

American National Standard



ANSI/AAMI RD47:2020

Reprocessing of
hemodialyzers

Reprocessing of hemodialyzers

Approved 23 December 2019 by
AAMI

Approved 16 January 2020 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

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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:

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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.

Foreword

This recommended practice was developed by the AAMI Renal Disease and Detoxification Committee. The committee's objectives are to acknowledge the 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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of the American National Standard ANSI/AAMI RD47:2020, *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 Galvreuse, 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. In addition, in 2011 Bond et al wrote that “Dialyzer reuse with peracetic acid does not impact patient mortality.” In 2012 Galvao et al concluded that “no significant differences were identified for the superiority or inferiority of dialyzer reuse versus single use when assessing the mortality of patients with end-stage renal disease”. The disinfectants used in the Galvao study on dialyzer reprocessing were hypochlorite, formaldehyde, glutaraldehyde, and peracetic acid.

In 2018, the percentage of centers practicing dialyzer reuse in the United States is estimated to have declined to less than 10 percent. While the practice of dialyzer reuse is no longer common within the United States, this document continues to be relevant and important for those centers in the United States (and outside the United States) that continue to practice dialyzer reuse. Moreover, in 2018, the Centers for Medicare and Medicaid Services (CMS)—in its Interpretive Guidance document (Version 1.1, October 3, 2008) used to survey (audit) dialysis centers—continues to incorporate by reference ANSI/AAMI RD47:2002/A1:2003. To withdraw RD47 would remove the document from publication and the ability to acquire the full stand-alone document for use in reference and self-assessment of a dialyzer reuse program. The AAMI RDD Committee also considered that in the event of a disaster scenario, it would be possible that it could become necessary to reuse dialyzers.

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 shall 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.

International Organization for Standardization (ISO). ISO 23500-3, *Preparation and quality management of fluids for haemodialysis and related therapies -- Part 3: Water for haemodialysis and related therapies*. Geneva, Switzerland: ISO, 2019.

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)

Occupational Safety and Health Administration. Occupational Safety and Health Standards. Hazard communications. Code of Federal Regulations. Title 29, Volume 6, Chapter XVII, Part 1910.1200 Revised as of August 14, 2006 (available from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10099)

Occupational Safety and Health Administration. Occupational Safety and Health Standards. Formaldehyde. Code of Federal Regulations. Title 29, Volume 6, Chapter XVII, Part 1910.1048 Revised as of August 14, 2006 (available from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10075)

3 Definitions

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

3.1 cleaning: Flushing of a solution or solutions through the blood and dialysate compartments or the passage of fluid through the membrane (i.e., reverse ultrafiltration) to purge the dialyzer of blood and other substances.

3.2 clearance: Measure of net flux of a given solute across the hemodialyzer membrane that is expressed as the number of milliliters of blood completely cleared of a solute per unit of time. For the purpose of this recommended practice, clearance includes clearance because of ultrafiltration. (See also **clearance, open-loop system**.)

3.3 clearance, open-loop system: Clearance determined in a test system in which the solutions perfusing the hemodialyzer are discharged to drain after one passage through the hemodialyzer. The calculation for clearance by this method is as follows:

$$\text{Clearance (mL/min)} = \frac{(C_{Bi} - C_{Bo})Q_{Bi}}{C_{Bi}} + \frac{C_{Bo}Q_{UF}}{C_{Bi}}$$

where

C_{Bi} = concentration of solute in the fluid entering the blood compartment,

C_{Bo} = concentration of solute in the fluid leaving the blood compartment,

Q_{Bi} = flow rate of fluid entering the blood compartment, and

Q_{UF} = ultrafiltration rate.

3.4 dialyzer: See **hemodialyzer**.

3.5 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 not necessarily all microbial forms. This definition of disinfection is equivalent to low-level disinfection in the Spaulding classification.

3.6 endotoxin: The major component of the outer cell wall of gram-negative bacteria. Endotoxins are lipopolysaccharides, consisting of a polysaccharide chain covalently bound to lipid A. Endotoxins can acutely activate both humoral and cellular host defenses, leading to an acute syndrome characterized by fever, shaking chills, hypotension, multiple organ failure, and even death if allowed to enter the circulation in a sufficient dose. Long-term exposure to low levels of endotoxin has been implicated in a chronic inflammatory response, which may contribute to some of the long-term complications seen in hemodialysis patients. However, the mechanisms of this process remain incompletely understood. (See also **pyrogen**.)

3.7 fiber bundle volume (FBV): Aggregate volume of patent hollow fibers contained within the blood compartment of a hollow-fiber dialyzer. Sometimes, incorrectly used interchangeably with total cell volume, which includes header volume.

3.8 first-use syndrome: Symptom complex characterized by chest tightness, back pain, dyspnea, angioedema or laryngeal edema, peripheral numbness and tingling, flushing of the skin, pruritis, and nausea and vomiting, occurring within minutes of the initiation of dialysis with a new dialyzer. Although usually mild in nature, the symptoms may, in extreme cases, progress to respiratory arrest and death. The etiology of first-use syndrome is not completely understood. However, the term is usually considered to include anaphylactoid reactions to residual ethylene oxide in ethylene oxide-sterilized dialyzers and anaphylactoid reactions resulting from the induction of

bradykinin release by negatively charged AN69®¹⁾ membrane. The latter reactions are exacerbated by the presence of ACE inhibitors, which suppress bradykinin degradation. Anaphylactoid reactions, similar to first-use syndrome, have also been reported with reused dialyzers. The risk of these reactions is also increased when ACE inhibitors are present.

3.9 formaldehyde: Formaldehyde (CH₂O) solution, USP (United States Pharmacopeia) (nominal concentration 37 % by weight (weight/weight [W/W]) or 40 % by volume (weight/volume [W/V])). Generally contains 8 % to 16 % methanol for stabilization. A dilution of 1 part of formaldehyde with 9 parts of water yields 4 % (W/V). Also called formalin. Concentrated formaldehyde stored under adverse conditions can polymerize to form paraformaldehyde, a white precipitate.

3.10 germicidal bleach: solution of 5.25%–6.15% sodium hypochlorite typically diluted in water at 1:10 or 1:100 for use as a disinfectant.

NOTE Sodium hypochlorite solutions used for disinfectant should not contain thickeners (e.g., thick bleach, splashless bleach) or scents (e.g., coconut, fresh scented, lemon, lavender, pumpkin spice, etc.).

3.11 germicide: Agent that kills microorganisms.

3.12 hazard: Situation or condition that could be detrimental to patients or staff members.

3.13 heat disinfection: Physical method of disinfection used in reprocessing some dialyzer types.

3.14 hemodialyzer: Extracorporeal device that (a) changes the chemical composition of the blood by diffusive and convective transfer of substances between the blood and a solution of chemicals through a semipermeable membrane and that (b) functions within clinically acceptable rates of water and solute transport.

3.15 high-level disinfection: Process that kills all vegetative bacterial cells, *Mycobacterium tuberculosis* var. *bovis*, fungi, all small or nonlipid viruses, and (if the contact time is long enough) most bacterial endospores.

3.16 labeling: Display of written, printed, or graphic matter on a dialyzer, including all packaging and package inserts.

3.17 lipopolysaccharide (LPS): Major outer membrane component of gram-negative bacteria. Lipopolysaccharides are important antigenic factors and are endotoxins. The general structure is a heteropolysaccharide chain (core polysaccharide and O-specific chain) covalently bound to a glycolipid (lipid A). (See also **endotoxin**.)

3.18 low-level disinfection: Process or procedure that inactivates most vegetative bacteria, except for *Mycobacterium tuberculosis* var. *bovis* and some viruses. (See also **disinfection**.)

3.19 membrane: Semipermeable material between the blood and dialysate compartments of a hemodialyzer.

3.20 multiple use: Use of a device for more than one procedure, after suitable reprocessing of the device.

3.21 OSHA: Occupational Safety and Health Administration.

3.22 performance: Solute and fluid mass transfer capabilities of a hemodialyzer.

3.23 port, blood: Opening into the blood compartment of a hemodialyzer.

3.24 port, dialysate: Opening into the dialysate compartment of a hemodialyzer.

3.25 ppm: Parts per million.

3.26 preprocessed dialyzer: Dialyzer subjected to reprocessing procedure before first use.

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

3.28 quality assurance (QA): Verification that written policies and procedures have been developed and are being implemented.

3.29 quality control (QC): Determination that the materials, process tests, and performance of the final product meet the designated specifications.

¹⁾AN69® is a registered trademark of Hospal.

3.30 rebound: Increase in germicide concentration after rinsing to a particular concentration.

3.31 removal of germicide: Passage of a solution through the blood and dialysate compartments of a hemodialyzer to purge it of the germicide.

3.32 reprocessing number: The number of times a dialyzer has been reprocessed.

NOTE—The reprocessing number is the number of times a dialyzer has been submitted to the clean–test–disinfect cycle. It may differ from the use number if a dialyzer is reprocessed more than once between actual treatments, as could occur if a dialyzer was prepared for a treatment, but not used.

3.33 reverse ultrafiltration: Passing of fluids through the membrane from the dialysate compartment to the blood compartment. This action is used to clean the membrane of blood products for the purpose of reuse.

3.34 risk: Event that is considered likely or possible and that is potentially hazardous but has not yet occurred or resulted in detrimental clinical consequences.

3.35 safety data sheets (SDS): Documents that identify, for any chemicals, the degree and type of any hazards and appropriate precautions. Manufacturers are required to provide these documents upon request.

3.36 standard precautions: Synthesis of the major features of universal (blood and body fluid) precautions (designed to reduce the risk of transmission of bloodborne pathogens) and body substance isolation (designed to reduce the risk of transmission of pathogens from moist body substances). Standard precautions apply to (a) blood; (b) all body fluids, secretions, and excretions, except sweat, regardless of whether they contain visible blood; (c) nonintact skin; and (d) mucous membranes. Standard precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in health care settings.

3.37 sterile: Free of all microbial life, including highly resistant bacterial spores.

3.38 total cell volume (TCV): Volume of an aqueous liquid to fully prime the blood compartment of a hollow-fiber hemodialyzer. This volume is the sum of the fiber bundle volume and the header volume.

3.39 toxic substance: Substance that, in sufficient amounts, causes harm to an exposed organism.

3.40 transmembrane pressure (TMP): Pressure exerted across the semipermeable membrane, from the blood to the dialysate side of the dialyzer, which can be expressed by the following equation:

$$\text{TMP} = (P_{\text{Bi}} + P_{\text{Bo}})/2 - (P_{\text{Di}} + P_{\text{Do}})/2 - P_{\text{oncotic}},$$

where

P_{oncotic} = oncotic pressure created by plasma proteins,

P_{Bi} = pressure at the arterial (inlet) port of a hemodialyzer blood compartment,

P_{Bo} = pressure at the venous (outlet) port of a hemodialyzer blood compartment,

P_{Di} = pressure at the inlet port of a hemodialyzer dialysate compartment, and

P_{Do} = pressure at the outlet port of a hemodialyzer dialysate compartment.

3.41 ultrafiltration (UF): Transfer of fluid from the blood compartment to the dialysate compartment through the dialysis membrane as a result of a pressure gradient (transmembrane pressure) existing between the blood and dialysate compartments.

3.42 use number: Number of times a hemodialyzer has been used for dialysis treatments with a single patient.

NOTE—The use number is the number of actual treatments performed with a dialyzer. It may differ from the reprocessing number if a dialyzer is reprocessed more than once between treatments, as could occur if a dialyzer was prepared for a treatment but not used.

3.43 validation or process validation: Establishment of documented evidence providing a high degree of assurance that a given process will consistently yield a result meeting predetermined specifications and quality characteristics.

4 Records

All records described in this recommended practice shall meet the requirements for medical records, including completeness, legibility, and security. A place should be provided for the signature or other unique mark of identification of the person completing each step of the reprocessing procedure (i.e., the persons performing

preventive maintenance procedures, the persons investigating complaints, and the persons conducting quality assurance and quality control activities). Maintaining these records is the responsibility of the medical director.

4.1 Dialyzer reprocessing manual

The dialyzer reprocessing manual should be a compilation of all specifications, policies, training materials, manuals, methodologies, and procedures that may be integrated into the dialysis facility's policy and procedures manual. The dialyzer reprocessing manual should also contain samples of forms and labels, if appropriate. The operational logs, manuals, and records may be kept separate from the dialyzer reprocessing manual. The manual should incorporate any special considerations specified by the dialyzer manufacturer.

4.2 Reprocessing record

Records shall be kept that identify the new dialyzer, the date of each reprocessing step, the person performing the procedure, his or her signature or other identifying mark, and the results of tests of device performance and safety. This information should be recorded in a reprocessing log or the patient's chart, whichever is more convenient. Patients shall be permitted to read records pertaining to the reprocessing and reuse of their own dialyzers.

4.3 Equipment maintenance record

Records shall be maintained of the dates of preventive maintenance procedures and the results of scheduled testing to ensure the proper functioning of reprocessing, environmental control, safety, or other equipment.

4.4 Personnel health monitoring records

A file shall be kept of the results of personnel medical examinations that are required by OSHA or other regulatory agencies.

4.5 Complaint investigation record

Records shall be kept of all complaints by patients and staff members about failures of preprocessed and reprocessed dialyzers or possible adverse reactions to any dialyzers; the results of a comprehensive investigation of these alleged problems; and, if appropriate, the corrective actions taken. The records should be reviewed periodically for trends of adverse reactions. Staff members should consider whether any adverse reactions need to be reported in compliance with the FDA's Medical Device User Reporting procedures.

4.6 Quality assurance and quality control record

A record shall be kept of the date and results of QA and QC evaluations and the person or persons conducting the evaluations.

5 Personnel qualifications and training

5.1 Qualifications

Personnel shall possess adequate education, training, or experience to understand and perform procedures outlined by the individual dialysis facility relevant to the facility's multiple-use program. New personnel range in knowledge from those with no medical background who are fully trained by the facility to licensed practitioners with extensive medical background. Education should be geared to meet the needs of this wide range of personnel.

5.2 Training

5.2.1 Curriculum

The dialysis facility's physician or director shall establish a training course for the personnel performing hemodialyzer reprocessing. A written document should give details about the curriculum and, in particular, address the potential risks to patients and staff members of not following correct procedures. The curriculum should include at least the following information:

- a) the facility's specific reprocessing procedure, including a rationale for each step;
- b) basic documentation requirements of the program;

- c) the operation and maintenance of the facility's specific equipment for reprocessing hemodialyzers and, if appropriate, the dialysis systems and components;
- d) microbiology with respect to aseptic technique, the collection and handling of samples, and personnel safety precautions for infectious hazards;
- e) the risks and hazards of multiple use of hemodialyzers;
- f) the consequences of not performing tasks properly;
- g) the risks and hazards associated with toxic substances used in reprocessing hemodialyzers, proper handling of these substances, and procedures for handling spills and proper disposal of toxic substances;
- h) the use and location of protective eyewear, respirators, masks, and special clothing;
- i) emergency procedures as required by the facility; and
- j) the principles of dialysis, emphasizing the characteristics of the hemodialyzer and the effect of reuse on those characteristics.

5.2.2 Documentation

Each person performing procedures for the multiple use of dialyzers should have successfully completed the dialysis facility's training course relevant to that person's task and demonstrated competence in the area covered by his or her training. Successful completion of training should be certified by the medical director or his or her designated representative and recorded in the trainee's personnel file along with verification of the trainee's having received the instruction. Retraining is necessary when new procedures are undertaken. Annual review of competence is required with appropriate retraining if deficiencies are found.

6 Patient considerations

6.1 Medical issues

An order to reprocess hemodialyzers shall be made by a physician knowledgeable about reprocessing and its medical and economic implications. Because the current human immunodeficiency virus (HIV), hepatitis B, or hepatitis C status of a patient cannot be known with certainty, all staff potentially exposed to the patient's blood shall observe standard precautions. Dialyzers should not be reprocessed from patients who have tested positive with hepatitis B surface antigens. Precautions for all infectious hazards should be emphasized and included in the reprocessing procedures. Written procedures should stipulate whether and how reprocessing will be done for patients who have shown sensitivity to materials used in the reprocessing of hemodialyzers.

6.2 Patient education

The Centers for Medicare and Medicaid Services (CMS) *Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services* states that all patients in a dialysis facility will be fully informed regarding reuse of dialyzers. Printed material such as brochures describing the facility's services should contain a statement about dialyzer reprocessing if reuse is performed. National renal organizations may have additional materials available.

7 Equipment

Each piece of equipment used for reprocessing shall be appropriately designed, constructed, and tested to perform its intended task. Types of reprocessing systems vary from sophisticated microprocessor-controlled systems to hand-operated valving systems. Satisfactory operation of manual and automated systems shall be ensured by appropriate functional tests. Strict QA and QC shall be maintained for any type of dialyzer reprocessing equipment. Additionally, complete documentation of system function, operating procedures, potential system failures, and dialyzer-reuse criteria shall be included in the dialyzer reprocessing manual, be known to the operator, and be available for review.

7.1 Water systems

The system providing water for reprocessing shall meet all the requirements for pressure and flow rate for operating the reprocessing equipment under minimal and peak load conditions. Product water used for rinsing, cleaning, filling,

and diluting the germicide shall be shown to comply with the chemical and microbiological quality requirements specified in ISO 23500-3, *Preparation and quality management of fluids for haemodialysis and related therapies -- Part 3: Water for haemodialysis and related therapies*. Water bacteriology monitoring shall be carried out where the dialyzer is connected to the reuse system or as close as possible to that point.

7.2 Reprocessing systems

7.2.1 Utility requirements

The quality, pressure, flow rate, and temperature of the water used for reprocessing should be specified in the dialyzer reprocessing manual, established before the initiation of a reprocessing program, and maintained thereafter. The manufacturer's or designer's recommendations for the water supply should be followed. Provision should also be made for adequate drains, ventilation, and electrical power.

7.2.2 Process control testing

7.2.2.1 Dialyzer test methods (11.3) shall be established before clinical use of the reprocessed dialyzers. Verification of tests should be repeated after each significant change in the reprocessing system. For automated systems, adherence to the manufacturer's instructions can verify the tests. For manual systems, confirmation of the accuracy of the TCV measurement and the membrane integrity test can verify the tests.

7.2.2.2 The test for the concentration of germicide or chemical shall be established before clinical use of the reprocessed dialyzers (11.4.1.6 and 12.3.2). For systems using heat disinfection, a means of verifying the time and temperature of disinfection shall be established before clinical use of the reprocessed dialyzers (12.3). If a chemical is used to enhance heat disinfection, both a test for the concentration of the chemical and a means of verifying time and temperature shall be established.

7.2.3 Maintenance

Written maintenance procedures and a schedule of preventive maintenance activities designed to minimize equipment malfunctions should be established. In the case of purchased reprocessing equipment or safety equipment, follow the recommendations of the manufacturer. If the manufacturer's recommendations are unavailable, reuse equipment and safety equipment should be inspected on a semiannual basis. A record shall be kept of preventive maintenance activities (see 4.3), accompanied by the signature of the person performing the maintenance.

7.2.4 Repairs

If the reprocessing system fails to function as expected, qualified personnel should investigate and correct the problem. The reprocessing system function testing should be repeated after repairs of automated equipment and, if appropriate, after repairs of manual equipment before either the dialyzer is reprocessed or the reprocessed dialyzer is used for clinical dialysis.

8 Physical plant and environmental safety considerations

8.1 Reprocessing area and ventilation

The reprocessing area should be designed to suit the operation carried out and shall be able to maintain acceptable ambient concentrations of harmful substances (see Table 1). The area should be kept clean and sanitary. It may be part of the dialysis treatment area, as long as equipment used is properly designed and vented to meet the requirements for environmental safety (see 8.5).

Table 1—OSHA environmental exposure limits (29 CFR 1910, 2018), except as indicated

Substance or material	PEL ^{a)}
Acetic acid	10 ppm TWA ^{b)}
Chlorine dioxide (syn.: chlorine oxide)	0.1 ppm TWA
Citric acid	None developed
Formaldehyde	0.75 ppm TWA

Substance or material	PEL ^{a)}
	2 ppm STEL ^{c)} (15 min) 0.5 ppm action level
Glutaraldehyde	0.2 ppm ceiling NIOSH/OSHA
Hydrogen peroxide	1 ppm TWA
Peracetic acid	None developed
Phenol	5 ppm TWA

ppm = parts per million; NIOSH = National Institute for Occupational Safety and Health; OSHA = Occupational Safety and Health Administration.

^{a)}PEL (permissible exposure limit) represents the limit of what employees can be exposed to; PELs can be TWAs or STELs.

^{b)}TWA (time-weighted average) represents the limit of what an employee can be exposed to in an 8-hour period.

^{c)}STEL (short-term exposure limit) represents the limit of what an employee can be exposed to in any 15-minute time period.

8.2 Storage area

Reprocessing materials, hemodialyzers awaiting reprocessing, and reprocessed hemodialyzers should be stored so as to minimize deterioration, contamination, or breakage. Access to the storage area should be limited to protect the integrity of the reprocessed dialyzers and the confidentiality of patient information included on the labels. New, used, and reprocessed dialyzers should be segregated to make clear the status of each group of dialyzers. Environmental contamination of the storage area should be controlled and monitored if the personnel determine those actions to be necessary. Storage areas for new dialyzers and reprocessing materials should be designed to facilitate rotation of stock and cleaning. Storage arrangements should also take into account fire safety considerations, OSHA regulations, and other appropriate regulations.

8.3 Laboratory area

Tests that do not require special facilities, such as certain tests for germicide levels, may be done in the reprocessing or dialysis treatment area, whichever is appropriate.

8.4 Personnel protection

Personnel shall wear durable gloves and protective clothing when handling the dialyzer during initiation and termination of dialysis and during the reprocessing procedure. Standard precautions shall be observed. Eyes should be protected at all times when spills or splashes may be an issue. These agents shall be handled only in areas with adequate ventilation, washing facilities, eyewash stations, appropriate respirators, and spill control materials. Personnel handling concentrated toxic substances shall wear aprons impervious to those substances.

8.5 Environmental safety

The dialysis facility shall have written procedures for safe storage and handling of chemicals used in reprocessing (see National Institute for Occupational Safety and Health [NIOSH]/OSHA, 1980; Sax, 1979; material safety data sheets). Vapors from reprocessing materials shall be maintained below potentially toxic levels (see Table 1).

9 Reprocessing supplies

9.1 Specifications and testing

Each reprocessing material should meet a written specification. The fulfillment of that requirement may be determined by the product supplier's certification that the product meets necessary specifications and labeling for its intended purpose or by testing procedures by trained personnel, as appropriate. The requirement may also be met by purchasing a specific grade as specified by the process, such as USP citric acid. When the user performs testing, he or she should maintain a log of the test date, the batch identifying number (lot number), the person performing any testing, and the test results. Over the past few years, bleach (sodium hypochlorite) manufacturers have begun selling many new formulas of germicidal bleach (fragrance-free, without additives). The concentration of sodium hypochlorite has risen from 5.25 % to 6.15 % in many cases. The Centers for Disease Control's recommendations for diluting bleach have not changed to take into account these percentage changes.

Manufacturers of bleach have also begun using additives such as fragrances in products that are commercially marketed in grocery stores. When bleach is purchased from a commercial outlet, the labeled concentration should be between 5.25 % and 6.15 %, and the formula should not contain fragrances.

9.2 Inventory control

Reprocessing supplies should be used on a first-in, first-out basis, and outdated supplies should be identified and discarded.

10 Hemodialyzer labeling

Each reprocessed hemodialyzer shall be used for only one patient. Therefore, the labeling shall uniquely identify the patient who is using the dialyzer. The dialyzer should also be labeled with other information essential to proper reuse procedure.

10.1 Time of labeling

Each hemodialyzer shall be labeled before or at the first use of the device, and the label shall be updated after each use (see 10.3).

10.2 Label composition

Markings should be resistant to normal reprocessing and dialysis procedures. The dialyzer labeling should not obscure the manufacturer's model number, lot number, or indicators of the direction of blood or dialysate flow or other pertinent information unless provision is made for recording this information on the label. The label on hemodialyzers with transparent casings should permit the blood path to be readily inspected.

10.3 Information recorded

The dialyzer shall be labeled with the patient's name, the number of previous uses, and the date of the last reprocessing. Dialyzers of patients with similar names should have a warning to the user to take extra care in ensuring that the name or other identifying information on the label corresponds to that of the patient. If there is sufficient room, the dialyzer may also be labeled with the results of tests, the signature or other unique means of identifying the person performing the various steps in the reprocessing procedure, and the reference values for performance parameters. Whether or not this information appears on the label, a permanent record should also be kept (see 4.2). Electronic records are acceptable. If records are electronic, the test results should be available to the user. Home dialysis patients are exempted from the recommendation that the patient's name appear on the label, unless the dialyzers are taken to a dialysis facility for reprocessing.

11 Reprocessing

The multiple use of a dialyzer begins with the labeling of the new dialyzer (see section 10) and then continues with the reprocessing procedures described in this section. Preparation of the reprocessed dialyzer for the next dialysis is described in section 12. The cycle is repeated after the next use of the dialyzer until the dialyzer no longer meets the criteria for continued use. A systems diagram of these procedures is given in annex B (normative). The results of the tests and the signature or other unique means of identifying the person performing each step should be maintained in a permanent record (see 4.2). Completion of all reprocessing steps, tests, and inspections should be documented in the reprocessing record. Documentation should be accompanied by the signature or other unique means of identification of the person completing the steps. When appropriate for the reprocessing procedure in use, all dialyzer manufacturer's instructions regarding reuse should be carefully followed.

11.1 Transportation and handling

The personnel handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining standard precautions until the dialyzer is disinfected both internally and externally. As a means of inhibiting bacterial growth, dialyzers that cannot be reprocessed within 2 hours should be refrigerated at 2° C to 6° C (35.6° F to 42.8° F) but not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not described in this recommended practice shall be validated and documented by the responsible party.

11.2 Rinsing and cleaning

11.2.1 Dialyzer precleaning

Many facilities preclean dialyzers. This process is typically accomplished with an apparatus developed by users and is intended to remove gross deposits of blood and products before rinsing and cleaning with a reprocessing machine or device. When precleaning is done, it needs to be included as part of the reprocessing procedures. The facility should establish a policy and practice to limit the time between the completion of precleaning and the initiation of disinfection, particularly when no germicide remains in the dialyzer after the precleaning process. All applicable requirements for design and maintenance of equipment included in this document should be adhered to for precleaning equipment. The maximum pressures for the dialyzer, or other limits set by the manufacturer, should also be adhered to.

11.2.2 Initiation of cleaning

Dialyzer reprocessing should be initiated in sufficient time to produce a reprocessed device that meets the requirements of section 11.3. Each dialysis facility should establish its time limits. Staff members involved in handling, transporting, or storing dialyzers locally or at remote locations shall follow standard precautions to prevent exposure to the operator, cross-contamination between dialyzers, and contamination of the physical environment.

11.2.3 Water quality for cleaning

Precleaning the dialyzer (rinsing and cleaning) shall be done with a fluid or fluids made with water that meets the specifications of ISO 23500-3.

11.2.4 Cleaning agents

Diluted solutions of hydrogen peroxide, sodium hypochlorite, peracetic acid, or other chemicals may be used as cleaning agents for the blood compartment, provided that the cleaning agent has been shown to be reduced to safe levels by subsequent flushing and has no significant adverse effects on the structural integrity and performance of the dialyzer.

Each chemical shall be rinsed from the dialyzer before the next chemical is added, unless mixing is known to be safe and effective for reprocessing. For example, a cleaning agent, such as sodium hypochlorite, shall be rinsed from the dialyzer before adding formaldehyde to avoid noxious fumes and degradation of disinfectant. Combining sodium hypochlorite and peracetic acid may produce hydrochloric acid vapors, which are harmful if inhaled.

11.3 Performance measurements

The performance characteristics of dialyzers may change following reprocessing. The ultrafiltration coefficient may increase or decrease. Clearances of low or high molecular weight solutes may also increase or decrease depending on the chemicals, methods, and dialyzer membrane used. The dialyzer labeling and medical literature should be consulted for information related to changes in *in vitro* and *in vivo* performance.

11.3.1 Performance test after each use

The purpose of the performance test is to measure the ability of the dialyzer membrane to remove low molecular weight uremic toxins. A direct or indirect measure of the *in vitro* clearance of a small molecule such as sodium or urea shall be used as the actual rejection criterion. If clearance is used, a 10 % loss is acceptable. If an indirect measure of the *in vitro* clearance is used, it shall be shown to correlate to urea or sodium clearance. TCV may be used for hollow-fiber dialyzers. The acceptable TCV is at least 80 % of the original TCV. The dialyzer prescription should take into account the 10 % loss in clearance (20 % loss in TCV) that may occur with dialyzer reuse. Dialyzers should be preprocessed to establish the original TCV.

11.3.2 Ultrafiltration

In vitro ultrafiltration coefficients should not be used to predict *in vivo* results. If the patient's expected weight loss is not achieved with the reprocessed dialyzer, the reprocessing method and all other weight removal variables should be reevaluated.

11.3.3 Blood path integrity test

A membrane integrity test such as an air pressure leak test shall be done between uses.

11.4 Germicide

The rinsed and cleaned dialyzer shall be treated by a process that prevents adverse effects caused by microbial contamination. The blood and dialysate compartments of the dialyzer shall be sterilized or subjected to high-level disinfection because an inadequate germicidal process may result in infection in the patient. Low-level disinfection is sufficient for the exterior of the device. The user shall consult the dialyzer labeling for contraindications or warnings regarding methods and applicability of specific germicidal processes or chemicals.

11.4.1 Interior (blood/dialysate compartment)

11.4.1.1 Germicidal process

Chemical germicides or other procedures used for disinfecting hemodialyzers shall have been shown to accomplish at least high-level disinfection when tested in dialyzers artificially contaminated with appropriate microorganisms. If formaldehyde is used as the sole germicidal agent, the Centers for Disease Control recommends that a concentration of 4 % weight/volume (W/V) be used in both the blood and dialysate compartments with a minimum contact time of 24 hours at a temperature of at least 20 °C; lower concentrations or shorter contact times are appropriate if equivalent results can be demonstrated under other conditions.

Formaldehyde used for reprocessing dialyzers should not be cloudy. Concentrated formaldehyde stored under adverse conditions can polymerize to form paraformaldehyde, a white precipitate. Formaldehyde should be of USP or better quality. When other germicides are used, the manufacturer's instructions should be followed.

If the germicide has an expiration date from the manufacturer, staff members should ensure that the chemical is not outdated. Some germicides have recommendations for maximum storage time after dilution or activation and before usage. If such recommendations exist, the expiration date of the prepared germicide solution should be marked on the outside of the germicide solution container, and that date should be checked at the beginning of each day, before reprocessing begins. If other germicides such as heat and citric acid are used, it is necessary to ensure that the correct time, temperature, and concentration are being used. If the temperature of the disinfection process is elevated, appropriate recording means shall be employed to ensure that this criterion has been met.

Germicides should be stored according to the manufacturer's recommendations, and records should be maintained to document compliance. The disinfection process shall not adversely affect the integrity of the dialyzer. Germicides shall be rinsed from the dialyzer to below known toxic levels within a rinse-out period established for the particular germicide (see 12.4). To prevent injury, staff members shall take care not to mix reactive materials such as sodium hypochlorite and formaldehyde or sodium hypochlorite and peracetic acid.

11.4.1.2 Dialyzer header cleaning and disinfection

The cleaning and disinfection of the header space should be done only when necessary and only before the dialyzer is reprocessed. The manufacturer's instructions should be followed. Header caps and O-rings shall be kept with their respective dialyzers.

If the header space is cleaned, it shall be done in a manner to prevent infection and damage to the dialyzer. If the header cap is removed to clean the header space, cleaning shall be done with water meeting the specifications of ISO 23500-3. If instruments or other materials (e.g., header caps and 4 x 4 gauze pads) are used, they should be shown not to cause damage to the end of the dialyzer and shall be new or cleaned and disinfected between uses. Once the O-ring and the header cap have been cleaned, they should be disinfected and reassembled while wet with disinfectant. This procedure is done before reprocessing the dialyzer. Overtightening the header caps may damage the cap, and undertightening the cap may cause blood leaks. If any cracking of the header occurs, the process should be evaluated.

If the header space is cleaned with the header cap in place, it is necessary to ensure that the cleaning device does not damage the end of the fiber bundle. The water used shall meet the specifications of ISO 23500-3. If an instrument such as a tie wrap is used, it should be made of soft plastic or other material that will not damage the end of the fiber bundle and be disinfected between uses.

If automated equipment is used, the manufacturer's instruction for use shall be followed.

11.4.1.3 Chemical germicide diluent

The water used to prepare the germicide solution shall meet the specifications of ISO 23500-3.