American National Standard

ANSI/AAMI 23500:2014

Guidance for the preparation and quality management of fluids for hemodialysis and related therapies

AAMI
Advancing Safety in Medical Technology

Guidance for the preparation and quality management of fluids for hemodialysis and related therapies

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

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American National Standards Institute, Inc.

Abstract: Addresses the user's responsibility for the dialysis fluid once the equipment used in its preparation has been delivered and installed. Includes dialysis water used for the preparation of dialysis fluid and substitution fluid, dialysis water used for the preparation of concentrates at the user's facility, as well as concentrates and the final dialysis fluid and substitution fluid.

Keywords: concentrate, microbiological, monitoring, quality, system, validation, water

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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:

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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 23500:2014

The International Organization for Standardization (ISO) published ISO 23500:2014*, Guidance for the preparation and quality management of fluids for hemodialysis and related therapies* as a revision of ISO 23500:2011 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 guidance on the user's responsibility for the dialysis fluid once the equipment used in its preparation has been delivered and installed. The 2014 ISO revision editorially aligned ISO 23500 with the ISO dialysis fluid standards ISO 11663, ISO 13958, ISO 13959, 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 23500:2014, 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 23500:2014 deviates from ISO 23500:2014 in the following aspect:

The following sentence has been added to the end of Subclause 8.3.3.3, Cultivation conditions:

> "See USP <1231> for guidance on adoption of alternative methods."

Also, the following row has been added to Table 5 ,Cultivation techniques:

Trypticase soy agar (TSA, a soybean casein digest agar) or standards method agar and plate count agar (also known as TGYE)	35 °C	48 h

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

This International Standard was developed by Working Group 5 of ISO/TC 150/SC 2. The Working Group's objective was to provide users with guidance for handling water and concentrates and for the production and monitoring of dialysis fluid used for hemodialysis. The need for such guidance is based on the critical role of dialysis fluid quality in providing safe and effective hemodialysis, and the recognition that day-to-day dialysis fluid quality is under the control of the healthcare professionals who deliver dialysis therapy.

Quality requirements for the water and concentrates used to prepare dialysis fluid, and for that dialysis fluid, are provided in ISO 13959, ISO 13958, and ISO 11663, respectively. This International Standard does not address clinical issues that might be associated with inappropriate usage of the water, dialysis water, concentrates, or dialysis fluid. Healthcare professionals involved in the provision of treatment for kidney failure should make the final decision regarding the applications with which these fluids are used, for example, hemodialysis, hemodiafiltration, high-flux hemodialysis, and the reprocessing of dialyzers, and need to be aware of the issues that the use of inappropriate fluid quality raises in each of the therapies.

The equipment used in the various stages of dialysis fluid preparation is generally obtained from specialized vendors. Dialysis practitioners are generally responsible for maintaining that equipment following its installation. Therefore, this International Standard provides guidance on monitoring and maintenance of the equipment to ensure that dialysis fluid quality is acceptable at all times. At various places throughout this International Standard, the user is advised to follow the manufacturer's instructions regarding the operation and maintenance of equipment. In those instances in which the equipment is not obtained from a specialized vendor, it is the responsibility of the user to validate the performance of the equipment in the hemodialysis setting and to ensure that appropriate operating and maintenance manuals are available. Annex B provides a general description of the system components that are used for water treatment, concentrate, and dialysis fluid preparation at a dialysis facility. These descriptions are intended to provide the user with a basis for understanding why certain equipment might be required and how it should be configured; they are not intended as detailed design standards. Requirements for water treatment equipment are provided in ISO 26722.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2:2004. For the purposes of this international 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;

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

This International Standard reflects the conscientious efforts of healthcare professionals, patients, and medical device manufacturers to develop recommendations for handling water and concentrates and for the production and monitoring of dialysis fluid for hemodialysis. This International Standard is directed towards the healthcare professionals involved in the management or routine care of hemodialysis patients and responsible for the quality of dialysis fluid. The recommendations contained in this International Standard might not be applicable in all circumstances and they are not intended for regulatory application.

The guidance provided by this International Standard should help protect hemodialysis patients from adverse effects arising from known chemical and microbial contaminants that might be found in improperly prepared dialysis fluid. However, the physician in charge of dialysis has the ultimate responsibility for ensuring that the dialysis fluid is correctly formulated and meets the requirements of all applicable quality standards.

The concepts incorporated in this International Standard should not be considered inflexible or static. The recommendations presented here should be reviewed periodically in order to assimilate increased understanding of the role of dialysis fluid purity in patient outcomes and technological developments.

Guidance for the preparation and quality management of fluids for hemodialysis and related therapies

1 Scope

1.1 General

This International Standard provides dialysis practitioners with guidance on the preparation of dialysis fluid for hemodialysis and related therapies and substitution fluid for use in online therapies, such as hemodiafiltration and hemofiltration. As such, this International Standard functions as a recommended practice.

1.2 Inclusions

This International Standard addresses the user's responsibility for the dialysis fluid once the equipment used in its preparation has been delivered and installed. For the purposes of this International Standard, the dialysis fluid includes dialysis water (see 3.18 for definition) used for the preparation of dialysis fluid and substitution fluid, dialysis water used for the preparation of concentrates at the user's facility, as well as concentrates and the final dialysis fluid and substitution fluid.

The scope of this International Standard includes

a) the quality management of equipment used to treat and distribute water used for the preparation of dialysis fluid and substitution fluid, from the point at which municipal water enters the dialysis facility to the point at which the final dialysis fluid enters the dialyzer or the point at which substitution fluid is infused,

b) equipment used to prepare concentrate from powder or other highly concentrated media at a dialysis facility, and

c) preparation of the final dialysis fluid or substitution fluid from dialysis water and concentrates.

NOTE Because water used to prepare dialysis fluid is commonly prepared and distributed using the same equipment as the water used to reprocess dialyzers, water used to reprocess dialyzers is also covered by this International Standard.

1.3 Exclusions

This International Standard does not apply to sorbent-based dialysis fluid regeneration systems that regenerate and recirculate small volumes of dialysis fluid, systems for continuous renal replacement therapy that use prepackaged solutions, and systems and solutions for peritoneal dialysis.

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.