AAMI TIR74: 2016
Change summary for ISO 11135:2014, Sterilization of health care products—Ethylene oxide—Requirements for the development, validation and routine control of a sterilization process for medical devices
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Change summary for ISO 11135:2014, Sterilization of health care products—Ethylene oxide—Requirements for the development, validation and routine control of a sterilization process for medical devices

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Association for the Advancement of Medical Instrumentation


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<table>
<thead>
<tr>
<th>Contents</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Committee representation</td>
<td>iv</td>
</tr>
<tr>
<td>Introduction</td>
<td>vi</td>
</tr>
<tr>
<td>Change summary</td>
<td>1</td>
</tr>
</tbody>
</table>

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Committee representation

Association for the Advancement of Medical Instrumentation
AAMI Industrial Ethylene Oxide Sterilization Working Group

This Technical Information Report was developed by the AAMI Industrial Ethylene Oxide Sterilization Working Group. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the AAMI Industrial Ethylene Oxide Sterilization Working Group had the following members:

Cochairs: Jonathan Bull, Johnson & Johnson
           Jeffrey Martin, Sterilization and Quality System Consulting

Members: Erin Armstrong, B Braun Medical
         Edward Arscott, NAMSA
         David Ballard, Dynatec Scientific Labs
         Anne F. Booth, MS, Booth Scientific
         Carolyn Braithwaite-Nelson, Spectranetics
         Jonathan Bull, Johnson & Johnson
         Tim Carlson, BD Medical
         Sarah Chamberlain, Accuratus Labs Services
         Gary N. Cranston, Consulting & Technical Services/PCS
         Elaine Daniell, Bard Medical Division
         Douglas D. Davie, Sterilization Validation Services
         Darci Diage, Direct Flow Medical
         Mary Ann Drosnock, MS, Healthmark Industries
         Paul Fioretti, PF Quality Consulting
         William F. FitzGerald, PE, FitzGerald & Associates Ltd.
         Dan B. Floyd, RM, Nelson Laboratories Inc.
         Lisa Foster, Adiuvo QS & SA Consulting
         Matthew Freeman, Terumo BCT
         Zony R. Glaser, PhD MPH CSPDM, Johns Hopkins University
         Michael Groendyk, Arthrex
         Douglas Habrecht, Sterility Assurance
         Arthur C. Harris, Cook
         Deborah A. Havlik, Hospira Worldwide
         Jason Hedrick, Medtronic
         Clark W. Houghting, Cosmed Group
         Krista Howard, WL Gore & Associates
         Naipur Jain, Intuitive Surgical
         Carolyn L. Kinsley, LexaMed
         Karen A. Kowalczyk, Centurion Sterilization Services
         Christine Loshbaugh, Edwards LifeSciences
         Mollie Love, Smiths Medical
         Jeffrey Martin, Sterilization and Quality System Consulting
         Ted May, Andersen Products Inc.
         Patrick McComick, PhD, Bausch & Lomb
         David Ford McGoldrick, BS, Abbott Laboratories
         Russell D. Mills, GE Healthcare
         Gerry A. O’Dell, MS, Gerry O’Dell Consulting
         Dave Parente, ECOLAB Healthcare
         Michelle Peterson, Stryker Instruments
         Andrew Porteous, Baxter Healthcare
         Nancy Rakiewicz,, IUVO BioScience
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         Liza Salerno, Accuratas Labs Services
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Introduction: Need for this AAMI TIR


The purpose of this document is to provide a summary of differences between the new 2014 version and the 2007 version of this standard. The intent is to provide end users with a quick reference when evaluating and implementing the 2014 version of ISO 11135 in their facilities. The document has been created and reviewed by AAMI Working Group 1, Industrial Ethylene Oxide Sterilization. However, it should be noted that this document is a guidance or summary only, and should not be considered a complete and definitive record of all changes. Final assessment of the changes, and possible impacts of these changes, is the responsibility of the end user.

The first column of the table references the clause in ISO 11135:2014, the second column provides a description of the change from the 2007 version to the 2014 version, and the 3rd column provides an opinion on the possible impact of the change.