

# Technical Information Report

AAMI TIR17:2008

## Compatibility of materials subject to sterilization



Association for the Advancement  
of Medical Instrumentation

# Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

## INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

# Compatibility of materials subject to sterilization

Approved 26 August 2008 by  
**Association for the Advancement of Medical Instrumentation**

**Abstract:** Provide guidance for health care manufacturers in the qualification of polymeric materials, ceramics, and metals 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; and f) 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 might 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 might 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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

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## Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

| International designation                | U.S. designation   | Equivalency                             |
|--|--|---|
| IEC 60601-1:2005                         | ANSI/AAMI ES60601-1:2005   | Major technical variations              |
| IEC 60601-1-2:2007                       | ANSI/AAMI/IEC 60601-1-2:2007                                       | Identical                               |
| IEC 60601-2-2:2006                       | ANSI/AAMI/IEC 60601-2-2:2006                                       | Identical                               |
| IEC 60601-2-4:2002                       | ANSI/AAMI DF80:2003  | Major technical variations              |
| IEC 60601-2-19:1990 and A1:1996          | ANSI/AAMI I136:2004  | Major technical variations              |
| IEC 60601-2-20:1990 and A1:1996          | ANSI/AAMI I151:2004  | Major technical variations              |
| IEC 60601-2-21:1994 and Amendment 1:1996 | ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts) | Identical                               |
| IEC 60601-2-24:1998                      | ANSI/AAMI ID26:2004  | Major technical variations              |
| IEC 60601-2-47:2001                      | ANSI/AAMI EC38:2007  | Major technical variations              |
| IEC 60601-2-50:2001                      | ANSI/AAMI/IEC 60601-2-50:2006                                      | Identical                               |
| IEC/TR 60878:2003                        | ANSI/AAMI/IEC TIR60878:2003  | Identical                               |
| IEC/TR 62296:2003                        | ANSI/AAMI/IEC TIR62296:2003  | Identical                               |
| IEC 62304:2006                           | ANSI/AAMI/IEC 62304:2006   | Identical                               |
| IEC/TR 62348:2006                        | ANSI/AAMI/IEC TIR62348:2006  | Identical                               |
| ISO 5840:2005                            | ANSI/AAMI/ISO 5840:2005  | Identical                               |
| ISO 7198:1998                            | ANSI/AAMI/ISO 7198:1998/2001/(R)2004                               | Identical                               |
| ISO 7199:1996                            | ANSI/AAMI/ISO 7199:1996/(R)2002                                    | Identical                               |
| ISO 8637:2004                            | ANSI/AAMI RD16:2007  | Major technical variations              |
| ISO 8638:2004                            | ANSI/AAMI RD17:2007  | Major technical variations              |
| ISO 10993-1:2003                         | ANSI/AAMI/ISO 10993-1:2003   | Identical                               |
| ISO 10993-2:2006                         | ANSI/AAMI/ISO 10993-2:2006   | Identical                               |
| ISO 10993-3:2003                         | ANSI/AAMI/ISO 10993-3:2003   | Identical                               |
| ISO 10993-4:2002 and A1:2006             | ANSI/AAMI/ISO 10993-4:2002 and A1:2006                             | Identical                               |
| ISO 10993-5:1999                         | ANSI/AAMI/ISO 10993-5:1999   | Identical                               |
| ISO 10993-6:2007                         | ANSI/AAMI/ISO 10993-6:2007   | Identical                               |
| ISO 10993-7:1995                         | ANSI/AAMI/ISO 10993-7:1995/(R)2001                                 | Identical                               |
| ISO 10993-9:1999                         | ANSI/AAMI/ISO 10993-9:1999/(R)2005                                 | Identical                               |
| ISO 10993-10:2002 and Amendment 1:2006   | ANSI/AAMI BE78:2002<br>ANSI/AAMI BE78:2002/A1:2006                 | Minor technical variations<br>Identical |
| ISO 10993-11:2006                        | ANSI/AAMI/ISO 10993-11:2006  | Identical                               |
| ISO 10993-12:2007                        | ANSI/AAMI/ISO 10993-12:2007  | Identical                               |
| ISO 10993-13:1998                        | ANSI/AAMI/ISO 10993-13:1999/(R)2004                                | Identical                               |
| ISO 10993-14:2001                        | ANSI/AAMI/ISO 10993-14:2001/(R)2006                                | Identical                               |
| ISO 10993-15:2000                        | ANSI/AAMI/ISO 10993-15:2000/(R)2006                                | Identical                               |
| ISO 10993-16:1997                        | ANSI/AAMI/ISO 10993-16:1997/(R)2003                                | Identical                               |
| ISO 10993-17:2002                        | ANSI/AAMI/ISO 10993-17:2002  | Identical                               |
| ISO 10993-18:2005                        | ANSI/AAMI BE83:2006  | Major technical variations              |
| ISO/TS 10993-19:2006                     | ANSI/AAMI/ISO TIR10993-19:2006                                     | Identical                               |
| ISO/TS 10993-20:2006                     | ANSI/AAMI/ISO TIR10993-20:2006                                     | Identical                               |
| ISO 11135-1:2007                         | ANSI/AAMI/ISO 11135-1:2007   | Identical                               |
| ISO/TS 11135-2:2008                      | ANSI/AAMI/ISO TIR11135-2:2008                                      | Identical                               |

| <b>International designation</b>                | <b>U.S. designation</b>                              | <b>Equivalency</b>         |
|---|--|----------------------------|
| ISO 11137-1:2006                                | ANSI/AAMI/ISO 11137-1:2006                           | Identical                  |
| ISO 11137-2:2006 (2006-08-01 corrected version) | ANSI/AAMI/ISO 11137-2:2006                           | Identical                  |
| ISO 11137-3:2006                                | ANSI/AAMI/ISO 11137-3:2006                           | Identical                  |
| ISO 11138-1: 2006                               | ANSI/AAMI/ISO 11138-1:2006                           | Identical                  |
| ISO 11138-2: 2006                               | ANSI/AAMI/ISO 11138-2:2006                           | Identical                  |
| ISO 11138-3: 2006                               | ANSI/AAMI/ISO 11138-3:2006                           | Identical                  |
| ISO 11138-4: 2006                               | ANSI/AAMI/ISO 11138-4:2006                           | Identical                  |
| ISO 11138-5: 2006                               | ANSI/AAMI/ISO 11138-5:2006                           | Identical                  |
| ISO/TS 11139:2006                               | ANSI/AAMI/ISO 11139:2006                             | Identical                  |
| ISO 11140-1:2005                                | ANSI/AAMI/ISO 11140-1:2005                           | Identical                  |
| ISO 11140-3:2007                                | ANSI/AAMI/ISO 11140-3:2007                           | Identical                  |
| ISO 11140-4:2007                                | ANSI/AAMI/ISO 11140-4:2007                           | Identical                  |
| ISO 11140-5:2007                                | ANSI/AAMI/ISO 11140-5:2007                           | Identical                  |
| ISO 11607-1:2006                                | ANSI/AAMI/ISO 11607-1:2006                           | Identical                  |
| ISO 11607-2:2006                                | ANSI/AAMI/ISO 11607-2:2006                           | Identical                  |
| ISO 11737-1: 2006                               | ANSI/AAMI/ISO 11737-1:2006                           | Identical                  |
| ISO 11737-2:1998                                | ANSI/AAMI/ISO 11737-2:1998                           | Identical                  |
| ISO 11737-3:2004                                | ANSI/AAMI/ISO 11737-3:2004                           | Identical                  |
| ISO 13408-1:2008                                | ANSI/AAMI/ISO 13408-1:2008                           | Identical                  |
| ISO 13408-2:2003                                | ANSI/AAMI/ISO 13408-2:2003                           | Identical                  |
| ISO 13408-3:2006                                | ANSI/AAMI/ISO 13408-3:2006                           | Identical                  |
| ISO 13408-4:2005                                | ANSI/AAMI/ISO 13408-4:2005                           | Identical                  |
| ISO 13408-5:2006                                | ANSI/AAMI/ISO 13408-5:2006                           | Identical                  |
| ISO 13408-6:2006                                | ANSI/AAMI/ISO 13408-6:2006                           | Identical                  |
| ISO 13485:2003                                  | ANSI/AAMI/ISO 13485:2003                             | Identical                  |
| ISO 14155-1:2003                                | ANSI/AAMI/ISO 14155-1:2003                           | Identical                  |
| ISO 14155-2:2003                                | ANSI/AAMI/ISO 14155-2:2003                           | Identical                  |
| ISO 14160:1998                                  | ANSI/AAMI/ISO 14160:1998                             | Identical                  |
| ISO 14161:2000                                  | ANSI/AAMI/ISO 14161:2000                             | Identical                  |
| ISO 14937:2000                                  | ANSI/AAMI/ISO 14937:2000                             | Identical                  |
| ISO/TR 14969:2004                               | ANSI/AAMI/ISO TIR14969:2004                          | Identical                  |
| ISO 14971:2007                                  | ANSI/AAMI/ISO 14971:2007                             | Identical                  |
| ISO 15223-1:2007 and A1:2008                    | ANSI/AAMI/ISO 15223-1:2007 and A1:2008               | Identical                  |
| ISO 15225:2000 and A1:2004                      | ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006 | Identical                  |
| ISO 15674:2001                                  | ANSI/AAMI/ISO 15674:2001                             | Identical                  |
| ISO 15675:2001                                  | ANSI/AAMI/ISO 15675:2001                             | Identical                  |
| ISO 15882:2003                                  | ANSI/AAMI/ISO 15882:2003                             | Identical                  |
| ISO/TR 16142:2006                               | ANSI/AAMI/ISO TIR16142:2005                          | Identical                  |
| ISO 17664:2004                                  | ANSI/AAMI ST81:2004                                  | Major technical variations |
| ISO 17665-1:2006                                | ANSI/AAMI/ISO 17665-1:2006                           | Identical                  |
| ISO 18472:2006                                  | ANSI/AAMI/ISO 18472:2006                             | Identical                  |
| ISO/TS 19218:2005                               | ANSI/AAMI/ISO 19218:2005                             | Identical                  |
| ISO 22442-1:2007                                | ANSI/AAMI/ISO 22442-1:2007                           | Identical                  |
| ISO 22442-2:2007                                | ANSI/AAMI/ISO 22442-2:2007                           | Identical                  |
| ISO 22442-3:2007                                | ANSI/AAMI/ISO 22442-3:2007                           | Identical                  |
| ISO 25539-1:2003 and A1:2005                    | ANSI/AAMI/ISO 25539-1:2003 and A1:2005               | Identical                  |
| ISO 25539-2:2008                                | ANSI/AAMI/ISO 25539-2:2008                           | Identical                  |
| ISO 81060-1:2007                                | ANSI/AAMI/ISO 81060-1:2007                           | Identical                  |

## 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. Working Group 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 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 the quality and reduce the costs and time required for performing material qualifications.

One of the activities encompassed within sterilization standards is the evaluation of the effect the mode of sterilization has on 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). In summary, the basic requirements for these standards include the implementation of a program to demonstrate the quality, safety, and performance of the product throughout its shelf life or expiration date. Components of such a program are 1) expeditious selection of materials, 2) prudent processing of those materials, 3) testing of any specific properties essential to the intended function of the product, and 4) accelerated aging programs. AAMI TIR17:1997 addressed these four components of a material qualification program for radiation sterilization. There have been many requests from the health care manufacturing industry to expand on the information provided on materials compatibility. Therefore, this current TIR supersedes AAMI TIR17:1997, with an expanded scope that includes the following sterilization modalities:

- radiation,
- ethylene oxide,
- moist heat (steam),
- dry heat,
- hydrogen peroxide, and
- ozone.

These modalities are individually addressed in clause 3 and Annexes A through F of this TIR. Guidance on the processing of materials is carried over from AAMI TIR17:1997 and is provided in clause 4. General guidance on the testing of materials is provided in clause 5. Accelerated aging program information is provided in clause 6. It has been carried over from AAMI TIR17:1997, 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 Annexes A through F. Each sterilization modality is described in enough detail for the reader to understand the parameters of the sterilization process that need to be considered in evaluating the compatibility of materials. 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. Brief reference to the application of each sterilization modality to pharmaceutical and biological agents is also provided.

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

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

NOTE—This foreword does not contain provisions of the AAMI TIR titled “Compatibility of materials subject to sterilization” (AAMI TIR17:2008), but it does provide important information about the development and intended use of the document.



# Compatibility of materials subject to sterilization

## 1 Scope

The focus of this document is to provide guidance for health care manufacturers in the selection and qualification of polymeric materials, ceramics, and metals in health care products that are sterilized by the following modalities:

- radiation (gamma, electron beam, or x-ray),
- ethylene oxide (EO),
- moist heat (steam),
- dry heat,
- hydrogen peroxide, and

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.

- ozone.

Guidance in this TIR relates to

- material selection—choosing sterilization-compatible materials (see clause 3 and Annexes A–F);
- material processing—optimizing the functional performance of materials selected, to avoid processing errors that can contribute to negative effects from sterilization (see clause 4);
- material testing—challenging critical aspects of the product for functionality and safety after sterilization and aging (see clause 5); and
- accelerated aging—applying programs that ensure correlation with real-time aging while reducing the cost and amount of time required for material qualifications (see clause 6).

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

## 2 Definitions, symbols, and abbreviations

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

### 2.1

#### **absorbed dose:**

quantity of ionizing radiation energy imparted per unit mass of a specified material.