American National Standard

ANSI/AAMI ST15883-1: 2009/(R)2014

(ISO 15883-1:2006, MOD)

Washer-disinfectors — Part 1: General requirements, terms and definitions and tests

AAMI
Advancing Safety in Medical Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Developed by
Association for the Advancement of Medical Instrumentation

Approved 15 September 2009 and reaffirmed 26 September 2014 by
American National Standards Institute, Inc.

Abstract: This document specifies general performance requirements for washer-disinfectors (WD) and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. It specifies performance requirements for cleaning and disinfection as well as for the accessories which can be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and re-validation, periodically and after essential repairs, are also specified.

Keywords: disinfection, medical instruments, performance qualification, thermal disinfection, chemical disinfection, mechanical requirements, WD, water, cleaning efficacy, residual proteinaceous contamination

AAMI Standard

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Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795
www.aami.org

Printed in the United States of America

ISBN 1-57020-365-2

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-30:2009	ANSI/AAMI/IEC 80601-2-30:2009	Identical (with inclusion)
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2009	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical

International designation	U.S. designation	Equivalency
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Washer-disinfectors Working Group

The adoption of ISO 15883-1:2006 as an American National Standard was initiated by the AAMI Washer-disinfectors Working Group of the AAMI Sterilization Standards Committee. The AAMI Washer-disinfectors Working Group also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Sterilization (ISO). U.S. representatives from the AAMI Washer-disinfectors Working Group (U.S. Sub-TAG for ISO/TC 198/WG 13) played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Washer-disinfectors Working Group** had the following members:

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NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of ISO 15883-1:2006

As indicated in the foreword to the main body of this document (page xvii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. 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 198, *Sterilization of health care products*, to fill a need for guidance regarding performance requirements for cleaning and disinfection by washer-disinfectors (WD) as well as for the accessories which can be required to achieve the necessary performance.

U.S. participation in this ISO TC is organized through the AAMI Sterilization Standards Committee which serves as the U.S. Technical Advisory Group for ISO/TC 198. Association for the Advancement of Medical Instrumentation (AAMI) ST/WG 13, *Washer disinfectors*, serves as the U.S. sub-TAG for the relevant ISO working group and supports the adoption of ISO 15883-1:2006 with substantive national deviations provided in this document for washer disinfectors.

The major differences between ANSI/AAMI ST15883-1:2009 and ISO 15883-1:2006 are the removal of A_0 as a means of evaluating the cleaning efficacy of thermal disinfection and the removal of user requirements. Deleted text that pertained to user actions after initial qualification have been placed in an informative annex in order to provide optional guidance for users on requalification and routine testing.

ANSI/AAMI ST15883-1:2009 was approved by the American National Standards Institute (ANSI) on 15 September 2009.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

U.S. Deviations to ISO 15883-1:2006

As part of an effort to harmonize sterilization standards throughout an increasing global industry, the AAMI Washer-disinfectors Working Group voted in 2009 to adopt ISO 15883-1:2006, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*. The AAMI Washer-disinfector Working Group also agreed that a number of U.S. deviations to the ISO standard would improve the document.

Deviations are listed below. A rationale for each change has also been provided by the working group. Within the document, deletions are indicated by ~~strikethrough~~ and additions are indicated by underline.

Introduction

1. 6th paragraph: User requirements deleted.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

2. 8th paragraph deleted: Reference to European water quality criteria removed.

Rationale: European water quality criteria are not appropriate for the U.S. version of this standard.

Scope

3. User requirements deleted from first paragraph.

Rationale: User requirements for routine testing are not appropriate for the U.S. version of this standard.

4. Reference to EN 285 replaced by AAMI/TIR 11139.

Rationale: AAMI/TIR 11139 is the harmonized U.S. standard.

5. Last paragraph deleted.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

Normative references

6. ANSI/AAMI ST72 added.

Rationale: Document is referenced in the U.S. deviation in 6.4.2.3

Terms and definitions

7. A_0 deleted.

Rationale: There is not sufficient peer-reviewed literature on A_0 for inclusion in this edition.

8. EN 285 definition of 'calibration' substituted with AAMI/TIR11139 definition.

Rationale: AAMI/TIR 11139 is the harmonized U.S. reference.

9. *D* value deleted.

Rationale: Not necessary following the deletion of A_0.

10. ISO 15883-1 definition of 'fault' substituted with AAMI/TIR11139 definition.

Rationale: AAMI/TIR 11139 is the harmonized U.S. reference.

11. Test microorganism deleted.

Rationale: Not necessary following the deletion of A_0.

12. *z* value deleted.

Rationale: Not necessary following the deletion of A_0.

4.1.1 NOTE

13. The word ‘user’ deleted.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

4.1.5

14. Reference to A_0 deleted.

Rationale: There is not sufficient peer-reviewed literature on A_0 for inclusion in this edition.

4.2.1.1

15. New text added.

Rationale: AAMI/TIR 30 added as an example reference.

4.3

16. New text added.

Rationale: The addition of the new text reflects the current practice in US.

4.3.1.1

17. References to A_0 deleted.

Rationale: There is not sufficient peer-reviewed literature on A_0 for inclusion in this edition.

4.3.1.2

18. References to A_0 deleted.

Rationale: There is not sufficient peer-reviewed literature on A_0 for inclusion in this edition.

5.1.3

19. Subclause deleted.

Rationale: Actual use conditions determine the number of operational cycles and vary significantly between customers.

Figure 1

20. Figure title modified.

Rationale: ISO 15883-1 is thought to be too design restrictive. The figure is now presented as one possible design option for the entry port.

5.1.10

21. Text modified.

Rationale: ISO 15883-1 is thought to be too design restrictive. Text now presents one possible design option for the entry port.

5.5.1.1

22. Deletion of the word ‘any’.

Rationale: The requirement that any residual flow toward the drain is thought to be too design restrictive.

5.5.1.1

23. Addition of new text.

Rationale: The new phrase clarifies the purpose of this subclause.

5.5.1.2 and 5.5.1.3

24. Subclause deleted.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

5.5.1.3

25. Subclause deleted.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

5.7.1

26. User requirements deleted.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

5.9.1 c)

27. Text deleted.

Rationale: Rationale for the requirement is not provided and the requirement is too restrictive.

5.9.1 d)

28. Reference to A_0 deleted.

Rationale: There is not sufficient peer-reviewed literature on A_0 for inclusion in this edition.

5.9.1 e)

29. Reference to A_0 deleted.

Rationale: There is not sufficient peer-reviewed literature on A_0 for inclusion in this edition.

5.9.1 g)

30. ISO 15883-1 item g) deleted.

Rationale: Rationale for the requirement is not provided and the requirement is too restrictive.

5.9.2 d)

31. Text deleted.

Rationale: Rationale for the requirement is not provided and the requirement is too restrictive.

5.12.1

32. Specific environmental condition requirements deleted.

Rationale: Rationale for the requirement is not provided and the requirement was too restrictive.

5.13.2

33. Text modified.

Rationale: Rationale for the requirement is not provided and the requirement was too restrictive.

5.13.2 a) through i)

34. List deleted.

Rationale: Rationale for the requirement is not provided and the requirement was too restrictive.

5.14 b), c), e), f), g)

35. 'bar' replaced with 'psi'

Rationale: psi is commonly used.

5.17.2.10, 2nd paragraph

36. Text deleted.

Rationale: Thermal paper is satisfactory for the duration of the storage period.

5.23.3

37. Requirements deleted.

Rationale: Previous agreement to delete the requirement that WD manufacturer request details of the user water quality were not reflected in the text. Text updated to reflect this agreement.

5.29

38. Specific environmental condition requirements deleted.

Rationale: Rationale for the requirement is not provided and the requirement was too restrictive.

6.1.1

39. Text regarding routine tests deleted.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

6.1.3.1.5

40. Change in terminology.

Rationale: Changes made to be consistent with definitions in section 3 and terminology changes made in ISO 15883-2.

6.1.3.2

41. Change in terminology.

Rationale: Changes made to be consistent with definitions in section 3 and terminology changes made in ISO 15883-2.

6.1.3.4.5

42. Text substituted in second paragraph.

Rationale: The addition of the new text reflects the current practice in US.

6.1.3.4.6

43. Reference to A_0 deleted.

Rationale: There is not sufficient peer-reviewed literature on A_0 for inclusion in this edition.

6.1.5

44. Text moved to new informative Annex E.

Rationale: Mandated activities after initial qualification of the WD are not appropriate in this U.S. standard. However this information may be useful as a guide to the user.

6.1.6

45. Paragraph 2, 3, and 4 moved to new informative Annex E.

Rationale: Mandated activities after initial qualification of the WD are not appropriate in this U.S. standard. However this information may be useful as a guide to the user.

6.4.2.3

46. Reference to EP and USP deleted, ANSI/AAMI ST72 substituted.

Rationale: ANSI/AAMI ST72 is a more precise reference.

6.5.1.1

47. Text deleted.

Rationale: User requirements are not appropriate for the U.S. edition of this standard.

6.5.1.4

48. Subclause deleted.

Rationale: User requirements are not appropriate for the U.S. edition of this standard.

6.6.1, 2nd paragraph

49. Text added.

Rationale: It is common practice in the U.S. to use equipment that complies with equivalent standards provided there is appropriate documentation.

6.10.2.1, 2nd and 3rd paragraph

50. Paragraph 2 and 3 deleted.

Rationale: User requirements are not appropriate for the U.S. edition of this standard.

6.10.3.1

51. Text deleted.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

6.10.3.2

52. Paragraph 4 deleted.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

6.11.1, 1st sentence

53. Text added.

Rationale: It is common practice in the U.S. to use equipment that complies with equivalent standards provided there is appropriate documentation.

8.2

54. Text deleted.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

8.2 c) and d)

55. Informative NOTE added.

Rationale: Note added to clarify that WD using chemical disinfection do not noticeably increase ambient temperature.

8.2 h)

56. Text deleted.

Rationale: This type of information is the responsibility of the chemical manufacturer/distributor and not the WD manufacturer.

8.2 i)

57. Text added.

Rationale: It is not mandatory that the source code be made available to the user (see 5.21) and this added text provides clarification of that point.

Clause 10

58. Clause deleted.

Rationale: This was a list of recommendations which were not required and therefore do not belong in the standard. The standard should address the types of information that the manufacturer is required to provide, not that the user is recommended to provide.

Annex A, Table A.1, line 10.1 and line 10.2

59. Reference deleted.

Rationale: Reference to a deleted section was removed.

Table A.1, footnote "O"

60. Text modified, discretionary test language added from below.

Rationale: User requirements are not appropriate for the U.S. version of this standard.

Annex B

61. Entire annex deleted.

Rationale: Insufficient peer-reviewed literature on A_0 for inclusion in this standard.

New Annex E

62. New informative annex created with text moved from 6.1.5 and 6.1.6.

Rationale: Mandated activities after initial qualification of the WD are not appropriate in this U.S. standard. However this information may be useful as a guide to the user.

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15883-1 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

— *Part 1: General requirements, terms and definitions and tests*

— *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

— *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

— *Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

— *Part 5: Test soils and methods for demonstrating cleaning efficacy* [Technical Specification]

Introduction

This part of ISO 15883 is the first of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to all washer-disinfectors. The requirements given in this part of ISO 15883 are applicable to all washer-disinfectors specified in subsequent parts of the ISO 15883 series, except insofar as they may be modified or added to by a subsequent part, in which case the requirements of that particular part will apply.

Fields of application within the scope of ISO 15883 series include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as washer-disinfectors for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Washer-disinfectors should be used only for processing the type of loads specified by the manufacturer of the washer-disinfector.

In selecting the appropriate washer-disinfector, reference should be made both to this part of ISO 15883 and to the relevant subsequent parts of ISO 15883 series. It is the user's responsibility to ensure that the choice of type of washer-disinfector, operating cycle or quality of services or process chemicals is appropriate for any particular load.

Safety requirements for washer-disinfectors are given in IEC 61010-2-045.

This part of ISO 15883 has been prepared on the basis that each individual washer-disinfector will be subject to validation tests (commissioning and performance qualification on first installation). ~~and that in use continued compliance will be established by periodic tests carried out by, or on behalf of, the user.~~

Verification of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector. The current state of knowledge has not permitted development of a single test method. As an interim measure reference has been made to test methods which are currently being applied in a number of different countries. The specification for these test methods including their test soils can be found in ISO/TS 15883-5. It remains the intention of the Technical Committee of TC 198 to develop a single test method.

~~In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfector:~~

~~a) it should be noted that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfector remain in force;~~

~~b) the ISO 15883 series of standards provides no information as to whether the washer-disinfector may be used without restrictions in any of the member states of the EU or EFTA.~~

Washer-disinfectors — Part 1: General requirements, terms and definitions and tests

1 Scope

This part of ISO 15883 specifies general performance requirements for washer-disinfectors (WD) and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. It specifies performance requirements for cleaning and disinfection as well as for the accessories which can be required to achieve the necessary performance. The methods and instrumentation required for validation~~, routine control and monitoring~~ and re-validation, ~~periodically and~~ after essential repairs, are also specified.

The requirements for washer-disinfectors intended to process specific loads are specified in subsequent parts of this standard. For washer-disinfectors intended to process loads of two or more different types the requirements of all relevant parts of this standard apply.

This part of ISO 15883 does not specify requirements intended for machines for use for laundry or general catering purposes.

This part of ISO 15883 does not include requirements for machines which are intended to sterilize the load, or which are designated as “sterilizers”, these are specified in other standards e.g. AAMI/TIR 11139 ~~EN 285~~.

The specified performance requirements of this standard may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE If it is considered that prion protein can be present, particular care is needed in the choice of disinfectants and cleaning agents to ensure that the chemicals used do not react with the prion protein in a manner that may inhibit its removal or inactivation.

~~This part of ISO 15883 may be used by prospective purchasers and manufacturers as the basis of agreement on the specification of a WD. The test methods for demonstration of compliance with the requirements of this part of ISO 15883 may also be employed by users to demonstrate continued compliance of the installed WD throughout its working life. Guidance on a routine test program is given in Annex A.~~

2 Normative references

The following referenced documents are indispensable for the application 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 228-1, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*