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)

Standards Council of Canada
Conseil canadien des normes

Legal Notice for Standards

Canadian Standards Association (operating as "CSA Group") develops standards through a consensus standards development process approved by the Standards Council of Canada. This process brings together volunteers representing varied viewpoints and interests to achieve consensus and develop a standard. Although CSA Group administers the process and establishes rules to promote fairness in achieving consensus, it does not independently test, evaluate, or verify the content of standards.

Disclaimer and exclusion of liability

This document is provided without any representations, warranties, or conditions of any kind, express or implied, including, without limitation, implied warranties or conditions concerning this document's fitness for a particular purpose or use, its merchantability, or its non-infringement of any third party's intellectual property rights. CSA Group does not warrant the accuracy, completeness, or currency of any of the information published in this document. CSA Group makes no representations or warranties regarding this document's compliance with any applicable statute, rule, or regulation.

IN NO EVENT SHALL CSA GROUP, ITS VOLUNTEERS, MEMBERS, SUBSIDIARIES, OR AFFILIATED COMPANIES, OR THEIR EMPLOYEES, DIRECTORS, OR OFFICERS, BE LIABLE FOR ANY DIRECT, INDIRECT, OR INCIDENTAL DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES, HOWSOEVER CAUSED, INCLUDING BUT NOT LIMITED TO SPECIAL OR CONSEQUENTIAL DAMAGES, LOST REVENUE, BUSINESS INTERRUPTION, LOST OR DAMAGED DATA, OR ANY OTHER COMMERCIAL OR ECONOMIC LOSS, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR ANY OTHER THEORY OF LIABILITY, ARISING OUT OF OR RESULTING FROM ACCESS TO OR POSSESSION OR USE OF THIS DOCUMENT, EVEN IF CSA GROUP HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES.

In publishing and making this document available, CSA Group is not undertaking to render professional or other services for or on behalf of any person or entity or to perform any duty owed by any person or entity to another person or entity. The information in this document is directed to those who have the appropriate degree of experience to use and apply its contents, and CSA Group accepts no responsibility whatsoever arising in any way from any and all use of or reliance on the information contained in this document.

CSA Group is a private not-for-profit company that publishes voluntary standards and related documents. CSA Group has no power, nor does it undertake, to enforce compliance with the contents of the standards or other documents it publishes.

Intellectual property rights and ownership

As between CSA Group and the users of this document (whether it be in printed or electronic form), CSA Group is the owner, or the authorized licensee, of all works contained herein that are protected by copyright, all trade-marks (except as otherwise noted to the contrary), and all inventions and trade secrets that may be contained in this document, whether or not such inventions and trade secrets are protected by patents and applications for patents. Without limitation, the unauthorized use, modification, copying, or disclosure of this document may violate laws that protect CSA Group's and/or others' intellectual property and may give rise to a right in CSA Group and/or others to seek legal redress for such use, modification, copying, or disclosure. To the extent permitted by licence or by law, CSA Group reserves all intellectual property rights in this document.

Patent rights

Attention is drawn to the possibility that some of the elements of this standard may be the subject of patent rights. CSA Group shall not be held responsible for identifying any or all such patent rights. Users of this standard are expressly advised that determination of the validity of any such patent rights is entirely their own responsibility.

Authorized use of this document

This document is being provided by CSA Group for informational and non-commercial use only. The user of this document is authorized to do only the following:

If this document is in electronic form:

- load this document onto a computer for the sole purpose of reviewing it;
- search and browse this document; and
- print this document if it is in PDF format.

Limited copies of this document in printed or paper form may be distributed only to persons who are authorized by CSA Group to have such copies, and only if this Legal Notice appears on each such copy.

In addition, users may not and may not permit others to

- alter this document in any way or remove this Legal Notice from the attached standard;
- sell this document without authorization from CSA Group; or
- make an electronic copy of this document.

If you do not agree with any of the terms and conditions contained in this Legal Notice, you may not load or use this document or make any copies of the contents thereof, and if you do make such copies, you are required to destroy them immediately. Use of this document constitutes your acceptance of the terms and conditions of this Legal Notice.

Standards Update Service

CSA Z23500-1:20
January 2020

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

To register for e-mail notification about any updates to this publication
- go to **store.csagroup.org**
- click on **Product Updates**

The **List ID** that you will need to register for updates to this publication is **2427183**.

If you require assistance, please e-mail **techsupport@csagroup.org** or call 416-747-2233.

Visit CSA Group's policy on privacy at **www.csagroup.org/legal** to find out how we protect your personal information.

Canadian Standards Association (operating as "CSA Group"), under whose auspices this National Standard has been produced, was chartered in 1919 and accredited by the Standards Council of Canada to the National Standards system in 1973. It is a not-for-profit, nonstatutory, voluntary membership association engaged in standards development and certification activities.

CSA Group standards reflect a national consensus of producers and users — including manufacturers, consumers, retailers, unions and professional organizations, and governmental agencies. The standards are used widely by industry and commerce and often adopted by municipal, provincial, and federal governments in their regulations, particularly in the fields of health, safety, building and construction, and the environment.

Individuals, companies, and associations across Canada indicate their support for CSA Group's standards development by volunteering their time and skills to Committee work and supporting CSA Group's objectives through sustaining memberships. The more than 7000 committee volunteers and the 2000 sustaining memberships together form CSA Group's total membership from which its Directors are chosen. Sustaining memberships represent a major source of income for CSA Group's standards development activities.

CSA Group offers certification and testing services in support of and as an extension to its standards development activities. To ensure the integrity of its certification process, CSA Group regularly and continually audits and inspects products that bear the CSA Group Mark.

In addition to its head office and laboratory complex in Toronto, CSA Group has regional branch offices in major centres across Canada and inspection and testing agencies in eight countries. Since 1919, CSA Group has developed the necessary expertise to meet its corporate mission: CSA Group is an independent service organization whose mission is to provide an open and effective forum for activities facilitating the exchange of goods and services through the use of standards, certification and related services to meet national and international needs.

For further information on CSA Group services, write to
CSA Group
178 Rexdale Boulevard
Toronto, Ontario, M9W 1R3
Canada

A National Standard of Canada is a standard developed by a Standards Council of Canada (SCC) accredited Standards Development Organization, in compliance with requirements and guidance set out by SCC. More information on National Standards of Canada can be found at www.scc.ca.

SCC is a Crown corporation within the portfolio of Innovation, Science and Economic Development (ISED) Canada. With the goal of enhancing Canada's economic competitiveness and social well-being, SCC leads and facilitates the development and use of national and international standards. SCC also coordinates Canadian participation in standards development, and identifies strategies to advance Canadian standardization efforts.

Accreditation services are provided by SCC to various customers, including product certifiers, testing laboratories, and standards development organizations. A list of SCC programs and accredited bodies is publicly available at www.scc.ca.

Standards Council of Canada
600-55 Metcalfe Street
Ottawa, Ontario, K1P 6L5
Canada

Standards Council of Canada
Conseil canadien des normes

Cette Norme Nationale du Canada est disponible en versions française et anglaise.

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)

Prepared by
International Organization for Standardization

Reviewed by

Published in January 2020 by CSA Group
A not-for-profit private sector organization
178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3

To purchase standards and related publications, visit our Online Store at store.csagroup.org or call toll-free 1-800-463-6727 or 416-747-4044.

ICS 11.040.40
ISBN 978-1-4883-2662-2

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

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.

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.

Inquiries regarding this National Standard of Canada should be addressed to
CSA Group
178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3
1-800-463-6727 • 416-747-4000
www.csagroup.org

To purchase standards and related publications, visit our Online Store at store.csagroup.org or call toll-free 1-800-463-6727 or 416-747-4044.

This Standard is subject to review within five years from the date of publication, and suggestions for its improvement will be referred to the appropriate committee. The technical content of IEC and ISO publications is kept under constant review by IEC and ISO. To submit a proposal for change, please send

the following information to inquiries@csagroup.org and include "Proposal for change" in the subject line:

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

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 Z23500-1 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 Z23500-1 to the International Standard shall be replaced by a reference to the equivalent Canadian Standard.

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

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

3 Terms and definitions

3.17 dialysis water

[Replace this defined term with the following]

standard dialysis water

[Add the following note]

NOTE 1A: *Ultrapure dialysis water can be used alternatively on a regular basis with all kinds of haemodialysis modalities. Ultrapure dialysis water is a highly purified water that can be used in the place of standard dialysis water. A widely accepted specification of ultrapure dialysis water is < 0.1 CFU/mL and < 0.03 UE/mL.*

4 Quality requirements

4.2 Dialysis water

4.2.1 General

[Add the following note]

NOTE 1A: *There are two levels of dialysis water: standard dialysis water and ultrapure dialysis water. Standard dialysis water is regarded as an acceptable quality. Ultrapure dialysis water can improve biocompatibility, reduce inflammation, and prevent dialysis-related complications. Ultrapure dialysis water can be used on a regular basis with all kinds of haemodialysis modalities. Several technical options and arrangements might be used to produce ultrapure water. One of these options is based on pretreatment and a double-stage RO module in series. If that option is chosen, microbiological contamination will be more stringent (see Table 2). Strategies for microbiological control are detailed in Clause 8.*

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.*

Table 3 — Maximum allowable levels for total viable microbial count (TVC) and endotoxins in dialysis water

[Replace Table 3 and its title with the following]

Table 3
Maximum allowable levels for total viable microbial count (TVC) and endotoxins of the different water purity grades in dialysis water

	Standard dialysis water*		Ultrapure water‡	
Contaminant	**Maximum allowable level**	**Typical action level†**	**Maximum allowable level**	**Typical action level**
TVC	< 100 CFU/mL	50 CFU/mL	< 0.1 CFU/mL	0.05 CFU/mL
Endotoxin	< 0.25 EU/mL	0.125 EU/mL	< 0.03 EU/mL	≥ 0.03 EU/mL

** The reader is cautioned to refer to the latest version of CSA Z23500-3 to ensure that there have been no changes to the values presented in this Table.*
† Typically set at 50% of the maximum allowable level. Other values may be set.
‡ Ultrapure water may be used alternatively on a regular basis with all kinds of haemodialysis modalities. Several technical options and arrangements may be used to produce ultrapure water. The most common water treatment system option is based on pretreatment and a double-stage RO module in series. Microbiological contamination in this case complies with more stringent standards.

4.4 Requirements for dialysis fluid

4.4.1 General

[Delete the last paragraph]

4.4.2 Microbiological requirements for standard dialysis fluid

[Add the following paragraph]

Samples shall be taken on a monthly rotational basis (see Table C.1) to provide verification of the effectiveness of the disinfection process. The monthly rotation should encompass at least 25% of the machines such that every 4 months, 100% of the machines should be tested.

4.4.3 Microbiological requirements for ultrapure dialysis fluid

[Delete the last paragraph]

4.4.4 Microbiological requirements for online-prepared substitution fluid

[Add the following paragraph]

Samples shall be taken on a monthly basis (see Table C.1) to provide verification of the effectiveness of the disinfection process.

5 Critical aspects of system design

5.1 General

[Replace the last paragraph with the following]

The spent or used dialysis fluid is discharged into the public sewage system without treatment. Disinfectant solutions may also be similarly discharged. Contact the local municipality for information regarding the risks to public health and the environment from such discharges.

6 Validation of system performance

6.2 Validation plan

[Replace the last paragraph with the following]

The validation plan should be approved by the physician in charge of the dialysis program and/or the dialysis technical lead or delegate.

6.4 Performance qualification

[Replace the last two paragraphs with the following]

For newly installed systems, the physician in charge of the dialysis program and/or the dialysis technical lead or delegate may authorize use of dialysis fluid for patient treatments once chemical and microbiological analyses are available that show full conformity with the quality requirements of Clause 4, the manufacturer's specifications, and any applicable regulatory requirements.

In some instances, the schematic approach shown in Figure 1 cannot be followed, and concurrent validation may be appropriate, e.g., following major refurbishment of an already existing system. The physician in charge of the dialysis program and/or the dialysis technical lead or delegate may authorize the use of dialysis fluid for patient treatments provided that an appropriate risk assessment has been performed and recorded.

6.5 Routine surveillance and revalidation

[In the first sentence of the fourth paragraph, delete “or no sooner than 24 h after disinfection”]

7 Quality management

7.2 Surveillance of fluid quality

7.2.1 Surveillance of dialysis water quality

[Replace the first sentence of the first paragraph with the following]

Dialysis water quality shall be monitored on a regular basis for the chemical contaminants and monthly for the microbiological contaminants listed in Clauses 4.2.2 and 4.2.4.

7.2.3 Surveillance of dialysis fluid quality

[Replace "regular" with "monthly" in the first paragraph]

[Delete Notes 1 and 2]

8 Strategies for microbiological control

8.3 Microbiological surveillance methods

8.3.1 General

[Replace "shall be routinely monitored" with "shall be monitored monthly" in the first paragraph]

[Replace Items a), b), and c) with the following]

a) Water system: The number of samples and positions of sampling should be based on the complexity and size of the water system. Samples shall be tested on a monthly basis for the microbiological contaminants listed in Clause 4.1.3.
b) Dialysis fluid/haemodialysis machines with or without a validated bacteria- and endotoxin-retentive filter: Samples shall be taken on a monthly rotational basis to provide verification of the effectiveness of the disinfection process. The monthly rotation should encompass at least 25% of the machines such that every 4 months 100% of the machines should be tested.
c) Ultrapure dialysis fluid/online substitution fluid for haemofiltration or haemodiafiltration therapy: Samples shall be taken on a monthly basis to provide verification of the injectable fluid. Testing shall be performed at the largest sample volume to meet ultrapure dialysis fluid quality according to Clause 8.3.3.2.1.

8.3.2.1 Dialysis water sample sites

[Replace this Clause with the following]

Samples are to be taken at outlets of the distribution system.

Prior to sampling, the inside of the outlet should be disinfected, especially if no haemodialysis machine is attached. The reason for such disinfection is that over time, residual water in an outlet will support microbial growth. The disinfection should be made by flushing the inside of the outlet with 70% ethanol or isopropanol. A sterile cotton swab wetted with alcohol may also be used. Exposure time is to be > 15 s. In principle, it is sufficient to let out enough water to rinse off the alcohol (200 to 500 mL) prior to sampling. Alternatively, hoses can be disconnected from the tap and the taps opened and allowed to flush for 2 to 3 min before aseptically collecting a sample. Other sampling methods may be appropriate, provided that they have been validated.

Sample volumes of 5 to 1000 mL or a volume as specified by the laboratory should be used. Containers used for samples to be cultured should be sterile and endotoxin free.

8.3.2.2 Dialysis fluid samples

[Delete the last sentence of the note]

[Add the following note]

Note 1A: *For ultrapure dialysis fluids, sample volumes must be sufficient. The following minimum sampling volumes are recommended:*

a) *100 mL for ultrapure dialysis fluid; and*
b) *500 mL for substitution fluid.*

8.3.3.3 Cultivation methods and conditions

[Replace the first paragraph with the following]

The recommended methods and cultivation conditions can be found in CSA Z23500-3, CSA Z23500-4, and CSA Z23500-5. The methodologies detailed use Tryptone Glucose Extract Agar (TGEA) or Reasoner's Agar No. 2 (R2A) incubated at 17 to 23 °C for a period of 7 days for the culturing of standard dialysis fluid and dialysis water.

[Delete the third and fourth paragraphs]

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

A.8 Heterotrophic plate count

[Delete the fourth, fifth, and sixth paragraphs]

[In the seventh paragraph, delete the phrase ", or Tryptic Soy Agar incubated at 35 °C for 48 hours" from the first sentence]

[In the last paragraph, delete the third sentence]

Annex B (informative)
Equipment

B.7 Central dialysis fluid storage and delivery systems

B.7.2 Design and maintenance

[Replace Item b) with the following]

b) Dialysis fluid/haemodialysis machines with or without a validated bacteria- and endotoxin-retentive filter: Machines should be sampled on a regular basis to provide affirmation of the effectiveness of the disinfection process. The schedule of sampling will depend on the type of disinfection process being used. Each machine should be sampled according to Table C.1 and different machines should be sampled on each occasion. Monthly surveillance is most frequently adopted.

Annex C (informative)
Surveillance guidelines for water treatment equipment, distribution systems, and dialysis fluid

C.1 Surveillance systems

[Add the following note]

NOTE 1A: *For ultrapure water quality, refer to Table 3. Bacterial growth and endotoxins should be monitored at least monthly with appropriate volume (1000 mL is suggested for testing the bacterial growth).*

Table C.1
Suggested framework for surveillance water treatment equipment, distribution systems, and dialysis fluid

[Replace this Table with the following]

Item to monitor	What to monitor	Typical range of values	Typical interval	Comments
Standard dialysis fluid for haemodialysis therapy	Bacterial growth and endotoxin concentration in standard dialysis fluid	Bacterial count < 100 CFU/mL; (action level set at 50% or ≥ 50 CFU/mL); (see Clause 4.4.2 and Table 4) Endotoxin < 0.5 EU/mL; (action level at ≥ 0.25 EU/mL) (see Clause 4.4.2 and Table 4)	Monthly rotational basis. The monthly rotation should encompass at least 25% of the machines such that every 4 months 100% of the machines should be tested	The sample should be collected at worst-case time (e.g., Monday morning) if possible
Ultrapure dialysis fluid for haemodialysis therapy	Bacterial growth and endotoxin concentration in ultrapure dialysis fluid	Bacterial count < 0.1 CFU/mL; (action level set at 50% or ≥ 5 CFU/100 mL) Endotoxin < 0.03 EU/mL; (action level at ≥ 0.03 EU/mL) (see Clause 4.4.3, Table 4, and the Canadian deviations for Clause 8.3.1 and Annex E)	Monthly rotational basis. The monthly rotation should encompass at least 25% of the machines such that every 4 months 100% of the machines should be tested. Testing should be performed at the largest sample volume to meet ultrapure dialysis fluid quality according to Clause 8.3.3.2.1	NA

(Continued)

Table C.1 (Concluded)

Item to monitor	What to monitor	Typical range of values	Typical interval	Comments
Ultrapure dialysis fluid for haemodiafiltration therapy	Bacterial growth and endotoxin concentration in ultrapure dialysis fluid	Bacterial count < 0.1 CFU/mL; (action level typically set at 50% or ≥ 5 CFU/100 mL) Endotoxin < 0.03 EU/mL; (action level at ≥ 0.03 EU/mL) (see Clause 4.4.3, Table 4, and the Canadian deviations for Clause 8.3.1 and Annex E)	Monthly. Testing should be performed at the largest sample volume to meet ultrapure dialysis fluid quality according to Clause 8.3.3.2.1	NA
Online substitution fluid for haemofiltration or haemodiafiltration therapy (except if a 3rd ultra-filter in single use)	Bacterial growth and endotoxin concentration in ultrapure dialysis fluid	Bacterial count < 0.1 CFU/mL; (action level typically at ≥ 1 CFU/500 mL) Endotoxin < 0.03 EU/mL; (action level at ≥ 0.03 EU/mL) (see Clause 4.4.4 and the Canadian deviations for Clause 8.3.1 and Annex E)	Monthly. Testing should be performed at the largest sample volume to meet ultrapure dialysis fluid quality according to Clause 8.3.3.2.1	NA

Annex D (informative)
Strategies for microbiological control

D.2 Microbial surveillance methods

D.2.1 General

[Replace "regularly" with "monthly" in the first sentence of the first paragraph]

Annex F (informative)
Special considerations for home haemodialysis

[Replace this Annex with the following]

For home dialysis requirements, refer to CSA Z364.5.

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

Reference number
ISO 23500-1:2019(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 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.