

# American National Standard

ANSI/AAMI RD52:2004  
and

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



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Association for the Advancement  
of Medical Instrumentation

# 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.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

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.

## INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

American National Standard

ANSI/AAMI RD52:2004 and  
ANSI/AAMI RD52:2004/A1:2007, A2:2007,  
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  
Strikethrough for deleted text



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## Dialysate for hemodialysis

Developed by  
**Association for the Advancement of Medical Instrumentation**

Approved 9 August 2004  
Amendments 1 and 2 Approved 10 December 2007  
Amendments 3 and 4 Approved 24 April 2009 by  
**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

## AAMI Recommended Practice

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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 TIR60878:2009	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

<b>International designation</b>	<b>U.S. designation</b>	<b>Equivalency</b>
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.
<i>Alternates:</i>	Marilyn Brierton, Baxter Healthcare Corporation Ted A. Kasperek, Davita Total Renal Care Inc. Gregory Montgomery, Siemens Water Technologies Corporation John A. Rickert, Minntech Corporation Brooks E Rogers, Fresenius Medical Care Renal Therapies Group Steve Rowles, Church & Dwight Co Inc. David Updyke, Fresenius Medical Care Renal Therapies Group Gary Warns, CaridianBCT Sterilization Services Inc. Michael Webb, NxStage Medical 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.

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## 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.

This is a preview edition of an AAMI guidance document, intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

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

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For a complete copy of this AAMI document,  
contact AAMI at (877) 249-8226  
or visit [www.aami.org](http://www.aami.org).

## 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.

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

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

**Highlight for new info**  
**Strikethrough for deleted text**

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.