American National Standard

ANSI/AAMI RD47:2008/(R)2013

Reprocessing of hemodialyzers

AAMI
Advancing Safety in Medical Technology

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.

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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*.

AAMI Recommended Practice

ANSI/AAMI RD47:2008/(R)2013
(Revision of ANSI/AAMI RD47:2002 and RD47:2002/A1:2003)

Reprocessing of hemodialyzers

Developed by
Association for the Advancement of Medical Instrumentation

Approved 8 May 2008 and reaffirmed 4 October 2013 by
American National Standards Institute, Inc.

Abstract: This recommended practice is addressed to the physician responsible for reprocessing hemodialyzers. It covers personnel and patient considerations, records, equipment, physical plant and environmental safety, reprocessing material, patient identification and hemodialyzer labeling, reprocessing and storage procedures, disposition of rejected dialyzers, preparation for subsequent use, patient monitoring, and quality assurance and quality control. This document does not endorse either single use or reuse of dialyzers.

Keywords: blood, dialysis, labeling, medical equipment, packaging, personnel, records, reprocessing, reuse, test

AAMI Recommended Practice

This Association for the Advancement of Medical Instrumentation (AAMI) recommended practice implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI recommended practice does not in any respect preclude anyone, whether they have approved the recommended practice or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the recommended practice. AAMI recommended practices are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI recommended practice may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this recommended practice no later than five years from the date of publication. Interested parties may obtain current information on all AAMI documents by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

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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 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	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 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	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 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	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 and Amendment 1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	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 ANSI/AAMI BE78:2002/A1:2006	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)2003	Identical

International designation	U.S. designation	Equivalency
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	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
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	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 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	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	ANSI/AAMI/ISO 15223-1:2007	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	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 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 the recommended practice does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Renal Disease and Detoxification Committee** had the following members:

Cochairs:
Conor Curtin
Richard A. Ward, PhD

Members:
G. Steven Acres, Carolina Regional Nephrology Associates
Larry Alexander, Florian Services
Matthew J. Arduino, DrPH, U.S. Centers for Disease Control and Prevention
James W. Baker, AmeriWater
Robert Berube, Church & Dwight Company Inc.
Wayne Carlson, Minntech Corporation
Danilo B. Concepcion, CHT, CCHT, St. Joseph Health System
Conor Curtin, Fresenius Medical Care North America
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/Office of Device Evaluation
Susan Hansen, Renal Solutions Inc.
Elizabeth Howard, Davita Total Renal Care Inc.
Bertrand Jaber, MD, Caritas St. Elizabeth's Medical Center
Byron Jacobs, CBET, Sanford USD Medical Center
David Katz, El Camino Hospital
Fei M. Law, Gambro Renal Products Inc.
Nathan W. Levin, MD, Renal Research Institute LLC
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Steve Rowles, Church & Dwight Company Inc.
Gary Warns, Gambro Renal Products Inc.
Michael Webb, BSIE, MBA, NxStage Medical Inc.

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.

Foreword

This recommended practice was developed by the AAMI Renal Disease and Detoxification Committee. The committee's objectives are to acknowledge the widespread practice of hemodialyzer reprocessing, without endorsement or criticism; to indicate risks associated with hemodialyzer reprocessing; and to provide recommendations for optimal hemodialyzer reprocessing, as a service to patients, physicians, and facilities.

This recommended practice reflects the conscientious efforts of health care professionals, patients, and medical device manufacturers to develop recommendations for optimal hemodialyzer reprocessing procedures. These recommendations are not meant to be construed as universally applicable in all circumstances. This document is intended to guide physicians in charge of hemodialyzer reprocessing, particularly the directors of dialysis facilities, in initiating a new hemodialyzer reprocessing program or evaluating an existing program against present day technology and accepted practices.

This recommended practice should be considered flexible and dynamic. As technology advances and new data are brought forward, this recommended practice will be reviewed and, if necessary, revised. The term "should" as used in this recommended practice 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 use of phrases such as "have been shown," "an established procedure," "demonstrated success," or others of similar words signifies that the basis for the process may be found in a manufacturer's labeling, medical or scientific literature, standards or publications from authoritative agencies, or clearly documented, scientifically sound studies performed locally.

These guidelines were developed by professionals and are not designed for regulatory applications but have been put into service as such.

The concepts incorporated in this recommended practice should not be considered inflexible or static. The recommendations presented here should be reviewed and updated periodically to assimilate technological developments.

The rationale for this recommended practice (annex A) not only contains explanations of the need for the provisions of the recommended practice, but also gives proposed revisions that were not included in this recommended practice and the reasons for those exclusions. The reader is encouraged to review the rationale for each section carefully to better understand the recommended practice itself and the state of the art in reprocessing hemodialyzers.

AAMI standards and guidelines are based on the national consensus of physicians, engineers, other health care professionals, government representatives, patients, and industry. This consensus has traditionally focused on technology design, performance, and testing—areas in which the AAMI membership has considerable knowledge and experience. During the development of this document, several interest groups requested detailed requirements for informed patient consent with respect to the reuse of hemodialyzers. It is unclear whether informed patient consent requirements can or should be developed by a consensus of the groups mentioned. It may be more appropriate for informed patient consent requirements to be developed by physicians, patients, and their representatives. This document does not go as far as the patients' representatives requested on that subject, although it does go further than previous documents of this type. The extent to which AAMI or any standards organization should develop informed patient consent requirements can be determined as this guideline is evaluated during its use.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions 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 RD47:2008, *Reprocessing of hemodialyzers*, but it does provide important information about the development and intended use of the document.

Introduction: Need for this AAMI recommended practice

In June 1980, the Bureau of Medical Devices of the U.S. Food and Drug Administration (FDA), now the Center for Devices and Radiological Health, transmitted to AAMI the final report of an FDA-sponsored study, "An Investigation of the Risks and Hazards Associated with Hemodialysis Devices," that was undertaken to recommend ways of controlling these risks and hazards. This information was compiled to assist the medical community and to provide data to support the development of recommended practices.

Beginning in 1980, the reported incidence of hemodialyzer reuse rose dramatically, from an estimated 16 % of patients in 1980 to an estimated 82 % of clinics in 1997. This increase was attributable, in part, to the increasing pressure of federal measures to contain the costs of health care implemented by the prospective reimbursement regulations initiated on 1 August 1983. The percentage of centers practicing reuse declined after 1997 to 63 % in 2002 (Finelli, et al., 2005), and in 2005, it was estimated that 61 % of patients were being treated with single-use dialyzers (Lacson and Lazarus, 2006).

Although good results have been demonstrated by the practitioner experienced in hemodialyzer reprocessing, the widespread application of this technique in the absence of detailed consensus guidelines has created greater opportunities for the nonexpert practitioner to use inadequate methods. Moreover, cost saving by any procedure that adds risks to the patient if improperly done may cause some patients and health care professionals to suspect that the welfare of the patient may not be the primary concern. These fears may be justified, because merely claiming that reuse is safe, without defining details of the process, allows unsafe procedures to appear under the guise of acceptable medical practice. Thus, failure to ensure that reuse is done safely for all patients causes the brush of mistrust to paint all practitioners alike, when, in fact, the multiple use of hemodialyzers may actually improve the quality of care and access to dialysis. Those who are expert in reprocessing hemodialyzers can, therefore, perform a valuable service by developing guidelines for the less experienced practitioner that will achieve the high quality of care that health care professionals want for their patients. This recommended practice has been written to respond to the concern of patients, health care professionals, and manufacturers that dialyzer reprocessing be conducted safely and effectively.

It was against this background that AAMI convened a consensus-development conference in May 1983 to examine the issues surrounding reuse of hemodialyzers and to discuss the position of the medical and scientific community on the subject. One recommendation emerging from this conference, in which representatives from many medical and scientific societies participated, was that approval by consensus of a nationally developed recommended practice for the reprocessing of hemodialyzers was desirable and necessary for patient safety and continued clinical efficacy. Another recommendation was that the guidelines be developed under the auspices of AAMI because AAMI could coordinate the development of a national consensus. AAMI subsequently established the Hemodialyzer Reuse Subcommittee of the Renal Disease and Detoxification Committee. The subcommittee's membership includes representatives of manufacturers, patients, health care organizations, government agencies, and health care professionals.

In November 1984, an AAMI technology assessment conference was held on the subject of hemodialyzer reuse. The conference attendees reviewed the fourth draft of the recommended practice being written by the AAMI subcommittee. Presentations were also made about the results of a survey of hemodialyzer reprocessing in the United States, water for reprocessing, germicides, statistical analysis, methods of performance testing, reprocessing machines, the perspective of patients, the viewpoint of manufacturers, reprocessing in the home, and the FDA's position on the reprocessing of medical devices. Future revisions of the recommended practice incorporated information gleaned from the conference and comments from other interested parties. In October 1987, the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration, adopted the recommended practice as part of their regulations governing Medicare reimbursement. Because the guideline was not constructed as a regulation, many questions arose as surveyors attempted to enforce compliance. The AAMI Hemodialyzer Reuse Subcommittee issued an interpretive guideline in 1991 that clarified the issue of dialyzer performance verification, the most common source of misunderstanding in the previous version. When the reuse document was reviewed in 1993, the interpretation was incorporated. Subsequently, the CMS adopted the 1993 revisions in a manner similar to their adoption of the 1987 version. Dialyzer manufacturers are now expected to follow the FDA guidance document titled "Guidance for Hemodialyzer Reuse Labeling" (6 October 1995). This guidance requires a manufacturer to label its dialyzers for either single use or multiple use. In cases of labeling a dialyzer for reuse, the FDA guidance document requires that the manufacturer perform certain bench testing using simulated reuse and then perform a limited clinical trial to support the bench results. Those data are submitted to the FDA and reviewed as part of the 510(k) Premarket Notification for the reusable dialyzer.

In the early 1990s, a statistically significant association was reported between mortality and the use of low-flux dialyzers reprocessed with certain germicides in freestanding clinics (Held, et al., 1994; Feldman, et al., 1996). No cause-and-effect relationship was established in those studies, and potentially confounding variables, such as a

“center effect” and the adequacy of dialysis, were not evaluated. Indeed, the results of more recent studies (Collins, et al., 1998; Ebben, et al., 2000; Port, et al., 2001) suggest that factors other than the choice of germicide may have contributed to the differences in outcome.

Reprocessing of hemodialyzers

1 Scope

This recommended practice describes the essential elements of good practice for reprocessing hemodialyzers to help ensure device safety and effectiveness. These practices embrace considerations of the device and the patient, as well as attention to equipment, facilities, cleaning and disinfection methods, labeling, preparation for multiple use, and quality control of the reuse process. This document does not endorse either single use or reuse of dialyzers.

Regardless of the labeling recommendations, prescription to reuse remains the sole responsibility of the patient's physicians. Therefore, this recommended practice is addressed to the physician responsible for the hemodialyzer reprocessing program. Users, however, should be aware that dialyzers intended for reuse must be labeled for reuse in accordance with the Food and Drug Administration (FDA) document "Guidance for Hemodialyzer Reuse Labeling" (6 October 1995).

The committee recognizes that reuse may affect such dialyzer characteristics as biocompatibility and clearance of larger molecules. Changes in dialyzer performance and biocompatibility vary with the materials of construction and the reuse method employed. Detailed analysis of these factors is beyond the scope of this document. Specific information on the effects of reuse on dialyzer performance and biocompatibility may be obtained from the dialyzer manufacturer and the scientific literature (Cheung, et al., 1999). This recommended practice does not address every risk or benefit that may be associated with reuse.

1.1 Inclusions

This recommended practice is directed to the physician in charge of hemodialyzer reprocessing by either the manual or the automated method. Subjects included within the scope of this recommended practice are recordkeeping, personnel considerations, patient considerations, equipment considerations, physical plant and environmental safety, reprocessing material considerations, patient identification and hemodialyzer labeling, reprocessing and storage procedures, disposition of rejected dialyzers, preparation for subsequent use, patient monitoring, quality assurance, and quality control.

1.2 Exclusions

This recommended practice does not cover the reprocessing of blood tubing sets, nor does it address labeling and performance requirements for single-use hemodialyzers.

2 Normative references

The following documents contain provisions that, through reference in this text, constitute provisions of this AAMI recommended practice. At the time of publication, the editions indicated were valid. All recommended practices are subject to revision, and parties to agreements that are based on this AAMI recommended practice are encouraged to investigate the possibility of applying the most recent editions of the documents listed below.

Association for the Advancement of Medical Instrumentation. *Water treatment equipment for hemodialysis applications.* ANSI/AAMI RD62:2006. Arlington (VA): AAMI, 2006.

Bolyard EA, Tablan OC, Williams WW, Pearson ML, Shapiro CN, Deitchman SD, and Hospital Infection Control Practices Advisory Committee. Infection Control in Healthcare Personnel: Guideline for infection control in healthcare personnel, 1998. *Infection Control and Hospital Epidemiology*, 19:407–463,1998. (available from http://www.cdc.gov/ncidod/dhqp/gl_hcpersonnel.html)

Centers for Disease Control and Prevention. *Recommendations for preventing transmission of infections among hemodialysis patients*. *MMWR* 50, RR-5, 2001. (available from http://www.cdc.gov/mmwr/PDF/rr/rr5005.pdf)

Occupational Safety and Health Administration. Occupational Safety and Health Standards. Bloodborne pathogens. Code of Federal Regulations. Title 29, Volume 6, Chapter XVII, Part 1910.1030 Revised as of August 14, 2006 (available from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051)