American National Standard

ANSI/AAMI 13959:2014

Water for hemodialysis and related therapies

AAMI
Advancing Safety in Medical Technology

Water for hemodialysis and related therapies

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

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American National Standards Institute, Inc.

Abstract Specifies minimum requirements for water to be used in hemodialysis and related therapies. Includes water to be used in the preparation of concentrates, dialysis fluids for hemodialysis, hemodiafiltration and hemofiltration, and for the reprocessing of hemodialyzers

Keywords: chemical, compliance, colony, endotoxin, fluid, microbiological, pyrogen

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www.aami.org/standards/glossary.pdf

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Association for the Advancement of Medical Instrumentation

AAMI Renal Disease and Detoxification Committee

This American National Standard was developed by the AAMI Renal Disease and Detoxification Committee. Approval of the American National Standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the AAMI Renal Disease and Detoxification Committee had the following members:

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

US deviation to ISO 13959:2014

The International Organization for Standardization (ISO) published ISO 13959:2014, Water for hemodialysis and related therapies as a revision of ISO 13959:2009 on 2014-04-01. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee 150, Subcommittee 2, Cardiovascular implants and extracorporeal systems, to fill a need for minimum requirements for water used for hemodialysis and related therapies. The 2014 ISO revision editorially aligned ISO 13959 with the ISO dialysis fluid standards ISO 11663, ISO 13958, ISO 23500, and ISO 26722 which had been developed serially over several years.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 150/SC 2, administered by the Association for the Advancement of Medical Instrumentation (AAMI). The U.S. TAG for ISO/TC 150/SC 2 supports the guidance provided in this document.

While considering the US adoption of ISO 13959:2014, the AAMI Renal Disease and Detoxification Committee (U.S. sub-TAG for ISO/TC 150/SC 2/WG 5, Renal replacement, detoxification and apheresis) approved a US deviation to the International Standard. ANSI/AAMI 13959:2014 deviates from ISO 13959:2014 in the following aspect:

The fourth paragraph of Subclause 4.1, Microbiology of dialysis water, which in ISO 13959:2014 reads:

> "Culture media shall be tryptone glucose extract agar (TGEA), Reasoner's 2A (R2A), or other media that can be demonstrated to provided equivalent results. Blood or chocolate agar shall not be used. Incubation temperatures of 17 °C to 23 °C and an incubation time of 168 h (7 d) are recommended. Other incubation times and temperatures may be used if it can be demonstrated that they provide equivalent results. No method will give a total microbial count."

is replaced in ANSI/AAMI 13959:2014 by the following:

> "Approved culture methods shall include one of the following:
>
> 1) tryptone glucose extract agar (TGEA) or Reasoner's 2A supplemented with 4 % sodium bicarbonate, or equivalent. Blood or chocolate agar shall not be used. Incubation temperatures of 17 °C to 23 °C, and an incubation time of 168 h (7 d); or
>
> 2) Trypticase soy agar (TSA, or soybean casein digest agar) or standards method agar and plate count agar (also known as TGYE) incubated at 35 °C for 48 hours.
>
> Other test methods may also be used, provided such methods have been appropriately validated and compared to the cited methods. See USP <1231> for guidance on adoption of alternative methods. No method will give a total microbial count."

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Introduction

Assurance of adequate water quality is one of the most important aspects of ensuring a safe and effective delivery of hemodialysis, hemodiafiltration, or hemofiltration.

This International Standard contains minimum requirements, chemical and microbiological, for the water to be used for preparation of dialysis fluids, concentrates, and for the reprocessing of hemodialyzers and the necessary steps to ensure compliance with those requirements.

Hemodialysis and hemodiafiltration can expose the patient to more than 500 l of water per week across the semi-permeable membrane of the hemodialyzer or hemodiafilter. Healthy individuals seldom have a weekly oral intake above 12 l. This over 40-fold increase in exposure requires control and monitoring 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 International Standard will evolve and be refined accordingly. The physiological effects attributable to the presence of organic contaminants in dialysis water are important areas for research. At the time this International Standard was published it was not possible to specify threshold values for organic contaminants permitted in water used for the preparation of dialysis fluids, concentrates, and reprocessing of hemodialyzers. The issue of organic contaminants will be reassessed on the next revision of this International Standard.

Within this International Standard, measurement techniques current at the time of publication have been cited. Other standard methods may be used, provided that such methods have been appropriately validated and compared to the cited methods.

The final dialysis fluid is produced from concentrates or salts manufactured, packaged, and labelled according to ISO 13958 mixed with water meeting the requirements of this International Standard. Operation of water treatment equipment and hemodialysis systems, including ongoing monitoring of the quality of water used to prepare dialysis fluids, and handling of concentrates and salts are the responsibility of the hemodialysis facility and are addressed in ISO 23500. Hemodialysis professionals make choices about the various applications (hemodialysis, hemodiafiltration, hemofiltration) and should understand the risks of each and the requirements for safety for fluids used for each.

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

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this International Standard,

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this International Standard, and

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

This International Standard is directed towards manufacturers and providers of water treatment systems and also to hemodialysis facilities.

Water for hemodialysis and related therapies

1 Scope

This International Standard specifies minimum requirements for water to be used in hemodialysis and related therapies.

This International Standard includes water to be used in the preparation of concentrates, dialysis fluids for hemodialysis, hemodiafiltration and hemofiltration, and for the reprocessing of hemodialyzers.

The operation of water treatment equipment and the final mixing of treated water with concentrates to produce dialysis fluid are excluded from this International Standard. Those operations are the sole responsibility of dialysis professionals. This International Standard does not apply to dialysis fluid regenerating systems.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
action level
concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels

2.2
chlorine, combined
chlorine that is chemically combined, such as in chloramine compounds

Note 1 to entry: There is no direct test for measuring combined chlorine, but it can be measured indirectly by measuring both total and free chlorine and calculating the difference.

2.3
chlorine, free
chlorine present in water as dissolved molecular chlorine (Cl_2), hypochlorous acid (HOCl), and hypochlorite ion (OCl^-)

Note 1 to entry: The three forms of free chlorine exist in equilibrium.

2.4
chlorine, total
sum of free and combined chlorine

Note 1 to entry: Chlorine can exist in water as dissolved molecular chlorine, hypochlorous acid, and/or hypochlorite ion (free chlorine) or in chemically combined forms (combined chlorine). Where chloramine is used to disinfect water supplies, chloramine is usually the principal component of combined chlorine.