This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
Abstract: This technical information report provides guidance for health care product manufacturers in the qualification of polymeric materials, ceramics, and metals for use in health care products that are sterilized by the following modalities: a) radiation (gamma, electron beam, or x-ray); b) ethylene oxide; c) moist heat (steam); d) dry heat; e) hydrogen peroxide; f) nitrogen dioxide, g) peracetic acid vapor, h) liquid peracetic acid, and i) hydrogen peroxide–ozone. Annexes address the specific sterilization modality concerns.

Keywords: material qualification, sterilization
AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Committee representation</td>
<td>iv</td>
</tr>
<tr>
<td>Foreword</td>
<td>vii</td>
</tr>
<tr>
<td>1 Scope</td>
<td>1</td>
</tr>
<tr>
<td>2 Definitions, symbols, and abbreviations</td>
<td>2</td>
</tr>
<tr>
<td>3 Selection of materials</td>
<td>4</td>
</tr>
<tr>
<td>4 Manufacturing process and design considerations</td>
<td>33</td>
</tr>
<tr>
<td>5 Material testing</td>
<td>36</td>
</tr>
<tr>
<td>6 Accelerated aging programs</td>
<td>42</td>
</tr>
<tr>
<td>Annex A (informative) Radiation sterilization—Material compatibility fundamentals</td>
<td>43</td>
</tr>
<tr>
<td>Annex B (informative) Ethylene oxide sterilization—Material compatibility fundamentals</td>
<td>49</td>
</tr>
<tr>
<td>Annex C (informative) Moist heat sterilization—Material compatibility fundamentals</td>
<td>55</td>
</tr>
<tr>
<td>Annex D (informative) Dry heat sterilization—Material compatibility fundamentals</td>
<td>64</td>
</tr>
<tr>
<td>Annex E (informative) Hydrogen peroxide sterilization—Material qualification fundamentals</td>
<td>72</td>
</tr>
<tr>
<td>Annex F (informative) Nitrogen dioxide sterilization—Material qualification fundamentals</td>
<td>77</td>
</tr>
<tr>
<td>Annex G (informative) Peracetic acid (PA) vapor sterilization—Material compatibility fundamentals</td>
<td>82</td>
</tr>
<tr>
<td>Annex H (informative) Liquid peracetic acid sterilization—Material compatibility fundamentals</td>
<td>87</td>
</tr>
<tr>
<td>Annex I (informative) Hydrogen peroxide–ozone sterilization—Material compatibility fundamentals</td>
<td>91</td>
</tr>
<tr>
<td>Annex J (informative) Accelerated aging programs</td>
<td>95</td>
</tr>
<tr>
<td>Annex K (informative) Example of a device evaluation process</td>
<td>101</td>
</tr>
<tr>
<td>Annex L (informative) Material abbreviations</td>
<td>103</td>
</tr>
<tr>
<td>Bibliography</td>
<td>104</td>
</tr>
</tbody>
</table>
Committee representation

Association for the Advancement of Medical Instrumentation

Compatibility of Materials Subject to Sterilization Working Group

This technical information report (TIR) was developed by the AAMI Compatibility of Materials Subject to Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the TIR does not necessarily mean that all working group members voted for its approval. At the time this standard was published, the AAMI Compatibility of Materials Subject to Sterilization Working Group had the following members:

Chair: Karl Hemmerich

Members:
- Agnieszka Baczek, Medline Industries Inc
- Jenny Berg, Steriluent Inc
- Carolyn Braithwaite-Nelson, Spectranetics Corporation
- Eunhee Cho, PhD, St Jude Medical Inc
- Nancy Chobin, RN, CSPM, CFER, Sterile Processing University LLC
- Sean Colwell, WuXi AppTec Inc
- Emily Craven, Mevex Corporation
- Chris Deneux, Becton Dickinson & Company
- John DiCaro, Medtronic Inc
- Mary Ann Drosnock, MS, Healthmark Industries Company Inc
- Gordon Ely, MMEdx Group
- Randy Eveland, PhD, STERIS Corporation
- Gloria Frost, PhD, Cardinal Health
- Joel Gorski, PhD, NAMSA
- Doug Harbrecht, Sterility Assurance LLC
- Arthur Harris, Cook Inc
- Fatima Hasanain, Sterigenics International
- Karl Hemmerich, Sterilization Validation Services
- Mollie Holter, Smiths Medical
- Nichole Jackson, Ecolab
- Nupur Jain, Intuitive Surgical Inc
- Carolyn Kinley, LexaMed Ltd
- Ryan Klabba, Integrated Medical Systems
- Stacy Krommenhoek, Boston Scientific Corporation
- Byron Lambert, Abbott Laboratories
- Jean-Luc Lemyre, TSO3 Inc
- Anne Lucas, PhD, FDA/CDRH
- Tania Lupu, Case Medical Inc
- Jeff Martin, Sterilization and Quality System Consulting Ltd
- Gerry McDonnell, PhD, Johnson & Johnson
- Jami McLaren, PhD, Boston Scientific Corporation
- John Nedick, Olympus America Inc
- Gerry O’Dell, Gerry O’Dell Consulting
- Wayne Rogers, Wayne J Rogers Enterprises
- Mason Schwartz, Cantel Inc
- Paul Somodi, Hospira, a Pfizer company
- Larry Talapa, 3M Healthcare
- Don Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc
- Wendy Wangsgard, Nelson Laboratories LLC
- Roberto Zumbado, Philips Electronics North America

Alternates:
- Jerome Bell, LexaMed Ltd
- Tim Carlson, Becton Dickinson & Company
- Peter Cheung, FDA/CDRH
- Alexandra Cooper, Arthrex Inc
- Mike DiCicco, PhD, Johnson & Johnson
- Dave Dion, Cardinal Health
- Chris Evans, Integrated Medical Systems
- Veronica Falkovitz, HIGHPOWER Validation Testing & Lab Services Inc
NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

At the time this document was published, the AAMI Sterilization Standards Committee had the following members:

**Cochairs:**
- Michael H. Scholla, MS, PhD
- Patrick Weixel

**Members:**
- Anas Aljabo, PhD, SteriPro Canada Inc
- Brett Anderson, Cochlear Ltd
- Hank Balch, University Health System
- Richard Bancroft, STERIS Corporation
- Trabue D. Bryans, BryKor LLC
- Tim Carlson, Becton Dickinson & Company
- Phil Cogdill, Medtronic Inc
- Sean Colwell, WuXi AppTec Inc
- Ramona Conner, RN, MSN, CNOR, FAAN, Association of periOperative Registered Nurses
- Lena Cordie, Qualitas Professional Services LLC
- Jacqueline Daley, Sharp Metropolitan Medical Campus
- Gordon Ely, MiMedx Group
- Lisa Foster, Adiuvo QS & SA Consulting
- Joel R. Gorski, PhD, NAMSA
- Joyce Hansen, Johnson & Johnson
- Stephanie Homuth (Independent Expert)
- Clark Houghtling, Cosmed Group Inc
- Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Material Management
- Byron J. Lambert, PhD, Abbott Laboratories
- Michelle Luebke, Baxter Healthcare Corporation
- Patrick J. McCormick, PhD, Bausch & Lomb Inc.
- Gerry McDonnell, PhD, Johnson & Johnson
- Gerry O’Dell, Gerry O’Dell Consulting
- Adrian Ponce, Verrix LLC
- Janet M. Prust, 3M Health Care
- Nancy J. Rakiewicz, IUVO BioScience
- Michael H. Scholla, MS, PhD, DuPont Protection Solutions
- Joan Spear, B Braun of America Inc
- Patrick Weixel, FDA/CDRH
- Sid Wiggs (Independent Expert)
- Martell Kress Winters, SM, Nelson Laboratories LLC
- Stephen Yeadon, Boston Scientific Corporation
- William E. Young, Sterigenics International
- Roberto Zumbado, Philips

© 2018 Association for the Advancement of Medical Instrumentation ■ AAMI TIR17:2017
Foreword

This AAMI technical information report (TIR) was developed to provide additional guidance in order to improve quality and reduce the costs and time required for performing material qualifications.

One of the activities encompassed within sterilization standards is to evaluate how the mode of sterilization affects product and packaging. This element is mentioned in each of the respective industrial sterilization standards (ANSI/AAMI/ISO 11135 series, ANSI/AAMI/ISO 11137 series, ANSI/AAMI/ISO 17665-1, and ANSI/AAMI/ISO 14937). The basic requirements of these standards include the implementation of a program to demonstrate the quality, safety, and performance of the product throughout its shelf life or until its expiration date. Components of such a program are 1) expeditious material selection, 2) prudent processing of those materials, 3) testing of any specific properties essential to the product’s intended function, and 4) accelerated aging programs. AAMI TIR17:1997 addressed these four components of a material qualification program for radiation sterilization, and AAMI TIR17:2008 addressed these four components for additional sterilization modalities. There have been many requests from the health care manufacturing industry to expand material compatibility information to cover more sterilization modalities. Therefore, this TIR supersedes AAMI TIR17:2008, with an expanded scope that includes the following sterilization modalities:

- Radiation
- Ethylene oxide
- Moist heat (i.e., steam)
- Dry heat
- Hydrogen peroxide
- Nitrogen dioxide
- Peracetic acid vapor
- Liquid peracetic acid
- Hydrogen peroxide–ozone

These modalities are individually addressed in Section 3 and Annexes A through I of this TIR. Guidance on the processing of materials is carried over from AAMI TIR17:2008 and is provided in Section 4. General guidance on the testing of materials is provided in Section 5. Accelerated aging program information is provided in Section 6. If it has been carried over from AAMI TIR17:2008, or if it has been subsequently published elsewhere, references have been provided. To facilitate aging programs with the advent of combination devices, the accelerated aging information is supplemented with a comparison of accelerated aging programs for devices and accelerated stability programs for pharmaceuticals.

The bulk of the guidance on the compatibility of materials subject to sterilization is provided in Section 3 and the tables found in Annexes A through I. Each sterilization modality is described in enough detail (Section 3) for the reader to understand the parameters of the sterilization process that must be considered in evaluating material compatibility. Brief reference to the application of each sterilization modality to pharmaceutical and biological agents is also provided. One of the most beneficial aspects of the guidance in each Annex is a list of compatible materials to aid in the material selection process.

This TIR contains guidelines that are not intended to be absolute or applicable in all circumstances. Judgment should be used in applying the information in this TIR.

NOTE—This document is not an AAMI standard or an American National Standard, and the material contained herein is not normative in nature.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the AAMI technical information report, Compatibility of materials subject to sterilization (AAMI TIR17:2017), but it does provide important information about the development and intended use of the document.
Compatibility of materials subject to sterilization

1 Scope

This document provides guidance for health care product manufacturers in the selection and qualification of polymeric materials, ceramics, and metals for use in health care products sterilized by the following methods:

- Radiation (gamma, electron beam, or x-ray)
- Ethylene oxide (EO)
- Moist heat (steam)
- Dry heat
- Hydrogen peroxide
- Nitrogen dioxide
- Vaporized peracetic acid
- Liquid peracetic acid
- Hydrogen peroxide–ozone

NOTE—All references to hydrogen peroxide sterilization in this TIR refer to sterilization in the gas phase. (Hydrogen peroxide is also used for liquid chemical sterilization, but that application is outside the scope of this TIR.)

Guidance in this TIR relates to the following:

a) **Material selection:** Choosing sterilization-compatible materials (see Section 3 and Annexes A–I)

b) **Material processing:** Optimizing the functional performance of materials selected to avoid processing errors that can contribute to negative effects from sterilization (see Section 4)

c) **Material testing:** Challenging critical aspects of the product for functionality and safety after sterilization and aging (see Section 5)

d) **Accelerated aging:** Applying programs that ensure correlation with real-time aging while reducing the cost and time required for material qualifications (see Section 6)

NOTE—The information in this TIR is not intended to provide a rationale for the use of materials without proper material qualification. The information is general and is intended only as a guide for successfully initiating material qualification programs.