ISO 14971:2019
Risk Management for Medical Devices

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Benefits to you

Welcome

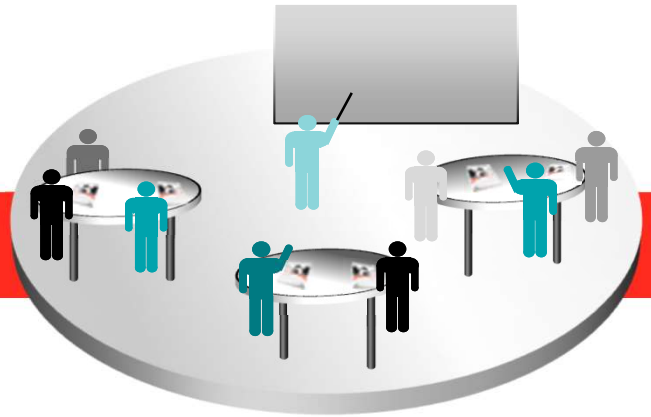
Introductions

Course aim

To enables greater understanding of the impact that ISO 14971:2019 has on the decision-making process when manufacturing medical devices.
It helps medical device professionals understand how ISO 14971:2019 can improve their business and risk management efforts.

Objectives

Knowledge



By the end of this course, delegates will be able to:

- Define risk management terminology
- Explain how risk management relates to the product lifecycle
- Outline the stages of the risk management process
- Define the key deliverables of the risk management process
- Apply risk management principles within your organization
- Identify the links between ISO 14971:2019, ISO 13485:2016 and the MDR 2017/745

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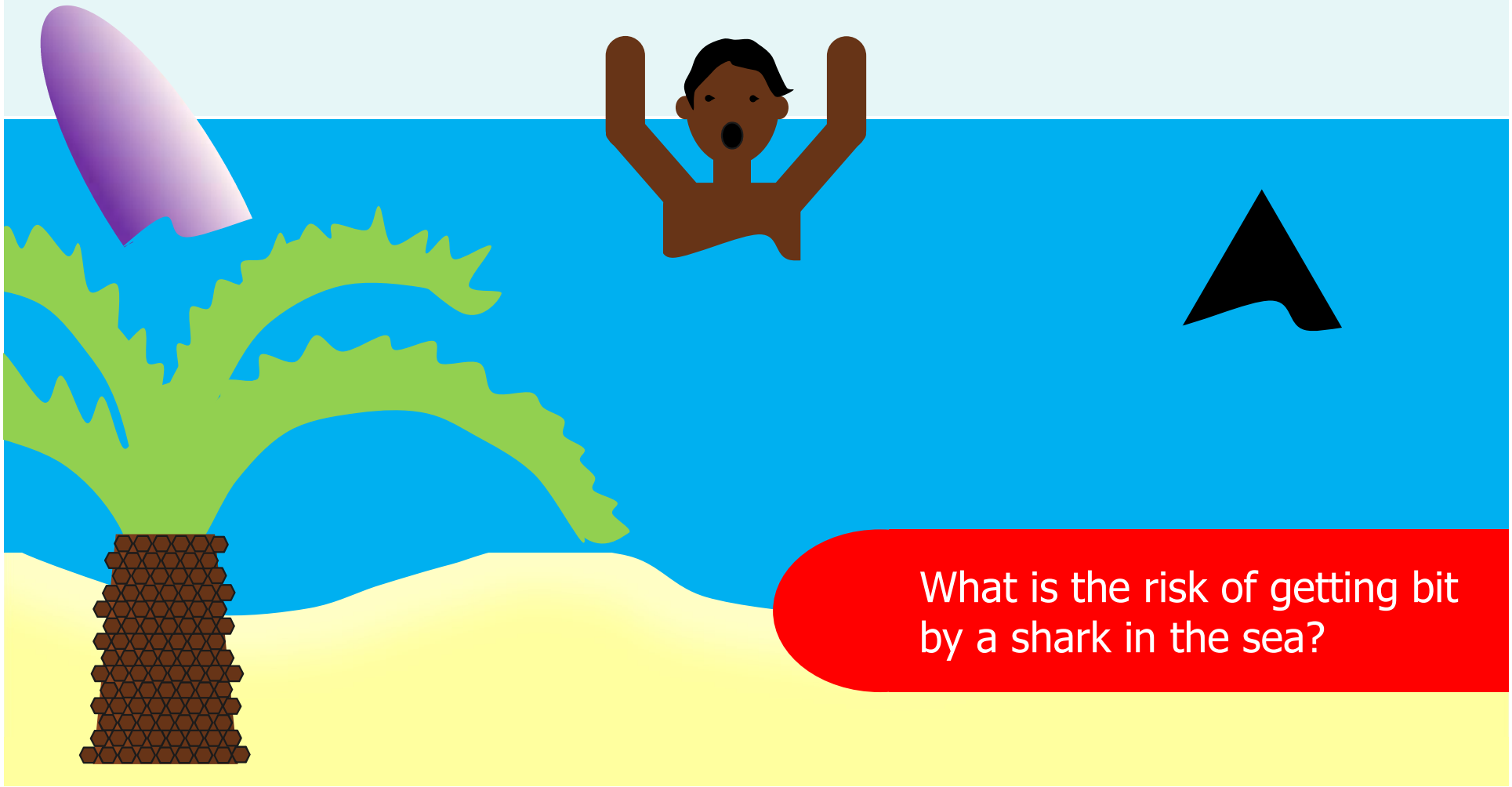
Terms and definitions

Risk

A combination of the probability of occurrence and the severity of that harm

Harm, hazardous situation and hazard



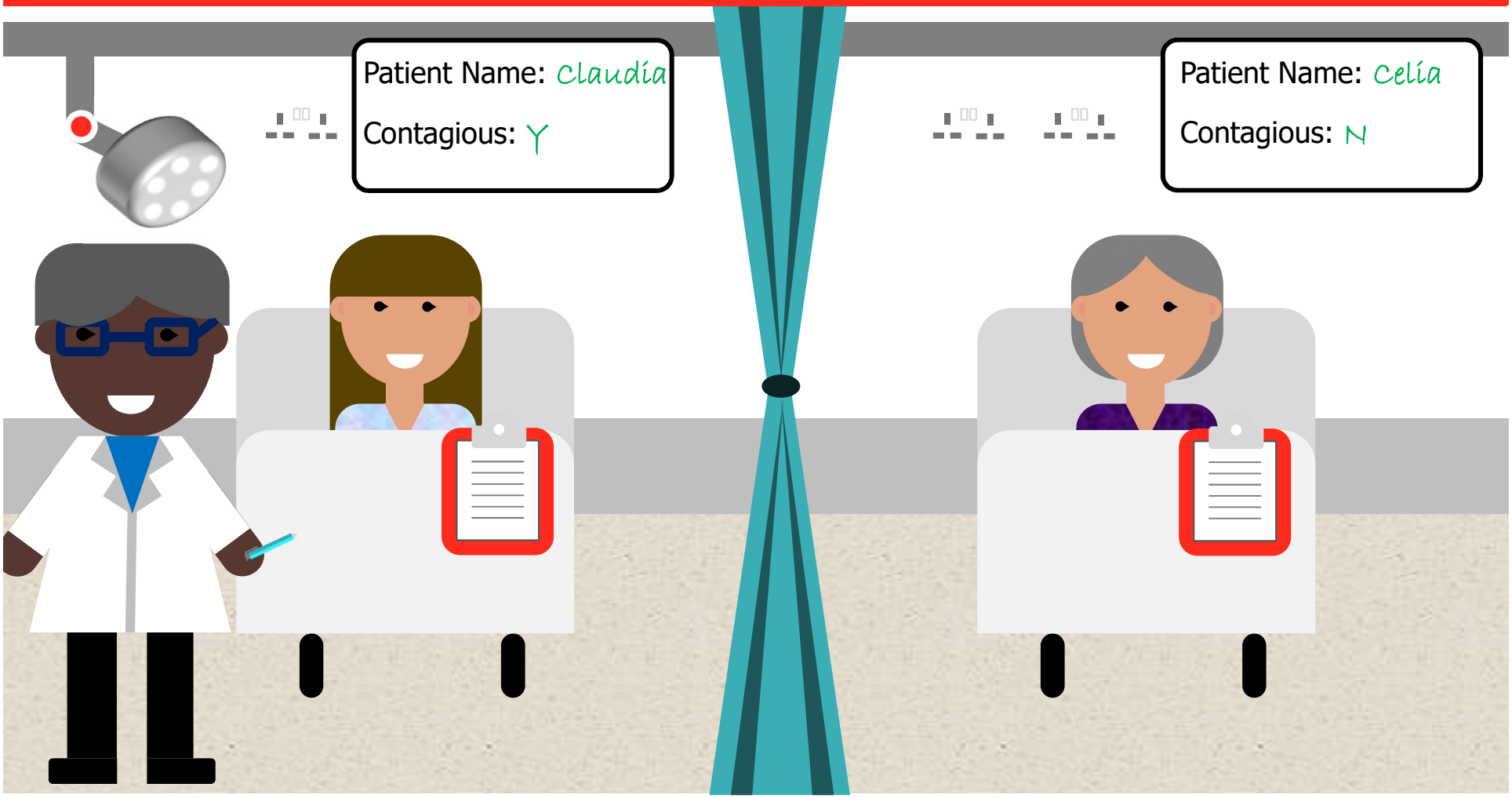
What is the risk of getting bit by a shark in the sea?

Risk management

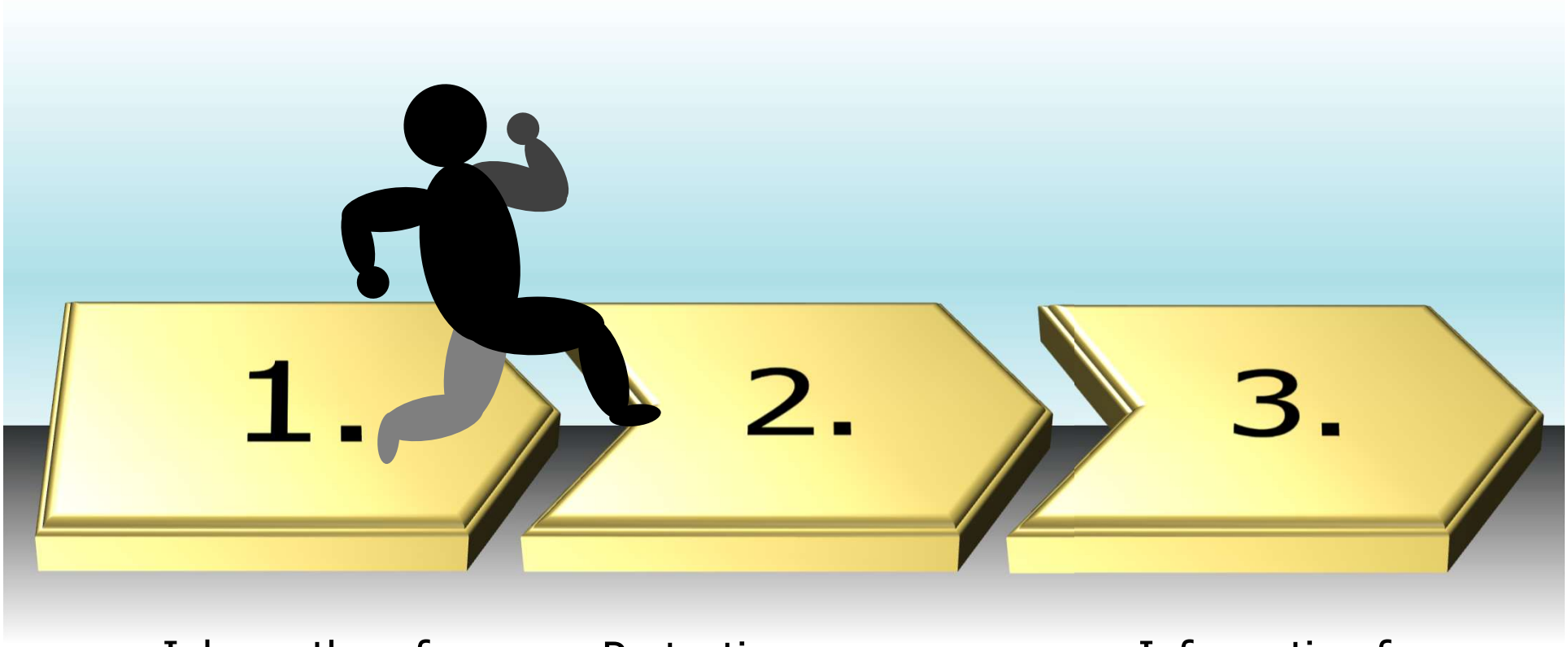
- Systematic **application** of management policies, *procedures* and practices to the tasks of... [ISO 14971:2019, Clause 3.24]

Risk analysis, evaluation and assessment

The systematic use of available information to identify hazards and to estimate the risk



Risk control



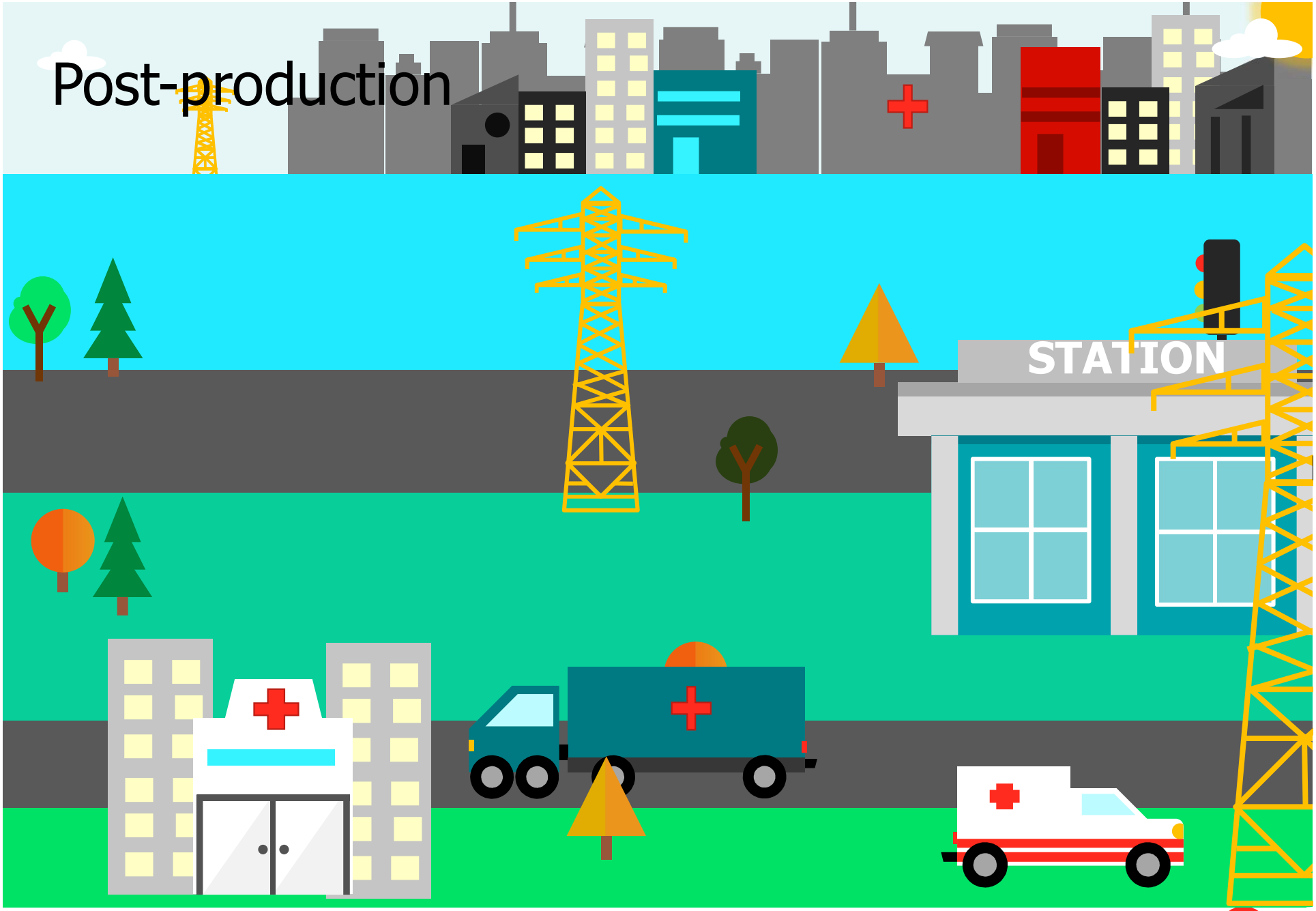
Inherently safe design and manufacture

Protective measures in the medical device or the manufacturing process

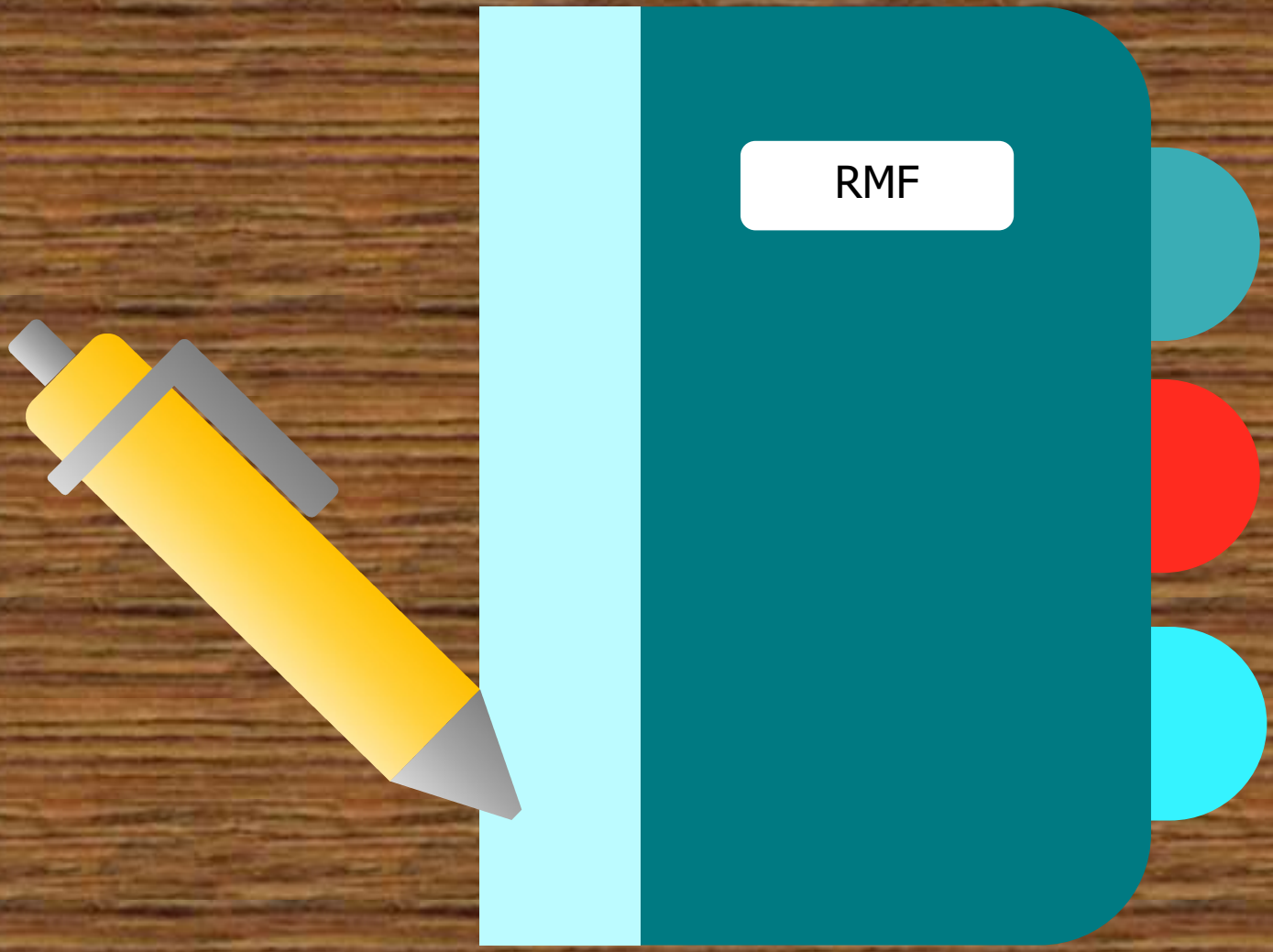
Information for safety

Residual risk and safety

Post-production



Risk management file



Risk Management: Terms & Definitions

Updated Definition

accompanying documentation
materials ~~document~~ accompanying a medical device and containing information for the operator, the user *or those accountable* for the installation, use, maintenance, *decommissioning and disposal* of the medical device, particularly regarding *safe use*

Note 1 to entry: The accompanying documentation can consist of the instructions for use, technical description, installation manual, quick reference guide, etc.
Note 2 to entry: Accompanying documentation is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.

harm
~~physical~~ injury or damage to the health of people, or damage to property or the environment

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Risk Management: Terms & Definitions

Updated Definition

in vitro diagnostic medical device
IVD medical device
~~medical~~ device, *whether used alone or in combination*, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body *solely or principally* to provide information for diagnostic, monitoring or compatibility purposes *and including* ~~EXAMPLE~~ reagents, calibrators, control materials, specimen ~~storage and collection~~ *receptacles*, *software*, and related instruments or apparatus or *other* articles

manufacturer
natural or legal person with responsibility for the design *and/or* manufacture ~~packaging, or labelling~~ of a medical device ~~assembling a system, or adapting a medical device before it is placed on the market or put into service~~ with the intention of making the medical device available for use, under his name, whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)
See also *Notes 1-7*

use error
~~act or omission~~ *user action or lack of user action while using the medical device that leads to a different result than that* intended by the manufacturer or expected by the user
See also *Notes 1-5*

Risk Management: Terms & Definitions

New Definition

benefit
positive impact or desirable outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health

reasonably foreseeable misuse
use of a product or system in a way not intended by the manufacturer, but which can result from readily predictable human behaviour

state of the art
developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

Note 1 to entry: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the "generally acknowledged state of the art".

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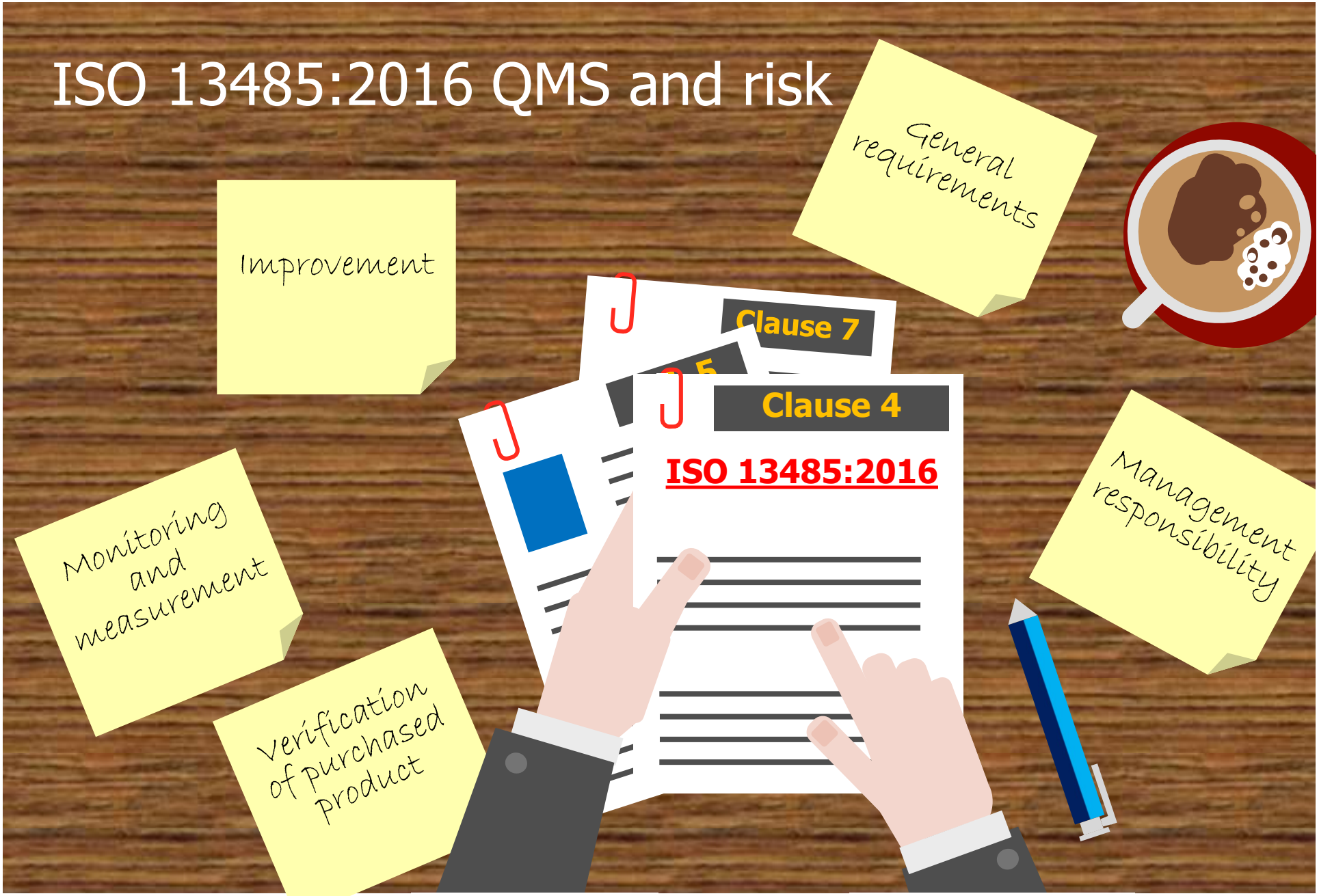
Risk management and the QMS

Links between ISO 13485 and EN
ISO 14971:2019

ISO 13485:2016 Product life cycle and risk

Planning, user needs and design inputs and development and design outputs/verification and validation

ISO 13485:2016 QMS and risk



Risk management and the MDR

Links between EU 2017/745 GSPRs and
ISO 14971:2019

Manufacturers’ top issues to comply with MDR

GSPR ‘Risk’ sections and ISO 14971:2019

GSPR #1

GSPR ‘Risk’ sections and ISO 14971:2019

GSPR #2

Risk reduction

GSPR ‘Risk’ sections and ISO 14971:2019

GSPR #3

Risk management process

ISO 14971:2019; Clauses
4.1, 4.2, 4.4, 5, 5.5, 6, 7, 10, 10.4

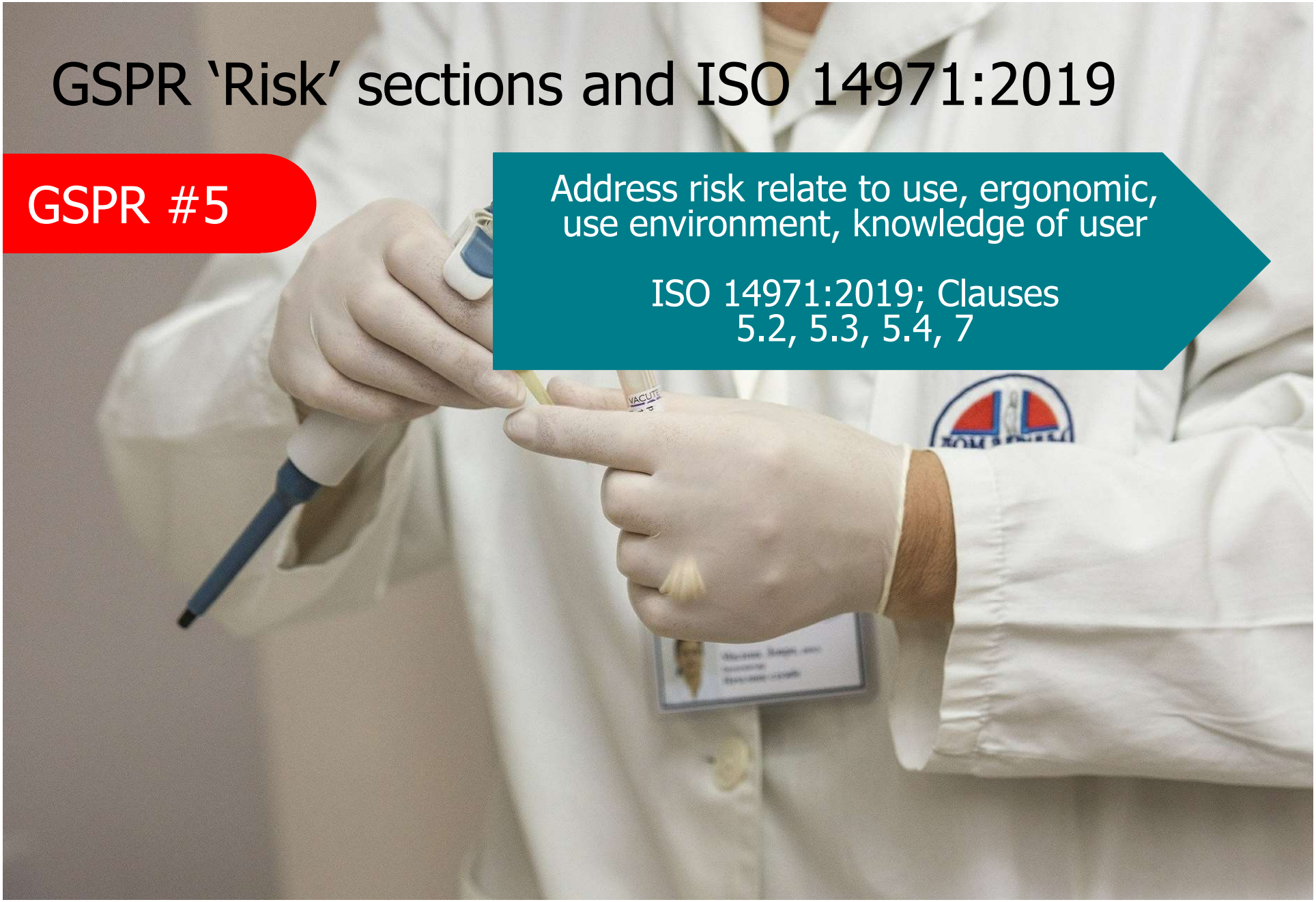
GSPR ‘Risk’ sections and ISO 14971:2019

GSPR #4

Risk control Measure

ISO 14971:2019; Clauses
4.2, 4.4, 6, 7, 8 7.1 (a, b, c), 8

GSPR ‘Risk’ sections and ISO 14971:2019



GSPR #5

Address risk relate to use, ergonomic, use environment, knowledge of user

ISO 14971:2019; Clauses 5.2, 5.3, 5.4, 7

GSPR ‘Risk’ sections and ISO 14971:2019

GSPR #8

Benefit-Risk analysis

ISO 14971:2019; Clauses 6, 7, 8

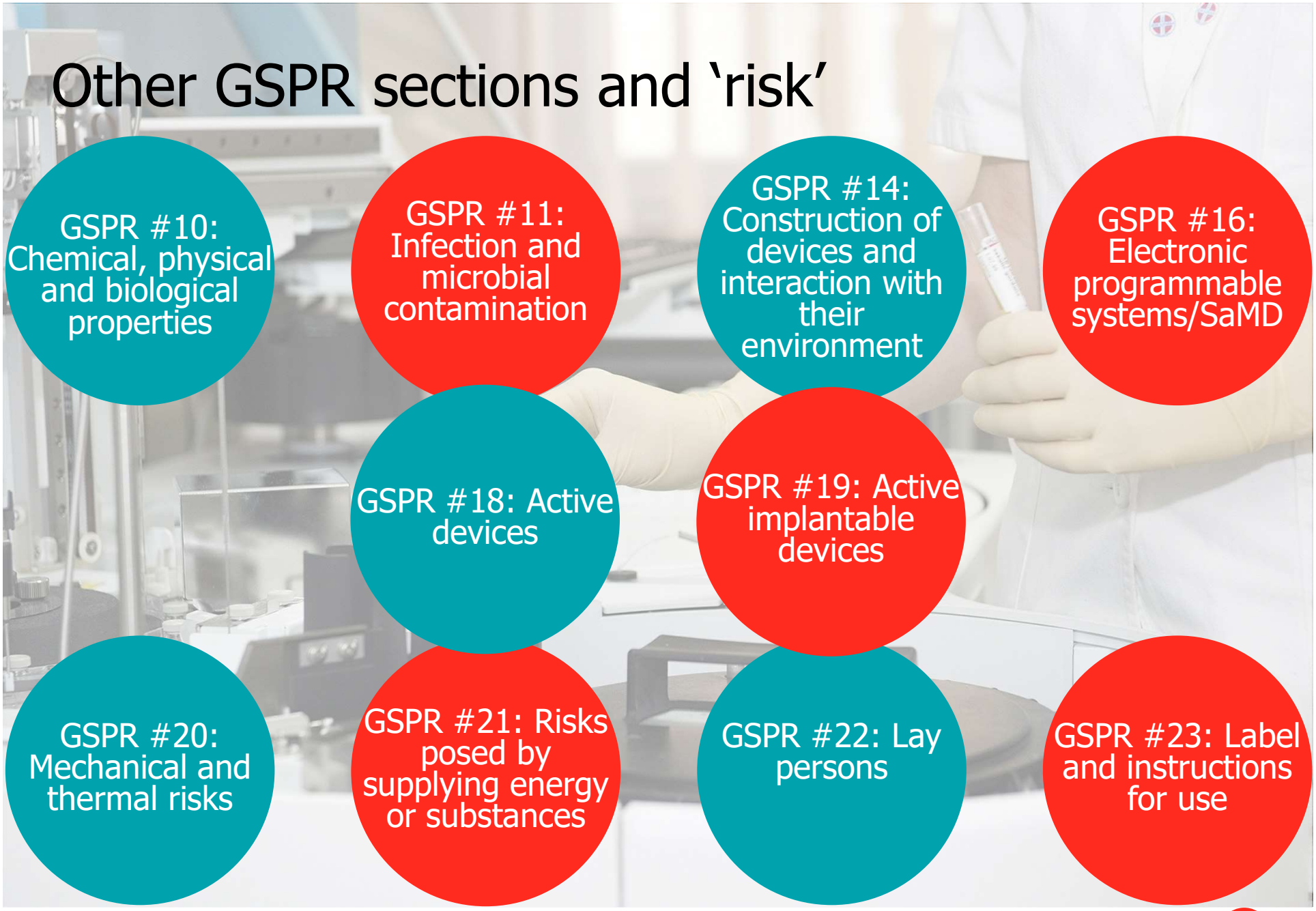
GSPR ‘Risk’ sections and ISO 14971:2019

GSPR #9

Address device without medical purpose

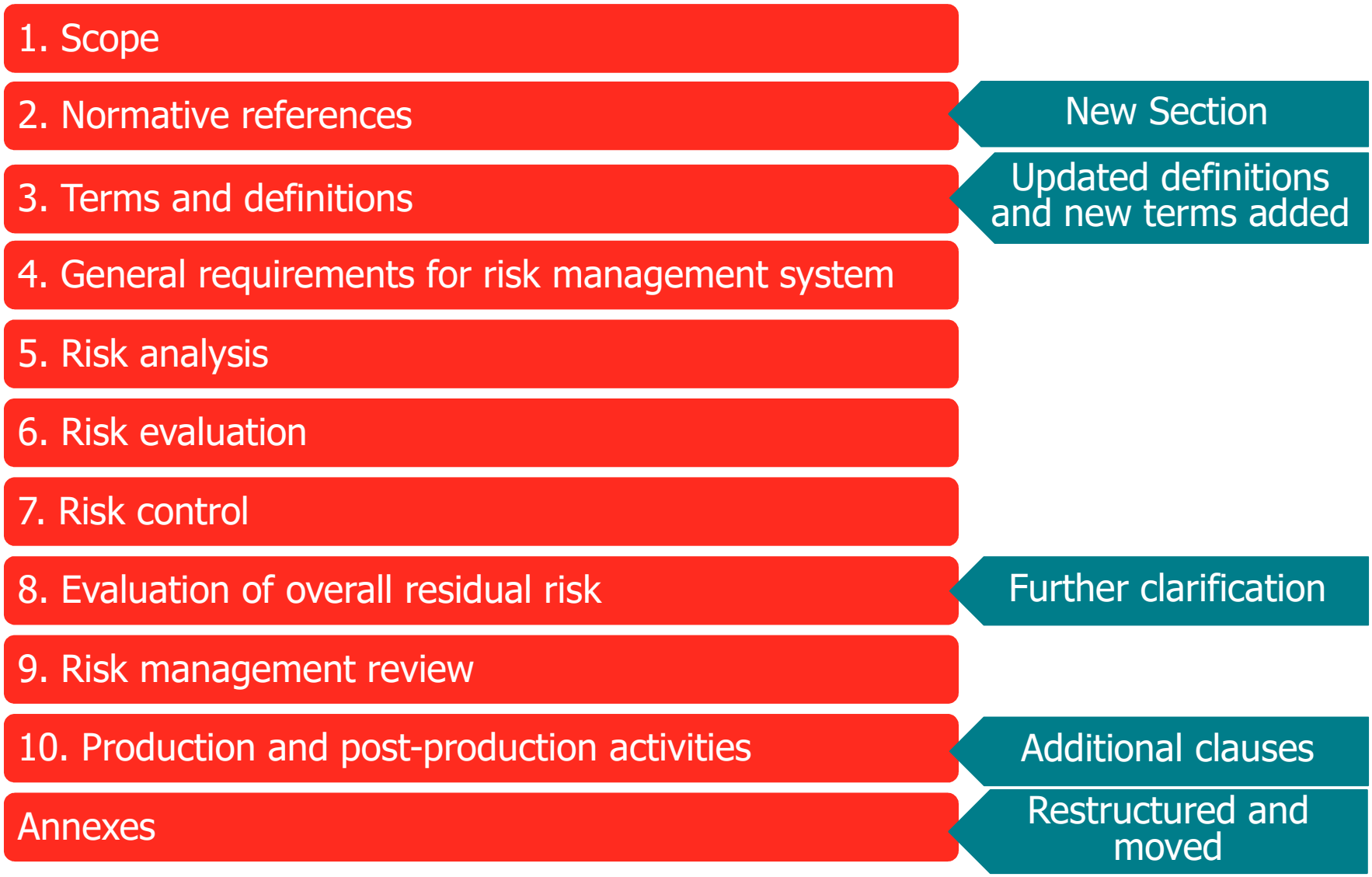
ISO 14971:2019; Clauses 1 to 10

Other GSPR sections and 'risk'



ISO 14971:2019 – Application of risk management to medical

General structure of ISO 14971:2019



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Annexes and ISO/TR 24971

2nd Edition (ISO 14971:2007/ISO 14971:2012)	3rd Edition (ISO 14971:2019)
Annex A: Rationale for requirements	**Annex A: Rationale for requirements**
Annex B: Overview of the risk management process for medical devices	**Annex B: Risk management process for medical devices**
Annex C: Questions that can be used to identify medical device characteristics that could impact on safety	*Moved to ISO/TR 24971*
Annex D: Risk concepts applied to medical devices	*Moved to ISO/TR 24971*
Annex E: Examples of hazards, foreseeable sequences of events and hazardous situations	**Annex C: Fundamental risk concepts**
Annex F: Risk management plan	*Moved to ISO/TR 24971*
Annex G: Information on risk management techniques	*Moved to ISO/TR 24971*
Annex H: Guidance on risk management for IVD medical devices	*Moved to ISO/TR 24971*
Annex I: Guidance on risk analysis process for biological hazards	*Annex deleted - covered by ISO10993 series*
Annex J: Information for safety and information about residual risk	*Moved to ISO/TR 24971*

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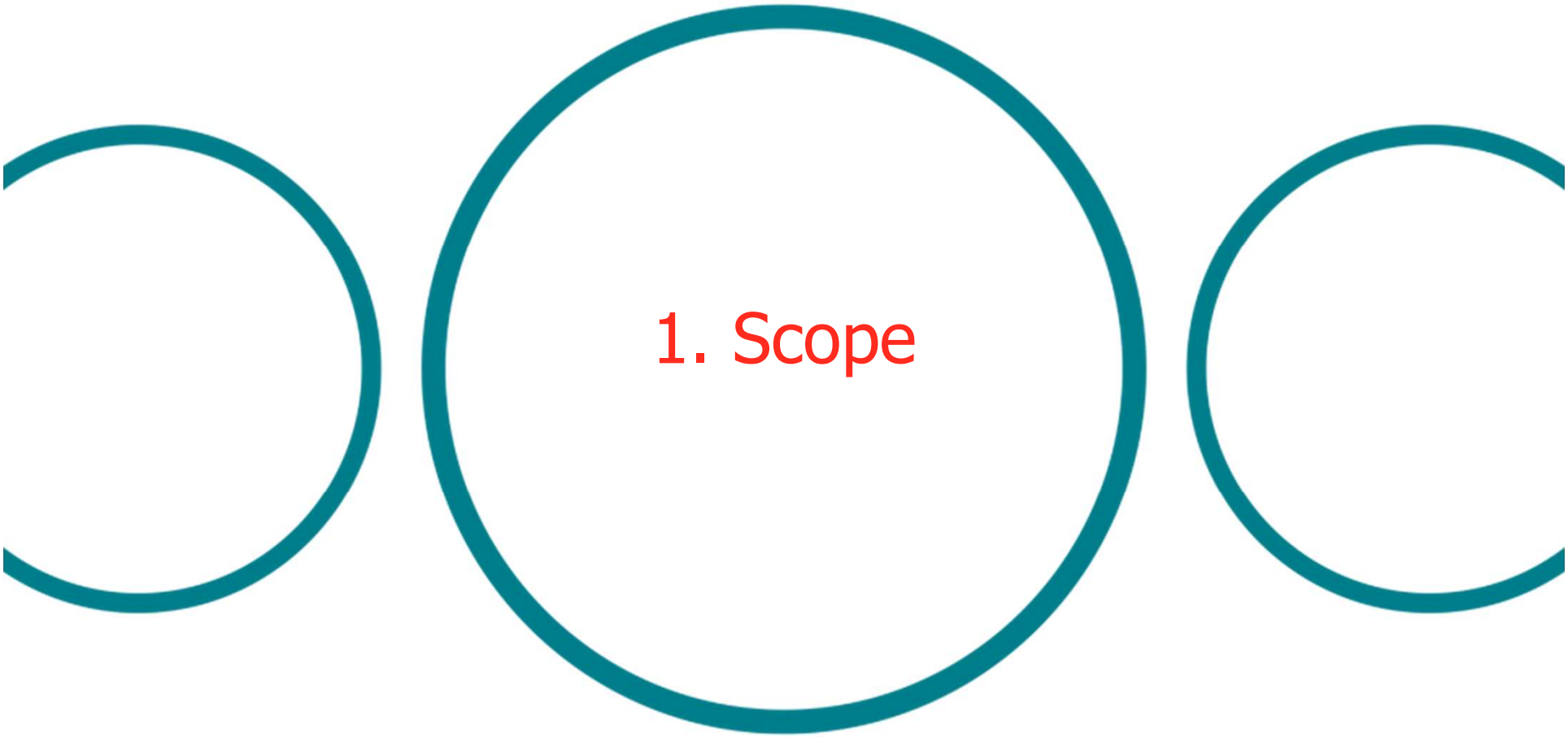
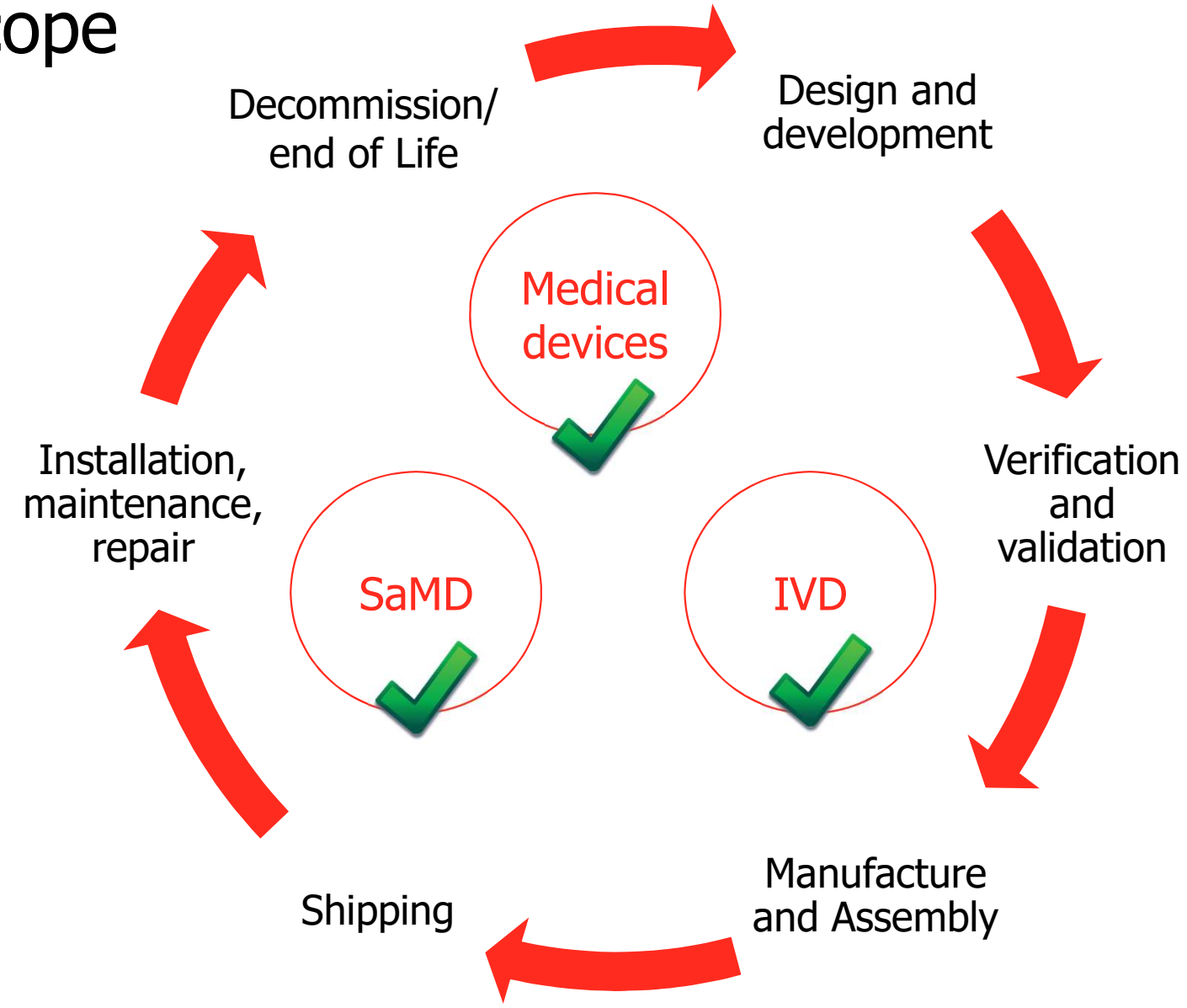
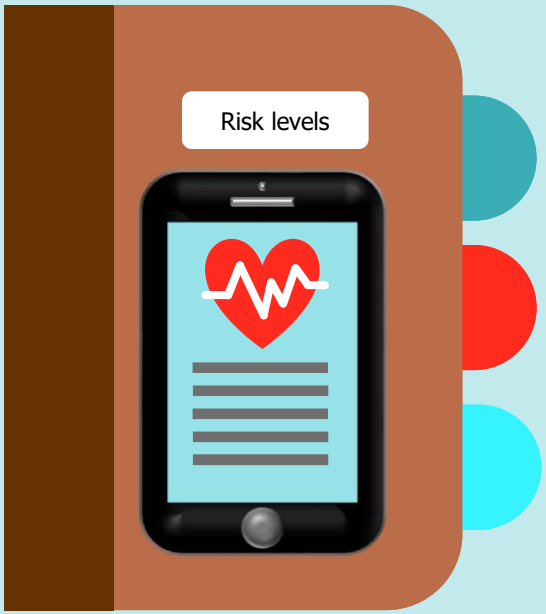


1. Scope

In scope



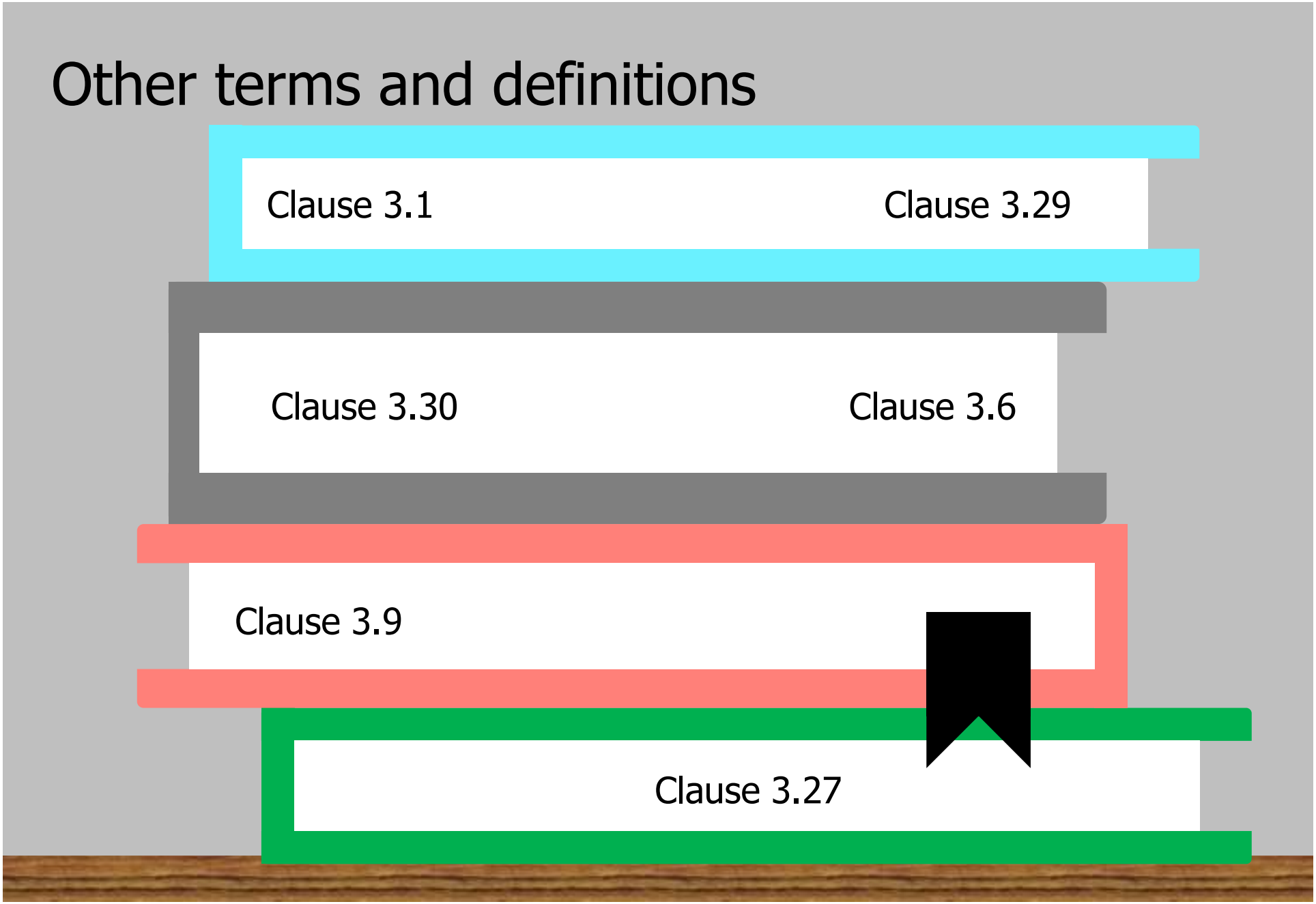
Out of scope



2. Normative reference

3. Terms and definitions

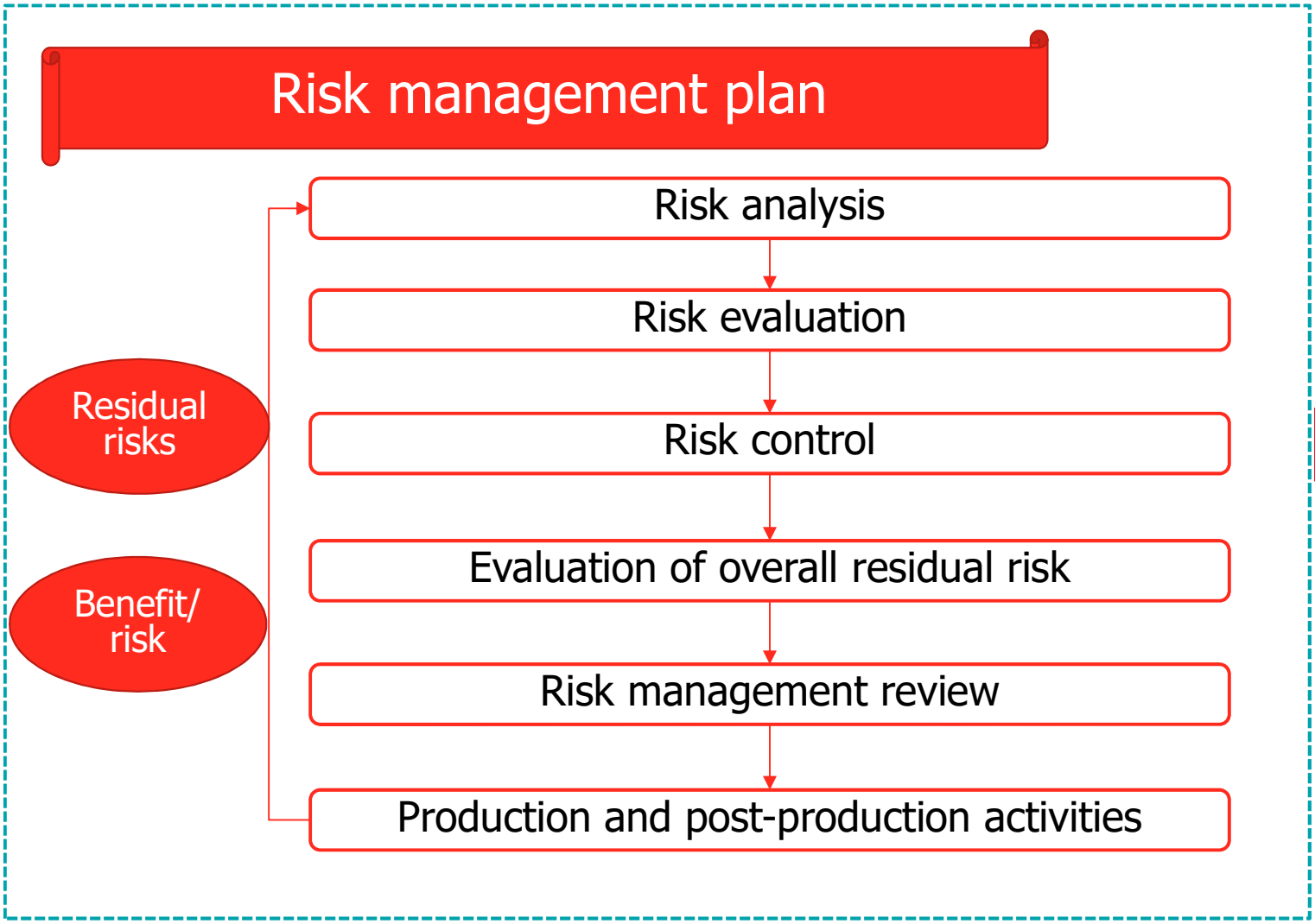
Other terms and definitions



4. General requirements for risk management systems

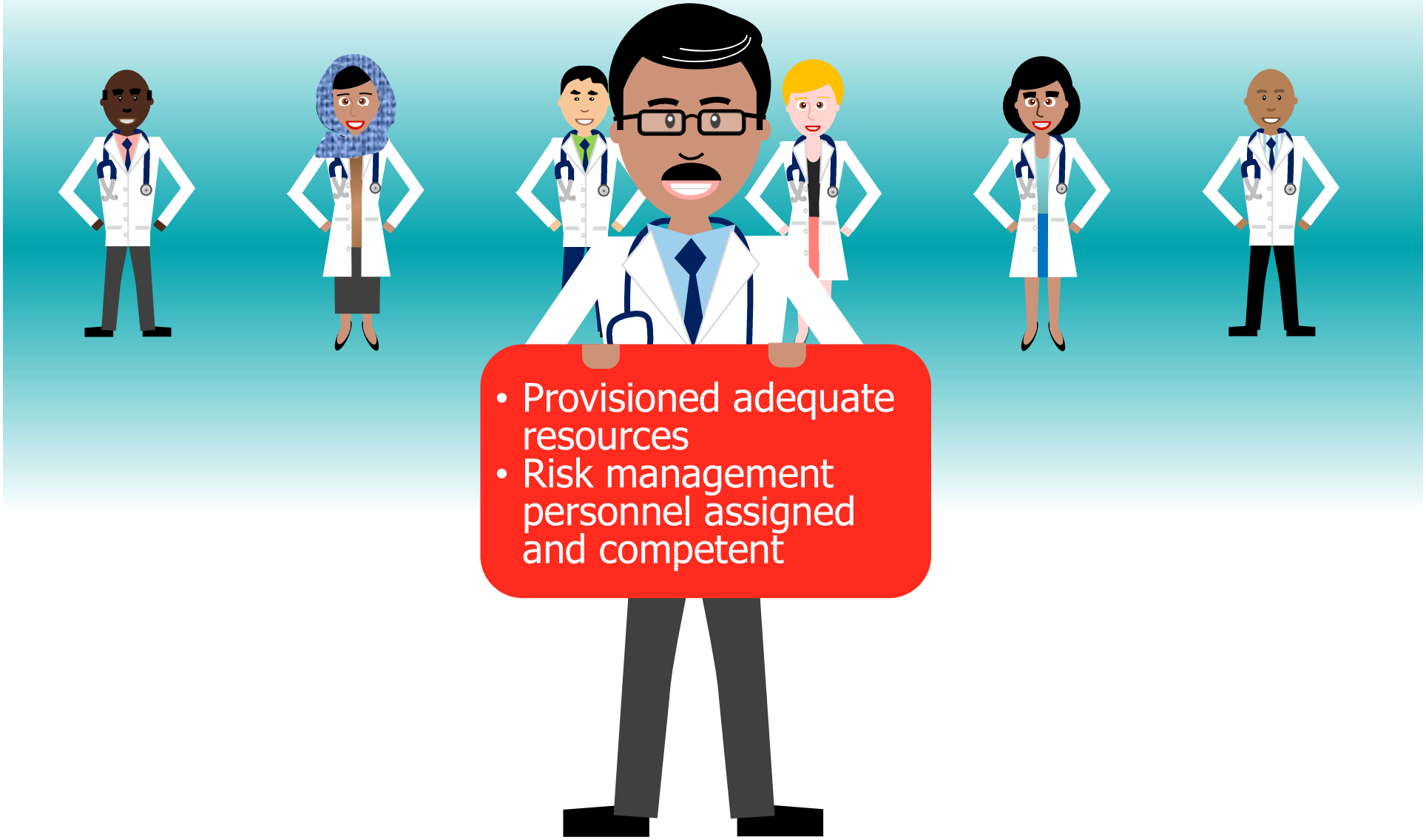
4. General requirement for risk management system

4.1 Risk management process



Adapted from ISO 14971:2019, Clause 4.1

4.2 Management responsibilities



4.3 Competence of personnel

The team should be competent, through training, experience, education or skills that are appropriate to the task

4.4 Risk management plan

4.5 Risk management file

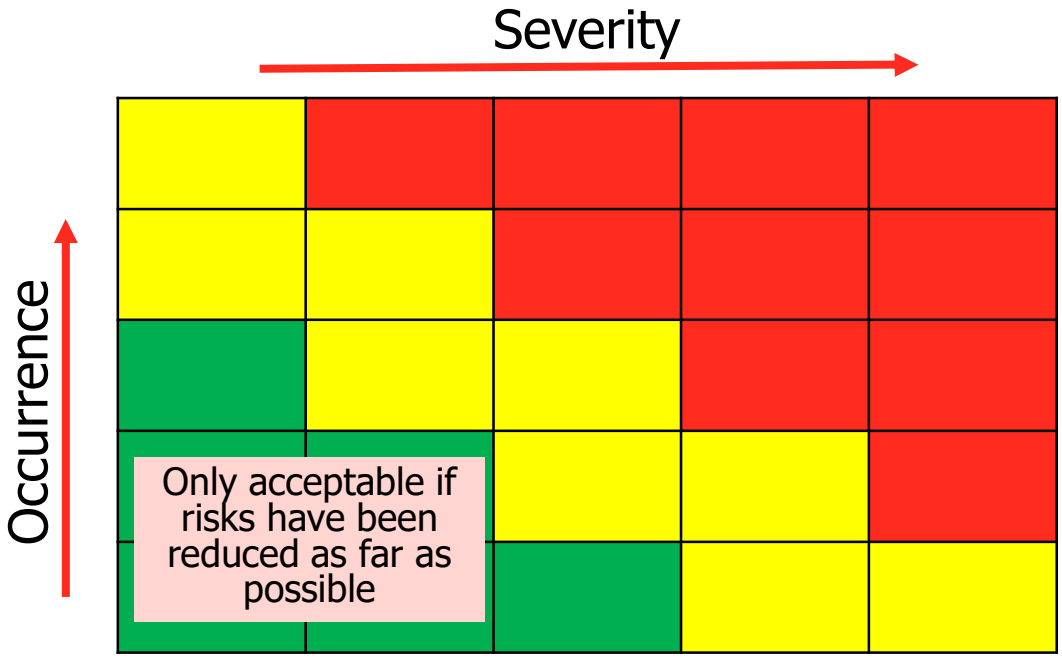
5. Risk analysis

5. Risk analysis

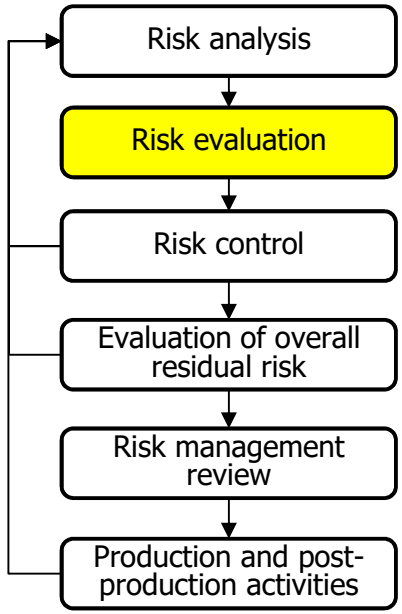
- 5.1 Risk analysis process
- 5.2 Intended use and reasonably foreseeable misuse
- 5.3 Identification of characteristics related to safety
- 5.4 Identification of hazards and hazardous situations
- 5.5 Risk estimation

6. Risk evaluation

6. Risk evaluation



Risk acceptability criteria

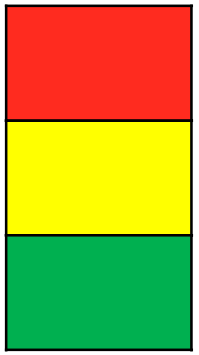


Note: ALL risks must be reduced as far as possible

Unacceptable/intolerable

Reduce as low or far as possible

Acceptable and **reduced as far as possible**



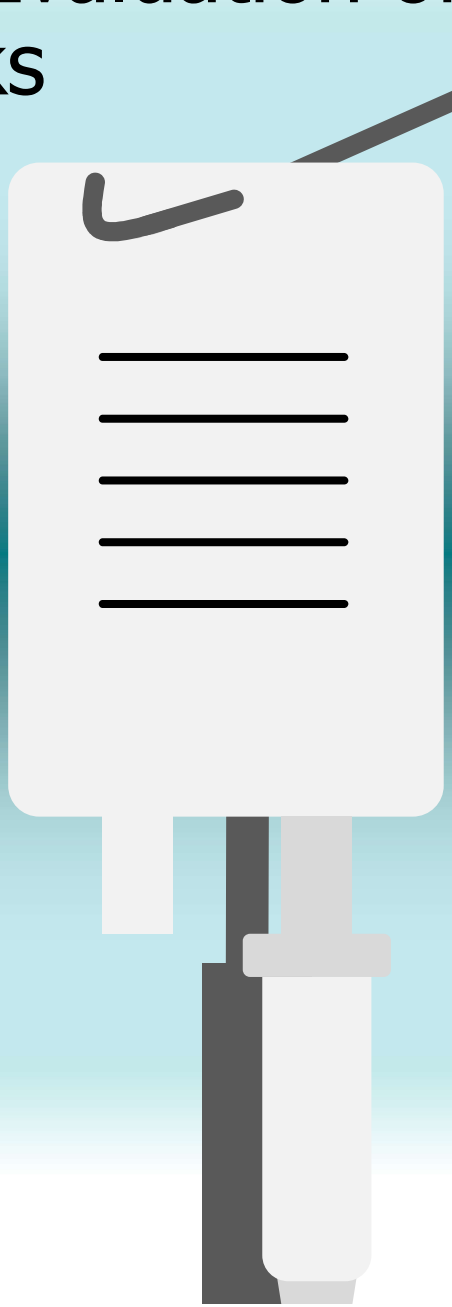
7. Risk control

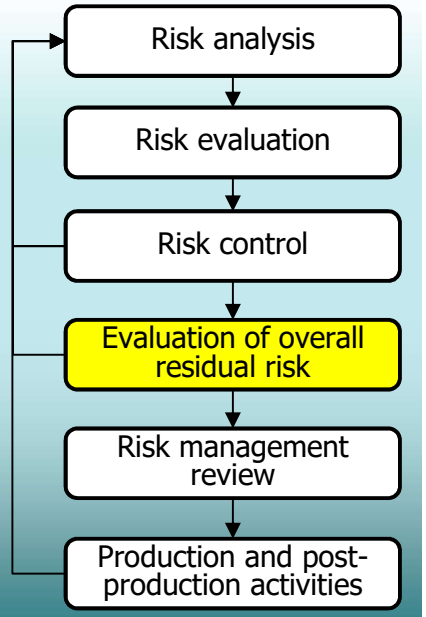
7. Risk control

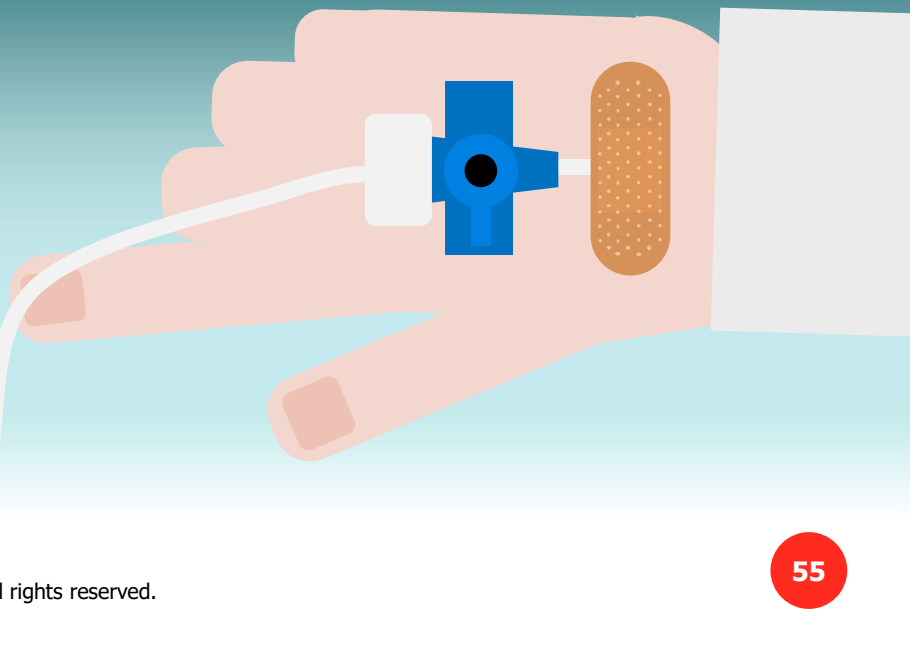
- 7.1 Risk control option analysis
- 7.2 Implementation of risk control measures
- 7.3 Residual risk evaluation
- 7.4 Benefit-risk analysis
- 7.5 Risks arising from risk control measures
- 7.6 Completeness of risk control

8. Evaluation of overall residual risk

8. Evaluation of overall residual risks

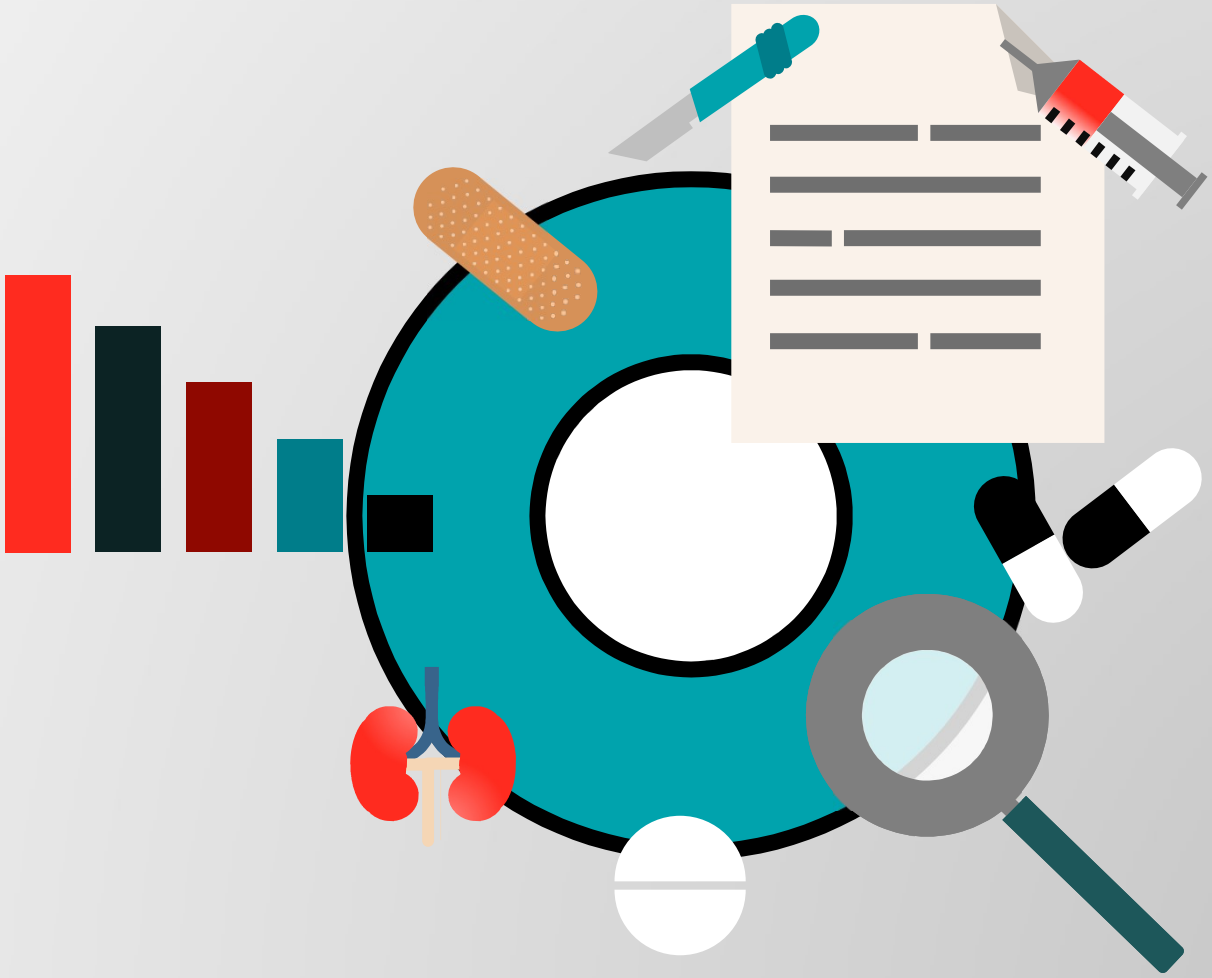


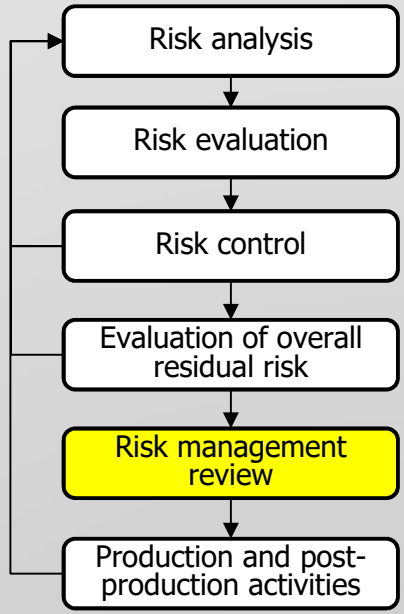




9. Risk management review

9. Risk management review





10. Production and post-production activities

10. Production and post-production activities

- 10.1 General
- 10.2 Information collection
- 10.3 Information review
- 10.4 Actions

Summary structure and requirement change in ISO 14971:2019

ISO 14971:2019 Overview of Structure and Contents

EN ISO 14971:2012

- Z Annexes (informative): 13 pages
- Main body of standard: 9 clauses, 14 pages
- 10 Annexes (informative): 68 pages

ISO 14971:2019

- Main body of standard: 10 clauses, 19 pages
- 3 Annexes (informative): 30 pages

ISO 14971:2019 Overview of Structure and Contents

ISO 14971:2019

Introduction
1. Scope
2. Normative References
3. Terms and definitions
4. General requirements for risk management
    1. Risk management process
    2. Management responsibilities
    3. Qualification of personnel
    4. Risk management plan
    5. Risk management file
5. Risk analysis
    1. Risk analysis process
    2. Intended use and reasonably foreseeable misuse
    3. Identification of characteristics related to safety
    4. Identification of hazards and hazardous situations
    5. Risk estimation
6. Risk evaluation
7. Risk control
    1. Risk control option analysis
    2. Implementation of risk control measures
    3. Residual risk evaluation
    4. Benefit-risk analysis
    5. Risks arising from risk control measures
    6. Completeness of risk control
8. Evaluation of overall residual risk
9. Risk management review
10. Production and post-production activities
    1. Information collection
    2. Information review
    3. Actions

ISO 14971:2007 / EN ISO 14971:2012

Introduction
1. Scope
2. Terms and definitions
3. General requirements for risk management
    1. Risk management process
    2. Management responsibilities
    3. Qualification of personnel
    4. Risk management plan
    5. Risk management file
4. Risk analysis
    1. Risk analysis process
    2. Intended use and identification of characteristics related to the safety of the medical device
    3. Identification of hazards
    4. Estimation of the risk(s) for each hazardous situations
5. Risk evaluation
6. Risk control
    1. Risk reduction
    2. Risk control option analysis
    3. Implementation of risk control measure(s)
    4. Residual risk evaluation
    5. Risk/benefit analysis
    6. Risks arising from risk control measures
    7. Completeness of risk control
7. Evaluation of overall residual risk acceptability
8. Risk management report
9. Production and post-production activities

ISO 14971:2019 Overview of Structure and Contents

ISO 14971:2019

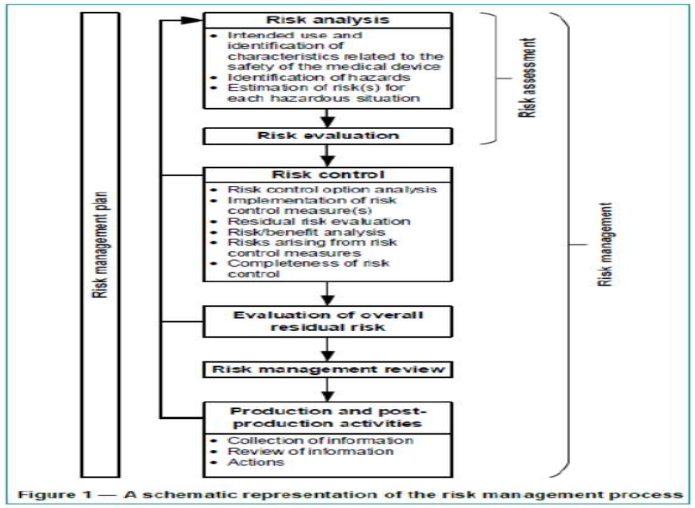


Figure 1 — A schematic representation of the risk management process

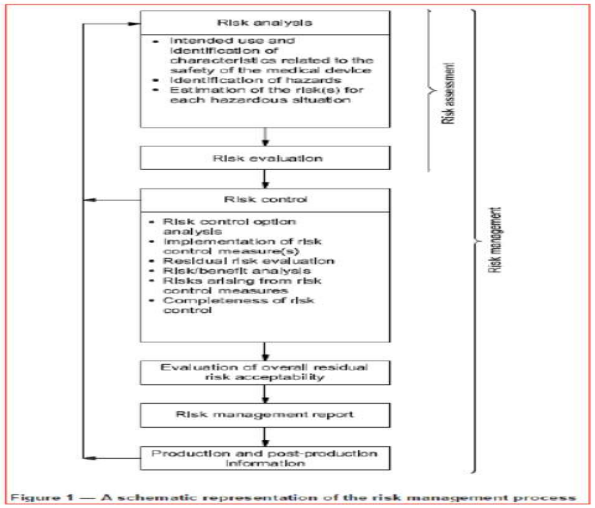
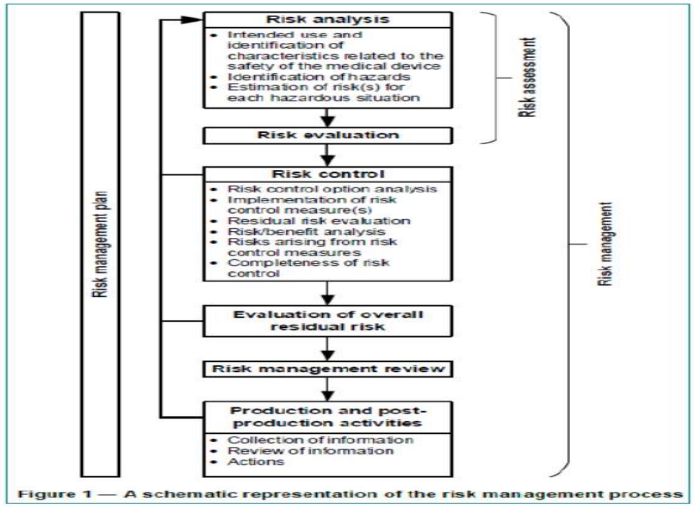


Figure 1 — A schematic representation of the risk management process

ISO 14971:2007 / EN ISO 14971:2012

ISO 14971:2019



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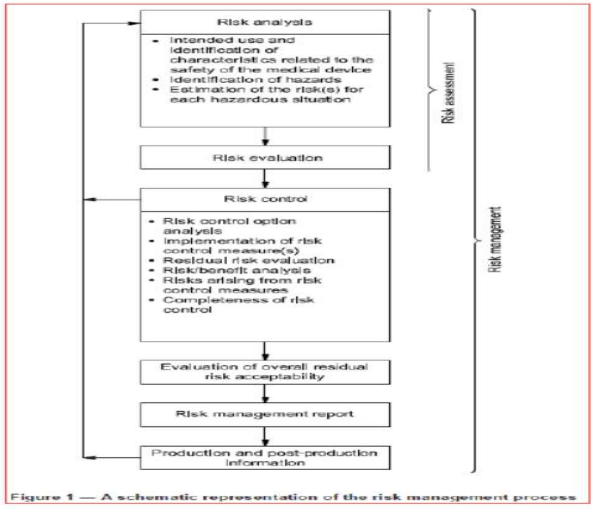

Figure 1 — A schematic representation of the risk management process

ISO 14971:2007 / EN ISO 14971:2012

ISO 14971:2019 Overview of Structure and Contents

ISO 14971:2019	ISO 14971:2007 / EN ISO 14971:2012
A. Rationale for requirements	A. Rationale for requirements
B. Risk management process for medical devices	B. Overview of the risk management process for medical devices
C. Fundamental risk concepts	C. Questions that can be used to identify medical device characteristics that could impact on safety
	D. Risk concepts applied to medical devices
	E. Examples of hazards, foreseeable sequences of events and hazardous situations
	F. Risk management plan
	G. Information on risk management techniques
	H. Guidance on risk management for in vitro diagnostic medical devices
	I. Guidance on risk analysis process for biological hazards
	J. Information for safety and information about residual risk

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ISO 14971:2019 Overview of Structure and Contents

4.4 Risk management plan (3.4)

a) the scope of the planned risk management activities, identifying and describing the medical device and the life-cycle phases for which each element of the plan is applicable;

b) assignment of responsibilities and authorities;

c) requirements for review of risk management activities;

d) criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk, including criteria for accepting risks when the probability of occurrence of harm cannot be estimated;

e) a method to evaluate the overall residual risk and the criteria for acceptability of the overall residual risk;

f) verification activities; and

g) activities related to collection and review of relevant production and post-production information.

Update to the content of Notes

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ISO 14971:2019 Overview of Structure and Contents

4.5 Risk management file (3.5)

Update to Notes only

5.1 Risk analysis process (4.1)

Update to Notes only

5.2 Intended use and reasonably foreseeable misuse & 5.3 Identification of characteristics related to safety (4.2)

Separates the requirements into two clauses
Clause 5.2 clarifies the requirement to document reasonably foreseeable misuse (see new definition also)
Requirement generally unchanged

5.4 Identification of hazards and hazardous situations (4.3)

Adds requirement for hazardous situations to be considered and documented
Refers to Annex C
This is a clarification in the standard

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ISO 14971:2019 Overview of Structure and Contents

7.2 Implementation of risk control measures (6.3)

Update to Notes
Requirement unchanged

7.3 Residual risk evaluation (6.4)

Deletion of disclosure of residual risk statement and Note
Requirement generally unchanged

7.4 Benefit-risk analysis (6.5)

Update to Notes
Requirement unchanged

7.5 Risks arising from risk control measures (6.6)

Requirement unchanged

ISO 14971:2019 Overview of Structure and Contents

7.6 Completeness of risk control (6.7)

Requirement unchanged

8 Evaluation of overall residual risk (7)

Addition of disclosure of residual risk statement
Clarification of the text
Update to Notes
Requirement generally unchanged

9 Risk management review (8)

Addition of requirement: The manufacturer shall determine when subsequent reviews of the execution of the risk management plan need to be performed and when the risk management report needs to be updated
Requirement generally unchanged

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ISO 14971:2019 Overview of Structure and Contents

10 Production and post-production activities (9)

Separated into three sub-clauses

10.1 Information collection

Clarifies the requirement and sources of information
Note on state of the art

10.2 Information review

Clarifies the requirement to review for possible relevance to safety and adds third bullet point for changes in general state of the art

10.3 Actions

Separates the actions into *particular medical device* and *risk process*
Adds consideration of devices on the market
Clarifies the requirement

Course summary

Summary

- Risk management terms and definitions
- Links between ISO 14971:2019 and ISO 13485
- Links between ISO 14971:2019 and the MDR
- Relationship between risk management activities and the product development life cycle
- Prerequisites before starting risk management activities
- Risk management process according to ISO 14971:2019

Reflective quiz

...making excellence a habit.™