TECHNICAL REPORT

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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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Contents

Page

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.

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.

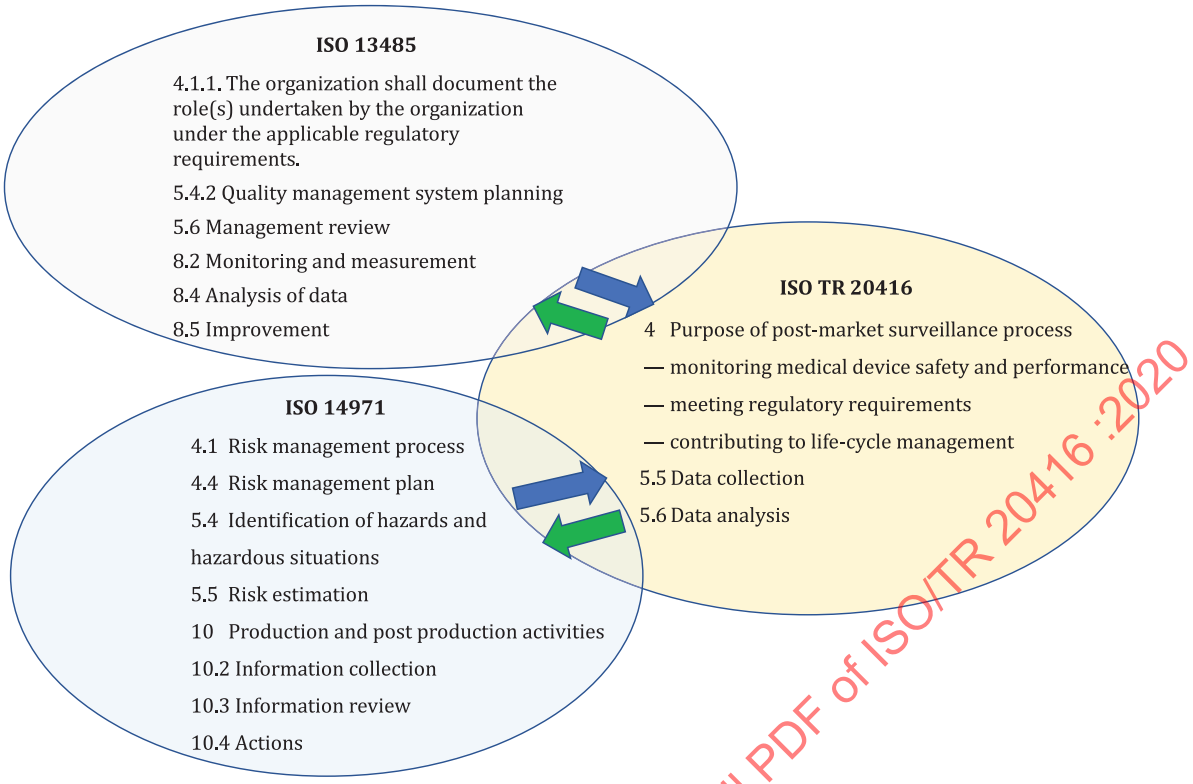


Figure 1 — Inter-relationship of ISO TR 20416 with ISO 13485 and ISO 14971 standards

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.

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 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.

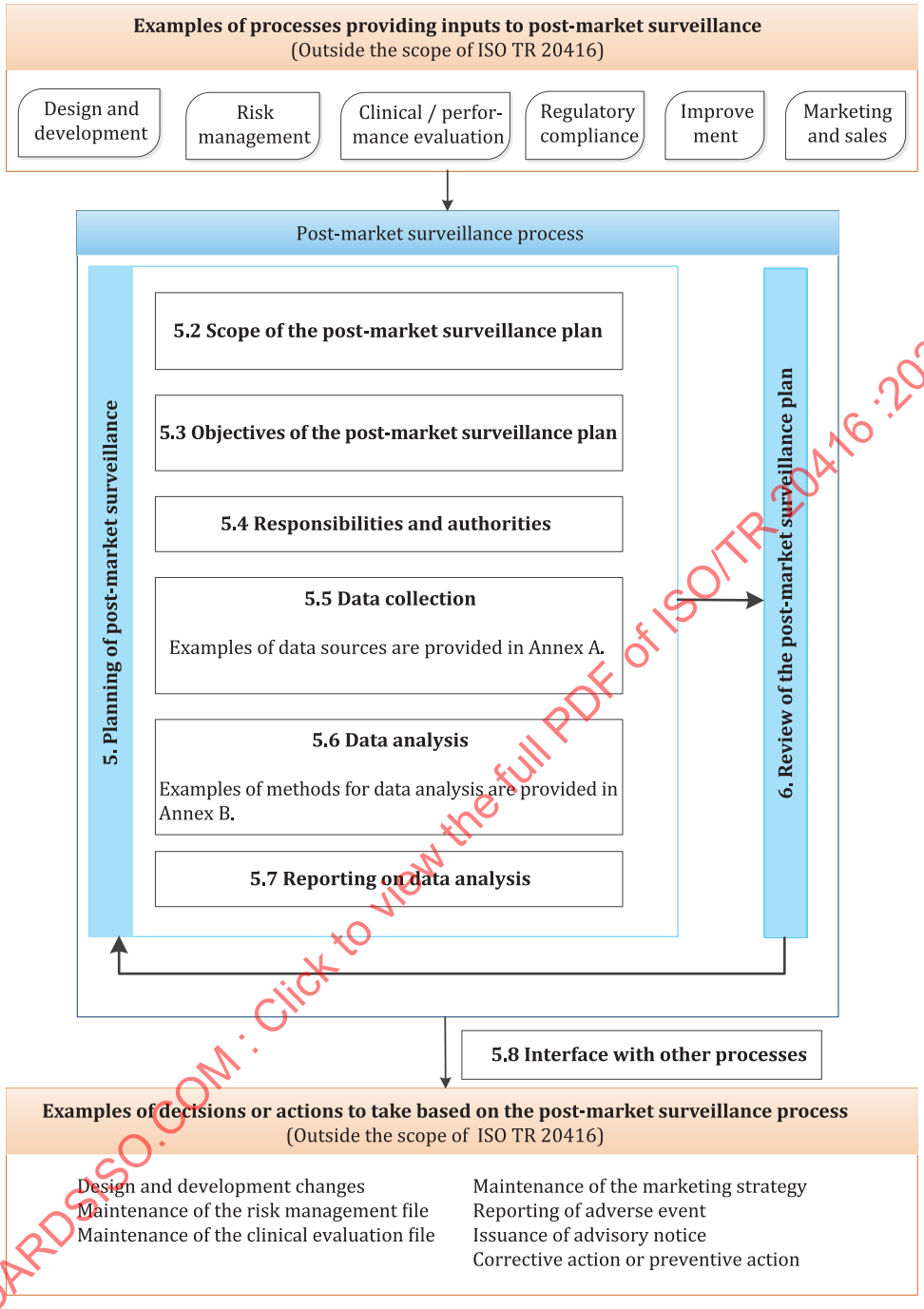


Figure 2 — Example schematic representation of post-market surveillance

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.

Table 1 — Examples of post-market surveillance plan objectives.

Input process	Situation	Possible objectives post-market surveillance plan
Design and development	A new medical device that has just been granted market approval.	Monitor the safety and performance on a more frequent basis, than for an established medical device for a limited period of time, as defined by the organization. Ensure that the links between the clinical evaluation, pre-clinical studies and risk management processes are robust and transparent.
Risk management	Commercial launch of a surgical instrument specifically developed for surgeons to perform the implantation of a medical device according to a break-through surgical technique. The surgical instrument itself has a similar risk profile to other surgical instruments on the market.	Continue to monitor the safety, performance and usability of the medical device to characterize the degree of satisfaction of the surgeons with the medical device and their ability to reliably perform the surgical technique using the surgical instrument. Ensure that the links between the clinical evaluation and risk management processes are robust and transparent.
Clinical evaluation/ performance evaluation	An implantable medical device for which a clinical investigation was performed to establish the short-term safety and performance of the medical device. See also ISO 14155: 2019 and ISO 20916 (for in-vitro diagnostic medical devices).	Obtain information on the long-term safety and performance of the medical device, including clinical benefits, which can be part of a PMCF-study. Confirm the prevalence of known or suspected adverse events.
Regulatory	Information from a user suggests that an existing medical device is being used for an indication not included in the instructions for use.	Invoke company feedback procedures to further investigate this issue. Collect data on the prevalence of the use and assess if current clinical data supports the new usage. Other actions can be considered necessary, such as updating technical documentation, evaluating the risk associated with the new intended use.
Improvement	Medical device already on the market for several years, in the maturity phase of its life cycle.	Monitor continued satisfaction of the users with the medical device and the evolution of the state of the art. Obtain feedback for improvement., not necessarily related to safety and performance issues.
Marketing and sales	An organization intends to market an existing medical device for use in the home environment in addition to the hospital.	Ensure appropriate usability data are being collected and that the medical device is appropriate for home use with the target patient population before extending the intended use. Consider new stakeholders as a source of data, such as community nurses and general practitioners.

Annex C contains several detailed examples of post-market surveillance activities for different types of medical devices, including the objectives for these situations.

5.4 Responsibilities and authorities

Top management should define, assign and communicate responsibilities and authorities for post-market surveillance activities and should ensure the availability of resources with the independence and competence for post-market surveillance activities. The post-market surveillance team should include cross-functional representatives, for example resources from design and development, risk management, quality assurance, complaint handling, returned medical device analysis, product evaluation (clinical and performance), production, marketing and sales, regulatory, or service. It should be noted, that the number of people involved largely depends on the size of the organization, the complexity or perceived risk of the medical device and the responsibilities of each person.

The assignment of responsibilities and determination of required competence can be developed into a resource allocation matrix, as shown in Table 2. The organization may choose to use external resources (see also ISO 13485:2016, 4.1.5), provided those responsibilities are detailed in an appropriate written quality agreement.

Table 2 — Example of post-market surveillance resources allocation matrix.

Post-market surveillance activity	Responsible functions	Competence
Post-market surveillance plan development and execution	Organization management	The medical device and its use, clinical/safety matters related to the medical device or the organization's post-market surveillance process
Post-production incident handling	Complaint handling	Complaint handling and adverse event reporting
Data analysis	Statistics	Quantitative statistical methods required for analysis of collected data
Ongoing clinical data collection	Clinical and medical affairs	Clinical evaluation methodologies, defined clinical circumstances and pathologies
Literature search	Information and medical affairs services	Data mining processes and methodologies, literature searches and defined clinical circumstances and pathologies
Production data collection	Production	Manufacturing methodologies and production non-conformance processes
External expert opinion	External healthcare professionals and end-users	Use and usability of medical devices in the clinical setting
Medical device in use	Sales and marketing	Use and usability of medical devices, including clinical setting
Post-market surveillance plan and report review and approval	All defined functions responsible for activities	Functional areas and activities under responsibility

5.5 Data collection

5.5.1 Data sources

It is the responsibility of the organization to determine and document the sources of post-market surveillance data. The data sources should be appropriate and reliable enough to give information relevant to the specified objectives within the post-market surveillance plan. When selecting

data sources, the different categories of parties involved (e.g. distributors, importers, healthcare professionals and patients) and the situation in which the medical devices are used are considered. Data quality and integrity should be considered before analysing data to ensure the information is reliable. For example, the use of unverifiable data can lead to over-reaction, as it can be based on non-scientific data sources such as social media and public media. Therefore, appraisal of data and its sources is recommended as part of the post-market surveillance plan.

The collection of data is a combination of both proactive and reactive activities. The data collected should be proportionate to the risk of and the experience with the medical device, its intended use and related technology, to facilitate early identification of safety and performance issues. Annex A contains a non-exhaustive list of examples of data sources that can be considered. Note that some sources might not be needed to fulfil the objectives. In addition, Annex B of GHTF/SG3/N18 contains additional guidance on specific data sources.

5.5.2 Defining data collection methods

After selecting the data sources, the method for collecting the data from these sources should be established. In some cases, the name of the source already encompasses the data collection method. There are several common methods of data collection, that can be divided into proactive and reactive methods. Examples include, but are not limited to:

Proactive:

— written or electronic surveys or questionnaires;

— interviews of users;

— literature search;

— use of medical device registries;

— post-market clinical follow-up studies (or post-market performance follow-up studies, IVDs);

— recall information and other information released from regulatory agencies.

Reactive:

— review of complaints (including incident reports);

— review of non-solicited observations by healthcare professionals or observations by the organization's sales and marketing team members;

— review of service reports or maintenance reports;

— review of regulatory compliance notifications.

For the selection of the appropriate data collection methods, the organization should consider the following characteristics:

— the analysis method, e.g. qualitative or quantitative (statistical), descriptive, transcription, codification (see 5.6);

— sample size, depending on medical device usage;

— the goal of the method, e.g. to establish cause, explore ideas, to identify what or where things happen.

The time span for which data are collected is established by the organization and should be in line with the objective of the post-market surveillance plan. The information to be collected in this time span should be applicable to the medical device and its intended use for which the post-market surveillance is performed. For example, when considering historical data, the organization would ensure that the time span is appropriate with the state of the art. Time spans can be specific to each data source and should be such that sufficient relevant data can be collected.

5.5.3 Developing the data collection protocol

After documenting the method(s) of data collection (note that this can be a combination of more than one method, depending on the nature of the medical device), the next step is to develop the data collection protocol. The protocol should describe all steps required, to ensure consistency of the collected data. Consideration should be given to the advantages or disadvantages of the method that has been chosen. Data collection protocols can be included in other documents, such as a post-market clinical follow-up study plan.

Important aspects that should be considered when developing the protocol are:

— how data collection is completed and managed;

— how data are recorded and by whom;

— how data are monitored and possibly updated;

— how to ensure data integrity and quality; or

— who is responsible for data integrity and quality.

5.6 Data analysis

5.6.1 General

This subclause provides guidance about choosing an appropriate method for data analysis, and outlines some of the more common methods which can be used. However, it does not, exclude other methods. There are many different data analysis methods including quantitative techniques, each having their own advantages or limitations. The possibilities range from qualitative data analysis or descriptive graphical methods (e.g. histograms or trending charts) to sophisticated quantitative evaluations using formal charting including statistical process control methods. Selection of the appropriate type of analysis depends on the objective and the underlying data for the analysis.

The quality of the data is essential to the selection of the appropriate methods due to the assumptions associated with the technique. The choice of statistical methods depends upon the data distribution, e.g. normal distribution vs Poisson distribution.

The method used for data analysis should be defined as part of the post-market surveillance plan prior to the start of data collection, to ensure that the results meet the objectives (see 5.3) of the analysis.

5.6.2 Considerations concerning planning the data analysis

As the types of medical devices and the patient populations can be different, various methods of analysing the data can be required. It should be determined, which parameters are analysed and what are the respective reference values (e.g. batches, sub-batches, total number of medical devices manufactured, hours/frequency of use, number of medical devices in-use, patient populations, if more than one exists). As an example, the down time (parameter) of an electric medical device can be compared with its hours of use (reference value). The rationale for the choice of the methods for data analysis should be documented.

The data analysis time span is established by the organization in line with the objective. The time span during which the data are analysed should be proportionate to the risk associated with the medical device and dependent upon the quantity and type of post-market surveillance data needed for the analysis.

5.6.3 Methods for data analysis

The method of analysis to be used depends on the type of the collected raw data. For example, customer communication including complaints is analysed differently than reports in a scientific publication,

and input from a public congress or media/press publication is analysed differently from the result of testing using international standards.

The format for the requested result of the analysis, as appropriate for post-market surveillance, is also a point for consideration. Examples of the objective and appropriate data analysis methods are given in Table 3.

Table 3 — Examples of the objective and appropriate data analysis methods

Objective	One possible example for methods
Monitoring medical device safety and performance	Trend analysis by charting data of the same attribute over a specified period. The analysis of patterns can follow the rules of the statistical process control (SPC).
Meeting regulatory requirements	Non-statistical (qualitative) analysis by document review (e.g. regulations, standards).
Contributing to life cycle management	Pareto analysis to rank the occurrence of specific attributes (e.g. defects), see also B.5.

The main distinction between data analysis methods is based on the ability to use quantitative or qualitative data.

Common quantitative methods include, but are not limited to:

— descriptive statistics (e.g. mean, median, mode, percentage, frequency, range);

— inferential statistics (e.g. correlation, regression, analysis of variance).

Common qualitative methods include, but are not limited to:

— content analysis;

— narrative analysis;

— discourse analysis;

— grounded theory.

Semi-quantitative methods include both features of a quantitative and qualitative method.

Data sources such as complaints can be analysed through quantitative methods, but a preliminary qualitative analysis could be necessary in order to be able to extract quantitative data. Data retrieved from peer-reviewed scientific literature can be analysed combining quantitative and qualitative methods. An example of quantitative analysis of data retrieved from peer-reviewed scientific literature is a meta-analysis of published clinical studies.

A non-exhaustive list of examples of data analysis methods and a short description on how to use them can be found in Annex B.

Any concerns regarding data reliability and the representative nature of that data as it relates to the market should be documented.

5.7 Report on data analysis

The report or summary should summarize all results and conclusions generated after implementation of the post-market surveillance plan. A possible list of contents could include, but is not limited to:

— summary: including report identification information and organization information;

— background information on the medical device: medical device identification information, short description of the medical device and commercial information, expected lifetime of the medical device;

— overview of gathered post-market surveillance data;

— analysis and evaluation of reported data;

— recommendations for actions to be taken;

— conclusions on benefit-risk determination.

The report should be written in such a way as to answer the questions identified in the post-market surveillance plan, and in alignment with the methods of data analysis used. When statistical quantitative methods are used, any decision-making criteria should be identified (e.g. significance, confidence intervals).

The report of the data analysis should include evidence that the post-market surveillance data are meeting the objectives documented in the post-market surveillance plan (5.3).

The report should include references to the location of the original data and the analysis performed, as well as documentation of individuals involved in the activities.

The level of details included in the report can depend on the risk class of the medical device(s) and on the applicable regulatory requirements.

The post-market surveillance report should include a conclusion as to the status of the post-market surveillance activities and recommendations based on the results of the analysis of gathered data.

The post-market surveillance report, and supporting records, should be considered as 'quality records' and treated as such within the organization.

The plan should specify the time span for systematically reviewing the post-market surveillance data to be included in the post-market surveillance report. It should be noted that there can be applicable regulatory requirements for intervals of post-market surveillance reporting.

Planned proactive post-market surveillance activities, such as post-market surveillance reports, clinical studies, or surveys and literature search routines, can have time spans influenced by internal or external processes or applicable regulatory requirements.

The defined time span for the review of the post-market surveillance data to be reported, should be proportionate to the risk of and the experience with the medical device, its intended use and related technology and the post-market surveillance experience already collected with similar or equivalent medical devices and the medical device itself. Additional factors that can be considered in determining the time spans are:

— experience with the medical device technology;

— experience of the medical device within a specific situation (e.g., hospital use, home use, or new patient group).

Event-based post-market surveillance activities, such as the collection of complaints and adverse events, are to be evaluated and reported according to the applicable regulatory requirements and as specified in the documented procedures. When repetitive events are identified, a trending approach, as described in 5.6 and Annex B, can be appropriate.

5.8 Interface with other processes

Post-market surveillance information, including recommended actions, can be used for a variety of processes within the quality management system (see also Figure 1), such as:

— *Design and development*: Post-market surveillance data can provide input for design and development of the medical device in question and similar medical devices, but can also provide input for necessary changes to the medical device design, due to the occurrence of incidents.

— *Risk management:* The information obtained in the post-market surveillance process can be used in the risk management process, e.g. to verify the frequency of occurrence of harm and the severity of harm or identifying new risks. The relevant risk management activities are executed in accordance with ISO 14971 and the organization's risk management plan for the medical device.

— *Clinical evaluation:* The clinical evaluation should be updated with information from post-market surveillance, e.g. to verify the benefit-risk determination (see also GHTF/SG5/N2R8:2007).

— *Activities to meet regulatory requirements:* These regulatory activities include communicating adverse events or trends to regulatory authorities. These activities also include updating the medical device file or technical documentation. When a medical device is on the market in a specific country or jurisdiction and then submitted to another country or jurisdiction, the post-market surveillance data can be compiled according to the regulatory authorities' requirements and submitted for pre-market approval.

— *Improvement:* Post-market surveillance data are input for the processes related to improvement to establish the opportunity or need for a change to the medical device, its intended use or related processes, such as logistics, servicing.

— *Marketing and sales:* Post-market surveillance data can also be used by the marketing and sales department, particularly feedback received from end-users.

Post-market surveillance information should be an input to management review.

Because post-market surveillance is planned to be used in the organization's processes, the data format, data quality and data summary format, can be specified in procedures for consistency.

6 Review of the post-market surveillance plan

6.1 Purpose of the review

Once the post-market surveillance plan has been established and implemented, the organization periodically reviews the plan for adequacy between the output and its objectives, using the criteria in 6.2.

6.2 Criteria

The organisation should document the criteria for the review of the post-market surveillance plan in the relevant quality management system procedure(s).

Criteria can include:

— the schedule, timeline and completion of planned activities (i.e. compliance to the plan);

— whether the selected data sources are still appropriate and sufficient;

— whether the collected data are adequate;

— whether generated outputs address the objectives of the plan;

— whether the outputs of the plan were appropriate to be used in the applicable processes, e.g.:

  — risk management processes;

  — product improvements;

  — communicating to regulatory authorities and use in pre-market approvals;

  — considerations as design and development input for future design and development.

— Changes needed to the plan for the next period.

6.3 Review

The evidence for review of the post-market surveillance plan can be gathered by audit of the relevant documented procedures and their outputs using the criteria in 6.2.

The reviews of the post-market surveillance plan should be provided as an input to management review to determine the effectiveness of the post-market surveillance process.

The post-market surveillance plan is maintained throughout the life cycle of the medical device.

Outcomes of post-market surveillance activities could indicate that a change in the time spans of future collection and review of data is appropriate. An increase in adverse events or trends that show increased risk of the medical device can indicate that more frequent data collection and analysis should be considered. Conversely, a maturing technology, which is demonstrating a reduced trend in adverse events, can allow for a less frequent data collection and analysis frequency.

Annex A
(informative)

Examples of data sources

Table A.1 contains a non-exhaustive list of examples of data sources which can be considered by the organization for the purpose of post-market surveillance, dependent on the scope and objective of the post-market surveillance plan. Annex B of GHTF/SG3/N18 contains additional guidance on specific data sources.

Table A.1 — Examples of data sources that can be used for post-market surveillance activities

Data source	Details	Information useful for
Complaints, including adverse events reported to the organization	According to the definition, a complaint communicates a deficiency related to the medical device's identity, quality, durability, reliability, usability, safety or performance. Complaints are often individual cases, which should be processed one by one. Complaints are potentially the source for regulatory reportable events. It is best practice, that any adverse event be initially treated as a complaint. Applicable regulatory requirements for the further processing of adverse events should be followed. Reports on events should include details on type of event, medical device, (or of the component involved), quantity of devices or components, severity/patient condition, user details (physician, healthcare facility, healthcare professional, patient, time period of events etc.). Over a period of time, a trend analysis of complaints can be performed. Complaints should be considered in every post-market surveillance plan.	Satisfying applicable regulatory requirements on the reporting of adverse events. Detecting early any unexpected problems experienced by users and patients. Analysing the occurrence of problems. Deciding whether an advisory notice and its associated field action (also known as recall) are appropriate. Initiating corrective or preventive actions. Reviewing the medical device risk management file. Determining the need for improvement of the medical device (i.e. medical device and related services). Reviewing the controls in place throughout the quality management system.

Table A.1 *(continued)*

Data source	Details	Information useful for
Maintenance (including preventive maintenance / corrective maintenance and repair / refurbishing)	Records should include details on medical device type, medical device identifier (e.g. lot, batch, serial number), medical device configuration, user location, infrastructure (fluids, electric current…), failure mode, acceptance activities, updates implemented, parts replaced (identity, number), usage of the medical device, servicing personnel, date of servicing.	The analysis of maintenance service reports can generate useful information to determine the reliability of the medical device. Some reliability indicators such as "mean time between failure" can highlight changes in the reliability of the medical device. The generated information can also be useful to re-evaluate the preventive maintenance schedule. It can also enable detecting unanticipated failure modes. Service reports can highlight malfunctions potentially or actually leading to adverse events, in which case they are also to be handled as complaints.
Installation	Installation records should contain details on the medical device, including its configuration, acceptance activities completed and their status, the identity of the installation personnel, and the installation date, as well as the user location and infrastructure (fluids, electric current…). Installation can also include the training to the users and the effectiveness of such training, for instance through direct witnessing of the use of the medical device by their intended users, and the first use failure to appreciate the learning curve.	The primary purpose of installation records is to ensure that the released medical devices meet their intended quality criteria for safety and performance, regardless whether the installation was performed by internal resources or outsourced. The analysis of installation records can highlight unforeseen situations where the medical device cannot be installed or does not operate as expected, or other hazardous conditions, due to the infrastructure, environment and interactions with other medical devices or user profiles.

Table A.1 *(continued)*

Data source	Details	Information useful for
Returned medical devices	The information to record about returned medical devices includes details on the medical device identity, the returned quantity, the reasons for returning the medical device, the customer, any defects claimed by the customer or observed by the organization, the disposition. Reasons for returning a medical device are varied and not all tied to concerns related to the safety or performance of the medical device. An organization should consider whether the returned medical device was used or damaged, whether the claimed concern could impact the safety or performance of the medical device if occurring while being used on or by a patient, whether the returned medical device may be distributed again (after re-processing or re-inspection, if appropriate). It is common for implant sets and the associated surgical instruments to be shipped to a healthcare facility to perform a procedure and returned to the organization. When returned, the organization examines the used medical devices to replenish the set and verify the quality and functionality of the various components of the set. This can enable the organization to determine the impact of repeated reprocessing on the medical devices.	A medical device can be returned to the organization for various reasons. Some of these reasons for the return can qualify as a complaint (see above). The analysis of a medical device quality and performance after repeated reprocessing can provide predictive information on the longevity of the medical device, and their need for maintenance or periodical re-inspection. Returned medical device can provide insight into possible causes for product issues.
Explants	An organization manufacturing implantable medical devices should encourage healthcare facilities to retrieve, preserve and return explanted medical devices in a way that is appropriate for their analysis. The organization should therefore also be prepared to receive, handle and analyse such retrieved explanted medical devices. See ISO 12891 for additional details on retrieval and analysis of surgical implants.	The investigation of retrieved surgical implants, adjacent tissues, and associated fluids can be undertaken to: — determine the cause of a clinical complication or surgical implant failure; — improve knowledge of surgical implant performance and safety; — improve knowledge of the interactions of surgical implants and human tissues; — develop materials with improved biocompatibility and implants with improved functional longevity.

Table A.1 *(continued)*

Data source	Details	Information useful for
Medical device registries	Medical device registries are tools for the identification and study of medical devices outcomes. Medical device registries are used for many purposes, including short- and long-term surveillance, fulfilment of post-market observational study commitments for regulatory bodies, and comparative safety and effectiveness assessments, including those in under-studied subpopulations. Unlike clinical trials, medical device registries allow assessment of medical device performance in a real-world setting. Registries contain data on large numbers of patients receiving care in diverse clinical settings and include clinical outcomes over time, thus providing a critical platform for capturing the experience with a medical device throughout the medical device lifecycle. Moreover, by linking medical device exposures and long-term outcomes, registries permit follow-up that can span decades. See Registries for Evaluating Patient Outcomes: A User's Guide from the Agency for Healthcare Research and Quality for detailed information. NOTE The term "medical device registry" as used here is not to be confused with the concept of medical device registration by regulatory authorities.	Because registries systematically collect the information from the use of all medical devices for a defined medical procedure, they generate information of high scientific value to establish the actual safety and performance of the medical device. If the protocol provides for it, it can include information on the long-term behaviour of medical devices, which is especially relevant for implantable medical devices, and enables establishing their long-term survival curve. The analysis of the collected information enables to reliably verify the risk estimation relative to complications and undesirable effects, including reportable adverse events. Registries focusing on the medical procedure collect information relative to all medical devices used for that procedure and enables the comparison of performances and safety profile between the various medical devices. Registry information can also be leveraged to support application for marketing authorizations of a medical device to new markets, or for the extension of their intended use according to the medical practice, or of the next generation of medical devices. Registries generate high quality data that can be used to draw scientifically valid conclusions. They should be used – when relevant – as real-world evidence.

Table A.1 *(continued)*

Data source	Details	Information useful for
Post-market clinical follow-up (PMCF) studies	A PMCF-study is 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. It can examine issues such as long-term performance and survival, the occurrence 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, see also GHTF/SG5/N1, ISO 14155:2019, and ISO 20916 (for in-vitro diagnostic medical devices). PMCF studies might be the continuation or extension of a pre-market clinical investigation. See GHTF/SG5/N4 for more detailed information. The protocol of PMCF studies should ensure the high quality of the clinical data collected. NOTE 1 because regulatory requirements for marketing authorization vary between jurisdictions, a pre-market clinical investigation in one jurisdiction can be seen as a post-market clinical follow-up study in another, and vice versa. NOTE 2 Additional information related to circumstances that can result in the need for post-market clinical follow-up studies can be found in GHTF/SG5/N4:2010.	Clinical data related to residual risks, review of long-term safety or performance, occurrence of clinical events and those events specific to defined patient population, safety or performance of the medical device in representative population of users and patients Outcomes of the adequacy of clinical data to address the safety, performance, benefit/risk profile, claims and side effects. Because PMCF studies generate high quality data, they can be used to draw scientifically valid conclusions that can be considered as real-world evidence.

Table A.1 *(continued)*

Data source	Details	Information useful for
Controlled market release phase	A controlled market release phase is a phase in the product life cycle that some organizations choose to implement to keep a close control of a new medical device by distributing it to a limited number of users and obtain systematic or periodical feedback about their experience with the medical device before it becomes available to a broader population of users. It is often implemented as a business risk mitigation approach. Such a phase does not substitute for design and development validation and takes place after the medical device obtained appropriate marketing authorizations. It is an opportunity to scrutinize how a medical device is received by the users and their experience using it, and the short-term outcome. A controlled market release phase does not necessarily involve the collection of patient information. If it does, it is considered to be a post-market clinical follow-up study (see above).	A controlled market release phase generates information that complement the design and development validation and the risk management file of the medical device. It can also help fine-tune the instructions on how to best use the medical device, including warnings, to accelerate the learning curve and remediate any identified problems early in the medical device life cycle. Problems identified during this phase can be reportable if they meet the criteria for complaints (see above). Additionally, a controlled market release phase can generate information relevant to the effectiveness of the overall design and development process.
User training	An organization can decide to train users to prevent the misuse of the medical device and shorten the learning curve on how to use it. This could be necessary to mitigate identified risks and is particularly relevant in case of innovative medical devices, necessitating the users to adapt their medical practices.	User training is an opportunity to observe the users, understand their thought process and challenges, and estimate the distribution of user skills. Medical device organizations tend to engage during the design and development of a medical device with highly experienced health practitioners, whose skills are above average. User training is an opportunity to confirm the usability of the medical device to the general population of users. Feedback from user training can provide insight into new risks due to unforeseen user interaction with the medical device and possibilities for improvement.

Table A.1 *(continued)*

Data source	Details	Information useful for
Advisory notices	The decision to deploy an advisory notice is generally made based on information generated through the post-market surveillance process. Although it seems counter-intuitive to include advisory notices as a source, deploying an advisory notice and implementing the associated field safety actions can also be used to collect or generate new information regarding, for example: — the prevalence of the problem; — the accessibility of the affected medical devices after they become out of the control of the organization; — the completion rate of the corresponding field safety action; — the controls that failed to prevent the release of nonconforming medical devices; — the conditions, at the user facility, that enable the hazardous situation.	Collecting additional information from users on how they use the medical device, experienced hazardous situations, any controls at the user facility preventing the hazardous situation to conduct to the harm.
Scientific literature	Published scientific literature can include various types of information, for example: — analysis of registries; — results of prospective clinical trials, randomized or not; — results of cohort follow-up studies; — report on individual cases; — new techniques, technology, therapies and other innovations.	Scientific literature on a medical device can describe cases that could be seen as complaints (see above). Scientific literature related to a medical device can offer clinical evidence to its manufacturer or manufacturers of similar medical devices that identify additional risk or support clinical data/performance evaluation results, which cannot be identified in existing documentation.

Table A.1 *(continued)*

Data source	Details	Information useful for
	The value and scientific validity of the published information can vary and should be determined considering factors such as: — whether the object of the published information is the organization's medical device, a similar medical device or a medical device presenting some similarities with the organization's medical device; — the methodology of the study; — whether the publication is peer-reviewed.	The extent to which valid conclusions on a medical device's continued safety and performance can be drawn from published literature depends on the scientific validity of their conclusion and the degree to which they apply to that medical device.
Market surveillance activities by regulatory authorities and their related publications and recommendations	Regulatory authorities publish warnings and safety alerts, that can cover a single medical device or a broad category of medical devices. Such information generally requires immediate attention or action to ensure public health, by manufacturers, healthcare professional, users or patients. Regulatory authorities also publish the result of their evaluation of medical technologies, as well as guidance on the use of these technologies. An organization should include this source of information in their post-market surveillance plan and determine whether the published information is relevant to their medical device, and its significance.	Warnings and safety alerts issued by the regulatory authorities is part of the critical sources for early identification of major public health issues and can trigger immediate actions by an organization, such as the clarification of instructions for use, or some containment actions, including advisory notices. The evaluation of medical technologies by regulatory authorities describe the state of the art to which an organization can compare their medical devices. The extent to which valid conclusions on a medical device's continued safety and performance can be drawn from evaluation of medical technologies by regulatory authorities, as a result of their market surveillance activities, depends on the scientific validity of their conclusion and the degree to which they apply to that medical device.

Table A.1 *(continued)*

Data source	Details	Information useful for
Publicly accessible databases from regulatory authorities on adverse events and advisory notices	Adverse events databases can contain information about events with similar medical devices. Collecting such information can allow insight into events that could also occur with the medical device for which the post-market surveillance plan is applicable. To be able to judge the applicability of events occurring with other medical devices, the similarities and differences between the original and the similar medical device should be available. Some regulatory authorities' databases on adverse events are publicly accessible (e.g. DAEN in Australia, MedSun or MAUDE in the USA). However, the ability to extrapolate information from regulatory authorities' databases to a particular medical device is often limited, considering the many biases associated with the submitted data.	Information on adverse events related to similar medical devices can enable identifying potential hazards applicable to a medical device, or prioritize identified risks considering their apparent prevalence. NOTE The ability to rely on such information as evidence of safety or performance is limited.
Conferences, tradeshows, etc.	Conferences and tradeshows are an opportunity for organizations to interact with users or non-users of their medical devices that can bring important feedback on the medical devices, the satisfaction of users, including the driving forces in favour or against the adoption of the technology, the competition. Some conferences present the result of scientific research. Such research can offer a view on arising cutting edge technologies and arising knowledge that pertains to the medical device technology or medical practices, or on the state of the art, including risks. Such research often leads to the publication of results in the literature, see scientific literature above.	Interactions with users and non-users is an opportunity to capture valuable information that would otherwise not be shared through more formal channels. Well attended conferences also give the chance to interact with a large number of people in a short timeframe, which can give a better chance to identify patterns and signals on various aspects of the organization's performance, beyond the medical device safety and performance. Feedback collected during conferences can include complaints (see above).
Regulatory requirements, standards, guidances and best practices	Medical device organizations should monitor applicable regulatory requirements for any change to evaluate upcoming gaps, and plan for continued compliance. Standards, guidance documents and best practices are not mandatory requirements (see regulatory requirements), but describe the state of the art.	Changes in regulatory requirements, standards, guidance documents and best practices can suggest a change in the state of the art, impacting design and development inputs and potentially requiring design and development changes (e.g. restricted use of a chemical). They can also offer opportunities for organizations to consider (e.g. use of real-world evidence as an alternative to premarket clinical investigation).

Table A.1 *(continued)*

Data source	Details	Information useful for
Social media	Social media are platforms to exchange thoughts and ideas. Most of them are not moderated and even when they are, it does not guaranty the truthfulness of the published information. Monitoring social media at large is unrealistic and most probably unreliable. However, organizations that set their own space as a two-way communication channel on social media platforms should monitor the information posted by external individuals on their space as feedback.	The reliability of the information on social media can be difficult to confirm. Information on social media should therefore be used with caution. Feedback posted on an organization social media space can concern any aspect of the organization and their medical devices and can be positive or negative. Negative feedback related to the organization's medical devices can include complaints (see above).
Public media	internet, press, TV	The information highlighted within the public media should be considered unverifiable, but provides insight into the trends within medical device usage. This information can be used as part of a design and development strategy or as part of lifecycle management.
Medical device distribution and medical device tracking	This relates to any traceability or distribution issues that can impact medical device quality. Testing of distribution systems can be useful to identify risks to traceability, storage and other issues that can impact on quality and delivery. Distribution records and sales analysis can be used to identify variations in the use of the medical device depending on the region, the practitioner, or other factors. The analysis can reveal trends that are patient related (for example, a population of short people can use smaller medical device sizes than a population of taller or heavier people) or for non-patient-related reasons, like a physician's preference for undersized medical devices, which could suggest a different risk profile and patient prognosis.	Confirming the robustness of traceability/tracking system Identifying patterns suggestive of difference in usage of the medical device.
Finished products, product quality information	This includes inspection and test records, summary of scrap, first pass acceptance rate. This also includes non-conformance reports, process performance measures, e.g. statistical process control data.	Establishes manufacturing efficiencies and provides quality data for traceability in the event of complaints and events that can occur post-market.

Table A.1 *(continued)*

Data source	Details	Information useful for
Internal audits and external inspections	This includes results of a regulatory audit, clinical audit or an inspection based on the following factors: — risk of the medical device; — the medical device's frequency of non-compliance; — specific information to suspect non-conformities of the medical devices or the quality management system.	Data derived through such activities is important to include within an organization's design and development and risk process and drives the quality requirement for continual development.
Market/customer inputs: *competitor's research*	Information on experience and research with similar medical devices	Provides input for the state of the art and can be used as part of an organization's design and development and risk management process.
Market/customer inputs: *customer preference surveys*	This includes detail on the customer segment queried versus the entire population of users, summary of results, and data obtained from similar medical devices or therapies made by the same or different manufacturer, manufacturer experience and history.	Data derived through such surveys is important to include within an organization's design and development and risk management process and drives the quality requirement for continual development.
Market/customer inputs: *solicited data on new or modified medical devices*	This includes data on customer population queried versus entire population of users.	These data are important to include within an organization's design and development and risk process, and drives the quality requirement for continual development.
Market/customer inputs: *meetings with medical experts, key opinion leader meetings or panels*	This includes summary of discussions and outcomes.	These data are important to include within an organization's design and development and risk process, and drives the quality requirement for continual development.
Market/customer inputs: *patient group experience of using medical devices, or encounters with them during episodes of treatment*	This includes summary of discussions and outcomes.	These data are important to include within an organization's design and development and risk process, and drives the quality requirement for continual development.
Market/customer inputs: *user interaction with the organization (sales workforce and customer service)*	This should be documented, preferably using a standard format.	These data are important to include within an organizations design and development and risk process, and drives the quality requirement for continual development.
Market/customer inputs: *user reactions during training programmes*	This includes surveys immediately following training.	Data derived through such training is important to include within an organization's design and development and risk process and drives the quality requirement for continual development. This can also provide feedback on use and misuse.

Annex B
(informative)

Examples of data analysis methods

B.1 General

This annex aims to provide guidance on some common descriptive methods for data analysis and format, which is needed to hand over the analysed data to other processes, like risk management, marketing and sales, quality management, in a way that these processes have a basis for further evaluation of root causes or decisions on taking action.

Other data analysis methods, not described in this annex, can be used. The bibliography contains references that can be used to find information on other methods.

Acceptance criteria and action levels for the purpose of evaluation should be specified by quality management or risk management departments and are not described in the examples of this annex.

NOTE ISO/TR 10017 describes other statistical techniques used for further analysis and evaluation, such as hypothesis testing, regression analysis, reliability analysis, and time series analysis.

B.2 Overview table: data analysis methods

Post-market surveillance objectives are generally specified in 5.3.

The purposes of the post-market surveillance process are:

A. monitoring medical device safety and performance;

B. meeting regulatory requirements;

C. contributing to life cycle management.

Examples of data sources and methods for data analysis that are suitable options to meet the objectives in the post-market surveillance plan are provided in Table B.1.

Table B.1 — Examples of data sources and suggested methods for data analysis

General objective	Objective(s) in the post-market surveillance plan	Data source (see Annex A)	Data analysis method	Comments
A	Is there a statistically significant increase in the frequency of incidents that are not serious incidents? Is there a reliability issue?	Incidents reported to the organization Product quality information Service reports	Trend analysis of plotted data	It can be recognized if something has changed above expected background variation.
A C	What are the most common complaints?	Complaint files	Plotting data using Pareto diagram or bar charts	Importance of the specific complaints can be derived from the Pareto diagram. Data should be adequately categorized.

Table B.1 *(continued)*

General objective	Objective(s) in the post-market surveillance plan	Data source (see Annex A)	Data analysis method	Comments
B	Are there new regulatory requirements? Are there new techniques available? Are there changes in the therapy? Is there a change in the state of the art or market experience for similar medical devices and technologies?	Market surveillance activities of authorities and their related publications and recommendations Regulatory requirements Competitor's research Solicited data on new or modified medical devices	Qualitative	Descriptive method that can be applied for a variety of data sources (single events, discontinuous data).
A	How many complaints relate to specific issues (e.g. holes in medical gloves)?	Complaint files	Plotting data using a bar chart	Distribution patterns can be visualized.

Based on the objective specified in the post-market surveillance plan, an appropriate method for data analysis should be selected.

The following subclauses provide examples for data analysis methods and how to execute the methods accordingly.

B.3 Descriptive methods for trend analysis

The trend analysis is used to identify a pattern for a specified time period and forms the basis for decisions on any further actions. Historical data can be used to define baselines. Alternatively, alerts and action levels could be defined by the quality management or risk management department.

The trend analysis prerequisites an amount of continuously collected data of the same attribute to be monitored over a time period.

There are three types of changes that can be indicated by a trend analysis:

1. a sudden significant deviation like an outlier or spike, respectively;

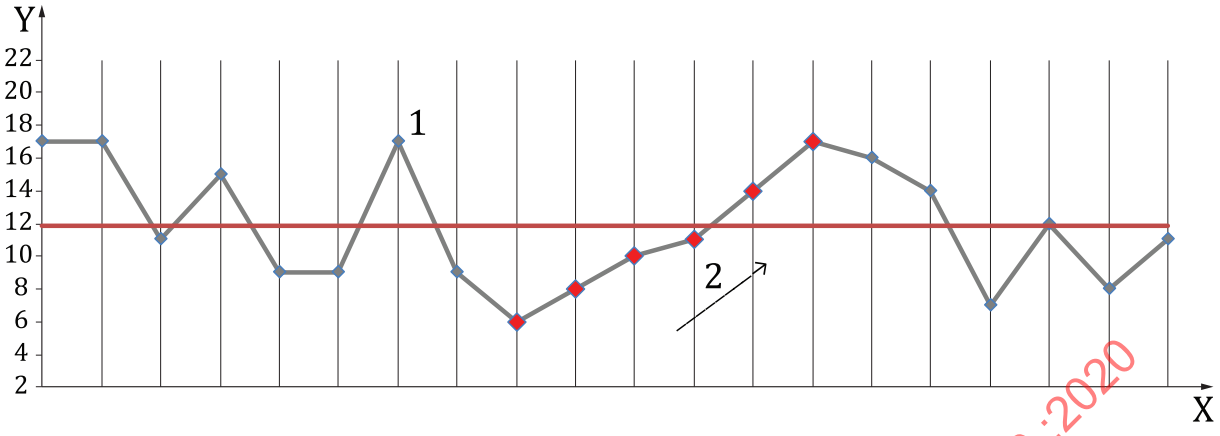
   NOTE If a new value is greater than three times the previous average value, the probability for an outlier is more than likely (derived from the chi-square distribution).

2. significant trends, i.e. repetitive deviations or continuous drifting away from the history of earlier values;

3. detection by visual inspection, whether the data are subject to cyclic effects, e.g. of calendar events like summer holidays or end of budget periods.

The length of the time period for trending should be adequate as to show and detect the cyclic effects and allow a comparison to corresponding earlier periods, e.g. first quarter this year to first quarter last year.

From the statistical process control, a general rule of six in a row has proven helpful to find a continuous drifting away (see Reference [18]).



Key

X	period
Y	normalized number of nonconformities
1	spike
2	6 in a row
	normalized number of nonconformities
	median value

Figure B.1 — Examples of types of changes identified using trend analysis

Example 1

Objective in the plan: Monitor the complaints referring to holes or skin irritation that occur in surgical gloves over time to observe if a material change has an unexpected negative impact on safety and performance.

Data analysis method: Plot the number of the specific complaint per month relative to the number of sold surgical gloves in that month.

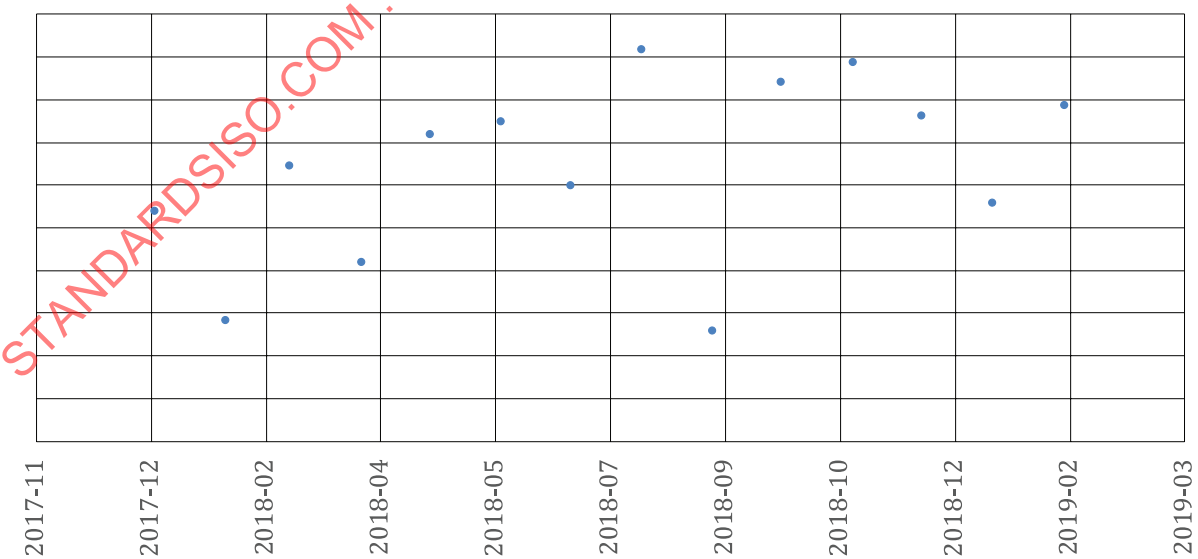


Figure B.2 — Trending of monthly complaint rate (% of number of gloves sold)"

When calculating and plotting complaint rates, it is important to select the correct reference value depending on the medical device in question:

— single use medical devices (e.g. surgical gloves): number of complaints can be related to number of sold medical devices per time period;

— reusable medical devices (e.g. infusion pumps): number of complaints can be related to installed base per time period.

For further evaluation of the data, a statistically justified methodology (e.g. linear regression) can be used to established averages, range and possible trends. In addition, limits specified by the risk management or quality management department could be used for further evaluation.

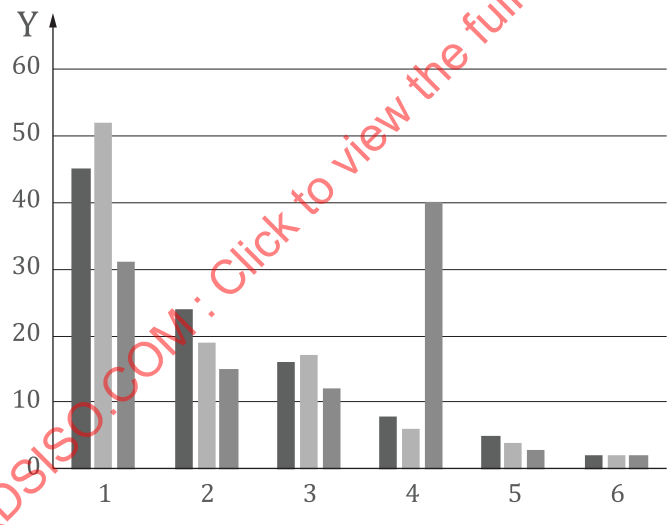
B.4 Descriptive method: Bar charts

Bar charts are used for a graphic presentation of a frequency distribution. Bar charts can be applied for discrete data.

Example 2

Objective in the plan: Is there a difference in the frequency of specific complaints between 3 medical device variants?

Data analysis method: Plotting number of the specific complaints for (e.g. 1 year for 3 Ref Numbers) as a bar chart



Key

MD 1

MD 2

MS 3

Y number of reported complaints

1 pin holes

2 itching

3 allergic reaction

4 donning problems

5 ripping

6 other

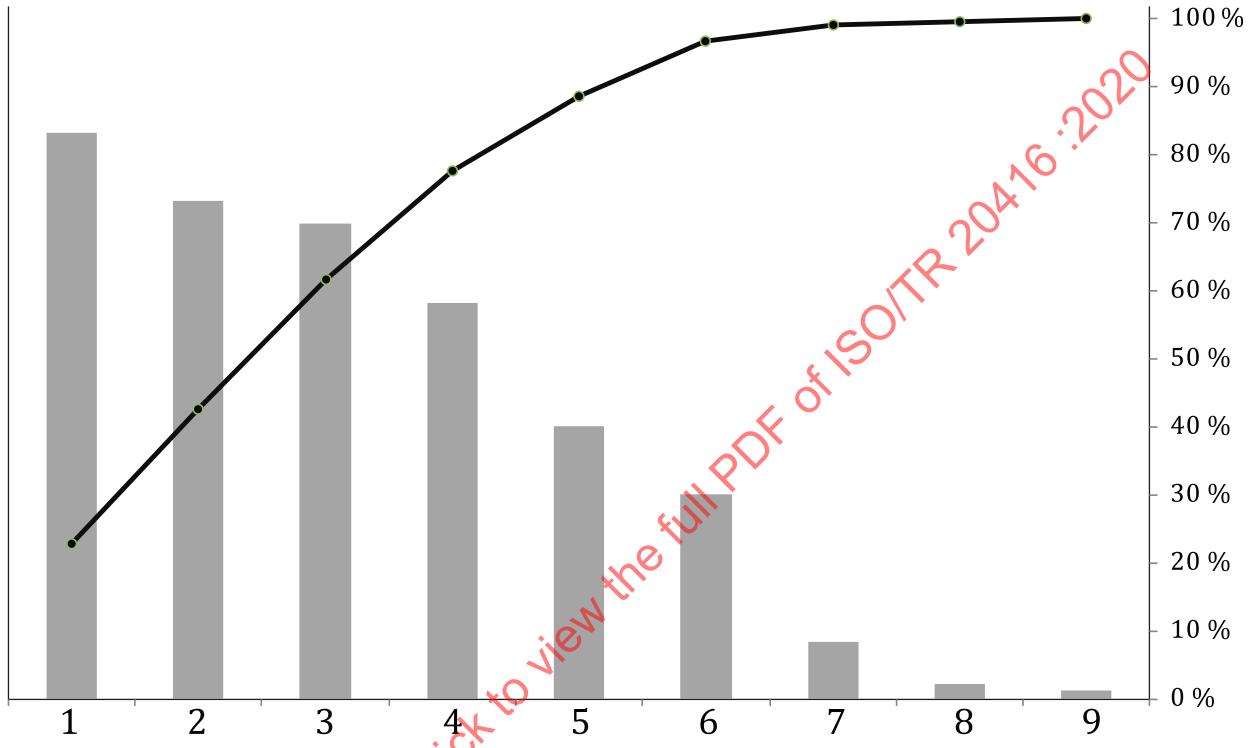
Figure B.3 — Bar chart showing the number of reported complaints for three medical device variants 1, 2 and 3

B.5 Descriptive method, Pareto analysis

Pareto analysis is another type of a bar chart that ranks related data (e.g. complaint causes) in decreasing order of occurrence. It is based on the assumption that in most cases 20 % of causes generate 80 % of problems. It helps to focus on those issues, which should be addressed first.

Example 3

Objective in the plan: What are the main complaint causes for a medical device?



Key

1 scratch
2 warpage
3 crack
4 dent
5 rust
6 stain
7 burr
8 dimensional error
9 other

Figure B.4 — Pareto diagram for complaint causes for implant instruments (product family)

B.6 Qualitative techniques

Some of the data related to a medical device or treatment procedure are single events and discontinuous. Therefore, a quantitative method for analysis of these data is not always adequate.

A single event can be found in (for example):

— customer communication;

— medical and scientific publication;

— input from a congress;

— media/press publication;

— standards and regulations;

— qualitative marketing and sales field staff feedback.

These types of data (documents or reports) are not open to statistical (quantitative) analysis methods, but can be used to substantiate or initiate further investigations.

Examples of objectives in the post-market surveillance plan for qualitative analysis are monitoring regarding:

— new, unknown, unexpected hints of safety or performance issues like side effects, malfunctions, use errors;

— new risks;

— new application techniques;

— new medical treatment methods.

Annex C
(informative)

Examples of post-market surveillance plans

NOTE This annex provides examples of post-market surveillance plans and is not intended to be exhaustive. They provide guidance for the organization and should be adapted for actual situations and specific medical devices.

C.1 Example of a post-market surveillance plan for a surgical scalpel

C.1.1 General

This is an example, it is not exhaustive. It provides guidance that the organization can use, but should be adapted to the actual situation for a specific medical device or medical device family. This example should not be copied as a plan for post-market surveillance for a scalpel.

C.1.2 Scope of the post-market surveillance plan

Brief description of the medical device: A scalpel is a simple, stainless steel, well-established medical device. Scalpels have been on the market for a long period without any relevant change to the medical device, storage, distribution, manufacturing process and use. Surgical scalpels commonly consist of a reusable handle and a single use blade. A surgical scalpel is used to make incisions during treatment. The medical device is considered to be invasive, albeit for short periods. Due to its invasive use, the medical device needs to be sterile prior to use.

Type of users: Surgical scalpels are used by trained medical professionals for treating patient either in an operating theatre or in a treatment room with a less controlled environment.

C.1.3 Objective of the post-market surveillance plan

The objective of a post-market surveillance plan for a scalpel is to collect data to support its continued safe use. Answers to the following questions provide the information needed to support the continued use of the scalpel.

— Are there defects in the scalpel's handle or blade?

— Are there other techniques replacing the scalpel (state of the art) or other developments, e.g. in the area of workers safety or waste disposal?

— Have incidents or other reportable events occurred?

— Are there any issues with decontaminating the handle?

— Are users satisfied?

— Is there any off-label use or misuse of the scalpel?

C.1.4 Responsibilities and authorities

No guidance provided, refer to 5.4.

C.1.5 Data collection

Possible data sources are, but not limited to:

— complaints, including adverse events;

— manufacturing data, including testing before release and supplier monitoring;

— information and testing on returned medical devices;

— contact with actual users, during training, sales meetings etc.;

— feedback from decontamination departments;

— conferences, mainly trade shows;

— data on competitor medical devices, comparing performance to the other medical devices;

— feedback from users about the performance of the scalpel and the use of the scalpel;

— literature on new technologies in the field of making incisions;

— audit and inspection results.

For some of the data sources, recent data are not always available.

C.1.6 Data analysis

Complaints need to be investigated upon receipt by the organization, see Annex A.

A trend analysis can be performed on complaints received over a period of time. If a change is made to the medical device, the trend data can be compared between the current design and the previous design. An organization should have a protocol for the testing of medical devices and returned medical devices.

The organization has a method or procedure available to compare the performance of the medical device to the intended performance.

Feedback from users can be in the form of an enquiry (actively collected) or passively received. For an enquiry, the analysis should be considered when setting up the enquiry, whereas for passive feedback, a case-by-case approach can be appropriate.

Frequency of the post-market surveillance activities can be based on the risk associated with the medical device. Considering the long period of safe use of the medical device, the risk associated with the medical device is relatively low. Apart from adverse events, a yearly or even two-yearly analysis of post-market surveillance data should be undertaken.

C.1.7 Report on data analysis

If a change is made to the scalpel, e.g. increasing the number of allowed episodes of use of the reusable blade, this impacts the timing of the post-market surveillance activities, as the impact of the change has to be monitored to assess the effect.

The frequency of post-market surveillance activities can consider issues such as:

— design and development changes;

— increased number of adverse events;

— identification of new risks or significant change in existing risk;

— unintended uses that would impact the risk management file.

It should be noted that there can be national requirements for intervals of post-market surveillance reporting.

C.1.8 Review of the post-market surveillance plan

Considering the risk, the organization initially decided to review this post-market surveillance plan annually. The time frame can be subsequently adjusted considering the outcomes of the post-market surveillance and changes to the medical device or its use.

No further guidance provided, refer to Clause 6 of this document.

C.2 Example of a post-market surveillance plan for a radiation therapy system

C.2.1 General

This is an example, it is not exhaustive. It provides guidance that the organization can use, but should be adapted to the actual situation for a specific medical device or medical device family. This example should not be copied as a plan for post-market surveillance for a radiation therapy system.

C.2.2 Scope of the post-market surveillance plan

Brief description of the medical device: Radiation therapy is a well-established and an essential component in the management of cancer patients, either alone or in combination with surgery or chemotherapy, both for cure and for palliation. Every day millions of patients are treated with radiation therapy. Radiation therapy is non-invasive, it can be done without anaesthesia and the patient is usually able to leave the hospital the same day.

Type of users: Radiation therapy systems are used by professional users, physicians and dedicated technicians. All of these users should have received relevant education and training.

C.2.3 Objective of the post-market surveillance plan

A post-market surveillance plan is developed for each type of radiation therapy system.

The objective of a post-market surveillance plan for a radiation therapy system is to maintain product compliance, improve the radiation therapy system and gather actual (clinical) evidence. In particular:

— to maintain currency of the benefit-risk determination and to update the risk management documentation;

— to evaluate the generally acknowledged state of the art;

— to maintain currency of the design and development and manufacturing information, the instructions for use, the labelling, training and servicing activities;

— to maintain currency of the clinical evaluation e.g. regarding residual risk of treatment in paediatrics related to radiation dose;

— to generate and submit regulatory reports on trends, clinical evidence and radiation and transport safety;

— to identify needs for preventive, corrective or field safety corrective action;

— to identify options to improve the usability, performance and safety of the system;

— to detect and report trends such as on clinical safety, (long-term) performance, reliability, use and misuse.

C.2.4 Responsibilities and authorities

The post-market surveillance process owner is responsible for coordinating the post-market surveillance activities with the relevant process owners on a yearly basis. The process owners per post-market surveillance activity are responsible for ensuring the data are collected, analysed and any interlinking procedures are carried out.

The post-market surveillance process owner is responsible to organize a post-market surveillance review meeting where the outcome of post-market surveillance activities is reviewed, discussed and an overall conclusion is drawn. Examples of departments involved in such a meeting are post-market surveillance, quality assurance, regulatory affairs, clinical, portfolio management, and safety engineering.

C.2.5 Data collection

Table C.1 describes which experience and compliance data should be collected.

Table C.1 — Data collection and data analysis activities

Data collection & data analysis activities for radiation therapy systems
Complaints Initially, each complaint is reviewed upon receipt, to check it constitutes an event that requires immediate action. Summarize complaint data across all regions, taking into account the number of systems sold in each region.
Adverse events Review of adverse events and identify any trends.
Non-serious incident cases Summarize non-serious incident cases, including data on undesirable side effects, breakdown of issues in a graph format, if possible, and reference supporting evidence. Provide detailed and graphical representation of the top-level trending issues and actions.
Clinical evaluation and literature search Summarize input from clinical evaluation and literature search.
PMCF-study Summarize input from the PMCF-study. A PMCF-study is considered where identification of possible emerging risks and the evaluation of safety and performance are critical.
Adverse event reports for similar medical devices of other manufacturers Describe all incidents that happened in the reporting period with details for similar medical devices from other manufacturers (e.g. using MAUDE).
Field safety corrective actions for similar medical devices Describe the field safety corrective actions following reportable incidents and dates of release.
System updates (field change orders) Provide field change orders, not related to reportable incidents.
Service/repairs trends Provide input from service engineering, typically spare part or work order analysis.