





Chemical Indicators from A to Z

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LEARNING OBJECTIVES

1. Define critical variables, end point and stated values in the context of chemical indicator performance
2. Describe the typical use of the six types of chemical indicators described in International Organization for Standardization (ISO) standards
3. Discuss the use of chemical indicators in hospital sterilization qualify control procedures

Chemical indicators (CIs) are used every day as part of quality control programs in healthcare facilities across the US and around the world. They come in many shapes and colors and are used in all types of disinfection and sterilization processes. Their common use and small size may make them seem simple and, perhaps, unimportant – seeming to be just part of the background of the reprocessing operations; however, CIs are quite complex. Proper use and interpretation of CIs are an important part of the quality control program that protects patients.

Objective 1: Define critical variables, end point and stated values in the context of chemical indicator performance

As defined by the International Organization for Standardization (ISO), CIs are a “test system that reveals change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process.”¹ ANSI/AAMI ST79: 2017, *Comprehensive guide to steam sterilization and sterility assurance in health care*

facilities, states that CIs are “devices 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.” The ISO definition is more generic, covering CIs used to monitor disinfection or sterilization processes, whereas the AAMI definition is specific to sterilization processes. This lesson will focus more on CIs used in sterilization processes, but most of the principles discussed apply to indicators for both sterilization and disinfection processes.

CIs contain a chemical or mixture of chemicals that change in some manner when exposed to a sterilization process. The most common type of change is a color change, when a chemical in or on the indicator reacts or changes during the sterilization process, resulting in an end color that is much different than the starting color of the CI. Another common CI design is called a moving front, where a dark material moves across a window in the CI until it crosses a line on the indicator that differentiates a pass and/or fail response. The moving front is based on the sterilization process melting



a chemical pellet contained in a pocket inside the CI, with the melted chemical then traveling down a paper wick. In all CIs, the information provided by the indicator (pass or fail) is based upon the effect of the sterilization process, the critical variables of the process, or the chemistry of the indicator.

Terminology

CIs have their own set of jargon. It is useful to understand some of these terms to better understand what the pass and fail results of CIs really mean. What follows are a few of the most important terms and definitions.

Critical Variables: These are the aspects of a sterilization or disinfection process that have the largest effect on the effectiveness of that process. For example, the critical variables for steam sterilization are the temperature, exposure time, and steam

quality. Other process variables, like pressure, may be important but are not considered critical to the effectiveness of the process. CIs are designed to respond to one or more of the critical variables of the processes they are designed to monitor.

End Point: This is a term used in CI standards and it essentially means a pass result. The manufacturer designs the CI to show a pass result, or reach its end point, after exposure to the correct level of the critical variable(s). The end point might be the correct shade of color, or the dark bar passing a line on the CI. The manufacturer is required to describe the end point response in the product's instructions for use (IFU). As internal CIs are assessed at the point of use, it is important that Operating Room (OR) professionals also know how to interpret the end point of CIs.

Stated Value: This is another term used in standards, and it is important to understand because several types of CIs are expected to be labeled with stated values if they claim to be compliant with the international standard. Stated values are the values of the specific critical variables where the CI must reach its end point or show a pass result. For example, a stated value on a CI for steam might be:

4 minutes
132°C

That means the manufacturer is stating that the CI must show a pass result if it is exposed to fully-saturated steam at 132°C for 4 minutes. Stated values are a way of understanding if the CI is designed to provide the appropriate challenge to the sterilization process.

ISO Type	ISO Name	Description	Typical Use
1	Process indicators	Exposure indicators	Indicator tapes and chemical dots to differentiate processed and unprocessed goods
2	Special indicators	Indicators for specific tests	Bowie-Dick tests
3	Single critical process variable indicators	Respond to a single critical variable	Inside packs and containers
4	Multicritical process variable indicators	Respond to more than one critical variable	Inside packs and containers
5	Integrating indicator	Respond to all critical variables with a relationship to a biological response	Inside packs and containers, and inside process challenge devices (PCDs)
6	Emulating indicators	Respond to all critical variables	Inside packs and containers, and inside process challenge devices (PCDs)

Table 1: ISO Chemical Indicator Types



Objective 2: Describe the typical use of the six types of chemical indicators described in International Organization of Standardization standards

The ISO standards that provide the performance and labeling requirements for CIs classify the products into six different categories or types.² These types are differentiated by the kind or amount of information provided by the indicator and are based on the performance requirements for each type detailed in the standard. The CI types are described in Table 1.

The type numbers do not imply any sort of hierarchy; that is, the types with higher numbers are not more important than types with lower numbers. They simply provide different information and may also have different applications.

What follows are the four primary applications for CIs:

Exposure or process indicators: These Type 1 CIs are placed outside the package or container and change color after the sterilization process. They are designed to provide easy visual evidence that the pack or container has been exposed to the sterilization process and differentiate exposed from unexposed packs to prevent accidental use of unprocessed devices. It is important to remember that these process indicators are not designed or intended to provide evidence that the sterilization process was effective, only that there was some level of exposure to the process.

Bowie-Dick tests: These Type 2 specialized tests are used to measure the effectiveness of the air removal from pre-vacuum steam sterilizers and air leaks. The Bowie-Dick indicator is contained in a test pack design that will retain some residual air if the vacuum process is not working properly. The residual air inside

of the pack will result in uneven color change of the CI on the strip or sheet, indicating an air removal failure.

ANSI/AAMI standards for sterilization processes used in healthcare facilities all provide information on quality control testing of the sterilization processes. ANSI/AAMI ST79 provides guidance on steam sterilization processes, ANSI/AAMI ST584 provides recommendations for vaporized hydrogen peroxide sterilization processes, and ANSI/AAMI ST415 provides guidance for ethylene oxide (EtO) sterilization processes.

of the pack will result in uneven color change of the CI on the strip or sheet, indicating an air removal failure.

Pack indicators: CIs are placed inside packs or containers to provide evidence that the sterilant penetrated each package and some or all (depending on the indicator) critical process variables were acceptable. The CIs used for this application are Type 3, Type 4, Type 5 or Type 6. The Type 3, Type 4 and Type 6 indicators respond to one variable, more than one variable, or all variables, respectively. Please note that Type 6 emulating indicators are cycle specific, meaning they can only be used in sterilization cycles defined by the indicator's stated values; therefore, a different Type 6 indicator must be used for each different sterilizer cycle in the department. The Type 5 integrating indicators respond to all the critical variables but must also provide a challenge similar to a biological indicator (BI) under specific test conditions. Type 5 CIs are considered the most practical (no cycle specific requirements) and the most robust CI (meaning they respond to all critical process variables and also have a response related to a biological

response under specific conditions).

Load indicators: There are applications where CIs are placed inside of PCDs to provide information on the sterilization process itself, and the information provided by the CI is used as part of the decision process regarding release of the sterilizer load for use on patients. These CIs may be used in PCDs that also contain a BI or they may be in a PCD without a BI. The ISO standard does not specifically address this application, but ANSI/AAMI ST79 states that CIs used in PCDs should be Type 5 or Type 6. Again, for Type 6, the cycle specific requirements will apply, and only the robust Type 5 integrating indicator can be used to make early release decisions for implant loads in emergency circumstances where the device is needed in surgery and the BI result is not yet available.²

Objective 3: Discuss the use of chemical indicators in hospital sterilization quality control procedures

ANSI/AAMI standards for sterilization processes used in healthcare facilities all provide information on quality control



testing of the sterilization processes. ANSI/AAMI ST79 provides guidance on steam sterilization processes, ANSI/AAMI ST58⁴ provides recommendations for vaporized hydrogen peroxide sterilization processes, and ANSI/AAMI ST41⁵ provides guidance for ethylene oxide (EtO) sterilization processes. CIs play an important role in the testing of all these processes. They are always to be used in combination with physical monitors and BIs, and the decisions regarding release of a sterilizer load or use of a package or device is made using the combined information from all the monitoring tools. Let's examine the current recommendations regarding the use of CIs.

Steam Sterilization

Pre-Vacuum Sterilizers

Bowie-Dick test: Daily empty chamber test, performed before the first processed load, for every sterilizer to be used that day

Non-implant Load Release

Process indicators: On the outside of every package (unless internal CI is visible).

Internal indicators: Inside every package. Use Type, 3, 4, 5 or 6, but preferably Type 5 or 6.

PCD: Optional. Type 5 integrating indicator or Type 6 emulating indicator.

Implant Load Release

Process indicators: On the outside of every package (unless internal CI is visible).

Internal indicators: Inside every package. Use Type, 3, 4, 5 or 6, but preferably Type 5 or 6.

PCD: Type 5 integrating indicator with a BI.

Other Tests

Routine sterilizer monitoring: Process

indicators and internal indicators in/on all packages. A CI inside a PCD with the BI is optional.

Sterilizer qualification testing (Pre-vacuum sterilizer): Three consecutive Bowie-Dick tests after three consecutive BI PCDs.

Periodic quality assurance testing:

Internal CIs with BIs within product test samples.

EtO Sterilization

Routine Load Release

Process indicators: On the outside of every package (unless internal CI is visible).

Internal indicators: Inside every package (type is not specified).

PCD: CI with a BI (CI type not specified)

Other Tests

Routine sterilizer monitoring: Process indicators and internal indicators in/on all packages. A CI with the BI inside the PCD.

Sterilizer qualification testing (after installation or relocation): Three consecutive cycles with a PCD containing a BI and CI (type is not specified)

Periodic quality assurance testing:

Internal CIs with BIs within product test samples

Vaporized Hydrogen Peroxide Sterilization

General Use

Process indicators: On the outside of every package (unless internal CI is visible).

Internal indicators: Inside every package (type is not specified).

Conclusion

CIs play an important role in quality assurance programs designed to ensure that medical devices reprocessed in healthcare settings are safe for patient use. CIs' chemistries respond to critical variables in disinfection or sterilization

processes and provide a visual end point that indicates a pass result. CIs cannot prove that an item or package is sterile; however, when used in conjunction with BIs and physical monitors, they can help indicate that a load or package or device can be released for patient use. **C**

REFERENCES

1. International Organization for Standardization. ISO 11139: *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*. 2018.
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4. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST58: *Chemical sterilization and high-level disinfection in health care facilities*. 2013.
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CRCST Self-Study Lesson Plan Quiz - Chemical Indicators from A to Z

Lesson No. CRCST 166 (Technical Continuing Education - TCE) • Lesson expires May 2022

1. Chemical indicators reveal changes in one or more sterilization processes based on:
 - a. Chemical and physical changes
 - b. Mechanical and chemical changes
 - c. Mechanical and physical changes
 - d. Mechanical changes and sterilant concentration
2. Which of the following indicators is a popular type of chemical indicator?
 - a. Multi-directional
 - b. Stationary
 - c. Multi-color
 - d. Front-moving
3. The critical variables for steam sterilization are:
 - a. Exposure time, temperature and chamber pressure
 - b. Exposure time, temperature and steam quality
 - c. Exposure time, sterilant concentration and temperature
 - d. Steam quality, sterilant concentration and temperature
4. Stated values are required on all types of chemical indicators.
 - a. True
 - b. False
5. When a chemical indicator reaches its end point, it means:
 - a. The indicator is showing a fail result
 - b. The item is sterile
 - c. The indicator is showing a pass result
 - d. None of the above
6. Currently, there how many types of chemical indicators?
 - a. Three
 - b. Four
 - c. Five
 - d. Six
7. Process indicators provide information on the effectiveness of the sterilization process.
 - a. True
 - b. False
8. Which type of chemical indicator is placed outside a package to show exposure to a sterilization process:
 - a. Type 1
 - b. Type 2
 - c. Type 3
 - d. Type 5
9. Which type of indicator is cycle specific?
 - a. Type 1
 - b. Type 6
 - c. Type 4
 - d. Type 3
10. Which type of indicator can be used for early release of implants?
 - a. Type 2
 - b. Type 5
 - c. Type 3
 - d. Type 6
11. The Bowie-Dick test is a Type 2 indicator that provides information about the efficiency of the air removal system in a pre-vacuum steam sterilizer.
 - a. True
 - b. False
12. Which type of chemical indicator is used inside of process challenge devices, either with or without a biological indicator?
 - a. Type 3
 - b. Type 4
 - c. Type 2
 - d. Type 5
13. Use of chemical indicators inside of packs is recommended for all types of hospital sterilization processes.
 - a. True
 - b. False
14. When monitoring a sterilization process, chemical indicators are used in conjunction with:
 - a. Biological Indicators and physical monitors
 - b. Biological indicators and sterilant concentration
 - c. Physical monitors and sterilant concentration
 - d. Biological indicators and steam quality
15. Chemical indicators provide information on sterilization processes based on a chemical response to the process.
 - a. True
 - b. False

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