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Medical devices - Post-market surveillance for manufacturers (ISO/PRF TR 20416:2020)

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Medical devices — Post-market surveillance for manufacturers

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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 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.

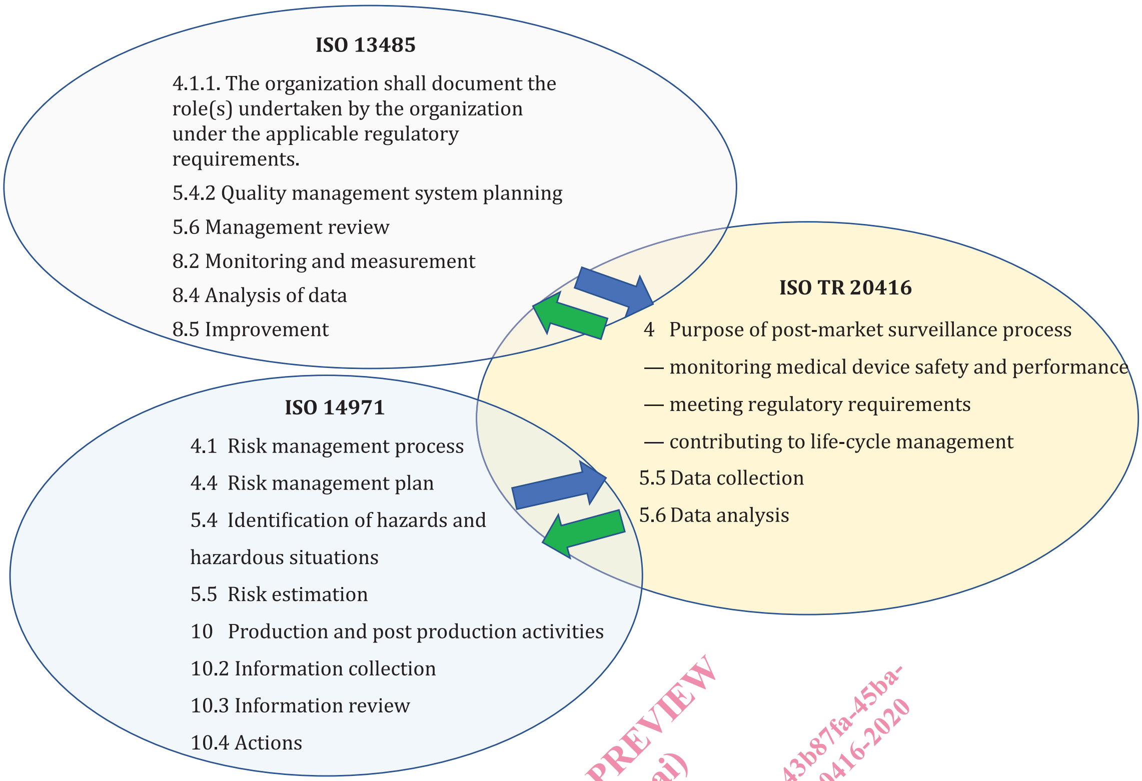
Introduction

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.


ISO 13485
4.1.1. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.
5.4.2 Quality management system planning
5.6 Management review
8.2 Monitoring and measurement
8.4 Analysis of data
8.5 Improvement
ISO TR 20416
4 Purpose of post-market surveillance process
— monitoring medical device safety and performance
— meeting regulatory requirements
— contributing to life-cycle management
5.5 Data collection
5.6 Data analysis
ISO 14971
4.1 Risk management process
4.4 Risk management plan
5.4 Identification of hazards and hazardous situations
5.5 Risk estimation
10 Production and post production activities
10.2 Information collection
10.3 Information review
10.4 Actions

Key

1 setting requirements

2 provide deliverables

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 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.

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.

[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 to 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.

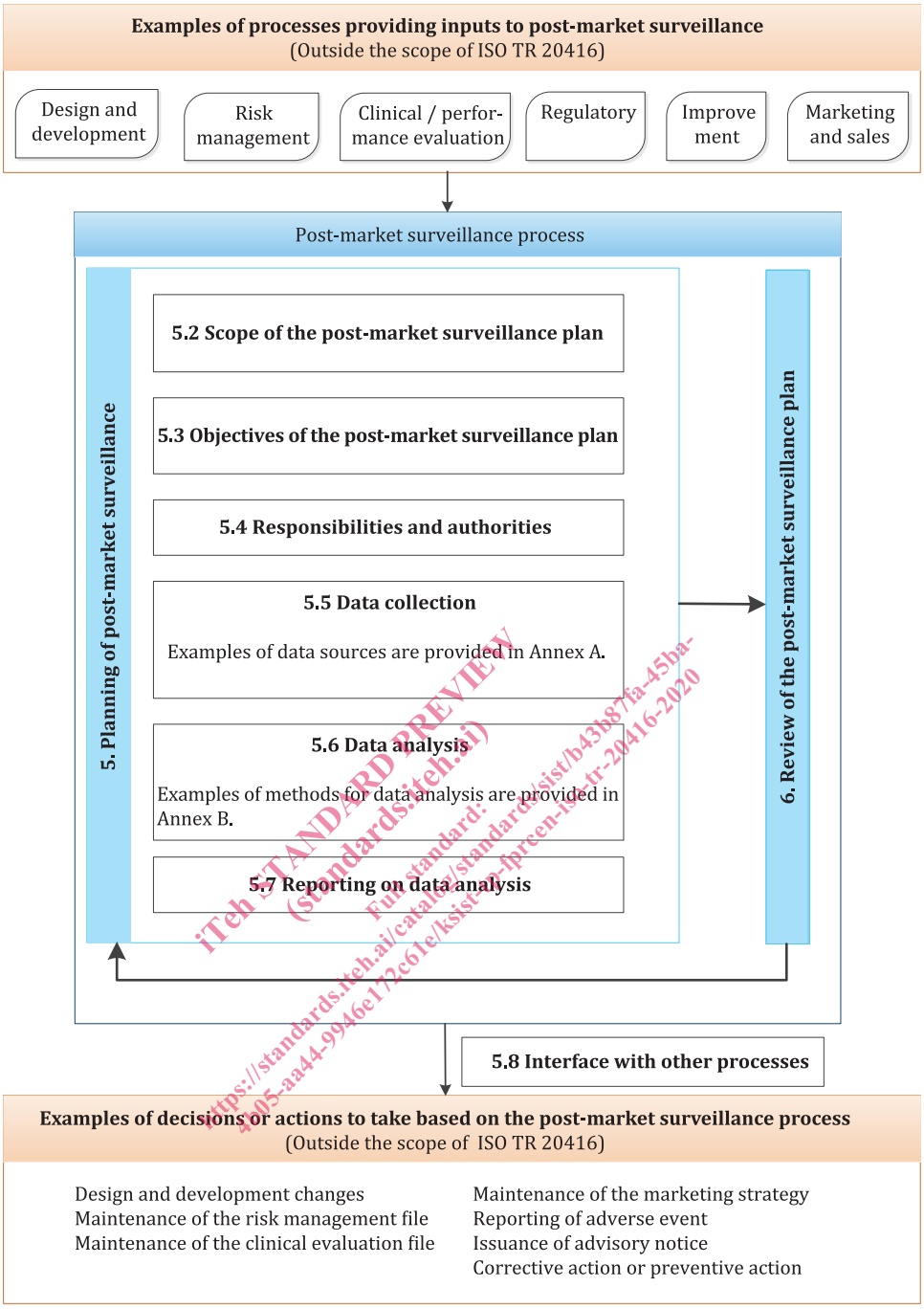


Figure 2 — Example schematic representation of post-market surveillance

5 Planning of post-market surveillance

5.1 General

The post-market surveillance plan defines how the organization intends to actively collect and analyse relevant data from the use of the medical device throughout the life cycle. Figure 2 outlines how the post-market surveillance process interacts with other processes in a quality management system.

NOTE If a quality management system is not established, the same principles apply, although the processes can be organized differently.

The organization should ensure post-market surveillance activities are carried out in line with documented methods and that the results of such activities are evaluated and reported to top management.

The post-market surveillance activities should be planned before the first placing on the market of the medical device and updated as necessary during product life cycle (see Clause 6).

A documented plan for post-market surveillance addresses the following:

— scope of the post-market surveillance plan (see 5.2);

— objective of the post-market surveillance plan (see 5.3);

— responsibilities and authorities (see 5.4);

— data collection (see 5.5);

— data analysis (see 5.6);

— report on data analysis (see 5.7);

— review of the post-market surveillance plan (see Clause 6).

The extent of post-market surveillance activities will depend upon several factors, such as the risks associated with the medical device, the chosen data sources or the expected robustness of the available information on safety and performance.

The post-market surveillance plan provides details on how the following clauses of this document are addressed for the medical device or medical device family subject to the plan. The post-market surveillance plan also addresses the methods used to collect and analyse available data in order to provide information for other relevant processes.

The plan, as well as any data, information and reports generated according to the plan are considered documents or records, see ISO 13485:2016 4.2.4 and 4.2.5.

An approved post-market surveillance plan should be contained within one or more documents within the quality management system and may include references to other documents or procedures containing post-market surveillance activities.

Post-market surveillance plans should consider input from a cross-functional team, see 5.4.

5.2 Scope of the post-market surveillance plan

The scope of the post-market surveillance plan depends on the type of the medical device. The following non-exhaustive list of factors should be considered when defining the scope:

— the medical device type or medical device family, including accessories;

— regulatory classification;

— jurisdictions where the medical device is available;

— expected lifetime of the medical device, expected number of uses or usage frequency of the medical device (single use vs. reusable instrument);

— the intended use;

— the available data related to safety and performance of the medical device, including clinical data;

— life cycle stage with regard to product and technology maturity in relation to state of the art.

By considering these examples and appropriately scoping the plan, the amount of resulting information and data should be sufficient to confirm post-production safety and performance.

5.3 Objective of the post-market surveillance plan

Regardless of the extent of design and development verification and validation activities, there will always be some uncertainty about the safety and performance of the medical device during its life cycle. The objectives of the post-market surveillance plan include reducing the identified uncertainty by collecting and analysing new relevant information.

The post-market surveillance plan sets the objectives for the post-market surveillance activities in relation with the medical device life cycle, the specification of the medical device, the intended use or application and the applicable regulatory requirements in different markets. The plan should identify the type and adequacy of information to be collected in order to satisfy the objectives. They can address various aspects of the medical device, such as safety and performance including usability, labelling, market adoption, user feedback and any other opportunities for improvement.

On defining the objectives of the post-market surveillance plan, the organization should specify the associated measurable criteria, alert and action levels, as appropriate (see also 5.6).

The questions below can help formulate the objectives:

— Has any new hazard or hazardous situation been identified for the medical device or similar medical devices or has the risk acceptability changed?

— Has any misuse of the medical device occurred?

— Does the medical device meet the user's needs after medium/long term clinical use?

— Are there any unforeseen side effects for the medical device or similar medical devices?

— Are there any improvements that can be made to the medical device?

— Has state of the art changed after design and development of the medical device?

— Does the patient's average age at medical device implantation, affect the medical device lifetime?

— Can user/patient training reduce the likelihood of malfunction?

— Is there a medical device malfunction that impacts the benefit-risk analysis?

— Are indications or contra-indications appropriate to ensure safety and effectiveness for the intended use of the medical device?

— Do users experience any usability issues?

— Are recurring malfunctions due to service/maintenance deficiencies?

— Can significant increasing/decreasing trends be identified for a specific medical device malfunction representing a possible source of harm?

— Is the expected lifetime correct?

— How does treatment affect the quality of life of the patient?

Table 1 and the example plans in Annex C provide more specific examples of objectives. The examples given in Table 1 illustrate how some situations can lead to different objectives of a post-market surveillance plan.

