QMS Manual

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Today

Contents

This QMS manual describes a quality management system that conforms to the standards stated by ISO 9001:2008.

1. Scope

1.1 Description of Organization

This organization is an agglomeration of open sources software contributors. The project is open source in nature.

1.2 Scope of Certification

This document is set up for ISO 9001:2008 certification. However, these headings will roughly generalize to other ISO QMS certifications, such as ISO 13485.

1.3 Third Party Certification

The certifying institution must be chosen based upon jurisdiction.

2. References

- AAMI TIR45-2012
- ISO 9001-2008
- ISO 9004-2009
- ISO 13485-2003
- ISO 14971-2012
- ISO 20000-1-2005

- ISO 62304-2006
- ISO 90003-2004

3. Terms & Definitions

3.1 Description

3.2 Implementation And Maintenance

4. Quality Management System

4.1 General Requirements

4.2 Documentation Requirements

4.2.1 General

4.2.2 Quality Management System Manual

4.2.3 Document and Data Control

All project and planning materials will be stored in a directory structure containing the documentation in a variety of formats. The directory structure will be version controlled.

4.2.4 Control of Records

Project records are referred to under the Compliance heading of the Project Guide. These records contain a history documenting this project's quality assurance activities.

5. Management Responsibility

5.1 Management Commitment

5.2 Customer Focus

5.3 Policy Statement

This project seeks to deliver defect-free results.

5.4 Planning

5.4.1 Quality Objectives

The project processes should deliver new features while reducing defects over time.

8.2.3 Process Monitoring & Measurement

8.2.4 Product Monitoring & Measurement

8.3 Control Of Non-conformances

When a defect is detected, the problem is recorded as a bug in the issue tracking system.

8.4 Analysis Of Data

8.5 Improvement

8.5.1 Continual Improvement

8.5.2 Corrective Action

A bug is handled by 1) creating a test that recreates the conditions of the bug (i.e. "regression test"); and 2) altering system code until the error condition has been corrected.

8.5.3 Preventive Action

The project uses a number of techniques to identify problems before they occur. This QMS is the primary action. More specific actions include:

- software version control
- test-driven development with unit tests
- continuous integration
- code reviews

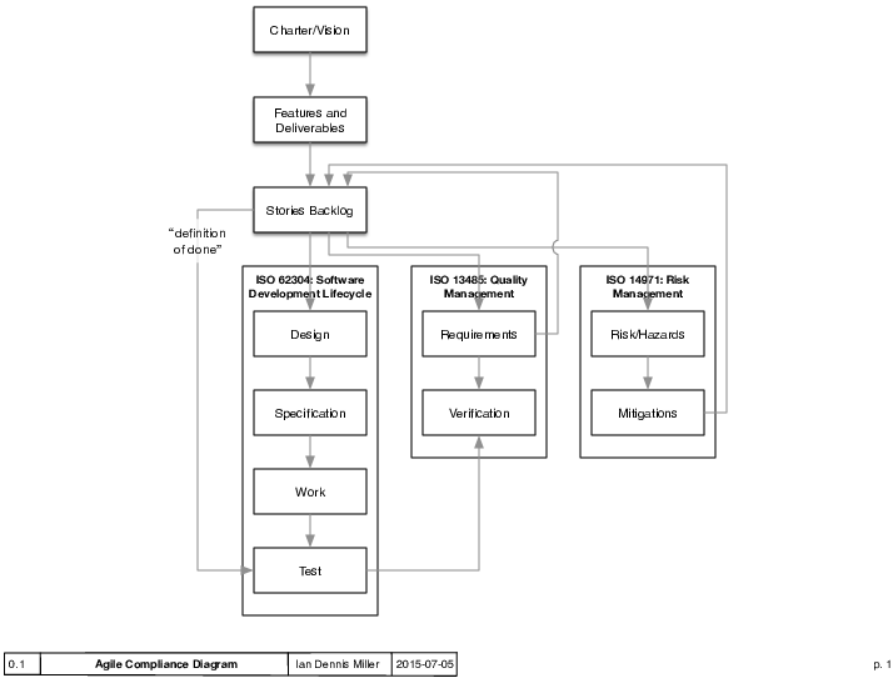

Figure 1: Agile QMS Process Diagram

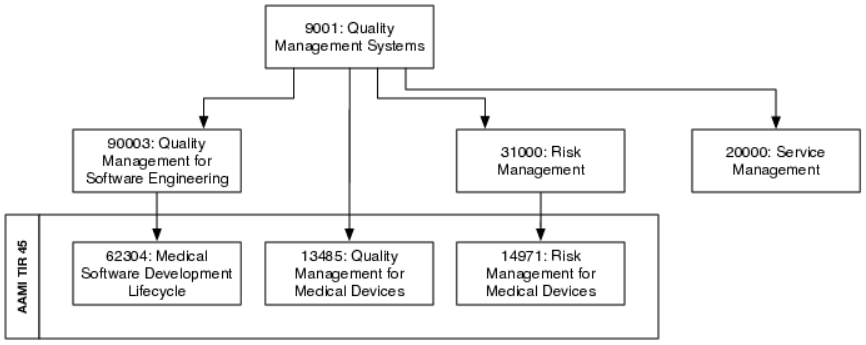

Figure 2: Compliance Hierarchy Diagram

Appendices

A.1 Abbreviations & Acronyms

A.2 Sequence & Interaction Of QMS Processes

A.3 Relationships between ISO standards

A.4 List Of Key Management System Documents

Operational Procedures

Forms & Records

A.5 Organization Chart