List of Titles

American National Standard

ANSI/AAMI ST:66:1999

Sterilization of health care products—Chemical indicators—Part 2: Class 2 indicators for air removal test

AAMI Association for the Advancement of Medical Instrumentation

American National Standard ANSI/AAMI ST66:1999

Sterilization of health care products — Chemical indicators — Part 2: Class 2 indicators for air removal test sheets and packs

Developed by
Association for the Advancement of Medical Instrumentation

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American National Standards Institute, Inc.

Abstract: This ANSI/AAMI Standard specifies the requirements for an indicator and alternative test system used to evaluate the effectiveness of air removal during the pre-vacuum phase of pre-vacuum steam sterilization cycles. Additionally, this standard includes test methods and equipment used to meet these performance requirements.

Keywords: Bowie-Dick Test, steam sterilization, steam penetration, test pack, test sheet, towel, user-assembled

List of Titles

AAMI Standard

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Committee Representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

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

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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.

Foreword to the American National Standard

This American National Standard was developed by the AAMI Chemical Indicators Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective is to specify requirements for chemical indicators intended for use as Class 2 indicators for the air removal test.

This standard is based on the International Organization for Standardization (ISO) Final Draft International Standard for chemical indicators, ISO/FDIS 11140-5, *Sterilization of health care products – Chemical indicators – Part 5: Class 2 indicators for air removal test sheets and packs*, developed by Working Group 6 of ISO Technical Committee (TC) 198, *Sterilization of health care products*.

The U.S. member body of ISO, the American National Standards Institute (ANSI), holds the International Secretariat of ISO/TC 198 and has assigned administration of this technical committee to AAMI. AAMI also coordinates U.S. participation in ISO/TC 198 and in WG 6 through the U.S. Technical Advisory Group (TAG) for ISO/TC 198. Specific participation on WG 6 is coordinated by the U.S. Sub-TAG for ISO/TC 198/WG 6 (AAMI Chemical Indicators Working Group).

This standard contains national deviations from the corresponding ISO standard. These deviations are described and explained in annex J, which is provided for information only.

As used within the context of this document, “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 should be avoided but is not prohibited; “may” is used to indicate 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.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword does not contain provisions of the ANSI/AAMI standard, *Sterilization of health care products—Chemical indicators—Part 2: Class 2 indicators for air removal test sheets and packs* (ANSI/AAMI ST66:1999), but it does provide important information about the development and intended use of the document.

Introduction

The air removal test is used to evaluate the efficacy of air removal during the pre-vacuum phase of a pre-vacuum sterilization cycle. Original work in this area was conducted by J. H. Bowie *et al*. in 1963[1]. Retention of air due to an inefficient air removal stage or the presence of an air leak during the air removal stage are circumstances that can lead to failure of the test. This standard describes the requirements for Class 2 indicators and systems for the air removal test.

NOTES—

1. For a description of the classes of chemical indicators, see ANSI/AAMI ST60.

2. Because a range of different tests in different countries have historically been named the Bowie-Dick Test, no reference to this term, other than on this page and in annex I, is used in this standard.

[1] Bowie, JH., Kelsey, JC. and Thompson, GR. The Bowie and Dick Autoclave Tape Test. *The Lancet*, 1963; i:586.

American National Standard ANSI/AAMI ST66:1999

Sterilization of health care products — Chemical indicators — Part 2: Class 2 indicators for air removal test sheets and packs

1 Scope

This American National Standard specifies the requirements for an indicator and alternative test system used to evaluate the effectiveness of air removal during the pre-vacuum phase of pre-vacuum steam sterilization cycles. Additionally, this standard includes test methods and equipment used to meet these performance requirements.

2 Normative references

The following standards contain provisions that, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

2.1 ANSI/AAMI ST60:1996. *Sterilization of health care products—Chemical indicators—Part 1: General requirements*.

2.2 IEC 584-2:1982. *Thermocouples—Part 2: Tolerances.*

2.3 IEC 751:1983. *Industrial platinum resistance thermometer sensors.*

3 Definitions

For the purpose of this standard, the definitions given in ANSI/AAMI ST60 apply. Additional definitions for this standard are:

3.1 air removal indicator: Indicator to be used in the standard test pack (annex E) to determine the efficacy of the air removal phase in the steam sterilization process.

3.2 air removal indicator system: Specific test load containing an indicator to determine the efficacy of the air removal phase in the steam sterilization process.

NOTE—The test load may be user-assembled or pre-assembled. Also, it may be disposable, for limited use, or reusable.

3.3 equilibration time: Period of time that elapses between the attainment of the sterilization temperature in the sterilizer chamber and the attainment of the sterilization temperature in all parts of the load.

4 General

Unless otherwise specified in this standard, the general requirements given in ANSI/AAMI ST60 apply.

5 Air removal indicator

5.1 Format

5.1.1 The indicator agent shall be uniformly distributed on its substrate to cover not less than 30% of the test area of the substrate.

NOTE—The pattern of indicator agent distribution should allow easy judgment of the uniformity of the color change.

5.1.2 The indicator shall have an air porosity greater than 0.026 ml/sec/mm^2. Compliance shall be tested in accordance with annex H.

5.1.3 The substrate of the indicator shall have a uniform ground color, which provides a difference in color density of not less than 0.3 between ground color and either the changed or the unchanged indicator, as specified by the manufacturer, when the difference in color density is determined using a reflective densitometer.

Compliance shall be tested in accordance with annex A.

5.1.4 The indicator shall be 220 mm ± 20 mm by 290 mm ± 25 mm.

5.2 Performance

5.2.1 The indicator shall show a uniform color change (as specified by the manufacturer) after exposure to saturated steam at 134 °C for 3.5 minutes (min) ± 5 seconds (s) and/or exposure to saturated steam at 121 °C for 15 min ± 5 s or such other combinations of time and temperature as the manufacturer specifies for the intended use of product. In all cases, the permitted tolerance on the test temperature shall be +1.5/-0 °C, and the time given shall be the time within which the color change shall occur. Compliance shall be tested in accordance with annex B.

5.2.2 When placed in the center of the standard test pack as given in annex E, the indicator shall show a non-uniform color change when the temperature at the center of the standard test pack is 2 °C +1/-0° C lower than the temperature of the chamber drain at the beginning of the final one minute of a three and a half minute cycle at 134 °C or at the beginning of the final five minutes of a 15 min cycle at 121 °C of the exposure phase of the steam exposure apparatus. This is the standard fault condition generated by inadequate air removal from the chamber. Any other combination of time and temperature stated by the manufacturer shall exhibit a similar response at the beginning of the final 30% of the exposure time. Compliance shall be tested in accordance with annex F.

5.2.3 After exposure to dry heat at 140 °C ± 2 °C for 30 min ± 1 min, the indicator shall show either no change or shall show a change that is markedly different from the change occurring after exposure to a steam sterilization process. Compliance shall be tested in accordance with annex C.

5.2.4 Transfer of the indicator agent to the material of the standard test pack, in which it is intended to be used, should not compromise the result of the test and the indicator agent should be completely removable from reusable items during the laundry process. Compliance shall be tested in accordance with annex D.

NOTE—Some transfer of the indicator agent may be possible without adversely affecting the performance of the indicator or test pack.

5.2.5 The indicator shall comply with the requirements of this standard for the duration of the specified shelf life when stored as prescribed by the manufacturer.

6 Air removal indicator system

6.1 Format

6.1.1 The indicator agent shall be uniformly distributed on its substrate to cover not less than 30% of the test area of the substrate.

6.1.2 The substrate of the indicator shall have a uniform ground color that provides a difference in color density of not less than 0.3 between ground color and either the changed or the unchanged indicator agent, as specified by the manufacturer, when the difference in color density is determined using a reflective densitometer.

Compliance shall be tested in accordance with annex A.

6.2 Performance

6.2.1 The indicator shall show a uniform color change complying with 6.1.2 both after exposure to saturated steam at 134 °C +1.5/-0 °C for 3.5 min ± 5 s and/or exposure to saturated steam at 121 °C +1.5/-0 °C for 15 min ± 5 s or such other combinations of time and temperature as the manufacturer shall specify for the intended use of product. In all cases, the permitted tolerance of the test temperature shall be +1.5/-0 °C, and the time given shall be the time within which the color change shall occur. Compliance shall be tested in accordance with annex B.

6.2.2 After exposure to conditions used to produce a standard fault condition as given in 5.2.2 in the standard test pack as given in annex E, the indicator shall show a non-uniform color change.

Compliance shall be tested in accordance with annex F.

6.2.3 After exposure to dry heat at 140 °C ± 2 °C for 30 min, the chemical indicator system shall show either no change or shall show a change that is markedly different from the change occurring after exposure to a steam sterilization process. Compliance shall be tested in accordance with annex C.

6.2.4 Transfer of the indicator agent to the chemical indicator system shall not compromise the result of the test, and the indicator agent should be completely removable from reusable items during the laundry process.

6.2.5 The indicator shall comply with the requirements of this standard for the duration of the specified shelf life when stored as prescribed by the manufacturer.

NOTE—A documented accelerated aging procedure may be used in demonstrating compliance.

7 Packaging and labeling

7.1 The general requirements in ANSI/AAMI ST60 apply.

7.2 In addition, each indicator, indicator system, and its packaging shall be clearly marked with

AIR REMOVAL

Where the size and format of the indicators do not permit this information to be stated on the product itself, the information shall be stated clearly either on separate literature or a packaging unit.

8 Quality Assurance

The general requirements in ANSI/AAMI ST60 apply.

9 Sample conditioning

All test samples shall be conditioned for at least one hour immediately prior to testing in an environment between 23 °C ± 7 °C with a relative humidity of 30–70%.

Annex A
(normative)

Method for determination of the degree of contrast between the color of the substrate and the indicator agent

A.1 Apparatus

The following equipment is required:

a) steam exposure apparatus complying with annex G;

b) reflective densitometer that has been calibrated with the calibration traceable to national standards;

c) standard test pack as described in annex E.

A.2 Method

A.2.1 To determine the degree of contrast between the substrate and the changed indicator agent, the indicator is placed in the center of a test pack and exposed to a cycle of the steam exposure apparatus at the specified operating temperature required for the indicator to produce uniform color change.

A.2.2 The difference in color density between the ground color of the substrate and that of the changed and/or unchanged indicator agent shall be determined on at least three pairs of locations on the indicator, using a reflective densitometer. Paired readings of the ground color of the substrate and of that of the changed and/or unchanged indicator agent shall be taken equidistantly over the indicator.

A.2.3 This test shall be repeated five times for each of three separate production batches of the indicator.

Annex B
(normative)

Method of demonstrating uniform color change on exposure to saturated steam

B.1 Apparatus

The following equipment is required:

a) steam exposure apparatus complying with annex G;

NOTE—The empty chamber includes chamber furniture.

b) temperature sensors (either Class A platinum resistance thermometers complying with IEC 751 or tolerance Class 1 thermocouples complying with IEC 584-2);

c) thermometric recording equipment with a limit of error of 0.5 °C;

d) standard test pack as described in annex E.

B.2 Air removal indicator

B.2.1 In an otherwise empty chamber, the standard test pack as described in annex E, with temperature sensors and the indicator under test inserted in the geometric center of the pack, shall be exposed to a cycle of the exposure apparatus at the specified operating temperature (see 5.2.1) and the temperatures recorded. When the temperature measured in the drain of the exposure apparatus has attained the set saturated steam temperature, the difference between the measured temperature in the drain of the steam exposure apparatus and in the center of the test pack shall be less than 0.5 °C and shall remain so for the duration of the exposure time exclusive of a 15 s equilibration time. At the completion of the cycle, the indicator shall be removed from the standard test pack and examined for compliance with 5.2.1.

B.2.2 This test shall be repeated five times for each of three separate production batches of the indicator.

B.3 Air removal indicator system

B.3.1 The air removal indicator system to be tested is placed in an otherwise empty chamber. A temperature sensor is placed in the chamber drain of the exposure apparatus. A cycle with the conditions outlined in B.2.1 is run. At the completion of the cycle, the indicator shall be removed from the system and examined for compliance with 6.2.1.

B.3.2 This test shall be repeated five times for each of three separate production batches of the indicator system.

B.3.3 The test program shall consist of:

a) two replicate cycles complying with 5.2.1 using a standard test pack (annex E) having temperature sensors in place;

b) three sets of test cycles complying with 5.2.1 alternating the standard test pack having temperature sensors in place (annex E) with the air removal indicator system.

Annex C
(normative)

Method for evaluating indicator color change on exposure to dry heat

C.1 Apparatus

The following equipment is required:

a) sample holder as specified by the indicator manufacturer;

b) dry heat oven capable of maintaining a steady temperature of 140 °C ± 2 °C.

NOTES—

1. The humidity in the oven should be less than 5% relative humidity throughout the period of the test.

2. A sample holder may be necessary. Advice should be sought from the manufacturer.

C.2 Air removal indicator

C.2.1 The oven shall be preheated to the operating temperature.

C.2.2 The test samples shall be placed in the oven and subjected to dry heat at 140 °C ± 2 °C for 30 min ± 1 min. The samples shall be removed and examined for color change in accordance with 5.2.3.

C.2.3 This test shall be repeated five times for each of three separate production batches of the air removal indicator. Several test samples may be exposed simultaneously.

C.3 Air removal indicator system

C.3.1 The oven shall be preheated to the operating temperature.

C.3.2 The indicator in the air removal indicator system shall be fitted with a temperature sensor to monitor the temperature of the indicator and subjected to dry heat at 140 °C ± 2 °C to determine the time required for the indicator to obtain 135 °C (the heat-up time).

C.3.3 The air removal indicator system shall be subjected to dry heat at 140 °C ± 2 °C for the heat-up time plus 30 min ± 1 min. The indicator shall be removed and examined for color change in accordance with 6.2.3.

C.3.4 This test shall be repeated five times for each of three separate production batches of the air removal indicator system. Several test samples may be exposed simultaneously.

Annex D
(normative)

Method for evaluating transfer of indicator to standard test pack

D.1 Apparatus

The following equipment is required:

a) rigid plate (e.g., acetal, polycarbonate, polysulfone) approximately 200 mm x 100 mm x 5 mm nominal thickness covered with the standard test pack material as described in annex E.1;

b) steam exposure apparatus complying with annex G.

D.1.1 The indicator shall be centered on the material-covered plate with the indicator agent uppermost. A second piece of material shall be placed on the indicator and secured by the taping along all sides to ensure intimate contact with the indicator.

D.1.2 The assembly shall be placed horizontally with the plate as the lowest layer in the steam exposure apparatus and subjected to dry saturated steam at 134 °C ± 1 °C for 3.5 min and/or 121 °C ± 1 °C for 15 min.

D.1.3 The indicator shall be removed and examined for non-uniform color change due to transfer of indicator agent to standard test pack material in accordance with 5.2.4.

D.1.4 This test shall be repeated five times for three separate production batches of the indicator system.

Annex E
(normative)

Standard test pack

E.1 The standard test pack consists of folded 100% cotton surgical towels. They shall be freshly laundered, but not ironed.

E.2 The towels shall be folded to a size 250 mm ± 20 mm in one direction and 300 mm ± 20 mm in the other direction and placed one above the other.

E.3 The height of the test pack shall be between 250 mm to 280 mm.

NOTE—The total number of towels may vary from test to test, depending on towel thickness and wear.

E.4 The weight of the pack shall be 4 kg ± 5%.

E.5 A single two-ply fabric wrap made of 100% cotton with a thread count both warp and weft of 5.5/mm shall be loosely applied to wrap the test pack.

E.6 The pack could be secured with tape not exceeding 25 mm in width.

Annex F
(normative)

Method of demonstrating non-uniform color change on exposure to a standard fault condition

F.1 Apparatus

The following equipment is required:

a) steam exposure apparatus complying with annex G;

b) temperature sensors (either Class A platinum resistance thermometers complying with IEC 751 tolerances or Class 1 thermocouples complying with IEC 584-2);

c) thermometric measuring equipment with a limit of error of 0.5 °C;

d) standard test pack as described in annex E.

F.2 Air removal indicator

F.2.1 Introduce the two temperature sensor leads into the sterilizer chamber through an entry connection.

F.2.2 One sensor is positioned in the geometric center of the test pack and separated from the indicator by one layer of material. Care must be taken to prevent the sensor lead from providing a channel for air entry into the test pack. The second sensor is placed in the chamber drain at a minimum depth of 10 mm. Care should be taken not to allow the sensor to come into contact with any surface in the drain.

F.2.3 The test load must be placed horizontally on the bottom shelf of the chamber furniture over the drain in an otherwise empty chamber.

F.2.4 The standard test pack, with temperature sensors and the indicator properly located, shall be exposed to a cycle of the exposure apparatus with a standard fault condition as described in section 5.2.2. Record the temperatures at each temperature sensor.

F.2.5 At the completion of the cycle, the indicator shall be removed from the test load and examined for compliance with 5.2.2.

F.2.6 This test shall be repeated five times for each of three separate production batches of the indicator system.

F.3 Air removal indicator system

F.3.1 The air removal indicator system, with a temperature sensor in the chamber drain of the exposure apparatus, shall be exposed to a cycle with the same conditions as outlined in F.2.4 above.

F.3.2 At the completion of the cycle, the indicator shall be removed from the air removal indicator system and examined for compliance with 5.2.2.

F.3.3 The test program shall consist of the following:

a) two replicate cycles using a standard test pack (annex E) having temperature sensors in place and a cycle complying with 5.2.2;

b) three sets of test cycles complying with 5.2.2 alternating the standard test pack (annex E) having temperature sensors in place with the air removal indicator system.

Annex G
(normative)

Steam exposure apparatus

G.1 Apparatus

The steam exposure apparatus shall be a pre-vacuum steam sterilizer for use in health care facilities for wrapped goods and porous loads and shall have a chamber volume between 54 and 800 liters. It must comply with the additional requirements for cycle control specified in this annex. The control system is required to allow the simulation of the porous load sterilization cycles currently operated on different machines and to create a standard fault condition. These cycles shall have a high level of reproducibility on replicate runs.

G.2 Instrumentation

G.2.1 Chamber temperature

G.2.1.1 The steam exposure apparatus shall be equipped with a means of continuous indication of chamber temperature with a frequency of at least one measurement every two seconds throughout the cycle.

NOTE—The indicating and recording means may be one and the same.

G.2.1.2 The sensor(s) for the indicator(s) and recorder shall be so positioned that the temperature measured is representative of the actual chamber conditions.

G.2.1.3 When tested against certified laboratory standards, the temperature indicator(s) and recorder shall be accurate to within ± 0.5 °C over the sterilizer's designated operating range.

G.2.1.4 Temperature graduations on the recorder chart shall not exceed 1 °C within a range of ± 5 °C of the set operating temperature.

G.2.2 Pressure

G.2.2.1 The steam exposure apparatus shall be equipped with an indicator(s) (mechanical gauge, digital indicator, or other device) for indicating the vacuum and the pressure within the chamber. The indicator shall be accurate to within ± 3% of full scale value. The indicator shall have graduations or a resolution of 10 kPa (0.1 psi) or less.

G.2.2.2 When a steam jacket is fitted, the steam exposure apparatus shall be equipped with an indicator that displays jacket pressure. The accuracy of an indicator shall be within ± 3% of full scale value, and each graduation or increment of resolution shall be 10 kPa (0.1 psi) or less.

G.2.3 Timer

G.2.3.1 The steam exposure apparatus shall be equipped with a resetable timer for timing exposure.

G.2.3.2 The timer shall have a minimum accuracy of ± 1% of the set value.

G.2.4 Sterilizer control systems

G.2.4.1 The control system shall control the chamber temperature to within +1/-0 °C of the set temperature.

G.2.4.2 The mechanism used by the operator to set the operating temperature shall be marked in or adjustable to increments no larger than 1 °C within a range of 110–140 °C.

Annex H
(normative)

Air porosity apparatus

H.1 Apparatus

A standard densitometer for measuring the air porosity of the indicator.

NOTE—The densitometer measures the time required for a given volume of air (25 ml to 300 ml) to flow through a standard area of the indicator being tested.

H.2 Calibration

Using a timer, measure the time required for 100 ml of air to pass through the test plate using the manufacturer's calibration card. This test should be run three times with results averaged. Each result must be within 5% of the average to be acceptable.

H.3 Method

The indicator is held between clamping plates having a circular orifice area of 645 mm^2 (1.0 in^2). The test shall be repeated five times for each of three batches of indicators.

Annex I
(informative)

Background information on the Bowie-Dick Test

The Bowie-Dick Test[2] is named after its developers, J. H. Bowie and J. Dick. Originally, this test was used to evaluate the vacuum phase of single deep vacuum sterilizers, called high vacuum sterilizers. It was a diagnostic test of the sterilizer's vacuum system. Specifically, the test could assess inadequate vacuum, meaning inadequate air removal from the sterilizer chamber or a leaky door gasket that would also allow for residual air in the sterilizer chamber. This residual air prevents thorough steam penetration into the chamber load during the steam exposure phase of the sterilization cycle. This diagnostic test utilized a sheet of paper to which were applied strips of autoclave tape in the form of a St. Andrews cross. The autoclave tape contained chemical indicator lines. The sheet of paper was located in the center of 29–36 folded huckaback towels made from flax. The assembled test pack was run in any empty chamber, positioned over the drain, at 134 °C for a three and a half minute cycle. Upon completion of the cycle, the sheet containing the autoclave tape was removed from the pack and observed for the uniformity of the indicator ink lines on the tape. A non-uniform or lighter ink line in the center of the sheet (at the intersection of the strips of tape) would indicate a lack of steam penetration to the center of the test pack. This non-uniformity of the indicator suggested that the steam was unable to reach the center of the test pack due to the presence of residual air in the sterilizer chamber.

Numerous changes have taken place in test pack construction, pack design, and sterilizer cycle characteristics since Bowie and Dick published their findings in 1963. Towels used in the standard test pack are derived from cotton rather than flax. An indicator sheet, called an "air removal indicator" in this standard, has replaced the autoclave tape. The chemical indicator ink is printed on these sheets in some design or pattern that may cover up to 50% of the total surface area of the sheet. A user assembled or pre-assembled test load (pack), called an "air removal indicator system" in this standard, has replaced the towel test pack. Frequently, these are disposable test packs that have been shown to perform equivalent to the standard test pack containing an indicator sheet.[3] Further, pre-vacuum steam sterilizers being marketed today do not use single deep vacuum phases; they use pulsed vacuum cycles. In these sterilizers, the depth of vacuum per pulse is not as great as in the older high vacuum sterilizers. Also, in the U.S., the Bowie-Dick Test is run at 270° F (132 °C) rather than 273 °F (134 °C).

Even though the Bowie-Dick Test has been conducted daily in most health care facilities for many years, it was not until 1984 that a method of evaluating Bowie-Dick indicator sheets was described.[4] This method, intended to be useful to both the user and the manufacturer of these indicators, is the basis of the test methodology and performance requirements provided in this standard. Refinements of the original work, as presented at the 19th Annual Meeting of AAMI, permit the evaluator to generate replicative test results without the need for expensive test apparatus. Only a temperature recorder, pre-vacuum steam sterilizer with the capability to shorten the pre-vacuum phase, and timer were required.

To study the performance of an air removal indicator (Bowie-Dick indicator sheet) as outlined in this standard, the evaluator must be able to shorten the pre-vacuum phase of the sterilization cycle. This shortened or incomplete air removal results in residual air in the sterilizer chamber. By varying the length of time for the pre-vacuum phase, the amount of residual air in the chamber can be adjusted to obtain the required 2 °C depression in the center of the standard test pack temperature. The 2 °C temperature depression is the difference in the drain temperature and the center of the standard test pack temperature that is generated by residual air in the chamber. This 2 °C depression in temperature at the beginning of the final one minute of the exposure phase (three and a half min at 134 °C) is the "standard fault condition" as discussed in 5.2.2 and 6.2.2 of this standard. Using a timer, this shortened pre-vacuum phase is accomplished by "trial and error" until the required 2 °C temperature depression is obtained. This residual air is forced into the center of the test pack during the exposure phase of the sterilization cycle.

The steam exposure apparatus used for testing (annex G) is described as a pre-vacuum steam sterilizer used in health care facilities. Health care facilities may or may not have single deep vacuum (high vacuum) sterilizers. However, the test does not necessitate the use of a particular type of pre-vacuum exposure phase. All that is

[2] Bowie, JH., Kelsey, JC. and Thompson, PR. 1963. The Bowie and Dick Autoclave Tape Test. *The Lancet*, 1963, i:586.

[3] Association for the Advancement of Medical Instrumentation. *Good hospital practice: Steam sterilization and sterility assurance.* ANSI/AAMI ST46:1993.

[4] Hart ML. April 16, 1984. "A New Simple Method To Evaluate Bowie-Dick Type Chemical Indicators." 19th Annual Meeting of AAMI.

necessary is the ability to generate the required “standard fault condition” reproducibly and repeatably. Not all pre-vacuum sterilizers will accommodate the adjustments necessary to generate a standard fault condition. For example, some sterilizers do not allow the operator to manually advance to the steam exposure phase without completing the appropriate pre-vacuum phase of the cycle. These sterilizers could not be used to evaluate these indicators.

5.2.1 and 6.2.1 include test temperatures other than 273 °F (134 °C). These test temperatures are for indicator applications in sterilizer cycles outside of the U.S. The only FDA cleared pre-vacuum sterilizer cycle temperature used in U.S. health care facilities is 270° F (132 °C). Sterilizers designed to operate at 250 °F (121 °C), etc. are used outside of the U.S. and because this standard was written as an international standard, it includes cycles that have not been cleared for use in the U.S. Therefore, demonstrated performance at these other cycle temperatures is not appropriate for indicators marketed in the U.S.

Several of the annexes in this standard discuss sample sizes for testing of indicators. These requirements are provided as a guide to be followed for product verification. The requirements must not be understood to be an appropriate sampling plan for product validation. Manufacturers are expected to develop a statistically valid sampling plan consistent with good quality control practices.

Annex J
(informative)

U.S. deviations from ISO/FDIS 11140-5, *Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for air removal test sheets and packs*

General

Changes: References to ISO 11140-1*, Sterilization of health care products—Chemical indicators—Part 1: General requirements*, have been replaced by references to ANSI/AAMI ST60:1996, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, throughout the text.

Rationale: ANSI/AAMI ST60:1996 is the U.S. adoption of ISO 11140-1 with national deviations. See annex A in ANSI/AAMI ST60:1996 for background on the development of the U.S. adoption and rationales for the national deviations.

Title

Change: "Part 5" in the title of ISO/FDIS 11140-5, *Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for air removal test sheets and packs*, has been changed to "Part 2" in ST66:1999. (ISO/FDIS 11140-5 was formerly designated as ISO/FDIS 11140-4, *Sterilization of health care products – Chemical indicators – Part 4: Class 2 indicators for air removal test.)*

Rationale: ANSI/AAMI ST60:1996 represents ISO 11140 Part 1 with national deviations. No American National Standard on chemical indicators representing ISO 11140 Part 2, Part 3, or Part 4 exists or will be adopted by AAMI at this time, as the requirements in those standards are not appropriate for products for use in the United States.

2 Normative references

Changes: The references in this section have been changed from the following:

ISO 11140-1:1995, *Sterilization of health care products—Chemical indicators—Part 1: General requirements.*

ISO 11140-2:1998, *Sterilization of health care products—Chemical indicators—Part 2: Test equipment and methods.*

ISO 11140-3:—[1], *Sterilization of health care products—Chemical indicators—Part 3: Class 2 indicators for steam penetration test sheets.*

ISO 11140-4:—[1], *Sterilization of health care products—Chemical indicators—Part 4: Class 2 indicators for steam penetration test packs.*

IEC 584-2:1982, *Thermocouples—Part 2: Tolerances.*

IEC 751:1983, *Industrial platinum resistance thermometer sensors.*

The references now read:

ANSI/AAMI ST60:1996. *Sterilization of health care products—Chemical indicators—Part 1: General requirements.*

IEC 584-2:1982. *Thermocouples—Part 2: Tolerances.*

IEC 751:1983. *Industrial platinum resistance thermometer sensors.*

Rationale: As the reference to ISO 11140-1 is normative, it is necessary that the U.S. version, designated ANSI/AAMI ST60:1996, be cited. ISO 11140 Part 2, Part 3, and Part 4 are omitted since no Part 2, 3, or 4 has been or will be adopted by AAMI at the present time, as the requirements in those standards are not appropriate for products for use in the United States.

[1] In preparation.

Annex I

Change: Annex I was added to the standard.

Rationale: The committee concluded that a historical perspective would be helpful.