Technical Information Report

AAMI TIR45: 2012/(R)2018

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

AAMI
Advancing Safety in Health Technology

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

Approved 20 August 2012 and reaffirmed 5 April 2018 by
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

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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years.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

Published by

AAMI
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 978-1-57020-445-6

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 Evolving 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	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/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 11633:2009	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.

At the time this document was published, the **AAMI Medical Device Software Committee** had the following members:

Cochairs:
Sherman Eagles, SoftwareCPR
John F. Murray, Jr., BS MS CSQE, FDA/CDRH

Members:
Michael Attili, Amaxo Inc
Catherine Bahr, GE Healthcare
Robert A. Bowser, Steris Corporation
Michael L Brendel, Spacelabs Medical Inc.
Kimberly Colasanti, Welch Allyn Inc.
Conor Curtin, Fresenius Medical Care Renal Therapies Group
Theresa Dennis, Sterigenics International
Harsh Dharwad, Hospira Worldwide Inc.
Christie Anita Evans, Hill-Rom Holdings
Christine M. Flahive, Chris Flahive Associates
Kenneth J. Fuchs, Mindray DS USA Inc.
Kerry A. Griffin, PMP CQE, 3M Healthcare
Rickey L. Hampton, Partners HealthCare Systems (Independent Expert)
John C. Hoffman, Quality Management Resources LLC
Jeremy Jensen, Boston Scientific Corporation
Ed R. Kimmelman, BME, JD (Independent Expert)
Thomas Kleinhenz, TUV SUD America
Patricia Krantz, Medtronic Inc.
Alan Kusinitz, SoftwareCPR
Bernie Liebler, Advanced Medical Technology Association
Dongping Lin, PhD (Independent Expert)
Jared Mauldin, Integrated Medical Systems
Mary Beth McDonald, St Jude Medical Inc.
Steven D. McDonnell, Baxter Healthcare Corporation
Julia Merritt, MPR Associates Inc.
Mulugeta Mideksa, BME, Tikur Anbessa Specialized Hospital (Independent Expert)
Mark C. Miller, Covidien
John F. Murray, Jr., BS MS CSQE, FDA/CDRH
Geoffrey A. Pascoe, MSCCS BEE GSEC (Independent Expert)
Ken Persen, Cameron Health Inc. (Independent Expert)
Dewey Phan, Becton Dickinson & Company
Dave Pouliot, Baxa Corporation
Inhel Rekik, MS, University of Maryland Medical System (Independent Expert)
Victor Rodrigues, Cochlear Ltd
Miguel Rodriguez, Johnson & Johnson
Daniel Rubery, NxStage Medical Inc.
Harvey Rudolph, PhD, Underwriters Laboratories Inc.
Richard A. Schrenker, Massachusetts General Hospital
Xianyu Shea, Stryker Instruments Division
Carla Sivak, Edwards LifeSciences
Donna-Bea Tillman, PhD, Microsoft Health Solutions Group
Stephen Vastagh, Medical Imaging & Technology Alliance a Division of NEMA
David W. Walker, SEI Partner for CMMI Services (Independent Expert)
Mark H. Walker, Focus Compliance & Validation Services
John Walz, IEEE (Independent Expert)

Gregory Whitney, CR Bard
Daidi Zhong, PhD, Chongqing University (Independent Expert)

Alternates:
Aziz Bhai, Hill-Rom Holdings
Christopher P. Clark, Bausch & Lomb Inc.
Kevin Crowe, Cochlear Ltd
Richard W. De La Cruz, Hospira Worldwide Inc.
Christina DeMur, Draeger Medical Systems Inc.
Sherman Eagles, SoftwareCPR
Rich Eaton, Medical Imaging & Technology Alliance a Division of NEMA
Jeff Gilham, Spacelabs Medical Inc.
Svetlana V. Gontcharenko, Baxter Healthcare Corporation
Ed Heierman, PhD, Abbott Laboratories
James P. Hempel, Covidien
Jinhua Huang, CQE,CSQE,CMQ/OE, GE Healthcare
Joshua Kim, Welch Allyn Inc
Yimin Li, Stryker Instruments Division
Don McAndrews, Philips Electronics North America
David McCall, Steris Corporation
Darin Seth Oppenheimer, Johnson & Johnson
Joe Petruzzelli, Mindray DS USA Inc.
Shane Pew, Becton Dickinson & Company
Chris Rice, MPR Associates Inc.
Robert Smith, St Jude Medical Inc.
Joseph Tingzon, Moog Medical Devices

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.

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

Cochairs:
Patricia Krantz, Medtronic, Inc.
Bakul Patel, FDA

Members:
Richard Chapman, FDA
Sherman Eagles, SoftwareCPR
Jochen Jäger, Roche
Patricia Krantz, Medtronic, Inc.
Mary Beth McDonald, St. Jude Medical Inc.
John F. Murray, Jr., BS MS CSQE, FDA/CDRH
Victor Rodrigues, Cochlear Ltd
Mike Russell, Surpetition
John Schmidt, Boston Scientific
Greg Urquhart, Toshiba Medical Visualization Systems
David Walker, David Walker SPCS
Marta Walker, Nucletron

Alternates:
Brian Pate, SoftwareCPR
Bakul Patel, FDA
Lori Pope, St. Jude Medical Inc.
Kelly Weyrauch, Medtronic, Inc.

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 **RETROSPECTIVE**s 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.

