What’s your type? Changes in chemical indicator categorization

by Susan Flynn, BESC CSPDT

As the aphorism goes, the only constant is change, and the field of sterile processing is certainly no exception. This self-study article is written to provide the reader with a heads-up about a change in the name of the categories used to describe chemical indicators. The International Standards Organization published a revised version of ISO-11140-1, Sterilization of health care products – Chemical indicators-Part 1: General requirements in late 2014. This document was subsequently adopted by the Association for the Advancement of Medical Instrumentation (AAMI) and approved as an American National Standard, ANSI/AAMI/ISO 11140-1:2014, replacing ANSI/AAMI ISO 11140-1:2005. Chemical indicator manufacturers wishing to sell product complying with the performance, testing, and labeling requirements specified in this revised standard will begin to offer “types,” rather than “classes” of chemical indicators. End-user guidance on the use and application of chemical indicators has not changed.

Background
Sterile Processing staff understand they play a critical role in their facility’s infection prevention program by ensuring the sterility of reprocessed medical devices. A variety of monitoring tools, including chemical, physical, and biological indicators, are used as part of an effective quality assurance program to determine whether to release a sterilized load. This article focuses on one of these tools, chemical indicators (CIs). ANSI/AAMI ST79 defines CIs as “devices 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 End-users rely on CIs for three main applications: special tests; exposure indicators; and internal indicators. Special test chemical indicators are designed for use in specific tests and/or procedures, such as the Bowie-Dick test. Exposure chemical indicators allow staff to distinguish between processed and unprocessed items at a glance. Internal chemical indicators verify sterilant has penetrated to the point of placement inside containers, wrapped packs or peel pouches. ANSI/AAMI/ISO 11140-1:2014 specifies the requirements and test methods “for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor the attainment of one or more of the process parameter(s) specified for a sterilization process.”2 The standard reminds the reader that, “Attainment of the chemical indicator’s end point should not be regarded as an indication of attainment of an acceptable sterility assurance level, but rather one of many factors which should be taken into consideration when judging the acceptability of a sterilization process.”3

While the new CI standard “specifies performance requirements and/or test methods for chemical indicators intended for use with sterilization processes employing steam, dry heat, ethylene oxide, γ or β radiation, low temperature steam and formaldehyde or vaporized hydrogen peroxide,” this article will focus only on CIs for those processes commonly used in U.S. healthcare facilities. Requirements for Type 2 indicators for specific tests (e.g., Bowie-Dick tests) are covered in other parts of ANSI/AAMI/ISO 11140 and therefore are also not discussed in this article.

Key changes
ISO 11140-1:2014 continues to categorize CIs into six types. A key change in the 2014 version of the standard is the use of the term “type” rather than the term “class.” The categorization structure is used solely to denote the characteristics and intended use of each type of indicator when used as specified by the manufacturer. The standard emphasizes that the categorization has no hierarchical significance, in other words, a larger number does not mean a better indicator. For example, internal CIs (Types 3, 4, 5, and 6) are not better than a Type 2 Bowie-Dick test, they simply have a different intended use. Similarly, Type 6 emulating indicators are not better at monitoring the sterilization process than Type 5 integrating indicators, etc.

Key nomenclature changes in the 2014 version of the standard include:

- Replacement of the term “class” with the term “type” to describe the use of indicators according to their intended use;
- The availability of “optional”, additional prefixes to these six indicator categories, as follows:
  - e = “Exposure” or process indicator (e.g., Tape, see Figure 1, next page)
users need to select a product that is appropriate for the method of sterilization they wish to monitor. When labeling chemical indicators, ANSI/AAMI/ISO 11140-1:2014 provides manufacturers with symbols to be used as abbreviated descriptions of the various sterilization modalities. These symbols help end-users to know at a glance for which sterilization modality a particular chemical indicator is designed. Symbols for the methods of sterilization commonly used in U.S. healthcare facilities, and that you may see on chemical indicators and/or their packaging, include:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEAM</td>
<td>Steam sterilization</td>
</tr>
<tr>
<td>EO</td>
<td>Ethylene oxide sterilization</td>
</tr>
<tr>
<td>VH202</td>
<td>Vaporized hydrogen peroxide sterilization</td>
</tr>
</tbody>
</table>

Another key change in ISO 11140-1:2014 were changes to the performance requirements for Type 1 indicators for steam, ethylene oxide (EO), and vaporized hydrogen peroxide processes; and to the performance requirements for Type 5 integrating indicators for steam processes and EO processes.

To better understand these changes, let’s review a few key definitions.

- **Critical process variable**: “variable identified as being essential to the attainment of sterilization and monitored by the chemical indicator.” The standard defines which process variables are critical for different sterilization processes. For example, time, temperature, which the indicator is exposed to dry heat for a specified period of time without reaching its endpoint, to ensure that the indicator requires the presence of steam in order to respond. • **Endpoint**: “point of the observed change defined by the manufacturer, occurring after the indicator has been exposed to specified stated values.” Some chemical indicators have an endpoint described by a visual change, typically changing from Color A to a distinctly different Color B (e.g., yellow to black). Other chemical indicators have a graduated response, for example moving front chemical integrators which show a progressive observable change towards a pass or accept region upon exposure to critical process variables (see picture above).

- **Resistometer**: a specialized test vessel capable of reproducible cycles and used by manufacturers to characterize the performance of chemical indicators, with the exception of Type 2 indicators. The standard states, “Resistometers allow for precise specification and control of the specific test conditions and cycle sequences in order to produce controlled, repeatable studies of the effect of process parameters on indicators. Resistometers differ from conventional sterilizers; therefore, if conventional sterilizers are used to attempt to duplicate resistometer conditions, erroneous and/or misleading results can occur.”

- **Stated value (SV)**: “value or values of a critical process variable at which the indicator is designed to reach its endpoint as defined by the manufacturer.” For Type 3, 4, 5 and 6 indicators, the standard states that each indicator (or the product label or instructions for use (IFU)) shall be clearly marked with the SVs.

**Type 5 integrating indicators for steam sterilization**

Sterile processing personnel find Type 5 steam integrating indicators particularly relevant and convenient for several reasons, including:

- they are the only type of chemical indicator that are designed to react to all critical process variables and for which the stated values are generated to be equivalent to, or exceed, the performance requirements for biological indicators;
- they can be used to monitor a variety of steam sterilization cycles over the entire range of temperatures used in health care facilities.

This is because Type 5 indicators have and are required to be tested at three stated values, 121°C (250°F) and 135°C (275°F) and at one or more equally spaced temperature points in between. Having these three stated values demonstrate how this CI integrates over the temperature range. Manufacturers document the performance of Type 5 indicators in a resistometer at the three stated values (at each of which the indicator should reach its endpoint) and at a second set of test points having a temperature 1°C lower and an exposure time 15 percent shorter. At these second test points, the indicator should not reach its endpoint. The revised standard moved this second or failing test point closer to the stated values.

In addition, the stated value for Type 5 integrating indicators for steam must be greater than 16.5 minutes at 121°C/250°F and greater than 1.2 minutes at 135°C (275°F). As explained in Annex C of ISO 11140-1, these minimum times link the performance of Type 5 integrating indicators to the minimum requirements for a biological indicator for moist heat sterilization as defined in ISO 11138-3.

**Chemical indicators for ethylene oxide (EO) sterilization processes**

The test and performance requirements for two types of CIs for EO were changed. Type 1 process indicators for EO are tested at a warm and a cool temperature. The 54°C test temperature remains unchanged while the lower test temperature was changed from 30°C to 37°C. Type 5 integrating indicators for EO processes are tested at the same two temperatures, 37°C and 54°C. As with steam integrating indicators, the test time at which the Type 5 integrating indicators for EO should not reach their endpoint was also moved closer to the stated values.

**Chemical indicators for vaporized hydrogen peroxide sterilization processes**

The requirement to test Type 1 process indicators designed for the vaporized hydrogen peroxide sterilization processes at 27°C was removed in the new version of the standard. Testing is now done only at 50°C, closer to the

![Figure 1: Wrapped pack with steam indicator tape indicating exposure to the sterilization process](https://example.com/figure1.png)
What to expect

Chemical indicator manufacturers will begin transitioning their products’ standard compliance claims and labeling from satisfying the 2005 to the 2014 version of the ANSI/AAMI/ISO 11140 standard. For those types of chemical indicators having new performance requirements and/or test methods, the first step will be to test products to substantiate compliance with the new requirements. The next step will be updating graphics on the actual devices, IFU, packaging and labeling to reflect the new term ‘type.’ Products that are sold globally often have multi-lingual packaging and labeling which will add complexity and time to this relabeling step.

Later this year, sterile processing personnel may begin to receive chemical indicators labeled as ‘Type X,’ rather than as ‘Class X.’ These CIs may also be marked with the letter ‘e,’ ‘s,’ or ‘i’ to signify the product’s intended use. This new labeling will indicate that the product satisfies the performance requirements specified in the current version of ANSI/AAMI/ISO 11140-1.

In the future we can also expect to see the terminology from this new ISO 11140-1:2014 standard incorporated into applicable healthcare user documents, for example in ANSI/AAMI ST79, as those documents are updated.

Summary

Chemical indicator categories are designed to enable the user to understand the performance parameters and tolerances of various types (formerly known as classes) of chemical indicators. The appropriate chemical indicator can then be selected and used to obtain the information needed to determine the effectiveness of the sterilization process. ISO has revised the international document detailing the general requirements for performance of chemical indicators. The revised document adopted the new term “type” rather than “class” of indicator in order to emphasize that the six categories of chemical indicators are not hierarchical.

AAMI and Association for PeriOperative Registered Nurses (AORN) guidance documents on the use and application of chemical indicators have not changed. At this time, their recommended practices have not yet incorporated use of the new term “type” of chemical indicators. What does this mean to you? During the transition phase, sterile processing personnel will observe some chemical indicators labeled by the new categorization term, “type” while AAMI and AORN recommended practices continue to reference the older term, “class.” Don’t be alarmed! Continue to choose the chemical indicator type (a.k.a. “class”) based on the information you need about a particular sterilization process. The industry will get through this transition together!

What’s your type? Changes in chemical indicator categorization

Circle the one correct answer:

1. The current chemical indicator (CI) standard that defines the performance requirements for CIs is ANSI/AAMI/ISO 11140-1:2014 Sterilization of healthcare products-Chemical Indicators-Part 1: General requirements.
   A. True B. False
2. The performance of chemical indicators is characterized by the manufacturer in a resistometer, a specialized test vessel capable of reproducible cycles.
   A. True B. False
3. The current standard uses the term “type,” rather than the term “class” of chemical indicators.
   A. True B. False
4. Sterile processing personnel should select the type of chemical indicator to use based on the information needed about a particular sterilization process.
   A. True B. False
5. The performance of Type 5 integrating indicators are equivalent to or exceed the performance requirements for biological indicators.
   A. True B. False
6. AAMI ST79 has been revised to reflect the new term “type” of chemical indicators.
   A. True B. False
7. Type 5 steam integrating indicators are required to be tested at three stated values.
   A. True B. False
8. Type 1 ‘exposure’ or process indicators allow differentiation between processed and unprocessed items.
   A. True B. False
9. Internal indicators, signified by the optional prefix ‘i’ are placed inside individual load items to assess the attainment of the critical process variable(s) at the point of placement.
   A. True B. False
10. If a chemical indicator reaches its endpoint, the user can be confident the sterilization process achieved an acceptable sterility assurance level.
    A. True B. False

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Typical temperature at which these sterilizers operate. An addition to the standard were performance requirements for Type 3 and 4 indicators for vaporized hydrogen peroxide sterilization processes. The 2005 version of the document only provided test and performance requirements for Class 1 process indicators for this method of sterilization.

References


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