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Technical Information Report



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AAMI/ISO TIR80002-2: 2017

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Medical device software—
Part 2: Validation of
software for medical device
quality systems

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A Technical Report prepared by AAMI and registered with ANSI

AAMI/ISO TIR80002-2:2017



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AAMI

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Abstract: This document applies to any software used in device design, testing, component acceptance, manufacturing, labelling, packaging, distribution and complaint handling or to automate any other aspect of a medical device quality system as described in ISO 13485.

Keywords: medical device, software, validation



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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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years.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, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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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 Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature.

Comments on the content of this document should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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Glossary of equivalent standards

International Standards and technical information reports adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard and technical information report 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 and technical information report..

www.aami.org/standards/glossary.pdf



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Committee representation

Association for the Advancement of Medical Instrumentation Software Working Group

The publication of AAMI/ISO TR 80002-2 as a new American Technical Report was initiated by the AAMI Software Working Group which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO) ISO/TC210 JWG2. U.S. representatives from the AAMI Software Working Group participate as US experts on the ISO committee.

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

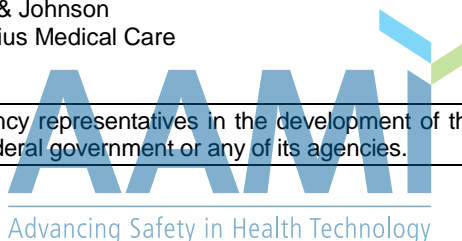
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Background of AAMI adoption of ISO TR 80002-2

As indicated in the foreword to the main body of this document (page ix), the International Standards Organization (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 210, *Quality management and corresponding general aspects for medical devices*, Joint Work Group 2, Medical device software, with IEC/SC 62A to provide guidelines which applies to any software used in device design, testing, component acceptance, manufacturing, labelling, packaging, distribution and complaint handling or to automate any other aspect of a medical device quality system as described in ISO 13485.

U.S. participation in ISO TC210/JWG2 is organized through the U.S. Technical Advisory Group to TC210/JWG2, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this technical information report.

AAMI/ISO 80002-2 was registered by the American National Standards Institute (ANSI) on 18 August 2017.

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 and technical information reports. See the Glossary of Equivalent Standards for a list of ISO standards and technical information reports adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard or technical information report.

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 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 come to light.

This is a preview edition of an AAMI guidance document and is not intended for use as a standard. For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

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

NOTE—Beginning with the ISO foreword on page ix, this AAMI TIR is identical to ISO TR 80002-2.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO should 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).

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

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, in collaboration with Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62A, *Common aspects of electrical equipment used in medical practice*, in accordance with ISO/IEC mode of cooperation 4.

A list of all parts in the ISO 80002 series can be found on the ISO website.

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Introduction

This document has been developed to assist readers in determining appropriate activities for the validation of process software used in medical device quality systems using a risk-based approach that applies critical thinking.

This includes software used in the quality management system, software used in production and service provision, and software used for the monitoring and measurement of requirements, as required by ISO 13485:2016: 4.1.6, 7.5.6 and 7.6.

This document is the result of an effort to bring together experience from medical device industry personnel who deal with performing this type of software validation and who are tasked with establishing auditable documentation. The document has been developed with certain questions and problems in mind that we all go through when faced with validating process software used in medical device quality systems such as the following: What has to be done? How much is enough? How is risk analysis involved? After much discussion, it has been concluded that in every case, a set of activities (i.e. the tools from a toolbox) was identified to provide a level of confidence in the ability of the software to perform according to its intended use. However, the list of activities varied depending on factors including, among others, the complexity of the software, the risk of harm involved and the pedigree (e.g. quality, stability) of vendor-supplied software.

The intention of this document is to help stakeholders, including manufacturers, auditors and regulators, to understand and apply the requirement for validation of software included in ISO 13485:2016, 4.1.6, 7.5.6 and 7.6.

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Medical device software—Part 2: Validation of software for medical device quality systems

1 Scope

This document applies to any software used in device design, testing, component acceptance, manufacturing, labelling, packaging, distribution and complaint handling or to automate any other aspect of a medical device quality system as described in ISO 13485.

This document applies to

- software used in the quality management system,
- software used in production and service provision, and
- software used for the monitoring and measurement of requirements.

It does not apply to

- software used as a component, part or accessory of a medical device, or
- software that is itself a medical device.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and ISO 13485 apply. ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

4 Software validation discussion

4.1 Definition

The term “software validation” has been interpreted both broadly and narrowly, from just testing to extensive activities including testing. This document uses the term software validation to denote all of the activities that establish a level of confidence that the software is appropriate for its intended use and that it is trustworthy and reliable. The chosen activities, whatever they might be, should ensure that the software meets its requirements and intended purpose.