

Technical Information Report



AAMI TIR59: 2017

Integrating human factors
into design controls

Integrating human factors into design controls

Approved 4 August 2017 by
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

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, 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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every 5 years but at least every 10 years. For a TIR, AAMI consults with a technical committee about 5 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CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time.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

© 2017 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI at 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: (703) 525-4890; Fax: (703) 276-0793.

Printed in the United States of America

ISBN 978-1-57020-666-5

Contents

Page

Glossary of equivalent standards.....	iv
Committee representation.....	v
Foreword.....	vii
Introduction	viii
1 Scope.....	1
2 Terms and definitions.....	3
3 Acronyms	9
4 HFE/UE Integration within existing DESIGN CONTROLS	9
5 Pre DESIGN CONTROLS	11
6 DESIGN CONTROLS—General [21 CFR 820.30(a)(1)].....	11
7 Design and development planning [21 CFR 820.30 (b)]	12
8 DESIGN INPUT [CFR 820.30 (c)]	13
9 DESIGN OUTPUT—[21 CFR 820.30 (d)].....	17
10 Design reviews—[21 CFR 820.30 (e)]	19
11 Design VERIFICATION—[CFR 820.30 (f)]	21
12 Design VALIDATION—[21 CFR 820.30 (g)]	21
13 Design transfer—[CFR 820.30 (h)].....	22
14 Design changes—[CFR 820.30 (i)].....	23
15 DESIGN HISTORY FILE—[CFR 820.30 (j)].....	24
16 POST-MARKET SURVEILLANCE.....	24
ANNEX A (INFORMATIVE) HFE/UE report	25
Bibliography	27

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.

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.

Cochairs: Mary Beth Privitera
Molly Story

Members: Tor Alden, HS Design Inc
Araya Amsalu, Hill-Rom Holdings
Michael Appel, Northeast Georgia Medical Center
Janey Barnes, User-View Inc
Eric Bergman Fresenius Medical Care
Sherri Biondi, Genentech Inc
Peter Boge Novo Nordisk
Rick Botney, Oregon Health & Science University
Joe Cesa Halyard Health
Shannon Clark UserWise Inc
Randi Cleverley, CR Bard
Ella Cozmi, Intuitive Surgical Inc
John DeFoggi, Business Process & Technology Management LLC (BPTM)
Wende Dewing, Usensus LLC
Serge Dubeau, Worrell Inc
Ronak Dunung, Cook Inc
Kathi Durdon, SUNY Upstate Medical University
Terry Fairbanks, MedStar Health Corporate Office
Valerie Fenster, Amgen Inc
Kristi Flury, Boston Scientific Corporation
Bryant Foster, Research Collective
Daryle Gardner-Bonneau, Bonneau and Associates
Rosemary Gonzales, Combination Product Partners
Carina Gregory, Cook Research Incorporated
Dan Haberstick, Johnson & Johnson
Sean Hagen, BlackHagen Design Inc
Katie Hansbro, Design Science Consulting
Diane Hayman, Spacelabs Healthcare
Ryann Hill, Terumo Americas Corporate
Wayne Ho, Healthcare Human Factors
Nate Hogan, Stryker Instruments Division
Dean Hooper, HE Consulting
Shannon Hoste, FDA/CDRH
Ed Israelski, Abbvie
Carolynn Johnson, Daedalus
Korey Johnson, GFK
Mike Kasamianian, Human Factors Consulting Services Inc
Michael Lau, Insight Product Development—Chicago, IL
Lee Leichter, P/L Biomedical
Melissa Lemke, Agilis Consulting Group LLC
Lana Lowry, National Institute of Standards & Technology
Megha Mahadevan Shah, Cardinal Health
Barb Majchrowski, Draeger Medical Systems Inc
Jennifer Martin, The University of Nottingham
Marsha McArthur, Integrated Medical Systems
Deborah McConnell, Battelle Medical Products
Susan McDonald, Ximedica
James Merritt, Hospira, a Pfizer company

Mark Moyer, ASQ Biomedical Division
Bill Muto, WHM Associates Inc
Bob North, Human Centered Strategies
Shawn O'Connell, B Braun of America Inc
Dave Osborn, Philips
Yossi Pri-Paz Laniado Hospital
Mary Beth Privitera, University of Cincinnati
Rob Radwin, University of Wisconsin
Mick Rakauskas, Baxter Healthcare Corporation
Tim Reeves, Human Factors MD LLC
Pooja Roychoudhury, Regulatory and Quality Solutions LLC
Adam Shames Core Human Factors Inc
Bhavesh Sheth, Intertek
Richard Sit Smiths Medical
Kathy Smith, Medical Device USE Consulting LLC
Richard Stein, British Standards Institution Inc
JP Stephens, Abbott Laboratories
Molly Story, Sanofi
Bob Sugarman, RCS Performance Systems Inc
Katie Tippey, Vanderbilt University Medical Center
Gerard Torenvliet, Medtronic Inc Campus
Matthew Trachtenberg, Becton Dickinson & Company
Denise Wagner, Johnson & Johnson
Chelsea Wanta GE Healthcare
Jon Ward AJW Technology Consultants Inc
Sara Waxberg, Eli Lilly & Company
Matt Weinger, Vanderbilt University Medical Center
Michael Wiklund, UL LLC
Stephen Wilcox, Design Science Consulting

Alternates:

Keith Anderson, Smiths Medical
Pamela Artibey, Philips
Barry Berson, Human Factors Consulting Services Inc
Paul Blowers, Abbvie
Justin Bushko AJW Technology Consultants Inc
Joe Cafazzo, Healthcare Human Factors
Conor Curtin, Fresenius Medical Care
Lynn Dixon, Boston Scientific Corporation
Xin Feng, FDA/CDRH
Amy Gallenberg, GE Healthcare
Kim Gibson, Johnson & Johnson
Jonathan Gimbel, Regulatory and Quality Solutions LLC
Ondrea Kassarian, Cardinal Health
Jim Kershner, Eli Lilly & Company
Cynthia Lepak, Hill-Rom Holdings
Willy Liou, Amgen Inc
Natalia Mazaeva, Sanofi
Avital Merl, Becton Dickinson & Company
Kim Neff, CR Bard
Chris Neoh, Cook Inc
Patt Ryder, Sanofi
Arathi Sethumadhavan, Medtronic Inc Campus
Peter Sneeringer, Design Science Consulting
Joan Spear, B Braun of America Inc
Anita Stenquist, Baxter Healthcare Corporation
Jennifer Tsai, St Jude Medical Inc
Tom Varricchione, Ximedica
Audra Wright, Halyard Health
Julia Yeh, Amgen Inc

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

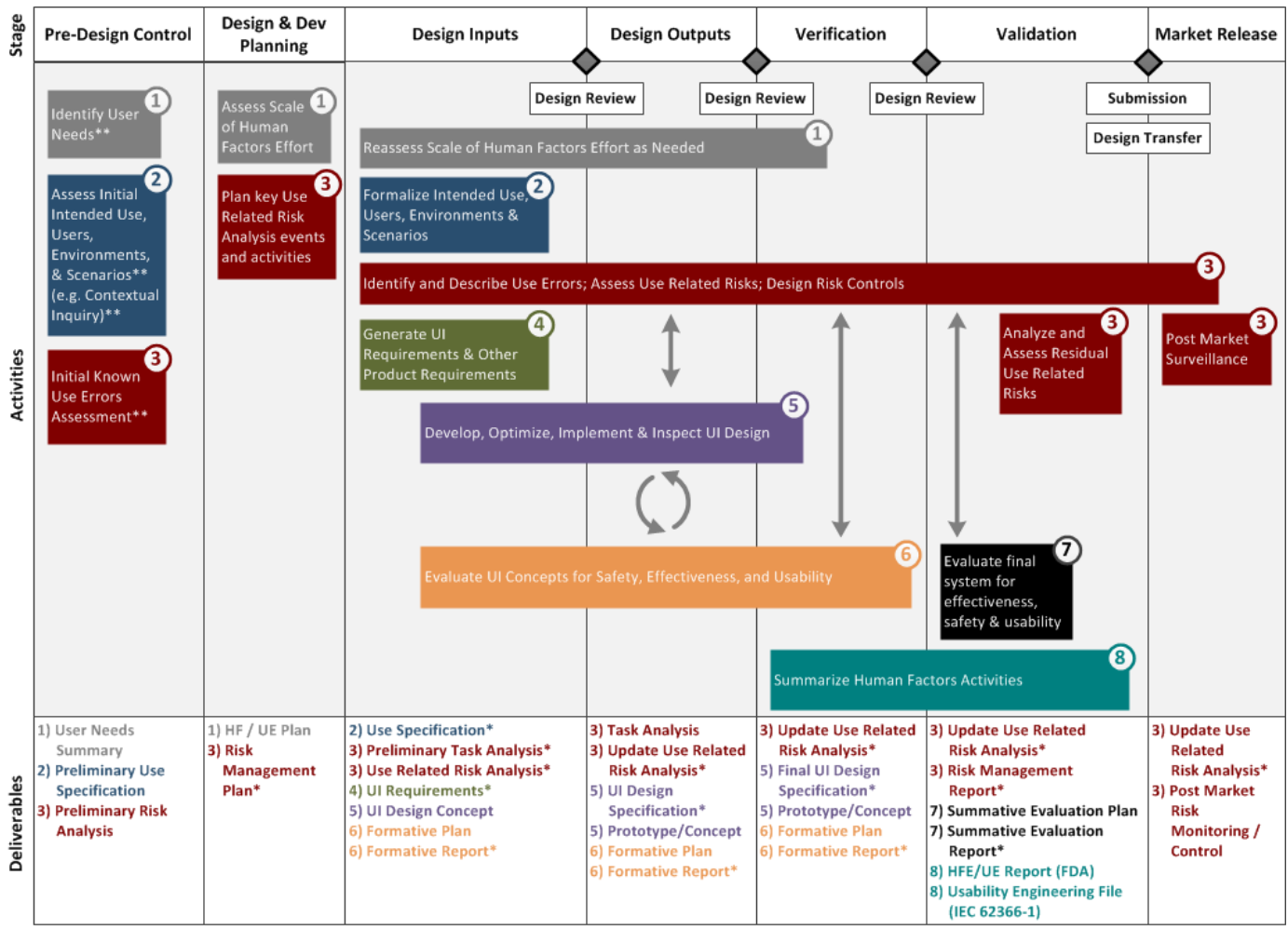
1 Scope

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.



* Items go into the Usability Engineering File per IEC 62366-1 ** These activities are an input to the Design Control process

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 referenced¹:

- *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.