Technical Information Report

AAMI TIR59: 2017

Integrating human factors into design controls

AAMI
Advancing Safety in Healthcare Technology

Integrating human factors into design controls

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AAMI

Abstract: This document provides information regarding human factors engineering/usability engineering activities and their corresponding applicability to design controls in accordance with 21 CFR 820.30.

Keywords: human factors, 21 CFR 820, usability, quality systems

AAMI Technical Information Report

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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.

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Glossary of equivalent standards

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www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Human Factors Engineering Committee

This AAMI Technical Information Report was developed by the **Human Factors Engineering Committee**.

Committee approval of this document does not necessarily imply that all committee members voted for its approval. At the time this document was published, the committee had the following members.

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NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

This technical information report (TIR) developed by the Human Factors Engineering Committee provides guidance on integrating HUMAN FACTORS ENGINEERING /USABILITY ENGINEERING (HFE/UE) into the DESIGN CONTROLS process.

Defined terms used throughout this document are capitalized.

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

NOTE—This foreword does not contain provisions of the AAMI TIR59, *Integrating human factors into design controls* (AAMI TIR59:2017), but it does provide important information about the development and intended use of the document.

Introduction

There is a recognized need for more guidance on how to integrate HUMAN FACTORS ENGINEERING/USABILITY ENGINEERING (HFE/UE) into a MANUFACTURER'S DESIGN CONTROLS process and QUALITY SYSTEM that has been developed in accordance with the FDA's QUALITY SYSTEM Regulation, Code of Federal Regulations (CFR) Title 21 Section 820.30, *Design Controls*. Therefore, this TIR has been developed to highlight the importance of consistency and alignment of processes throughout a MANUFACTURER'S product development process to ensure recognition of and compliance with industry best practice, applicable FDA regulations, and recognized standards.

It is important to note that HFE/UE activities do not need to be a separate, parallel, or additional process but can be integrated into existing processes.

For the purposes of this TIR, the terms HUMAN FACTORS ENGINEERING and USABILITY ENGINEERING are considered to be equivalent and interchangeable.

While the focus of this TIR is on applicability of HFE/UE within DESIGN CONTROLS, RISK MANAGEMENT and the emphasis of use-related RISK identification are inherent and strongly emphasized as being central to a MANUFACTURER'S product development process. As such, RISK MANAGEMENT implications are included at the conclusion of each clause.

Integrating human factors into design controls

1 Scope

This TIR was developed to provide background and information regarding HFE/UE activities and their corresponding applicability to DESIGN CONTROLS in accordance with 21 CFR 820.30. The scope of this TIR applies to all developers and MANUFACTURERS of medical devices and combination products that contain a device constituent part. The TIR is for those MANUFACTURERS intending to commercialize products in the United States and therefore does not address all requirements for commercializing products outside the U.S.

While this TIR presents specific recommendations for aligning HFE/UE processes to DESIGN CONTROLS, it is recognized that MANUFACTURERS may develop their own methodologies, processes, and customized QUALITY SYSTEMS in order to ensure compliance with 21 CFR 820.30 and other regulations. MANUFACTURERS should consider evaluating the recommendations in this TIR and the resultant impact to their existing QUALITY SYSTEMS and processes, including compliance with ANSI/AAMI/ISO 13485 and ANSI/AAMI/ISO 14971, as applicable.

This TIR presents specific DESIGN CONTROLS activities as specified in 21 CFR 820.30; however, it does not cover all elements within 21 CFR 820 or 21 CFR 820.30. The focus of this TIR is DESIGN CONTROLS activities that overlap functionality with HFE/UE processes, leading to robust HFE/UE documentation in support of a MANUFACTURER'S DESIGN HISTORY FILE [21 CFR 820.30 (j)] and HFE/UE FILE [ANSI/AAMI/IEC 62366-1:2015]. In addition, MANUFACTURERS establish QUALITY SYSTEMS to be compliant with 21 CFR, as well as ANSI/AAMI/IEC 62366-1:2015 (referred to as "ANSI/AAMI/IEC 62366-1" throughout this document), and the scope of these systems is dependent on multiple variables, such as overall MANUFACTURER size and device complexity. As such, this TIR is intended to provide general overviews, recommendations, and deliverables with respect to DESIGN CONTROLS and HFE/UE for MANUFACTURERS to utilize and customize according to their own QUALITY SYSTEMS and procedures.

Figure 1 below provides a detailed mapping of HFE/UE integration as part of DESIGN CONTROLS where activities performed produce HFE/UE deliverables. Some of these deliverables are considered "live" and are required to be updated when new information is produced. For instance, "Updated RISK ANALYSIS" is a HFE/UE deliverable due to activities produced in DESIGN OUTPUT, VERIFICATION, VALIDATION, Submission, and In Market after the initial RISK ANALYSIS deliverable performed in DESIGN INPUTS.

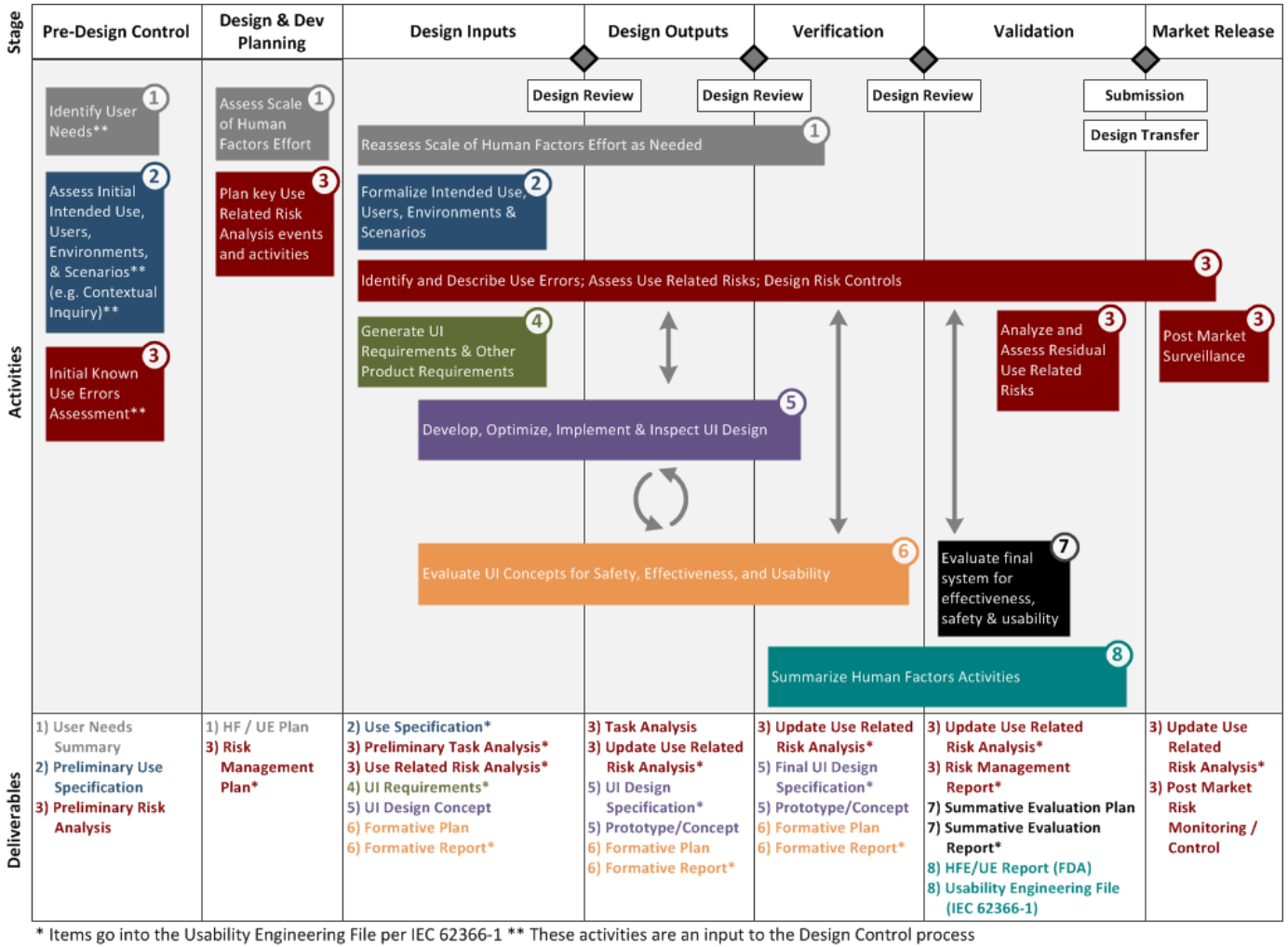

Figure 1: DESIGN CONTROLS and HFE/UE activity mapping

RISK MANAGEMENT in accordance with ANSI/AAMI/ISO 14971:2007 (referred to as "ANSI/AAMI/ISO 14971" throughout this document) is discussed in this TIR as it relates to use-related RISK ANALYSIS and evaluation, RISK CONTROL, RESIDUAL RISK analyses and risk/benefit analyses; however, a detailed analysis of ISO 14971 is not presented in this TIR. RISK MANAGEMENT is essential and at the core of the product development processes as a part of HFE/UE and DESIGN CONTROLS. As such, an overview of RISK MANAGEMENT activities is discussed with respect to each DESIGN CONTROLS "phase" and is represented in the DESIGN CONTROLS and HFE/UE activity mapping.

Found within this TIR and integral to implementation of HFE/UE within DESIGN CONTROLS, the following FDA guidance documents are also referenced[1]:

- *Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff* (3 Feb 2016).
- *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (11 May 2005).
- *Infusion Pumps Total Product Life Cycle: Guidance for Industry and FDA Staff* (2 Dec 2014).
- *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff* (17 Mar 2015).
- *Guidance on Medical Device Patient Labeling* (19 Apr 2001).
- *Human Factors Points to Consider for IDE Devices* (Pre-1997).
- *Design Considerations for Devices Intended for Home Use: Guidance for Industry and Food and Drug Administration Staff* (24 Nov 2014).
- *Design Control Guidance for Medical Device Manufacturers* (11 Mar 1997).
- *Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation*.

Although the scope of this TIR is on aligning HFE/UE processes with a QUALITY SYSTEM'S DESIGN CONTROLS, there are significant HFE/UE best practices that should precede the initiation of DESIGN CONTROLS (see clause 5 below). Because DESIGN INPUTS often originate during pre-DESIGN CONTROL activities, such as market assessment, technology research and development, and contextual inquiry, the integration of HFE/UE methodologies enables more robust definitions of those DESIGN INPUTS. Examples of DESIGN INPUTS that benefit from the scientific rigor of HFE/UE methodologies utilized in pre-DESIGN CONTROL activities include definitions of USER NEEDS, preliminary RISK ASSESSMENT, and characterization of use scenarios.

2 Terms and definitions

NOTE Terms used throughout the document are in SMALL CAPS.

2.1

ACCOMPANYING DOCUMENTATION (see also LABELING)

materials accompanying a medical device and containing information for the USER or those accountable for the installation, use, and maintenance of the medical device, particularly regarding safe use

Note 1 The ACCOMPANYING DOCUMENTATION can consist of instructions for use, technical description, installation manual, quick reference guide, etc.

Note 2 ACCOMPANYING DOCUMENTATION is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.

Note 3 Medical devices that can be used safely without instructions for use are exempted from having instructions for use by some authorities with jurisdiction.

[SOURCE: ANSI/AAMI/IEC 62366-1:2015, 3.2]

2.2

CRITICAL TASKS

USER TASKS that, if performed incorrectly or not performed at all, would or could cause serious HARM to the patient or USER, where HARM is defined to include compromised medical care

[1] The latest revision of each standard and guidance should be utilized when referring to this TIR.