# Technical Information Report

# AAMI TIR17: 2017

## Compatibility of materials subject to sterilization

AAMI
Advancing Safety in Health Technology

**AAMI Technical Information Report**

**AAMI TIR17:2017**
(Revision of AAMI TIR17:2008)

# Compatibility of materials subject to sterilization

Approved 11 June 2017 by
**Association for the Advancement of Medical Instrumentation**

**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.

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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.

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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.

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## 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:

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*Members:*
Agnieszka Baczek, Medline Industries Inc
Jenny Berg, Sterilucent Inc
Carolyn Braithwaite-Nelson, Spectranetics Corporation
Eunhee Cho, PhD, St Jude Medical Inc
Nancy Chobin, RN, CSPM, CFER, Sterile Processing University LLC
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Fatima Hasanain, Sterigenics International
Karl Hemmerich, Sterilization Validation Services
Mollie Holter, Smiths Medical
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Nupur Jain, Intuitive Surgical Inc
Carolyn Kinsley, LexaMed Ltd
Ryan Klebba, Integrated Medical Systems
Stacy Kromenhoek, Boston Scientific Corporation
Byron Lambert, Abbott Laboratories
Jean-Luc Lemyre, $TSO_3$ Inc
Anne Lucas, PhD, FDA/CDRH
Tania Lupu, Case Medical Inc
Jeff Martin, Sterilization and Quality System Consulting LLC
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 Falkevitz, HIGHPOWER Validation Testing & Lab Services Inc

Niki Fidopiastis, Sterigenics International
Elyse Gaudreau, $TSO_3$ Inc
Betty Howard, STERIS Corporation
Sandra Iverson, Cantel Inc
Britt Jones, WuXi AppTec Inc
Peter Kalkbrenner, Sterilucent Inc
Kaumudi Kulkarni, Healthmark Industries Corporation
Vu Le, Abbott Laboratories
Nicole McLees, 3M Healthcare
Michael O'Hara, FDA/CDRH
Dave Parente, Ecolab
Nicole Pasquino, Case Medical Inc
Deanna Porter, St Jude Medical Inc
Gary Socola, HIGHPOWER Validation Testing & Lab Services Inc
Laxmismita Sreedasyam, Boston Scientific Corporation
Mara Tafoya, WuXi AppTec Inc
Brian Wallace, Intuitive Surgical Inc
Martell Winters, Nelson Laboratories LLC

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
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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
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Joel R. Gorski, PhD, NAMSA
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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

*Alternates:* Stacy Bohl, Boston Scientific Corporation
Jonathan Bull, Johnson & Johnson
Greg Crego, IUVO BioScience
Niki Fidopiastis, Sterigenics International
Jeffrey Marx, STERIS Corporation
Kimberly Patton, Becton Dickinson & Company
Christine Render, Cosmed Group Inc
Michael Sadowski, Baxter Healthcare Corporation
Sharon Van Wicklin, Association of periOperative Registered Nurses
Craig A. Wallace, 3M Health Care

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## 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.