Technical Information Report

AAMI TIR45: 2023

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

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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

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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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.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N Glebe Road, Suite 800, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the AAMI TIR45, *Guidance on the use of* **AGILE** *practices in the development of medical device software* (AAMI TIR45:2023), but it does provide important information about the development and intended use of the document.

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

*Set the correct expectations by defining the **SOFTWARE DEVELOPMENT LIFE CYCLE MODEL**. Demonstrate how an **INCREMENTAL/EVOLUTIONARY** life cycle satisfies regulatory requirements.*

As part of its **INCREMENTAL**/**EVOLUTIONARY** life cycle, **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 13485:2016, *Quality management systems—Requirements for regulatory purposes;*
- IEC 62304:2006+AMD1:2015, *Medical device software–Software life cycle processes;*
- ISO 14971:2019, *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;

