Technical Information Report

AAMI TIR58: 2021

Water testing methodologies

AAMI
Advancing Safety in Health Technology

Water testing methodologies

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AAMI

Abstract: This Technical Information Report (TIR) includes common test methods used to monitor hemodialysis water treatment systems and product water. The TIR identifies numerous contaminants of interest in the care of ESRD patients or that could impact the safe and effective operations of water purifications systems used in the care or treatment of ESRD patients; provides the maximum allowable levels and action levels from various standards (AAMI/ISO) and other references as applicable; describes symptoms that hemodialysis patients might experience with exposure to the contaminant; describes effects of the contaminant on hemodialysis equipment and water treatment systems; lists common test methodologies used for analysis/detection of the contaminant at the laboratory and clinic level; notes test interferences that can be associated with a specific test method.

Keywords: hemodialysis water, product water, chemical contaminants, test methods, test interference, clinical exposure symptoms, dialysis equipment, water treatment system

AAMI Technical Information Report

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Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. A TIR must be acted on and the action formally approved usually every three years.

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Committee representation

Association for the Advancement of Medical Instrumentation

Renal Disease and Detoxification Committee

This technical information report was developed by the AAMI Renal Disease and Detoxification Committee. Committee approval of this technical information report 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:
Gema Gonzalez
Denny Treu

Members:
Tom Allocco, US Renal Care
Matthew J. Arduino, DrPH, U.S. Centers for Disease Control and Prevention
Christian Bluechel, Singapore
Aaron Brown, Baxter Healthcare
Karla Byrne, Rockwell Medical
Christopher A. Cloonan, CBNT, CDWS, UVA Augusta Dialysis
Danilo B. Concepcion, CBNT, CCHT-A, FNKF, St. Joseph Health System
Claudia Cotca, Chevy Chase, MD
Conor Curtin, Boston, MA
Jack Dillon, Medical Solutions International
Pamela Elliott, MHA, BSN, McLeod Regional Medical Center
Bruce Fife, Reprocessing Products Corporation
Gema Gonzalez, U.S. Food and Drug Administration/CDRH/ODE
Kalub Hahne, PhD, Cook Research Inc.
Joe Haney, AmeriWater
Steven Hoffman, CBET, Children's Hospital of Pittsburgh
Robert Hootkins, MD, PhD, FASN, ESRD Consulting
Byron Jacobs, CBET, GE Healthcare
Cong Jiang, AWAK Technologies
Richard J. Kaestner, Jr., Absolute Water Technologies
Ted A. Kasparek, Davita
Kristi Keller, Iredell Health System
Theresa Klein, Spectrum Health System
Kendall Larson, Mar-Cor Purification
Duane Martz, AAET/MBA, B Braun of America
John Matthis, MS, MBA, Calgon Carbon Corporation
Klemens Meyer, MD, Tufts Medical Center
Emily Michalak, AAS, BS, Satellite Healthcare
Paul E. Miller, MD, Dialysis Clinic/Kidney Consultants of Louisiana
Arulkamal Natarajan, Sidra Medical & Research Center, Qatar
Glenda Payne, RN, MS, CNN, American Nephrology Nurses Association
William Poirier, Greenfield Health Systems
Tashiya Roberts, American Renal Associates
Joseph Sala, BSc Ed, Mount Sinai Medical Center
David Schmidt, Mayo Clinic
Chris Skarzynski, McLeod Regional Medical Center
Amanda Tilles, Design Science Consulting
Denny Treu, BSME, Fresenius Medical Care-NxStage
Ashish Upadhyay, Boston University – School of Medicine
Richard A. Ward, PhD, Nelson, New Zealand

Alternates:
Emily Borst, Design Science Consulting
Jenalle Brewer, Calgon Carbon Corporation
Logan Cabral, AmeriWater
Martin Crnkovich BSEE, Fresenius Medical Care
Mark Pasmore, PhD, Baxter Healthcare

Sanjay Singh, AWAK Technologies
Vern S. Taaffe, Reprocessing Products Corporation
Ronald Trammell, American Renal Associates
Michael Verguldi, Mar Cor Purification
Richard Williams, U.S. Food and Drug Administration/CDRH

NOTE Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Foreword

This technical information report (TIR) was developed by the AAMI Renal Disease and Detoxification Committee. The objective is to provide dialysis practitioners with additional information and background related to recommendations made in ANSI/AAMI/ISO and ANSI/AAMI standards, in particular, the contaminants in water, the test methodologies available and suitable for testing to the requirements of these standards to keep dialysis patients safe. Some of the methods are complex, requiring sophisticated instrumentation and these are noted as laboratory test methods to distinguish them from those that can be done at the clinic level. Maximum allowable levels as well as action levels where applicable are provided and the source of the limits noted. The limits are often based on those specified for drinking water with a safety margin to allow for the larger exposure volume of this water to hemodialysis patients. Agents that can interfere with the accuracy and validity of a given type of test method are noted where relevant. Any adverse effects of a contaminant on components of the water treatment or hemodialysis delivery systems are also covered. Emphasis is placed upon known toxicities to hemodialysis patients, but other contaminants that may affect the dialysis treatment are also provided.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the AAMI TIR58, *Water testing methodologies* (AAMI TIR58:2021), but it does provide important information about the development and intended use of the document.

Introduction

While the ANSI/AAMI/ISO Standard 23500-3:2019 [8] specifies the maximum allowable levels of chemical contaminants acceptable in water used for hemodialysis and the recommended frequency of testing, it does not necessarily provide all the information that would be useful to the hemodialysis clinic personnel regarding water testing. This technical information report (TIR) provides maximum allowable levels, notes clinical symptoms in dialysis patients exposed to the various contaminants, provides toxic levels where available and applicable, and lists the updated test methods and any interfering substances that can result in inaccurate analysis. In addition, while ANSI/AAMI/ISO 23500-3:2019 [8] provides a list of acceptable tests, these have often been replaced by more up-to-date methods and techniques that are now commonly used by the testing labs providing such analyses to the hemodialysis community. Given that the typical hemodialysis clinic personnel may not be skilled in or have the necessary knowledge of the test methods, this updated list will ensure that the hemodialysis clinic personnel can assess whether the testing laboratory is using the appropriate testing methodologies. Historically, the AAMI Renal Disease and Detoxification Committee has recommended certain acceptable levels based on known toxicities and/or the Environmental Protection Agency (EPA) Drinking Water requirements, adding a safety margin based on the increased exposure volume for a hemodialysis patient during treatment. The committee has not evaluated methods for sensitivity and accuracy. Thus, there is a need, and a TIR is the appropriate vehicle to inform/educate the hemodialysis community regarding the nuances of testing for contaminants in water and what levels are known or suspected to be hazardous to the hemodialysis patient.

NOTE The Centers for Medicare and Medicaid Services (CMS) currently references ANSI/AAMI RD5, *Dialysate for Hemodialysis* [10] and ANSI/AAMI RD62, *Water Treatment Equipment for Hemodialysis Applications* [11], in their Conditions for Coverage. These American National Standards have been superseded by ANSI/AAMI/ISO 23500-1, *Guidance for the preparation and quality management of fluids for hemodialysis and related therapies* [3] [4] [5] [6]; ANSI/AAMI/ISO 23500-2, *Water treatment equipment for hemodialysis applications and related therapies* [7]; ANSI/AAMI/ISO 23500-3, *Water for hemodialysis and related therapies* [8]; and ANSI/AAMI/ISO 23500-5, *Quality of dialysis fluid for hemodialysis and related therapies* [9].

Water testing methodologies

1 Scope

This Technical Information Report (TIR) identifies common contaminants as well as the test methods commonly used to monitor contaminants in a hemodialysis water treatment system and product water. The TIR will: 1) identify each contaminant with its chemical symbol, as applicable; 2) list maximum allowable levels and action levels as applicable as found in AAMI/ISO Standards and other pertinent references; 3) identify symptoms in hemodialysis patients associated with exposure to a given contaminant; 4) describe adverse effects of a contaminant on hemodialysis equipment and the water treatment system; and 5) identify test(s) used to detect the contaminants while describing the pros and cons of each method, e.g. interference elements.

This TIR does not supersede *Standard Methods for the Examination of Water and Wastewater*, but rather provides common test methods used within the dialysis industry. The reader is advised to reference The Food and Drug Administration (FDA) approval as appropriate or for those tests that The Centers for Medicare and Medicaid Services (CMS) requires FDA approved methods (i.e., bacteria and endotoxin testing). This document excludes sampling recommendations. Check the manufacturer's instructions for use, test kit or test method instructions, AAMI and/or International Organization for Standardization (ISO) documents, CMS regulations as applicable for sampling guidance.

Applicability and use

This TIR contains information intended to assist end users in making informed decisions regarding which test methodologies are useful to test for the presence of specific contaminants commonly found in water in settings where hemodialysis is delivered, allowable limits and action levels and substances that can interfere with accurate test results.

Disclaimer: Users of any selected test methodology must understand the level of sensitivity, precision, and accuracy and how the test results will correlate to the selected action level/maximum allowable limits.

2 Normative references

There are no normative references for this report.

3 Terms and definitions

For the purposes of this AAMI TIR, the following acronyms and definitions apply.

3.1
accuracy
closeness of agreement between a measured quantity value and a true quantity value of a measurement

Note 1 to entry: A measurement is said to be more exact when it has a smaller measurement error [bias].

3.2
acid
chemical substance having a pH of less than 7 that neutralizes alkalis, dissolves some metals, and turns litmus red; typically, a corrosive or sour-tasting liquid of this kind

