Technical Information Report

AAMI TIR36:2007

Validation of software for regulated processes

Association for the Advancement
of Medical Instrumentation

Validation of software for regulated processes

Developed by
Association for the Advancement of Medical Instrumentation

Approved 13 December 2007 by
Association for the Advancement of Medical Instrumentation

Abstract: Applies to any software used to automate device design, testing, component acceptance, manufacturing, labeling, packaging, distribution, and complaint handling or to automate any other aspect of the quality system as defined by the Quality System Regulation (21 CFR 820). In addition, it applies to software used to create, modify, and maintain electronic records and to manage electronic signatures that are subject to the validation requirements (21 CFR 11). This TIR can also be broadly applied wherever software automates processes regulated by the FDA. This TIR applies to software used in the production of a device and to software used in implementation of the device manufacturer's quality system. 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.

Keywords: medical device software, medical electrical equipment, electromedical equipment, risk management

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

Printed in the United States of America

ISBN 1-57020-306-7

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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 DE80:2003	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 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 Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006	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 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations 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

International designation	U.S. designation	Equivalency
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 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
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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	ANSI/AAMI/ISO 15223-1:2007	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

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Medical Device Software Committee

This technical information report (TIR) was developed by the AAMI Medical Device Software Committee. Committee 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 Medical Device Software Committee** had the following members:

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Acknowledgments

The AAMI Medical Device Software Committee gratefully acknowledges the work of its Validation of Software for Regulated Processes Task Group, which handled the development of this TIR. The Task Group has the following members:

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A special acknowledgment goes to the following contributors to this document: Debbie Iampietro, Jennifer V. Anderson, and Kathleen O'Donnell.

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.

Foreword

In the historical approach to validation, the terms *value added* and *software validation* tended to be mutually exclusive. Software validation historically may or may not have been value added. How well have the historical approaches truly ensured software performance according to its intended use? How often has “validated” software been deployed and still not performed as the users thought it should?

It is important to get the most value out of your software validation activities. After all, you or your company is committing valuable resources to the validation efforts; therefore, it is essential that you receive an appropriate return on this investment.

So, why do some people feel that they are not getting as much value out of their software validation activities as they should? Why do some people feel as if they have to do too much to achieve compliance with this requirement? Why do some people feel as if their software validation activities are not aligned with their business goals or interest? Why do some people feel as if their internal software validation activities are redundant when they use high-quality off-the-shelf (OTS) software? Why are some people doing too little or doing nothing at all? Why is there uncertainty about which software requires validation and which software does not?

This technical information report (TIR) is intended to help you understand the issues behind these questions and to give you suggestions on how to develop a more value-added approach to software validation.

It is important to note that a medical device regulation requiring software validation does exist. The regulation section, 21 CFR 820.70(i), Automated processes, is written in broad terms so that it can apply to all medical device manufacturers. The regulation section identifies a problem to be solved or an end point to be achieved, but it does not provide any information about how to solve this problem and meet the intent of this regulatory requirement. Other specific information that the U.S. Food and Drug Administration (FDA) has provided on this topic is contained in the *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (GPSV). Section 6 of the GPSV provides guidance on the validation of automated process equipment and quality system software.

This report is not establishing a new direction, but it represents a view of the issues from a medical device industry perspective and a description of methods many in the industry may already follow. This report is meant to be a step toward better understanding the industry’s perspective on how to be compliant with the regulation in a value-added way.

Over time, many practices have evolved into a checklist-mentality approach based on a compliance need. At times the checklist approach inadvertently causes activities to stray from value-added activities that appropriately substantiate that the software performs as intended. Straying occurs when a single solution is sought that is intended to satisfy a large number of stakeholders, each with a potentially different set of objectives and requirements. The stakeholders represent many perspectives focused on quality system implementation, regulatory needs, engineering practices, auditing and assessment requirements, business and legal needs, consulting services, and the like.

One of the key challenges is to find a solution that is aligned with the needs of all stakeholders, especially the needs of the individuals performing the validations and the auditors measuring the adequacy of the validations. The belief is that the manufacturer is expected to apply due diligence in the form of best practices in the areas of risk management, quality, and engineering, to create a solution that not only would satisfy this regulatory requirement but also would align with the intent of the regulation.

This report is intended to provide an awareness of concepts and tools that can be applied to the task of software validation. To begin, a simple analogy conveys the basic concept behind this report. A carpenter’s toolbox contains various tools such as hammers, wrenches, screwdrivers, and drills. When a carpenter is faced with a task, he or she chooses an appropriate tool that will complete the task in a safe and effective manner. For example, when a carpenter is nailing boards together, the most appropriate tool would be a hammer rather than a wrench or screwdriver. In addition, it is important to choose the type of hammer applicable to the user’s circumstances. A sledgehammer may get the job done, but it will probably leave the boards damaged or leave the user exhausted if there are a significant number of boards to be nailed together. However, if the sledgehammer is the only tool in the toolbox, the carpenter’s only choice is to use the inappropriate tool.

The sledgehammer analogy represents the one-size-fits-all type of validation that uses one set of tools for all regulated process software and is an example of not applying critical thinking. Like the sledgehammer, the one-size-fits-all type of validation gets the job done but at a price that does not always include value-added activities. In addition, it is probable that unidentified risks have not been properly controlled. In other words, a one-size-fits-all

checklist mentality typically creates extra work for simple, low-risk software or falls short of the work required for complex, high-risk software.

Software that needs to be validated might have many different intended uses and be used in many different scenarios, which involve very different risks. Different tools and associated approaches are necessary to accomplish an optimal validation for a vast variety of situations.

This report offers suggestions on how to apply critical thinking to determine the best approach for validation of software through selection of the best tools from the toolbox, thereby allowing implementation of value-added solutions that are both compliant and consistent with business requirements.

For the software validation efforts to be viewed as highly successful, the following statements should be true:

- The automated process or associated software functions as intended, without compromising device safety, device quality, or the integrity of the quality system.
- The people performing the necessary activities believe that the efforts are meaningful and worthwhile (i.e., least burdensome or most valuable activities).
- The manufacturer is in a state of compliance.
- Auditors and inspectors view the activities applied and the resulting records as acceptable evidence of compliance.

Introduction

This technical information report (TIR) has been developed to assist readers in determining appropriate activities for the validation of regulated process software using a risk-based approach that applies critical thinking.

This TIR 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 TIR has been developed with certain questions and problems in mind that we all go through when faced with validating regulated process software, such as the following: What has to be done? How much is enough? How is risk analysis involved? After much discussion, the AAMI Validation of Software for Regulated Processes Task Group concluded that in every case a set of activities (i.e., the tools from the 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 resulting report includes two key elements:

- A method of applying critical thinking to identifying what needs to be completed for regulated process software validation. That method includes a risk-based approach that considers whether a software failure can cause harm.
- A toolbox of tools that can be used to establish a sufficient level of confidence that the software will perform as intended. It should be noted that such tools have been included on the basis of experience showing what works and what has not worked. The toolbox represents current knowledge of good software engineering practice. As more experience is gained and technology evolves, what works will also evolve, and the content of the toolbox may change.

NOTE—This introduction does not contain provisions of the AAMI TIR, *Validation of software for regulated processes* (AAMI TIR36:2007), but it does provide important information about the development and intended use of the document.

Validation of software for regulated processes

1 General

1.1 Purpose and intent

The purpose of this technical information report (TIR) is to provide guidance on what to think about when determining the appropriate content and size of a validation effort applied to software used for regulated processes. In addition, this TIR provides guidance on a method of reaching the appropriate depth and rigor of activities through analyzing and evaluating various aspects of the software and its environment. The TIR is intended to define this method through description, definition, and examples of applying critical thinking in a variety of circumstances.

This TIR is *not* intended to create a new U.S. Food and Drug Administration (FDA)–authorized minimum set of validation tasks and documentation. An Association for the Advancement of Medical Instrumentation (AAMI) TIR is a collection of "best practices," and this document reflects the collective judgment of the AAMI Validation of Software for Regulated Processes Task Group of the best practices for validating software for regulated processes.

1.2 Scope

This TIR applies to any software used to automate device design, testing, component acceptance, manufacturing, labeling, packaging, distribution, and complaint handling or to automate any other aspect of the quality system, as defined by the Quality System Regulation (21 CFR 820), or QSR. In addition, the TIR applies to software used to create, modify, and maintain electronic records and to manage electronic signatures that are subject to the validation requirements (21 CFR 11). This TIR can also be broadly applied wherever software automates processes regulated by the FDA.

This TIR applies to

- software used in the production of a device, and
- software used in implementation of the device manufacturer's quality system.

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.

This TIR may provide useful information and recommendations to

- people responsible for determining the appropriate content and size of a validation effort;
- people responsible for performing the analyses and evaluations that drive the content or size determination;
- people responsible for planning and executing the validation activities;
- people responsible for reviewing and approving the adequacy of the validation effort; and
- people responsible for auditing, inspecting, and evaluating the validation for compliance to regulation.

The TIR discusses how the general provisions of the QSR apply to regulated process software and describes an approach to evaluating this software. However, the TIR does not list the tasks and activities that must be used to comply with the law. The TIR does not create or confer any rights for or on any person and does not operate to bind the user. An alternative approach may be used if such an approach satisfies the requirements of the applicable statute, regulations, or both. No specific methodology or specific validation technique or method is required or suggested by this TIR. For each software project, the responsible party should determine and justify the specific approach, the combination of software risk management activities to be used, and the level of effort to be applied. Specific training or experience in medical device quality management systems and the regulations governing these systems is recommended.

1.3 Document organization

This document is arranged as a main body with five annexes. The main body encompasses 21 pages from page 2 through page 22 and establishes the following:

- the context for validation of software for regulated processes;
- the concept of critical thinking and its relation to software validation;
- the application of critical thinking within the software life cycle, using a simplified waterfall process model as an example; and
- the systems and processes needed to support critical thinking and the software life cycle.

The five annexes contain the following information:

- Annex A is referred to throughout the document as the toolbox and contains more information about the various tools or confidence-building activities.
- Annex B is a brief discussion of risk management, including an example risk model.
- Annex C presents example studies demonstrating how critical thinking can be applied to software validation of regulated software in a variety of situations, including different complexities, pedigrees, and risk levels.
- Annexes D and E contain definitions and resources.