Medical devices—Post-market surveillance for manufacturers

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Abstract: This Technical Report will provide a common understanding of post-market surveillance, or PMS facilitating international cooperation in this area. The Technical Report is intended for use by manufacturers of medical devices. With PMS, the manufacturers can collect, evaluate, and analyze experience gained with their devices after placing on the market. The resulting information can be used for, among others, improvement of the devices. The proposed Technical Report aims to describe a comprehensive data collection process and activities that allow characterization of the behavior of the devices as used in practice, and identify necessary and/or possible actions. PMS information may include material that requires reporting to Regulatory Authorities. The proposed Technical Report will not provide information for such reporting, nor for achieving compliance with any other (PMS) requirement by Regulatory Authorities. Market surveillance by national authorities, as well as actions legally required to be performed by manufacturers as part of PMS or vigilance are outside the scope of the proposed Technical Report. The document is not intended to replace or change national or regional legislation on PMS.

Keywords: post market surveillance, medical device, safety
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAMI Technical Information Report</td>
<td>iv</td>
</tr>
<tr>
<td>ANSI Registration</td>
<td>iv</td>
</tr>
<tr>
<td>Committee representation</td>
<td>v</td>
</tr>
<tr>
<td>Background of AAMI adoption of ISO TR 20416 Ed.1</td>
<td>vi</td>
</tr>
<tr>
<td>Foreword</td>
<td>vii</td>
</tr>
<tr>
<td>Introduction</td>
<td>viii</td>
</tr>
<tr>
<td>1 Scope</td>
<td>1</td>
</tr>
<tr>
<td>2 Normative references</td>
<td>1</td>
</tr>
<tr>
<td>3 Terms and definitions</td>
<td>1</td>
</tr>
<tr>
<td>4 Purpose of post-market surveillance process</td>
<td>2</td>
</tr>
<tr>
<td>5 Planning of post-market surveillance</td>
<td>4</td>
</tr>
<tr>
<td>6 Review of the post-market surveillance plan</td>
<td>13</td>
</tr>
<tr>
<td>Annex A (informative) Examples of data sources</td>
<td>15</td>
</tr>
<tr>
<td>Annex B (informative) Examples of data analysis methods</td>
<td>25</td>
</tr>
<tr>
<td>Annex C (informative) Examples of post-market surveillance plans</td>
<td>32</td>
</tr>
<tr>
<td>Bibliography</td>
<td>44</td>
</tr>
</tbody>
</table>
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. A TIR must be acted on and the action formally approved usually every three years.

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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.

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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.

ANSI Registration

Publication of this Technical Report that has been registered with ANSI has been approved by the Accredited Standards Developer (AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203). This document is registered as a Technical Report according to the Procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature.

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.
Committee representation

Association for the Advancement of Medical Instrumentation
Application of post market surveillance systems to medical devices Working Group

The adoption of AAMI/ISO TIR 20416/Ed.1, Medical devices - Post-market surveillance for manufacturers as an AAMI Technical Information Report was initiated by the AAMI QM/WG06 Application of post market surveillance systems to medical devices Working Group. AAMI QM/WG06 provides input to the Quality management and corresponding general aspects for medical devices Committee which is the responsible group for providing the U.S. input to the relevant group in the International Organization for Standardization (ISO). U.S. representatives from the Application of post market surveillance systems to medical devices Working Group and the TAG played an active part in developing the ISO document.

At the time this document was published, the AAMI Application of post market surveillance systems to medical devices Working Group had the following members:

Cochairs: Mark Swanson
Marc-Henri Winter

Members: Jahan Azizi, Healthmark Industries Company Inc
Tim Croft, Hill-Rom Holdings
John DeFoggi, Business Process & Technology Management LLC (BPTM)
Hugo Felix, Owlet Baby Care
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Marcia Orozco, Alcon Laboratories Inc
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Susumu Nozawa, Siemens Healthineers
Kevin Randall, ComplianceAcuity 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.
Background of AAMI adoption of ISO TR 20416 Ed.1.

As indicated in the foreword to the main body of this document (page vii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO/TC210 to provide requirements and recommendations to writers of medical device standards on the inclusion of aspects related to safety in International Standards, based on well-established risk management concepts and methodology.

U.S. participation in ISO/TC210 is organized through the U.S. Technical Advisory Group to QM, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI/ISO TR 20416 Ed.1 was registered by the American National Standards Institute (ANSI) on 16 February 2020.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication. AAMI procedures require that technical information reports are reviewed every three years.

AAMI (and ANSI) have adopted other ISO standards and technical reports.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “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 recommended practice. “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.

NOTE Users of this technical information report are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

— British English spelling (e.g. colour instead of color)
— Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
— Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—Beginning with the ISO foreword on page vii, AAMI/ISO DTIR20416:2020, Medical devices—Post-market surveillance for manufacturers, is identical to ISO TR 20416 Ed.1.
Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee 210, Quality management and corresponding general aspects for medical devices.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.
Introduction

As medical devices are designed, developed, manufactured and distributed on the global market, a residual risk with regard to the medical device’s safety and performance remains throughout the product life cycle. This is due to a combination of factors, such as product variability, factors affecting the medical device’s use environment, the different end user interaction, as well as unforeseen medical device failure or misuse. Design and development activities of medical devices ensures that the residual risk is acceptable before product release (i.e. pre-market). However, it is important to collect and analyse information on the medical device during production and post-production to meet requirements for monitoring of product and processes and ensure the residual risk remains acceptable. Appropriate processes for collecting and analysing the information on the production and post-production feedback allows for early detection of any undesirable effects. These processes can also reveal opportunities for improvement, as specified in ISO 13485, or possible relevance to safety, as specified in ISO 14971.

Post-market surveillance is the process to enable manufacturers to perform such monitoring, by collecting data from actual use of medical devices, analysing these data and then using the information from post-market surveillance in the appropriate processes, such as product realization, risk management, communicating to regulatory authorities or product improvement. The extent of a post-market surveillance process needs to be appropriate and proportionate to the medical device and its use.

The intent of this document is to provide guidance to manufacturers who are planning and executing their post-market surveillance activities. Other organizations, such as importers, distributors and reprocessors, that are connected to the manufacturer in the product lifecycle and who play a role in post-market surveillance activities, can also utilize the guidance in this document for their activities. In the rest of this document, the term organization will be used instead of manufacturer, as far as applicable.

The guidance on the post-market surveillance process described in this document is complimentary to requirements in ISO 13485 and ISO 14971 for production and post-production activities to conduct post-market surveillance, see Figure 1.
Decisions and actions, based on the information collected and analysed by application of this document, are described in other standards, such as ISO 13485 and ISO 14971, and are therefore not included in this document. The organization may be required to perform post-market surveillance activities to fulfil applicable regulatory requirements for medical devices. While regulatory requirements are not described here, this document can be helpful for organizations in fulfilling those regulatory requirements. This TR uses the definition of post-market surveillance from ISO 13485. Users of this standard should note that the use of terms with respect to post-production data can vary in different jurisdictions and define different activities and responsibilities, for example market surveillance.

Figure 1 — Inter-relationship of ISO TR 20416 with ISO 13485 and ISO 14971 standards

Key
1 setting requirements
2 provide deliverables
1 Scope

This document provides guidance on the post-market surveillance process and is intended for use by medical device manufacturers. This post-market surveillance process is consistent with relevant international standards, in particular ISO 13485 and ISO 14971. This document describes a proactive and systematic process that manufacturers can use to collect and analyse appropriate data, to provide information for the feedback processes and use this to meet applicable regulatory requirements to gain experience from the post-production activities. The output of this process can be used:

— as input into product realization;
— as input into risk management;
— for monitoring and maintaining product requirements;
— for communicating to regulatory authorities; or
— as input into improvement processes.

This document does not address market surveillance activities to be performed by regulatory authorities. Neither does it specify a manufacturer’s actions required by the applicable regulatory requirements resulting from their production or post-production activities, nor reporting to regulatory authorities. This document is not intended to replace or change applicable regulatory requirements for post-market surveillance.

2 Normative references

There are no normative references for this document.

3 Terms and definitions

For the purpose of this document, the definitions given in ISO 14971:2019 and ISO 13485:2016 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp