Technical Information Report

AAMI TIR17: 2024

Compatibility of materials subject to sterilization

AAMI

Advancing Safety in Health Technology

AAMI Technical Information Report

AAMI TIR17:2024
(Revision of AAMI TIR17:2017(R)2020)

Compatibility of materials subject to sterilization

Approved 15 October 2024 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) vaporized hydrogen peroxide, f) nitrogen dioxide, g) peracetic acid vapor, h) liquid peracetic acid, i) hydrogen peroxide–ozone, and j) chlorine dioxide. Annexes address the specific sterilization modality concerns.

Keywords: material qualification, sterilization

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Published by

AAMI
901 N Glebe Rd, Suite 300
Arlington, VA 22203
www.aami.org

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Printed in the United States of America

ISBN 978-1-57020-886-7

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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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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, ANSI/AAMI/ISO 14937, ISO 20857 (dry heat), ISO 25424 (steam and formaldehyde), ISO 14160 (liquid chem) and ISO 22441 (vaporized hydrogen peroxide)). 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 include efficient material selection, prudent processing of those materials, testing of any specific properties essential to the product's intended function, and real-time and 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. AAMI TIR17:2017 addressed many requests from the health care manufacturing industry to expand material compatibility information to cover more sterilization modalities. This TIR supersedes AAMI TIR17:2017, and includes additional information on chlorine dioxide sterilization, refined information on aging programs as they relate to material compatibility and expanded information on addressing material compatibility concerns when changing sterilization processes or modalities. The modalities in scope of this TIR include:

— Radiation (e.g., e-beam, X-ray, and gamma);

— Ethylene oxide;

— Moist heat (i.e., steam);

— Dry heat;

— Vaporized hydrogen peroxide;

— Nitrogen dioxide;

— Peracetic acid vapor;

— Liquid peracetic acid;

— Vaporized hydrogen peroxide–ozone;

— Chlorine dioxide.

These modalities are individually addressed in Section 3 and Annexes C through K of this TIR. Guidance on the processing of materials is carried over from AAMI TIR17:2017 and is provided in Section 5. General guidance on the testing of materials is provided in Section 6. Accelerated aging program information is provided in Section 8. If it has been carried over from AAMI TIR17:2017, or if it has been subsequently published elsewhere, references have been provided.

The bulk of the guidance on the compatibility of materials subject to sterilization is provided in Section 4 and the tables found in Annexes C–K. Each sterilization modality is described in enough detail (Section 4) for the reader to understand the parameters of the sterilization process that could impact material compatibility. Brief reference to the application of each sterilization modality to pharmaceutical and biological agents is also provided. Annexes C–K contains material compatibility ratings 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 technical information report are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the AAMI technical information report, *Compatibility of materials subject to sterilization* (AAMI TIR17:2024), but it does provide important information about the development and intended use of the document.

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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 (e.g., gamma, e-beam, and X-ray);

— Ethylene oxide;

— Moist heat (i.e., steam);

— Dry heat;

— Vaporized hydrogen peroxide;

— Nitrogen dioxide;

— Peracetic acid vapor;

— Liquid peracetic acid;

— Vaporized hydrogen peroxide–ozone;

— Chlorine dioxide.

Guidance in this TIR relates to the following:

a) *Sterilization modality basics and material selection:* Choosing sterilization-compatible materials (see Section 4 and Annexes C–K).

b) *Material processing:* Optimizing the functional performance of materials selected to avoid processing errors that can contribute to negative effects from sterilization (see Sections 4 and 5).

c) *Material testing:* Challenging critical aspects of the product and packaging for functionality and safety after sterilization and aging (see Sections 5, 6, and 7).

d) *Accelerated aging:* Applying programs that ensure correlation with real-time aging while reducing the cost and time required for material qualifications (see Section 8 and Annex A).

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 for sterilized products.

2 Normative references

There are no normative references.

3 Definitions, symbols, and abbreviations

For the purposes of this TIR, the following definitions and abbreviations apply.

NOTE For the abbreviations of materials discussed in this TIR, see Annex L.

3.1
absorbed dose
quantity of ionizing radiation energy imparted per unit mass of a specified material

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