for the preparation of dialysate and other hemodialysis applications; (2) use, maintenance, and monitoring of equipment used to prepare concentrate from powder at a dialysis facility; and (3) preparation of the final dialysate from purified water and concentrate. The equipment used in the various stages of dialysate preparation is generally obtained from specialized vendors. This recommended practice provides a general description of the system components that these vendors may provide. These descriptions are intended to provide the user with a basis for understanding why certain equipment may be required and how it should be configured; they are not intended as detailed design standards. Dialysis practitioners are generally responsible for maintaining the equipment used to prepare dialysate following its installation. Therefore, this recommended practice provides guidance on monitoring and maintenance of the equipment to ensure that dialysate quality is acceptable at all times. At various places throughout this recommended practice, the user is advised to follow the manufacturer's instructions regarding the operation and maintenance of equipment. In those instances in which the equipment is not obtained from a specialized vendor, it is the responsibility of the user to validate the performance of the equipment in the hemodialysis setting and to ensure that appropriate operating and maintenance manuals are available.

The guidance provided by this recommended practice should help protect hemodialysis patients from adverse effects arising from known chemical and microbial contaminants that may be found in improperly prepared dialysate. However, the physician in charge of dialysis has the ultimate responsibility for ensuring that the dialysate is correctly formulated and meets the requirements of all applicable quality standards.

1.2 Inclusions

This recommended practice addresses the user's responsibility for the dialysate once equipment has been delivered and installed. For the purposes of this recommended practice, the dialysate includes water used for the preparation of dialysate, water used for the preparation of concentrates at the user's facility, and water used for the preparation of ultrapure dialysate, as well as the final dialysate and concentrates. Because it is commonly prepared and distributed using the same equipment as the water used to prepare dialysate, water used to reprocess dialyzers is also covered by this recommended practice. This recommended practice includes an annex containing recommendations for home hemodialysis.

1.3 Exclusions

Excluded from the scope of this recommended practice are sorbent-based dialysate regeneration systems that regenerate and recirculate small volumes of dialysate, systems for continuous renal replacement therapy that use prepackaged solutions, and systems and solutions for peritoneal dialysis. This recommended practice excludes home hemodialysis, although this document may be of use to the home hemodialysis practitioner.

2 Normative references

The following documents contain provisions that, through reference in this text, constitute provisions of this recommended practice. At the time of publication, the editions indicated were valid. All standards are subject to revision. For this reason, it is recommended that the user obtain the most recent editions of the documents indicated below. The Association for the Advancement of Medical Instrumentation maintains a register of currently valid AAMI/American National Standards.

- 2.1** U.S. FOOD AND DRUG ADMINISTRATION. *Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis*. Rockville (MD): U.S. Food and Drug Administration, 1997. <<http://www.fda.gov/cdrh/ode/hemodial.pdf>>

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Hemodialysis systems* (ANSI/AAMI RD5:2003). Arlington (VA): AAMI, 2003. American National Standard.

2.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Water treatment equipment for hemodialysis applications* (ANSI/AAMI RD62:2001). Arlington (VA): AAMI, 2001. American National Standard.

2.4 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Concentrates for hemodialysis* (ANSI/AAMI RD61:2000). Arlington (VA): AAMI, 2000. American National Standard.

2.5 UNITED STATES PHARMACOPEIAL CONVENTION, INC. *United States Pharmacopoeia—National Formulary* (USP-26-NF21). Rockville (MD): United States Pharmacopeial Convention Inc., 2003.

2.6 U.S. ENVIRONMENTAL PROTECTION AGENCY. *Safe Drinking Water Act, 1996* (Public law 104–182). Washington (DC): EPA, 1996.

(See also *National Primary and Secondary Drinking Water Regulations*. U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water. <<http://www.epa.gov/OGWDW/creg.html>>)

2.7 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Bacterial endotoxins—Test methodologies, routine monitoring, and alternatives to batch testing* (ANSI/AAMI ST72:2002). Arlington (VA): AAMI, 2002. American National Standard.

3 Definitions

For the purposes of this recommended practice, the following terms and definitions apply.

3.1 acetate concentrate: Concentrated solution of salts that may contain dextrose (sometimes referred to as “glucose”), which, when diluted with water, yields dialysate for use in dialysis. Sodium acetate is normally used as the buffer. This concentrate is used as a single concentrate.

3.2 acetate dialysate: Dialysate without bicarbonate, using acetate as a substitute for the bicarbonate buffer.

NOTE—Acetate dialyzing fluid is generally produced from a single concentrate. Acetate is metabolized by the patient to produce bicarbonate.

3.3 acid concentrate: Acidified concentrated solution of salts that may contain dextrose (sometimes referred to as “glucose”), which, when diluted with water and bicarbonate concentrate, yields dialysate for use in dialysis. The term “acid” refers to the small amount of acid (usually acetic acid) that is included in the concentrate to establish the buffer system in the final dialysate by reaction with a small amount of bicarbonate from the bicarbonate concentrate.

3.4 action level: Concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels.

3.5 anions: Ions carrying a negative charge.

3.6 bacteriology: Area of study within the field of microbiology that deals with the study of bacteria.

3.7 batch system: Apparatus in which the dialysate is prepared in bulk before each dialysis session.

3.8 bicarbonate concentrate: Concentrated solution of sodium bicarbonate that, when diluted with water and acid concentrate, makes dialysate used for dialysis. Some bicarbonate concentrates also contain sodium chloride.

3.9 bicarbonate dialysate: Dialysate containing physiological or higher concentrations of bicarbonate.

NOTE—Bicarbonate dialysate is generally produced from two concentrates: one containing bicarbonate and the other containing acid and other electrolytes (see **acid concentrate** and **bicarbonate concentrate**).

3.10 biofilm: Coating on surfaces that consists of microcolonies of bacteria embedded in a protective extracellular matrix. The matrix, a slimy material secreted by the cells, protects the bacteria from antibiotics and chemical disinfectants.

3.11 bulk delivery: Delivery of large volumes of concentrate in which the product is transferred (pumped) from the delivery container to a user’s storage tank. Bulk delivery may include containers such as 55 gallon drums, which are pumped into a storage tank maintained at the user’s facility.

3.12 cations: Ions carrying a positive charge.

3.13 chlorine, combined: Chlorine that is chemically combined, such as in chloramine compounds.

NOTE—There is no direct test for measuring combined chlorine, but it can be measured indirectly by measuring both total and free chlorine and calculating the difference.

3.14 chlorine, free: Dissolved molecular chlorine.

3.15 colony-forming unit (CFU): Organism capable of replicating to form a distinct, visible colony on a culture plate. In practice, a colony may be formed by a group of organisms.

3.16 concentrate generators: System in which the concentrate is delivered to the consumer as a powder in a container and then converted on-line into a saturated solution by a dialysis delivery machine. This solution is used by an individual proportioning system to make the final dialysate delivered to the dialyzer.

3.17 dialysate: Aqueous fluid containing electrolytes and, usually, dextrose, which is intended to exchange solutes with blood during hemodialysis. The word “dialysate” is used throughout this document to mean the fluid made from water and concentrates that is delivered to the dialyzer by the dialysate supply system. Such phrases as “dialyzing fluid” or “dialysis solution” may be used in place of dialysate.

3.18 dialysate supply system: Devices that: (1) prepare dialysate on-line from water and concentrates or that store and distribute premixed dialysate; (2) circulate the dialysate through the dialyzer; (3) monitor the dialysate for temperature, conductivity (or equivalent), pressure, flow, and blood leaks; and (4) prevent dialysis during disinfection or cleaning modes. The term includes reservoirs, conduits, proportioning devices for the dialysate, and monitors and associated alarms and controls assembled as a system for the characteristics listed above. The dialysate supply system is often an integral part of single-patient dialysis machines (see 2.2).

3.19 disinfection: Destruction of pathogenic and other kinds of microorganisms by thermal or chemical means. Disinfection is a less lethal process than sterilization, because it destroys most recognized pathogenic microorganisms but does not necessarily destroy all microbial forms. This definition of “disinfection” is equivalent to low-level disinfection in the Spaulding classification.

3.20 electrolyte: Ion capable of transferring or exchanging electrons. In dialysate, the electrolytes are the charged ions that result from dissociation of salts when they are dissolved in water. These charged ions are responsible for the conductive property of dialysate.

3.21 empty-bed contact time (EBCT): Measure of how much contact occurs between particles, such as activated carbon, and water as the water flows through a bed of the particles. EBCT (minutes) is calculated from the following equation:

$$\text{EBCT} = (7.48 \times V)/Q$$

where V is the volume of particles in the bed (ft³),

Q is the flow rate of water through the bed (gal/min), and

7.48 is the conversion factor for gallons to ft³.

3.22 endotoxin: Major component of the outer cell wall of gram-negative bacteria. Endotoxins are lipopolysaccharides, which consist of a polysaccharide chain covalently bound to lipid A. Endotoxins can acutely activate both humoral and cellular host defenses, leading to a syndrome characterized by fever, shaking chills, hypotension, multiple organ failure, and even death if allowed to enter the circulation in a sufficient dose. (See also pyrogen.)

3.23 endotoxin units (EU): Units assayed by the *Limulus* amoebocyte lysate (LAL) method when testing for endotoxins. Because activity of endotoxins differs on a mass basis, their activity is referred to a standard *E. coli* endotoxin. The current standard (EC-6-1) is prepared from *E. coli* O:113:H10. The relationship between the mass of an endotoxin and its activity varies with both the lot of LAL and the lot of control standard endotoxin being used. Since standards for endotoxin were harmonized in 1983 with the introduction of EC-5, the relationship between mass and activity of endotoxin has been approximately 10 EU/ng.

NOTE—In some countries, endotoxin concentrations are expressed in international units (IU). Since the 1983 harmonization of endotoxin assays, EU and IU are equivalent.

3.24 feed water: Water supplied to a water treatment system or an individual component of the system.

3.25 germicide: Agent that kills microorganisms.

3.26 hemodiafiltration: Form of renal replacement therapy in which waste solutes are removed from blood by a combination of diffusion and convection through a high-flux membrane. Diffusive solute removal is achieved using a dialysate stream as in hemodialysis. Convective solute removal is achieved by adding ultrafiltration in excess of that

needed to obtain the desired weight loss; fluid balance is maintained by infusing a replacement solution into the blood either before the dialyzer (predilution hemodiafiltration) or after the dialyzer (postdilution hemodiafiltration).

3.27 hemodialysis: Form of renal replacement therapy in which waste solutes are removed primarily by diffusion from blood flowing on one side of a membrane into dialysate flowing on the other side. Fluid removal that is sufficient to obtain the desired weight loss is achieved by establishing a hydrostatic pressure gradient across the membrane. This fluid removal provides some additional waste solute removal, particularly for higher molecular weight solutes.

3.28 hemofiltration: Form of renal replacement therapy in which waste solutes are removed from blood by convection. Convective transport is achieved by ultrafiltration through a high-flux membrane. Fluid balance is maintained by infusing a replacement solution into the blood either before the hemofilter (pre-dilution hemofiltration) or after the hemofilter (post-dilution hemofiltration).

NOTE—There is no dialysate stream in hemofiltration.

3.29 *Limulus* amoebocyte lysate (LAL) test: Assay used to detect endotoxin. Exploits the immune response of the horseshoe crab to endotoxin (*Limulus polyphemus*).

3.30 manufacturer: Person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturers include, but are not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

3.31 microbial: Referring to microscopic organisms, bacteria, fungi, and so forth. (See also **bacteriology**.)

3.32 microbiological contamination: Contamination with any form of microorganism (e.g., bacteria, yeast, fungi, and algae) or with the by-products of living or dead organisms such as endotoxins, exotoxins, and microcystin (derived from blue-green algae).

3.33 microfilter: Filter designed to remove particles in the range 0.1 μm to 3 μm in diameter. Microfilters have an absolute size cut-off and are available in both dead-end and cross-flow configurations.

3.34 product water: Water produced by a water treatment system or by an individual component of a system.

3.35 proportioning system: Apparatus that proportions water and hemodialysis concentrate to prepare dialysate.

3.36 pyrogen: Fever-producing substance. Note that pyrogens are most often lipopolysaccharides of gram-negative bacterial origin. (See also **endotoxin**.)

3.37 spike: Small amount of a single chemical used to increase a constituent or constituents in the concentrate for a single patient's treatment.

NOTE—The spike may be in the form of a dry chemical or may be dissolved in water.

3.38 sterile: Free from all living organisms and viable spores, within the limits of tests for sterility, and maintained in that state by suitable means.

NOTE—For solutions used in hemodialysis and related therapies, “sterile” can be used to describe a packaged solution that was prepared using a terminal sterilization process that has been demonstrated to achieve a six log reduction in appropriate indicator microorganisms. Alternatively, “sterile” can be used to describe a solution prepared for immediate use by a continuous process that has been validated to produce a solution free of microorganisms when challenged with a defined test fluid and that is capable of meeting this challenge even with a single fault failure.

3.39 storage tank: Large tank at the user's facility for storage of purified water or concentrate from bulk deliveries, or for concentrate prepared in bulk at the user's facility from powder and purified water.

3.40 total dissolved solids (TDS): Sum of all ions in a solution, often approximated by means of electrical conductivity or resistivity measurements. TDS measurements are commonly used to assess the performance of reverse osmosis units. TDS values are often expressed in terms of CaCO_3 or NaCl equivalents (ppm).

3.41 ultrafilter: Membrane filter with a pore size in the range 0.001 μm to 0.05 μm . Performance is usually rated in terms of a nominal molecular weight cut-off (MWCO), which is defined as the smallest molecular weight species for which the filter membrane has more than 90 % rejection. Depending on their nominal MWCO, ultrafilters may be used to remove particles and solutes as small as 1,000 dalton. Ultrafilters with a nominal MWCO of 20,000 or less are generally adequate for endotoxin removal.

NOTE—Ultrafilters are usually configured in a cross-flow mode. Some ultrafilters also remove endotoxins by adsorption.

3.42 ultrapure dialysate: Highly purified dialysate that can be used in place of conventional dialysate or as feed solution for further processing to create fluid intended for injection directly into the blood. The definition of “ultrapure dialysate” varies, but the recommendation used in the European Renal Association–European Dialysis and Transplant Association (ERA/EDTA) Best Practice Guidelines (ERA–EDTA, 2002) is < 0.1 CFU/mL and < 0.03 EU/mL. The endotoxin level may be reduced in the future as more sensitive tests become available.

3.43 United States Pharmacopoeia (USP): The current version of this official compendium (see 2.5).

3.44 user: Physician or physician’s representative responsible for the actual production and handling of dialysate.

NOTE—This recommended practice is directed to the “user.”

3.45 water treatment system: Collection of water purification devices and associated piping, pumps, valves, gauges, etc., that together produce purified water for hemodialysis applications and deliver it to the point of use.

4 Fluid quality

4.1 Water

The requirements contained in clause 4.1 apply to the purified water as it enters the equipment used to prepare dialysate or concentrates from powder at a dialysis facility. 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.

4.1.1 Maximum level of chemical contaminants in water

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 (see 2.3), which is reproduced in Table 1 below. The manufacturer or supplier of a complete water treatment system should recommend a system that is capable of meeting the requirements of this clause given the analysis of the feed water. The system design should reflect possible seasonal variations in feed water quality. The manufacturer or supplier of a complete water treatment and distribution system shall demonstrate that the complete water treatment, storage, and distribution system is capable of meeting the requirements of RD62 at the time of installation.

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.

**Table 1—Maximum allowable chemical contaminant levels in water used to prepare dialysate and concentrates from powder at a dialysis facility and to reprocess dialyzers for multiple uses
(Reproduced from ANSI/AAMI RD62:2001)**

Contaminant	Maximum concentration (mg/L)
Calcium	2 (0.1 mEq/L)
Magnesium	4 (0.3 mEq/L)
Potassium	8 (0.2 mEq/L)
Sodium	70 (3.0 mEq/L)
Antimony	0.006
Arsenic	0.005
Barium	0.10
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Lead	0.005
Mercury	0.0002
Selenium	0.09
Silver	0.005
Aluminum	0.01
Chloramines	0.10
Free Chlorine	0.50
Copper	0.10
Fluoride	0.20
Nitrate (as N)	2.0
Sulfate	100
Thallium	0.002
Zinc	0.10

NOTE—American National Standards are revised every three to five years. Users should consult the most recent edition of ANSI/AAMI RD62 to ensure that the levels listed in this table are still valid.

4.1.2 Bacteriology of water

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. 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. The manufacturer or supplier of a complete water treatment and distribution system shall demonstrate that the complete water treatment, storage, and distribution system is capable of meeting the requirements of RD52 at the time of installation.

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.

4.2 Concentrate

4.2.1 Maximum level of chemical contaminants in concentrate

Users do not have to test concentrates to demonstrate compliance with the requirements of this clause when using commercially available packaged chemicals intended for use in preparing liquid concentrates at a dialysis facility or when using commercially available liquid concentrates, provided that the concentrates are manufactured in accordance with the requirements of ANSI/AAMI RD61 (see 2.4).

If a user purchases raw chemicals for the formulation of concentrate, all chemicals used shall meet the requirements of the current *United States Pharmacopoeia—National Formulary*, including all applicable portions of the General Notices and of the General Requirements for Tests and Assay (see 2.5). If all other requirements are met, monograph limits for sodium, potassium, calcium, magnesium, or pH may be exceeded provided that correction is made, if necessary, for the presence of those ions in the final formulation. Also, users need not comply with the USP labeling requirements that specify labeling for use in hemodialysis if the user performs testing to meet the USP requirements.

Water used to prepare concentrates at a dialysis facility shall not contain chemical contaminants at concentrations in excess of those in Table 1.

4.2.2 Bacteriology of concentrate

Water used to prepare concentrates at a dialysis facility shall meet the requirements of 4.1.2. Any concentrate prepared at a dialysis facility should be capable of allowing the dialysis machine to prepare dialysate meeting the recommendations of 4.3.2.1.

No recommendations are made regarding the bacteriology of concentrate prepared at a dialysis facility. (See A.4.2.2 for further details.)

4.3 Dialysate

4.3.1 Maximum level of chemical contaminants in dialysate

With the exception of those solutes normally present in dialysate (calcium, magnesium, potassium, and sodium), dialysate should not contain chemical contaminants at concentrations in excess of those in Table 1.

4.3.2 Bacteriology of dialysate

The recommendations contained in this clause apply to the dialysate collected from a dialysate port of the dialyzer or from a sampling port in the inlet dialysate line that can be accessed using a syringe.

4.3.2.1 Bacteriology of conventional dialysate

Conventional dialysate should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration of lower than 2 EU/mL. 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.

4.3.2.2 Bacteriology of ultrapure dialysate

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.

4.3.2.3 Bacteriology of dialysate for infusion

The recommendations contained in this clause apply to highly purified dialysate as it enters the patient's blood. Dialysate for infusion may be used for substitution fluid in convective therapies, such as hemodiafiltration and hemofiltration, and may be produced on-line from dialysate by processes such as sequential ultrafiltration through bacteria- and endotoxin-retentive membranes. Dialysate for infusion should contain less than 10^{-6} CFU/mL (< 1 CFU/1000 L) and endotoxin concentration of lower than 0.03 EU/mL. Compliance with a maximum bacterial level of 10^{-6} CFU/mL cannot be demonstrated by culturing. Therefore, dialysate for infusion should be produced by a device or process that has been validated by the manufacturer to produce fluid meeting the above recommendations for a specified time or number of treatments when supplied with dialysate of a specified quality. For example, when dialysate for infusion is produced from conventional dialysate meeting the recommendations of 4.3.2.1, the process should be validated to provide at least a nine-log reduction in bacteria and at least a two-log reduction in endotoxin. The function of the validated system should be verified according to the manufacturer's instructions at the time of

installation and confirmed by the user with a regular monitoring and maintenance schedule. The user should follow the manufacturer's instructions for use of the validated system, and the user's monitoring and maintenance schedule should be designed to confirm that the dialysate used to prepare the dialysate for infusion continues to meet the specifications of the manufacturer of the device or process.

5 Equipment

5.1 General

This clause 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 in the following clauses will be necessary in every purification and distribution system.

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. 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 of the water purification and distribution system.

5.2 Water purification systems

5.2.1 General

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.

5.2.2 Sediment filters

NOTE—Requirements for sediment filters intended for use in hemodialysis applications can be found in subclause 4.3.8 of normative reference 2.3.

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 layer 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.

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. 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 (delta pressure or ΔP), which serves as an index of resistance to flow and provides a basis for setting the frequency of backwashing.

5.2.3 Cartridge filters

Cartridge filters consist of a cylindrical cartridge of the filter medium with a central drainage core. The cartridge is contained within an opaque filter housing with seals to separate the feed and product water streams. Although cartridge filters may be installed at the inlet to a water system, their usual application is as a final filtration step prior to reverse osmosis. As the cartridge accumulates particulate material, resistance to flow through the filter increases, as indicated by an increase in ΔP . When the maximum ΔP recommended by the filter manufacturer is reached, the cartridge should be replaced according to the manufacturer's instructions.

5.2.4 Softeners

NOTE—Requirements for softeners intended for use in hemodialysis applications can be found in subclause 4.3.10 of normative reference 2.3.

Water that contains calcium or magnesium can form relatively hard deposits and is called “hard water.” Water that has had these elements replaced by sodium ion exchange is called “soft water,” hence, the term “softener.” Softeners also remove other polyvalent cations, most notably iron and manganese, although they are somewhat limited in this regard. The primary use of softeners in hemodialysis water systems is to prevent hard water deposits from damaging sensitive reverse osmosis membranes.

A softener is a cylinder or vessel that contains insoluble spheres or beads, called “resin,” to which sodium ions are attached. During operation, exchangeable sodium ions in the resin are progressively replaced by calcium and magnesium ions. When all the sodium ions have been used, the resin bed has reached a condition referred to as “exhaustion.” Prior to exhaustion, softeners should be restored; that is, new exchangeable sodium ions are placed on the resin by a process known as “regeneration,” which involves exposure of the resin bed to a saturated sodium chloride solution.

Softeners that automatically regenerate also include a brine tank, from which saturated sodium chloride solution is drawn during regeneration, and a control valve that regulates regeneration and service cycles.

5.2.5 Carbon adsorption

NOTE—Requirements for carbon adsorption beds intended for use in hemodialysis applications can be found in subclause 4.3.9 of normative reference 2.3.

Carbon adsorption systems, often referred to as carbon filters, are the principal means of removing both free chlorine and chloramine. Removal of free chlorine to a maximum level of 0.5 mg/L and chloramine to a maximum level of 0.1 mg/L is necessary to protect hemodialysis patients from red cell hemolysis. In addition, free chlorine may also degrade some reverse osmosis membranes, depending on the membrane material.

In addition to removing free chlorine and chloramine, carbon also adsorbs a wide variety of other substances, including both naturally occurring and synthetic organic compounds. The capacity of carbon to remove free chlorine and chloramine may be reduced when other substances “mask” reactive sites on the carbon media. In addition, the efficiency of free chlorine and chloramine removal is reduced as pH increases or as temperature decreases. The net effect of those variables is that the finite capacity of carbon beds to remove free chlorine and chloramine cannot be predicted with any certainty. Therefore, their performance needs to be monitored frequently.

For free chlorine and chloramine removal, carbon adsorption systems and carbon media should be selected and configured as described in ANSI/AAMI RD62:2001 (see 2.3). That is, two carbon beds shall be installed in series with a sample port following the first bed. A sample port should also be installed following the second bed for use in the event of free chlorine or chloramine breaking through the first bed. When samples from the first sampling port are positive for chlorine or chloramine, operation may be continued for a short time (up to 72 hours) until a replacement bed is installed, provided that samples from the second sampling port remain negative. The replacement bed should be placed in the second position, and the existing second bed should be moved to the first position to replace the exhausted bed. If it is not possible to rotate the position of the beds, both beds should be replaced.

Carbon beds are sometimes arranged as series-connected pairs of beds so that they need not be overly large. The beds within each pair are of equal size and water flows through them are parallel. In this situation, each pair of beds should have a minimum empty bed contact time of 5 minutes at the maximum flow rate through the bed. When series-connected pairs of beds are used, the piping should be designed to minimize differences in the resistance to flow from inlet and outlet between each parallel series of beds to ensure that an equal volume of water flows through all beds.

When granular activated carbon is used as the media, it shall have a minimum iodine number of 900, and each bed shall have a minimum empty bed contact time of 5 minutes at the maximum flow rate through the bed. Other forms of carbon should not be used unless there is performance data to demonstrate that each adsorption bed has the capacity to reduce the chloramine concentration in the feed water to less than 0.1 mg/L when operating at the maximum anticipated flow rate for the maximum time interval between scheduled testing of the product water for chloramines. Regenerated carbon shall not be used for hemodialysis applications. Some granular activated carbon contains aluminum, which can elute from the carbon and add to the burden of aluminum to be removed by reverse osmosis or ion exchange. The use of acid-washed carbon minimizes this source of aluminum in the water.

In some circumstances, carbon adsorption may not adequately remove chloramines from water. High pH of feed water, the occurrence of *N*-chloramines, and the use of orthophosphate or polyphosphate for corrosion control have been associated with a decrease in the removal of chloramines by carbon adsorption. In those situations, carbon adsorption may need to be supplemented with other methods of chloramine removal.

5.2.6 Chemical injection systems

Chemical injection systems may be used in the pretreatment section of a water purification system to supplement the physical purification processes described in the previous clauses. Applications of chemical injection include the addition of sodium metabisulfite to remove chloramines and the addition of acid to adjust pH.

Chemical injection systems consist of a reservoir that contains the chemical to be injected, a metering pump, and a mixing chamber located in the main water line. Chemical injection systems also include some means of regulating the metering pump to control the addition of a chemical. This system should be designed to tightly control the addition of the chemical. The control system should ensure that a chemical is added only when water is flowing through the pretreatment cascade and that it is added in fixed proportion to the water flow or based on some continuously monitored parameter, such as pH, using an automated control system. If an automated control system is used to inject the chemical, the controlling parameter should be independently monitored. There should also be a means of verifying that the concentrations of any residuals arising from the chemical added to the water are reduced to a safe level before the water reaches its point of use.

When acid is added to adjust pH, a mineral acid should be used; organic acids may act as a nutrient and allow bacteria to proliferate.

5.2.7 Reverse osmosis

NOTE—Requirements for reverse osmosis systems intended for use in hemodialysis applications can be found in subclause 4.3.7 of normative reference 2.3.

Reverse osmosis (RO) systems have become widely used in hemodialysis water purification systems, largely because these devices remove dissolved inorganic solutes as well as bacteria and bacterial endotoxins.

The RO membrane separation process components are a semipermeable membrane, typically in a spiral-wound configuration, a pump, and various flow and pressure controls to direct the flow of water through the system. In operation, feed water is pressurized by the RO pump and is then directed along the surface of the semipermeable membrane. A portion of the water is forced through the membrane, a process that removes inorganic salts, bacteria, and bacterial endotoxins. The remainder of the water continues along the membrane surface and is directed to drain. Water passing through the membrane is referred to as “product water” or “permeate.” The water that flows along the membrane surface and to the drain is known as “reject water” or “concentrate.” This flow configuration, known as “cross-flow filtration,” prevents a progressive build-up of materials on the membrane surface that would eventually lead to fouling and membrane failure. In some reverse osmosis systems, a portion of the reject water stream is recycled to the feed water stream. This recycling allows higher velocities across the membrane surface, which may help reduce membrane fouling, as well as allowing higher overall use of water. RO systems usually operate in a single-stage configuration. However, if a higher level of purification is required, a two-stage RO can be used. In a two-stage RO, the product water from the first stage acts as the feed water for the second stage.

Depending on membrane configuration and materials of construction, RO systems are sensitive to various feed water conditions that may lead to diminished performance or premature failure. To avoid such problems, users should carefully follow the manufacturer’s instructions for feed water treatment and monitoring to ensure that the RO is operated within its design parameters.

RO systems should be fitted with a variety of sensors to monitor the system’s performance. Conductivity or total dissolved solids (TDS) sensors in the feed water and product water streams are used to monitor the membrane’s ability to remove dissolved inorganic solutes. Flow meters, usually in the product water and reject water streams, are used to monitor the output of the RO system. RO systems are also fitted with gauges to monitor the pressure at various points in the system. Although not indicative of treated water quality, monitoring flow rates and pressures can help ensure that the system is operating within the manufacturer’s specifications and thus will help ensure RO reliability.

5.2.8 Deionization

NOTE—Requirements for deionizers intended for use in hemodialysis applications can be found in subclause 4.3.10 of normative reference 2.3.

Deionization (DI) is an ion exchange process that removes both anions (negatively charged ions) and cations (positively charged ions) from water. During the exchange process, hydroxyl ions replace other feed water anions, and hydrogen ions replace other feed water cations; the hydroxyl and hydrogen ions then combine to form pure water. Water treated by DI may be very high quality with regard to ionized contaminants, but the process does not remove nonionized substances, including bacteria and bacterial endotoxins. DI systems may contain anion and cation resin in separate vessels, known as “dual-bed systems,” or have may both resin types mixed together in a single vessel, known as “mixed-bed” or “unibed systems.”

Systems that include deionizers as a component shall also contain carbon adsorption and ultrafiltration. In such systems, carbon is placed upstream of the deionizer to avoid formation of carcinogenic nitrosamines, and ultrafiltration is placed downstream of the deionizer to remove bacteria and endotoxins. The usual application for a deionizer is as a polisher following reverse osmosis or as a standby process if the reverse osmosis system fails. Use of deionization as the primary means of purification is not recommended because of the inability of deionization and ultrafiltration to remove certain low-molecular-weight toxic bacterial products, such as microcystins. In all instances, deionizers shall be followed by an ultrafilter or other bacteria- and endotoxin-reducing device to remove microbiological contaminants that may originate in the deionizer resin bed.

DI has a finite capacity that, when exceeded, will cause dangerously high levels of contaminants in the product water. Fortunately, the quality of product water from DI is easily monitored by resistivity monitors that, when used as specified in ANSI/AAMI RD62:2001 (see 2.3) (minimum resistivity 1 megohm-cm or greater), can prevent inadvertent operation of an exhausted deionization system. Specifically, the resistivity monitor following the final deionizer bed shall be connected to an audible and visible alarm in the dialysis treatment area, and the DI system shall divert product water to drain or otherwise prevent product water from entering the distribution system should an alarm condition occur. Under no circumstances shall DI be used when the product water of the final bed has a resistivity below 1 megohm-cm.

The most common configuration for DI is to have two mixed beds in series, with resistivity monitors being placed downstream of each bed. Upon exhaustion of the first bed, reliance for water of sufficiently high resistivity shifts to the second bed, and dialysis operations may be continued for a short time (up to 72 hours) until a replacement bed is installed.

5.2.9 Ultrafiltration

NOTE—Requirements for ultrafilters intended for use in hemodialysis applications can be found in subclause 4.3.12 of normative reference 2.3.

Ultrafilters are membrane-based separation devices that may be used to remove particles as small as 1,000 dalton and are thus well suited to remove both bacteria and endotoxins. Endotoxin-retentive ultrafilters should be placed in dialysis water systems at locations downstream of deionization, if deionization is the last process in a water treatment system (see subclause 4.3.6 of normative reference 2.3) or following ultraviolet irradiation (see subclause 4.3.13 of normative reference 2.3).

Ultrafiltration membranes used for dialysis applications are typically in either a spiral-wound configuration or in a hollow-fiber configuration. Spiral-wound ultrafilters are usually operated in a cross-flow mode, with a fraction of the feed water being forced through the membrane and the remainder being directed along the membrane surface to drain. As with reverse osmosis, cross-flow filtration is intended to minimize membrane fouling. Hollow-fiber ultrafilters are typically housed in vessels similar to those used for cartridge sediment filters and these are operated in a dead-end (no cross-flow) mode.

Ultrafilters should be fitted with pressure gauges on the inlet and outlet water lines to monitor the pressure drop (ΔP) across the membrane. Such monitoring will indicate when membrane fouling has progressed to the point at which membrane replacement or cleaning is needed. Monitoring also ensures that the device is being operated in accordance with the manufacturer's instructions. Ultrafilters should be included in routine disinfection procedures to prevent uncontrolled proliferation of bacteria in the feed water compartment of the filter. If bacterial proliferation is not controlled, bacteria may "grow through" the membrane and contaminate the product water compartment of the filter. Ultrafilters operated in the cross-flow mode should also be fitted with a flow meter to monitor the flow rate of water being directed to drain.

5.3 Water storage and distribution

5.3.1 General

The function of the water storage and distribution system is to distribute product water from the purification cascade to its points of use, including individual hemodialysis machines, hemodialyzer reprocessing equipment, and concentrate preparation systems. A water storage and distribution system typically contains a large volume of water exposed to a large surface area of piping and storage tank walls. Because chlorine and chloramines are removed in the purification process, the water does not contain a bacteriostatic agent. This combination of circumstances predisposes wetted surfaces to bacterial proliferation and biofilm formation. Therefore, a water storage and distribution system should be designed specifically to facilitate bacterial control, including measures to prevent bacterial colonization and to allow for easy and frequent disinfection.

5.3.2 Water storage

When used, storage tanks should have a conical or bowl-shaped base and should drain from the lowest point of the base. Storage tanks should have a tight-fitting lid and be vented through a hydrophobic 0.2 μm air filter. The filter

should be changed on a regular schedule according to the manufacturer's instructions. A means shall be provided to effectively disinfect any storage tank installed in a water distribution system. Internal spray mechanisms can facilitate effective disinfection and rinsing of a storage tank.

5.3.3 Water distribution systems

Two types of water distribution systems are used: direct feed systems and indirect feed systems. In a direct feed system, water flows directly from the last stage of the purification cascade to the points of use. In an indirect feed system, water flows from the end of the purification cascade to a storage tank. From there, it is distributed to the points of use. In general, direct feed systems offer the least favorable environment for bacterial proliferation. However, with a direct feed system the purification cascade must be sized to provide sufficient water to meet the peak demand, and the system must have sufficient pressure at the end of the purification cascade to distribute the water to the points of use. Those two requirements often preclude the use of a direct feed system. Whichever type of system is used, water distribution systems should be configured as a continuous loop and designed to minimize bacterial proliferation and biofilm formation (see clause 7). A centrifugal pump made of inert materials is necessary to distribute the purified water and aid in effective disinfection. A multistage centrifugal pump is preferred for this purpose.

Product water distribution systems shall be constructed of materials that do not contribute chemicals, such as aluminum, copper, lead, and zinc, or bacterial contaminants to the purified water. The choice of materials used for a water distribution system will also depend on the proposed method of disinfection. Table 2 provides some guidance on the compatibility of different materials and disinfection agents. Whatever material is used, care should be taken to select a product with properties that provide the least favorable environment for bacterial proliferation, such as smooth internal surfaces.

Table 2—Compatibility of common disinfectants with piping materials used in water distribution systems

Material	Bleach	Peracetic acid	Formaldehyde	Hot water	Ozone
PVC	X	X	X		
CPVC	X	X	X		X
PVDF	X	X	X	X	X
PEX	X	X	X	X	
SS		X	X	X	X
PP	X	X	X	X	
PE	X	X	X		
ABS		X			
PTFE	X	X	X	X	X
Glass	X	X	X	X	X

PVC = polyvinylchloride, CPVC = chlorinated polyvinylchloride, PVDF = polyvinylidene fluoride, PEX = cross-linked polyethylene, SS = stainless steel, PP = polypropylene, PE = polyethylene, ABS = acrylonitrile butadiene styrene, PTFE = polytetrafluoroethylene.

NOTE—Table 2 is not intended as an exhaustive compilation of all possible compatible combinations of piping material and disinfectant. Users should verify compatibility between a given germicide and the materials of a piping system with the supplier of that piping system before using the germicide. Considerations of compatibility should include any joint materials and pipe fittings, as well as the actual piping material. The concentration of germicide and the duration and frequency of exposure also should be taken into account.

5.3.4 Bacterial control devices

5.3.4.1 Ultraviolet irradiators

NOTE—Requirements for ultraviolet (UV) irradiators intended for use in hemodialysis applications can be found in subclause 4.3.13 of normative reference 2.3. The recommendations provided in this clause concern UV irradiators used specifically for bacterial