Risk Management Plan

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Andersen Site

Revision History

Date	Version	Description of change	Author	Approved Name	Approved Date
08.11.2022	0.1	Initial version	Andrei Belski		
08.11.2022	1.0	Effective	Andrei Belski	Jim Hopkins	08.11.2022

Table of contents

Introduction

1.1 Purpose

This document is a Risk Management Plan for a healthcare application (HA), which contains the adopted requirements for hazard and risk mitigation on the product level with respect to ISO 13485 and ISO 14971.

The purpose of this document is to establish project rules so that Andersen's team can plan and perform risk management activities on the product level for the HA.

This Risk Management Plan is based on Product Risk Management Procedure Description.

1.2 Scope of Document

This document is applied to the HA. It is created and maintained with respect to Medical Device Regulations (MDR).

1.3 Scope of Risk Management Plan

Roles

- The Compliance Assurance Engineer is responsible for facilitating management activities and defining risk acceptance criteria;

- The Development Team is responsible for developing the product according to healthcare professional standards (including ISO 14971);

- The customer as Product Owner is responsible for product compliance with General Safety and MDR, as well as Risk Management File handling and actualization during the post-market surveillance.

3.1 Inputs and Requirements for Product Security and Safety

3.1.1 Production and Post-Production Information

The production and post-production information must be collected and stored in the Periodic Safety Update Report (PSUR).

3.1.2 Production and Post-Production Information

The following requirements are defined for specialists performing risk management tasks:

- Knowledge of and experience with the medical device and its use: ISO 13485, IEC 62304, IEC 62366, and ISO14971;
- Knowledge of risk management techniques (external or internal training).

Competency records are stored in the training log.

3.1.3 Additional Security/Safety Requirements

Security/safety requirements are defined in AS.HP.PD.04 Software Requirements Specification.

3.2 Risk Management Workflow

Andersen's risk management activities are regulated by AS.QMS.DP.7.1 Risk Management.

3.2.1 Workflow

Andersen has defined the risk management process within the life cycle of a medical device.

The risk management process includes the following:

- Risk analysis;
- Risk assessment;
- Risk control;
- Production and post-production activities.

This process is aimed at comprehensively addressing safety issues – in particular, at enabling early detection of hazards in the medical device.

Figure 1 is a schematic representation of the risk management process:

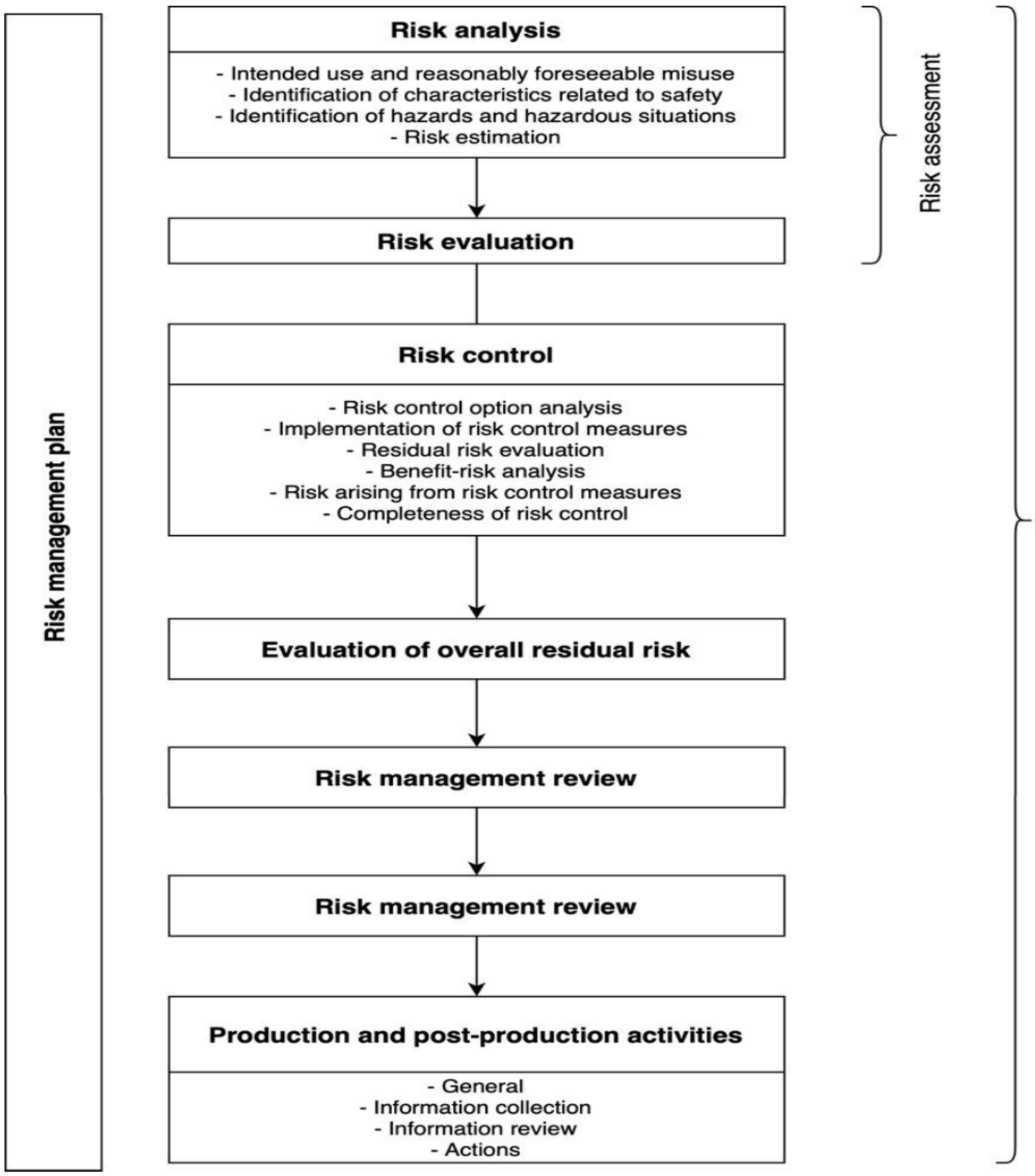

Figure 1 - risk management process flow

3.2.2 Risk Acceptance Criteria

This plan defines the criteria for severity, probability, and risk acceptability.

The probability of hazard occurrence (P) is rated as follows:

Table 1 – Probability of Hazard Occurrence		
Probability of harm from a specific hazard or hazardous situation (value)		
Frequent	P5	Happens often
Probable	P4	Very likely to happen
Occasional	P3	Might happen
Remote	P2	Unlikely to happen
Improbable	P1	Very unlikely to happen

The severity of hazard exposure consequences (S) is rated as follows:

Table 2 – Severity Level		
The severity of harm (value)		
Catastrophic/Fatal	S5	Results in death
Critical	S4	Results in permanent impairment or irreversible injury
Serious/Major	S3	Results in injury or impairment requiring medical or surgical intervention
Minor	S2	Results in temporary injury or impairment not requiring medical or surgical intervention
Negligible	S1	Results in inconvenience or temporary discomfort

The following risk acceptance criteria (R) are defined (intervals can be different):

Table 1 – Probability of Hazard Occurrence

		Qualitative severity levels				
		Negligible	Minor	Serious/ Major	Critical	Catastrophic/ Fatal
Probability levels	Improbable	R1	R1	R2	R2	R3
	Remote	R1	R1	R2	R2	R3
	Occasional	R2	R2	R2	R2	R3
	Probable	R2	R2	R2	R2	R3
	Frequent	R2	R2	R3	R3	R3

RED – The risk must be addressed and requires preparing an obligatory risk mitigation plan;

YELLOW – The residual risk. This type of risk is not negated by medical benefits. It must be decided what information is necessary to handle the residual risk. Also, the risk requires benefit analysis;

GREEN – The risk can be accepted at the current project phase and reevaluated during the next risk tracking step.

3.2.2 Risk Acceptance Criteria

The following artifacts will be created during the risk management process according to ISO 14971:

Table 4 – Risk Management Artifacts

No.	Artifact (document/record)
1	Product Risk Management Plan
2	Product risk assessment included in Risk Management File
3	Usability risks included in Usability Engineering File
4	Product IT security risks included in Risk Management File
5	A risk management review and report included in Risk Management File