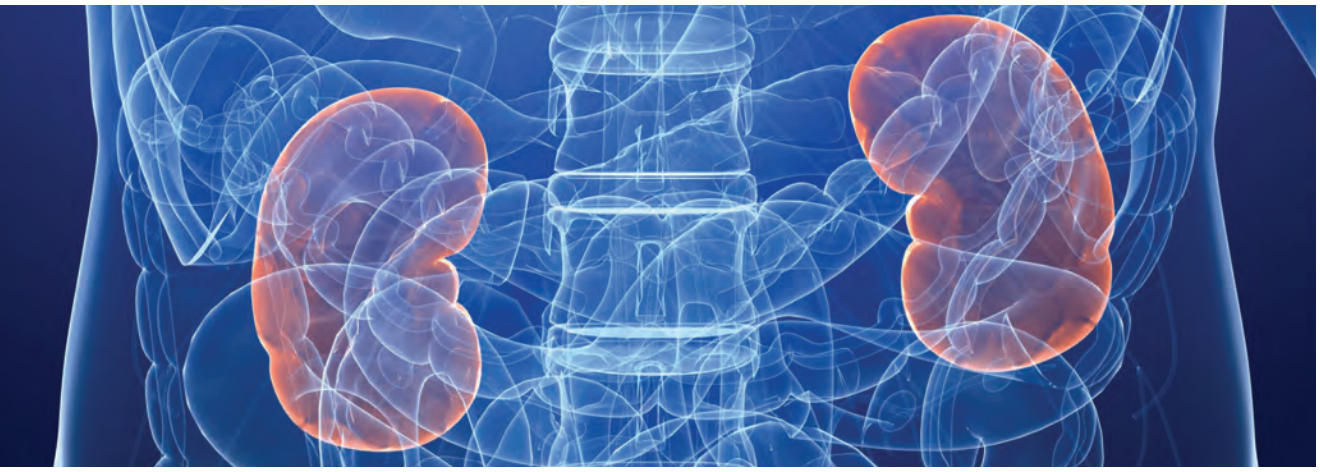
AAMI
Advancing Safety in Medical Technology

Dialysis Water and Dialysate Recommendations: A User Guide



Glenda M. Payne

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This publication is intended to be a helpful information resource,
and reflects the expert advice and views of the editor.
It is not to be construed as an interpretation of AAMI standards,
nor does it constitute legal or regulatory advice.

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

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Printed in the United States of America

ISBN 1-57020-518-3

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Foreword

It has long been known that potable water, suitable for drinking by the general population, can contain substances harmful to dialysis patients if that water is used directly to prepare dialysate. As early as the 1960s, the presence in dialysate of chemicals commonly found in drinking water was being linked to the development of a number of hemodialysis-associated comorbidities, including anemia, bone disease and neurological abnormalities. To help protect patients from injury, maximum allowable levels for a range of chemical contaminants, as well as for bacteria, were included in the first edition of the American National Standard for Hemodialysis Systems published by AAMI in 1981. An appendix to the standard provided guidance to dialysis professionals on how to treat drinking water to ensure compliance with the quality standard.

AAMI standards are not static documents; they are subject to regular review and revision as the related science and technology advance. Thus, the hemodialysis systems standard evolved over the years as our understanding of the risks posed to hemodialysis patients by contaminants in drinking water increased and water treatment practices changed. For example, introduction of the *Limulus* amebocyte lysate assay allowed a maximum limit for endotoxin to be added to the water quality standard in 2001 as we became more aware of the role microbiological contaminants play in dialysis-associated inflammation. Other changes were spurred by changes in water treatment practices, such as the replacement of free chlorine by monochloramine for microbial control in drinking water in response to the Environmental Protection Agency's introduction of an upper limit for trihalomethanes. These changes led to a series of revisions to the AAMI hemodialysis systems standard, culminating in the publication of separate standards for the treatment of water and the preparation of dialysate in 2001 and 2004, respectively. Finally, in 2011 those AAMI standards were replaced by adoption of a comprehensive suite of five standards developed by the International Organization for Standardization (ISO) that covered all aspects of fluid preparation for hemodialysis and related therapies and which was based on the existing AAMI standards. It is important to recognize that different parts of that suite of standards are directed at different audiences. Standards setting forth requirements for devices and commercially produced fluids, such as concentrates, are directed at manufacturers of those items, while standards setting forth the quality requirements of water and the dialysate prepared from that water, as well as guidance on achieving those quality requirements are primarily directed at the dialysis professionals responsible for delivering the actual dialysis treatments.

The Centers for Medicare and Medicaid Services (CMS) is the largest funder of dialysis therapy in the United States. As part of its oversight activities, CMS requires providers of dialysis to comply with certain performance criteria intended to promote improved outcomes and ensure the safety of dialysis patients. These requirements are set forth in the CMS Conditions for Coverage for End Stage Renal Disease Facilities (the CfC). Following publication of the original AAMI

hemodialysis standard in 1981, CMS—then known as the Health Care Financing Administration—made compliance with the water quality standard part of the CfC. That requirement was limited to complying with the maximum allowable contaminant levels and the guideline for monitoring water purity. Nevertheless, it is likely that inclusion of the AAMI water quality standard in the CfC promoted widespread acceptance of the standard and helped protect hemodialysis patients from harm during a time when patient numbers were increasing rapidly and significant changes were occurring in municipal water treatment practices.

The CfC is published as a Federal Regulation and changing it can be a long process involving publication of a proposed new regulation, a period of public comment on that proposal, publication of responses to the public comments, review by other governmental entities, such as the Office of Management and Budget, and publication of a final regulation. In 2008, 30 years after its initial publication, CMS published a major revision of the CfC. In that revision, the simple requirement that the water used for hemodialysis comply with the AAMI standard was replaced by incorporation of essentially all of the existing AAMI guideline for dialysate preparation (ANSI/AAMI RD52:2004), including fluid quality, water treatment equipment and monitoring guidelines. In addition, CMS published an Interpretive Guidance document intended to promote consistent application of the regulations contained in the CfC.

The AAMI standards have continued to evolve since the CMS CfC were published in 2008. That evolution has inevitably led to differences between the standards and the CfC, such that the CfC no longer mirrors exactly the recommendations contained in the current AAMI standards. Discrepancies involve both performance criteria, such as the maximum allowable levels for bacteria and endotoxin in water and dialysate, and recommended approaches to maintaining compliance with the fluid quality standards, with the current AAMI standards emphasizing compliance through the development and implementation of a facility-specific quality management program in contrast to the prescriptive approach included in ANSI/AAMI RD52:2004 and adopted in the CfC. As a consequence, we now have two diverging sets of documents that increasingly create problems for dialysis facilities, dialysis professionals, and the surveyors responsible for ensuring compliance with the CfC. A reader might ask why the CMS cannot deal with this problem by simply referencing the current edition of the AAMI standard in the CfC rather than including verbatim long sections of the standard. Alas, that action would have the effect of leaving AAMI in the position of writing Federal Regulation, since significant changes could be made to the standard without any Federal review or oversight; a clearly untenable position for a government agency.

This book, by an author with experience in writing both the CMS CfC and the AAMI standards, addresses the challenges posed by the existence of two sets of documents by systematically comparing the current AAMI standards with the CfC and the CMS Interpretive Guidance. The comprehensive tables clearly identify where differences occur between the documents and allow the reader to understand what is required by CMS, where the AAMI standards recommend more rigorous practices that would also be acceptable to CMS, and where the prescriptive approach generally favored by CMS makes it difficult to adopt more flexible practices recommended in the AAMI standards. Finally, the analysis undertaken in this book shows the reader the likely future direction of fluid preparation for hemodialysis and its related therapies. Altogether, this work makes an important contribution to reducing conflict between the surveyors and the surveyed and will help advance the cause of patient safety.

Richard A. Ward
Past user co-chair, AAMI Renal Disease and Detoxification Committee

CHAPTER 1

Introduction

Purpose and Intended Use of This Document

The purpose of this document is to provide a side-by-side comparison of the Centers for Medicare & Medicaid Services (CMS) regulations and interpretive guidance for the Condition of Water and Dialysate Quality and the section related to water and dialysate from the Condition of Care at Home with the suite of ANSI/AAMI/ISO Standards that have been adopted by AAMI as replacement for ANSI/AAMI RD52:2004. The suite of Standards includes the following:

- ANSI/AAMI/ISO 23500:2011, *Guidance for the preparation and quality management of fluids for hemodialysis and related therapies*;
- ANSI/AAMI/ISO 11663:2009, *Quality of dialysis fluid for hemodialysis and related therapies*;
- ANSI/AAMI/ISO 13958:2009, *Concentrates for hemodialysis and related therapies*;
- ANSI/AAMI/ISO 13959:2009, *Water for hemodialysis and related therapies*; and
- ANSI/AAMI/ISO 26722:2009, *Water treatment equipment for hemodialysis applications and related therapies*.

This document is provided as a tool for individuals who have responsibility for the oversight and operation of hemodialysis facilities to use in clarifying their understanding of the regulatory requirements and the current AAMI guidance. In those areas where the ANSI/AAMI/ISO Standards are more stringent, dialysis facility medical directors and technical supervisors may choose to follow the more stringent standard. In the few areas where the CMS regulation is more stringent, the regulation must be followed to maintain compliance.

Background

In February 2005, CMS issued a Notice of Proposed Rule Making (NPRM) to completely revise the Conditions for Coverage (CfC) for End Stage Renal Disease (ESRD) outpatient dialysis facilities. The NPRM included a proposal that the Association for the Advancement of Medical Instrumentation (AAMI) publication, *Dialysate for Hemodialysis*, ANSI/AAMI RD52:2004 (RD52) be adopted as part of the ESRD regulations.

The renal community supported the proposed inclusion of RD52, and the AAMI Renal Disease and Detoxification Committee (RDD) collaborated with CMS to edit this document for clarity and to facilitate its use as regulation and interpretive guidance. CMS published the final rule defining the CfC for ESRD on April 15, 2008, with an implementation date of October 14, 2008.