List of Titles

American National Standard

ANSI/AAMI ST19:1999

Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

American National Standard

ANSI/AAMI ST19:1999
(Revision of ANSI/AAMI ST19:1986/(R)1994)

Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization

Developed by
Association for the Advancement of Medical Instrumentation

Approved 13 September 1999 by
American National Standards Institute, Inc.

Abstract: This standard provides specific requirements for test organisms and biological indicators intended for use in assessing the performance of sterilizers employing moist heat as the sterilizing agent at sterilizing temperatures in excess of 100° C.

Keywords: carrier, organism, resistance, packaging, value

List of Titles

AAMI Standard

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

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time.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

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-5762

© 1999 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this draft should be submitted to AAMI. 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 Kurt C. Larrick, Director, Technical Publishing, at AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201. Phone: (703) 525-4890, Ext. 239; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1-57020-124-2

List of Titles

Contents

Committee Representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

This American National Standard was developed by the Biological Indicators Working Group under the auspices of the AAMI Sterilization Standards Committee.

The **AAMI Sterilization Standards Committee** has the following members:

Cochairs:	Virginia C. Chamberlain, PhD William Young
Members:	Carl W. Bruch, PhD, Consultant, Hudson, WI Virginia C. Chamberlain, PhD, VC Chamberlain and Assoc., Hendersonville, NC Neal E. Danielson, D's Enterprise, Wichita, KS Judith Dowler, Medical Devices Bureau, Health Canada, Ottawa, ON Frank B. Engley, Jr., PhD, University of Missouri, Columbia, MO Virginia Hitchins, PhD, Center for Devices and Radiological Health, U.S. Food and Drug Administration Robert F. Morrissey, PhD, Johnson & Johnson S. Richard Nusbaum, Pennsylvania Engineering Company Barry F. J. Page, Barry Page Consulting, Garner, NC Marimargaret Reichert, RN, Reichert Consulting, Olmsted Falls, OH Janet K. Schultz, RN, Medascend James Whitbourne, Sterilization Technical Services James L. Whitby, MA, MB, FRCP, University of Western Ontario, London, Ontario William Young, Baxter Healthcare Corporation

The **Biological Indicators Working Group** has the following members:

Cochairs:	Lois Jones Phil Schneider
Members:	Krisann Anderson, St. Jude Medical, Inc. Trabue D. Bryans, Viromed Biosafety Labs Karla Byrne, Getinge/Castle, Inc. Virginia C. Chamberlain, PhD, VC Chamberlain and Assoc., Hendersonville, NC Gary Cranston, Consulting and Technical Services, Taunton, MA Douglas Davie, Sterilization Validation Services Brian Drumheller, CR Bard John Dyckman, PhD, Propper Manufacturing Corporation Gordon Ely, BS RM, Nelson Laboratories, Inc. Jerry Falkowski, PhD, Steris Corporation Janie Fuller, Center for Devices and Radiological Health, U.S. Food and Drug Administration James Gibson, Jr., J.M. Gibson Associates, Odessa, FL Joel R. Gorski, PhD, NAMSA Thomas L. Hansen, Kendall Healthcare Arthur C. Harris, Chicago Sterilization Services Lois Jones, Becton Dickinson and Company Carolyn Kinsley, Baxter Healthcare Corporation James P. Kulla, BS MS, BEC Laboratories, Inc. Linda Lavelle, Johnson and Johnson Patrick McCormick, Bausch & Lomb, Inc. James McGowan, Kimberly-Clark Corporation Gregg Mosely, Biotest Laboratories Robert Reich, BS MS, Pharmaceutical Systems, Inc. Phil Schneider, 3M Health Care Zenius Seliokas, Stericon, Inc. Scott Sutton, PhD, Alcon Laboratories, Inc. James Whitbourne, Sterilization Technical Services

 © 1999 Association for the Advancement of Medical Instrumentation

Alternates:	Edward F. Arscott, NAMSA
	Gene Burson, Alcon Laboratories, Inc.
	Anthony DeMarinis, BS MS CQA CQM, CR Bard
	Dan Floyd, BS RM, Nelson Laboratories, Inc.
	Susan Gouge, Center for Devices and Radiological Health, U.S. Food and Drug Administration
	Joyce Hansen, Baxter Healthcare Corporation
	Larry Joslyn, Steris Corporation
	Jim Kaiser, Getinge/Castle, Inc.
	David Liu, Johnson and Johnson
	Lisa Macdonald, Becton Dickinson and Company
	J. Sue McAllister, 3M Health Care
	Margaret M. McFarland, Kimberly-Clark Corporation
	Susan Norton, Bausch & Lomb, Inc.

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

Acknowledgment

The Biological Indicators Working Group would like to thank Dr. Gary Graham, PhD for his contribution to the development of this standard during his tenure as cochair of the Biological Indicators Working Group.

Foreword to the American National Standard

This American National Standard, ANSI/AAMI ST19, *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization*, details additional specific requirements for biological indicators intended for use with moist heat sterilization. Other parts are available, including:

Part 1: General

Part 2: Biological indicators for ethylene oxide sterilization

These standards replace the previous editions of ANSI/AAMI Standards covering biological indicators (ANSI/AAMI ST19:1986/(R)1994 and ANSI/AAMI ST21:1986/(R)1994).

These American National Standards were developed by the AAMI Biological Indicators Working Group under the auspices of the AAMI Sterilization Standards Committee.

These American National Standards are based on the International Organization for Standardization (ISO) series of standards for biological indicators (ISO 11138 series) developed by Working Group 4 (WG 4), *Biological indicators* of ISO Technical Committee 198, *Sterilization of health care products.* The U.S. member body of ISO, the American National Standards Institute (ANSI), held the international secretariat of ISO/TC 198 and assigned administration of this technical committee to AAMI.

AAMI also coordinated U.S. participation in ISO/TC 198 and in WG 4 through the U.S. Technical Advisory Group (TAG) for ISO/TC 198. Specific participation on WG 4 was coordinated by the U.S. Sub-TAG for ISO/TC 198/WG 4 (AAMI Biological Indicators Working Group).

This ANSI/AAMI Standard is not intended to stand alone and can only be used effectively with ANSI/AAMI ST59.

This American National Standard contains significant national deviations from the corresponding ISO standard. All substantive national deviations are described in annex B, and a rationale for each change is provided.

Annex A to this standard is normative. Annex B to this standard is informative.

As used within the context of this standard, “shall” indicates requirements strictly to be followed in order to conform to the standard; “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 is discouraged but not prohibited; “may” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations.

NOTE—This foreword does not contain provisions of the American National Standard, *Sterilization of health care products—Biological Indicators—Part 3: Biological indicators for moist heat sterilization* (ANSI/AAMI ST19:1999), but it does provide information about the development and intended use of the document.

 © 1999 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST19:1999

Introduction

This standard, in conjunction with ST59, specifies general production, labeling, and performance requirements for the manufacture of biological indicators (BIs) intended for use as monitors of moist heat sterilization cycles. The procedures and methods described in these standards should be carried out by suitably trained personnel.

BIs are not intended for use in any process other than that specified by the manufacturer on the labeling. The use of an inappropriate BI can give misleading results. BIs are used to test the effectiveness of sterilization processes and equipment.

The performance of a BI can be adversely affected by the conditions of transportation, storage prior to use, the methods of use, or the techniques employed after exposure to the process. For these reasons, the recommendations of the manufacturer for storage and use should be followed, and BIs should be transferred to the specified recovery conditions as soon as possible after exposure to the process. BIs should not be used beyond any expiry date stated by the manufacturer.

American National Standard **ANSI/AAMI ST19:1999**

Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization

1 Scope

This American National Standard provides specific requirements for test organisms and biological indicators (BIs) intended for use in assessing the performance of sterilizers employing moist heat as the sterilizing agent at sterilizing temperatures in excess of 100° C. Compliance with this standard necessitates compliance with ST59, *Sterilization of health care products—Biological indicators—Part 1: General*.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this American National Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. The American National Standards Institute maintains a register of currently valid American National Standards.

ANSI/AAMI ST59:1999, *Sterilization of health care products—Biological indicators—Part 1: General*

ANSI/AAMI/ISO 11134:1994, *Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization*

ANSI/AAMI ST45:1992, *BIER/Steam vessels*

3 Definitions

For the purposes of this American National Standard, the definitions given in ANSI/AAMI ST59 apply.

Additionally, for the purposes of this standard, the following definition applies:

3.1 z-value: For a thermal sterilization process, the change in exposure temperature that corresponds to a 10-fold change in D-value.

4 General

The requirements of ANSI/AAMI ST59 shall apply, except as modified in subsequent clauses of this standard, ST19, *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization*.

5 Test organisms

The test organism shall be spores of *Bacillus stearothermophilus* or other strains or organisms of demonstrated equivalent performance as required by this standard.

NOTES—

1. *Bacillus stearothermophilus NCTC* (National Collection of Type Cultures [of the U.K. Central Public Health Laboratory]) *10003, DSM* (Deutsche Sammlung von Mikroorganismen*) 494, B. stearothermophilus ATCC (*American Type Culture Collection) *7953, DSM 22* and *B. stearothermophilus CIP* (Collection of the Institut Pasteur) *52.81, DSM 5934, ATCC 12980, NCTC 10007* have been found to be suitable.

2. If an organism other than *B. stearothermophilus* is used, then the suitability of the resistance of the test organism chosen should be determined during process qualification.

© 1999 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST19:1999

6 Suspensions

Replicate determinations of the viable test organism count on the same batch of test organism suspension shall be within ± 35% of the nominal population.

7 Carriers and primary packaging

NOTE—For specific requirements for the carrier and primary packaging, see ANSI/AAMI ST59, subclause 4.4.

The test conditions used to establish suitability shall be as follows:

Temperature—not less than the manufacturer's stated maximum exposure temperature + 5° C. When not stated, a temperature of 145° C shall be used.

NOTE—Equipment tolerances should be checked before attempting this test.

Exposure time—not less than the manufacturer's stated maximum exposure time. When not stated, an exposure time of 30 minutes (min) shall be used.

NOTE—These conditions have been selected to represent a realistic challenge to the carrier while remaining within the practical limits of a steam sterilization process.

8 Biological indicators (BIs)

8.1 The number of recoverable test organisms on each BI shall be controlled during manufacture to be either within ± 50% of the nominal population stated by the manufacturer or within the minimum and maximum populations stated by the manufacturer.

8.2 Retrospective determination of the count shall be made by performing a viable test organism count under the manufacturer's stated culture conditions on a suspension of test organisms obtained by physical removal of the test organisms from the carrier through ultrasonication, shaking with glass beads, or other appropriate validated methods. Counts obtained shall be regarded as acceptable if they are within – 50% and + 300% of the stated value or, if minimum and maximum populations are stated by the manufacturer, within those stated minimum and maximum populations.

8.3 For inoculated carriers or BIs intended for use in routine monitoring, the nominal number of test organisms shall be not less than 1×10^5 and shall be stated in increments no greater than 0.1×10^5.

For self-contained BI systems, the nominal number of test organisms may be less than 1×10^5 for routine monitoring, provided the requirements of clause 9.3 are met.

NOTE—Inoculated carriers and/or BIs intended for other purposes, (e.g., qualification, validation, and other specific tests) could require other nominal populations: a nominal population of 1×10^5 could be required for some routine monitoring applications. Other inoculum levels may be utilized for routine monitoring of industrial moist heat sterilization processes, provided that level has been shown to be appropriate during process qualification.

9 Resistance

9.1 Resistance performance testing shall be performed as required in ANSI/AAMI ST59, *Sterilization of health care products—Biological indicators—Part 1: General,* section 5.

9.2 The manufacturer shall state the D-value of each batch of biological indicators or inoculated carriers to an accuracy of ± 0.5 min.

9.3 Determination of the resistance characteristics of each batch of biological indicators shall be performed in accordance with ANSI/AAMI ST45:1992, *BIER/Steam vessels*.

9.4 D-value: The D-values obtained by either the survivor curve method or fraction negative analysis using the Most Probable Number (MPN) procedure (see clause 5 and annexes B, C, D and G of ANSI/AAMI ST59) for test organism populations on the BI shall be not less than 1.5 min when exposed to moist heat at 121° C ± 1° C. The population log times the D-value shall not be less than 7.5 min.

NOTE—If an organism other than *B. stearothermophilus* is used, then the resistance of that organism at the sterilizing conditions should be known and the suitability of the resistance determined. This determination should be made by the user during process qualification.

9.5 z-value: The D-values of the test organisms on the inoculated carrier shall be determined at not less than two other temperatures in the range 110° C to 130° C by either of the two methods given. These data shall be used to

 © 1999 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST19:1999

calculate the z-value, which shall be not less than 6° C and which shall be stated in increments no greater than 0.1° C. The z-value shall be calculated according to annex A of this part of the standard.

NOTE—Since many steam sterilizers in U.S. hospitals routinely perform sterilization cycles in the range of 132° to 135° C, it is important to understand the resistance performance characteristics of BIs in this temperature range. One way to accomplish this is through the accurate determination of the z-value, which allows one to calculate D-values at temperatures other than the reference temperature, 121° C. Although a minimum z-value of 6° C is stated, typical values for *B. stearothermophilus* are in the range of 9° to 11° C. For BIs intended for use in health care facilities, the U.S. FDA may have additional resistance testing requirements at 132° C and/or may require a minimum z-value greater than 6° C.

10 Test methods

Test methods given in this standard are reference methods. When alternative method(s) are used, these shall be defined, validated, and have proven correlation with the reference method(s).

Annex A
(normative)

Calculation of z-value

Using the procedures and data specified in 9.3, calculate the z-value, in degrees Celsius, using the following formula:

$$z = \frac{T_2 - T_1}{\log_{10} D_1 - \log_{10} D_2}$$

where D_1 and D_2 are the D-values obtained at temperatures T_1 and T_2, respectively (see 9.4).

 © 1999 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST19:1999

Annex B
(informative)

Background of the development of ANSI/AAMI ST19 and rationale for national deviations

B.1 Background on development of International Standards on biological indicators (BIs)

In 1994 and 1995, the ISO published the ISO 11138 series of standards for biological indicators. This series consisted of three parts:

ISO 11138-1:1994, *Sterilization of health care products—Biological indicators—Part 1: General*

ISO 11138-2:1994*, Sterilization of health care products—Biological indicators—Part 2: Biological indicators for ethylene oxide sterilization*

ISO 11138-3:1995, *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization*

The International Standards were developed by Working Group 4, *Biological indicators* of ISO/TC 198, *Sterilization of health care products*.

B.2 Consideration of the International Standards on biological indicators for adoption as American National Standards

Following the completion of the ISO 11138 series, the AAMI Biological Indicators Working Group agreed, in the interests of international harmonization, to consider adoption of the International Standards as replacements for two existing American National Standards—ANSI/AAMI ST19:1986, *Biological indicators for saturated steam sterilization processes in health care facilities*, and ANSI/AAMI ST21:1986, *Biological indicators for ethylene oxide sterilization processes in health care facilities*. These earlier documents had been developed by the AAMI Biological Indicators Working Group under the auspices of the AAMI Sterilization Standards Committee. They were originally published in 1986 and had been reaffirmed in early 1994, pending completion of the ISO 11138 series.

In 1995, a canvas of the AAMI Sterilization Standards Committee and the AAMI Biological Indicators Working Group was undertaken. Members of the committee and the working group were asked whether the ISO standards should be considered for adoption as American National Standards without change, should be modified for U.S. adoption, or whether the U.S. should continue to maintain ANSI/AAMI ST19 and ANSI/AAMI ST21 as domestic standards.

Based on the results of the canvas and the discussion at the meeting, the AAMI Biological Indicators Working Group agreed that several modifications were required before the ISO 11138 series would be acceptable as American National Standards. These modifications were considered necessary, given traditions of use of BIs in the U.S., and were consistent with positions advocated by the U.S. during the development of the ISO Standards.

B.3 National deviations

Four major changes to the ISO standards were identified as necessary before the standards would be acceptable as American National Standards.

a) *The use of dual species*: Part 1 would have to be modified to allow dual-species BIs to comply with the standards.

b) *Requirements for the population log times the D-value for moist heat indicators*: The requirements for the population log times the D-value for moist heat BIs given in Part 3 would require modification.

c) *Requirements for resistometers*: The requirements for resistometers used to test biological indicators would have to be revised in Part 2 and Part 3.

d) *Reference to the Stumbo-Murphy-Cochran Procedure*: An additional annex would have to be added to Part 1 to list the SMCP as an acceptable alternative reference method to the Limited Spearman-Karber Procedure.

B.4 National deviations specific to ANSI/AAMI ST19, *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization*

B.4.1 References to other American National Standards

Changes: ISO 11138-3 makes normative reference to ISO 11138-1. In the American National Standard ANSI/AAMI ST19, all references to ISO 11138-1 have been changed to specify the American National Standard version (ANSI/AAMI ST59). The citations of ISO 11138-1 in the Normative References section have also been replaced with references to ANSI/AAMI ST59.

Rationale: When ISO 11138-1 was adopted as ANSI/AAMI ST59, significant national deviations were incorporated into the standard. As the references to this standard in ANSI/AAMI ST19 are normative, it was necessary that the U.S. version be cited.

B.4.2 Changes to the requirement for the population log times the D-value

Changes: Subclause 9.3 of ISO 11138-3 requires that "[t]he population log times the D-value shall not be less than 10 minutes." The U.S. adoption replaces the statement with "[t]he population log times the D-value shall not be less than 7.5 minutes."

Rationale: While the 10-min requirement is appropriate for some BI uses, it is not appropriate for all current uses of BIs in the U.S., such as routine cycle monitoring. The specification of 7.5 min is consistent with the recommendations of the U.S. Pharmacopeial Convention. This change to the International Standard was advocated by the U.S. during the development of ISO 11138-3.

B.4.3 Changes to the performance requirements for resistometers

Changes: The requirements for resistometers used to test moist heat biological indicators in ISO 11138-3 have been replaced by a normative reference requiring that equipment comply with ANSI/AAMI ST45:1992, *BIER/Steam vessels*.

Rationale: ISO 11138-3 provides minimum performance requirements for resistometers used to evaluate moist heat sterilization BIs, which conflicted with the requirement given in the existing American National Standard for such resistometers. It was the judgment of the AAMI Biological Indicators Working Group that the requirements given in ANSI/AAMI ST45:1992, *BIER/Steam vessels*, were acceptable, while those given in ISO 11138-3 were not achievable.

When a system is being evacuated, the temperature of the system changes considerably. A vacuum level cannot be pulled to a set point within this tight tolerance as the temperature changes will alter the consistency of the actual vacuum level obtained. The tolerance given is so tight (± 0.4 kPa) that it approaches the feasible measurement level of precision pressure instrumentation, much less achievable control levels. At the rate of vacuum change prescribed, a control system cannot measure the pressure and stop the evacuation within such a tight tolerance.

B.4.4 Minor and editorial changes

B.4.4.1 *Change to the introduction:* The following paragraph from ISO 11138-3 was deleted from the introduction of ANSI/AAMI ST19:

> Biological indicators should always be used in combination with physical and/or chemical monitoring in demonstrating the efficacy of a sterilizing process. When a physicochemical variable of a sterilizing process is outside its specified limits, a sterilization cycle should always be regarded as unsatisfactory, irrespective of the results obtained from BIs.

Rationale: As the deleted paragraph is user guidance, it is not appropriate in the introduction of a standard for the manufacture of BIs.

B.4.4.2 *Change to note under clause 5:* The following sentence has been added to the NOTE under Clause 5 of the American National Standard:

> If an organism other than *B. stearothermophilus* is used, then the suitability of the resistance of the test organism chosen should be determined during process qualification.

Rationale: ISO 11138-3 specifies that the test organisms should be ". . . *Bacillus stearothermophilus* or strains of demonstrated equivalent performance . . ." While such organisms may be appropriate for an overkill method of process qualification, they may not be appropriate for a bioburden-based process qualification. The addition to the note is a caution to ensure that the suitability of the resistance of the test organism is determined.

 © 1999 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST19:1999

B.4.4.3 *Change to clause 7:* The following precaution has been added as a note in the American National Standard:

> Equipment tolerances should be checked before attempting this test.

Rationale: Many BI manufacturers label their products for use at temperatures of 132° C or higher; for this test, a temperature of 137° C would be required which is 2° C beyond the control range of 135° C specified by many sterilizer manufacturers. It would not be appropriate for this standard to recommend that equipment be operated beyond its control range.

B.4.4.4 *Change to subclause 8.2:* The following phrase has been added to the last sentence of subclause 8.2 in the American National Standard:

> . . . or, if minimum and maximum populations are stated by the manufacturer, within those stated maximum and minimum populations.

Rationale: If a manufacturer states the minimum and maximum population for a BI, then the actual population must fall within the stated minimum and maximum populations, and it is acceptable for the actual population to fall anywhere within the stated minimum and maximum populations.

B.4.4.5 *Change to subclause 8.3:* The following sentence has been added to the end of Note 4 in the American National Standard:

> Other inoculum levels may be utilized for routine monitoring of industrial moist heat sterilization processes, as long as that level has been shown to be appropriate during process qualification.

Rationale: While a population of 1×10^5 may be appropriate for monitoring overkill cycles, it may not be appropriate for a bioburden-based process qualification.

B.4.4.6 *Change to clause 9:* A new subclause 9.1 was added to reference resistance performance testing to the requirements of ST59, and the subsequent subclauses of section 9 were renumbered accordingly.

Rationale: To clarify that the requirements of ST21 are to be used in conjunction with the requirements of ST59.

B.4.4.7 *Change to subclause 9.4:* The following note has been added to subclause 9.4:

NOTE—If an organism other than *B. stearothermophilus* is used, then the resistance of that organism at the sterilizing conditions should be known and the suitability of the resistance determined. This determination should be made by the user during process qualification.

Rationale: This note was added to ensure that the use of BIs with resistances other than those observed for *B. stearothermophilus* is allowed.

B.4.4.8 *Change to subclause 9.5:* The following note has been added to subclause 9.5:

NOTE—Since many steam sterilizers in U.S. hospitals routinely perform sterilization cycles in the range of 132° C to 135° C, it is important to understand the resistance performance characteristics of BIs in this temperature range. One way to accomplish this is through the accurate determination of the z-value which allows one to calculate D-values at temperatures other than the reference temperature, 121° C. Although a minimum z-value of 6° C is stated, typical values for *B. stearothermophilus* are in the range of 9° C to 11° C. For BIs intended for use in health care facilities, the U.S. FDA may have additional resistance testing requirements at 132° C and/or may require a minimum z-value greater than 6° C.

Rationale: This note was added to address the use of other temperatures in testing for resistance.

B.4.5 Other changes

Other minor national deviations were necessary to improve consistency between the different parts of ISO 11138 and also to conform with U.S. spelling. This informative annex (annex C) was also added to identify the substantive differences between the ISO Standard and the American National Standard and to provide rationale for these changes.

B.5 Harmonization of ANSI/AAMI ST19 and ISO 11138-3

It is the judgment of the AAMI Sterilization Standards Committee and the AAMI Biological Indicators Working Group that ANSI/AAMI ST19 and ISO 11138-3 are sufficiently harmonized and BIs complying with the requirements of ISO 11138-3 should be in compliance with the requirements of ANSI/AAMI ST19. Because the modifications to ANSI/AAMI ST19 are permissive rather than restrictive, however, BIs complying with ANSI/AAMI ST19 may or may not be in compliance with ISO 11138-3.