List of Titles

American National Standard

ANSI/AAMI ST60:1996

Sterilization of health care products—Chemical indicators—Part 1: General requirements

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

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ST60 Chemical indicators—Part 1: General requirements

Part 1: General requirements

American National Standard

ANSI/AAMI ST60—1996

Sterilization of health care products—
Chemical indicators—Part 1: General requirements

Approved 12 June 1996 by
Association for the Advancement of Medical Instrumentation

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American National Standards Institute, Inc.

Abstract:

This document specifies requirements for chemical indicators intended for use with sterilization processes employing steam, ethylene oxide, γ or β radiation, or dry heat. Also included are acceptance criteria that can be used to establish an indicator's compliance. This standard is based on the International Organization for Standardization (ISO) standard for chemical indicators (ISO 11140-1:1995) but contains significant national deviations. These deviations are described and explained in annex A.

Keywords

acceptance criteria, dry heat, ethylene oxide, performance requirements, radiation, steam

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.

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

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Virginia C. Chamberlain, PhD

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

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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 Chemical Indicators Working Group wishes to acknowledge the efforts of ISO/TC 198, *Sterilization of health care products*, and ISO/TC 198/WG 6, *Chemical indicators,* in developing the International Standard (ISO 11140-1:1995) from which this American National Standard is derived.

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 with sterilization processes employing steam, ethylene oxide, γ or β radiation, or dry heat. This standard also includes acceptance criteria that can be used to establish an indicator's compliance.

This standard is based on the International Organization for Standardization (ISO) standard for chemical indicators, ISO 11140-1:1995, 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), 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 6 through the U.S. Technical Advisory Group (TAG) for ISO/TC 198. Specific participation on WG 6 was coordinated by the U.S. Sub-TAG for ISO/TC 198/WG 6 (AAMI Chemical Indicators Working Group).

This standard contains significant national deviations from the corresponding ISO standard. These deviations are described and explained in annex A, 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 AAMI standard, *Sterilization of health care products—Chemical indicators—Part 1: General requirements* (AAMI ST60—1996), but it does provide important information about the development and intended use of the document.

Introduction

This American National Standard specifies requirements for chemical indicators intended for use with sterilization processes employing steam, ethylene oxide, γ or β radiation, or dry heat.

Additional requirements for indicators intended for use with other sterilization methods (e.g., other forms of moist heat sterilization) are not specifically provided in this standard, however the general requirements will apply.

The requirements for specific test indicators (e.g., Bowie-Dick test indicators) will be covered in other parts of this American National Standard.

Compliance with the performance requirements given in this document may be established using the test methods and equipment described in part 2 of this standard.2

Sterilization of health care products—Chemical indicators—Part 1: General requirements

1 Scope

1.1 This American National Standard specifies performance requirements for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances.

NOTE—These indicators are used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or are used in specific tests of sterilization equipment.

1.2 This American National Standard also includes acceptance criteria used to establish whether or not an indicator complies with it.

NOTE—Relevant test methods and equipment will be described in part 2 of this standard (in preparation). Until

this document is completed, chemical indicators may be evaluated using equipment complying with ANSI/AAMI ST44—1992, *BIER/EO gas vessels,* and ANSI/AAMI ST45—1992, *BIER/Steam vessels.*

NOTE—Additional requirements for (Class 2) Bowie-Dick test indicators will be given in part 3 of this standard (in preparation).

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this American National Standard. 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 editions of the standards indicated below.

ISO 9001:1994, *Quality systems—Model for quality assurance in design/development, production, installation and servicing.*

ISO 9002:1994, *Quality systems—Model for quality assurance in production and installation.*

AAMI ST59, *Sterilization of health care products—Biological indicators—Part 1: General requirements.*3

AAMI ST21, *Sterilization of health care products—Biological indicators—Part 2: Biological indicators for ethylene oxide sterilization.*

AAMI ST19, *Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization.*

3 Definitions

For the purposes of all parts of this American National Standard, the following definitions apply.

3.1 endpoint: Observable change specified by the manufacturer that occurs after the indicator has been exposed to certain predefined physical conditions.

3.2 indicator: Combination of the indicator agent and its substrate in the form in which it is intended to be used.

NOTE—The different types of indicators are defined in clause 4.

3.3 indicator agent: Active ingredient or combination of ingredients.

3.4 saturated steam: Steam with a dryness value between 0.85 and 1.0 (i.e., a liquid water content not exceeding 15% *(m/m)* and where the temperature corresponds to the vaporization pressure).

3.5 critical parameters: Parameters identified as being essential to the sterilization process.

3.6 stated value: Value or range of values of a critical parameter, to which the indicator is designed to react.

4 Classification of indicators

4.1 Class 1: Process indicators

Process indicators are intended for use with individual units, (e.g., packs, containers) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.

4.2 Class 2: Indicators for use in specific tests

These indicators are designed for use in specific test procedures as defined in relevant sterilizer/sterilization standards.

NOTE—The requirements for specific test indicators (Class 2 indicators) will be provided in other parts of this American National Standard.

4.3 Class 3: Single parameter indicators

A single parameter indicator shall be designed for one of the critical parameters (see 3.5 and 5.1) and shall indicate exposure to a sterilization cycle at a stated value of the chosen parameter.

4.4 Class 4: Multi-parameter indicators

A multi-parameter indicator shall be designed for two or more of the critical parameters (see 3.5 and 5.1) and shall indicate exposure to a sterilization cycle at stated values of the chosen parameters.

4.5 Class 5: Integrating indicators

Integrating indicators are indicators designed to react to all critical parameters over a specified range of sterilization cycles. The stated values are those required to achieve a stated inactivation by referring to a stated test organism with stated D and, if applicable, z values (as described for biological indicators for ethylene oxide sterilization in ANSI/AAMI ST21 and for biological indicators for moist heat sterilization in ANSI/AAMI ST19).

5 General requirements

The requirements given in this clause shall apply to all indicators unless specifically excluded or amended in a subsequent clause or in an additional part of this American National Standard.

5.1 For the different sterilization processes, the following parameters are defined as being critical:

STEAM	Time, temperature, and saturated steam
DRY HEAT	Time and temperature
ETHYLENE OXIDE (EO)	Time, temperature, humidity, and EO concentration
IRRADIATION	Total absorbed dose

NOTE—The inclusion of specifications for radiation chemical indicators in this document is not intended as a recommendation of the use of chemical indicators with radiation sterilization.

NOTE—Other factors can also influence the efficacy of the sterilization process.

5.2 The manufacturer shall establish, document, and maintain a formal quality system.

NOTE—Unless a superseding Good Manufacturing Practice is employed, the quality system should comply with ISO 9001 and/or ISO 9002 to cover all operations required to produce a product conforming with this standard.

5.3 The change that occurs after exposure of the indicator to the specified conditions shall be clearly observable.

5.4 Each indicator shall be clearly marked with the type of sterilization process for which it is intended to be used.

The abbreviated description of the process shall be in accordance with the following:

STEAM	All steam sterilization processes
DRY	All dry heat sterilization processes
EO	All ethylene oxide sterilization processes
IRRAD	All ionizing irradiation sterilization processes

These descriptions are symbols and should not be translated.

Where the size and format of the indicators do not permit this information to be stated, it shall be stated clearly in either a separate instruction or packaging unit.

5.5 If the use of the indicator is limited to specific sterilization cycles, this information shall be stated or coded on the product (e.g., **STEAM** 15 min 121° C).

5.6 Each package of indicators or the technical information leaflet supplied with the package shall state:

a) the change that is intended to occur; and for color change indicators where the color change cannot be adequately described, samples of the expected color range for both changed and unchanged indicators;

b) the critical parameter(s) to which the indicator will respond and, where applicable, their values;

c) the type (classification) of the indicator, stated as process indicator, specific test indicator, single parameter indicator, multi-parameter indicator, or integrating indicator;

d) the storage conditions;

e) the manufacturing date and shelf life or expiry date under the specified storage conditions;

f) a number or code that allows the manufacturing history to be traced;

g) instructions for use essential to ensure proper functioning of the indicator;

h) the name and address of the manufacturer or supplier; and

i) the storage conditions for the indicator after use, if the indicator is intended to be retained as part of a record.

NOTE—Process indicators printed on packaging material or presented as self-adhesive labels, packaging tapes, tags, insert labels, etc., are exempt from the requirements of subclause 5.6.

5.7 The manufacturer shall retain documentary evidence that the indicator does not release any substance known to be toxic in sufficient quantities to cause either a health hazard or a deleterious effect to the intended properties of the product being sterilized, before, during, or after the sterilization process for which it is designated.

5.8 The endpoint condition of an indicator that has been exposed to a sterilization process during which all the values of critical parameters required to produce an endpoint reaction were met or exceeded shall not change to an extent that could lead to an interpretation other than that apparent on removal from the sterilizer when stored as specified by the manufacturer for up to 6 months.

Incompletely changed indicators can deteriorate on storage, either returning to the unchanged conditions or slowly changing to the defined endpoint condition. If such deterioration can occur, this information should be stated in the technical information supplied by the manufacturer. Such indicators might not be suitable for use as permanent records.

6 Additional requirements for process (Class 1) indicators

NOTE—Process indicators may be printed on packaging material or presented as self-adhesive labels, packaging, tapes, tags, insert labels, etc.

6.1 Process indicators for steam sterilization

6.1.1 After exposure to a previously stabilized condition of dry heat at 140° C ± 2° C for 30 min ± 1 min, the indicator shall show either no change or a change that is markedly different from the change occurring after exposure to the relevant steam sterilization process.

6.1.2 The endpoint indicating exposure to a steam sterilization process shall not occur until the indicator has been exposed to saturated steam for not less than 2 min at 121° C +3/–0° C or for 20 s at 134° C +3/–0° C.

6.1.3 The indicator shall provide clear visual evidence of exposure to the process after being subjected to saturated steam for not more than 10 min at 121° C +3/–0° C, and not more than 2 min at 134° C +3/–0° C.

6.2 Process indicators for dry heat sterilization

6.2.1 The endpoint indicating exposure to a dry heat sterilization process shall not occur until the indicator has been exposed to a previously stabilized condition of 160° C +5/–0° C for not less than 20 min.

6.2.2 The endpoint indicating exposure to a dry heat sterilization process shall occur when the indicator has been exposed to a previously stabilized condition of 160° C +5/–0° C for a time not exceeding 40 min.

6.3 Process indicators for ethylene oxide sterilization

6.3.1 After exposure to 60° C ± 2° C at greater than 85% relative humidity (RH) for not less than 90 min, the indicator shall show either no change or a change that is markedly different from the change occurring after exposure to the relevant ethylene oxide sterilization process.

This test is done without ethylene oxide being present and therefore should not be carried out in an ethylene oxide sterilizer where traces of the gas could be present.

6.3.2 The endpoint indicating exposure to an ethylene oxide sterilization process shall not occur until the indicator has been exposed to (600 ± 30) mg/l ethylene oxide and (60 ± 10) % RH at 30° C ± 1° C for not less than 5 min.

6.3.3 The endpoint indicating exposure to an ethylene oxide sterilization process shall occur when the indicator has been exposed to (600 ± 30) mg/l ethylene oxide and (60 ± 10) % RH at 30° C ± 1° C for a period not exceeding 30 min.

The reaction of some ethylene oxide indicators can be impaired by the presence of diluent gases, such as carbon dioxide. In formulations where this can occur, the indicator should be tested in ethylene oxide with the diluent gas.

6.4 Process indicators for ionizing irradiation sterilization

6.4.1 The endpoint indicating exposure to an irradiation sterilization process shall not occur until the indicator has been exposed to an absorbed dose of at least 1 kGy.

6.4.2 The indicator shall show clear visual evidence of exposure to the process after being subjected to an absorbed dose not exceeding 5 kGy.

7 Additional requirements for single parameter (Class 3) indicators

7.1 Single parameter indicators shall be designed for one of the critical parameters listed in 5.1.

7.2 Single parameter indicators shall undergo a clearly detectable change indicating exposure to a sterilization cycle defined at a given value within the relevant tolerances listed in table 1.

7.3 The defined parameter shall be identified or coded on the product.

7.4 The stated value at which the indicator reaches its endpoint shall be identified or coded on the product.

8 Additional requirements for multi-parameter (Class 4) indicators

8.1 Multi-parameter indicators shall be designed for two or more of the critical parameters which affect the efficacy of the sterilization process to be monitored.

8.2 Multi-parameter indicators shall undergo a clearly detectable change indicating exposure to a sterilization cycle at defined parameters within the relevant tolerances listed in table 1.

8.3 The defined parameters shall be identified or coded on the indicator.

8.4 The stated values at which the indicator reaches its endpoint shall be identified or coded on the product.

9 Additional requirements for integrating (Class 5) indicators

9.1 Integrating indicators shall undergo a clearly detectable change indicating exposure to a sterilization cycle at defined parameters within the relevant tolerances given in table 2.

9.2 The stated values shall be identified or coded on the product.

9.3 The exposure required to effect the change in the indicator shall be related to the inactivation of a stated microorganism with stated D and z values (see 4.5). These values shall be not less than those specified in ANSI/AAMI ST19 or ANSI/AAMI ST21, as appropriate for biological indicators for use in routine monitoring of the relevant sterilization process. The inactivation of the microorganism shall be stated as the fractional reduction in the population, expressed as the $\log_{10}$.

TABLE 1— Tolerances and limiting values for the response to critical parameters for Class 3 and Class 4 indicators

Sterilization method	**Time**	**Temperature**	**Gas concentration**	**RH**	**Saturation**	
				Limiting values	Limiting values	
	min.	°C	mg/l	%	LL[1)]	UL[2)]
Steam	sv[3)] +0/-25%	sv +0/-2° C			0.85	1.0
Dry heat	sv +0/-25%	sv +0/-5° C				
Ethylene oxide	sv +0/-25%	sv +0/-5° C	sv +0/-25%	> 30%		

[1)] LL = lower limit (dryness value)

[2)] UL = upper limit (dryness value)

[3)] sv = stated value: reaction value identified for the product with respect to a critical parameter; it is either stated or coded on the product.

TABLE 2—Tolerances and limiting values for the response to critical parameters for Class 5 indicators

Sterilization method	Time	Temperature	Gas concentration	RH	Saturation	
				Limiting values	Limiting values	
	min.	°C	mg/l	%	LL[1]	UL[2]
Steam	sv[3] +0/-15%	sv +0/-1° C			0.85	1.0
Dry heat	sv +0/-20%	sv +0/-5° C				
Ethylene oxide	sv +0/-20%	sv +0/-5° C	sv +0/-15%	> 30%		

[1] LL = lower limit (dryness value)

[2] UL = upper limit (dryness value)

[3] sv = stated value: reaction value identified for the product with respect to a critical parameter; it is either stated or coded on the product.

10 Examples of multi-parameter indicators

Some examples of multi-parameter indicators are given below.

EXAMPLE 1

Steam sterilization indicator (Class 4: Multi-parameter indicator [see 4.4])

Stated values: 3.5 min at 134° C (See 8.3)

Table 1 provides the tolerances and limiting values for this Class 4 indicator. The tolerances from this table are 3.5 +0/-25% min and 134 +0/-2° C when tested in a saturated steam condition with a dryness value between 0.85–1.0. Therefore, to reach its endpoint, the time needed shall be at least 2.7 min [i.e., 3.5-(3.5 x 0.25)] with a temperature of 132° C, [i.e., (134-2)] and a dryness value between 0.85 and 1.0. Any time shorter than 2.7 min and any temperature below 132° C must not result in the indicator reaching its endpoint. If the time is 3.5 min or longer, the temperature is 134° C or higher and the dryness value is between 0.85 and 1.0, the indicator must reach its endpoint.

An indicator with the above stated values will respond as follows when exposed to the conditions below:

Exposed to the following conditions	Based on table 1 an acceptable indicator
2.6 min @ 131° C*	must show fail
2.6 min @ 132° C	will show pass or fail
2.7 min @ 131° C	will show pass or fail
3.5 min @ 134° C**	must show pass

* or if either one or both are below these values

** or if either one or both are above these values

EXAMPLE 2

Steam sterilization indicator (Class 4: Multi-parameter indicator [Section 4.4])

Stated values: 15 min at 121° C, saturated steam (see Section 8.3)

Table 1 provides the tolerances and limiting values for this Class 4 indicator. The tolerances from this table are 15 +0/-25% min and 121 +0/-2° C when tested in a saturated steam condition with a dryness value between 0.85–1.0. Therefore, the indicator requires steam with a dryness value between 0.85 and 1.0 for at least 11.3 min [i.e.,15–(15 x 0.25)] at a temperature of 119° C [i.e., (121-2)] or higher to reach its endpoint. The indicator must reach its endpoint if the time is 15 min or longer and the temperature is 121° C or higher and the dryness value is between 0.85 and 1.0.

An indicator with the above stated values will respond as follows when exposed to the conditions below:

Exposed to the following conditions	Based on table 1 an acceptable indicator
11.2 min @ 118° C*	must show fail
11.2 min @ 119° C	will show pass or fail
11.3 min @ 118° C	will show pass or fail
15 min @ 121° C**	must show pass

* or if either one or both are below these values

** or if either one or both are above these values

EXAMPLE 3

Ethylene oxide sterilization indicator (Class 4: Multi-parameter indicator [see 4.4])

Stated values: 60 min at 900 mg/l (see Section 8.3).

Table 1 provides the tolerances and limiting values for this Class 4 indicator. The tolerances from this table are 60 +0/-25% min and 900 +0/-25% mg/l when tested at a relative humidity > 30%. Therefore, the indicator will not reach its endpoint if the time is less than 45 min [i.e., 60-(60 x 0.25)], the gas concentration is less than 675 mg/l [i.e., 900-(900 x 0.25)] and the relative humidity is greater than 30%. If the time is 60 min or longer, and the EO concentration is 900 mg/l or higher and the relative humidity is greater than 30%, the indicator must reach its endpoint.

An indicator with the above stated values will respond as follows when exposed to the conditions below:

Exposed to the following conditions	Based on table 1 an acceptable indicator
44 min @ 650 mg/l*	must show fail
44 min @ 675 mg/l	will show pass or fail
45 min @ 650 mg/l	will show pass or fail
60 min @ 900 mg/l**	must show pass

* or if either one or both are below these values

** or if either one or both are above these values

Annex A
(informative)

Background of the development of ANSI/AAMI ST60 and rationale for national deviations

A.1 Background on development of the International Standard on chemical indicators

In 1995, the International Organization for Standardization (ISO) published ISO 11140-1:1995, *Sterilization of health care products—Chemical indicators—Part 1: General requirements.* This document was developed by Working Group 6, *Chemical indicators,* of Technical Committee 198, *Sterilization of health care products*.

As of 1996, ISO/TC 198 intended to develop other parts of ISO 11140-1:1995, including:

Part 2—*Test methods and equipment*

Part 3—*Steam penetration test—User assembled and pre-assembled test packs*

Part 4—*Indicators for air removal test*

A.2 Consideration of the International Standards on chemical indicators for adoption as American National Standards

Following the completion of ISO 11140-1:1995, the AAMI Chemical Indicators Working Group agreed, in the interests of international harmonization, to consider adoption of the International Standard as a proposed American National Standard. At a meeting of the working group held in January 1995, it was agreed that the document as approved by ISO/TC 198 would require extensive modifications before it would be acceptable as an American National Standard.

At the January and June 1995 meetings of the AAMI Chemical Indicators Working Group, the text of ISO 11140-1:1995 was reviewed and modified. An informative annex was also added to describe the substantive differences between ISO 11140-1:1995 and ANSI/AAMI ST60.

A.3 Specific national deviations from ISO 11140-1:1995

This subclause describes and explains the specific differences between the American National Standard ANSI/AAMI ST60 and the International Standard ISO 11140-1:1995.

A.3.1 Exclusion of references to steam-formaldehyde chemical indicators from ANSI/AAMI ST60

Changes: ISO 11140-1:1995 includes requirements for chemical indicators used in conjunction with low-temperature steam-formaldehyde sterilization processes.

All references and requirements for this type of chemical indicator have been deleted from ANSI/AAMI ST60.

Rationale: Steam-formaldehyde sterilization processes are extremely uncommon in the United States and such indicators are not known to be marketed in this country. Therefore it was not appropriate to provide requirements for such indicators in the American National Standard.

A.3.2 Exclusion of references to emulating chemical indicators from ANSI/AAMI ST60

Changes: ISO 11140-1:1995 contains requirements for a category of indicators labeled "emulating" indicators. ISO 11140-1:1995 describes these indicators as being "designed to react to all critical parameters over a specified range of sterilization cycles, for which the stated values are based on the settings of the selected sterilization cycles" (ISO 11140-1:1995, subclause 4.6). In this American National Standard, ANSI/AAMI ST60, all requirements and references to emulating indicators have been deleted.

Rationale: Such indicators were not known to be marketed at the time of publication of the standard. It was not appropriate to provide requirements for a category of chemical indicators that did not exist when the standard was developed.

A.3.3 Changes to the normative references

Changes: ISO 11140-1:1995 makes normative reference to the ISO 11138 series on biological indicators. In the American National Standard ANSI/AAMI ST60, all references to these two International Standards have been changed to specify the American National Standard versions. The references to ISO 11138-1, ISO 11138-2 and ISO 11138-3 in the Normative References section have also been replaced with references to ANSI/AAMI ST59, ANSI/AAMI ST21 and ANSI/AAMI ST19.

Rationale: When adopting the ISO 11138 series as American National Standards, minor but significant national deviations are being incorporated into the standards. As the references to these standards in ANSI/AAMI ST60 are normative, it was necessary that the U.S. versions be cited.

A.3.4 Inclusion of a note on radiation sterilization under subclause 5.1

Change: A note has been added under 5.1 to clarify that the inclusion of requirements for chemical indicators in ANSI/AAMI ST60 was not intended as a recommendation that chemical indicators be used in conjunction with radiation sterilization.

Rationale: The American National Standard for radiation sterilization of health care products (ANSI/AAMI/ISO 11137-1994) requires the use of dosimeters for monitoring radiation sterilization and states that "[r]adiation sensitive visual indicators shall not be used as proof of satisfactory radiation processing or as the sole means of differentiating irradiated products from non-radiated products" (ANSI/AAMI/ISO 11137, subclause 7.3). The clarifying note was added to ANSI/AAMI ST60 to prevent readers from misinterpreting AAMI's position in this regard.

A.3.5 Changes to clause 5.2 to allow the use of superseding GMPs in place of ISO 9001 and/or ISO 9002

Changes: The text of 5.2 (as it appears in ISO 11140-1:1995) was deleted beginning with "in accordance with ISO 9001 and/or ISO 9002..." and was replaced by the following note:

NOTE—Unless superseding GMPs are employed, the quality system should comply with ISO 9001 and/or ISO 9002 to cover all operations required to produce a product conforming with this standard.

Rationale: In cases where manufacturers are required by law to comply with mandated GMPs, it is not appropriate to require conformance with ISO 9001 or ISO 9002.

A.3.6 Deletion of the requirement that dates be formatted in accordance with ISO 8601

Changes: ISO 11140-1:1995 requires (in 5.6[e]) that manufacturing dates, shelf life dates, or expiry dates on each package or technical information leaflet be formatted in accordance with ISO 8601 (i.e., YYYY-MM-DD). This requirement has been deleted from the American National Standard, ANSI/AAMI ST60, and the reference to ISO 8601 appearing in the Normative references has also been deleted.

Rationale: This format is not widely used in the United States and might confuse some users of chemical indicators.

A.3.7 Deletion of items under subclause 5.6

Changes: ISO 11140-1:1995 requires that the following items be included on each package of indicators or technical information leaflet:

"h) any interfering substances or conditions that are likely to be encountered or to occur during the intended use of the indicator and which are known to adversely affect the performance of the indicator;

i) any additional safety precautions required during and/or after use;"

.....

l) the nature of any change that can occur when completely/incompletely changed indicators are stored according to the manufacturer's instructions; and

m) the interaction between responses to the critical parameters detected, if any.

These items have been deleted from ANSI/AAMI ST60.

Rationale: The above requirements are ambiguous or vague; either it is not clear exactly what information is expected or the requirements are already covered under other items. For item [h], the number of substances of concern could be almost infinite. Item [i] is subsumed by item [k] in ISO 11140-1:1995 (item [i] in ANSI/AAMI ST60). Item [l] is covered by item [d] and the AAMI Chemical Indicators Working Group does not understand the intent of item [m].

A.3.8 Exemption of indicators printed on packaging materials from clause 5.6

Changes: A note was added to 5.6 of ANSI/AAMI ST60 to exempt process indicators printed on packaging labels, packaging tape, tags, insert labels, etc., from the requirements of this clause.

Rationale: It is not practical for chemical indicators printed on packaging labels, tape, tags, or labels to include the extensive information required under 5.6.

A.3.9 Revision of requirements for steam sterilization process indicators in subclause 6.1.2

Changes: Subclause 6.1.2 of ISO 11140-1:1995 requires that, for process indicators for steam sterilization, the endpoint indicating exposure shall not occur until the indicator has been exposed to saturated steam for not less than 3 min at 121° C +3/-0° C or for 30 sec at 134° C +3/-0° C. In ANSI/AAMI ST60, this has been changed to not less than 2 min at 121° C +3/-0° C or for 20 s at 134° C +3/-0° C.

Rationale: The revised requirements are adequate for the intended use of Class 1 process indicators.

A.3.10 Deletion of requirements for resistance of radiation indicators to ultraviolet light given in 6.4.1

Changes: Subclause 6.4.1 of ISO standard 11140-1, which reads as given below, has been deleted from the American National Standard:

6.4.1 After exposure to ultraviolet light (235-280 nm) with a surface intensity of not less than 3.3 W/m2 for not less than 120 min, the indicator shall show either no change or a change that is markedly different from the change occurring after exposure to an ionizing radiation sterilization process.

Rationale: While many indicators of this class are susceptible to premature change when exposed to sunlight or certain artificial light sources, the wavelengths specified in clause 6.4.1 of ISO 11140-1:1995 are not a factor at the surface of the earth. Those wavelengths are absorbed by the atmosphere. As the manufacturer is required to specify storage conditions in 5.6, item [d], this additional requirement is not necessary.

A.3.11 Deletion of additional labeling requirement for integrating indicators in clause 9.4

Changes: Subclause 9.4 from ISO 11140-1:1995, which reads as given below, has been deleted from the American National Standard.

9.4 The manufacturer shall state clearly any factors of which he is aware that can adversely affect the efficacy of the sterilization process but which are not detected by the indicator, or not detected in a manner that will give assurance of satisfactory attainment of that critical parameter or attribute.

NOTE 8 An example of such a statement is as follows.
"This indicator will not react in the absence of water vapor, but a successful indicator reaction does not necessarily indicate the presence of optimal levels of moisture. This should be verified by other means."

Rationale: An integrating indicator's performance is intended to be comparable to a biological indicator, but no similar requirement is given for biological indicator labeling in the ISO or AAMI biological indicator standards.

A.3.12 Revision of examples for multi-parameter indicators

Changes: The examples for multi-parameter indicators appearing in ISO 11140-1:1995 have been revised.

Rationale: The examples appearing in ISO 11140-1:1995 need additional clarification and the explanation of example 2 from ISO 11140-1:1995 contains a mathematical error. The revisions given in the American National Standard expand and correct the ISO examples and are intended to clarify the intent of table 1.

A.3.13 Minor or editorial changes

3.5 Critical parameters: The parenthetical phrase "and requiring monitoring" was considered extraneous and was deleted.

Clause 5.7: The second occurrence of "hazard" in the clause was replaced with "deleterious effect" as this is more appropriate wording.

The sentence "In the absence of relevant International Standards, regional or national requirements shall apply" has also been deleted. Because this is a national standard, national requirements will automatically apply.

Clause 6.1.1: The word "relevant" has been added before "steam sterilization" because the endpoint resulting from the intended sterilization process is what is important.

Clause 6.1.3: The word "dry" has been deleted before "saturated steam" because the dryness value of saturated steam is given in definition 3.4.

Clause 6.3.1: The word "relevant" has been added before "ethylene oxide" because the endpoint resulting from the intended sterilization process is what is important.

Clause 6.3.3: The text of the second paragraph of 6.3.3 has been revised because the gas mixture specified by ISO 11140-1:1995 might not be the most appropriate for testing potential impairment of ethylene oxide indicator performance.

Clause 9.3: The first occurrence of the word "theoretical" has been replaced by "stated"; the second occurrence has been deleted. The performance of an integrating indicator is correlated with a "stated" biological indicator rather than a theoretical one.

A.3.14 Other changes

Other minor national deviations were necessary to conform with U.S. spelling and usage. This informative annex (Annex A) was also added to identify the substantive differences between the ISO standard and the American National Standard and to provide rationale for these changes.

A.4 Harmonization of ANSI/AAMI ST60 and ISO 11140-1:1995

The AAMI Sterilization Standards Committee and the AAMI Chemical Indicators Working Group believe that ANSI/AAMI ST60 and ISO 11140-1:1995 are compatible but do contain substantive differences. It can not be assumed that chemical indicators complying with the requirements of this American National Standard will automatically comply with the requirements of the International Standard, or visa versa.

Annotations from ST60.pdf

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2 In preparation. Until the test methods and equipment document (part 2) is completed, chemical indicators may be evaluated using equipment complying with ANSI/AAMI ST44—1993, BIER/EO gas vessels, and
ANSI/AAMI ST45—1992, BIER/Steam vessels.

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Annotation 1; Label: AAMI; Date: 10/05/2000 8:06:41 AM
3 In preparation.