Risk Management

SCSD 11th March 2024

ISO 31000:Risk Management - Guidelines

Introduction

This document is for use by people who create and protect value in organizations by managing risks, making decisions, setting and achieving objectives and improving performance.

Organizations of all types and sizes face external and internal factors and influences that make it uncertain whether they will achieve their objectives.

Managing risk is iterative and assists organizations in setting strategy, achieving objectives and making informed decisions.

Managing risk is part of governance and leadership, and is fundamental to how the organization is managed at all levels. It contributes to the improvement of management systems.

Managing risk is part of all activities associated with an organization and includes interaction with stakeholders.

Managing risk considers the external and internal context of the organization, including human behaviour and cultural factors.

Managing risk is based on the principles, framework and process outlined in this document, as illustrated in Figure 1. These components might already exist in full or in part within the organization, however, they might need to be adapted or improved so that managing risk is efficient, effective and consistent.

Clauses 4, 5 and 6 – Main elements of 31000

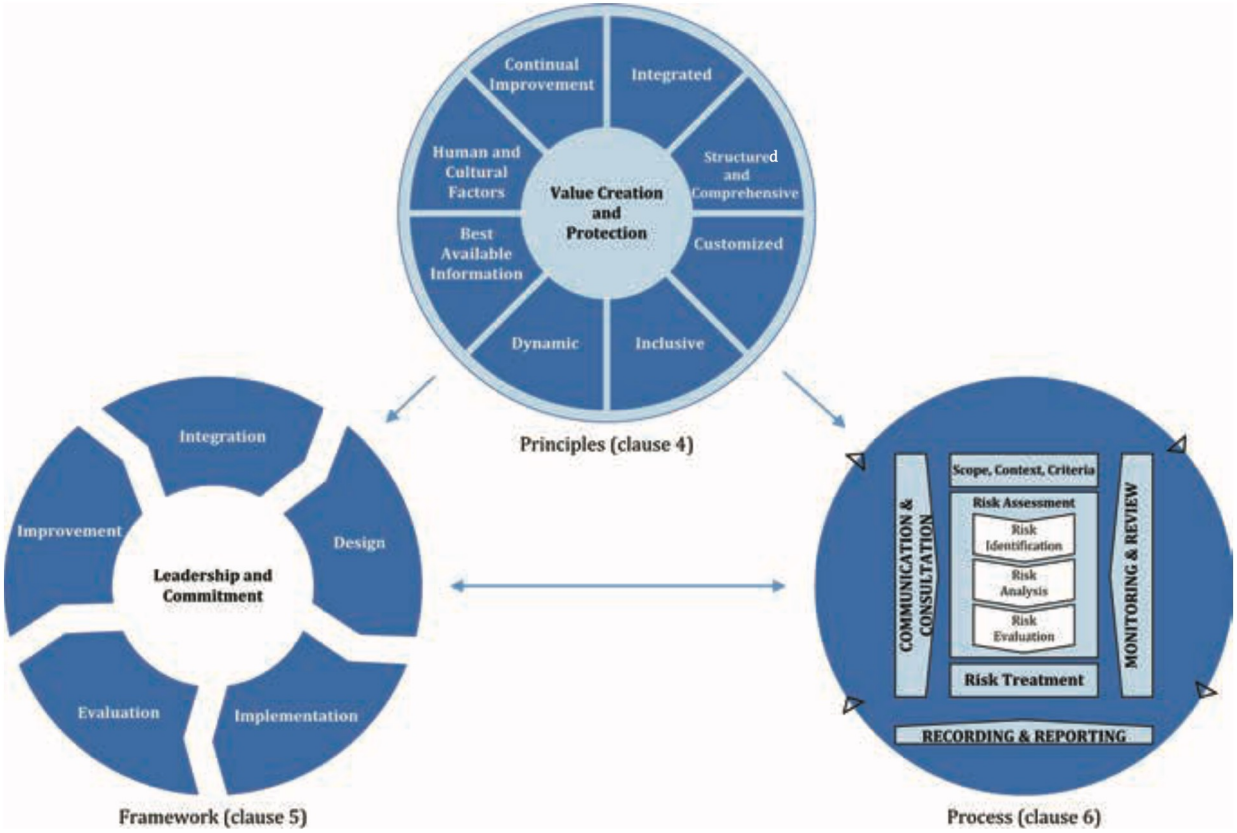


Figure 1 — Principles, framework and process

Definitions

- **risk**: effect of uncertainty on objectives
- **risk management:** coordinated activities to direct and control an organization with regard to risk
- **stakeholder:** person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity
- **risk source:** element which alone or in combination has the potential to give rise to risk
- **event:** occurrence or change of a particular set of circumstances
- **consequence:** outcome of an event affecting objectives
- **likelihood:** chance of something happening
- **control:**measure that maintains and/or modifies risk

ISO 31000 Principles (Clause 4)

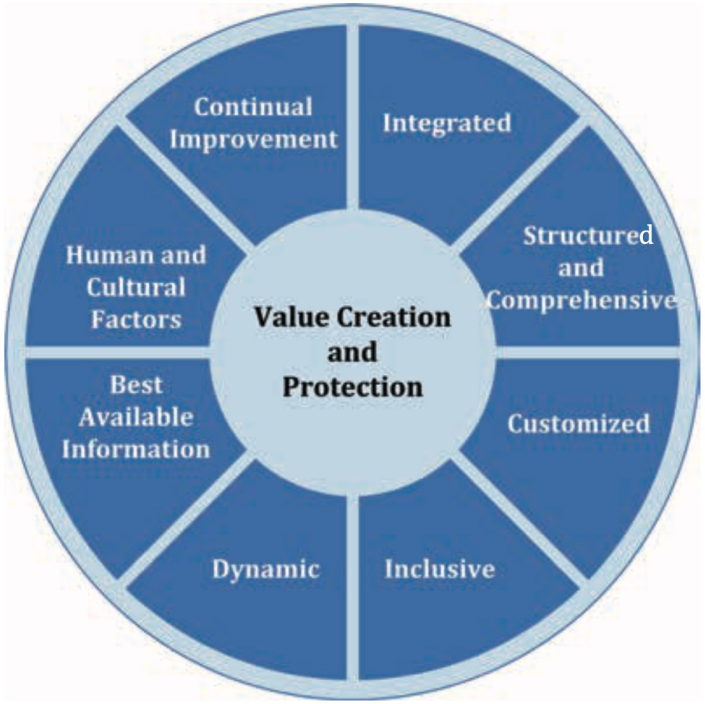


Figure 2 — Principles

a) **Integrated:** Risk management is an integral part of all organizational activities. b)

b) **Structured and comprehensive:** A structured and comprehensive approach to risk management contributes to consistent and comparable results.

c) **Customized:** The risk management framework and process are customized and proportionate to the organization's external and internal context related to its objectives.

d) **Inclusive:** Appropriate and timely involvement of stakeholders enables their knowledge, views and perceptions to be considered. This results in improved awareness and informed risk management.

e) **Dynamic:** Risks can emerge, change or disappear as an organization's external and internal context changes. Risk management anticipates, detects, acknowledges and responds to those changes and events in an appropriate and timely manner.

ISO 31000 Principles (Clause 4)

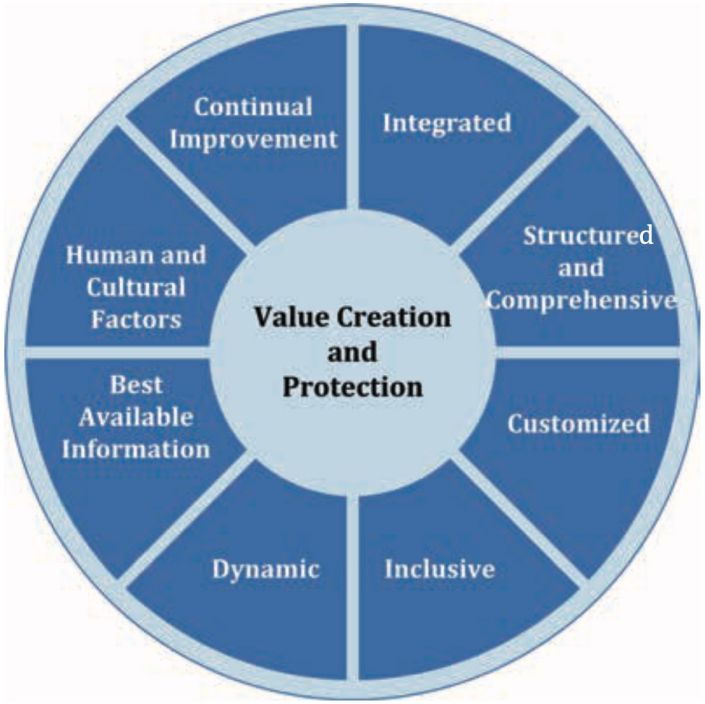


Figure 2 — Principles

f) **Best available information:** The inputs to risk management are based on historical and current information, as well as on future expectations. Risk management explicitly takes into account any limitations and uncertainties associated with such information and expectations. Information should be timely, clear and available to relevant stakeholders.

g) **Human and cultural factors:** Human behaviour and culture significantly influence all aspects of risk management at each level and stage.

h) **Continual improvement:** Risk management is continually improved through learning and experience.

ISO 31000 Framework (Clause 5)

Figure 3 — Framework

- Leadership and commitment are the key elements to ensure:
  - Risk management is integrated into all activities
  - Aligned to the needs of the organization and pursued systematically and engages with all in the organization
  - Top management is accountable for the management of risk and oversight bodies oversee risk management

Integration of Risk Management

- Risk management takes place in all parts of an organization
- Risk management shouls be incorporated into governance of the organization
- Management structure translates governance into objectives and strategies
- Risk management accountability and oversight roles are a key part of governance
- Integration is iterative, dynamic and ongoing.

Design of the risk management framework

- Understanding the organization and its internal and external context.
- Commitment to articulating risk management.
- Assigning organizational roles, authorities, responsibilities and accountabilities.
- Allocating resources.
- Establishing communication and consultation

Integration, Evaluation, Improvement

- Implementation:
  - Plans that include timing and resources
  - Identifying roles – where, when, how, and by whom different types of decision are taken
  - Processes are well defined and aligned with risk management.
- Evaluation:
  - is the risk management framework good at managing risk? (How to measure?)
  - Decide if it is still fit for purpose in supporting business objectives
- Improvement:
  - Adapting to take account of internal and external change
  - Continually improving to strengthen risk management

ISO 31000: Process (Clause 6)

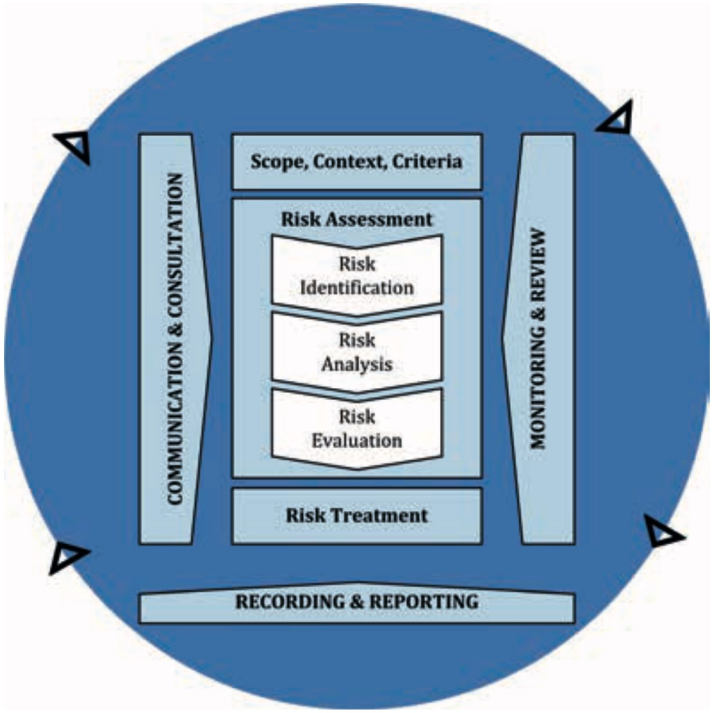


Figure 4 — Process

- Communication and consultation: good risk management need to bring people and information from across the organization
- Scope, context, criteria: frames risk assessment by establishing what risk assessment is supposed to be doing, where it comes from and how to decide on how serious a risk is.

Risk Identification

- Finding risks
- Look for uncertainties and the different possibilities arising from these.
- Use techniques like SWOT (Strengths, Weaknesses, Opportunities, Threats) to evaluate the organization and identify uncertainty.
- Possible internal and external events should be identified and their consequences outlined, …

Risk Analysis

- Refine the analysis of risks
- Estimate likelihood of events
- Estimate the consequences of events
- Explore complexity and connectivity of the collection of risks
- Explore timing and volatility
- Estimate sensitivity to change and confidence in estimates
- Estimate the effectiveness of existing controls

Risk Evaluation

- Support decisions with recommendations:
  - No further action
  - Consider risk treatment options
  - Do additional analysis
  - Maintain existing controls
  - Reconsider the risk management objective for this class of risk

Risk Treatment

- Overall: consider treatment options, plan and implement treatment, assess effectiveness, decide if further treatment is necessary.
- Treatment options:
  - Avoid the risk by not doing the risky activity.
  - Deciding the risk/opportunity balance justifies the risk
  - Changing the risk by removing the source; changing likelihood, changing consequences OR deciding the risk is acceptable.
- Preparing and implementing risk treatment plans
  - Explain the plan, who is responsible for approving and implementing
  - Actions, resources, performance measures, constraints, reporting and measurement, timing

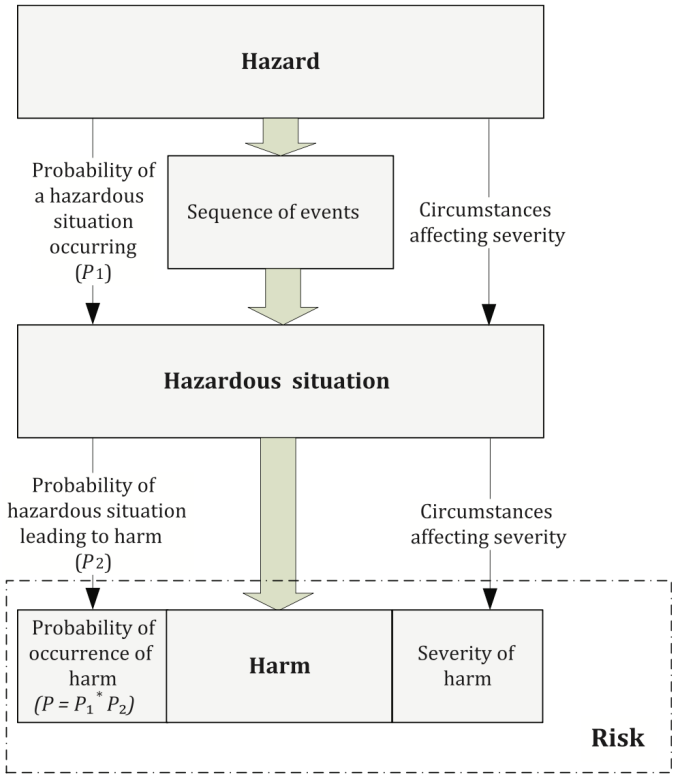
Monitoring, review, recording, reporting

- Establish indicators and expected values
- Establish mechanisms to collect indicator values
- Review against expected values and implement change if risk management needs improvement.
- Establish a reporting framework and what will be reported and how this is retained and acted on.

ISO 31000 is Generic

- This covers all types of risk.
- ISO 14971 is specifically about the management of risk in Medical Devices
- ISO 14971 is more specific both in context and process

ISO 14891: Risk Management of Med Devices



- Oriented towards manufacturers.
- Aiming at controlling hazards by assessing probability of occurrence and severity.

Hazards can be exemplified

Table C.1 — Examples of *hazards*

Energy *hazards*	Biological and chemical *hazards*	Performance-related *hazards*
Acoustic energy	**Biological agents**	**Data**
— infrasound	Bacteria	— access
— sound pressure	Fungi	— availability
— ultrasonic	Parasites	— confidentiality
Electric energy	Prions	— transfer
Electric fields	Toxins	— integrity
Leakage current	Viruses	**Delivery**
— earth leakage	**Chemical agents**	— quantity
— enclosure leakage	Carcinogenic, mutagenic, reproductive	— rate
Magnetic fields	Caustic, corrosive	**Diagnostic information**
Static discharge	— acidic	— examination result
Voltage	— alkaline	— image artefacts
Mechanical energy	— oxidants	— image orientation
Kinetic energy	Flammable, combustible, explosive	— image resolution
— falling objects	Fumes, vapors	— patient identity / information
— high pressure fluid injection	Osmotic	**Functionality**
— moving parts	Particles (including micro- and nanoparticles)	— alarm
— vibrating parts	Pyrogenic	— critical performance
Potential (stored) energy		— measurement

Sequence of Events can be exemplified

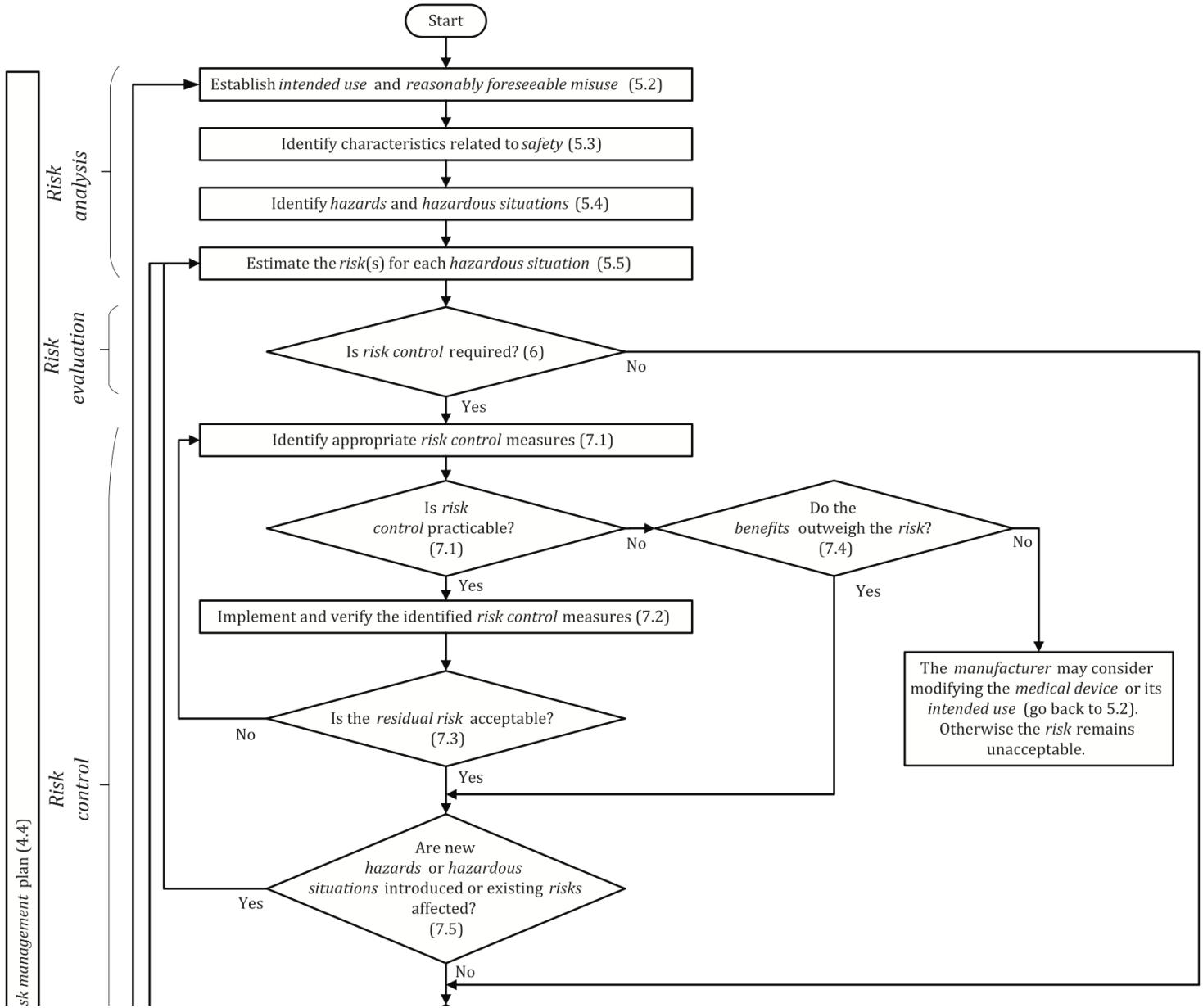
Table C.2 — Examples of events and circumstances

General category	Events and circumstances
Requirements	Inadequate specification of: — design parameters — operating parameters — performance requirements — in-service requirements (e.g. maintenance, reprocessing) — end of life
Manufacturing *processes*	Insufficient control of: — manufacturing *processes* — changes to manufacturing *processes* — materials — materials compatibility information — subcontractors
Transport and storage	Inadequate packaging Contamination or deterioration Inappropriate environmental conditions

Hazard, Events, Hazardous Situation, Harm

Table C.3 — Relationship between *hazards*, foreseeable sequences of events, *hazardous situations* and the *harm* that can occur

Hazard	Foreseeable sequence of events	*Hazardous situation*	*Harm*
Electromagnetic energy (high voltage)	(1) Electrode cable unintentionally plugged into power line receptacle	Line voltage appears on electrodes	Serious burns Heart fibrillation
Chemical (volatile solvent, embolus)	(1) Incomplete removal of volatile solvent used in manufacturing (2) Solvent residue converts to gas at body temperature	Development of gas embolism (bubbles in the blood stream) during dialysis	Infarct Brain damage
Biological (microbial contamination)	(1) Inadequate instructions provided for decontaminating re-used anaesthesia tubing (2) Contaminated tubing used during anaesthesia	Bacteria released into airway of patient during anaesthesia	Bacterial infection
Functionality (no delivery)	(1) Electrostatically charged patient touches infusion pump (2) Electrostatic discharge (ESD) causes pump and pump alarms to fail	Failure to deliver insulin to patient with elevated blood glucose level, no warning given	Minor organ damage Decreased consciousness
Functionality (no output)	(1) Implantable defibrillator battery reaches the end of its useful life (2) Inappropriately long interval between clinical follow-up visits	Defibrillator cannot deliver shock when an arrhythmia occurs	Death


Start
Establish *intended use* and *reasonably foreseeable misuse* (5.2)
Identify characteristics related to *safety* (5.3)
Identify *hazards* and *hazardous situations* (5.4)
Estimate the *risk*(s) for each *hazardous situation* (5.5)
Is *risk control* required? (6)
No
Yes
Identify appropriate *risk control* measures (7.1)
Is *risk control* practicable? (7.1)
No
Do the *benefits* outweigh the *risk*? (7.4)
No
Yes
Yes
Implement and verify the identified *risk control* measures (7.2)
The *manufacturer* may consider modifying the *medical device* or its *intended use* (go back to 5.2). Otherwise the *risk* remains unacceptable.
Is the *residual risk* acceptable? (7.3)
No
Yes
Are new *hazards* or *hazardous situations* introduced or existing *risks* affected? (7.5)
Yes
No
Risk analysis
Risk evaluation
Risk control
sk management plan (4.4)

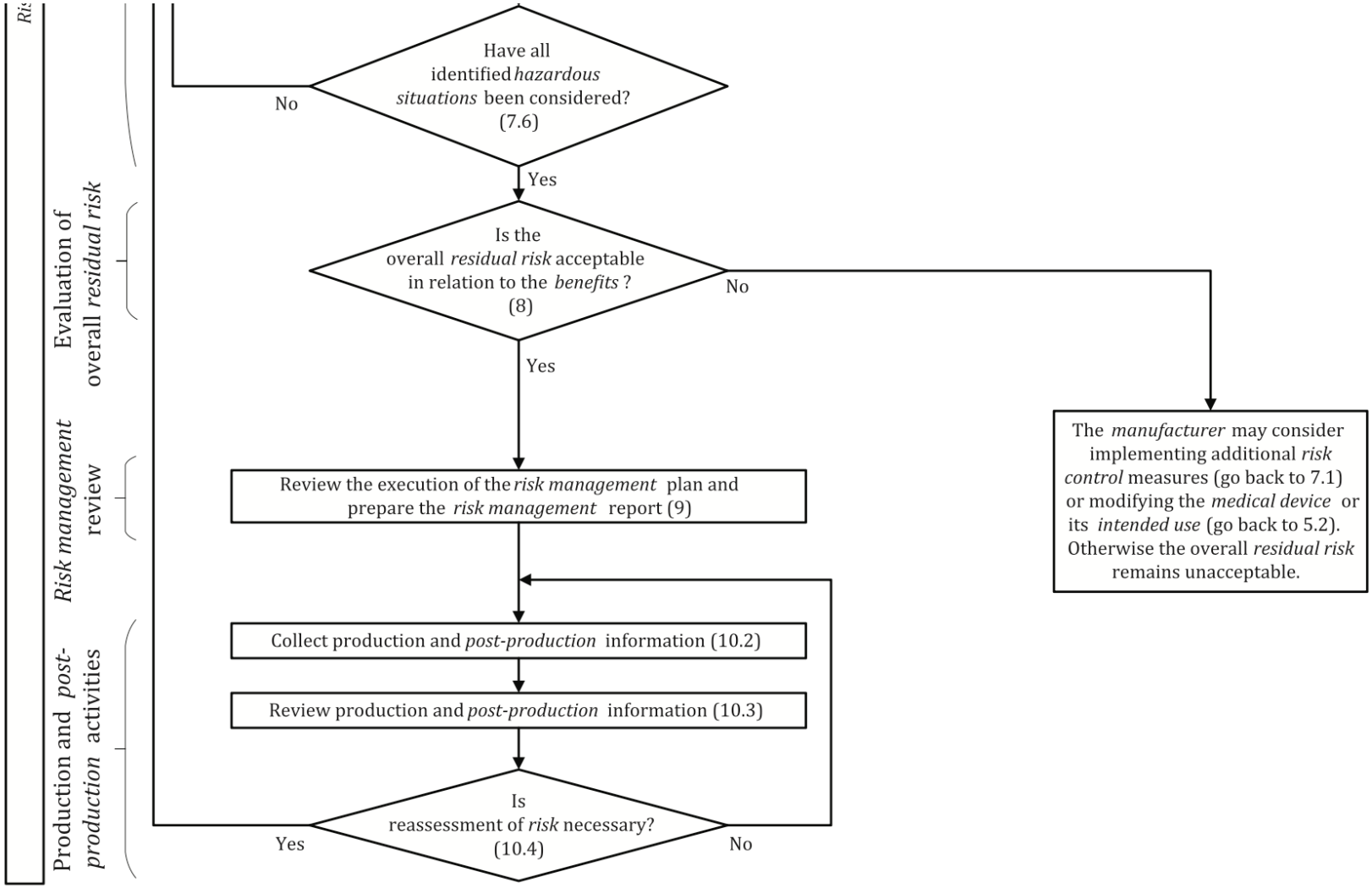


Figure B.1 — Overview of *risk management* activities as applied to *medical devices*

Generic Software Engineering Risk Management

- ISO 15288: System Lifecycle
- ISO 12207: Software Lifecycle
- ISO 16085: Risk Management

Summary

- ISO 31000 covers the completely generic approach to risk management.
- As a result, there are general principles, but the standard can make few requirements
- Looking at a particular domain the lifecycle (EN 62304) and the incorporated risk management (ISO 14971) can be much more specific around device risk.
- The generic systems and software lifecycles and risk management are more specific than the overarching standard (ISO 31000)