Technical Information Report

AAMI TIR102: 2019

U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016 Quality Management Systems

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Advancing Safety in Health Technology

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AAMI

Abstract: This document provides a mapping of the US FDA 21 CFR requirements to the "regulatory requirements" references in ISO 13485:2016. This mapping is intended to be a tool for US industry to help identify the regulatory requirements from the US medical device regulations to be addressed through an ISO 13485 quality management system.

Keywords: quality systems, regulations, 21 CFR 820, medical devices

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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

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 TIR. “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 technical information report are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE—This foreword does not contain provisions of the AAMI TIR102, *U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016 Quality Management Systems* (AAMI TIR102:2019), but it does provide important information about the development and intended use of the document.

Introduction

This Technical Information Report (TIR) is intended to demonstrate alignment of regulatory requirements for quality management systems applicable to organizations involved in one or more stages of the life-cycle of a medical device.

This TIR is a comparison of the requirements of 21 CFR 820 and ANSI/AAMI/ISO 13485:2016. Within this TIR, 21 CFR 820 may be referred to as the Quality System (QS) Regulation. In addition, ANSI/AAMI/ISO 13485:2016 may be referred to as ISO 13485:2016 or the standard.

AAMI Quality Management working group (AAMI QM/WG 01) has completed an analysis to identify differences between the requirements of 21 CFR 820 and the clauses of ISO 13485:2016, as well as some key considerations in the evolution of global quality management system for the medical device industry.

U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016, Quality management systems

1 Scope

This document is a comparison of requirements between 21 CFR 820 and ANSI/AAMI/ISO 13485:2016 that demonstrates similarities, highlights differences, and discusses key considerations for medical device manufacturers. It is not a word-for-word literal identification of differences; thus, the reader must be familiar with quality management system requirements along with the statutory definitions to apply this report.

This document provides the basis for interpretation of the associated requirements and applicable U.S. FDA rules. Users must be aware that this analysis provides a comparison of the QS Regulation and the standard only. It is not inclusive of all global regulatory requirements applicable to medical device quality systems.

The comparison covers all parts of 21 CFR 820 including appropriate references to the Preamble to the QS Regulation and ANSI/AAMI/ISO 13485:2016. Other standards or parts of the U.S. regulations may be referenced but are not explicitly included in this report.

2 Using this technical information report

This document was produced by AAMI QM/WG 01 comprised of representatives from the medical device sector. For the proper use of this TIR, readers should have full understanding of both 21 CFR 820 and ISO 13485:2016. Although the information contained in this document has been carefully considered, it is up to the individual organization to ensure compliance with all regulatory requirements. This document is intended for manufacturers and it is expected that the reader is familiar with regulatory quality management system requirements and definitions within the medical devices sector and regulations. It is intended for informational purposes and it is not intended to be used to assess or audit compliance with regulatory requirements.

- The working group has listed the primary and some secondary core references, not all referenced sections of the standard or QS Regulation are listed.

- The users of this document should keep in mind that a quality management system is a set of interrelated processes. Since both the QS Regulation and ISO 13485:2016 require the organization to define the interrelationships of quality management system, the user should keep in mind that there may be additional linkages connections that an organization must consider as you define your quality management system.

The Key Considerations section discusses notable differences between the QS Regulation and ISO 13485:2016. This part also includes narrative relative to any systemic differences between the U.S. FDA QS Regulation and ISO 13485:2016, which may have impact beyond a specific section.

The second section of the TIR consists of two mapping tables: 21 CFR 820 to ISO 13485:2016; and ISO 13485:2016 to 21 CFR 820. The mapping is provided in two directions purposefully. When evaluating the two quality management systems, the full intent and similarities can only be determined by comparing in both directions. Therefore, both tables should be reviewed in their entirety.

An example of this is 21 CFR 820 supplier controls compared to ISO 13485:2016 outsourced suppliers and purchasing controls and the need for quality agreements. While there are no incongruities among the requirements for the quality management systems, there may be some verbiage or directed differences. This difference may not have been noticed reviewing the requirements in only one direction. The requirements of both the QS Regulation and ISO 13485:2016 require quality agreements and allow a risk-based approach to meet this requirement (i.e. contracts, purchase orders, drawings, or specifications). The requirements of both the QS Regulation and ISO 13485:2016 can be met with flexible risk-based solutions and fulfill the obligation of both quality management systems.