This is a preview of "ANSI/AAMI ST40:2004 ...". Click here to purchase the full version from the ANSI store.

# American National Standard

ANSI/AAMI ST40:2004/(R)2010



This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document,

Table-top dry heat (heated air)
sterilization and
sterility assurance
in health care facilities



## The 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 in the should be showlded with the device has erstelevant to the specific needs be the user he including performance characteristics, instructions for use warnings in a pull Particular care should be taken in applying a product standard to 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 at (877s afety and performance criteria defined in a standard, professional uniformity in reporting; reaching consensus on these tests can/www a judgment must be used in applying these criteria to existing equiprepresent 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 fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care 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 decisionmaking.

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

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 ment. 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.

#### INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the AAMI News. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an official interpretation in the AAMI News.

American National Standard

ANSI/AAMI ST40:2004/(R)2010 (Revision of ANSI/AAMI ST40:1992/(R)1998)



# Table-top dry heat (heated air) sterilization and intended tosterility tassurance in health care facilities

document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at (877) 249-8226 or visit www.aami.org.

Developed by Association for the Advancement of Medical Instrumentation

Approved 7 October 2004 and reaffirmed 24 March 2010 by American National Standards Institute Inc.

Abstract: This recommended practice provides guidelines for dry heat sterilization in health care facilities. It

covers functional and physical design criteria for work areas; staff qualifications, education, and other personnel considerations; sterilization processing procedures; installation, care, and maintenance of table-top dry heat sterilizers; and quality control. Definitions, a bibliography, and

annexes providing supplementary information are also included

**Keywords:** dry heat sterilization, quality control, table-top sterilizers

#### **AAMI Recommended Practice**

This Association for the Advancement of Medical Instrumentation (AAMI) recommended practice implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI recommended practice does not in any respect preclude anyone, whether they have approved the recommended practice or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the recommended practice. AAMI recommended practices are subject to periodic review, and users are cautioned to obtain the latest editions.

**CAUTION NOTICE:** This AAMI recommended practice may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this recommended practice no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards and recommended practices by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at (877) 249-8226 or visit www.aami.org.

#### Published by

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

© 2005 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1-57020-226-5

### Contents

|       |            |   | Page   |
|-------|------------|---|--------|
| Glo   | ossary o   | of equivalent standards   | vi     |
| Со    | mmittee    | e representation  | viii   |
| Acl   | knowled    | dgments   | ix     |
| Fαι   | reword.    |   | X      |
|       |            | on: Need for this recommended practice  |        |
| ırıtı | oductic    | e   | XI     |
| 1     | Scope      | θ   | 1      |
|       | 1.1        | General   |        |
|       | 1.2<br>1.3 | Inclusions Exclusions PREVIEW COPY  | 1<br>1 |
| 2     | Dofini     | itions, symbols, and abbreviations  |        |
|       |            | This is a preview edition of an AAMI guidance document and is   |        |
| 3     | Desig      | This is a preview edition of an AAMI guidance document and is considerations. In considerations intended to allow potential purchasers to evaluate the content of the | 3<br>e |
|       | 3.1<br>3.2 | General rational comment before making a purchasing decision.  Work area design and functional workflow   | 3      |
|       | 3.2        | 3.2.1 Definitions of work areas   | 4<br>4 |
|       |            | 3.2.2 Design criteria. complete copy of this AAMI document,   | 4      |
|       |            | 3.2.3 Functional workflow patterns AIVII at (877) 249-8226 3.2.4 Traffic control Physical facilities Or VISIT WWW.aami.org.   | 5<br>5 |
|       | 3.3        | Physical facilities Of VISIT WWW.aami.org.  | 5      |
|       |            | 3.3.1 Space requirements  |        |
|       |            | 3.3.3 General area requirements   |        |
|       |            | 3.3.4 Special area considerations   |        |
|       | 3.4        | Housekeeping  | 8      |
| 4     | Perso      | onnel considerations  | 8      |
|       | 4.1        | General rationale   | 8      |
|       | 4.2        | Qualifications  | 8      |
|       | 4.3        | Training and continuing education   |        |
|       | 4.4<br>4.5 | Health and personal hygiene Attire  |        |
|       | 4.5        | 4.5.1 General   | _      |
|       |            | 4.5.2 Decontamination area  | _      |
|       | 4.6        | Standard/transmission-based (enhanced) precautions  | 11     |
| 5     | Proce      | essing recommendations  | 11     |
|       | 5.1        | General rationale   | 11     |
|       | 5.2        | Receiving   |        |
|       |            | <ul><li>5.2.1 General considerations</li><li>5.2.2 Newly purchased reusable items and repaired reusable items</li></ul>   | 12     |
|       |            | 5.2.3 Disposable items  | 12     |
|       | 5.3        | Disposition of sterile items (issued but not used)  | 12     |
|       | 5.4        | Handling, collection, and transport of items previously used in patient care  | 12     |
|       | 5.5        | Cleaning and other decontamination processes  |        |
|       |            | 5.5.1 General considerations  |        |
|       |            | 5.5.3 Sorting and disassembly   |        |
|       |            | 5.5.4 Cleaning  | 14     |
|       | _          | 5.5.5 Microbicidal processes  |        |
|       | 5.6        | Selection of packaging materials  | 17     |

|   | 5.7                            | Sterilizat   | ion of packaged items  | 18   |
|---|--------------------------------|--|--|--|
|   |                                | 5.7.1  | Preparation of items to be sterilized  | 18   |
|   |                                | 5.7.2  | Loading the sterilizer   |  |
|   |                                | 5.7.3  | Equipment operation  |  |
|   |                                | 5.7.4  | Sterilization cycle parameters   | 19   |
|   |                                | 5.7.5  | Unloading the sterilizer   |  |
|   |                                | 5.7.6  | User safety factors  |  |
|   |                                | 5.7.7  | Common operator errors   |  |
|   | 5.8                            |  | ion of unwrapped items   |  |
|   |                                | 5.8.1  | General considerations   |  |
|   |                                | 5.8.2  | Preparation of unwrapped items   |  |
|   |                                | 5.8.3  | Cycle parameters for unwrapped items   |  |
|   |                                | 5.8.4  | Unloading the sterilizer   |  |
|   | 5.9                            |  | orage of packaged items  |  |
|   |                                | 5.9.1  | Dust covers  | 20   |
|   |                                | 5.9.2  | Storage environment  | 21   |
|   |                                | 5.9.3  | Storage shelving   | 21   |
|   | E 40                           | 5.9.4  | Shelf life   |  |
|   | 5.10                           |  | ion  | 21   |
|   |                                | 5.10.1   | Handling and inspection R  | 21   |
|   |                                | 5.10.2   | Distribution containers and cassettes  | 22   |
| 6 | Inctall                        | lation car   | o and maintenance of eterilizors   | 22   |
| 0 | mstan                          | ialion, gar  | ี่คร <sup>อ</sup> กูร่ สา <b>จากยาง ยาว และ เ</b> ลื่อเรียง คราม AAMI guidance document and is   | ∠∠   |
|   | 6.1                            | Géhéran  | rationale allow potential purchasers to evaluate the content of the  | 22   |
|   | 6.2                            | Instruction  | n manualsument hefere making a nurchasing decision   | 22   |
|   | 6.3                            | Installati   | on manualscument before making a purchasing decision   | 22   |
|   | 6.4                            | Routine  | care and maintenance   | 22   |
|   | 6.5                            | Repair a   | nd component replacemente.copy.of.this.AAML.document,  | 23   |
|   | 6.6                            |  | oncontact-AAMI at (877) 249-8226   |  |
|   |                                |  | CONTACT AAIVII at (077) 249-0220   | 23   |
|   | 6.7                            | Recordk  | eeping   |  |
|   | -                              | Recoluk  | or visit www.aami.org.   | 0  |
| 7 | -                              | Recoluk  | or visit www.aami.org.   | 23   |
| 7 | Qualit                         | ty control.  | or visit www.aami.org.   | 23   |
| 7 | Qualit                         | ty control .  General  | or visit www.aami.org.   | 23<br>23   |
| 7 | Qualit                         | ty control.  General  Product  | rationaleidentification and traceability   | 23<br>23   |
| 7 | Qualit                         | ty control.  General  Product  7.2.1   | rationale  | 23<br>23<br>24   |
| 7 | Qualit                         | General<br>Product<br>7.2.1<br>7.2.2   | rationale  | 23<br>24<br>24<br>24   |
| 7 | Qualit<br>7.1<br>7.2           | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3  | rationale  | 23<br>24<br>24<br>24   |
| 7 | Qualit                         | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical  | rationale  | 23<br>24<br>24<br>24<br>24   |
| 7 | Qualit<br>7.1<br>7.2           | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1   | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors   | 23<br>24<br>24<br>24<br>24   |
| 7 | Qualit 7.1 7.2 7.3             | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2  | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction  | 23<br>24<br>24<br>24<br>24   |
| 7 | Qualit<br>7.1<br>7.2           | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica   | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction.   | 23<br>24<br>24<br>24<br>24<br>25   |
| 7 | Qualit 7.1 7.2 7.3             | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1  | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction. I indicators Definition   | 23<br>24<br>24<br>24<br>24<br>25<br>25   |
| 7 | Qualit 7.1 7.2 7.3             | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2   | rationale  | 23<br>24<br>24<br>24<br>24<br>25<br>25   |
| 7 | Qualit<br>7.1<br>7.2<br>7.3    | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3  | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction. I indicators Definition Selecting chemical indicators Using chemical indicators   | 23<br>24<br>24<br>24<br>24<br>25<br>25   |
| 7 | Qualit 7.1 7.2 7.3             | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica   | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction. I indicators Definition Selecting chemical indicators Using chemical indicators al indicators   | 23<br>24<br>24<br>24<br>25<br>25<br>25   |
| 7 | Qualit<br>7.1<br>7.2<br>7.3    | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1  | rationale  | 23<br>24<br>24<br>24<br>24<br>25<br>25<br>25   |
| 7 | Qualit<br>7.1<br>7.2<br>7.3    | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1  | rationale  | 23<br>24<br>24<br>24<br>24<br>25<br>25<br>25<br>27   |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5     | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1<br>7.5.2<br>7.5.3  | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction I indicators Definition Selecting chemical indicators Using chemical indicators al indicators Definition Selecting biological indicators Frequency of use of biological indicators   | 23<br>24<br>24<br>24<br>24<br>25<br>25<br>25<br>25   |
| 7 | Qualit<br>7.1<br>7.2<br>7.3    | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1<br>7.5.2<br>7.5.3<br>Sterilizer  | rationale  | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>27<br>27   |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5     | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1<br>7.5.2<br>7.5.3<br>Sterilizer  | rationale  | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>25<br>27<br>27<br>27   |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5     | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1<br>7.5.2<br>7.5.3<br>Sterilizer<br>7.6.1   | rationale  | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>27<br>27<br>27   |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5     | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1<br>7.5.2<br>7.5.3<br>Sterilizer  | rationale  | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>25<br>27<br>27<br>27<br>27   |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5     | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1<br>7.5.2<br>7.5.3<br>Sterilizer<br>7.6.1<br>7.6.2<br>7.6.3   | rationale  | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>25<br>27<br>27<br>27<br>27<br>28<br>28<br>28   |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5     | General Product 7.2.1 7.2.2 7.2.3 Physical 7.3.1 7.3.2 Chemica 7.4.1 7.4.2 7.4.3 Biologica 7.5.1 7.5.2 7.5.3 Sterilizer 7.6.1 7.6.2 7.6.3 7.6.4  | rationale  | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>27<br>27<br>27<br>27<br>28<br>28<br>28<br>28   |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5     | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1<br>7.5.2<br>7.5.3<br>Sterilizer<br>7.6.1<br>7.6.2<br>7.6.3<br>7.6.4<br>7.6.5                               | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction I indicators Definition Selecting chemical indicators Using chemical indicators Definition Selecting biological indicators Definition Selecting biological indicators Peficacy testing General considerations. Construction of the PCD Placement of the PCD Test procedure Acceptance criteria Positive BI results   | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>27<br>27<br>27<br>27<br>28<br>28<br>28<br>28<br>29   |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5     | General Product 7.2.1 7.2.2 7.2.3 Physical 7.3.1 7.3.2 Chemica 7.4.1 7.4.2 7.4.3 Biologica 7.5.1 7.5.2 7.5.3 Sterilizer 7.6.1 7.6.2 7.6.3 7.6.4 7.6.5 7.6.6 7.6.7  | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction I indicators Definition Selecting chemical indicators Using chemical indicators Using chemical indicators Definition Selecting biological indicators Perquency of use of biological indicators Frequency of use of biological indicators Prequency of use of biological indicators Trequency of use of biological indicators Prequency of the PCD Test procedure Acceptance criteria. Positive BI results Microbiological testing  | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>27<br>27<br>27<br>27<br>28<br>28<br>28<br>28<br>28<br>28<br>29   |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5 7.6 | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1<br>7.5.2<br>7.5.3<br>Sterilizer<br>7.6.1<br>7.6.2<br>7.6.3<br>7.6.4<br>7.6.5<br>7.6.6<br>7.6.7<br>Periodic | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction I indicators Definition Selecting chemical indicators Using chemical indicators Definition Selecting biological indicators Definition Selecting biological indicators Peficacy testing General considerations. Construction of the PCD Placement of the PCD Test procedure Acceptance criteria Positive BI results   | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>27<br>27<br>27<br>27<br>28<br>28<br>28<br>28<br>28<br>29<br>29   |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5 7.6 | General<br>Product<br>7.2.1<br>7.2.2<br>7.2.3<br>Physical<br>7.3.1<br>7.3.2<br>Chemica<br>7.4.1<br>7.4.2<br>7.4.3<br>Biologica<br>7.5.1<br>7.5.2<br>7.5.3<br>Sterilizer<br>7.6.1<br>7.6.2<br>7.6.3<br>7.6.4<br>7.6.5<br>7.6.6<br>7.6.7<br>Periodic | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction I indicators Definition Selecting chemical indicators Using chemical indicators Using chemical indicators Definition Selecting biological indicators Experiment of the PCD Placement of the PCD Placement of the PCD Positive BI results Microbiological testing.  | 23<br>23<br>24<br>24<br>24<br>24<br>25<br>25<br>25<br>27<br>27<br>27<br>27<br>27<br>28<br>28<br>28<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29 |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5 7.6 | General Product 7.2.1 7.2.2 7.2.3 Physical 7.3.1 7.3.2 Chemica 7.4.1 7.4.2 7.4.3 Biologica 7.5.1 7.5.2 7.5.3 Sterilizer 7.6.1 7.6.2 7.6.3 7.6.4 7.6.5 7.6.6 7.6.7 Periodic Product   | rationale identification and traceability Lot control numbers Sterilizer records Expiration dating monitoring Use of physical monitors Sterilizer malfunction Identificators Definition Selecting chemical indicators Using chemical indicators Using chemical indicators Selecting biological indicators Definition Selecting biological indicators Using chemical indicators Selecting biological indicators Selecting Seneral considerations Construction of the PCD Seneral considerations Selecting Seneral considerations Selecting Seneral considerations Selecting Seneral considerations Selecting Seneral considerations Seneral considerations Seneral considerations Seneral considerations Seneral considerations Seneral | 23<br>23<br>24<br>24<br>24<br>24<br>25<br>25<br>25<br>27<br>27<br>27<br>27<br>27<br>28<br>28<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29 |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5 7.6 | General Product 7.2.1 7.2.2 7.2.3 Physical 7.3.1 7.3.2 Chemica 7.4.1 7.4.2 7.4.3 Biologica 7.5.1 7.5.2 7.5.3 Sterilizer 7.6.1 7.6.2 7.6.3 7.6.4 7.6.5 7.6.6 7.6.7 Periodic Product 7.8.1   | rationale  | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>25<br>27<br>27<br>27<br>28<br>28<br>28<br>28<br>28<br>28<br>28<br>23<br>23<br>24<br>24<br>24<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25<br>25 |
| 7 | Qualit 7.1 7.2 7.3 7.4 7.5 7.6 | General Product 7.2.1 7.2.2 7.2.3 Physical 7.3.1 7.3.2 Chemica 7.4.1 7.4.2 7.4.3 Biologica 7.5.1 7.5.2 7.5.3 Sterilizer 7.6.2 7.6.3 7.6.4 7.6.5 7.6.6 7.6.7 Periodic Product 7.8.1 7.8.2   | rationale  | 23<br>24<br>24<br>24<br>25<br>25<br>25<br>25<br>27<br>27<br>27<br>27<br>28<br>28<br>28<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29<br>29 |

This is a preview of "ANSI/AAMI ST40:2004 ...". Click here to purchase the full version from the ANSI store.

#### **Annexes**

| Α           | The science of dry heat sterilization   | 32 |
|-------------|---|----|
| В           | User verification of cleaning processes   | 36 |
| С           | Example of documentation of premature release of implants   | 41 |
| D           | Bibliography  | 43 |
| Tab         | eles  |    |
| 1           | IES-recommended illuminance levels for work environments  | 6  |
| B.1         | In-use tests available to assess efficacy of cleaning of medical devices*   | 39 |
| B.2         | In-use tests available to assess efficacy of washer-disinfectors used for medical device reprocessing                               | 40 |
| Fig         | ures  |    |
| <b>A.</b> 1 | Batch cycle: Convective dry heat (static air)   | 33 |
| A.2         | Batch cycle: Convective dry heat (forced air) with chamber heat continuously maintained and is                                      | 34 |
|             | Batch cyclet Convective dry neat (forced ain) with toad remaining in chamber during cooked winfthe                                  | 34 |
| C.1         | Implantable devices load record   | 41 |
| C.2         | Exception form for premature release of implantable device/tray,AMI-document; contact AAMI at (877) 249-8226 or visit www.aami.org. | 42 |

### 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 60601-1-2:2001 and<br>Amendment 1:2004                         | ANSI/AAMI/IEC 60601-1-2:2001 and<br>Amendment 1:2004                                | Identical                              |
| IEC 60601-2-04:2002  | ANSI/AAMI DF80:2003   | Major technical variations             |
| IEC 60601-2-19:1990 and<br>Amendment 1:1996                        | ANSI/AAMI II36:2004 COPY  | Major technical variations             |
| IEC 60601-2-20:1990 and<br>Amendment 1:1996 is a preview           | ANSI/AAMI II51:2004 edition of an AAMI guidance docur                               | Major technical variations nent and is |
| IEC 60601-2-21111994 ลิกีสาด allow po<br>Amendment 1:1996 document | tansitaami/ieb366615-2-21eamiluate the<br>Amendmental:2000 (consolidated texts)ecis | c <b>ଢ଼ନ୍ଦରୀ</b> of the<br>ion.        |
| IEC 60601-2-24:1998  | ANSI/AAMI ID26:2004   | Major technical variations             |
| IEC TR 60878:2003  | ANSI/AAMI/IEC TIR60878:2003 documer   | <sup>1†</sup> Identical                |
| IEC TR 62296:2003  | ANSI/AAMI/IEC TIR62296:2003   | Identical                              |
| ISO 5840:200x <sup>1</sup>   | ANSI/AAMI/ISO 5840:2005   | Identical                              |
| ISO 7198:1998  | ANSI/AAMI/ISO 7198:1998/2001/(R)2004  | Identical                              |
| ISO 7199:1996  | ANSI/AAMI/ISO 7199:1996/(R)2002   | Identical                              |
| ISO 10993-1:2003   | ANSI/AAMI/ISO 10993-1:2003  | Identical                              |
| ISO 10993-2:1992   | ANSI/AAMI/ISO 10993-2:1993/(R)2001  | Identical                              |
| ISO 10993-3:2003   | ANSI/AAMI/ISO 10993-3:2003  | Identical                              |
| ISO 10993-4:2002   | ANSI/AAMI/ISO 10993-4:2002  | Identical                              |
| ISO 10993-5:1999   | ANSI/AAMI/ISO 10993-5:1999  | Identical                              |
| ISO 10993-6:1994   | ANSI/AAMI/ISO 10993-6:1995/(R)2001  | Identical                              |
| ISO 10993-7:1995   | ANSI/AAMI/ISO 10993-7:1995/(R)2001  | Identical                              |
| ISO 10993-9:1999   | ANSI/AAMI/ISO 10993-9:1999  | Identical                              |
| ISO 10993-10:2002  | ANSI/AAMI BE78:2002   | Minor technical variations             |
| ISO 10993-11:1993  | ANSI/AAMI 10993-11:1993   | Minor technical variations             |
| ISO 10993-12:2002  | ANSI/AAMI/ISO 10993-12:2002   | Identical                              |
| ISO 10993-13:1998  | ANSI/AAMI/ISO 10993-13:1999/(R)2004   | Identical                              |
| ISO 10993-14:2001  | ANSI/AAMI/ISO 10993-14:2001   | Identical                              |
| ISO 10993-15:2000  | ANSI/AAMI/ISO 10993-15:2000   | Identical                              |

<sup>&</sup>lt;sup>1</sup> Currently at FDIS stage

| International designation                            | U.S. designation                               | Equivalency                 |
|--|--|-----------------------------|
| ISO 10993-16:1997                                    | ANSI/AAMI/ISO 10993-16:1997/(R)2003            | Identical                   |
| ISO 10993-17:2002                                    | ANSI/AAMI/ISO 10993-17:2002                    | Identical                   |
| ISO 11134:1994                                       | ANSI/AAMI/ISO 11134:1993                       | Identical                   |
| ISO 11135:1994                                       | ANSI/AAMI/ISO 11135:1994                       | Identical                   |
| ISO 11137:1995 and Amdt 1:2001                       | ANSI/AAMI/ISO 11137:1994 and A1:2002           | Identical                   |
| ISO 11138-1:1994                                     | ANSI/AAMI ST59:1999                            | Major technical variations  |
| ISO 11138-2:1994                                     | ANSI/AAMI ST21:1999                            | Major technical variations  |
| ISO 11138-3:1995                                     | ANSI/AAMI ST19:1999                            | Major technical variations  |
| ISO TS 11139:2001                                    | ANSI/AAMI/ISO 11139:2002                       | Identical                   |
| ISO 11140-1:1995 and<br>Technical Corrigendum 1:1998 | ANSI/AAMI ST60:1996<br>PREVIEW COPY            | Major technical variations  |
| ISO 11607:2003                                       | ANSI/AAMI/ISO 11607:2000                       | Identical                   |
|  | eansnaami/iso 447841191995ance docur           |                             |
| ISO 11737-2:1998                                     | ANSI/AAMI/ISO 19737-2:1998                     | content of the<br>Identical |
| ISO 11737-3:2004                                     | ANSI/AAMI/ISO 11737-3:2004                     | Identical                   |
| ISO TR 13409:1996 For a co                           | r <b>aamiisqjrajosii</b> ssaAMI documer        | ntldentical                 |
| ISO 13485:2003                                       | TANSI/AAMI/ISO 13465:20039-8226                | Identical                   |
| ISO 13488:1996                                       | ANSI/AAMI/ISO 13488:1996                       | Identical                   |
| ISO 14155-1:2003                                     | ANSI/AAMI/ISO 14155-1:2003                     | Identical                   |
| ISO 14155-2:2003                                     | ANSI/AAMI/ISO 14155-2:2003                     | Identical                   |
| ISO 14160:1998                                       | ANSI/AAMI/ISO 14160:1998                       | Identical                   |
| ISO 14161:2000                                       | ANSI/AAMI/ISO 14161:2000                       | Identical                   |
| ISO 14937:2000                                       | ANSI/AAMI/ISO 14937:2000                       | Identical                   |
| ISO TR 14969:2004                                    | ANSI/AAMI/ISO TIR14969:2004                    | Identical                   |
| ISO 14971:2000 and A1:2003                           | ANSI/AAMI/ISO 14971:2000 and A1:2003           | Identical                   |
| ISO 15223:2000, A1:2002, and A2:2004                 | ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004 | Identical                   |
| ISO 15225:2000 and A1:2004                           | ANSI/AAMI/ISO 15225:2000 and A1:2004           | Identical                   |
| ISO 15674:2001                                       | ANSI/AAMI/ISO 15674:2001                       | Identical                   |
| ISO 15675:2001                                       | ANSI/AAMI/ISO 15675:2001                       | Identical                   |
| ISO TS 15843:2000                                    | ANSI/AAMI/ISO TIR15843:2000                    | Identical                   |
| ISO TR 15844:1998                                    | AAMI/ISO TIR15844:1998                         | Identical                   |
| ISO 15882:2003                                       | ANSI/AAMI/ISO 15882:2003                       | Identical                   |
| ISO TR 16142:1999                                    | ANSI/AAMI/ISO TIR16142:2000                    | Identical                   |
| ISO 17664:2004                                       | ANSI/AAMI ST81:2004                            | Major technical variations  |
| ISO 25539-1:2003                                     | ANSI/AAMI/ISO 25539-1:2003                     | Identical                   |

#### Committee representation

#### Association for the Advancement of Medical Instrumentation

#### **Dry Heat Sterilization Working Group**

This recommended practice was developed by the AAMI Dry Heat Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of this recommended practice does not necessarily mean that all working group members voted for its approval.

At the time this document was published, the AAMI Dry Heat Sterilization Working Group had the following members:

Cochairs: Deborah A. Havlik

David Abram, Baxter Healthcare Corporation Members:

Krisann Anderson, St. Jude Medical Inc.

Carl W. Bruch, PhD, Hudson, WI

Marc Chaunet, TSO<sub>3</sub>

Mark Chiffon, STERIS Corporation /

Nancy Chobin, RN, CSPDM, St. Barnabas Health Care System, Lebanon, NJ

Anne M. Cofiell, CRCST, International Association of Healthcare Central Service Materiel

This Managementey edition of an AAMI guidance document and is Douglas D. Davie, Sterlization Validation Services international Demarks, MS, COA, COM, Davoi CR Bardaluate the content of the

Steven Dauglash Cardinal Health making a purchasing decision.

Gordon M. Ely, SM, Nelson Laboratories Inc.

Dorothy M. Fogg, RN, MA, Association of periOperative Registered Nurses James M. Gibson J.C. O.M. Gibson Associates his AAMI document,

Barbara J. Goodman, RN, CNOR Rising Sun, MD 49-8226 Charles Oren Hancock, RAC, H&W Technologies LLC Deborah A. Havlik, Hospira, Inc. St. WWW. aami. org.

Richard M. Johnson, MSc, Abbott Laboratories

John W. Levchuk, PhD, RPh, U.S. Food and Drug Administration

Teckla Ann Maresca, LPN, CSPDM, Saint Clare's Health System, Denville, NJ

Gary Mitchel, PE, Johnson & Johnson Janet K. Schultz, RN, MSN, Parker, CO

Frank Sizemore, American Society for Healthcare Central Service Professionals

Linda A. Slone, RN, CNOR, Sibley Memorial Hospital, Washington, DC

Gary J. Socola, SPS Medical

Bonnie Stewart, PhD, Closure Medical Corporation

Ralph Stick, AppTec Laboratory Services

James Whitbourne, STS duoTEK

Nora E. Wikander, RN, CSPDM, St. Joseph's Wayne Hospital, Wayne, NJ

Casimir John Woss, PhD, Alcon Laboratories Inc.

Martha Young, 3M Health Care

Alternates: Charles J. Buckle, Johnson & Johnson

Romona Conner, RN, Association of periOperative Registered Nurses

Joseph R. Durbin, Abbott Laboratories

John Karlovsky, Baxter Healthcare Corporation

Amy Karren, Nelson Laboratories Inc. Anshu G. Khandpur, 3M Health Care

Susan G. Klacik, ACE, International Association of Healthcare Central Service Materiel Management

Elaine Mayhall, PhD, U.S. Food and Drug Administration

Gerald E. McDonnell, PhD, STERIS Corporation

Kelly R. Mitchell, SPS Medical

Laurie L. Peterson, AppTec Laboratory Services

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

Cochairs: Victoria Hitchins, PhD

William E. Young

Members: Trabue D. Bryans, AppTec Laboratory Services Virginia C. Chamberlain, PhD, Hendersonville, NC

Nancy Chobin, RN, CSPDM, St. Barnabas Health Care System, Lebanon, NJ

Anne M. Cofiell, CRCST, International Association of Healthcare Central Service Materiel Management

Charles Cogdill, Boston Scientific Corporation

Kimbrell Darnell, CR Bard

Georgia P. Dash, RN, MS, CIC, Association for Professionals in Infection Control and Epidemiology

Dorothy M. Fogg, RN, MA, Association of periOperative Registered Nurses

Lisa Foster, Sterigenics International

James M. Gibson Jr., JM Gibson Associates

Barbara J. Goodman, RN, CNOR, Rising Sun, MD

Joel R. Gorski, PhD, NAMSA

Susan Hadfield, Canadian Standards Association

Deborah A. Havlik, Hospira, Inc.

Victoria Hitchins, PhD, U.S. Food and Drug Administration

Clark W. Houghtling, Cosmed Group Inc.

Richard M. Johnson, MSc, Abbott Laboratories

Lois Atkinson Jones, MS, Cary, NC

Byron J. Lambert, PhD, Guidant Corporation

Joseph J. Lasich, Alcon Laboratories Inc.

Sandra A. Lee, RN, STERIS Corporation

David Liu, Johnson & Johnson

Patrick J. McCormick, PhD: Bausch & Lomb Inc. guidance document and is Thomas K. Moore, Getinge USA

interación to page volunte notal purchasers to evaluate the content of the

Phil M. Schneider 3M Health Carenaking a purchasing decision.

Michael H. Scholla, MS, PhD, DuPont Nonwovens

Frank Sizemore, American Society for Healthcare Central Service Professionals

Gregory O. Stecklein MSpMSM, Cardinal Health AAMI document,

William N. Thompson, TYCO Healthcare/Kendall 249-8226 James Whitbourne, STS duoTEK

James L. Whitby, MA, MB, FRCP, London, Ontario, Canada

Thelma Wilcott, Becton Dickinson & Company Martell Kress Winters, Nelson Laboratories Inc.

William E. Young, Baxter Healthcare Corporation

Lloyd Brown, TYCO Healthcare/Kendall Alternates:

Lina C. Bueno, DuPont Nonwovens Romona Conner, RN, Association of periOperative Registered Nurses

Craig M. Herring, Johnson & Johnson Jim Kaiser, Bausch & Lomb Inc.

Susan G. Klacik, ACE. International Association of Healthcare Central Service Materiel Management

Colleen Patricia Landers, RN, Canadian Standards Association

Chiu Lin, PhD, U.S. Food and Drug Administration Lisa N. Macdonald, Becton Dickinson & Company

Ralph Makinen, Guidant Corporation

David Ford McGoldrick, Abbott Laboratories

Jerry R. Nelson, MS, PhD, Nelson Laboratories Inc.

Jeff Peltier, Boston Scientific Corporation

Janet Prust, 3M Health Care Nancy J. Rakiewicz, STS duoTEK Ralph Stick, AppTec Laboratory Services John W. Walker, STERIS Corporation Valerie Welter, Hospira, Inc.

William T. Young, Sterigenics International

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

#### **Acknowledgments**

The AAMI Dry Heat Sterilization Working Group gratefully acknowledges the contributions of Bonnie Stewart. PhD. of Closure Medical Corporation, who served as co-chair of the working group during the development of this recommended practice, and Heide M. Ames of STERIS Corporation, who served as a member of the working group.

#### **Foreword**

This recommended practice was developed by the AAMI Dry Heat Sterilization Working Group, under the auspices of the AAMI Sterilization Standards Committee. This document provides guidelines for dry heat sterilization in dentists' and physicians' offices, laboratories, ambulatory care facilities, and other health care facilities. These guidelines are intended to promote sterility assurance and assist health care personnel in the proper use of dry heat sterilization processing equipment.

This document is the second edition of the recommended practice, which was first published in 1992 as *Table-top dry heat (heated air) sterilization and sterility assurance in dental and medical facilities* and reaffirmed in 1998. In this edition, the recommendations have been updated, where necessary, to reflect current good practice; and information on user verification of cleaning processes and documentation of premature release of implants has been added.

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with sterilizer manufacturers, to develop recommendations for optimum performance in the processing of medical and dental devices to be dry heat sterilized. These recommendations are not intended to be construed as universally applicable to all circumstances. It is also recognized that in many cases these recommendations might not be immediately achievable. Therefore, the document should serve as a guide to desirable performance objectives, and all of the document's provisions should be considered and applied using professional judgment and experience.

As used within the context of this document, "shall" indicates requirements to be strictly followed to conform to the recommended practice; "should" vindicates; 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; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulation only of this AAMI document,

The provisions of this recommended practice should be reviewed by office and departmental managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with appropriate departments, committees, and professionals (e.g., safety, infection control, hazardous materials). Policies and procedures should take into account federal, state, and local regulations; the recommendations of the Centers for Disease Control and Prevention; national voluntary standards and recommended practices; and device and equipment manufacturers' recommendations. The policies and procedures should be uniform throughout a health care facility, and compliance should be monitored.

The concepts incorporated in this recommended practice should be considered flexible and dynamic. The recommendations set forth in this document are reviewed and updated periodically to assimilate new data and advancements in technology. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every 5 years.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of the American National Standard *Table-top dry heat (heated air)* sterilization and sterility assurance in health care facilities (ANSI/AAMI ST40:2004), but it does provide important information about the development and intended use of the document.

#### Introduction: Need for this recommended practice

Preventing infection in persons undergoing dental, medical, or surgical treatment is important in avoiding human suffering and lessening health care costs. One aspect of the prevention of infection in health care facilities is the effective reprocessing or sterilization of reusable dental and medical devices by dry heat sterilization.

In dry heat sterilization, the energy of heated air is transferred to objects and kills microorganisms. Typically, devices to be sterilized are placed in a chamber that uses electrical elements as the heat source; hot, dry air at a specified temperature is circulated around the devices for a specified time.

Advances in dry heat sterilization technology have led to the increased use of this mode of sterilization in dental and medical offices, ambulatory care clinics, and other health care facilities. As many as 40,000 dental and medical facilities currently use dry heat sterilizers. Dental and medical offices and ambulatory care clinics might differ greatly from hospitals in their physical design and in their level of personnel training. Consequently, guidelines are needed for good processing practices, facility design, and personnel considerations that take into account the specific characteristics and needs of this segment of the health care community.

For any sterilization method, sterility assurance depends not only on the process itself but also on the ability to minimize bioburden before sterilization and to prevent contamination after sterilization. Consequently, in addition to processing recommendations, this recommended practice covers facility design considerations, personnel considerations, work practices, and other variables that affect the achievement and maintenance of sterility.

This is a preview edition of an AAMI guidance document and is Although these guidelines are intended to help health care personnel accomplish dry heat sterilization safely and effectively, they are not intended to be a substitute for facility procedures or professional judgment. In document before making a purchasing decision.

NOTE—This introduction does not contain provisions of the American National Standard *Table-top dry heat (heated air)* sterilization and sterility assurance in health care facilities (ANSI/AAMI \$T40:2004), but it does provide important information about the development and intended use of the document 49-8226

or visit www.aami.org.

This is a preview of "ANSI/AAMI ST40:2004 ...". Click here to purchase the full version from the ANSI store.



This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at (877) 249-8226 or visit www.aami.org.

#### **American National Standard**

**ANSI/AAMI ST40:2004** 

# Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities

#### 1 Scope

#### 1.1 General

This recommended practice provides guidelines for decontamination and dry heat sterilization procedures used in dentists' and physicians' offices, laboratories, ambulatory care clinics, and other health care facilities. These guidelines are intended to promote the assurance of sterility by identifying the special considerations that apply to this method of sterilization and by providing recommendations on the proper use of table-top dry heat sterilization processing equipment. This recommended practice also covers facility design considerations, personnel considerations, work practices, and other variables that affect sterility assurance.

1.2 Inclusion\(\frac{1}{3}\) his is a preview edition of an AAMI guidance document and is

This recommended plactice specifically addresses the followings to evaluate the content of the

- a) functional and physical design criteria for work areas;
- b) staff qualifications, education, and other personnel considerations; document,
- c) preparation and packaging of devices (wrapped and unwrapped methods);
- d) sterilization procedures;
- or visit www.aami.org.
- e) sterile storage and distribution;
- f) installation, care, and maintenance of table-top dry heat sterilizers; and
- g) quality control.

Definitions of terms, a bibliography, and annexes providing supplementary information about dry heat sterilization are also included.

#### 1.3 Exclusions

This recommended practice does not cover

- a) construction and performance criteria for table-top dry heat sterilizers (see ANSI/AAMI ST50);
- b) conduction-type or radiation-type dry heat sterilization processes;
- c) table-top sterilization processes that use sterilizing agents other than dry heat (such as ethylene oxide, steam, unsaturated chemical vapor, or peracetic acid); or
- d) reprocessing of devices labeled for single use only.

#### 2 Definitions, symbols, and abbreviations

For the purposes of this recommended practice, the following definitions apply.

- **2.1 ambulatory care:** Short-term treatment of medical, dental, or surgical needs (within 24 hours) in an office or clinic type of environment.
- **2.2 bioburden:** Population of viable microorganisms on a product and/or a package.

NOTE—When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.

**2.3 biofilm:** Matrix that contains cells, living and dead, as well as polysaccharide (sometimes referred to as *glycocalyx*), and that is exuded by microorganisms when they are growing in water or water solutions or *in vivo* (e.g.,