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# American National Standard



## ANSI/AAMI/ ISO 22442-1:

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2016

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Medical devices utilizing  
animal tissues and their  
derivatives—Part 1:  
Application of risk  
management

## 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*.

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ANSI/AAMI/ISO 22442-1:2016



## Medical devices utilizing animal tissues and their derivatives—Part 1: Application of risk management

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Approved 29 April 2016 by  
AAMI

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Approved 17 November 2016 by  
American National Standards Institute

**Abstract:** Applies to medical devices other than in vitro diagnostic medical devices manufactured utilizing materials of animal origin, which are non-viable or have been rendered non-viable. Specifies, in conjunction with ANSI/AAMI/ISO 14971, a procedure to identify the hazards and hazardous situations associated with such devices, to estimate and evaluate the resulting risks, to control these risks, and to monitor the effectiveness of that control. Outlines the decision process for the residual risk acceptability, taking into account the balance of residual risk, as defined in ANSI/AAMI/ISO 14971, and expected medical benefit as compared to available alternatives. This part of ANSI/AAMI/ISO 22442 is intended to provide requirements and guidance on risk management related to the hazards typical of medical devices manufactured utilizing animal tissues or derivatives.

**Keywords:** animal tissue, non-viable, transmissible agents, risk management

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## Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

[www.aami.org/standards/glossary.pdf](http://www.aami.org/standards/glossary.pdf)



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## Committee representation

### Association for the Advancement of Medical Instrumentation

#### Tissue Product Safety Committee

The adoption of ISO 22442-1 as an AAMI standard was initiated by the AAMI Tissue Product Safety 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 Tissue Product Safety Committee (U.S. TAG for ISO/TC 194/SC 1), chaired by Rich Hutchinson and Scott McNamee, played an active part in developing the ISO Standard.

Committee approval of this document does not necessarily imply that all committee members voted for its approval.

At the time this standard was published, the **AAMI Tissue Product Safety Committee** had the following members:

*Cochairs:* Richard Hutchinson  
Scott McNamee

*Members:* Crystal Anderson-Cunanan, Boston Scientific Corporation  
Scott Brubaker, American Association of Tissue Banks  
Kim Darnell, CR Bard  
Steven Elliott, NAMSA  
Gary Fischman, National Academies  
Deborah Gessell-Lee, Baxter Healthcare Corporation  
Richard Hutchinson, Johnson & Johnson  
Christine Loshbaugh, Edwards Lifesciences  
Scott McNamee, FDA/CDRH  
Susumu Nozawa, Becton Dickinson & Company  
Nicole Soucy, 3M Healthcare  
Sean Werner, Cook Inc  
Jennifer Zwiefelhofer, St Jude Medical Inc

*Alternates:* Matt Beauchane, Boston Scientific Corporation  
Steve Binion, Becton Dickinson & Company  
Trabue D. Bryans, BryKor LLC  
David Cardin, Cook Inc  
Ken Eddington, NAMSA  
Aditee Kurane, St Jude Medical Inc

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

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## Background of ANSI/AAMI adoption of ISO 22442-1:2016

As indicated in the foreword to the main body of this document (page vii), 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 standard, which was developed by ISO Technical Committee 194, Subcommittee 1, *Tissue product safety*, to fill a need for an international standard for utilization of animal tissues and their derivatives in medical devices.

U.S. participation in ISO/TC 194/SC 1 is organized through the U.S. Technical Advisory Group to ISO/TC 194/SC 1, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

ANSI/AAMI/ISO 22442-1 was approved by the American National Standards Institute (ANSI) on 17 November 2016.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. 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.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

“May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, 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 come to light.

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NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

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Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Dr, Suite 301, Arlington, VA 22203-1633.

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NOTE—Beginning with the ISO foreword on page vii, this American National Standard is identical to ISO 22442-1:2016.

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## 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: [Foreword—Supplementary information](#).

The committee responsible for this document is ISO/TC 194, *Biological and clinical evaluation of medical devices*, SC 1, *Tissue product safety*.

This second edition cancels and replaces the first edition (ISO 22442-1:2007), of which it constitutes a minor revision.

ISO 22442 consists of the following parts, under the general title *Medical devices utilizing animal tissues and their derivatives*:

- Part 1: *Application of risk management*
- Part 2: *Controls on sourcing, collection and handling*
- Part 3: *Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*
- Part 4: *Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes [Technical Report]*

## Introduction

Certain medical devices utilize materials of animal origin.

Animal tissues and their derivatives are used in the design and manufacture of medical devices to provide performance characteristics that have been chosen for advantages over non-animal based materials. The range and quantities of materials of animal origin in medical devices vary. These materials can comprise a major part of the device (e.g. bovine/porcine heart valves, bone substitutes for use in dental or orthopaedic applications, haemostatic devices), can be a product coating or impregnation (e.g. collagen, gelatine, heparin), or can be used in the device manufacturing process (e.g. tallow derivatives such as oleates and stearates, foetal calf serum, enzymes, culture media).

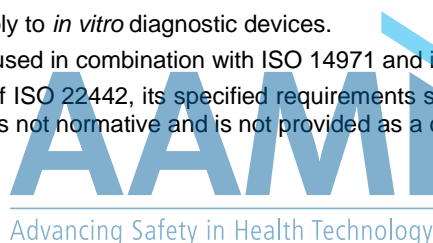
ISO 14971 is a general standard which specifies a process for a manufacturer by identifying hazards and hazardous situations associated with medical devices, including *in vitro* medical devices, to estimate and evaluate the risks associated with those hazards, to control these risks and to monitor the effectiveness of the control throughout the life cycle. This part of ISO 22442 provides additional requirements and guidance for the evaluation of medical devices manufactured utilizing animal tissues or derivatives which are non-viable or rendered non-viable.

This part of ISO 22442 is intended to cover medical devices including active implantable medical devices such as implantable infusion pumps.

This part of ISO 22442 does not apply to *in vitro* diagnostic devices.

This part of ISO 22442 can only be used in combination with ISO 14971 and is not a “standalone” standard.

To show compliance with this part of ISO 22442, its specified requirements should be fulfilled. The guidance given in the Notes and informative annexes is not normative and is not provided as a checklist for auditors.



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# Medical devices utilizing animal tissues and their derivatives—Part 1: Application of risk management

## 1 Scope

This part of ISO 22442 applies to medical devices other than *in vitro* diagnostic medical devices manufactured utilizing materials of animal origin, which are non-viable or have been rendered non-viable. It specifies, in conjunction with ISO 14971, a procedure to identify the hazards and hazardous situations associated with such devices, to estimate and evaluate the resulting risks, to control these risks, and to monitor the effectiveness of that control. Furthermore, it outlines the decision process for the residual risk acceptability, taking into account the balance of residual risk, as defined in ISO 14971, and expected medical benefit as compared to available alternatives. This part of ISO 22442 is intended to provide requirements and guidance on risk management related to the hazards typical of medical devices manufactured utilizing animal tissues or derivatives such as

- a) contamination by bacteria, moulds or yeasts;
- b) contamination by viruses;
- c) contamination by agents causing Transmissible Spongiform Encephalopathies (TSE);
- d) material responsible for undesired pyrogenic, immunological or toxicological reactions.

For parasites and other unclassified pathogenic entities, similar principles can apply.

This part of ISO 22442 does not stipulate levels of acceptability which, because they are determined by a multiplicity of factors, cannot be set down in such an International Standard except for some particular derivatives mentioned in Annex C. Annex C stipulates levels of TSE risk acceptability for tallow derivatives, animal charcoal, milk and milk derivatives, wool derivatives and amino acids.

This part of ISO 22442 does not specify a quality management system for the control of all stages of production of medical devices.

This part of ISO 22442 does not cover the utilization of human tissues in medical devices.

NOTE 1 It is not a requirement of this part of ISO 22442 to have a full quality management system during manufacture. However, attention is drawn to International Standards for quality management systems (see ISO 13485) that control all stages of production or reprocessing of medical devices.

NOTE 2 For guidance on the application of this part of ISO 22442, see Annex A.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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, *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices—Application of risk management to medical devices*

ISO 22442-2, *Medical devices utilizing animal tissues and their derivatives—Part 2: Control on sourcing, collection and handling*