CSA Z23500-3:20
(ISO 23500-3:2019, MOD)
National Standard of Canada

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)

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National Standard of Canada

CSA Z23500-3:20

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

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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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a) *Standard designation (number);*
b) *relevant clause, table, and/or figure number;*
c) *wording of the proposed change; and*
d) *rationale for the change.*

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Canadian deviations

The following deviations are intended to align with local healthcare practices and to meet the requirements of Canadian healthcare regulators.

Introduction

[Add the following paragraph]

For instructions regarding installation, operation, and testing frequency, refer to CSA Z364.5. For instructions on quality management, refer to CSA Z364.6.

2 Normative references

[Add the following]

Any reference to International Standards that are adopted as National Standards of Canada subsequent to the publication of CSA Z23500-3 shall be replaced by the relevant National Standard of Canada.

Where reference is made to CSA Group publications, such reference shall be considered to refer to the latest edition and all amendments published to that edition. This Standard refers to the following publications, and the years shown indicate the latest edition available at the time of printing:

CSA Group

Z364.5-17
Safe installation and operation of hemodialysis and peritoneal dialysis in a home setting

Z364.6-17
Quality management for kidney dialysis providers

The following National Standards of Canada, published by CSA Group, are adoptions of ISO Standards. The requirements of these CSA Group standards shall take precedence over the International Standards on which they are based. Any reference within CSA Z23500-3 to the International Standard shall be replaced by a reference to the equivalent Canadian Standard.

CSA Z23500-1:20
Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements

CSA Z23500-4:20
Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies

CSA Z23500-5:20
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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4 Requirements

Table 2 — Maximum allowable levels of other trace elements in dialysis water

[Add the following note]

NOTE 1A: *Canadian provincial and territorial drinking water standards differ and are unique to specific geographical areas within Canada. In some cases, the limits defined within a local Canadian jurisdiction might be lower than the limit set in Tables 1 and 2. Selenium and antimony are some examples where the Canadian drinking water standards are lower or equivalent to the ISO standard for dialysis water. In cases where the ISO limit is above the Canadian local jurisdiction limit, the user should use the lower of the two limits as the maximum acceptable concentration for the contaminant. The reader is cautioned to periodically review their local drinking water limits as they compare to Tables 1 and 2 to determine the maximum level of contaminants allowable in dialysis water.*

4.3 Dialysis water microbiological requirements

[Replace the first two paragraphs with the following]

Total viable microbial counts in standard dialysis water shall be less than 100 CFU/mL, or lower if required by national legislation or regulations. If the water treatment system allows the production of ultrapure dialysis water, total viable microbial counts shall be less than 0.1 CFU/mL. An action level shall be set based on knowledge of the microbial dynamics of the system. Typically, the action level will be 50% of the maximum allowable level.

Endotoxin content in standard dialysis water shall be less than 0.25 EU/mL, or lower if required by national legislation or regulations. An action level shall be set, typically at 50% of the maximum allowable level. In ultrapure dialysis water, endotoxin content shall be less than 0.03 EU/mL.

5 Tests for microbiological and chemical requirements

5.2 Microbial contaminant test methods

[Replace the second, third, and fourth paragraphs with the following]

Recommended methods and cultivation conditions can also be found in CSA Z23500-4 and CSA Z23500-5 as well as this Standard. (See Table 3.) The methodology detailed uses Tryptone Glucose Extract Agar (TGEA) and Reasoner's Agar No. 2 (R2A) incubated at 17 to 23 °C for a period of 7 days.

Table 3 — Culture techniques

[Delete the fourth row and footnote [b]]

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Annex A (informative)
Rationale for the development and provisions of this document

A.4 Microbiology of dialysis water

[Replace the last three paragraphs with the following]

Recommended methods and cultivation conditions can be found in CSA Z23500-4 and CSA Z23500-5 as well as this Standard. (See Table 3.)

In addition to bacteria and endotoxins, yeasts and filamentous fungi can also be present, and their presence implies a potential risk to the patient[65][66]. Further studies are required to investigate the organism's ability to persist, their role in biofilm formation and their clinical significance. In view of this, no limits in respect of yeasts and filamentous fungi have been set in this revision. In cases where the presence of yeasts and filamentous fungi in fluids is of clinical concern, Malt Extract Agar (MEA) can be used to identify the species rather than Sabouraud Agar which is less effective. For mould, Corn Meal Agar or Czapek-Dox Agar are suitable growth media.

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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 13959:2014, 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.

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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.

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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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