Self-Study Series

Which chemical indicator is right for me?

by Heide Ames

All chemical indicators are equal.” Many people may agree with this statement. After all, they all look the same. They are often used in the same way. They must be equal. Nothing can be further from the truth. Chemical indicators have a variety of purposes, specializations and specifications that make each chemical indicator unique. Given the variety, evaluating and selecting the right chemical indicator can be challenging. Proper selection begins with knowledge of the types of chemical indicators and their purpose.

Types of chemical indicators

As the Association for the Advancement of Medical Instrumentation (AAMI) states, a chemical indicator “utilizes one or more chemicals which undergo either a physical or chemical change that is visible to the human eye.” (ANSI/AMMI ST79, ANSI/AAMI ISO 11140-1) This complex statement simply means that when exposed to either high-level disinfection or sterilization conditions, the indicator will change color. Though this may imply an easy process, chemical indicators are actually complex systems.

Chemical indicators may be categorized into two groups. The first group, called Solution Test Strips, is used with high-level disinfection processes and liquid chemical sterilization processes. They can be defined as indicators used to monitor whether the concentration of the active ingredient(s) in a chemical disinfectant or sterilant solution is above or below a defined concentration for effective high-level disinfection or sterilization. These types of indicators are designed to be used in liquids such as glutaraldehyde-based, high-level disinfection solutions, hydrogen peroxide high-level disinfection solutions and liquid chemical sterilization processes such as the SYSTEM 1E Liquid Chemical Sterilant Processing System.

Some Solution Test Strips are made to detect the Minimum Effective Concentration (MEC) or Minimum Recommended Concentration (MRC) of the active ingredient in the solution. These strips are typically dipped into the solution and removed for inspection, in accordance with manufacturers’ instructions. The chemicals in the indicator react with the active agent creating a color change. The color change, as well as the time to complete the chemical reaction, is different for each type of solution test strip.

Solution Test Strips may also measure the total amount of the active ingredient present over a certain period of time. These strips are most often utilized in defined automated systems. The strip is placed within the tray with the items to be high-level disinfected or liquid chemically sterilized. The strips are processed with the instrumentation, including any rinses.

These types of Solution Test Strips are used to verify that a specific dose of the disinfectant MEC or MRC has been delivered to the instrumentation.

The second group of indicators is simply called Chemical Indicators. This group is used in quality assurance programs for sterilization processes, such as those based on steam, ethylene oxide and hydrogen peroxide gas. This category has the largest variety of uses, including as indicator tape used on the outside of wrapped packs, Air Removal Tests used to check the vacuums on steam sterilizers and many more.

Process Indicators

Process Indicators come in many shapes and sizes, but all serve one need: to help identify items that have been sterilized from items that have not been sterilized. These types of indicators are typically placed on the outside of packs, pouches, container systems and other items that are to be sterilized. Examples include steam indicator tape and container data cards with indicator inks.

Of all the types of indicators, this one gives the least amount of information about...
the sterilization conditions. These types of indicators can change to passing conditions even if full sterilizing conditions are not present.

**Bowie and Dick tests**
The age old Bowie and Dick test, a specific type of air removal test used to test steam sterilization processes has seen many improvements over the years. This chemical indicator was originally designed to confirm that steam could get to the center of a fabric pack when utilizing vacuum-assisted steam sterilization processes. Today’s test packs often provide additional information often times capturing common steam quality issues.

**Process challenge devices (PCD)/test packs**
The Air Removal and Steam Penetration Tests. Both types work in the same way. These test packs are used in an empty chamber. A specialized vacuum test cycle is run. During the preconditioning, air must be removed from the challenge pack and replaced by steam. The sterilizer is working properly if it can pass this test. The difference between the Air Removal and Steam Penetration test packs lies in the sensitivity of the packs to detect air left in the chamber. The Air Removal Tests can often require more air within the chamber to indicate a failed cycle as compared to the Steam Penetration Test. This makes the Air Removal Test typically less sensitive than a Steam Penetration Test.

**Internal indicators strips**
All the chemical indicators discussed thus far provide crucial information about the performance of the sterilizer. They have also been used to prevent the confusion between processed and unprocessed items. The last chemical indicator job is arguably the most important; internal indicator strips.

**Internal Indicator Strips** are placed in each pack, wrapped tray, container system, pouch and any other items to be sterilized. The internal indicator strip should provide an indication that sterilization conditions were achieved within the pack at the location of the instrumentation. Internal indicator strips provide the only information related to the actual conditions that an instrument was exposed to. They are also the last safety check prior to use of an instrument.

**Chemical indicator performance**
In the USA, AAMI has adopted a global standardization of chemical indicator performance that places chemical indicators into one of six classes.

- Class 1 process indicators
- Class 2 indicators for specific tests
- Class 3 single variable indicators
- Class 4 multivariable indicators
- Class 5 integrating indicators
- Class 6 emulating indicators

Each class of chemical indicator is defined by its ability to detect processing parameters that are critical for achieving sterilization. Classes 5 and 6 are most often used in process challenge devices. Classes 3, 4, 5 and 6 are typically utilized for internal indicator strips.

**Critical Variables** are different for each sterilization process. The Critical Variables for ethylene oxide include concentration, humidity, time and temperature, for example. Some chemical indicator classes monitor two or three critical variables whereas other chemical indicators can measure all the critical variables. Chemical indicator performance is further defined by the tolerance at which they operate. A tolerance is the window of error for a particular measurement. A small tolerance provides a smaller window of error and a more accurate chemical indicator. Table 1 is an example of the tolerances for the stated values of the critical variables necessary for ethylene oxide sterilization.

**Table 1:** Tolerances for the stated values of the critical variables necessary for ethylene oxide sterilization.

<table>
<thead>
<tr>
<th>Class of Internal Indicator Strip</th>
<th>Test Point*</th>
<th>Sterilization Time</th>
<th>Sterilization Temperature</th>
<th>Sterilization Agent Concentration</th>
<th>% RH</th>
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<tr>
<td>Class 3</td>
<td>1</td>
<td>SV – 0%</td>
<td>SV – 0°C</td>
<td>SV – 0%</td>
<td>&gt;30</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>SV – 25%</td>
<td>SV – 2°C</td>
<td>SV – 25%</td>
<td>&gt;30</td>
</tr>
<tr>
<td>Class 4</td>
<td>1</td>
<td>SV – 0%</td>
<td>SV – 0°C</td>
<td>SV – 0%</td>
<td>&gt;30</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>SV – 25%</td>
<td>SV – 2°C</td>
<td>SV – 25%</td>
<td>&gt;30</td>
</tr>
<tr>
<td>Class 5**</td>
<td>1</td>
<td>SSV – 33.7%</td>
<td>Not Applicable</td>
<td>SV – 0%</td>
<td>&gt;30</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td>SV – 25%</td>
<td>&gt;30</td>
</tr>
<tr>
<td>Class 6</td>
<td>1</td>
<td>SV – 0%</td>
<td>SV – 0°C</td>
<td>SV – 0%</td>
<td>&gt;30</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>SV – 6%</td>
<td>SV – 1°C</td>
<td>SV – 15%</td>
<td>&gt;30</td>
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*Test Point 1 must show passing conditions and Test Point 2 must show failing results.
**Class 5 have additional performance requirements independent of the stated value and have been correlated to biological indicator performance when exposed under the same test conditions.
for ethylene oxide sterilization previously mentioned.

The stated values for chemical indicators are chosen by the chemical indicator manufacturer. It is typically based on one of two conditions: the response of a biological indicator or the validated sterilizer cycle parameters. Figure 3 shows four classes of chemical indicators used for gravity steam sterilization cycles operating at 250°F with a 30-minute exposure. In this example, the Class 6 emulating indicator shows a smaller window of green as compared with the Class 1 process indicator. Additionally, the Class 1 process indicator’s stated value is much lower than the Class 6 emulating indicator.

**Evaluation and selection**

Healthcare facilities will typically use a variety of solution test strips and chemical indicators for their specific high-level disinfection, liquid chemical sterilization and gas sterilization process used at the facility. These should be chosen based on the types of processes being used, manufacturers’ instructions and to be compliant to standards such as AAMI/ANSI ST 79 (for steam sterilization), ST58 (for chemical disinfection and sterilization) and ST 41 (for ethylene oxide).

As part of the quality assurance program, the various products and applications should be reviewed on a regular basis. The review should include, but is not limited to:

- A listing of the products used, the sterilization cycles they are used in and confirmation of their clearance for use in those cycles
- Review of the frequency of inconclusive results
- Review of reports in which the chemical indicators did not perform correctly
- Recalls or notices for the chemical indicators being used

- Technician feedback on the ease of use
- New chemical indicators that may have become available

Sometimes, the need for evaluation and review is driven by facility initiatives, such as standardizations or cost-savings programs. Regardless of why, the evaluation process is recommended to consider five items:

**ITEM 1: Risk Tolerance**

The facility should consider the risks of using the indicator, such as inappropriate use, ease of use or interpretation, and time for result.

**Example:** If evaluating internal indicator strips used for 270°F steam sterilization cycles, a facility may consider an indicator that requires all the critical parameters for steam to be determined. This limits the choice to either a Class 5 or Class 6 indicator. Then, depending on the cycle parameters utilized at the facility, they may choose an indicator that monitors the greatest portion of the validated cycle. Using Figure 4 and the stated values for Class 5 and Class 6 indicators, the facility may choose Class 6 indicators to monitor the steam sterilization cycles with 10-minute and 15-minute exposures.

![Indicator Classification](image)

**Figure 3:** Example of the expected amount of time required to show failing conditions and passing conditions for chemical indicator stated values of chemical indicators used for 250°F 30-minute gravity steam sterilization cycle.

**ITEM 2: OEM Recommendations**

Consider whether the product is recommended by the Original Equipment Manufacturer (OEM). OEM recommendations typically include testing performed by, or at the commission of, the OEM. Use of supported products confirms product appropriateness for the equipment and solutions.

When a chemical indicator supported by the OEM detects a failure, the OEM is better able to support the indicator’s result and help resolve the situation. An indicator that is not supported by the OEM can create a situation in which the OEM is unfamiliar with the indicator and unable to quickly resolve the situation.

**ITEM 3: FDA Clearance**

Determine if the chemical indicator will be used in a manner consistent with local regulatory requirements, such as the FDA cleared claim for the product. Products may be used outside of the cleared claim; however, when a facility chooses to do this, all liability for its use falls on the facility. A risk averse facility may choose to avoid off-label use. In the U.S., healthcare facilities can confirm any cleared product claims by searching on the FDA database for 510(k)s or by contacting the FDA directly.

Remember that chemical indicators cleared prior to the introduction of a new exposure time or preconditioning phase for the same sterilization process are not automatically cleared for the new use. The FDA stated in its draft guidance for off-label use that an “approval of a drug or medical device for one intended use does not assure its safety and effectiveness for other uses.”

**ITEM 4: Impact Review**

Review the impact of the product’s features on the processing department. This is not a review of cost, but of the impact to the people and capacity of the department.

Ask if the product is easier to use than the current one. Is the increased complexity justified by a larger safety net, better patient outcomes. higher productivity and lower environmental impact, for example?

**ITEM 5: Process changes**

Does the product eliminate, add or change current practices? It is important to think through the entire process. Changing processes can lead to simplification of complex processes reducing user errors, but may also cause increased user errors.

**Example:** An Air Removal Test provides a result that is not a failure, but a prediction of a failure to come. This provides time to schedule a repair reducing the impact to the steam sterilization department. The ability to schedule a repair when it is convenient allows flexibility.

A facility may decide to change its processes to increase the frequency of air removal tests performed while awaiting the scheduled repair. This reduces the potential of the sterilizer failure going undetected for a long period of time.
This adds both costs and time. A facility would need to weigh the benefits of early detection with the potential of increased risk or testing.

The outcome
After evaluating the types, claims and usage of new chemical indicators the selection should be easier. Once the selection is made the proposed changes may require a trial period. The trial period should be limited and controlled. Documentation of expected outcomes and user feedback should be completed and included as part of the overall evaluation.

Chemical indicators are an essential part of a quality assurance process within a facility to ensure a consistent and expected outcome. But all chemical indicators are not equal, and are used for a variety of purposes. Only after careful consideration of the chemical indicator’s purpose, the risk of using the indicator (or not) and the processes that may be affected by the potential change can a confident decision be made.

References:
1. ANSI/AAMI ST79:2010/A4:2013 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Association for the Advancement of Medical Instrumentation
2. 21 CFR 807 Subpart E Premarket Notification Procedures
3. ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities
4. ASNI/AAMI ST41:2008 Ethylene oxide sterilization in health care facilities: Safety and effectiveness
5. ANSI/AAMI/ISO 11140-1 Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements

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Which chemical indicator is right for me?
Circle the one correct answer:

1. Which of the following processes use Solution Test Strips?
   a. High Level Disinfectant Solution
   b. Liquid Chemical Sterilization
   c. Steam Sterilization
   d. All of the above
   e. A and B only

2. A chemical indicator for hydrogen peroxide gas measures the minimum effective concentration (MEC) of liquid hydrogen peroxide.
   a. True
   b. False

3. Which of the following can be tested with an Air Removal Test?
   a. An ethylene oxide sterilizer
   b. A pre-vacuum steam sterilizer
   c. A high-level disinfection solution

4. In which class does chemical indicator tape belong?
   a. Class 1 process indicators
   b. Class 2 indicators for special tests
   c. Class 3 single parameter indicators
   d. Class 5 integrating indicators

5. Process Challenge Devices (PCDs) test the sterilization process at the time that instruments are being sterilized to confirm that certain processing conditions were achieved.
   a. True
   b. False

6. Which item is not included in a process challenge device?
   a. Biological indicator
   b. Class 5 chemical indicator
   c. Steam Penetration Test

7. What is the purpose for using an internal indicator strip?
   a. Detects an air leak
   b. Confirmation that sterilization conditions were achieved at the location of the instrumentation
   c. Prevents confusion between processed and unprocessed items

8. Which item is not considered when reviewing chemical indicator products and product application as part of a Quality Assurance Program?
   a. Technician feedback
   b. The sterilization applications used for each chemical indicator
   c. The on-time delivery rate of the distributor

9. Which items are considered when evaluating a new chemical indicator?
   a. The cost
   b. The facility’s tolerance for risk
   c. The cleared claims of the chemical indicator
   d. All of the above
   e. B and C

10. When should a chemical indicator that changes current practices be considered?
    a. When the cost savings exceed 20%
    b. When the patient benefit outweighs the cost to change practices
    c. When the cost savings outweighs the new complexity introduced by the change

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