Technical Information Report

AAMI TIR58: 2014

Water testing methodologies

AAMI
Advancing Safety in Medical Technology

Water testing methodologies

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Association for the Advancement of Medical Instrumentation

Abstract: The Technical Information Report (TIR) includes common test methods used to monitor hemodialysis water treatment systems and product water. The TIR identifies the contaminants; 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

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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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

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:

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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 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.

This TIR is intended to be used as supplementary to other ANSI/AAMI/ISO and ANSI/AAMI standards and provides information in an easy-to-refer-to-and-use chart for quick reference and to better understand the requirements and their rationales.

As used within the context of this document, “should” indicates that among several possibilities one is recommended as particularly suitable without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the TIR. “Can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulations.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

NOTE This foreword does not contain provisions of AAMI TIR58, but does provide important information about the development and intended use of the document.

Acknowledgment

The AAMI Renal Disease and Detoxification Committee would like to thank the team led by Jo-Ann B. Maltais, Ph.D. including Vern Taaffe and Organizational Member Liaisons Paul Smith and Mark Rolston, who worked tirelessly to bring this much needed TIR to completion.

Introduction

While the ANSI/AAMI/ISO Standard 13959:2009 specifes 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 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 13959 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 lab 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 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 RD52, *Dialysate for Hemodialysis* and ANSI/AAMI RD62, *Water Treatment Equipment for Hemodialysis Applications*, in their Conditions for Coverage. These American National Standards have been superseded by ANSI/AAMI/ISO 11663, *Quality of dialysis fluid for hemodialysis and related therapies,* ANSI/AAMI/ISO 13959, *Water for hemodialysis and related therapies*, ANSI/AAMI/ISO 23500*, Guidance for the preparation and quality management of fluids for hemodialysis and related therapies*, and ANSI/AAMI/ISO 26722, *Water treatment equipment for hemodialysis applications and related therapies*.

Testing methodologies for water

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 document in no way supersedes *Standard Methods for the Examination of Water and Wastewater*[1] but rather provides common test methods used within the dialysis industry. The reader is advised to reference FDA approval as appropriate or for those tests that 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 ISO documents, CMS regulations as applicable for sampling guidance.

2 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.

3 Acronyms and definitions

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

3.1
AAMI
Association for the Advancement of Medical Instrumentation

3.2
accuracy
closeness of agreement between a measured quantity value and a true quantity value of a measurement

NOTE A measurement is said to be more accurate when it has a smaller measurement error [bias].

3.3
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

3.4
Act
Federal Food, Drug, and Cosmetic Act which establishes the US Food and Drug Administration as the law enforcement agency with the authority to regulate food, drugs, and device manufacturing through a comprehensive Code of Federal Regulations (CFR)

