

Technical Information Report

AAMI TIR45: 2012/(R)2018

Guidance on the use of
AGILE practices in the
development of medical
device software

Guidance on the use of AGILE practices in the development of medical device software

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AAMI

Abstract: Over the past several years, AGILE software development has become an accepted method for developing software products. There have been questions from both manufacturers and regulators as to whether (or which) AGILE practices are appropriate for developing medical device software. Enough medical device manufacturers have implemented AGILE practices in their software development so that answers to these questions can be documented. Having clear guidance of which practices have been found to be appropriate will be very useful for all developers of medical device software. This TIR will provide recommendations for complying with international standards and U.S. Food and Drug Administration (FDA) guidance documents when using AGILE practices to develop medical device software.

Keywords: AGILE, software

AAMI Technical Information Report

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Contents

	Page
Glossary of equivalent standards.....	vi
Committee representation.....	ix
Foreword.....	xi
Introduction.....	xii
Why read this TIR?.....	xii
Initial recommendations.....	xii
1 Scope.....	1
1.1 Inclusions.....	1
1.2 Exclusions.....	1
1.3 Organization: Navigating this document.....	2
2 References.....	3
3 Terms and definitions.....	4
4 Setting the stage.....	11
4.1 The AGILE perspective.....	11
4.1.1 AGILE goals, values, principles, and practices.....	11
4.1.2 Expectations for tailoring.....	13
4.2 The regulatory perspective.....	13
4.2.1 The U.S. FDA regulatory perspective.....	13
4.2.2 International and other regulatory perspectives.....	13
4.2.3 IEC 62304.....	14
4.2.4 Regulatory goals, values, principles, and practices.....	14
4.2.5 Expectations for tailoring.....	15
4.2.6 Where to learn more.....	15
4.3 Aligning perspectives.....	15
4.3.1 Aligning on goals.....	15
4.3.2 Aligning on values.....	16
4.3.3 Transitioning to the use of AGILE for medical device software development.....	19
5 Aligning on concepts.....	20
5.1 INCREMENTAL/EVOLUTIONARY lifecycle.....	20
5.1.1 Specifying the software development lifecycle.....	21
5.1.2 Mapping the process model to the lifecycle model.....	22
5.1.3 Executing process activities in multiple layers of abstraction.....	24
5.1.4 Process flow: the timing and sequence of process activity execution.....	25
5.1.5 Frequency and granularity of process activities.....	25
5.1.6 The importance of integration activities.....	26
5.1.7 The importance of software configuration management.....	26
5.1.8 Defining “DONE”.....	27
5.1.9 Feedback mechanisms and ITERATIONS.....	27
5.2 Inputs and outputs.....	27
5.2.1 Which inputs.....	28
5.2.2 Entry criteria for inputs.....	28
5.2.3 Exit criteria for outputs.....	29

5.3	DESIGN INPUTS and DESIGN OUTPUTS	29
5.3.1	Activities for producing DESIGN INPUTS and DESIGN OUTPUTS	30
5.3.2	Breaking up the work	31
5.3.3	Timing of DESIGN INPUTS and DESIGN OUTPUTS within an AGILE STORY	32
5.3.4	Inputs to AGILE STORIES	34
5.3.5	Synchronizing DESIGN INPUTS and DESIGN OUTPUTS	34
5.3.6	Final VERIFICATION	36
5.4	Design reviews	36
5.4.1	Formal design review at stage boundaries	36
5.4.2	Reviews as a VERIFICATION activity	36
5.4.3	Independence of review	37
5.5	Documentation	37
5.5.1	Use of documentation	37
5.5.2	Sequencing of documentation activities	39
5.5.3	Sum-of-the-parts of documentation	39
5.5.4	Process artifacts (the audit trail)	40
5.6	Managing the dynamic nature of AGILE	40
5.6.1	Embrace change, manage change	40
5.6.2	Satisfy the customer	41
5.6.3	Maintain the software development process	41
5.7	Human safety risk management	41
6	Aligning on Practices	42
6.1	Topics related to planning	42
6.1.1	Is AGILE too undisciplined to meet planning requirements?	42
6.1.2	Is shippable software, after every INCREMENT, a realistic expectation?	43
6.1.3	AGILE's focus on "working software" and continuous integration forms a very effective integration strategy	43
6.1.4	AGILE's DONE IS DONE concept is core to creating a VERIFICATION plan	43
6.2	Topics related to team structure and collaboration	44
6.2.1	Pairing	44
6.2.2	Stop the line	46
6.2.3	RETROSPECTIVES/reflections	46
6.2.4	Collective ownership	46
6.3	Topics related to product definition and requirements documentation	47
6.3.1	When does a STORY have enough definition for the team to begin work?	47
6.3.2	Requirements DONE when a STORY IS DONE	47
6.3.3	Requirements documentation	48
6.3.4	Can STORIES' acceptance tests be used for final requirements?	48
6.3.5	Can EXECUTABLE REQUIREMENTS be a valid part of the requirements definition and documentation?	48
6.3.6	How does AGILE help with requirements VERIFICATION and VALIDATION?	48
6.4	Topics related to software architecture	49
6.4.1	Involving architecture	49
6.4.2	Architecture planning	49
6.4.3	Architecture VERIFICATION	50
6.5	Topics related to detailed design	50
6.5.1	Activities of detailed design	50
6.5.2	EMERGENT design	51
6.5.3	Documentation of detailed design	51
6.6	Topics related to implementation and unit VERIFICATION	52
6.7	Topics related to integration and integration testing	53
6.8	Topics related to software system testing	53
6.8.1	The importance of software system test planning	54
6.8.2	The value of continuous testing	54

6.8.3	The importance of regression testing	54
6.8.4	Tests are as important as the code	54
6.8.5	Documentation of software system testing results.....	55
6.8.6	TRACEABILITY	55
6.9	Topics related to software RELEASE	55
6.10	Topics related to configuration management and change management.....	56
6.10.1	Software configuration identification	56
6.10.2	Management of SOUP on AGILE projects.....	56
6.10.3	AGILE's impact on change control	56
6.11	Topics related to corrective and preventive action	57
Bibliography		58

Figures

1	EVOLUTIONARY lifecycle	6
2	INCREMENTAL lifecycle: "Staged delivery"	7
3	INCREMENTAL lifecycle: "Design to schedule"	8
4	Mapping IEC 62304's activities into AGILE's INCREMENTAL/EVOLUTIONARY lifecycle	23
5	DESIGN INPUT/OUTPUT relationship: Highest level of abstraction	30
6	DESIGN INPUT/OUTPUT relationship: WATERFALL development	31
7	DESIGN INPUT/OUTPUT relationship: INCREMENTAL/EVOLUTIONARY	31
8	DESIGN INPUT/OUTPUT relationship: STORY level.....	32
9	DESIGN INPUT/OUTPUT relationship: STORY level showing activities.....	32
10	DESIGN INPUT/OUTPUT relationship: STORY level showing detail and sequencing	33
11	Synchronizing DESIGN INPUT/OUTPUT at INCREMENT and RELEASE boundaries	35
12	A linear flow of process activities.....	38
13	A parallel flow of process activities.....	38

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. The code in the US column, “(R)20xx” indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

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 IEC 60601-1:2005/A1:2012 IEC Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005/(R)2012 ANSI/AAMI ES60601-1:2005/A1:2012 ANSI/AAMI ES60601-1:2005/C1:2009/(R)2012 (amdt) ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012	Major technical variations A1 identical C1 identical to Corrigendum 1 & 2 A2 applies to AAMI, only
IEC 60601-1-11:2010	ANSI/AAMI HA60601-1-11:2011	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007/(R)2012	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2010	ANSI/AAMI/IEC 60601-2-4:2010	Identical
IEC 60601-2-16:2012	ANSI/AAMI/IEC 60601-2-16:2012	Identical
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-25:2011	ANSI/AAMI/IEC 60601-2-25:2011	Identical
IEC 60601-2-27:2011	ANSI/AAMI/IEC 60601-2-27:2011	Identical
IEC 60601-2-47:2012	ANSI/AAMI/IEC 60601-2-47:2012	Identical
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 61289:2011	ANSI/AAMI/IEC TIR61289:2011	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC 62366:2007	ANSI/AAMI/IEC 62366:2007	Identical
IEC 80001-1:2010	ANSI/AAMI/IEC 80001-1:2010	Identical
IEC/TR 80001-2-1:2012	ANSI/AAMI/IEC 80001-2-1:2012	Identical
IEC/TR 80001-2-3:2012	ANSI/AAMI/IEC 80001-2-3:2012	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009 and Amendment 1:2012	ANSI/AAMI/ISO 7199:2009 and Amendment 1:2012	Identical
ISO 8637:2010	ANSI/AAMI/ISO 8637:2010	Identical
ISO 8638:2010	ANSI/AAMI/ISO 8638:2010	Identical
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical

International designation	U.S. designation	Equivalency
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006/(R)2010	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007/(R)2010	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008/(R)2012	Identical
ISO 10993-9:2009	ANSI/AAMI/ISO 10993-9:2009	Identical
ISO 10993-10:2010	ANSI/AAMI/ISO 10993-10:2010	Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006/(R)2010	Identical
ISO 10993-12:2012	ANSI/AAMI/ISO 10993-12:2012	Identical
ISO 10993-13:2010	ANSI/AAMI/ISO 10993-13:2010	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 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006/(R)2011	Minor 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
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Identical
ISO 11137-2:2012	ANSI/AAMI/ISO 11137-2:2012	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006/(R)2010	Identical
ISO 11138-1:2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2:2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
ISO 11138-3:2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4:2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5:2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007/(R)2012	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007/(R)2012	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007/(R)2012	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006/(R)2010	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006/(R)2010	Identical
ISO 11658:2012	ANSI/AAMI/ISO 11658:2012	Identical
ISO 11663:2009	ANSI/AAMI/ISO 11663:2009	Identical
ISO 11737-1:2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO/TS 12417:2011	ANSI/AAMI/ISO TIR12417:2011	Identical
ISO 13022:2012	ANSI/AAMI/ISO 13022:2012	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008/(R)2011	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 13408-7:2012	ANSI/AAMI/ISO 13408-7:2012	Identical

International designation	U.S. designation	Equivalency
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 13958:2009	ANSI/AAMI/ISO 13958:2009	Identical
ISO 13959:2009	ANSI/AAMI/ISO 13959:2009	Identical
ISO 14155:2011	ANSI/AAMI/ISO 14155:2011	Identical
ISO 14160:2011	ANSI/AAMI/ISO 14160:2011	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14708-5:2010	ANSI/AAMI /ISO 14708-5:2010	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007/(R)2010	Identical
ISO 15223-1:2012	ANSI/AAMI/ISO 15223-1:2012	Identical
ISO 15223-2:2010	ANSI/AAMI/ISO 15223-2:2010	Identical
ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009 and A2:2012	Major technical variations
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 (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006/(R)2010	Identical
ISO/TS 19218-1:2011	ANSI/AAMI/ISO TIR19218:2011	Identical
ISO 20857:2010	ANSI/AAMI/ISO 20857:2010	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/TR 22442-4:2010	ANSI/AAMI/ISO TIR22442-4:2010	Identical
ISO 23500:2011	ANSI/AAMI/ISO 23500:2011	Identical
ISO/TS 23810:2012	ANSI/AAMI/ISO TIR23810:2012	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 25539-3:2011	ANSI/AAMI/ISO 25539-3:2011	Identical
ISO 26722:2009	ANSI/AAMI/ISO 26722:2009	Identical
ISO 27185:2012	ANSI/AAMI/ISO 27185:2012	Identical
ISO 27186:2010	ANSI/AAMI/ISO 27186:2010	Identical
ISO 80369-1:2010	ANSI/AAMI/ISO 80369-1:2010	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Medical Device Software Committee

This AAMI Technical Information Report was developed by the AAMI Agile Software Task Group under the auspices of the AAMI Medical Device Software Committee. Approval of the Technical Information Report does not necessarily mean that all members voted for its approval.

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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.

Foreword

Over the past several years, **AGILE** software development has become an accepted method for developing software products. There have been questions from both manufacturers and regulators as to whether (or which) **AGILE** practices are appropriate for developing medical device software. Enough medical device manufacturers have implemented **AGILE** practices in their software development so that answers to these questions can be documented. Having clear guidance of which practices have been found to be appropriate will be very useful for all developers of medical device software.

This TIR will provide recommendations for complying with international standards and U.S. Food and Drug Administration (FDA) regulations and guidance documents when using **AGILE** practices to develop medical device software.

The concepts incorporated herein are not inflexible or static. They are reviewed periodically to assimilate new data and advances in technology.

As used within the context of this document, “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.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Introduction

AGILE software development (hereafter referred to simply as “**AGILE**”) has been evolving for many years. **AGILE** began as a niche concept being used in small pockets of the software industry and has since grown to be well established in many different software development contexts. As it has grown, it has been adapted to fit the unique needs of a specific context. For **AGILE** to be established in the medical device software industry, guidance is needed to adapt it to fit that unique context. This TIR fulfills that need.

Why read this TIR?

AGILE was developed in response to quality and efficiency concerns posed by existing methods of software development. It can bring benefits that are valuable to the medical device software world, including the following:

- Continuous focus on safety, risk management, and delivering customer value through **BACKLOG** prioritization, planning practices, and customer feedback
- Continuous assessment of quality through continuous integration and testing
- Continuous improvement of the software development process through **RETROSPECTIVES** and team accountability
- Continuous focus on "getting to **DONE**" and satisfying quality management stakeholders through the regular completion of activities and deliverables

AGILE can bring value to medical device software.

There are concerns about **AGILE**'s compatibility with the regulated world of medical device software development. For example, the **AGILE** Manifesto has value statements that seem contrary to the values of a quality management system; and because **AGILE** initially grew from the information-technology space where human safety and risk management were not of primary importance, there is concern that **AGILE** lacks the proper controls for producing safety-critical software.

Fortunately, **AGILE**'s fundamental nature is to be adaptable to the context in which it is applied, allowing for **AGILE** principles and practices to be applied in ways that are compatible with the needs of the safety-critical, medical device software world.

AGILE can be adapted to the unique needs of medical device software.

This TIR will examine **AGILE**'s goals, values, principles, and practices, and provide guidance on how to apply **AGILE** to medical device software development. It will

- provide motivation for the use of **AGILE**;
- clarify misconceptions about the suitability of **AGILE**; and
- provide direction on the application of **AGILE** to meet quality system requirements.

Following the guidance provided by this TIR can help medical device software manufacturers obtain the benefits provided by **AGILE** and satisfy regulatory requirements and expectations.

Initial recommendations

This TIR provides recommendations for ways to effectively apply **AGILE** to medical device software. Here are some of the initial recommendations that are explained further later.

AGILE is driven by the value statements written in the *Manifesto for **AGILE** Software Development*. These value statements can seem to be contradictory to the values of the regulated world of medical device software, but they

need not be interpreted that way. Instead, they can be aligned to enhance the effectiveness of the quality management system.

*Apply the values of **AGILE** in a way that enhances a robust quality management system.*

AGILE emphasizes the need for the team to own its practices, inspect them, adapt them, and optimize them to their context. Regulatory requirements emphasize the need to establish a robust quality management system. Within the context of an established quality management system, **AGILE** practices can be applied without disrupting the quality system and without raising undue concern among regulators.

*Apply the practices of **AGILE** within the context of an established quality management system.*

AGILE embraces a highly **INCREMENTAL/EVOLUTIONARY** lifecycle for software development. Although regulations and standards do not mandate a particular lifecycle model, if stakeholders have expectations for linear lifecycle models, an **INCREMENTAL/EVOLUTIONARY** lifecycle might bring challenges.

*Set the correct expectations by defining the **SOFTWARE DEVELOPMENT LIFECYCLE MODEL**. Demonstrate how an **INCREMENTAL/EVOLUTIONARY** lifecycle satisfies regulatory requirements.*

As part of its **INCREMENTAL/EVOLUTIONARY** lifecycle, **AGILE** emphasizes the ability to respond quickly to change. Because rapid change can increase risks to product quality, effective change management systems are essential to align the desire to change quickly and the need to manage risk.

Establish robust change management systems to manage changes and mitigate risks associated with rapid change.

Guidance on the use of AGILE practices in the development of medical device software

1 Scope

1.1 Inclusions

This Technical Information Report (TIR) provides perspectives on the application of **AGILE** during medical device software development. It relates them to the following existing standards, regulations, and guidance:

- ISO 13485:2003, *Quality management systems—Requirements for regulatory purposes*
- IEC 62304, *Medical device software—Software lifecycle processes*
- ISO 14971:2007, *Medical devices—Application of risk management to medical devices*
- FDA *Code of Federal Regulations* (CFR), Title 21, Part 820.30, Quality System Regulation: Design Controls—
- FDA *Guidance for the content of premarket submissions for software contained in medical devices*
- FDA *General principles of software validation; Final guidance for industry and FDA staff*

Although this TIR does not provide a particular perspective for IEC TR 80002-1 (*Guidance on the application of ISO 14971 for medical device software*), the pertinent aspects of software risk management for medical devices were integrated throughout this TIR.

The following groups are the intended audience for this TIR:

- Medical device manufacturers who are planning to use **AGILE** techniques
- Manufacturers who are currently practicing **AGILE** and are entering the regulated medical device space
- Software development teams, including software test and quality groups
- Software definers, including marketing, sales, and other representatives of the customer
- Senior management, project managers, quality managers
- Quality systems and regulatory affairs personnel
- Internal and external auditors
- Regulating bodies, agencies, and organizations responsible for overseeing the safety and effectiveness of medical devices

1.2 Exclusions

This TIR is not intended to be used as an educational tool or tutorial for the following:

- **AGILE** development practice
- Quality system regulations

This TIR should be regarded as a reference and as a guidance intended to provide recommendations for complying with international standards and FDA guidance documents when using **AGILE** practices in the development of medical device software. This TIR is not intended to be a prescription for a specific situation or method.