3. The stated value of a chemical indicator generally will not correlate with the time the chemical indicator will reach its endpoint response in your hospital sterilizer.
   A. True   B. False

4. Biological indicators do not have stated values because their performance is based on spore population, D-values, and survival/kill times.
   A. True   B. False

5. A chemical indicator can assure the Sterility Assurance Level (SAL) of a steam sterilization process.
   A. True   B. False

6. Only a biological indicator that contains spores can measure the lethality of a sterilization process.
   A. True   B. False

7. Per ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities a Class 5 Integrating Indicator should not be used to release loads that contain implantable devices.
   A. True   B. False

8. Per ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities a Class 6 Emulating Indicator can be used to replace Class 5 Integrating Indicators and biological indicators.
   A. True   B. False

9. When a positive biological indicator result occurs, recall all items processed in that sterilizer since the last cycle having the negative biological indicator.
   A. True   B. False

10. The geometric center of a sterilization containment device or a tray of complex instrumentation is the most challenging area for sterilant penetration.
    A. True   B. False
Introduction

Are you overwhelmed by the information supplied to you about chemical and biological indicators when making decisions related to monitoring the sterilization process? This self-study activity will review the recommended practices and state of the art for monitoring the steam sterilization process.

These recommendations are based on the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Nurses (AORN) recommended practices. This inservice replaces Did You Know Part Two published in Managing Infection Control in October, 2004 that is out of date.

Subjects covered include:
- History of the chemical indicator performance standard;
- Definitions of the classes of chemical indicators;
- Labeling requirements for chemical indicators;
- Labeling requirements for biological indicators;
- Appropriate use of chemical and biological indicators.

Chemical Indicators

History


The major changes in the chemical indicator (CI) standard were:
- Inclusion of performance requirements for a Class 1 Process Indicator for the Vaporized Hydrogen Peroxide sterilization process;
- Upgraded performance requirements for Class 5 Integrating Indicators so the results align more closely with biological indicators in saturated steam;
- Addition of Class 6 Emulating Indicators.

ANSI/AAMI/ISO 11140-1:2005 is not referenced in ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities. But this is the standard that all medical device manufacturers use for testing and labeling their chemical indicators.

Did you know that there are six classes of chemical indicators?

There are six classes of chemical indicators defined in the ANSI/AAMI/ISO 11140-1: 2005 CI standard. However, ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text) only recognize five of the six classes of chemical indicators and there is no information regarding use and application for Class 6 Emulating Indicators.2

ANSI/AAMI/ISO 11140:1:2005 states:

“The classification structure used is solely to denote the characteristics and intended use of each type of indicator when used as defined by the manufacturer. This classification has no hierarchical significance.”

The term “no hierarchical significance” means that an indicator with a higher number is not necessarily better than an indicator with a lower number; the numbers merely designate the type of indicator.

As you review Table 1, which defines the classes of steam chemical indicators and how they are used, you will see that you choose a class of indicator based on the information or type of testing being performed.
Education & Training

Practical Application

- Understand which critical variables each class of chemical indicator measures and how they should be used so you choose the correct class of chemical indicators for the information you want to obtain.

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**Table 1: Steam Chemical Indicator Classes Defined**

<table>
<thead>
<tr>
<th>Class</th>
<th>ANSI/AAMI/ISO 11140-1:2005 Definition</th>
<th>How They Are Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1: Process Indicators</td>
<td>&quot;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.&quot;</td>
<td>Indicator tapes, indicator labels, and load cards are examples of externally visible chemical indicators that should be on the outside of every package.²³</td>
</tr>
<tr>
<td>Class 2: Indicators for use in Specific Tests</td>
<td>&quot;Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer/sterilization standards.&quot;</td>
<td>Bowie-Dick type tests are specific tests used for equipment control to evaluate the efficacy of air removal and steam penetration. This test should be done each day in dynamic-air-removal sterilizers and during sterilizer qualification testing.²³</td>
</tr>
<tr>
<td>Class 3: Single Variable Indicators</td>
<td>&quot;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.&quot;</td>
<td>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 when used as an internal chemical indicator.² Internal chemical indicators should be used inside each pack.²³</td>
</tr>
<tr>
<td>Class 4: Multi-variable Indicators</td>
<td>&quot;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.&quot;</td>
<td>Multi-variable chemical indicators are used for pack control monitoring. These internal chemical indicators are usually paper strips printed with a color change chemical indicator. Internal chemical indicators should be used inside each pack.²³</td>
</tr>
<tr>
<td>Class 5: Integrating Indicators</td>
<td>&quot;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.&quot;</td>
<td>May be used as an internal chemical indicator for pack control monitoring. Internal chemical indicators should be used inside each pack.²³ May be used as an additional monitoring tool to release loads that do not contain implants. For this application the Class 5 Integrating Indicator must be used in the appropriate Process Challenge Device (PCD).² Should be used in a PCD to monitor implant loads. The PCD should also contain a BI. The implant should not be released until the BI result is known, except in defined emergencies.²</td>
</tr>
<tr>
<td>Class 6: Emulating Indicators</td>
<td>&quot;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.&quot;</td>
<td>Could be used as internal chemical indicators for pack control monitoring only for the specific cycle for which they are labeled. The use of Class 6 Emulating Indicators is presently not covered in any AAMI or AORN healthcare facility user documents.²³</td>
</tr>
</tbody>
</table>

---

Did you know that you can tell what the chemical indicator class is by reading the product labeling?

Refer to Table 2 for the critical variables and symbols used for selected sterilization processes that maybe used in the product labeling. Critical variables are the "parameters identified as being essential to the sterilization process (and requiring monitoring).”¹
Do you know what is meant by the stated value of a chemical indicator?

The definition of a stated value in ANSI/AAMI/ISO 11140-1:2005 is:

“Value or range of values of a critical variable at which the indicator is designed to reach its endpoint as defined by the manufacturer.”

Examples of stated values are listed in Figure 2. One stated value at 121°C (250°F) is 22.1 minutes. This means that this chemical indicator, when tested in a highly controlled laboratory test vessel called a resistometer under ideal steam sterilization conditions, will reach its endpoint in 22.1 minutes. Because the test vessel has a short come-up time and no load, the stated value may not accurately reflect when the CI will reach its endpoint in a hospital sterilizer with a longer come-up time and a load. In fact, in a hospital sterilizer the CI will probably reach its endpoint sooner because of the lethality (killing) effect in the come-up time of the sterilizer.

In addition ANSI/AAMI/ISO 11140-1:2005 states that the following information should be included in “each package of indicators or technical information leaflet supplied with the package.”

a) “the change that is intended to occur; and for color change indicators where the color change cannot be adequately described, samples of expected color range for both changed and unchanged indicators (this would be the endpoint of the chemical indicator);
b) the critical variables(s) to which the indicator will respond and, where applicable, their values (see Table 1);
c) the class, process and intended user for which the indicator is designed;
d) the storage conditions, before and after use;
e) the expiry date, or the manufacturing date plus shelf life, under the specified storage conditions;
f) a unique code number (e.g., lot number) to provide traceability;
g) instructions for use essential to ensure proper functioning of the indicator;
h) any interfering substances that are likely to be encountered, or conditions that are likely to occur, during the intended use of the indicator and which are known to affect adversely the performance of the indicator;
i) any safety precautions required during and/or after use;
j) the manufacturer’s or supplier’s name and address;
k) the nature of any change that can occur when completely/incompletely changed indicators are stored according to the manufacturer’s instructions.

NOTE: National or regional regulations could contain additional or different requirements.”

The manufacturer of the CIs “shall establish, document and maintain a formal quality system to cover all operations required by this part of ISO 11140.” See Figure 1 as an example of appropriate labeling for a Class 5 Integrating Indicator that meets the ANSI/AAMI/ISO 11140-1:2005 CI standard.
The stated value can be used to compare the performance of different brands of CIs but these values generally will not correlate with the time in which the CI will reach its endpoint response in your hospital sterilizer.

This statement is supported by the data presented in Figure 2. The study tested 15 indicators of one brand of Class 5 Integrating Indicators that meets the ANSI/AAMI/ISO 11140-1:2005 CI standard and two brands of Class 6 Emulating Indicators. Notice that the SV (stated value) for the Class 5 Integrating Indicators is a shorter time than the SV for the Class 6 Emulating Indicators when tested in a resistometer which is a standardized test vessel. But when these CIs are run in a 1-minute, 134°C (273°F), hospital gravity steam sterilization cycle with a 4-minute come-up time the results are very different. All of the Class 6 Emulating Indicators showed a pass and failed to detect the shortened exposure time even though their Stated Values (SV’s) at 134°C (273°F) were greater than that of the Class 5 Integrating Indicator.

Why is that? Because the response of Class 5 Integrating Indicators has to correlate to a BI over a wide temperature range and is better at integrating all of the variables of a steam sterilization process than Class 6 Emulating Indicators whose response is just cycle specific and whose response does not correlate to a BI over a wide temperature range.

### Table 1

<table>
<thead>
<tr>
<th>Indicator Type</th>
<th># Indicators Showing Fail/ # Indicators Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 5 (SV:2.2 min. @134°C)</td>
<td>15/15</td>
</tr>
<tr>
<td>Class 6 (SV: 3.5 min. @134°C)</td>
<td>0/15</td>
</tr>
<tr>
<td>Class 6 (SV: 3.5 min. @134°C)</td>
<td>0/15</td>
</tr>
</tbody>
</table>

### Practical Application

- Read the CI package labeling or technical information leaflet for information about performance and the Class of the CI.
- Remember that the stated value (SA) of the CI was determined in a resistometer test vessel and its performance in a hospital sterilizer will be different.

### Biological Indicators

**Did you know that biological indicators Do Not have stated values?**

As indicated above, the definition of stated value found in the ANSI/AAMI/ISO 11140-1:2005 CI document but does not apply to biological indicators (BIs). The BI standards (ISO 11138 2006 series) define the performance requirements for BIs used to monitor steam and EO sterilization processes. BI performance is based on spore population, D-value and survival/kill values. See Figure 3 for biological indicator performance data.

**Figure 3. Biological Indicator Performance Data**

For use in monitoring the 250°F (121°C), gravity and 270°F (132°C) vacuum assisted steam sterilization process.

Organism: *Geobacillus stearothermophilus* ATCC 7953

*Population (mean/strip): 3.7 X106 C.F.U.*

**Resistance Testing Data:**

*Test D-Value (121°C): 1.6 minutes
**Survival time (121°C): 7.3 minutes
Survival time (in minutes) = not less than labeled D value x (log10) labeled population + 2
**Kill time (121°C): 16.9 minutes
Kill time (in minutes) = not less than labeled D value x (log10) labeled population + 4

*Determined at time of manufacture. Population is reproducible only under the exact conditions under which it was determined.

**Survival/kill is verified and D-value is determined in a BIER vessel using a gravity cycle. D-values are determined by a fraction negative procedure after graded exposures to sterilization conditions. D-value is reproducible only under the exact conditions under which it is determined. User would not necessarily obtain the same results and would need to determine the biological indicators suitability for their particular use.
Sterility is defined as being free from all living organisms. Since it is not practical to test every device for the absence of microorganisms, the concept of sterility is assumed to be a statistical probability. This concept of sterility defines an assurance level commonly referred to as SAL for validated sterilization processes. An SAL is defined in ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text) as:

“Probability of a single viable microorganism occurring on an item after sterilization.”

Hospital sterilizer and medical device manufacturer’s (MDM’s) validate their sterilization processes to ensure the probability of finding a surviving organism is one in a million, or an SAL of 10^-6. This validation is done using biological indicators not chemical indicators. This is why ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text) states in 10.7.1 Rationale:

“Sterilizer manufacturers validate their sterilization cycles using BIs; therefore, routine sterilizer efficacy monitoring in health care facilities should also be conducted using BIs.”

Given that the number of resistant spores contained in a BI is far greater than the routinely encountered microbial challenge on medical devices, a negative BI result indicates that the process delivered sufficient lethality. This ensures a built-in margin of safety inherent to the BI. No other margin of safety is needed when monitoring hospital steam sterilizers.

**Practical Application**

- Check the package insert for the performance data for biological indicators.
- Biological indicators are used to determine the Sterility Assurance Level (SAL) of a validated steam sterilization cycle by hospital sterilizer manufacturer’s and MDM’s and that is why AAMI recommends BIs to monitor the effectiveness of hospital steam sterilizers.

**Appropriate Use of Chemical and Biological Indicators**

**Did you know that Class 5 Integrating Indicators may be used to release non-implant loads?**

ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text) section 10.5.2.1 General considerations under 10.5.2 Chemical indicators (CIs) states that a Class 5 Integrating Indicator used within a PCD (process challenge device) may be used to release non-implant loads.

“In this application, they provide additional information about the critical parameters of the sterilization process to supplement the results of physical monitors and Class I process indicators.”

All available data from the sterilization process should be used to determine if the load should be released. This decision “should be made by an experienced, knowledgeable person at the conclusion of the sterilization cycle.” If the Class 5 Integrating Indicator has not reached its endpoint the load should not be released, but reprocessed and the reason for the failure should be determined.

This means that a Class 5 Integrating Indicator should not be used to routinely release implants. If an implantable is in the load, it should be monitored with a BI PCD that contains a Class 5 Integrating Indicator and quarantined until the BI is negative (see next question).

Class 5 Integrating Indicators should not be used in place of BIs for routine sterilizer efficacy testing, qualification testing and product testing as described in ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text).

The rationale for why Class 5 Integrating Indicators should not be used in place of BIs for all these applications is stated in ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text):

“While the performance of Class 5 integrating CIs and enzyme-only indicators has been correlated to the performance of BIs, these sterilization monitoring devices do not contain spores and thus do not directly measure the lethality of a sterilization cycle; however, they provide information about the attainment of the critical parameters of the sterilization process.”
Editorial Note: Enzyme-only indicators are no longer on the market.

The response of Class 6 Emulating Indicators is not required to correlate to the performance of BIs and these indicators do not contain spores; thus they do not directly measure the lethality of the sterilization process. The use of Class 6 Emulating Indicators is presently not covered in any AAMI or AORN healthcare facility user documents.\(^2,3\)

Running a BI PCD in each load (non-implant and implants) will improve patient safety by detecting all sterilization process failures, reducing the number of loads to be recalled, and applying the same high standard of care for all patients.

**Practical Application**
- Class 5 Integrating Indicators may be used to release non-implant loads.
- Running a BI PCD in non-implant loads will improve patient safety.

**Did you know that implants should only be released based upon the results of biological indicators?**

ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text) states:

Section 10.5.2 Using biological indicators:
"Additionally, BIs with PCDs should be used to monitor every load containing implants (see 10.6.1)."\(^2\)

Section 10.5.4 Process challenge devices (PCDs):
"For routine release of loads containing implantable devices, a PCD containing a BI and either a Class 5 integrating indicator or an enzyme-only indicator (a BI challenge test pack) should be used to monitor the load (see 10.6.1)."\(^2\)

Editorial Note: Enzyme-only indicators are no longer on the market.

Section 10.6.3 Release criteria for implants:
"The load should be quarantined until the results of the BI testing are available (CDC, 2003a)."\(^2\)

"When documented medical exceptions dictate (e.g., the need for trauma-related orthopedic screw-plate sets), it could be necessary to release an implantable device before the BI results are known. In this case, the release of the device before the BI results are known should be documented; the BI result obtained later should also be documented."\(^2\)

**Did you know that Class 5 integrating indicators may not respond the same as biological indicators in all cycles and that they Do Not always predict the outcome of the biological indicator results?**

A published study shows that integrating indicators do not detect sterilization process failures with the same sensitivity as conventional BIs or BIs with an enzyme-based early-readout capability.\(^7,8\)

The study compared the performance of several commercially available chemical integrators to BIs, with both conventional and enzyme-based early-readout capabilities in optimal and suboptimal steam sterilization cycles. At the time of this study, the Class 5 Integrating Indicator category was not recognized in the United States. Today:
- Integrator A is a Class 5 Integrating Indicator that meets the ANSI/AAMI/ISO 11140-1:2005 CI standard;
- Integrator B was the same type that was sold as a Class 6 Emulating Indicator sold outside the United States;
- Integrator C is a Class 5 Integrating Indicator that does not meet the ANSI/AAMI/ISO 11140-1:2005 CI standard because it does not have 3 stated values and the stated value at 250°F (121°C) is not greater than 16.5 minutes.

The Class 5 Integrating Indicator result in the BI PCD should be read before releasing the implant in a defined emergency situation. If the Class 5 Integrating Indicator failed the implant would not be released. If the Class 5 Integrating Indicator passed and the BI was positive when the results were available then a decision would need to be made about recalling or removing the implant from the patient. To avoid this situation, quarantine implants until the BI is negative. This will improve patient safety and eliminate the need to make this decision.

Since the response of Class 6 Emulating Indicators does not correlate to the performance of BIs, and these indicators do not contain spores and thus do not directly measure the lethality of the sterilization process, they should not be used to release implants. The issue is patient safety, not costs, or convenience. The use of Class 6 Emulating Indicators is presently not covered in any AAMI or AORN healthcare facility user documents.\(^2,3\)

**Practical Application**
- A BI PCD with a Class 5 Integrating Indicator should be used to monitor implant loads. Implantable devices should not be released before the BI results are available except in documented emergency situations.
In general, the chemical integrators (including what is now labeled and sold as a Class 6 Emulating Indicator) did not respond the same as the BIs when using different cycle types and temperatures. More importantly, the chemical integrators failed to detect defined failure conditions of superheated steam and incomplete chamber air removal by indicating “accept” results; whereas, the BIs consistently identified these cycles as “fail” by demonstrating positive results.

Data from this study showing a cycle with an 8-minute exposure at 250°F (121°C) using superheated steam is presented in Figure 4. As superheated steam is not as effective as saturated steam for achieving sterilization, the expectation for a sterilization indicator would be to identify this cycle as failed and alert the user to the need for sterilizer/ utilities maintenance. Note, however, that none of the three chemical integrators detected this condition at an acceptable frequency, while all of the BI responses indicated that there was a problem with this cycle.

At the Association of Professionals in Infection Prevention (APIC) 2008 Annual meeting in Denver, Colo., Dr. William Rutala noted the following in his seminar entitled Disinfection & Sterilization: Current Issues & New Technologies.

“No professional organization (e.g., AORN) has recommended the use of Class 6 emulating indicators as a substitute for biological indicators and there are no data that demonstrate that it mimics a BI at suboptimal sterilization times.”

Dr. Rutala recommends the following which is aligned with AAMI ST79 and AORN sterilization recommended practice:

○ “Monitor each load with physical and chemical (internal and external) indicators. If the internal indicator is visible, an external indicator is not needed.
○ Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer (Class 6 emulating indicators are not a substitute).
○ Use biological indicators for every load containing implantable items and quarantine items, whenever possible, until the biological indicator is negative.”

Practical Application

- Only biological indicators consistently detect sterilization process failures.
- Class 6 Emulating Indicators do not mimic the results of BIs and should not be used to replace them.

Did you know that a recall is based on the result of the biological indicator and not the Class 5 Integrating Indicator?


addresses recall procedures when a positive biological indicator result is obtained in Section 7.7.5. Positive BI results:

“If it is determined that the sterilization failure was not the result of operator error (e.g., selection of the incorrect cycle), items processed in that sterilizer since the last negative BI results should be considered unsterile. They should be retrieved, if possible, and reprocessed (see 10.11). The sterilizer in question should be taken out of service.”

This means that you must retrieve all products processed since the last negative BI even if the Class 5 Integrating Indicator PCD in the loads showed a pass result. A recall policy and procedure is part of a continuous quality improvement process to improve patient safety.

Running a BI PCD in each load (non-implant and implants) and quarantining the load until the BI is negative will eliminate recalls and apply the same high standard of care for all patients.

Did you know that the only way you can determine whether or not the sterilant penetrated into the package is to have an internal chemical indicator inside the package?
The ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text) Section 10.5.2.2.2 Internal chemical indicators states:

“Rationale: There are no practical means of verifying the sterility of individual items. Chemical indicators do not verify sterility, but some types may allow detection of certain equipment malfunctions (e.g. air leaks, wet steam, adequate temperature or time), and they may assist in the identification of certain procedural errors.”

The only way to detect packaging or loading problems, or that cycle parameters were incorrect for a specific package or load, is by placing a Class 4 Multi-variable or Class 5 Integrating Indicator inside each package, tray or container system.2,3 The ANSI/AAMI ST79:2006 and A1:2008 (Consolidated text) recommended practices state that Class 4 Multi-variable and Class 5 Integrating Indicators provide more information than Class 3 Single-variable Indicators.2 Internal CIs are at the same location as the medical device and provide assurance that the sterilant has penetrated into the package. The physical monitors and the Class 1 CIs on the outside of each package do not provide that information.

Did you know that the geometric center of the package may not be the most challenging area for sterilant penetration?
The information provided by the internal CI is only as good as its placement inside the package. Placement of an internal CI in the geometric center of a package is recommended for wrapped fabric packs. Today you process a variety of sterilization containment devices and complex instrumentation. Contact the manufacturer of the containment devices for correct placement of internal chemical indicators.2

The AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization, 2009 suggests the following placement of internal CIs.4 Place:

- A CI in the geometric center not on the top of a wrapped pack or tray;
- Two CIs inside rigid containers, one in each of two opposite corners of the inside basket,
  - Multi-level rigid containers should have a CI placed in two opposite corners (e.g., one in each of two corners) of each level;
  - A CI on each level of multi-level wrapped sets.

Did you know that the geometric center of the package may not be the most challenging area for sterilant penetration?

The information provided by the internal CI is only as good as its placement inside the package. Placement of an internal CI in the geometric center of a package is recommended for wrapped fabric packs. Today you process a variety of sterilization containment devices and complex instrumentation. Contact the manufacturer of the containment devices for correct placement of internal chemical indicators.2

The AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization, 2009 suggests the following placement of internal CIs.4 Place:

- A CI in the geometric center not on the top of a wrapped pack or tray;
- Two CIs inside rigid containers, one in each of two opposite corners of the inside basket,
  - Multi-level rigid containers should have a CI placed in two opposite corners (e.g., one in each of two corners) of each level;
  - A CI on each level of multi-level wrapped sets.

Summary
What does this all mean to you? CI classifications enable the user to understand performance parameters and tolerances of various CI products. The appropriate CI can then be used to obtain the information needed to determine the effectiveness of the sterilization process. BIs, not Class 5 Integrating Indicators or Class 6 Emulating Indicators, should be used to release implantable devices. If a BI is positive all items processed since the last negative BI should be recalled no matter what the results of the CIs.

It is also important to understand that scientific data shows:

- CIs Do Not confirm cycle lethality or always predict the outcome of the BI;
- BIs are the only indicators that contain spores and measure the lethality of the sterilization process;

Practical Application
• Use a CI inside each package, tray or container to identify that the sterilant has penetrated where the instruments are located.
• Place the internal CI in the most challenging areas inside the package, tray or container.

Practical Application
• If a positive biological indicator occurs, recall all items processed since the last negative BI and reprocess.
• Eliminate recalls by running a BI PCD in each load and quarantining the load until the BI is negative.
Class 5 Integrating Indicators inside a PCD (process challenge pack or test pack) in the load tells you sterilant penetrated the PCD, which should be the greatest challenge in that load and may be used to monitor non-implant loads;

The usage of Class 6 Emulating Indicators is not covered in any hospital recommended practices (AAMI, AORN);

CIs inside each package, tray or container tell you if the sterilant penetrated through the packaging and reached the inside where the instruments are located;

BI PCDs tells you that the sterilization process was capable of killing spores inside of a highly challenging environment and should be used to release implants, for routine sterilizer efficacy testing, sterilizer qualification testing, and product testing.

The combined results of all of these monitors in conjunction with the physical monitors (readouts, charts, gauges, etc.) should be used to determine if a load should be released for use. Make sure all users know how to read and interpret each of the monitors used and how to respond if a sterilization process failure is detected. Patient safety is the ultimate goal in sterilization process monitoring program.

Ordering Information

AAMI


- Available in an attractive binder featuring sturdy metal rings, ledger-weight pages, and a laminated tab for each section for easy navigation. AAMI will issue revised pages that can be substituted into the binder when changes are made.
- Also available in PDF format and as part of AAMI’s electronic CD and subscription products.
- The ST79 Amendments, ANSI/AAMIST79:2006 and A1:2008 can be purchased separately on 3-hole punched paper or the PDF can be downloaded for free.
- Order code: ST79A or ST79-A-PDF or ST79 Amendments 1-PDF can be downloaded for free.
- AAMI documents can be purchased through AAMI by credit card using the following four options:
  1. Internet: http://marketplace.aami.org
  2. Call: 1-877-249-8226
  3. Fax: 301-206-9789
  4. Mail: AAMI Publications, P.O. Box 0211, Annapolis Junction, MN 20701-0211

AORN

AORN Perioperative Standards and Recommended Practices can be purchased through AORN as can the AAMI ST79 recommended practice using the following options:

1. Internet: www.aorn.org/bookstore/ordering.htm
2. Call: 1-800-755-2676 x 1 or 303-755-6304 ext. 1 (Monday - Friday, 8 a.m. to 4:30 p.m. Mountain Standard Time)
3. Fax: 303-750-3212
4. By mail: AORN, Inc., Customer Service/Book Orders, 2170 South Parker Road, Suite 300, Denver, CO 80231-5711, USA

Payment can be made by: VISA, MasterCard, American Express, or Discover, either online or by mail/fax/phone.

A CD-Rom of the standards is available for the first time this year.

Glossary of Terms

- **Chemical indicator (CI):** “Device used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment.”
- **Critical variables:** “Parameters identified as being essential to the sterilization process (and requiring monitoring).”
- **Stated Value (SV):** “Value or range of values of a critical variable at which the indicator is designed to reach its endpoint as defined by the manufacturer.”
- **Resistometer or BIER Vessel:** A specialized test vessel capable of reproducible cycles and used by manufacturers to characterize the performance of chemical indicators.
- **Come-up-time:** The time it takes a sterilizer to reach its set sterilization temperature.
- **Biological Indicator (BI):** Microbiological test system providing a defined resistance to a specified sterilization process.
- **D-value:** Time or dose required to achieve inactivation of 90 percent of a population of a test microorganism under stated exposure conditions.
- **Survival/Kill time:** Extent of exposure to a sterilization process under defined conditions when there is a transition from all BIs showing growth (survival exposure) to all BIs showing no growth (kill exposure).
- **Sterilization:** Validated process used to render a product free of all forms of viable microorganisms.
- **Sterile:** Free from viable microorganisms.
- **Sterility assurance level (SAL):** “Probability of a single viable microorganism occurring on an item after sterilization.”
- **Process challenge device (PCD):** “Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.”
Routine sterilizer efficacy testing: Testing with a BI PCD weekly, preferably daily, to directly measure the lethality of a sterilization cycle.  
Sterilizer qualification testing: Testing the sterilizer with a biological indicator process challenge device and Bowie-Dick test after sterilizer installation, relocation, malfunction, major repair of sterilizer or utilities, or sterilization process failure, which could affect the ability of the sterilizer to perform.  
Product testing: Part of a complete quality assurance program to ensure effective processing of all items routinely processed and to avoid wet packs.  
Physical monitors: Time, temperature and pressure recorders; displays; digital printouts; and gauges that provide real-time assessment of the sterilization cycle conditions and permanent records.  
External chemical indicator: Chemical indicator used outside of packages to distinguish processed from unprocessed items.  
Internal chemical indicator: Chemical indicator used on the inside of packages to determine that the sterilant has penetrated inside the packaging.  
Dynamic-air-removal steam cycle: Type of steam sterilization cycle in which “air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure-pulse [SFPP] cycle).”

References

Martha Young, BS, MS, CSPDT is a senior technical service specialist in the sterilization assurance group of 3M’s Infection Prevention Division in St. Paul, Minn. She has more than 25 years of experience in the area of sterilization and disinfection. Ms. Young lectures around the world and has numerous publications on infection prevention with an emphasis on improving the performance of the sterilization process. She is a member of IAHCSMM, AORN (Professional Practice Issues Chair for AORN specialty assembly for Sterile Processing Materials Management) and APIC, and a certified central sterile processing and distribution technician. She is a member of several AAMI working group committees that are developing recommended practices, and the special technical editor for the 3M sponsored inservice in Managing Infection Control. Ms. Young was named in 2007 by HPN as one of the “30 Pros to Know” who are the most influential in healthcare sterile processing.
Sterile Process and Distribution CEU Information

CEU Applicant Name ________________________________________________

Address __________________________________________________________

City __________________________________ State ______ Zip Code __________

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for one (1) contact hour for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until recertification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding Certification contact: CBSPD, 121 State Hwy 31N, Suite 500, Flemington, NJ 08822 or call 908-788-3847 or visit the Web site at www.sterileprocessing.org.

IAHCSMM has awarded one (1) Contact Point for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CE Application Form

This inservice is approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five (5) years from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions. KEEP A COPY FOR YOUR RECORDS.
6. Submit this form and the answer sheet to:
   3M Sterilization Assurance, Attn HC4160
   RR Donnelly Fulfillment Services
   585 Hale Ave N., Oakdale, MN 55128-9935
7. For questions or follow-up, contact craig@manageinfection.com.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of Managing Infection Control's receipt of the application.

Application

Please print or type.

Name _____________________________________________________________

Mailing Address ___________________________________________________

City, State, Country, Zip _____________________________________________

Daytime phone (__________) ___________________________________________

Position/Title ______________________________________________________

Social Security or Nursing License Number ______________________________

Date application submitted ___________________________________________

Signature __________________________________________________________

Offer expires February 2014

On a scale of 1-5, 5 being Excellent and 1 being Poor, please rate this program for the following:

1) Overall content ______________________
2) Met written objectives ________________
3) Usability of content _________________

ANSWERS

1. A 6. A
2. A 7. A
3. A 8. B
4. A 9. A

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