Technical Information Report

AAMI TIR17: 2017/(R)2023

Compatibility of materials subject to sterilization

AAMI
Advancing Safety in Health Technology

AAMI Technical Information Report

AAMI TIR17:2017/(R)2023
(Revision of AAMI TIR17:2008)

Compatibility of materials subject to sterilization

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AAMI

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

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Committee representation

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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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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.

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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 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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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.