Sterilization Monitoring
Chemical Indicators (CIs) – Class to Type

Updated ISO 11140-1 Document
- The International Standards Organization (ISO) writes standards that apply across the world.

Examples include: Product performance testing, Updated Instructions for Use, Packaging and Labeling to read “Type”, etc.

References
Association for the Advancement of Medical Instrumentation (AAMI)
Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79

What to expect?
- There will be a transition period as manufacturers of chemical indicators comply with the new requirements outlined in ISO 11140-1:2014
- Examples include: Product performance testing, Updated Instructions for Use, Packaging and Labeling to read “Type”, etc.
- In the future you might expect to see this new ISO 11140-1:2014 Standard incorporated into applicable healthcare user documents, as they become updated.

Chemical Indicators
- ISO 11140-1:2005 is referenced in various publications worldwide, including ANSI/AAMI ST79

In the future you might expect to see this new ISO 11140

ISO 11140-1:2014 Chemical Indicators (CIs): Key changes
- The term “class” has been replaced with “type” to describe the use of indicators according to their intended use.
- CIs are categorized into six types - The categorization structure is used solely to denote the characteristics and intended use of each type of indicator when used as specified by the manufacturer.
- ISO 11140-1:2014 emphasizes the categorization has no hierarchical significance. For example:
  - Internal CIs, Type 3, 4, 5, and 6, are not better than a Type 2 Bowie-Dick test
  - Type 6-emulating indicators are not better at monitoring the sterilization process than Type 5 integrating indicators, etc.

ISO 11140-1:2014 - Chemical Indicators (CIs): Key definition
- Critical Process Variable – variable identified as being essential to the attainment of sterilization and monitored by the chemical indicator:
  - E.g., for steam sterilization, the critical process variables are time, temperature, and moisture (steam)

ISO 11140-1:2014 Chemical Indicators (CIs): Key changes
- Optional", additional prefixes to these six indicator categories are also now specified, as follows:
  - e = “Exposure” or process indicator (e.g., Tape)
  - s = “Special” indicator (e.g., Bowie-Dick)
  - i = “Internal” indicator (e.g., CI strip)
- There have been changes to the performance requirements for:
  - Type 1 indicators for steam, EO, and vaporized hydrogen peroxide processes
  - Type 5 indicators for steam processes and EO processes

ISO 11140-1:2014 Chemical Indicators (CIs): Key changes
- What has changed?
- What does this mean for me?

Chemical Indicators
- The term “class” has been replaced with “type” to describe the use of indicators according to their intended use.
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ISO 11140-1:2014 - Chemical Indicators (CIs): Key changes
Table describing the three categories according to their intended use.

<table>
<thead>
<tr>
<th>TYPE</th>
<th>CATEGORY</th>
<th>INTENDED USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1 “Exposure” or Process indicator</td>
<td>e1</td>
<td>Indicates exposure to a process to allow differentiation between unprocessed and processed items, and/or indicates gross failure of a sterilization process.</td>
</tr>
<tr>
<td>Type 2 “Special” indicator</td>
<td>e2</td>
<td>For use in special applications (e.g., Bowie-Dick).</td>
</tr>
<tr>
<td>Type 3, 4, 5, 6 “Internal” indicators</td>
<td>i(s)</td>
<td>Placed inside individual load items to assess attainment of the critical process variable(s) at the point of placement.</td>
</tr>
<tr>
<td>Type 3 Internal indicator</td>
<td>i(s)</td>
<td>Reacts to one critical process variable.</td>
</tr>
<tr>
<td>Type 4 Internal indicator</td>
<td>i</td>
<td>Reacts to more than one critical process variable.</td>
</tr>
<tr>
<td>Type 5 integrating indicator</td>
<td>i</td>
<td>Reacts to all critical process variables.</td>
</tr>
<tr>
<td>Type 6 emulating indicator</td>
<td>i</td>
<td>Reacts to all critical process variables.</td>
</tr>
</tbody>
</table>

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