American National Standard

ANSI/AAMI 13958:2014

Concentrates for hemodialysis and related therapies

AAMI
Advancing Safety in Medical Technology

American National Standard **ANSI/AAMI 13958:2014**

Concentrates for hemodialysis and related therapies

Approved 21 July 2014 by
Association for the Advancement of Medical Instrumentation

Approved 15 August 2014 by
American National Standards Institute, Inc.

Abstract: Specifies minimum requirements for concentrates used for hemodialysis and related therapies. Addressed to the manufacturer of concentrates. Includes concentrates in both liquid and powder forms. Also included are additives, also called spikes, which are chemicals that may be added to the concentrate to increase the concentration of one or more of the existing ions in the concentrate and thus in the final dialysis fluid. Gives requirements for equipment used to mix acid and bicarbonate powders into concentrate at the user's facility.

Keywords: action, acid, bicarbonate, biofilm, fluid, endotoxin, pyrogen, sterile

AAMI Standard

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

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time.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

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.

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 1-57020-548-5

Contents

Page

Glossary of equivalent standards ..... **iv**
Committee representation ..... **v**
US deviation to ISO 13958:2014 ..... **vi**
Introduction ..... **vii**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **2**
4 Requirements **7**
4.1 Concentrates **7**
4.2 Manufacturing equipment **10**
4.3 Systems for mixing concentrate at a dialysis facility **10**
5 Tests **12**
5.1 General **12**
5.2 Concentrates **12**
5.3 Manufacturing equipment **14**
5.4 Systems for mixing concentrate at a dialysis facility **15**
6 Labelling **16**
6.1 General **16**
6.2 General labelling requirements for concentrates **16**
6.3 Labelling requirements for liquid concentrate **17**
6.4 Labelling requirements for powder concentrate **18**
6.5 Additives **18**
6.6 Labelling requirements for concentrate generators **18**
6.7 Labelling for concentrate mixer systems **19**
Annex A (informative) **Rationale for the development and provisions of this International Standard** **21**
Bibliography **27**

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Renal Disease and Detoxification Committee

This American National Standard was developed by the AAMI Renal Disease and Detoxification Committee. Approval of the American National Standard 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:

Chairs:
Conor Curtin
David Roer, MD, FACP, FASN, FASH

Members:
G Steven Acres, MD, Carolina Regional Nephrology Associates
James Weldon Baker, AmeriWater
Alex Barten, Baxter Healthcare Corporation
Christian Gert Bluchel, AWAK Technologies Pte Ltd.
Karla S. Byrne, Rockwell Medical Inc
Danilo B. Concepcion, CBNT, CCHT-A, St Joseph Hospital Renal Center
Deborah A. Cote, MSN ,RN, CNN, National Renal Administrators Association
Conor Curtin, Fresenius Medical Care North America
Jim Curtis, Portland, OR
R. Barry Deeter, RN MSN, University of Utah Dialysis Program
Martin T. Gerber, Medtronic Inc.
Gema Gonzalez, FDA/CDRH/ODE
Elizabeth Howard, DaVita, Inc.
Byron L. Jacobs, CBET, Sanford USD Medical Center
Judith Kari, Health Care Financing Administration
Kendall Larson, Mar Cor Purification
Nathan W. Levin, MD, Renal Research Institute LLC
Jo Ann Maltais, PhD, Maltais Consulting
Duane Martz, B Braun of America, Inc.
Lane McCarthy, CCHT, Hortense & Louis Rubin Dialysis Center
Bruce H. Merriman, Central Florida Kidney Centers
Klemens Meyer, MD, Tufts Medical Center
Paul E. Miller, MD, Kidney Consultants of Louisiana
Judith Noble-Wang, Centers for Disease Control and Prevention
Glenda Payne, RN, MS,CNN, American Nephrology Nurses Association
David Roer, MD, FACP, FASN, FASH, Nephrology and Hypertension Associates
David Schmidt, Mayo Clinic, Rochester, MN
James D. Stewardson, Brighton, CO
Vern S. Taaffe, Reprocessing Products Corp
Denny Treu, BSME, NxStage Medical Inc
Robert J. Vargo, Dialysis Clinic Inc

Alternates:
Roger Hall, Reprocessing Products Corp
Ted A. Kasparek, DaVita, Inc.
Robert Levin, Renal Research Institute LLC
Ken Leypoldt, Baxter Healthcare Corporation
Anthony Messana, National Renal Administrators Association
Thomas Meyer, Medtronic Inc.
Martin Roberts, AWAK Technologies Pte Ltd
Brooks E. Rogers, Fresenius Medical Care North America
Teri B. Spencer, RN, TB Spencer Consulting LLC
Michael Verguldi, Mar Cor Purification

NOTE—Participation by federal agency representatives in the development of this American National Standard does not constitute endorsement by the federal government or any of its agencies.

US deviation to ISO 13958:2014

The International Organization for Standardization (ISO) published ISO 13958:2014*, Concentrates for hemodialysis and related therapies* as a revision of ISO 13958:2009 on 2014-04-01. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee 150, Subcommittee 2, *Cardiovascular implants and extracorporeal systems*, to fill a need for minimum requirements for concentrates used for hemodialysis and related therapies. The 2014 ISO revision editorially aligned ISO 13958 with the ISO dialysis fluid standards ISO 11663, ISO 13959, ISO 23500, and ISO 26722 which had been developed serially over several years.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 150/SC 2, administered by the Association for the Advancement of Medical Instrumentation (AAMI). The U.S. TAG for ISO/TC 150/SC 2 supports the guidance provided in this document.

While considering the US adoption of ISO 13958:2014, the AAMI Renal Disease and Detoxification Committee (U.S. sub-TAG for ISO/TC 150/SC 2/WG 5, Renal replacement, detoxification and apheresis) approved a US deviation to the International Standard. ANSI/AAMI 13958:2014 deviates from ISO 13958:2014 in the following aspect:

The second paragraph of Subclause 5.2.4, Bacteriology of bicarbonate concentrates, which in ISO 13958:2014 reads:

> "Blood or chocolate agar shall not be used. Incubation temperatures of 17 °C to 23 °C, and an incubation time of 168 h (7 d) are recommended. Other test methods may also be used, provided such methods have been appropriately validated, and compared to the cited methods."

is replaced in ANSI/AAMI 13958:2014 by the following:

> "Approved culture methods shall include one of the following:
>
> 1) tryptone glucose extract agar (TGEA) or Reasoner's 2A supplemented with 4 % sodium bicarbonate, or equivalent. Blood or chocolate agar shall not be used. Incubation temperatures of 17 °C to 23 °C, and an incubation time of 168 h (7 d); or
>
> 2) Trypticase soy agar (TSA, a soybean casein digest agar) or standards method agar and plate count agar (also known as TGYE), incubated at 35 °C for 48 hours.
>
> Other test methods may also be used, provided such methods have been appropriately validated and compared to the cited methods. See USP <1231> for guidance on adoption of alternative methods."

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Introduction

The requirements and goals established by this American National Standard will help ensure the effective, safe performance of hemodialysis concentrates and related materials. This American National Standard reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians and dialysis patients, in consultation with device manufacturers and government representatives, to develop a standard for performance levels that could be reasonably achieved at the time of publication. The term “consensus” as applied to the development of voluntary medical device standards does not imply unanimity of opinion, but rather reflects the compromise necessary in some instances when a variety of interests must be merged.

Throughout this American National Standard, recommendations are made to use ISO-quality water. Therefore, it is recommended to review ISO 13959 along with this American National Standard.

This American National Standard does not cover the dialysis fluid that is used to clinically dialyze patients. Dialysis fluid is covered in ISO 11663. The making of dialysis fluid involves the proportioning of concentrate and water at the bedside or in a central dialysis fluid delivery system. Although the label requirements for dialysis fluid are placed on the labelling of the concentrate, it is the user's responsibility to ensure proper use.

In addition, this American National Standard does not cover hemodialysis equipment, which is addressed in the new edition of IEC 60601-2-16.

The verbal forms used in this American National Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this American National Standard, the auxiliary verb

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this International Standard,

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this International Standard, and

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Concentrates for hemodialysis and related therapies

1 Scope

This International Standard specifies minimum requirements for concentrates used for hemodialysis and related therapies. For the purpose of this International Standard, “concentrates” are a mixture of chemicals and water, or chemicals in the form of dry powder or other highly concentrated media, that are delivered to the end user to make dialysis fluid used to perform hemodialysis and related therapies. This International Standard is addressed to the manufacturer of such concentrates. In several instances in this International Standard, it became necessary to address the dialysis fluid, which is made by the end user, to help clarify the requirements for manufacturing concentrates. Because the manufacturer of the concentrate does not have control over the final dialysis fluid, any reference to dialysis fluid is for clarification and is not a requirement of the manufacturer.

This International Standard includes concentrates in both liquid and powder forms. Also included are additives, also called spikes, which are chemicals that may be added to the concentrate to increase the concentration of one or more of the existing ions in the concentrate and thus in the final dialysis fluid. This International Standard also gives requirements for equipment used to mix acid and bicarbonate powders into concentrate at the user's facility.

Concentrates prepared from prepackaged salts and water at a dialysis facility for use in that facility are excluded from the scope of this International Standard. Although references to dialysis fluid appear herein, this International Standard does not address dialysis fluid as made by the end user. Also excluded from the scope of this International Standard are requirements for the monitoring frequency of water purity used for the making of dialysis fluid by the dialysis facility. Recommendations from the technical committee responsible for this International Standard for monitoring water quality are contained in ISO 23500. This International Standard does not address bags of sterile dialysis fluid or sorbent dialysis fluid regeneration systems that regenerate and recirculate small volumes of the dialysis fluid.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11663, *Quality of dialysis fluid for hemodialysis and related therapies*

ISO 13959:2014, *Water for hemodialysis and related therapies*

ISO 14971, *Medical devices — Application of risk management to medical devices*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*