CSA Z23500-1:20
(ISO 23500-1:2019, MOD)
National Standard of Canada

CSA Z23500-1:20
Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements
(ISO 23500-1:2019, MOD)

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Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users to judge its suitability for their particular purpose.

National Standard of Canada

CSA Z23500-1:20

Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements

(ISO 23500-1:2019, MOD)

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Reviewed by

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Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements
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CSA Preface

This is the first edition of CSA Z23500-1, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements,* which is an adoption, with Canadian deviations, of the identically titled ISO (International Organization for Standardization) Standard 23500-1 (first edition, 2019-02). It replaces CAN/CSA-Z23500:16 (adopted ISO 23500:2014), *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies*.

For brevity, this Standard will be referred to as "CSA Z23500-1" throughout.

This Standard was reviewed for Canadian adoption by the CSA Subcommittee on Quality Management for Kidney Dialysis, under the jurisdiction of the CSA Technical Committee on Kidney Dialysis and the CSA Strategic Steering Committee on Health and Well-being, and has been formally approved by the Technical Committee.

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INTERNATIONAL STANDARD

ISO 23500-1

First edition
2019-02

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 1: General requirements

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes —

Partie 1: Exigences générales

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This first edition cancels and replaces ISO 23500:2014, which has been technically revised. The main changes compared to the previous edition are as follows:

— The document forms part of a revised and renumbered series dealing with the preparation and quality management of fluids for haemodialysis and related therapies. The series comprise ISO 23500-1 (previously ISO 23500), ISO 23500-2, (previously ISO 26722), ISO 23500-3, (previously ISO 13959), ISO 23500-4, (previously ISO 13958), and ISO 23500-5, (previously ISO 11663).

A list of all parts in the ISO 23500 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is the base standard for a number of other standards dealing with water treatment and the production of dialysis fluid (ISO 23500 series).

The objective of the ISO 23500 series is to provide users with guidance for handling water and concentrates and for the production and quality oversight of dialysis fluid used for haemodialysis. The need for such guidance is based on the critical role of dialysis fluid quality in providing safe and effective haemodialysis, and the recognition that day-to-day dialysis fluid quality is under the control of the healthcare professionals who deliver dialysis therapy.

Annex A provides further information on the rationale for the development and provisions of this document.

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 document provides guidance on quality oversight 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 haemodialysis setting and to ensure that appropriate operating and maintenance manuals are available.

Annex B to this document provides further information on 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 23500-2.

Increasingly, self-contained, integrated systems designed and validated to produce water and dialysis fluid are becoming available and used clinically. This document applies to systems assembled from individual components. Consequently, some of the requirements in ISO 23500-1 and ISO 23500-2 might not apply to integrated systems, however such systems are required to comply with the requirements of ISO 23500-3, ISO 23500-4, and ISO 23500-5. In order to ensure conformity when using such systems, adherence to the manufacturer's instructions regarding the operation, testing, and maintenance of such systems is required to ensure that the system is being operated under the validated conditions.

This document 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 surveillance of dialysis fluid for haemodialysis and protecting haemodialysis patients from adverse effects arising from known chemical and microbial contaminants that might be found in improperly prepared dialysis fluid. Annexes F and G provide further information in respect of special considerations for home and acute haemodialysis The standard together with its constituent parts is directed towards the healthcare professionals involved in the management or routine care of haemodialysis patients and responsible for the quality of 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 provisions contained in this document might not be applicable in all circumstances and they are not intended for regulatory application.

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 1: General requirements

1 Scope

1.1 General

This document is the base standard for a number of other standards dealing with water treatment equipment, water, dialysis water, concentrates, and dialysis fluid (ISO 23500 series) and provides dialysis practitioners with guidance on the preparation of dialysis fluid for haemodialysis and related therapies and substitution fluid for use in online therapies, such as haemodiafiltration and haemofiltration. As such, this document functions as a recommended practice.

This document 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, haemodialysis, haemodiafiltration, high-flux haemodialysis, and the reprocessing of dialysers, and need to be aware of the issues that the use of inappropriate fluid quality raises in each of the therapies.

The concepts incorporated in this document 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.

1.2 Inclusions

This document addresses the user's responsibility for dialysis fluid once the equipment used in its preparation has been delivered and installed.

For the purposes of this document, dialysis fluid includes:

a) dialysis water (see 3.17 for definition) used for the preparation of dialysis fluid and substitution fluid,

b) dialysis water used for the preparation of concentrates at the user's facility,

c) concentrates,

d) the final dialysis fluid and substitution fluid.

The scope of this document 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 dialyser 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.

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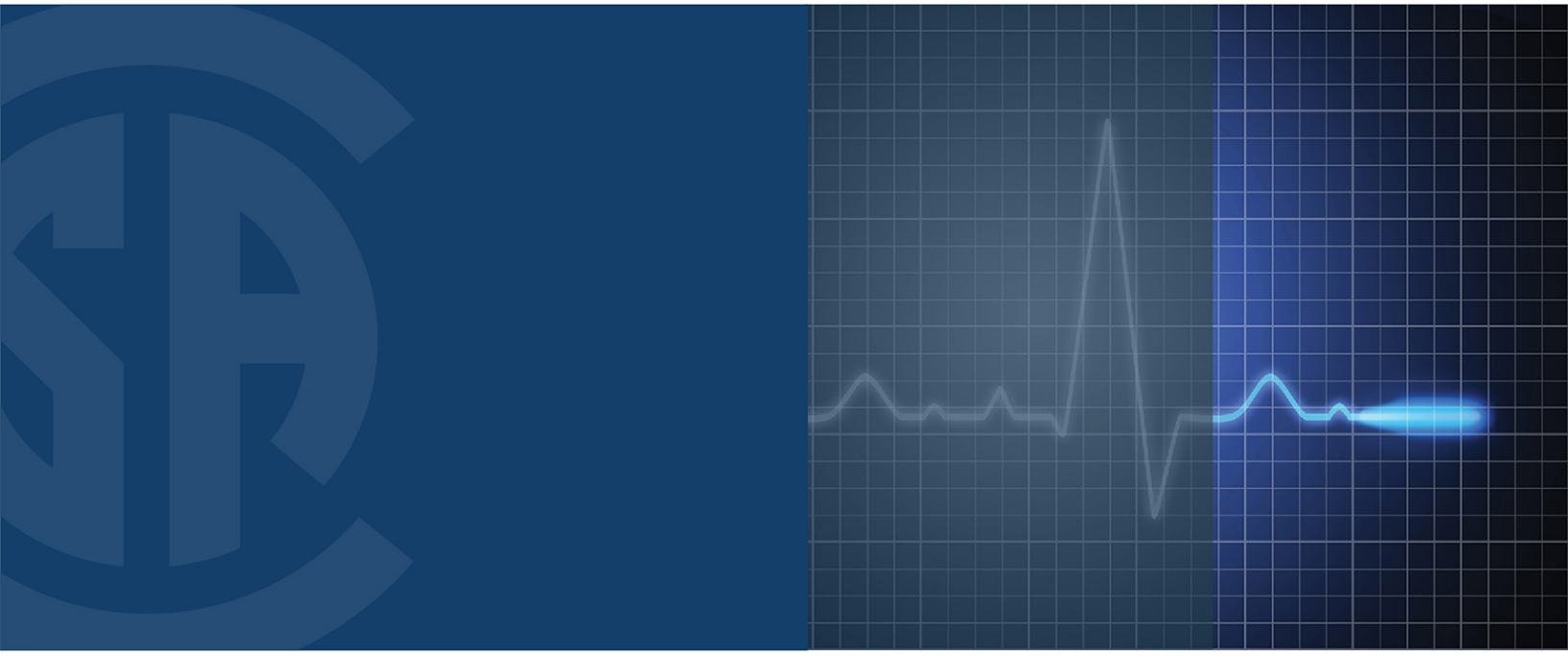

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ISO 23500-2

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Part 2: Water treatment equipment for haemodialysis applications and related therapies

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes —

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This first edition cancels and replaces ISO 26722:2014, which has been technically revised. The main changes compared to the previous edition are as follows:

— The document forms part of a revised and renumbered series dealing with the preparation and quality management of fluids for haemodialysis and related therapies. The series comprise ISO 23500-1 (previously ISO 23500), ISO 23500-2, (previously ISO 26722), ISO 23500-3, (previously ISO 13959), ISO 23500-4, (previously ISO 13958), and ISO 23500-5, (previously ISO 11663).

A list of all parts in the ISO 23500 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians, and dialysis patients, in consultation with device manufacturers and regulatory authority representatives, to develop an International 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 documents, does not imply unanimity of opinion, but rather reflects the compromise necessary in some instances when a variety of interests should be merged.

This document applies to individual water treatment devices and to water treatment systems assembled from one or more of these devices. In the first instance, this document is directed at the individual or company that specifies the complete water treatment system and, second, at the supplier who assembles and installs the system. Since systems can be assembled from a number of individual water treatment devices, the provisions of this document are also directed at the manufacturers of these devices, provided that the manufacturer indicates that the device is intended for use in haemodialysis applications. This document is written principally to address water treatment systems for dialysis facilities treating multiple patients. However, many of its provisions apply equally to water treatment systems used in applications where a single patient is treated, such as in a home dialysis or acute hospital dialysis setting. Specifically, requirements for the chemical and microbiological quality of water are considered to apply in all settings, regardless of whether a single patient or many patients are being treated.

Increasingly, self-contained, integrated systems designed and validated to produce water and dialysis fluid are becoming available and used clinically. The provisions included in this document apply to systems assembled from individual components. Consequently, some of the provisions in ISO 23500-1 and ISO 23500-2 might not apply to integrated systems, however such systems are required to comply with ISO 23500-3, ISO 23500-4, and ISO 23500-5. In order to ensure conformity when using such systems, the user shall follow the manufacturer's instructions regarding the operation, testing, and maintenance of such systems in order to ensure that the system is being operated under the validated conditions.

This document helps protect haemodialysis patients from adverse effects arising from known chemical and microbial contaminants found in water supplies. However, dialysis and patient safety is ultimately dependent on the quality of the dialysis fluid. Since the manufacturer or supplier of water treatment equipment does not have control over the dialysis fluid, any reference to dialysis fluid in this document is for clarification only and not a requirement of the manufacturer. The responsibility for assuring that the dialysis fluid is not contaminated, mismatched, or otherwise damaging to the patient rests with the clinical professionals caring for the patient under the supervision of the medical director. Requirements and recommendations on the preparation and handling of water and dialysis fluid in a dialysis facility are provided in ISO 23500-5. The rationale for the development of this document is given in Annex A.

Since the chemical and microbiological content of the water produced need to meet the requirements of ISO 23500-3, the maximum allowable levels of contaminants are listed in Annex B (Tables B.1 and B.2). The values shown include the anticipated uncertainty associated with the analytical methodologies listed in Table B.3.

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 2:
Water treatment equipment for haemodialysis applications and related therapies

1 Scope

1.1 General

This document is addressed to the manufacturer and/or supplier of water treatment systems and/or devices used for the express purpose of providing water for haemodialysis or related therapies.

1.2 Inclusions

This document covers devices used to treat potable water intended for use in the delivery of haemodialysis and related therapies, including water used for:

a) the preparation of concentrates from powder or other highly concentrated media at a dialysis facility;

b) the preparation of dialysis fluid, including dialysis fluid that can be used for the preparation of substitution fluid;

c) the reprocessing of dialysers intended for single use where permitted for multiple uses,

d) the reprocessing of dialysers not specifically marked as intended for single use.

This document includes all devices, piping and fittings between the point at which potable water is delivered to the water treatment system, and the point of use of the dialysis water. Examples of the devices are water purification devices, online water quality monitors (such as conductivity monitors), and piping systems for the distribution of dialysis water.

1.3 Exclusions

This document excludes dialysis fluid supply systems that proportion water and concentrates to produce dialysis fluid, sorbent dialysis fluid regeneration systems that regenerate and recirculate small volumes of the dialysis fluid, dialysis concentrates, haemodiafiltration systems, haemofiltration systems, systems that process dialysers for multiple uses, and peritoneal dialysis systems. Some of these devices, such as dialysis fluid delivery systems and concentrates, are addressed in other documents such as ISO 23500-4 and ISO 23500-5,

This document also excludes the on-going surveillance of the purity of water used for dialysis fluid, concentrate preparation, or dialyser reprocessing which is addressed in ISO 23500-1.

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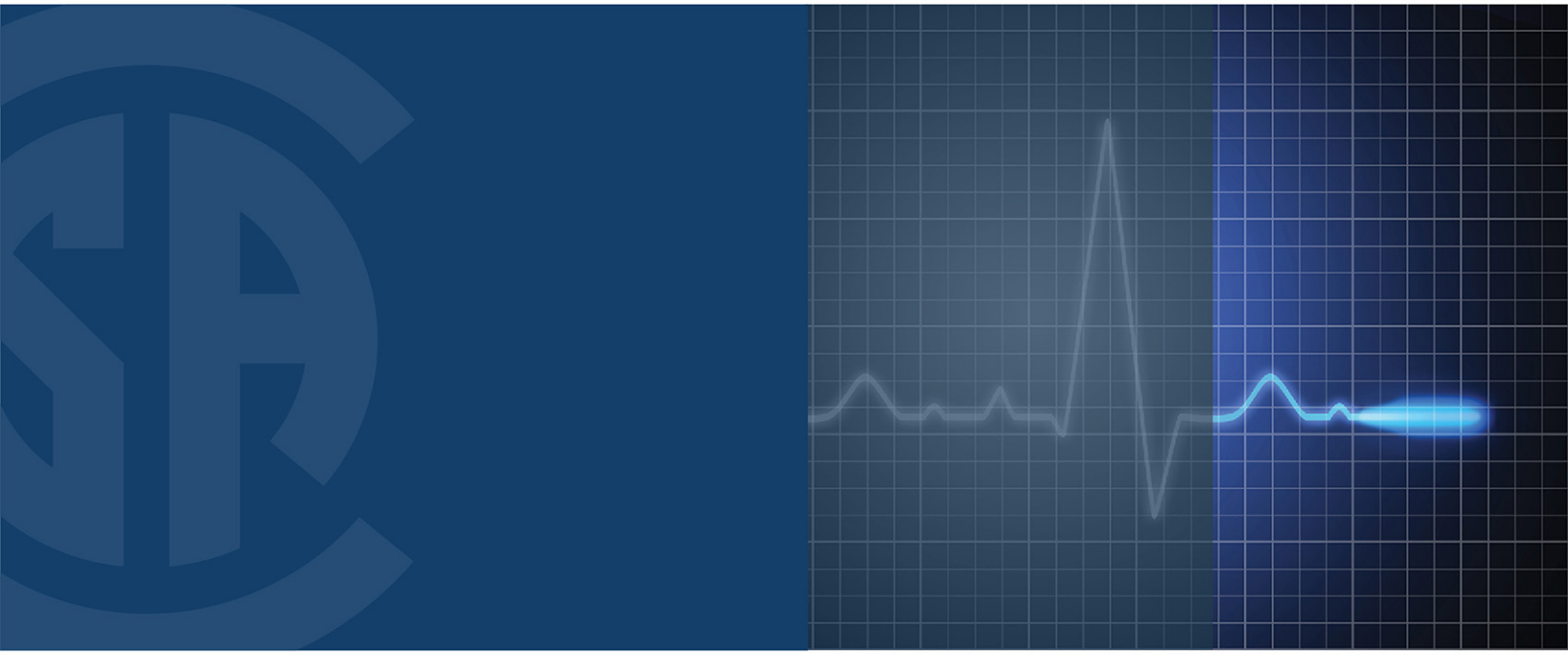

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CSA Z23500-3:20
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Title: *Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies*

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CSA Z23500-3:20

Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies

(ISO 23500-3:2019, MOD)

Prepared by
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CSA Z23500-3:20
Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies
(ISO 23500-3:2019, MOD)

CSA Preface

This is the first edition of CSA Z23500-3, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies,* which is an adoption, with Canadian deviations, of the identically titled ISO (International Organization for Standardization) Standard 23500-3 (first edition, 2019-02). It replaces CAN/CSA-ISO 13959:15 (adopted ISO 13959:2014), *Water for haemodialysis and related therapies*.

For brevity, this Standard will be referred to as "CSA Z23500-3" throughout.

This Standard was reviewed for Canadian adoption by the CSA Subcommittee on Quality Management for Kidney Dialysis, under the jurisdiction of the CSA Technical Committee on Kidney Dialysis and the CSA Strategic Steering Committee on Health and Well-being, and has been formally approved by the Technical Committee.

This Standard has been developed in compliance with Standards Council of Canada requirements for National Standards of Canada. It has been published as a National Standard of Canada by CSA Group.

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c) *wording of the proposed change; and*
d) *rationale for the change.*

INTERNATIONAL STANDARD

ISO 23500-3

First edition
2019-02

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 3: Water for haemodialysis and related therapies

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes —

Partie 3: Eau pour hémodialyse et thérapies apparentées

Reference number
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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Assurance of adequate water quality is one of the most important aspects of ensuring a safe and effective delivery of haemodialysis, haemodiafiltration, or haemofiltration.

This document contains minimum requirements, chemical and microbiological, for the water to be used for preparation of dialysis fluids, concentrates, and for the reprocessing of haemodialysers and the necessary steps to ensure conformity with those requirements.

Haemodialysis and related therapies such as haemodiafiltration can expose the patient to more than 500 l of water per week across the semi-permeable membrane of the haemodialyser or haemodiafilter. Healthy individuals seldom have a weekly oral intake above 12 l. This over 40-fold increase in exposure requires control and regular surveillance of water quality to avoid excesses of known or suspected harmful substances. Since knowledge of potential injury from trace elements and contaminants of microbiological origin over long periods is still growing and techniques for treating drinking water are continuously developed, this document will evolve and be refined accordingly. The physiological effects attributable to the presence of organic contaminants in dialysis water are important areas for research, however, the effect of such contaminants on patients receiving regular dialysis treatment is largely unknown, consequently no threshold values for organic contaminants permitted in water used for the preparation of dialysis fluids, concentrates, and reprocessing of haemodialysers has been specified in this revised document.

Within this document, measurement techniques current at the time of publication have been cited. Other standard methods can be used, provided that such methods have been appropriately validated and are comparable to the cited methods.

The final dialysis fluid is produced from concentrates or salts manufactured, packaged, and labelled according to ISO 23500-4 mixed with water meeting the requirements of this document. Operation of water treatment equipment and haemodialysis systems, including on-going surveillance of the quality of water used to prepare dialysis fluids, and handling of concentrates and salts are the responsibility of the haemodialysis facility and are addressed in ISO 23500-1. Haemodialysis professionals make choices about the various applications (haemodialysis, haemodiafiltration, haemofiltration) and should understand the risks of each and the requirements for safety for fluids used for each.

This document is directed towards manufacturers and providers of water treatment systems and also to haemodialysis facilities.

The rationale for the development of this document is given in informative Annex A.

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 3:
Water for haemodialysis and related therapies

1 Scope

This document specifies minimum requirements for water to be used in haemodialysis and related therapies.

This document includes water to be used in the preparation of concentrates, dialysis fluids for haemodialysis, haemodiafiltration and haemofiltration, and for the reprocessing of haemodialysers.

This document excludes the operation of water treatment equipment and the final mixing of treated water with concentrates to produce dialysis fluid. Those operations are the sole responsibility of dialysis professionals. This document does not apply to dialysis fluid regenerating systems.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 23500-1, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 23500-1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Requirements

4.1 Dialysis water quality requirements

The quality of the dialysis water, as specified in 4.2 and 4.3, shall be verified upon installation of a water treatment system. Regular surveillance of the dialysis water quality shall be carried out thereafter.

NOTE Throughout this document it is assumed that the water undergoing treatment is potable water and therefore meets the appropriate regulatory requirements for such water. If the water supply is derived from an alternate source such as a privately-owned borehole or well, contaminant levels cannot be as rigorously controlled.

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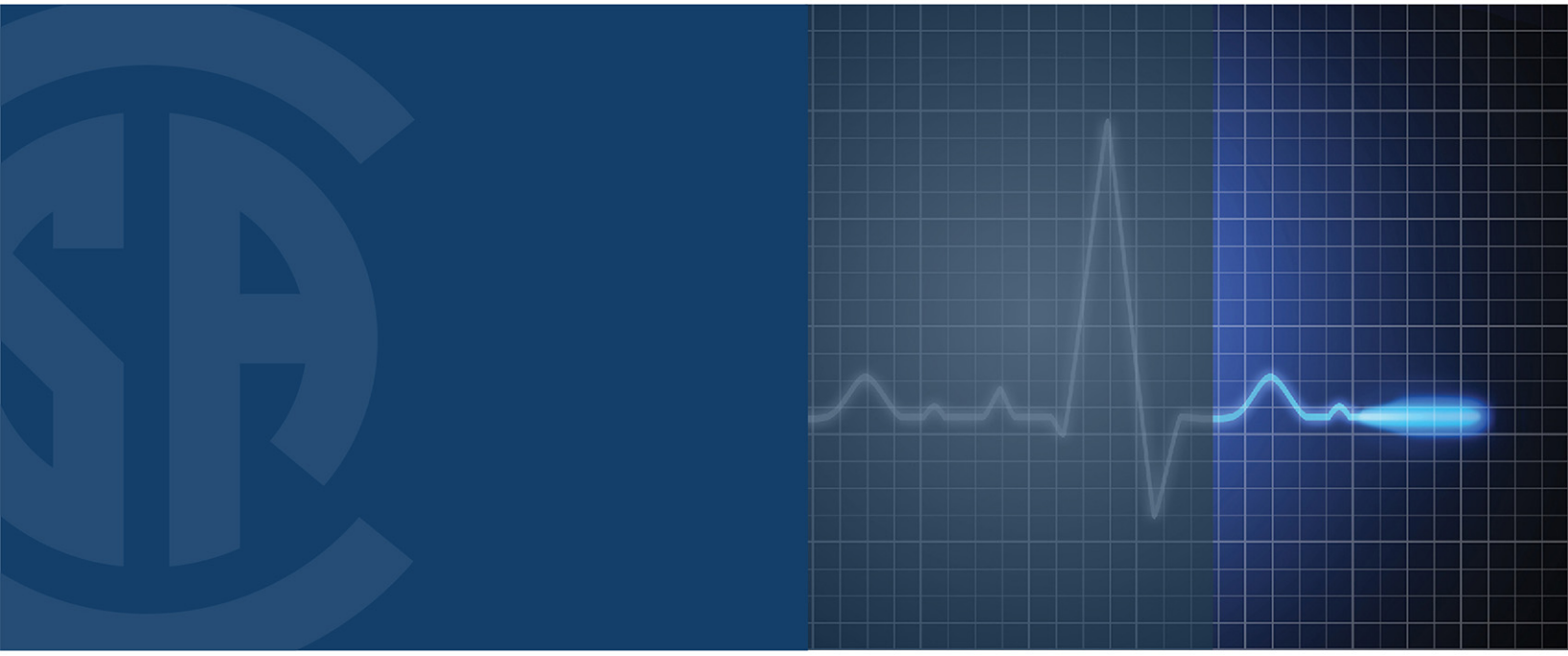

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CSA Z23500-4:20

Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies

(ISO 23500-4:2019, MOD)

Prepared by
International Organization for Standardization

Reviewed by

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CSA Preface

This is the first edition of CSA Z23500-4, *Preparation and quality management of fluids for haemodialysis and related therapies —Part 4: Concentrates for haemodialysis and related therapies,* which is an adoption, with Canadian deviations, of the identically titled ISO (International Organization for Standardization) Standard 23500-4 (first edition, 2019-02). It replaces CAN/CSA-ISO 13958:15 (adopted ISO 13958:2014), *Concentrates for haemodialysis and related therapies*.

For brevity, this Standard will be referred to as "CSA Z23500-4" throughout.

This Standard was reviewed for Canadian adoption by the CSA Subcommittee on Quality Management for Kidney Dialysis, under the jurisdiction of the CSA Technical Committee on Kidney Dialysis and the CSA Strategic Steering Committee on Health and Well-being, and has been formally approved by the Technical Committee.

This Standard has been developed in compliance with Standards Council of Canada requirements for National Standards of Canada. It has been published as a National Standard of Canada by CSA Group.

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ISO 23500-4

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2019-02

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 4: Concentrates for haemodialysis and related therapies

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes —

Partie 4: Concentrés pour hémodialyse et thérapies apparentées

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This first edition cancels and replaces ISO 13958:2014, which has been technically revised. The main changes compared to the previous edition are as follows:

— The document forms part of a revised and renumbered series dealing with the preparation and quality management of fluids for haemodialysis and related therapies. The series comprise ISO 23500-1 (previously ISO 23500), ISO 23500-2, (previously ISO 26722), ISO 23500-3, (previously ISO 13959), ISO 23500-4, (previously ISO 13958), and ISO 23500-5, (previously ISO 11663).

A list of all parts of the ISO 23500 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The requirements and goals established by this document will help ensure the effective, safe performance of haemodialysis concentrates and related materials. This document reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians and dialysis patients, in consultation with device manufacturers and regulatory agency 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 shall be merged.

The rationale for the development of this document is given in informative Annex A.

Throughout this document, requirements and recommendations are made to use ISO-quality water. Therefore, it is recommended to refer to ISO 23500-3 along with this document.

For the purpose of this document, “concentrates” are a mixture of chemicals and water, or chemicals in the form of dry powder or other highly concentrated media, which are delivered to the end user to make dialysis fluid used to perform haemodialysis and related therapies.

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 4: Concentrates for haemodialysis and related therapies

1 Scope

This document specifies minimum requirements for concentrates used for haemodialysis and related therapies.

This document is addressed to the manufacturer of such concentrates. In several instances in this document, the dialysis fluid is addressed, 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 document includes concentrates in both liquid and powder forms. It also includes additives, also called spikes, which are chemicals that can be added to the concentrate to supplement or increase the concentration of one or more of the existing ions in the concentrate and thus in the final dialysis fluid.

This document also specifies requirements for equipment used to mix acid and bicarbonate powders into concentrate at the user's facility.

Concentrates prepared from pre-packaged salts and water at a dialysis facility for use in that facility are excluded from the scope of this document. Although references to dialysis fluid appear herein, this document does not address dialysis fluid as made by the end user. This document also excludes requirements for the surveillance frequency of water purity used for the making of dialysis fluid by the dialysis facility. This document does not address bags of sterile dialysis fluid or sorbent dialysis fluid regeneration systems that regenerate and recirculate small volumes of the dialysis fluid.

This document does not cover the dialysis fluid that is used to clinically dialyse patients. Dialysis fluid is covered in ISO 23500-5. 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.

This document does not cover haemodialysis equipment, which is addressed in IEC 60601-2-16:2012.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 23500-1, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements*

ISO 23500-3, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies*

ISO 23500-5, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 5: Quality of dialysis fluid for haemodialysis and related therapies*

CSA Z23500-5:20
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Preparation and quality management of fluids for haemodialysis and related therapies — Part 5: Quality of dialysis fluid for haemodialysis and related therapies
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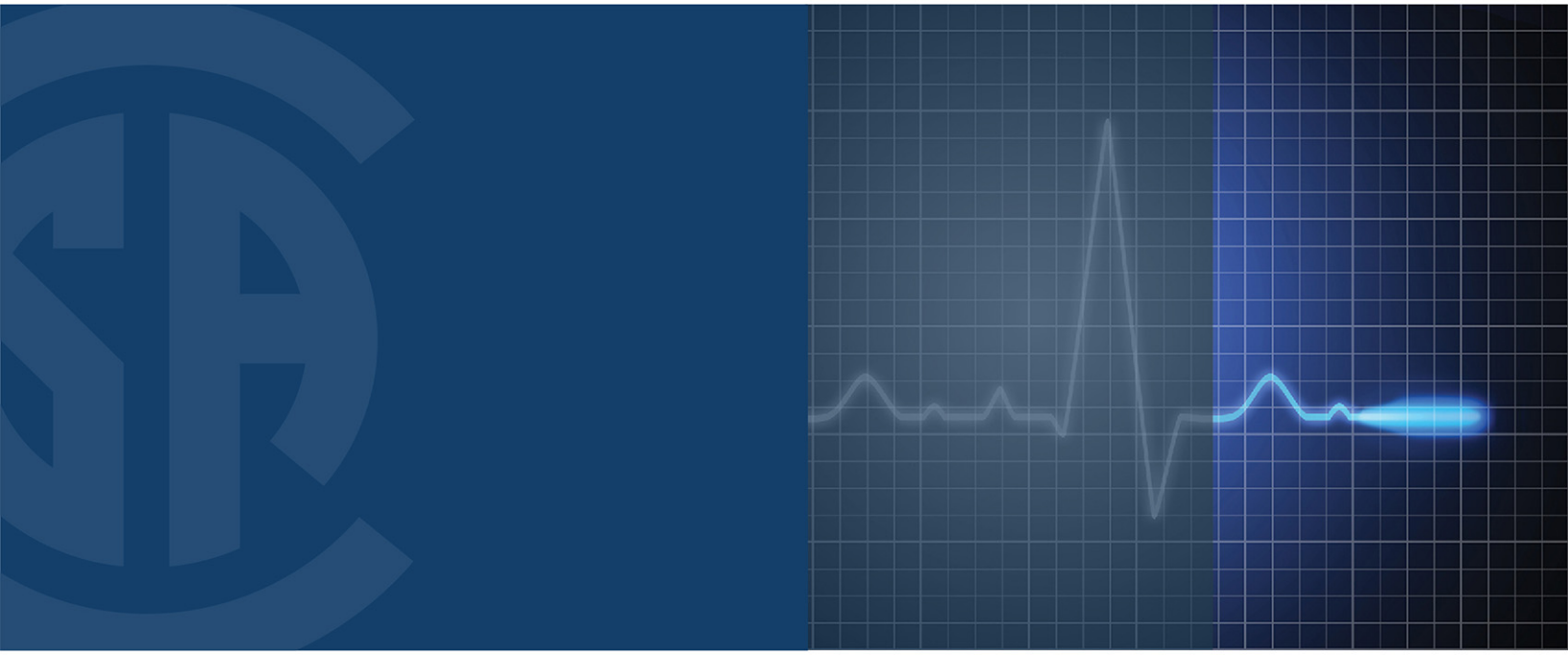

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Preparation and quality management of fluids for haemodialysis and related therapies — Part 5: Quality of dialysis fluid for haemodialysis and related therapies

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CSA Preface

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For brevity, this Standard will be referred to as "CSA Z23500-5" throughout.

This Standard was reviewed for Canadian adoption by the CSA Subcommittee on Quality Management for Kidney Dialysis, under the jurisdiction of the CSA Technical Committee on Kidney Dialysis and the CSA Strategic Steering Committee on Health and Well-being, and has been formally approved by the Technical Committee.

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Preparation and quality management of fluids for haemodialysis and related therapies —

Part 5: Quality of dialysis fluid for haemodialysis and related therapies

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes —

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A list of all parts in the ISO 23500 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Haemodialysis patients are directly exposed to large volumes of dialysis fluid, with the dialyser membrane being the only barrier against transfer of hazardous contaminants from the dialysis fluid to the patient. It has long been known that there could be hazardous contaminants in the water and concentrates used to prepare the dialysis fluid. To minimize this hazard, ISO 23500-3 and ISO 23500-4 set forth quality requirements for the water and concentrates used to prepare dialysis fluid. However, if the dialysis fluid is not prepared carefully, it could contain unacceptable levels of contaminants even though it is prepared from water and concentrates, conforming to the requirements of ISO 23500-3 and ISO 23500-4. Further, the dialysis fluid might be used as the starting material for the online preparation of fluids intended for infusion into the patient, for example, in therapies such as online haemodiafiltration. For these reasons, this document for dialysis fluid quality was developed to complement the existing International Standards for water and concentrates, ISO 23500-3 and ISO 23500-4, respectively. Guidelines to aid the user in routinely meeting the requirements of this document and ISO 23500-3 can be found in ISO 23500-1.

Within these International Standards, measurement techniques current at the time of preparation have been cited. Other standard methods can be used, provided that such methods have been appropriately validated and are comparable to the cited methods. The rationale for the development of this document is given in Annex A.

This document reflects the conscientious efforts of healthcare professionals, patients, and medical device manufacturers to develop recommendations for the quality of dialysis fluid. This document is directed at the healthcare professionals involved in the management of dialysis facilities and the routine care of patients treated in dialysis facilities, since they are responsible for the final preparation of dialysis fluid. The recommendations contained in this document are not intended for regulatory application.

This document aims to help protect haemodialysis patients from adverse effects arising from known chemical and microbiological contaminants that can 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 applicable quality standards.

The concepts incorporated in this document should not be considered inflexible or static. The requirements and 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.

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 5:
Quality of dialysis fluid for haemodialysis and related therapies

1 Scope

This document specifies minimum quality requirements for dialysis fluids used in haemodialysis and related therapies.

This document includes dialysis fluids used for haemodialysis and haemodiafiltration, including substitution fluid for haemodiafiltration and haemofiltration.

This document excludes the water and concentrates used to prepare dialysis fluid or the equipment used in its preparation. Those areas are covered by other International Standards.

Sorbent-based dialysis fluid regeneration systems that regenerate and recirculate small volumes of dialysis fluid, systems for continuous renal replacement therapy that use pre-packaged solutions, and systems and solutions for peritoneal dialysis are excluded from this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 23500-1, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements*

ISO 23500-3, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Quality of water for haemodialysis and related therapies*

ISO 23500-4, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 23500-1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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