

Steam Chemical Indicator Classifications

Background:

In 1996, the Association for the Advancement of Medical Instrumentation published the American National Standard: *Sterilization of health care products—Chemical indicators—Part 1: General requirements (ANSI/AAMI ST60)*. This document specifies requirements for Chemical Indicators intended for use with sterilization processes. The standard also includes general performance requirements that a Chemical Indicator must meet to establish its Chemical Indicator classification. This standard was based on the International Organization for Standardization (ISO) standard for Chemical Indicators (ISO 11140-1:1995 Sterilization of healthcare products—Chemical indicators—Part 1:General requirements) but with significant US deviations.

In 2005, this ISO 11140-1 standard was updated and the AAMI organization has approved this standard without US deviations. The new document is: ANSI/AAMI/ISO 11140-1, 2005 Sterilization of health care products – Chemical indicators – Part 1: General requirements. The major changes are that the Class 5 Integrating Indicator requirements were upgraded and an additional class of Chemical Indicators, Class 6 Emulating Indicators, was added to the AAMI standard.

Key Learnings:

For Steam Chemical Indicators;

- In ANSI/AMMI/ISO 11140-1: 2005, Class 5 Integrating Indicator performance requirements were strengthened to ensure performance is comparable to Biological Indicators in saturated steam. As a result, Class 5 Integrating Indicators are the most accurate of the internal Chemical Indicator classes when compared to the performance of Biological Indicators
- Class 6 Emulating Indicators are now a recognized Chemical Indicator classification in ANSI/AAMI/ISO 11140-1, 2005 Sterilization of health care products—Chemical indicators—Part 1: General requirements
- **Classes have no hierarchical significance.** Each class has its own characteristics and intended use
- Your choice of Chemical Indicator class should be based on the information you need about a particular sterilization process

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Steam Chemical Indicators Defined:

The ANSI/AAMI/ISO 11140-1:2005 document defines six classes of Chemical Indicators (**see table on last page**)

“...The chemical indicators described in this part of the ISO 11140 document are classified into six groups. The chemical indicators within each of these classifications are further subdivided by the sterilization process for which they are designed to be used. The classification structure used is solely to denote the characteristics and intended use of each type of indicator as defined by the manufacturer. **The classification has no hierarchical significance.**” (*emphasis added*)

This means the class number is not as important as the information provided by the Chemical Indicators in that class. The class number does not mean that one class is necessarily better or measures more parameters of the sterilization process than another class. Class 2 Chemical Indicators probably provide the most information about the sterilization process. Class 3 indicators are not necessarily better than Class 2 indicators, Class 6 indicators are not necessarily better than Class 4, and so on. In addition, a Chemical Indicator should only be labeled as complying with one Class because the required performance characteristics of the classes are distinctly different. It is important to understand the classes of Chemical Indicators so that you can choose the correct Chemical Indicator for the sterilization process being monitored. Your choice should be based on the information you need about a particular sterilization process.

Summary:

What do the Chemical Indicator classifications mean to the end user? Chemical Indicator classifications enable the end user to understand performance parameters and tolerances of various Chemical Indicators. The appropriate Chemical Indicator can then be used to obtain the information needed to determine the effectiveness of the sterilization process.

The ANSI/AAMI/ISO 11140-1:2005
is available from AAMI
at www.aami.com
or by calling 1-877-249-8226

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Steam Chemical Indicator Classes Defined:

Class	ANSI/AAMI/ISO 11140-1: 2005 Definition*	Practical Application
Class 1: Process Indicators	“Process indicators are intended for use with individual units, (e.g., packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units. They shall be designed to react to one or more of the critical process variables.”	Indicator tapes, indicator labels, and load cards are examples of externally visible Chemical Indicators that are Process Indicators used for exposure control.
Class 2: Indicators for use in Specific Tests	“Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer/sterilization standards.”	Bowie-Dick type tests are specific tests used for equipment control to evaluate the sterilizer performance.
Class 3: Single Variable Indicators	“A single variable indicator shall be designed to react to one of the critical variables and is intended to indicate exposure to a sterilization process at a stated value (SV) of the chosen variable.”	An example of a Single Variable Indicator is a temperature tube that contains a chemical pellet that melts at a specific temperature. Single variable indicators may be used for pack control monitoring but would not provide as much information as a Class 4 or Class 5 Chemical Indicator. Single Variable Indicators may also be used for exposure control monitoring. This temperature tube would be used to determine that a specific temperature was reached at a specific location in the sterilizer chamber.
Class 4: Multi-variable Indicators	“A multi-variable indicator shall be designed to react to two or more of the critical variables and is intended to indicate exposure to a sterilization cycle at SVs of the chosen variable.”	Multi-variable Chemical Indicators are used for pack control. These internal Chemical Indicators are usually paper strips printed with a Chemical Indicator.
Class 5: Integrating Indicators	“Integrating indicators shall be designed to react to all critical variables. The SVs are generated to be equivalent to, or exceed the performance requirements given in the ISO 11138 series for BIs.”	Integrating Indicators are the most accurate of the internal Chemical Indicators. Integrating Indicators are used for pack control monitoring. They can also be used as an additional monitoring tool to release loads that do not contain implants. For this additional monitoring the Class 5 Integrating Indicator must be used in the appropriate challenge test pack or Process Challenge Device (PCD). These indicators must now have SVs at 121°C/250°F, 135°C/276°F, and at least one more temperature in between. Also, the SV at 121°C MUST be greater than 16.5 minutes to ensure performance is comparable to BIs in saturated steam.
Class 6: Emulating Indicators	“Emulating indicators are cycle verification indicators which shall be designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilization process.”	Emulating Indicators can be used as internal Chemical Indicators for pack control. Emulating Indicators are specified for specific sterilization cycles which means an end user will need to inventory a different Class 6 Emulating Indicator for each sterilization cycle time and temperature (i.e., 3 min, 5 min, 10 min, 18 min, 40 min, etc.) run in the facility. The response of a Class 6 Emulating Indicator does not necessarily correlate to a Biological Indicator so the indicator cannot be used as an additional monitoring tool to release loads that do not contain implants. (See Class 5 definition) The use of Class 6 Emulating Indicators is presently not covered in any AAMI health-care facilities user documents.

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