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Medical devices — Post-market surveillance for manufacturers

Dispositifs médicaux — Surveillance après mise sur le marché incombant aux fabricants

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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 ISO/TC 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.

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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 ensure 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.

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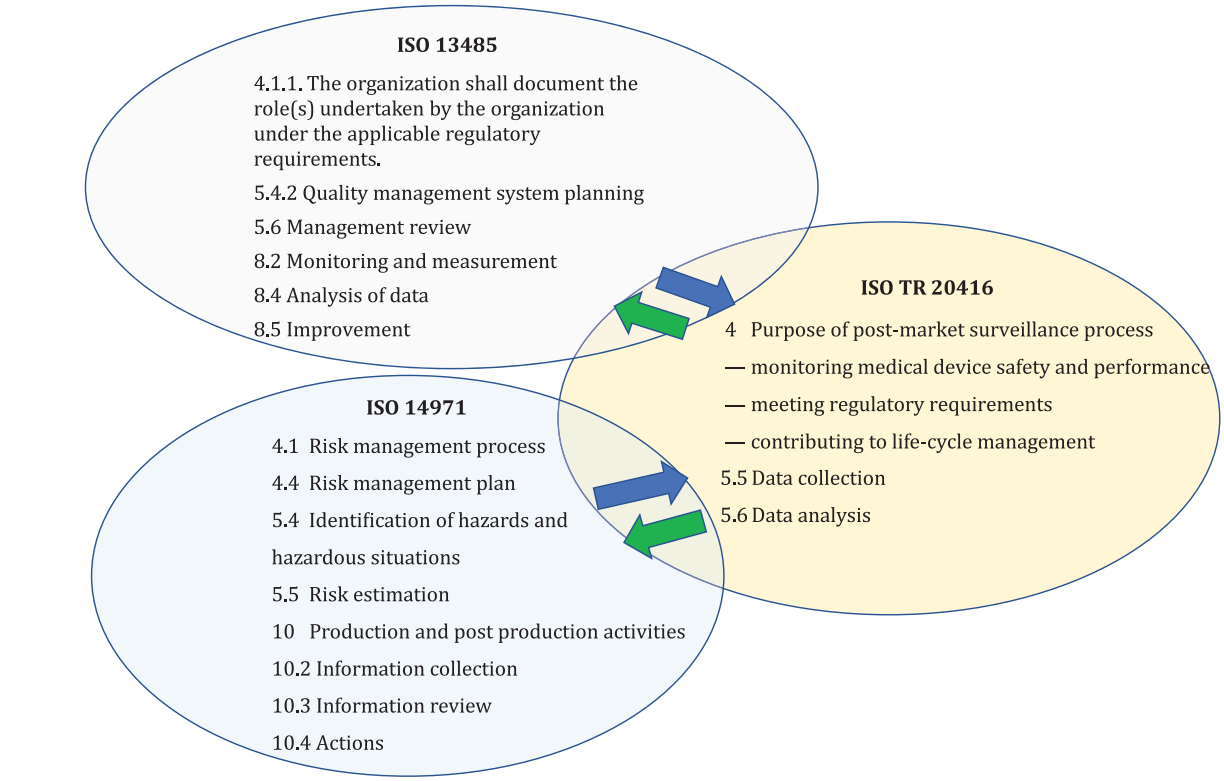


Figure 1 — Inter-relationship of ISO TR 20416 with ISO 13485 and ISO 14971 standards

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 document uses the definition of post-market surveillance from ISO 13485. Users of this document 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.

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Medical devices — Post-market surveillance for manufacturers

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

— IEC Electropedia: available at http://www.electropedia.org/

3.1
post-market clinical follow-up study
PMCF-study
study carried out following marketing approval intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a medical device when used in accordance with its approved labelling

Note 1 to entry: These may examine issues such as long-term performance, the appearance of clinical events (such as delayed hypersensitivity reactions or thrombosis), events specific to defined patient populations, or the performance of the medical device in a more representative population of providers and patients.

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[SOURCE: GHTF/SG5/N4:2010, modified — "device" changed to "medical device"]

Note 2 to entry: For in-vitro diagnostics, a similar type of studies exists, e.g. post-market performance follow-up (PMPF) study in Europe.

3.2
post-market surveillance
systematic process to collect and analyse experience gained from medical devices that have been placed on the market

[SOURCE: ISO 13485:2016, 3.14]

4 Purpose of post-market surveillance process

In accordance with the requirements outlined in ISO 13485:2016, Clause 8 and ISO 14971:2019, Clause 10, the organization documents one or more processes for collecting and analysing data from production and post-production activities. This information can then be used as input into product realization, risk management processes, determination of achievement of quality objectives or other actions for improvement.

Post-market surveillance can also identify new opportunities for improvement associated with the medical device in accordance with ISO 13485. It also provides the input for the risk management process in accordance to ISO 14971. Furthermore, it provides input into the design and development change processes, in accordance to ISO 13485.

Post-market surveillance serves the following main purposes:

— *Monitoring medical device safety and performance:* Post-market surveillance links to other processes established in the quality management system, including, but not limited to, feedback, analysis of data, improvement, design and development processes, including design and development inputs, risk management, clinical evaluation or performance evaluation. Post-market surveillance activities help to ensure that available data are analysed and utilized to help make determinations about the safety and performance of a medical device in accordance with the intended use.

— *Meeting regulatory requirements:* This document contains suggestions and techniques that can be used to meet the applicable regulatory requirements. This can include analysing and reviewing information to gain specific experience from production and post-production activities, trending of processes and product, as well as feedback to the organisation for improvement activities, as specified in the applicable regulatory requirements.

— *Contributing to life cycle management:* Post-market surveillance can also identify if the medical device is not current state of the art, based on the information from medical devices used for similar purposes, the evolution to the state of the art, or alternative medical treatment procedures. These signals can trigger a design modification, a change in intended use or purpose, a new medical device design or removal of the medical device from the market. Post-market surveillance can generate real world information that can be leveraged either to obtain new marketing authorizations for the medical device (new markets, new indications supported by actual use of the medical device), or of the next generation of medical device.

Figure 2 explains the position of post-market surveillance in the quality management system and its relationship with the other processes.

NOTE Figure 2 is a more detailed representation of phases I and II from Figure 4 provided in the ISO 13485:2016 Medical Device - A practical guide, Advice from ISO/TC210.

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