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Chemical Indicators for monitoring sterilization processes: Part two

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LEARNING OBJECTIVES

1. *To understand the International and National standards and guidance for chemical indicators*
2. *To understand how chemical indicators are tested*
3. *To understand how standards of practice prescribe the use of chemical indicators*

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In this second article covering chemical indicators, we will examine the international standards for chemical indicators, how they are categorized, how they are tested and how practice standards describe they should be used.

National and international standards and guidance

International Standards, termed ISOs, are developed by expert committees working within the International Standards Organization (ISO). The committees are made up of individuals who represent their country's standards organization and are experts in the field drawn from academia, industry, and professional organizations. National standards and guidance are created by country-based committees made up of experts coming from within the country.

Once completed, international standards are often published as local country standards possibly with minor modification. Thus, some of the chemical indicator series ISO 11140 are published in the US and under such circumstances the standard will be labelled with an ANSI/AAMI ISO number e.g., ANSI/AAMI ISO 11140-1.[1] This indicates that the international standard has been adopted and published as a national standard by, in this case, the American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI). International standards are sometimes developed in cooperation with the European standards organization, CEN (Committee European de Normalization or European Committee for Standardization). Under such circumstances, a standard will then be published for use in Europe and have an EN ISO notation which, when published by a European country's standards body, will appear as a local standard. For example, the United Kingdom will publish these jointly developed standards as British Standards with the notation BS EN ISO such as BS EN ISO 11140-1 and these will in principle be the same as those published in the US.[1]

Standards for chemical indicators

The requirements for chemical indicators are described in the series of international standards numbered 11140 and some of these are published in the US as AAMI/ANSI standards as discussed above.[1] There are six parts in the series. The first part covers general requirements, as well as requirements for the majority of indicators printed on a substrate or designed as a moving front indicator for use with sterile medical device packs, such as surgical instrument sets. Part 2 is unused. Parts 3, 4 and 5 cover special test chemical indicators used for the daily Bowie-Dick test. Part 6, which is in development, is an international replacement for European Standard EN 867-5, which specifically covers indicators for testing small steam sterilizers and covers the helix device often used by practitioners.

Part 1 of the 11140-1 series describes six types of indicators.[1] These are shown in table 2. Each type has specific requirements that are associated with it. Part 1 of the standard also describes the require-

Table 2: The six types of CI described in EN ISO 11140-1:2014

CI Type	Title	Description
1	Process Indicator	For use with every pack to distinguish processed from unprocessed load items
2	Special Test Indicator	Intended for use in specific tests defined in relevant sterilizer/sterilization standards (e.g. Bowie- Dick Test [9] described in EN ISO 17665)
3	Single Variable Indicator	Reacts to one of the process variables of the sterilization process
4	Multi Variable Indicator	Reacts to two or more of the process variables of the sterilization process
5	Integrating Indicator	Reacts to all of the process variables of the sterilization process that mimic the response of a biological indicator
6	Emulating Indicator	Reacts to all of the process variables of the sterilization process giving a result related to the standard exposure conditions specified in a sterilization standard e.g., 132 for 4 minutes [4]

ments for CIs used in different sterilization processes including steam (often termed moist heat sterilization), dry heat, ethylene oxide, radiation, low temperature steam and formaldehyde and vaporized hydrogen peroxide sterilization processes. (Table 2, previous page.)

Terminology: endpoint and stated values

Each type of CI will have a specific function and requirement associated with it. Before considering each of the types of CI, it is imperative that the reader understands two fundamental terms associated with the performance of CI's. The first is the term "endpoint" and the second is the term "stated value" and both are interrelated. The "endpoint" of a CI is the point at which a pass color change result is indicated after exposure to the conditions specified by the manufacturer or the standard, ANSI/AAMI ISO 11140-1.[1] The exposure conditions which give rise to the pass color change or endpoint are called the "stated values", and there may be one or multiple stated values for each of the process variables the CI responds to depending on which type of indicator is in use. Figure 4 illustrates the endpoint and stated values for a type 5 CI.

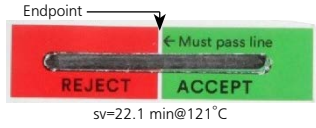

Figure 4: *Showing the endpoint on a moving front CI (the reject/accept line) and the stated values (sv) which give rise to the endpoint being reached.*

The six types of CI

Table 2 describes the six types of CI described in ANSI/AAMI/ISO 11140-1.[1]

Type 1 CIs are designed for placement on the outside of individual packs of sterile medical devices including surgical instrument sets. These indicators may be in the form of an indicator tape which is used to secure instrument sets wrapped in flexible tray wrap. They may be in the form of an adhesive label which contains information about the pack contents. In some cases, a bar code for use within a track and trace systems and an indicator imprint which changes color with exposure to the sterilization process. They may also be in the form of some other device which has a specific function. For example, some tamper evident sealing systems used with sterilization containers may have a CI printed on them which changes color when exposed to the sterilization process. The indicator may also be printed directly onto packaging materials such as paper bags or paper/film pouches. Type 1 chemical indicators provide a very important function because they help ensure non-processed instrument sets are not released into use. Before sets are released from the SPD, operators should be trained to examine every pack to make sure the CI has changed color. Similarly, operating room practitioners must also be trained to do the same. Sadly, reports still appear in the press which recount the use of non-sterilized sets by surgeons.[2] It is important to understand that type 1 CIs are not intended to provide evidence of sterility and should not be regarded as sterility indicators.

Type 2 CIs are used in special tests usually related to making sure the sterilizer is performing correctly before it is used for processing loads. A prime example of this type of indicator is the Bowie-Dick type indicators used daily to ensure that a steam sterilizer is achieving adequate air removal and steam penetration when tested using a standardized test load (3, 4). Parts 3, 4, 5 and in the future 6 of ISO 11140 describe the requirements for such indicators. The Bowie-Dick test will be discussed in more detail in part 3.

Type 3 CIs are single variable indicators which are designed to respond to just one process variable of the sterilization process. A good example of these types of indicators are the Diack tubes which contain a pellet of wax material sealed inside a glass tube that melts when exposed to the correct sterilization temperature.[5] Clearly these types of indicators have limited utility because in order to know that a sterilization process has been effective, we need evidence that all of the process variables (i.e., those contributing to microbial kill), have been present at a sufficient level during the process.

Type 4 CIs are multi-variable indicators, which are designed to respond to two or more process variables. For a steam sterilization process whose process variables are time and temperature in the presence of moisture, a type 4 CI must react to at least two of these variables. It is important to note that the practitioner must make careful choices when using such indicators since in a steam sterilization process, the presence of moisture is vital in ensuring efficacy of the process. So, a type 4 CI, which only responds to time and temperature, may give rise to misleading conclusions because such an indicator would also respond to identical dry heat conditions. The manufacturer of a type 4 indicator is required to specify the stated values for each of the process variables the indicator responds to however, there is no requirement for the manufacturer to choose a stated value with a relationship to the sterilization process in which the indicator might be used (see type 6). Practitioners should be aware of this and ensure that if they are using a Type 4 indicator, the stated values are of relevance to the sterilization process they are using. For example, a Type 4 may have stated values of 1 minute at 132 °C in moist heat, which clearly has little relevance to a sterilization process that is being operated at 132 °C for 4 minutes.

Type 5 CIs are integrating indicators and are designed to respond to all of the variables of a sterilization process. Thus, in a steam sterilization process they must respond to time, temperature, *and* the presence of moisture (typically in saturated steam; see later section). Conversely, they must not give a 'pass' result when exposed to the same time and temperature of exposure in the absence of moisture (i.e., dry heat) and they are tested to make sure they do not. Similarly, in an EO process they must respond to the process variables of time, temperature, ethylene oxide concentration and humidity, and for vaporized hydrogen peroxide, time, temperature, and hydrogen peroxide vapor concentration. They must not give a pass result if EO gas or humidity are at inadequate levels.

Type 5 integrating indicators have a special characteristic in that they provide a result that is similar to one that would be expected from a biological indicator - effectively mimicking the response of a biological indicator.[6] With this in mind, the manufacturer of a steam type 5 indicator must provide at least three stated values. The first should be at an exposure temperature of 121 °C and must be not less than 16.5 minutes. The second value must be at 135 °C and should not be less than 1.2 minutes, and at least a third must be declared at an equidistant intermediate time and temperature of exposure. The temperature coefficient (theoretical z value) of the color change reaction must then fall between 10 and 27°C. All of these requirements mirror the minimum values that are given for a biological indicator for steam sterilization in ISO 11138.[6]

Type 6 CIs are emulating indicators and are designed to provide a pass result which has a direct relationship to a time/temperature combination which may be cited in a standard, local guidance, national regulation or a pharmacopoeia. As an example, a type 6 steam CI might have stated values of 132 °C and 4 minutes, which means it will give a pass result after exposure to moist heat at 132 °C for 4 minutes -- a commonly used time/temperature combination used in the US. In theory, a type 6 CI should only have one set of stated values related to a particular sterilization process. However, it is common practice for manufacturers to

Self-Study Test Answers: 1. A, 2. B, 3. A, 4. B, 5. B, 6. A, 7. A, 8. A, 9. A, 10. B

specify a range of stated values covering a range of sterilization temperatures used by practitioners around the world. For example, 121, 132 and 134 °C are common exposure temperatures used in various parts of the world and a CI may have stated values for each of these temperatures with appropriate exposure time stated values.

Testing chemical indicators

All chemical indicators have to be tested before they are released into use, and this includes every batch produced by a manufacturer. Type 1, 3, 4, 5 and 6 CIs are tested in a special type of "exposure apparatus" called a Chemical Indicator Evaluating Resistometer (CIER) vessel or Resistometer. CIER vessels are designed for accurate control of the exposure conditions occurring within what is usually a very small chamber - typically 10 to 20l in volume.

International standard ISO 18472 [7] is the standard that describes the requirements for CIER vessels. The CIER vessel is also designed to ensure that the required exposure conditions (e.g., 132°C for 4 minutes) are reached very quickly and that the chamber is vented equally quickly at the end of the exposure period. For example, a typical test carried out within a steam CIER vessel would involve mounting the samples on a sample holder, (which should not influence the outcome of the results) and placing the samples in the chamber, closing the door, and then drawing a vacuum to 45 mB absolute pressure (1.33 inches of mercury). Steam is then admitted to the chamber to the required exposure temperature and pressure within 10 seconds. The exposure temperature is then held within a tolerance of +/- 0.5 °C for the required exposure time (the stated value for the indicator or as prescribed in the standard); at which point the chamber is evacuated to 10mB (3 inches of mercury) within 60 seconds. By using such a test cycle, the indicator is exposed to carefully controlled, constant conditions that are often termed 'square wave' conditions. This is in contrast to the conditions that would be encountered in a production sterilizer where multiple pulses of vacuum and steam injection would be employed to remove the air trapped within the chamber and load prior to exposure to the sterilization phase where temperature and pressure are maintained relatively constant. These multiple pulses can give rise to some color change in CIs prior to exposure to the sterilization phase which is unavoidable and quite normal.

Testing chemical indicators: pass and fail

As described above, type 3, 4, 5 and 6 CIs will have stated values associated with them that are defined by the manufacturer of the product. When the p-roduct is exposed to these stated values in a CIER vessel, a pass result (called its endpoint) should be observed. Clearly CIs will also show a fail response under certain exposure conditions and ANSI/AAMI ISO 11140-1[1] prescribes test conditions under which such a failure response should be observed in the CI. Thus, the CI will be tested for both a pass and a failure response. Generally, the exposure conditions which should be used for testing for a failure response are related to the stated values for the indicator. The failure exposure test condition is usually a percentage reduction in the CI's stated value for exposure time (and concentration) and a defined reduction in the CI's stated value for temperature. The test requirements for type 1 CI's are an exception to this approach in that the standard specifies which test conditions should be used for a pass and fail exposure condition .

To illustrate this further, table 3 shows the test conditions for type 1, 3, 4, 5 and 6 steam sterilization CIs.(Table 3)

Table 3: The exposure conditions in a steam CIER vessel allowing establishment of the performance to ANSI/AAMI/ISO 11140-1 of various types of a chemical indicator for monitoring steam sterilization

CI Type	Pass Exposure Conditions		Fail Exposure Conditions	
	Temperatures (°C)	Time (min)	Temperatures (°C)	Time (min)
1	121	10	121	2
	134	2	134	0.3
3	SV	SV	SV-2	SV-25%
4	SV	SV	SV-2	SV-25%
5	121	SV >16.5	SV-1	SV-15%
	135	SV >1.2	SV-1	SV-15%
	T[a]	SV	SV-1	SV-15%
6	SV	SV	SV-1	SV-6%

Type 2 are special test indicators for which separate parts of ISO 11140 exist. The manufacturer of a type 5 CI declares SV's at 121 and 135 °C and at one other temperature

Sv = manufacturers stated value

Standards for using Chemical Indicators

Chemical indicators are used in various applications as discussed above.

There are a number of standards and local guidance documents which provide information on how and when they should be used. International standards for various sterilization processes and local guidance documents require the use of a system for differentiating processed from non-processed items.[4] Whilst a carefully controlled segregation system might be used in an industrial manufacturing setting, the most obvious and secure means of complying with this requirement in a healthcare facility is to use a type 1 process indicator which should be attached to every pack. This provides evidence to the SPD operators that each and every pack has been processed and to the end user it signals that that particular pack has similarly been processed.

Internal pack indicators are vital for indicating that sterilant has penetrated into the pack and that sterilizing conditions have been achieved at the point of placement. An internal pack indicator of type 5 or 6 showing a pass result will provide some evidence that the correct conditions have been met, because the performance of these types of indicators are linked to the response of a biological indicator or relate to a recognized sterilization time temperature relationship. Conversely a CI that shows a fail result should sound immediate alarm bells that something has gone wrong during the sterilization cycle, or incorrect packaging materials or accessory items have adversely affected the process.

The requirements for the use of internal pack indicators are described in a number of national guidance documents. Thus ANSI/AAMI ST 79[4] requires the placement of a CI in every pack which is to be steam sterilized. The use of such indicators is primarily aimed at the healthcare professionals who will eventually use the packs during patient therapy. The Operating Room (OR) teams will normally carry out a series of checks on instrument sets prior to use. This will include checks to ensure the sterile barrier system is intact with no signs of perforation or staining. If sterilization container systems are used, they will check the tamper evident seal and once opened, the filter systems or valve assemblies to make sure they appear operational. The lid seals will also be checked for integrity. One of the most important checks that will be carried out is on the process indicator attached to the instrument set to make sure it has changed color. In addition, the OR teams will also check the color change of any internal CI included with the instruments. It is vital that such indicators have a very clear endpoint, and that full instructional material is available to the end user to enable correct interpretation of the CI. Any changes in supplier should also be notified to the end users so that appropriate training and instructional material can be made available to those who will interpret CI results.

All of these checks are described in the World Health Organization's Surgical

Safety Checklist [8] which describes CIs as "sterility indicators" which is technically incorrect, but in common use by medical and nursing practitioners. The checklist is designed to prevent accidental harm arising due to unforeseen circumstances and has been shown to be highly effective when implemented in practice. Clearly the use of non-sterile instruments during an OR procedure could be catastrophic for the patient, leading to infection or morbidity.[2] Examination of the internal and external CIs provides one of the vital pieces of evidence ensuring sets are safe to use.

Conclusions

Chemical Indicators are one of three basic types of technology that can be used to routinely monitor the efficacy of sterilization processes used in industry and the hospital SPD. They can be used to identify unprocessed from processed surgical instrument sets when adhered to the outside of packs, thereby avoiding non sterilized packs being sent to the OR department. They can be used to indicate that sterilizing agent has penetrated through the sterile barrier system packaging and stated exposure conditions have been met, thereby avoiding inadequately or incorrectly processed loads being used.

Chemical Indicators are therefore an extremely useful and practical tool for ensuring SPD processes are functioning correctly. There are six types of Chemical Indicators and the test requirements for each is specified in standards. Several standards used by medical personnel describe the use of CIs to help OR teams determine if a surgical instruments set is sterile. HPN

This article is part of a three-article series. Part three will be in our February issue.

References online at: https://hpnonline.com/21246339

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Chemical Indicators for monitoring sterilization processes: Part two

Circle the one correct answer:

1. **Process indicators can identify processed from unprocessed load items (from Table 2)**
   A. True B. False
2. **Type 4 chemical indicators can effectively monitor all critical variables in any sterilization cycle**
   A. True B. False
3. **Type 5 chemical indicators or integrators can detect all the critical variables on steam sterilization cycles.**
   A. True B. False
4. **Type 6 chemical indicators or emulators can be used in every modern steam sterilization cycle.**
   A. True B. False
5. **Testing chemical indicator can be conducted in any steam sterilization equipment.**
   A. True B. False
6. **The use of chemical indicators is part of the tools SPD's professionals can use to detect potential cycle failure.**
   A. True B. False
7. **The use of internal chemical indicator in every pack or containers is required on ANSI/AAMI ST 79:2017.**
   A. True B. False
8. **Internal Chemical Indicators must be checked at the OR prior to the use of the instruments.**
   A. True B. False
9. **Chemical indicators can be used only following its manufacturers instruction for use.**
   A. True B. False
10. **Containers do not need to be assessed with external chemical indicators**
    A. True B. False

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