Technical Information Report

ANSI/AAMI/ISO TIR10993-19:2006

Biological evaluation of medical devices — Part 19: Physico-chemical, morphological, and topographical characterization of materials

Association for the Advancement of Medical Instrumentation

Biological evaluation of medical devices—Part 19: Physico-chemical, morphological, and topographical characterization of materials

Approved 17 October 2005 by
Association for the Advancement of Medical Instrumentation

Registered 20 November 2005 by
American National Standards Institute

Abstract: Provides a compilation of parameters and test methods that can be useful for the identification and evaluation of the physico-chemical, morphological, and topographical (PMT) properties of materials in finished medical devices.

Keywords: physico-chemical, morphological, topographical

Copyright information

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

Printed in the United States of America

ISBN 1–57020–266–4

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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years.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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

ANSI Technical Report

This AAMI TIR has been registered by the American National Standards Institute as an ANSI Technical Report. Publication of this ANSI Technical Report has been approved by the accredited standards developer (AAMI). This document is registered as a Technical Report series of publications according to the Procedures for the Registration of ANSI Technical Reports. This document is not an American National Standard and the material contained herein is not normative in nature.

Contents

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 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	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/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 62348:200x[1]	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 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:200x[2]	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	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 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	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

International designation	U.S. designation	Equivalency
ISO/TS 10993-20:200x[1]	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:200x[1]	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 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
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 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	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 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	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/TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2006	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:200x[1]	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 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Biological Evaluation of Medical Devices Committee

The adoption of ISO Technical Specification (TS) 10993-19:2006 as an AAMI Technical Information Report was initiated by the AAMI Biological Evaluation of Medical Devices Committee, which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Material Characterization Working Group (U.S. Sub-TAG for ISO/TC 194/WG 14) played an active part in developing the ISO Technical Specification.

At the time this document was published, the **AAMI Biological Evaluation of Medical Devices Committee** had the following members:

Cochairs:	Donald E. Marlowe
	Peter William Urbanski
Members:	James M. Anderson, MD, PhD, Case Western Reserve University (Independent Expert)
	Roger Dabbah, PhD, US Pharmacopeia Convention Inc
	Lawrence H. Hecker, PhD, Hospira Inc
	John G. Miller, DVM, AAALAC International
	Barry F.J. Page, Barry Page Consulting (Independent Expert)
	Anita Y. Sawyer, Becton Dickinson & Company
	Melvin E. Stratmeyer, PhD, FDA/CDRH
	Paul J. Upman, PhD, NAMSA
	Peter William Urbanski, Medtronic Inc
Alternates:	Raju G. Kammula, DVM PhD, FDA/CDRH
	Donald E. Marlowe, FDA/CDRH
	Sharon J. Northup, PhD, US Pharmacopeia Convention Inc
	Michael F. Wolf, Medtronic Inc

At the time this document was published, the **AAMI Material Characterization Working Group** had the following members:

Cochairs:	Joseph C. Hutter, PhD
	Jim McDivitt
Members:	Paul C. Adlaf, PhD, Northview Biosciences
	David E. Albert, MS,DPM,PhD, NAMSA
	Carolyn Braithwaite, Cobe Sterilization Services Inc
	Kimbrell Darnell, CR Bard
	Leslie Eleanor Frick, Kimberly-Clark Corporation
	Yeong Huang, Cardinal Health (MP&S)
	Joseph C. Hutter, PhD, FDA/CDRH
	Dennis Jenke, PhD, Baxter Healthcare Corporation
	Anita Kore, DVM,PhD, 3M Healthcare
	Jim McDivitt, Johnson & Johnson
	Mark I. Ostler, PhD, Hospira Inc
	Audrey Turley, B.S. RM (NRM), Nelson Laboratories Inc
	Peter William Urbanski, Medtronic Inc
Alternates:	Jon Cammack, PhD, DABT, Baxter Healthcare Corporation
	Anthony J. DeMarinis, BS MS CQA CQM, CR Bard
	John Dooley, PhD,DABT, Johnson & Johnson
	Gloria H. Frost, PhD, Cardinal Health (MP&S)
	Joel R. Gorski, PhD, NAMSA

Lawrence H. Hecker, PhD, Hospira Inc
Tina May, B.S., Nelson Laboratories Inc
Mary H. Olson, Kimberly-Clark Corporation
Anita Y. Sawyer, Becton Dickinson & Company
LeRoy W. Schroeder, PhD, FDA/CDRH

NOTE—Participation by federal agency representatives in the development of this TIR does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI adoption of ISO/TS 10993-19:2006

As indicated in the foreword to the main body of this document (page x), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this technical specification.

International Technical Specification 10993-19 was developed by Working Group (WG) 14 *Material Characterization,* of ISO Technical Committee (TC) 194, *Biological evaluation of medical devices*, to provide a compilation of parameters and test methods that can be useful for the identification and evaluation of the physico-chemical, morphological and topographical (PMT) properties of materials in finished medical devices.

U.S. participation in this ISO/TC 194/WG 14 is organized through the U.S. Technical Advisory Group for ISO/TC 194, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the American National Standards Institute (ANSI). U.S. experts made a considerable contribution to this technical specification.

AAMI encourages its committees to harmonize their work with international standards as much as possible. Upon review of ISO/TS 10993-19, the AAMI Biological Evaluation of Medical Devices Committee and the AAMI Material Characterization Working Group decided to adopt ISO/TS 10993-19:2006 verbatim as an AAMI Technical Information Report.

AAMI (and ANSI) have adopted other ISO documents. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

The concepts incorporated into this technical information report should not be considered inflexible or static. This technical information report, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the ISO foreword on page x, this ANSI Technical Report//AAMI Technical Information Report is identical to ISO/TS 10993-19:2006.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 10993-19 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

ISO 10993 consists of the following parts, under the general title *Biological evaluation of medical devices*:

— *Part 1: Evaluation and testing*

— *Part 2: Animal welfare requirements*

— *Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity*

— *Part 4: Selection of tests for interactions with blood*

— *Part 5: Tests for in vitro cytotoxicity*

- *Part 6: Tests for local effects after implantation*
- *Part 7: Ethylene oxide sterilization residuals*
- *Part 9: Framework for identification and quantification of potential degradation products*
- *Part 10: Tests for irritation and delayed-type hypersensitivity*
- *Part 11: Tests for systemic toxicity*
- *Part 12: Sample preparation and reference materials*
- *Part 13: Identification and quantification of degradation products from polymeric medical devices*
- *Part 14: Identification and quantification of degradation products from ceramics*
- *Part 15: Identification and quantification of degradation products from metals and alloys*
- *Part 16: Toxicokinetic study design for degradation products and leachables*
- *Part 17: Establishment of allowable limits for leachable substances*
- *Part 18: Chemical characterization of materials*
- *Part 19: Physico-chemical, morphological, and topographical characterization of materials*
- *Part 20: Principles and methods for immunotoxicology testing of medical devices*

Introduction

ISO 14971 points out that a toxicological risk analysis should take account of the nature of the materials.

ISO 10993-1 provides a framework for a structured program of assessment for the evaluation of biological safety. ISO 10993-1:2003, Clause 3, states that in the selection of materials to be used for device manufacture, the first consideration should be fitness for purpose. This should have regard to the characteristics and properties of the material, which include chemical, toxicological, physical, electrical, morphological, and mechanical properties. This information is necessary prior to any biological evaluation. ISO 10993-1:2003, 7.2 notes that the continuing acceptability of a biological evaluation is an aspect of a quality management system.

The identification and evaluation of the physico-chemical, morphological and topographical properties of materials used in a finished medical device are important in determining the biological evaluation of that device and its materials. Such information can be used in:

a) assessing the overall biological evaluation of a medical device (ISO 10993);

b) screening of potential new materials and/or processes for suitability in a medical device for a proposed clinical application.

The compositional characteristics of the materials of manufacture are mainly under the control of the suppliers of these materials. However, other characteristics are chiefly influenced by the requirements to be met by the finished medical device as well as the production processes used by the medical device manufacturer.

Biological evaluation of medical devices — Part 19: Physico-chemical, morphological, and topographical characterization of materials

1 Scope

This Technical Specification provides a compilation of parameters and test methods that can be useful for the identification and evaluation of the physico-chemical, morphological and topographical (PMT) properties of materials in finished medical devices. Such an assessment is limited to those properties that are relevant to biological evaluation and the medical device's intended use (clinical application and duration of use) even if such properties overlap with clinical effectiveness.

This part of ISO 10993 does not address the identification or quantification of degradation products, which are covered in ISO 10993-9, ISO 10993-13, ISO 10993-14, and ISO 10993-15. Chemical characterization of materials is covered by ISO 10993-18.

The ISO 10993 series of International Standards is not applicable when the material or device does not contact the body directly or indirectly (see ISO 10993-1:2003, 4.2).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1:2003, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1, ISO 10993-18, and the following apply.

3.1
physico-chemical
relating to the physical chemistry (of materials)

3.2
morphological
relating to the shape, contours and microstructural organization (of materials)