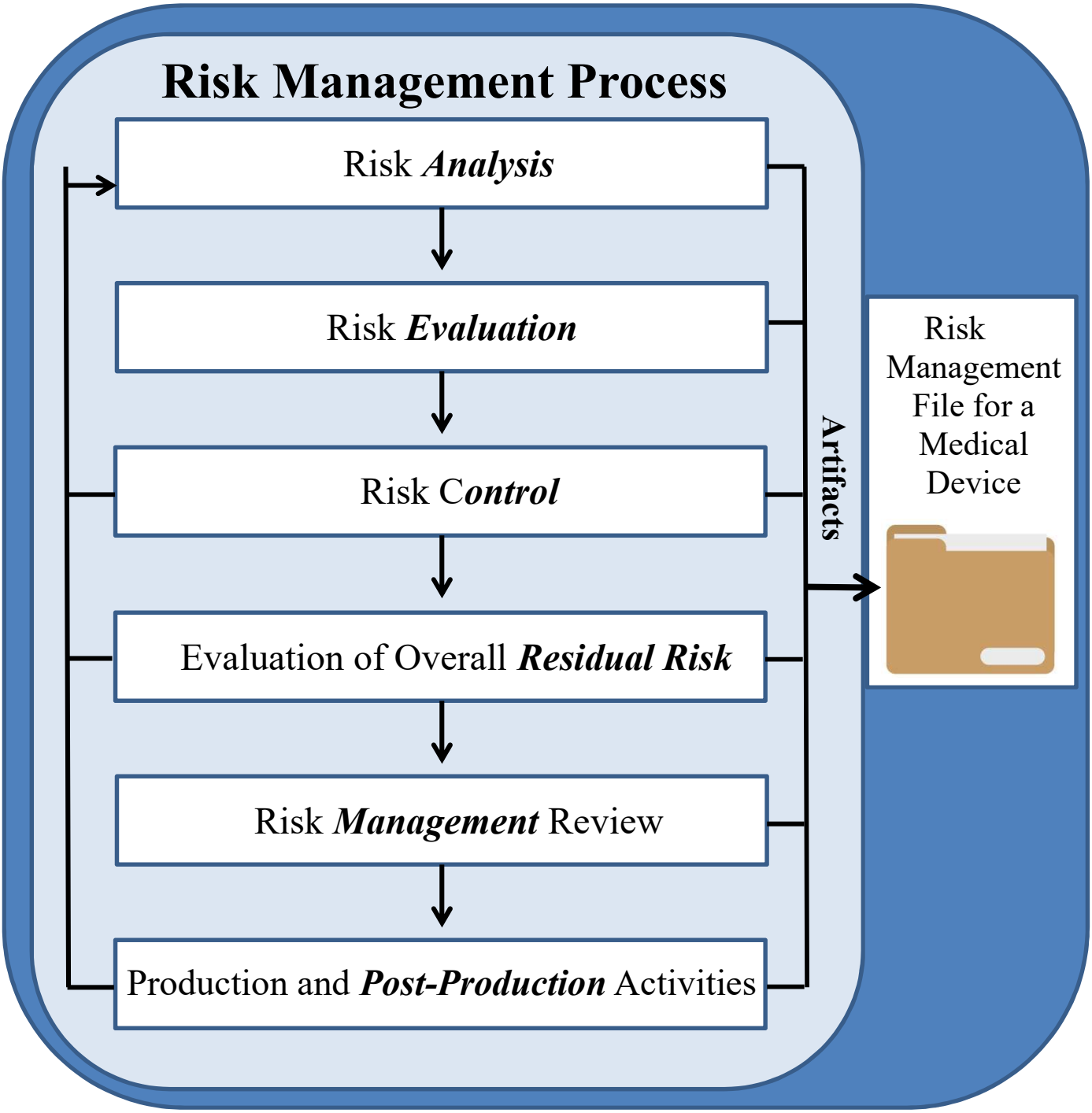
SEPT Evidence Product Checklist
For Standard ISO 14971:2019
Medical Devices – Application of Risk Management to Medical Devices



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Contents

Change Page History

Date	Change	Reason
26-Aug-2019	First Version	Original checklist for the 2019 version of ISO 14971.

Section 1

Introduction

Components of the Checklist

This checklist is composed of 9 sections:

- Section 1. Introduction
- Section 2. Composites of all required and suggested "ISO 14971:2019 artifacts.
- Sections 3-7. Individual checklists for each type of artifact (policies &. procedures, plans, records, documents and reviews)
- Section 8. Artefacts to be placed in the Risk Management File.
- Section 9. About the author

Overview of the Standard ISO 14971:2019

ISO 14971 is a key standard specifying a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements of this standard are applicable to all stages of the lifecycle of a medical device.

It does not apply to clinical decision making, does not specify acceptable risk levels and does not require that the manufacturer have a quality management system in place. However, risk management can be an integral part of a quality management system.

ISO 14971 was developed specifically for medical device/system manufacturers using established principles of risk management. For other manufacturers, e.g., in other healthcare industries, this standard could be used as informative guidance in developing and maintaining a risk management system and process.

It deals with processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment and the environment.

The changes in the 2019 version of ISO 14971 include a significant reorganization of content, new terms, and more detailed requirements around evaluating residual risks and collecting production and post-production information. It also refocuses the standard on benefit-risk evaluation, which is in line with changing regulatory requirements such as the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

Relationship to other key Standards

ISO 14971:2019 is a companion document and is harmonized with expectations of ISO 13485:2016 requirements.

Technical Report (TR) 24971, Medical devices – Guidance on the application of ISO 14971, will align with ISO 14971:2019 and retain the guidance previously in ISO 14971:2007 and TR 24971:2013.

Introduction to the SEPT Checklist for ISO 14971:2019

For 25 + years Software Engineering Process Technology (SEPT) has produced checklists for international standards. They have been produced for Medical Devices, Quality, Security and Software processes. Organization buy and use these checklists for:

1. Perform a gap analysis-Standard requirement requires versus what the organization does;
2. Ensuring that all the artifacts that are cited in the standard are addressed;
3. Providing the traceability by artifact from the standard to a process step;
4. To demonstrate that the organization was following an international standard in case of litigation;
5. More economical to purchase a checklist than develop one internally; and
6. Insurance that they have a checklist that is compiled by a company experienced in deciphering international standards and verified by domain experts.

This is a checklist for ISO 14971:2019, another checklist related to medical device standards. The purpose of the checklist is to define clearly all the artifacts (policy, procedure, plan, records, document, or reviews) that the underlying standard calls out. Normally the SEPT checklist has a section for the artifact "audit". However, the ISO 14971:2019 standard does not specify any requirements for "audits," so this section is left blank for this checklist. Nevertheless, in many sections there is a requirement to inspect the risk management file. Furthermore, what constitutes physical evidence (Artifacts) to meet the guidance outlined in ISO 14971 is sometimes difficult to identify. To bridge this gap the author and SEPT experts have identified items of physical evidence called out in the standard based on their knowledge of the document and their experience in the standards field. Each item of physical evidence that was identified by these experts is listed in the checklist as an artifact (policy, procedure, plan, records, document, or reviews.)

There must be an accompanying record of some type when a review has been accomplished. This record would define the findings of the review and any corrective action to be taken. For the sake of brevity this checklist does not call out a separate record for each review. All procedures should be reviewed but the checklist does not call out a review for each procedure, unless the standard calls out the procedure to be reviewed.

The author has carefully reviewed the Standard ISO 14971:2019 and defined the physical evidence required based upon this classification scheme. SEPT's engineering department has conducted a second review of the complete list and baseline standard to ensure that the documents' producers did not leave out a physical piece of evidence that a "reasonable person" would expect to find. If an artifact is called out more than one time, only the first reference is stipulated. If an artifact is required by ISO 14971:2019, it

appears in the checklist without appended symbol. If an item is "suggested" either by ISO 14971:2019 or by inference when a document or plan is called out it appears with an appended asterisk (*). If an item is required to be included in the associated Risk Management File by ISO 14971:2019 it appears in the checklist with an appended symbol (➢). In this way traceability of requirements and suggested items as well as the need to include a required item in the Risk Management File is possible.

Note: These notations are listed in the footnotes for each section.

There are occasional situations in which a procedure or document is not necessarily separate and could be contained within another document. For example, the 'Manufacturer Medical Device Reasonably Foreseeable Misuse Document' could be a part of the 'Manufacturer Medical Device Intended Use Document'. The author has called out these individual items separately to ensure that the organization does not overlook any facet of physical evidence. If the organization does not require a separate document, and an item can be a subset of another document or record, then this fact should be denoted in the detail section of the checklist for that item. This should be done in the form of a statement reflecting that the information for this document may be found in section XX of Document XYZ. If the organizational requirements do not call for this physical evidence for a project, this should also be denoted with a statement reflecting that this physical evidence is not required and why. The reasons for the evidence not being required should be clearly presented in this statement. Many of the procedures referenced could in fact be a part of a detailed Risk Management (Process) procedure. Further details on this step are provided in the Detail Steps section of the introduction. The size of these documents could vary from paragraphs to volumes depending upon the size and complexity of the project or business requirements.

General Principles of the Checklist for ISO 14971:2019

This checklist was prepared by analyzing each clause of the Standard for the key words that signify a:

- Policy
- Procedure
- Plan
- Records
- Document
- Review

This checklist specifies evidence that is unique. After reviewing the completed document, the second review was conducted from a common sense "reasonable person" approach.

The information was transferred into checklist tables, based on the type of product or evidence. In total, there are 183 artifacts identified by SEPT in the checklist, of which 104 are required to be stored in the Risk Management File.

Using the Checklist

When a company is planning to use ISO 14971:2019 standard, the company should review the evidence checklist. If the company's present process does not address an ISO 14971:2019 standard product, then the following question should be asked: "Is the evidence product required for the type of business of the organization?" If, in the view of the organization, the evidence is not required, the rationale should be documented and inserted in the checklist and quality manual. This rationale should pass the "reasonable person" rule. If the evidence is required, plans should be prepared to address the missing item(s).

Detail Steps

An organization should compare the proposed output of their organization against the checklist. In doing this, they will find one of five conditions that exist for each item listed in the checklist. The following five conditions and the actions required by these conditions are listed in the table below.

Condition	Action Required
• The title of the documented evidence specified by the checklist (document, plan, etc.) *agrees* with the title of the evidence being planned by the organization.	Record in checklist that the organization is compliant.
• The title of the documented evidence specified by the checklist (document, etc.) *disagrees* with the title of the evidence planned by the organization but the content is the same.	Record in the checklist the evidence titles the organization uses and record that the organization is compliant, and the evidence is the same although the title is different.
• The title of the documented evidence specified by the checklist (document, etc.) is *combined* with another piece of evidence.	Record in the checklist the title of the evidence (document, etc.) in which this information is contained.
• The title of the documented evidence specified by the checklist (document, etc.) *is not planned* by the organization because it is not required.	Record in the checklist that the evidence is not required and the rationale for this decision.
• The title of the documented evidence called out by the checklis*t* (document, etc.*) is not planned* by the organization and *should be* planned by it.	Record in the checklist when this evidence will be planned and reference a plan for accomplishing the task.

Product Support

All reasonable questions concerning this checklist, or its use will be addressed by SEPT free of charge for 60 days from time of purchase, up to a maximum of 4 hours of consultation time.

Guarantees and Liability

Software Engineering Process Technology (SEPT) makes no guarantees implied or stated with respect to this checklist, and it is provided on an "*as is"* basis. SEPT will have no liability for any indirect, incidental, special, or consequential damages or any loss of revenue or profits arising under, or with respect to the use of this document.

Section 2
ISO 14971:2019 Evidence Products Checklist by Clause

ISO 14971:2019 Clause Number and Name		**Policies** and Procedures	Plans	Records	Documents	Reviews
4	**General requirements for risk management system**					
4.1	Risk management process	• Monitoring the Effectiveness of The Risk Control Measures of Hazards and Hazardous Situations Procedure • Process for Identification of Hazards and Hazardous Situations Associated with a Medical Device Procedure • Product Realization (Incorporating Risk Management Process) Procedure			• Risk Management Process Document	• Risk Management Process Document Review* • Risk Management Process Document Inspection Review

* Identifies ISO 14971 Suggested artifact

➢ Identifies artifact to be placed in the ISO14971 Risk Management File

Section 2
ISO 14971:2019 Evidence Products Checklist by Clause

ISO 14971:2019 Clause Number and Name		**Policies** and Procedures	Plans	Records	Documents	Reviews
4.1	Risk management process (Cont. 1)	• Risk Management Process Document Procedure* • Risk Management Process (Throughout the Life Cycle of The Medical Device) Procedure • Risk Process Control of Hazards and Hazardous Situations Procedure • Risk Process Estimation and Evaluation of Associated Risks from Hazards and Hazardous Situations Procedure				

* Identifies ISO 14971 Suggested artifact

➢ Identifies artifact to be placed in the ISO14971 Risk Management File

Section 2
ISO 14971:2019 Evidence Products Checklist by Clause

ISO 14971:2019 Clause Number and Name		**Policies** and Procedures	Plans	Records	Documents	Reviews
4.2	Management responsibilities	• Risk Management Process Compliance Procedure • Top Management Assignment of Competent Personnel for the Risk Management Process Procedure • **Top Management Criteria for Risk Acceptability Policy** • Top Management Provision of Adequate Resources for the Risk Management Process Procedure	• Top Management Suitability of Risk Management Process Review Plan	• Risk Management Document Responsibilities Inspection Records	• Top Management Risk Review Decisions and Actions Document	• Top Management Risk Review Decisions and Actions Document Review* • Top Management Suitability of Risk Management Process Review • Top Management Suitability of Risk Management Process Review Plan Review* • Management Responsibility Document Inspection Review

* Identifies ISO 14971 Suggested artifact

➢ Identifies artifact to be placed in the ISO14971 Risk Management File

Section 2
ISO 14971:2019 Evidence Products Checklist by Clause

ISO 14971:2019 Clause Number and Name		**Policies** and Procedures	Plans	Records	Documents	Reviews
4.2	Management responsibilities (Cont. 1)	• Top Management Risk Review Decisions and Actions Document Procedure • Top Management Suitability of Risk Management Process Review Plan Procedure*				

* Identifies ISO 14971 Suggested artifact

➢ Identifies artifact to be placed in the ISO14971 Risk Management File

Section 2
ISO 14971:2019 Evidence Products Checklist by Clause

ISO 14971:2019 Clause Number and Name		**Policies** and Procedures	Plans	Records	Documents	Reviews
4.3	Competence of personnel	• Personnel Competency Review of Risk Management Education, Training, Skills and Experience Procedure • Personnel Knowledge and Experience of Particular Medical Device(s) and their Use Review Procedure		• Personnel Risk Management Skills Competence Records		• Risk Management Competency Records Inspection Review

* Identifies ISO 14971 Suggested artifact

➢ Identifies artifact to be placed in the ISO14971 Risk Management File

Section 2
ISO 14971:2019 Evidence Products Checklist by Clause

ISO 14971:2019 Clause Number and Name		**Policies** and Procedures	Plans	Records	Documents	Reviews
4.4	Risk management plan Note: (Section) indicates as related to a particular section of the Risk management plan	• Risk Management Activities for Collection and Review of Production and Post-Production Information (Section) Plan Procedure* • Risk Management Activities for Verification and Effectiveness of Risk Control Measures (Section) Plan Procedure*	• Risk Management Activities for Collection and Review of Production and Post-Production Information (Section) Plan ➢ • Risk Management Activities for Verification and Effectiveness of Risk Control Measures (Section) Plan ➢ • Risk Management Activities (Section) Plan ➢	• Risk Management Medical Device Plan Changes Record➢	• Risk Management File Document	• Risk Management Activities for Collection and Review of Production and Post-Production Information (Section) Plan Review* • Risk Management Activities for Verification and Effectiveness of Risk Control Measures (Section) Plan Review* • Risk Management Activities (Section) Plan Review*

* Identifies ISO 14971 Suggested artifact

➢ Identifies artifact to be placed in the ISO14971 Risk Management File