“ISO 14971:2019 Medical devices- Application of risk management to medical devices”

Bob Deysher

Senior Consultant

Quality Support Group, Inc.

bob.deysher@qualitysupportgroup.com

© 2020

Agenda

- Structural Changes of ISO 14971:2019
- Changes and Additions to ISO 1971:2019
- Applicability of ISO 14971:2019
- New and Updated Definitions
- Expanded Requirements Mapped to the Risk Management Process
- EN ISO 14971:2019 & Medical Device Regulations (MDR) In-vitro Diagnostic Device Regulations (IVDR)
- Conclusions
- Questions?

© 2020

Structural Changes

Obvious Change

ISO 14971:2007 ISO 14971:2019

Item	ISO 14971:2019	ISO 14971:2007	Comments
Clauses	10	9	Normative references added
Standard Pages	19	16	Normative references added; Minimal Changes but Expanded Clause 10
Annexes	3	10	Moved to ISO/TR 24971; Justification is that this will allow more frequent updates to ISO/TR 24971 and not impact the ISO 14971 Standard. Impact – Need to buy 2 documents
Annex Pages	30	68	Fewer Annexes

ISO 14971:2019 has added more details but ISO/TR 24971:2020 becomes a companion document providing guidance for the risk management process

© 2020

ISO 14971:2019 Structure

1. **Scope**
2. **Normative references**
3. **Terms and definitions**
4. **General requirements for risk management system**
   1. Risk management process
   2. Management responsibilities
   3. Competence 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. Risk arising from risk control measures
   6. Completeness of risk control
8. **Evaluation of overall risk**
9. **Risk management review**
10. **Production and post production activities**
    1. General
    2. Information collection
    3. Information review
    4. Actions

© 2020

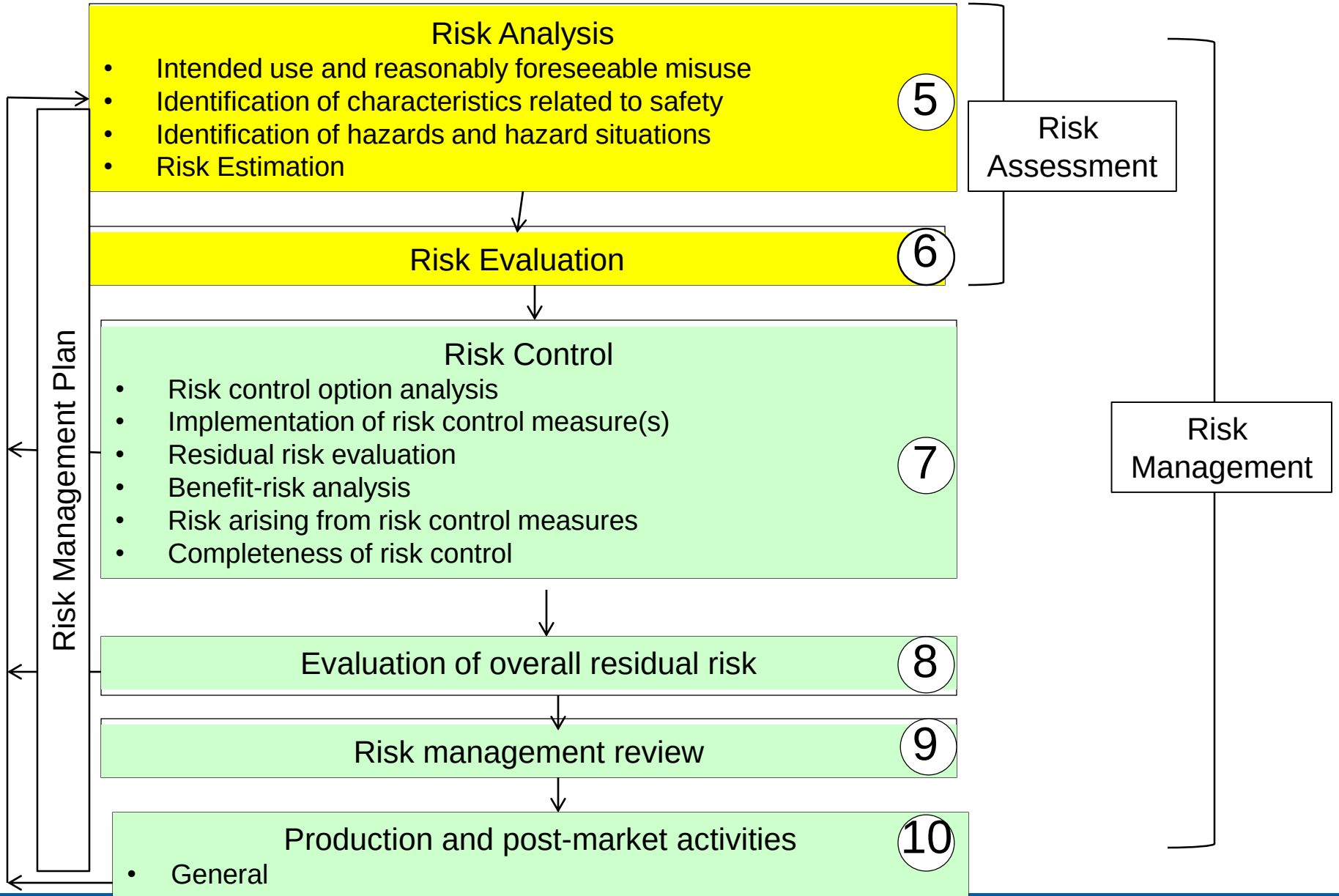


Figure 1 — A schematic representation of the risk management process

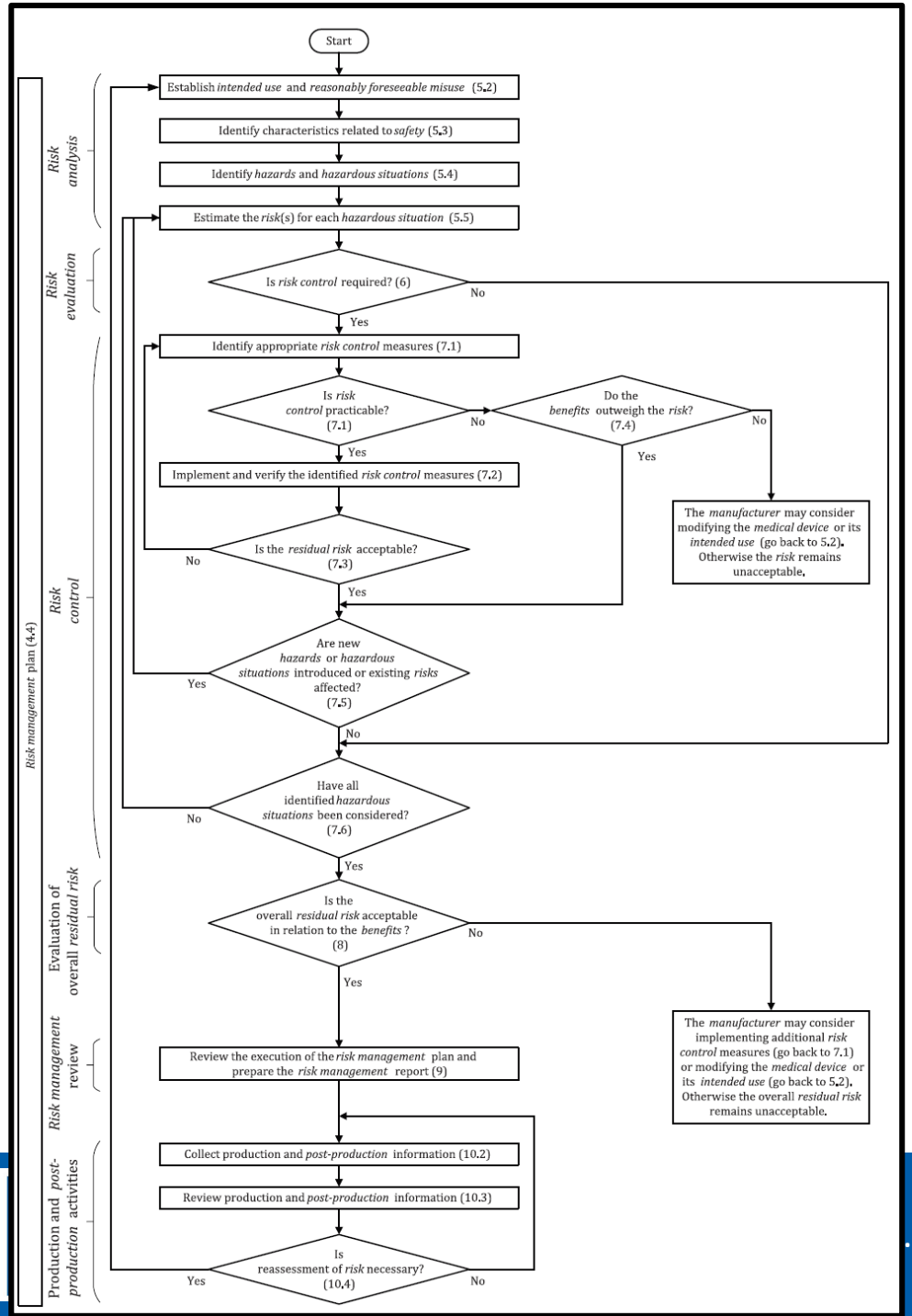
ISO 14971:2007 Annex

- Annex A Rationale for requirements
- Annex B Overview of the risk management process for medical devices
- Annex C Questions that can be used to identify medical device characteristics that could impact on safety
- Annex D Risk concepts applied to medical devices
- Annex E Examples of hazards, foreseeable sequences of events and hazardous situations
- Annex F Risk management plan
- Annex G Information on risk management techniques
- Annex H Guidance on risk management for in vitro diagnostic (IVD) medical devices
- Annex I Guidance on risk analysis process for biological hazards
- Annex J Information for safety and information about residual risk

ISO 14971:2019 Annex

- Annex A Rationale for requirements
- Annex B Risk management process for medical devices (Next Slide)
- Annex C Moved to ISO/TR 24971:20xx
- Annex D Moved to ISO/TR 24971:20xx
- Annex C Fundamental risk concepts (Next Slide)
- Annex F Moved to ISO/TR 24971:20xx
- Annex G Moved to ISO/TR 24971:20xx
- Annex H Moved to ISO/TR 24971:20xx
- Annex I Deleted
- Annex J Moved to ISO/TR 24971:20xx

© 2020

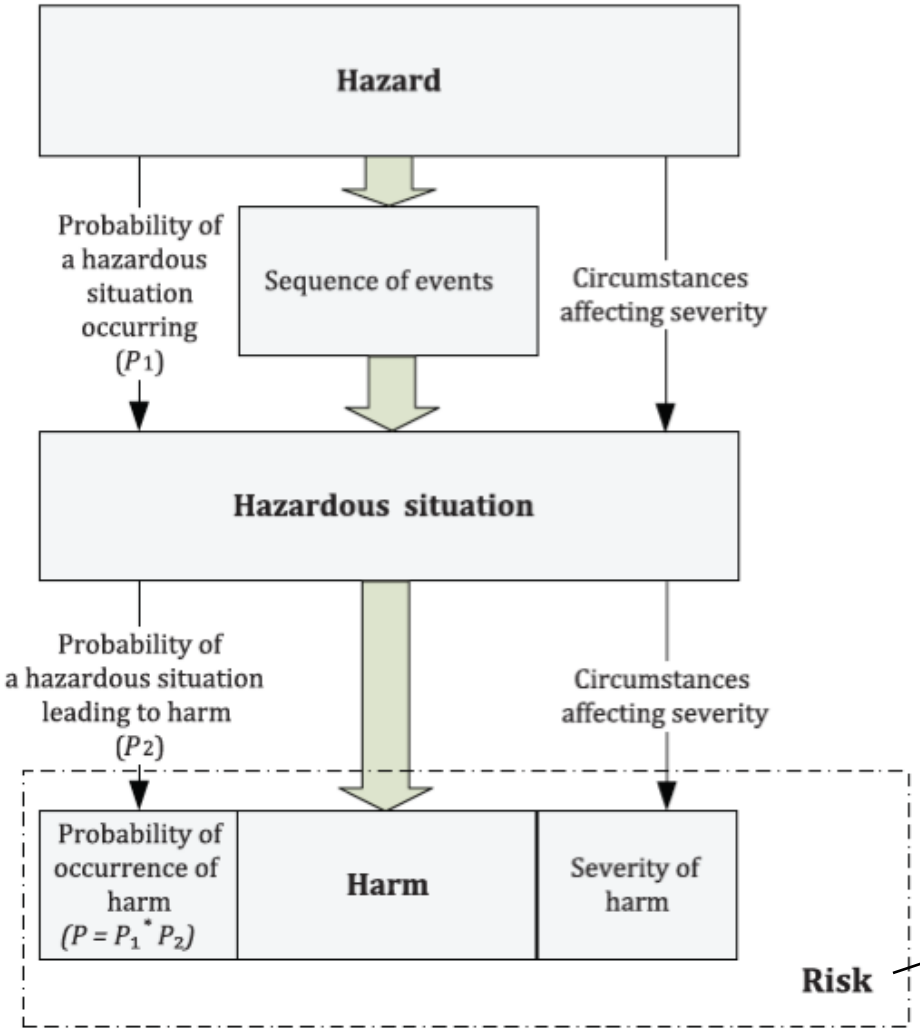


Risk management process for medical devices (Annex B)

The device manufacturer should review this flow chart while implementing risk management focusing on the decision points and feedback loops

© 2020

Fundamental Risk Concepts (Annex C)



Risk:
Combination of the probability of occurrence of harm and the severity of that harm

Figure C.1 — Pictorial example of the relationship between hazard, sequence of events, hazardous situation and harm (from ISO/IEC Guide 63:2019[2])

ISO/TR 24971:20xx Structure

- Section 1-10 (Maps to ISO 14971:2019)
- Annex A – Identification of hazards and characteristics of safety
- Annex B – Techniques that support risk analysis
- Annex C – Relationship between the policy criteria for risk acceptability, risk control, and risk evaluation
- Annex D – Differentiation of information for safety and information about residual risk
- Annex E – The role of international product safety and process standards in risk management
- Annex F – Guidance on risks related to security
- Annex G – Components and devices designed without using ISO 14971
- Annex H – Guidance on risk management for in vitro diagnostic medical devices

As of May 2020 ISO/TR 24971 has not been released

© 2020

Changes & Additions ISO 14971:2019

- Attention is given to the benefits that are expected from the use of the medical device.
- ISO 14971 can be used for managing risks associated with medical devices, including those related to data and systems security.
- Overall residual risk and the criteria for its acceptability are required.
  - The method can include gathering and reviewing data and literature for the medical device and for similar medical devices and similar other products on the market.

© 2020

Changes & Additions ISO 14971:2019

- Acceptability of the overall residual risk can be different from the criteria for acceptability of individual risks.
- Residual risks are to be disclosed after the overall residual risk has been evaluated and judged acceptable.
- The results of the review prior to commercial distribution are documented in the risk management report.
- The requirements for production and post-production activities have been clarified. More detail is given on the information to be collected and the actions to be taken.

© 2020

Applicability of ISO 14971:2019

Risk Management Definition

systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk

© 2020

Applicability of ISO 14971:2019

ISO 31000:2018

ISO 9001:2015

Focus on organizational risk

- Risk: Effect of uncertainty on objectives. Note 1 to entry: An effect is a deviation from the expected. It can be positive, negative or both, and can address, create, or result in opportunities and threats

ISO 14971:2019

ISO 13485:2016

Focus on product safety & performance risks

- Risk: Combination of the probability of occurrence of harm and the severity of that harm

© 2020

Applicability of ISO 14971:2019

- Risk management process of:
  - medical devices
  - software as a medical device
  - in vitro diagnostic medical devices.
- Assist manufacturers to:
  - identify the hazards associated with the medical device
  - estimate and evaluate the associated risks
  - control these risks
  - monitor the effectiveness of the controls at all phase of the device's life cycle
- Described risks associated related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability.

© 2020

Applicability of ISO 14971:2019

- Requires objective criteria for risk acceptability but does not specify acceptable risk levels.
- Does not require the manufacturer to have a quality management system in place.

© 2020

New Definitions

- Benefit
  - Positive impact or desirable outcome of the use of a medical device (3.10) on the health of an individual, or a positive impact on patient management or public health
  - Note 1 to entry: Benefits can include positive impact on clinical outcome, the patient's quality of life, outcomes related to diagnosis, positive impact from diagnostic devices on clinical outcomes, or positive impact on public health.
- Reasonably foreseeable misuse
  - Use of a product or system in a way not intended by the manufacturer (3.9), but which can result from readily predictable human behaviour
  - Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of users, e.g. lay and professional users.
  - Note 2 to entry: Reasonably foreseeable misuse can be intentional or unintentional.

© 2020

Key Definitions

- State of the art
  - Developed stage of technical capability at a given time as regards products, processes (3.14) 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”.

© 2020

Updated Definitions

- Accompanying documentation
  - materials ~~document~~ accompanying a medical device and containing information for the user *or those accountable* for the installation, use, maintenance*, decommissioning and disposa*l 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

© 2020

Updated Definitions

- 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 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 Notes 1-5

© 2020

Updated Definitions

- 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

© 2020

Expanded Requirements

© 2020

ISO 14971:2007 - Clauses

1 Scope

2 Normative references

3 Terms and definitions

4 General requirements for risk

- 4.1 Risk management proces
- 4.2 Management resp
- 4.3 Qualificati personnel
- 4.4 Risk management plan
- 4.5 Risk management file

- Document risk management plan for each medical device
- *A method to evaluate the overall residual risk and the criteria for acceptability of the overall residual risk*

© 2020

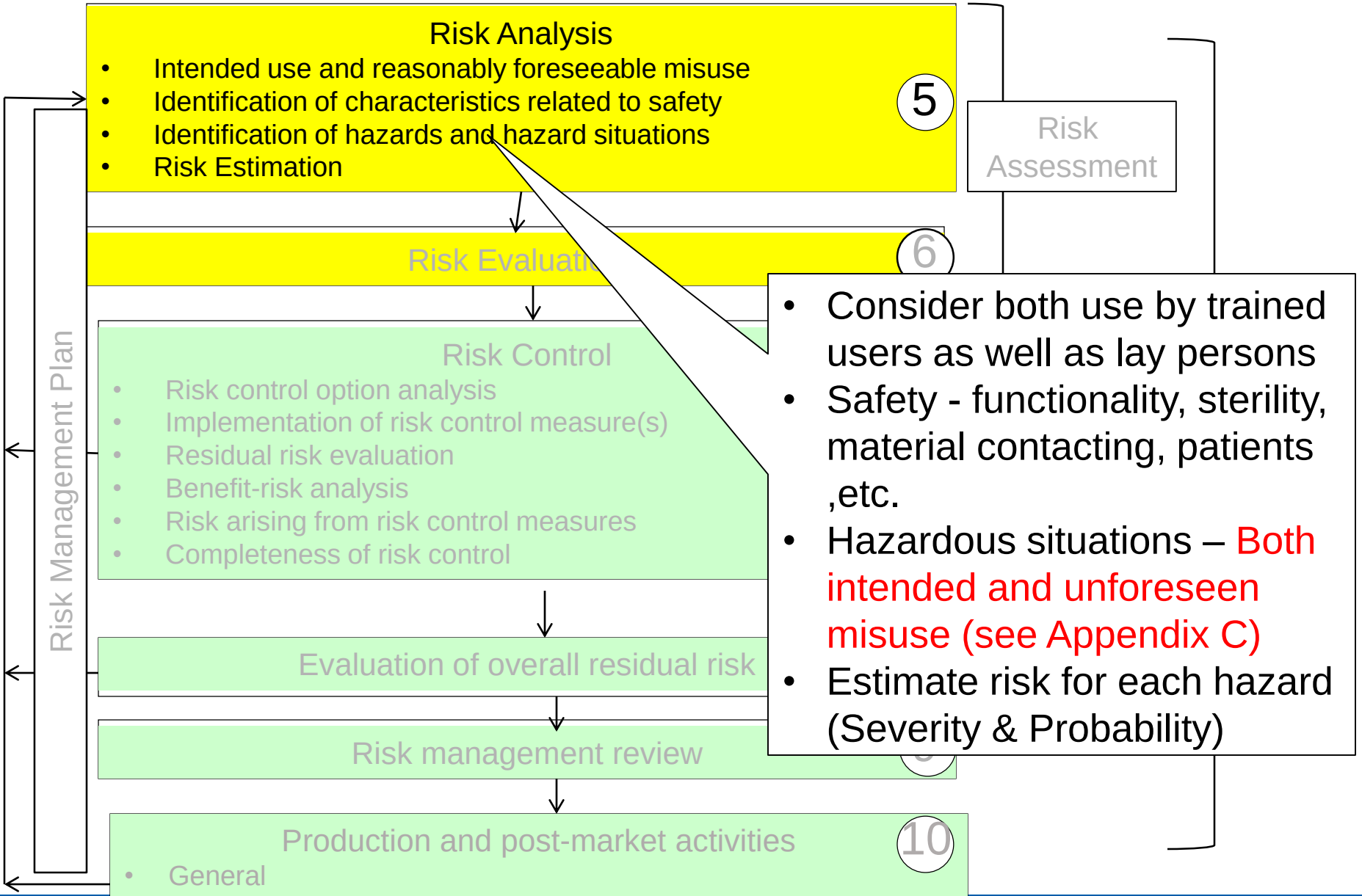
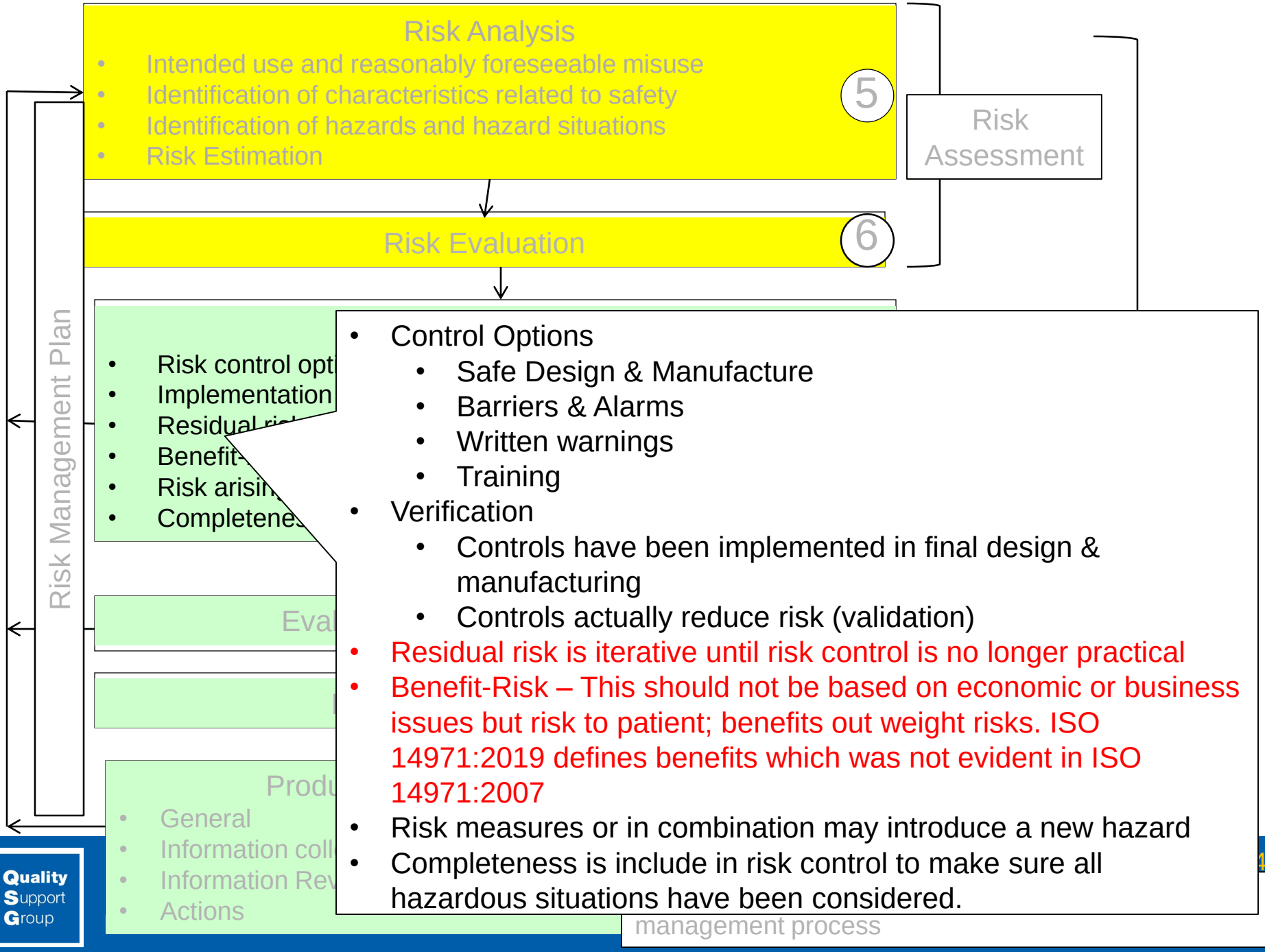


Figure 1 — A schematic representation of the risk management process


Risk Analysis
• Intended use and reasonably foreseeable misuse
• Identification of characteristics related to safety
• Identification of hazards and hazard situations
• Risk Estimation
5
Risk Assessment
Risk Evaluation
6
Risk Management Plan
• Risk control opt
• Implementation
• Residual ris
• Benefit-
• Risk arisin
• Completene
Eva
Produ
• General
• Information coll
• Information Rev
• Actions
management process
• Control Options
• Safe Design & Manufacture
• Barriers & Alarms
• Written warnings
• Training
• Verification
• Controls have been implemented in final design & manufacturing
• Controls actually reduce risk (validation)
• Residual risk is iterative until risk control is no longer practical
• Benefit-Risk – This should not be based on economic or business issues but risk to patient; benefits out weight risks. ISO 14971:2019 defines benefits which was not evident in ISO 14971:2007
• Risk measures or in combination may introduce a new hazard
• Completeness is include in risk control to make sure all hazardous situations have been considered.

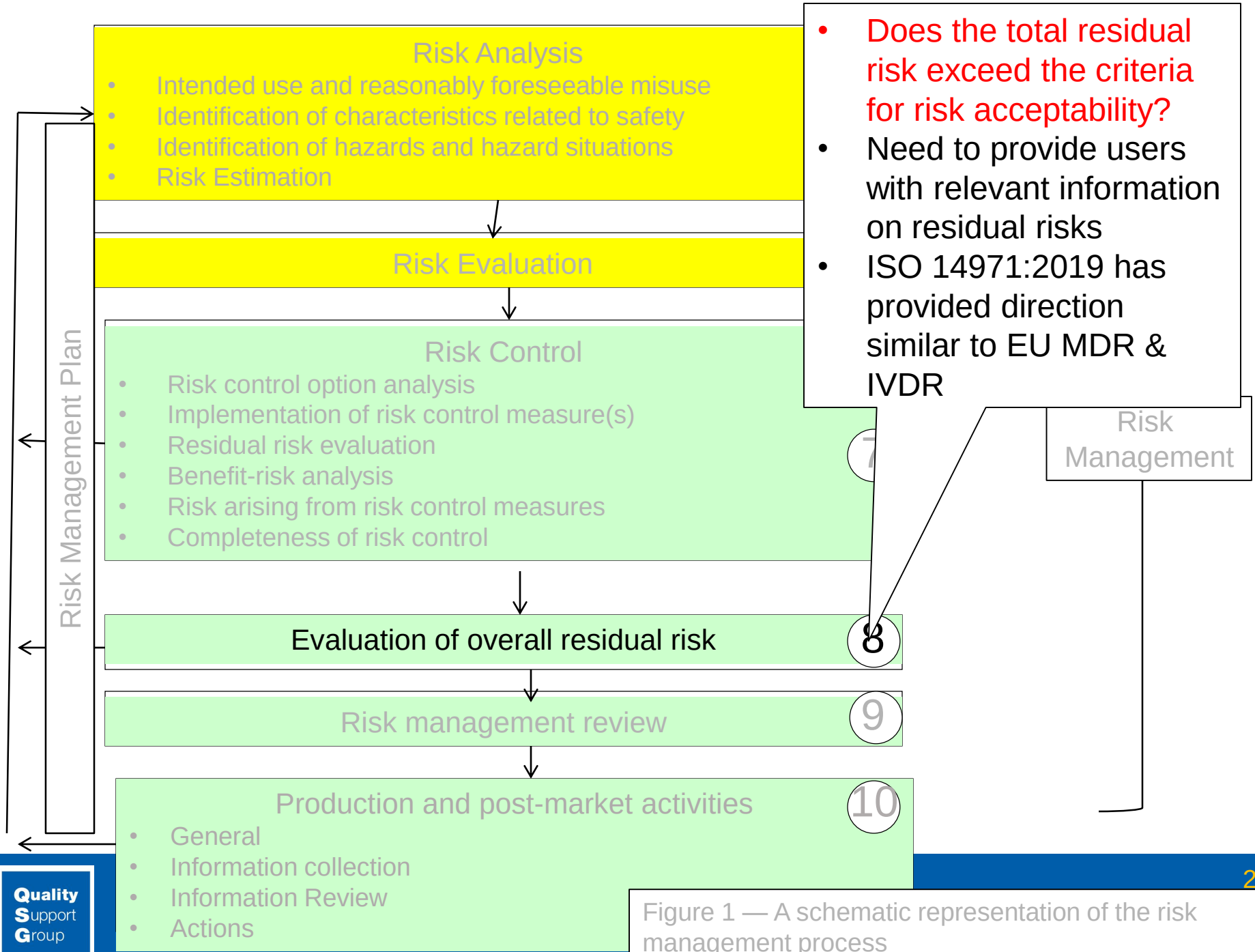


Figure 1 — A schematic representation of the risk management process

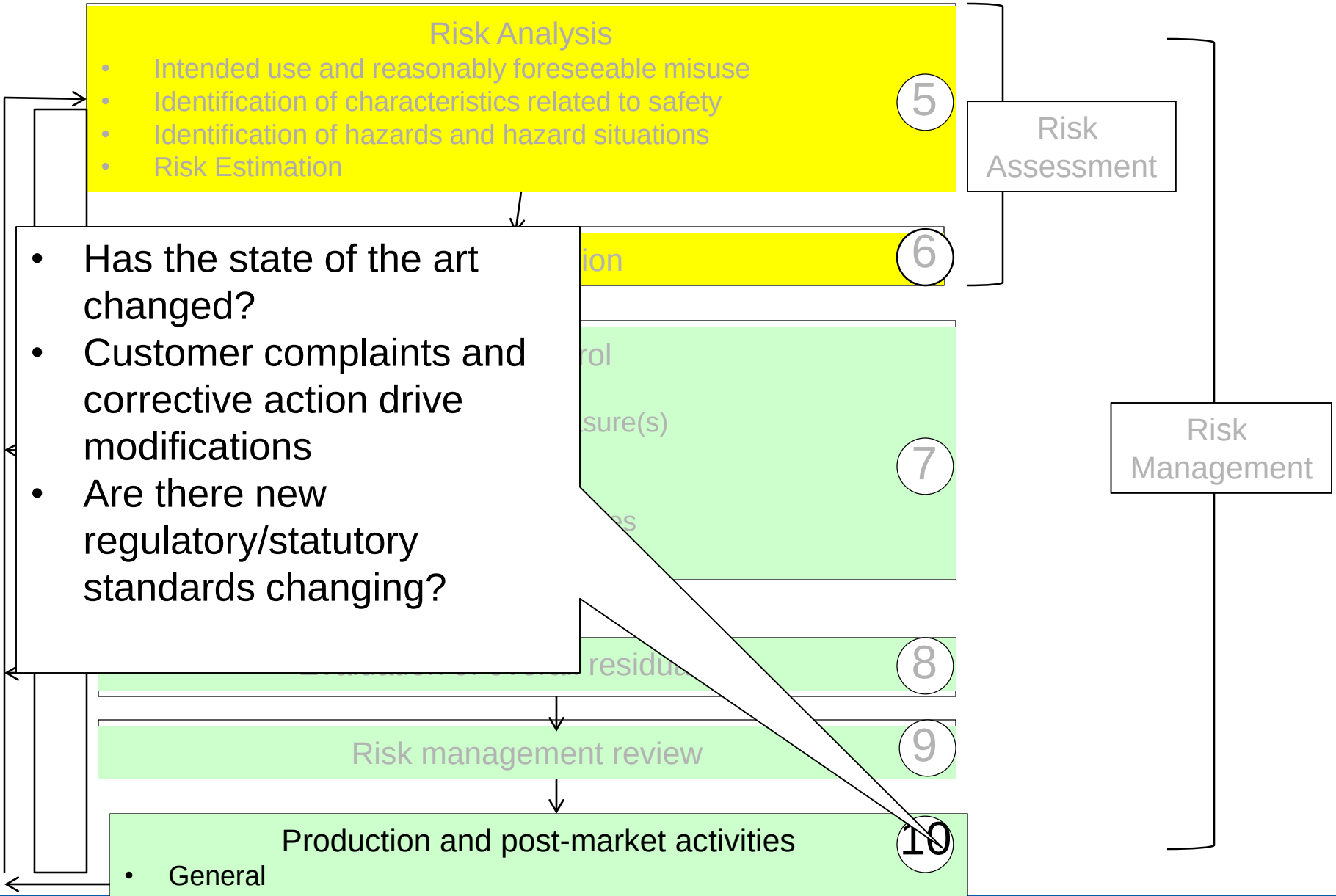


Figure 1 — A schematic representation of the risk management process

EN ISO 14971:2012 &
EN ISO 14971:2019

© 2020

EN ISO 14971:2012 – Why?

- EN ISO 14971:2012 was created to define deviations between ISO 14971:2007 and three EU directives (Medical Device Directives).
  - MDD 93/42/EEC – Medical device directives
  - AIMDD 90/385/EEC Implantable medical device directive
  - IVDD 98/97/EC In vito diagnostics directives
- Text is the same for versions 2007 and 2012
- Annexes ZA, ZB, and ZC added
  - Directives have precedence
  - Directives provide recommendations
- If you are selling medical devices in Europe use EN (Harmonized) version

© 2020

ISO 14971:2012 Key Deviations

- Reduce ALL risks as far as possible (AFAP) versus as low as reasonably practical (ALARP)
- Establish risk control for ALL risks not just the unacceptable ones until control measures do not result in risk reduction
- Identify risk–benefit analysis for ALL risks
- Risk reduction by information provided (labeling and information) to a user is not sufficient

© 2020

EN ISO 14971:2019

- The EU released EN ISO 14971:2019 in January 2020 with no Z Annexes
- EU has issued Medical Device Regulations (MDR) & In-vitro Diagnostic Device Regulations (IVDR) replacing
  - MDD 93/42/EEC – Medical device directives
  - AIMDD 90/385/EEC Implantable medical device directive
- MDR & IVDR were issued in May 2017; companies have 3 years to comply (May 2020)

  (Extended to 2021 due to COVID-19)

© 2020

EN ISO 14971:2019 (Continued)

- ISO 14971:2019 only partially covered the MDR & IVDR
  - EN ISO 14971:2019 is not ‘Harmonized” but decoupled from these regulations.
  - Common specifications were to be issued but have been delayed. In particular Clinical Evaluation & Risk Management
- Expect additional requirements to be issued by the EU against ISO 14971:2019
- If you intend to sell into the EU be aware of these requirements; meeting EN ISO 1497:2019 is not sufficient.

© 2020

Conclusions

- Only minor changes have been made to the risk process in the transition from ISO 14971:2007 to ISO 14971:2019 that clarify, explain and elaborate
- ISO 14971:2019 deals with risk of medical devices across the device life cycle with additional emphasis on production and post-production activities
- More emphasis on benefits of medical devices and balance overall residual risks with benefits
- ISO 14971 can be applies to all types of hazards and risks (data and system security, electricity, moving parts, radiation, usability)

© 2020

Questions???

© 2020

Bibliography

- *ISO 14971:2019 Medical devices – Application of risk management to medical devices*
- *"BSI - ISO 14971:2019, ISO/TR 24971:20XX"*, Peter Bowness, 2019
- *"A Look at the ISO 14971 and ISO TR 24971 Updates"*, Edwin Bills, 2018
- "*ISO 14971:2019 – Changes in the Current Version of ISO 14971*" ORIEL, February 2020
- "*What is the difference between EN and ISO versions of 14971:2019" ,* SQT, John Lafferty

© 2020

Bob Deysher - Senior Consultant Quality Support Group

Bob has over 40 years of manufacturing experience in the semiconductor industry. In that time he has held senior management positions in industrial engineering, process engineering, package assembly, manufacturing, quality, and reliability. He has also worked as a senior staff member and consulting engineer in quality and reliability in between senior managerial assignments.

At QSG, Bob's areas of training and consulting include ISO 9001 & AS9100, Toyota Production System (TPS) and Lean, Corrective Action and Problem Solving (8D), as well as Risk Based Thinking (RBT), ISO 31000, and ISO 14971

Bob has a B.S. and M.S. in Metallurgy and Material Science from Lehigh University.

© 2020

A Little About Quality Support Group

Quality Support Group Inc. (QSG) is a leading international consulting and training firm delivering organizational continuous improvement. Headquartered in Boston, Massachusetts, QSG has been helping organizations reach their core objectives since 1993.

QSG offers on-site training, public workshops, consulting, grant writing and much more.

Areas of Expertise

All Quality System Standards, Lean Six Sigma, Technical Skills (SPC, FMEA, DOE, Problem Solving), Process Improvement, Professional Development, Quality Tools, Business Management & much more.

Check out our website

www.qualitysupportgroup.com

or contact us at

info@qualitysupportgroup.com

to find out how we can help you

Always Keep Improving!

© 2020