

This is a preview of "AAMI TIR50:2014 (R20...)". Click here to purchase the full version from the ANSI store.

Technical Information Report



AAMI TIR50: 2014/(R)2017 Post-market surveillance of use error management

PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.



PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

AAMI Technical Information Report

AAMI TIR50:2014/(R)2017



Post-market surveillance of use error management

Advancing Safety in Health Technology

PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Approved 10 March 2014 and reaffirmed 6 December 2017 by
AAMI

Abstract: This document will address the issue of use error detection for medical devices from clinical, manufacturer, and regulatory perspective regarding human factors assessment. The goal is to provide guidance on how clinicians and manufacturers can best collect and leverage post-market use error data to improve product safety and usability.

Keywords: human factors, usability, hospital, clinical

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, by 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 five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five 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.

For a complete copy of this AAMI document, contact AAMI at
+1-877-249-8226 or visit www.aami.org.

Published by

AAMI
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

© 2014 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, complete the reprint request form at www.aami.org or contact AAMI at 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: +1-703-525-4890; Fax: +1-703-525-1067.

ISBN 978-1-57020-514-9

Contents

	Page
Glossary of equivalent standards	v
Committee representation	vi
Foreword	viii
1 Purpose.....	1
2 Scope.....	1
2.1 Stakeholder entities (not all inclusive).....	1
2.2 Reporting entities (not all inclusive)	1
3 Terms and definitions.....	2
4 How to use this document.....	3
5 Background.....	3
5.1 Manufacturer's perspective.....	3
5.2 Clinical perspective.....	4
5.3 Lay users perspective.....	5
6 Regulatory focus on use error post-market surveillance.....	5
7 Process recommendations for manufacturers.....	6
7.1 Process flow high level introduction.....	6
7.1.1 Deployment	8
7.1.2 Valid use event reports received (inputs for "reports").....	11
7.1.3 Triage	12
7.1.4 Analysis	14
7.1.5 Monitor and trend	15
7.1.6 Action	17
7.2 How post-market surveillance use error management drives value for your company	18
7.2.1 Data trending	18
7.2.2 Recommendations for how and when to take action	18
8 Process recommendations for clinical users.....	19
8.1 Process flow high-level introduction.....	19
8.2 Use error event.....	20
8.3 Immediate impact on user/patient.....	20
8.4 Evaluate experience to determine root cause.....	22
8.4.1 Monitor, trend and report to patient safety bodies	24
8.5 Reporting to manufacturer.....	24
8.6 Organization activities.....	24
8.6.1 General training on use error.....	24
8.6.2 Develop an understanding of the value of reporting close calls.....	24
8.6.3 Address the blame game.....	25
8.6.4 How post-market surveillance use error management drives value in clinical environments	25
8.6.5 Develop use error and close call reporting process for clinical organizational environments	25
8.6.6 User dissatisfaction	26
8.6.7 Utilize internal resources to identify use error events	26
8.6.8 Proactive assessment	26
8.6.9 Scalability	27
Annexes	
A Example questions for collecting use error or close call data.....	28
B Connecting use error to customer complaints.....	33
Bibliography	36

Tables

Table 1 — Potential use error complaint scenarios.....	10
Table B.1 — Tie use error to customer complaints	34

Figures

Figure 1 — Process overview flow chart on post-market surveillance of use error for manufacturers	7
Figure 2 — Deployment flow chart.....	8
Figure 3 — Triage flow chart.....	13
Figure 4 — Analysis flow chart.....	14
Figure 5 — Monitor and trend flow chart.....	16
Figure 6 — Action process flowchart.....	17
Figure 7 — Process overview flow chart on post-market surveillance of use error for clinical users.....	19
Figure 8 — Mitigate impact on user/patient.....	21
Figure 9 — Evaluate experience to determine root cause	22
Figure 10 — Sources of information.....	26



PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf



PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Committee representation

Association for the Advancement of Medical Instrumentation

Human Factors Engineering Committee

This AAMI technical information report was developed and approved by the AAMI Human Factors Engineering Committee.

At the time this document was published, the **AAMI Human Factors Engineering Committee** had the following members:

Chairs: Janine A. Purcell, MS, Philips Electronics North America
Molly F. Story, PhD, FDA/CDRH

Members: Tor Alden, BS MS, HS Design Inc.
Araya Amsalu, PhD, Hill-Rom Holdings
Keith B. Anderson, BSEE, Smiths Medical
Eric D. Bergman, PhD, Johnson & Johnson
Barry Berson, Human Factors Consulting Services Inc.
Prashant Bhadri, CareFusion
Sherri Biondi, PhD, Genentech Inc.
Peter Boge, Novo Nordisk
Bill Buresh, Draeger Medical Systems Inc.
Joseph Cafazzo, Healthcare Human Factors
Ken Catchpole, Cedars-Sinai Medical Hospital
Ella Cozmi, Hospira Worldwide Inc.
Conor Curtin, Fresenius Medical Care Renal Therapies Group
John M DeFoggi, DBA, Business Process & Technology Management LLC (BPTM)
Serge Dubeau, Worrell Inc.
Kathi Durdon, Welch Allyn Inc.
Evan T. Edwards, BSME MSSE, Kaleo Inc.
Rollin J. Fairbanks, MD MS, MedStar Washington Hospital Center
Daryle Jean Gardner-Bonneau, PhD, Bonneau and Associates
Rosemary Gonzalez, Combination Product Partners
R. Sean Hagen, BlackHagen Design Inc.
Diane Hayman, Spacelabs Medical Inc.
Dean A. Hooper, HE Consulting
Shannon M. Hoste, Stryker Instruments Division
Edmond W. Israelski, PhD CHFP, Abbvie
James Kershner, Eli Lilly & Company
Merrick F. Kossack, MS BS, Intuitive Surgical Inc.
Michael Lau, PhD, Insight Product Development
Lee Leichter, P/L Biomedical
Melissa R. Lemke, MS, Agilis Consulting Group LLC
Svetlana Lowry, PhD, National Institute of Standards & Technology
Jennifer Martin, PhD, The University of Nottingham
Marsha McArthur, Integrated Medical Systems
Cindy A. Miller, PhD, GE Healthcare
Mark Moyer, ASQ Biomedical Division
William H. Muto, PhD, Abbott Laboratories
Dan Nathan-Roberts, University of Wisconsin (Madison)
Susan Nichols, Kwikpoint/Gaia LLC
Robert A. North, PhD, Human Centered Strategies
Edward Nuber, B Braun of America Inc.
Shawn O'Connell, MS, RN, B Braun of America Inc.
David G. Osborn, Philips Electronics North America
Joseph Pri-Paz, MSc, Laniado Hospital
Mary Beth Privitera, University of Cincinnati
Robert G. Radwin, PhD, University of Wisconsin
Tim Reeves, PhD CHFP, Human Factors MD Inc.

Arathi Sethumadhavan, PhD, Medtronic Inc. WHQ Campus
Adam R. Shames, Core Human Factors Inc.
Mani Shanmugham, CR Bard
Vijender Singh, Intertek
Debora Stapleton, Covidien
Robert C. Sugarman, PhD, RCS Performance Systems Inc.
Tom Varricchione, Ximedica
Matt B. Weinger, MS MD, Vanderbilt University Medical Center
Tracy Weldon, Kimberly-Clark Corporation
Michael E. Wiklund, PE CHFP, UL LLC
Stephen Wilcox, PhD, Design Science Consulting
Lee Wood, F Hoffman-La Roche Ltd

Alternates:

Paul A. Blowers, Abbvie
Joe Cesa, BA, Kimberly-Clark Corporation
Shannon Clark, Intuitive Surgical Inc.
Wende Dewing, Medtronic Inc WHQ Campus
Elise Edson, Covidien
Amy Gallenberg, GE Healthcare
Stuart J. Garvin, Eli Lilly & Company
David H. Hoffmeister, Baxter Healthcare Corporation
Mike Kasamarian, Human Factors Consulting Services Inc.
Ronald D. Kaye, FDA/CDRH
Cynthia Ann Lepak, RN, Welch Allyn Inc.
Patricia Ryder, Fresenius Medical Care Renal Therapies Group
Joan M. Spear, MBA RM CMPR, B Braun of America Inc.
Svetlana Taneva, Healthcare Human Factors

Advancing Safety in Health Technology

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

PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Foreword

This technical information report (TIR) was developed by the Human Factors Engineering Committee.

It is widely recognized that there is little existing guidance for conducting post-market surveillance.

The objective of this TIR is to provide guidance on how people in various areas can collect, assess, and leverage post-market use error data to mitigate medical device product risk, and to improve product safety and usability.

Suggestions for improving this technical information report 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 TIR50, *Post-market surveillance of use error management* (AAMI TIR52:2014), but it does provide important information about the development and intended use of the document.



PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.

Post-market surveillance of use error management

1 Purpose

This document addresses the issue of use error detection for medical devices from the clinical, manufacturer, patient, user and regulatory perspective. The goal is to provide guidance on how these individuals can best collect, assess, and leverage post-market use error data to mitigate product risk, and to improve product safety and usability.

2 Scope

The guidelines described in this technical information report (TIR) are not separate from or in opposition to the existing U.S. Food and Drug Administration's (FDA's) and other regulatory bodies' reporting protocols for product failure or adverse events (concerning morbidities or mortalities), which already have standardized protocols. This TIR focuses instead on a process for handling complaints associated with use errors occurring from medical devices, drug delivery systems and combination medical products. These use errors could be from close calls, user dissatisfaction and/or quality complaints as they relate to use error events and therefore would not normally be reported and evaluated. User dissatisfaction is important, as it can be the source of complaints regarding how devices interfere with the normal workflow and require inappropriate levels of attention. This document recognizes the significant efforts during the pre-market phase to evaluate and improve usability. However, products used in the post-market environment can provide the largest usability study data set available. This document seeks to enhance the opportunity to have access to such information.

The process described in this TIR is not intended to be prescriptive but instead to provide a framework of guidelines for developing protocols and systems for capturing use errors in order to assure they are available to the appropriate stakeholders. This high-level guidance describes process flow, training and scalability and includes sample questions for data collection. The intended audience of this TIR not only includes manufacturers and clinicians, but also patients, caregivers and other laypersons who would be reporting the events.

2.1 Stakeholder entities (not all inclusive)

- Clinicians
- Human Factors and Usability Specialists
- Clinical Human Factors Professionals
- Safety Officers
- Complaint Handlers
- Technical Support
- Customer Facing Personnel (Marketing, Sales, Field Service, Customer Service)
- Product Quality Management (Risk Managers, Quality Engineers)
- Post-market Quality Organizations
- Pharmacovigilance Groups
- Patient Safety Organizations
- Medical Affairs
- Service Organizations (internal and subcontractors)
- Product Development Support/Maintenance Teams
- All Manufacturer Employees (if receiving complaints from customers)
- Manufacturer Usability Practitioner

2.2 Reporting entities (not all inclusive)

- Technicians (Biomedical Engineer, Scrub Tech, etc.)
- Laypersons (Patients, Family Members, Caregivers, etc.)