Your Regulatory Partner

Breakfast Seminar

What can we expect in the new revision of the ISO 14971 standard?

Cristina.Barkman@QAdvis.com,
+46 704 88 88 19

QAdvis

SEK SVENSK ELSTANDARD

SIS SWEDISH STANDARDS INSTITUTE STANDARD DEVELOPER 2016

EAAR European Association of Authorised Representatives

SWEDISH Medtech

QAdvis – Key competence areas

QMS In-the-cloud

Turn Key QMS
Digital Signatures
Efficient and Lean

System Development

Product Software Validation
Computer Systems Validation
Risk Management
Verification and Validation
Process Validation

European Authorised Representation

Providing European representation for non-EU MedTech companies
Active member of EAAR (European Association of Authorized Reps)

Training/Courses

CE-Marking, MDR, IVDR
ISO 13485 & QSR & MDSAP
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
Risk Management
And more…

Agile, Lean and Six Sigma

Training and consulting in cooperation with US partner

QA&RA/Clinical Consulting

Interim Management, Expert Advise
Audits/Mock audit/Due Diligence
Warning Letters, Compliance Projects
PMA, 510k, CE-Marking, Tech Files
Global Regulatory Support
Vigilance, Recalls, PMS
Clinical Evaluation and Clinical Studies

QAdvis

Presentation of the speaker Cristina Barkman

- >20 years experience from development & manufacture of medical devices
- Extensive experience from risk management for medical devices
- Member of the standardization committee ISO/IEC TC210 JWG1

QAdvis

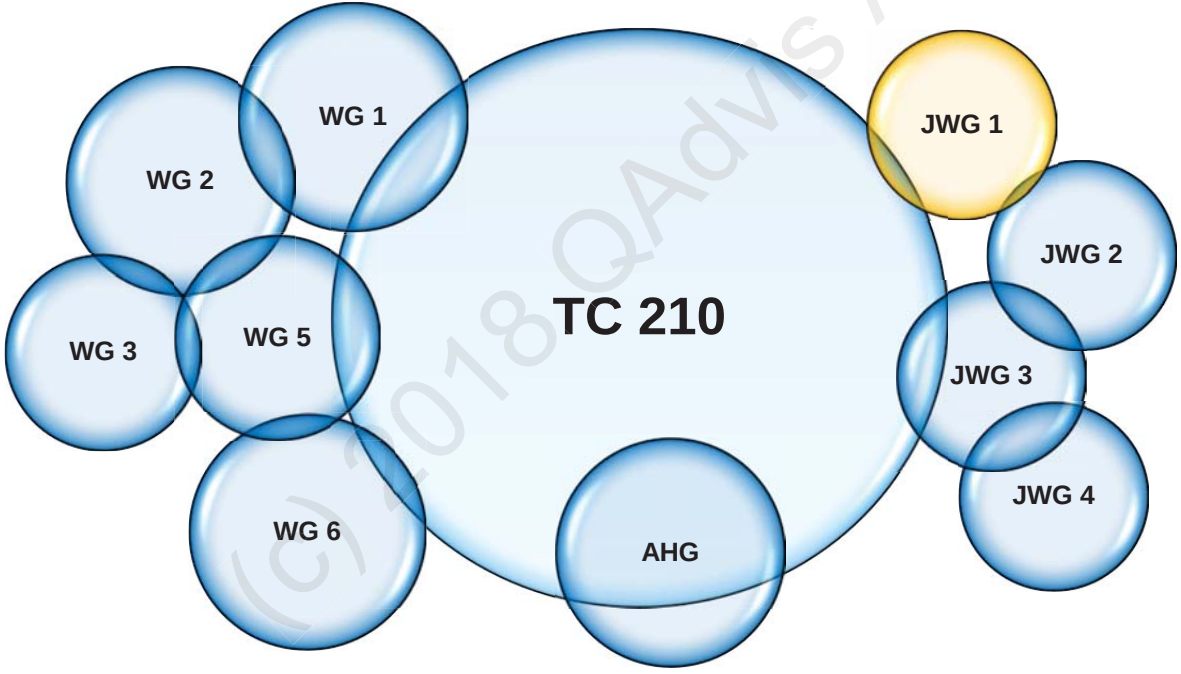
Agenda

- Standardization process
- Timeline
- Main changes in ISO 14971
- Main changes in ISO/TR 24971
- Take away notes

QAdvis

Standardization process

Standardization Process - ISO TC 210



QAdvis

Standardization process –JWG 1

- Joint work group with IEC
- Responsible for medical device risk management
- Author of ISO 14971 and ISO TR 24971
- Members – NB, FDA, competent authorities, industry representatives

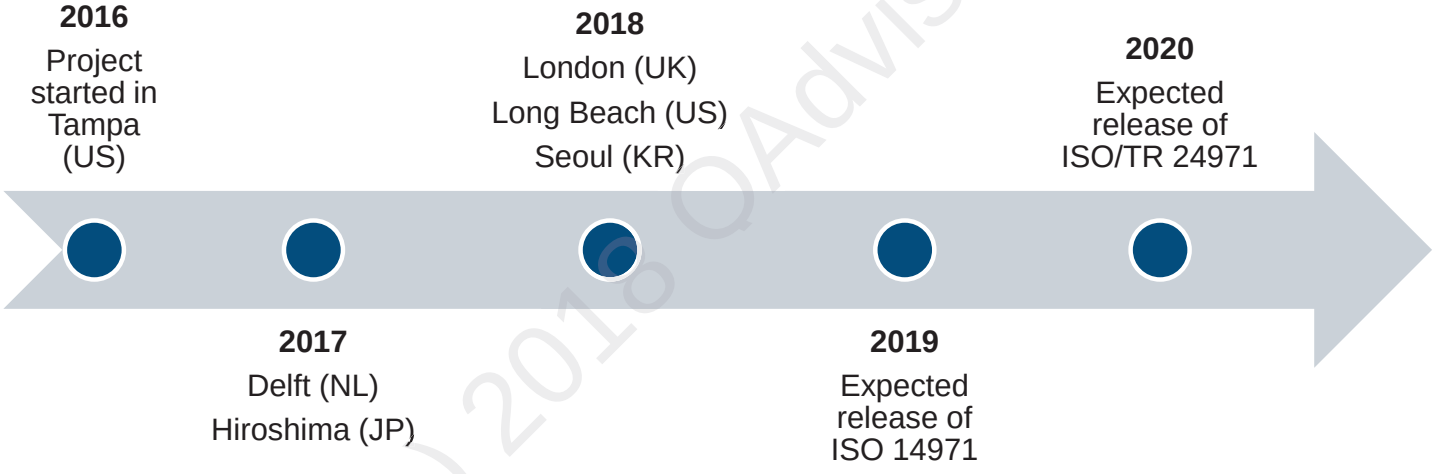
QAdvis

Standardization process - Assignment

- 2016 revision process started
- Risk management process not to be revised
- A requirement to move most informative annexes to ISO/TR 24971

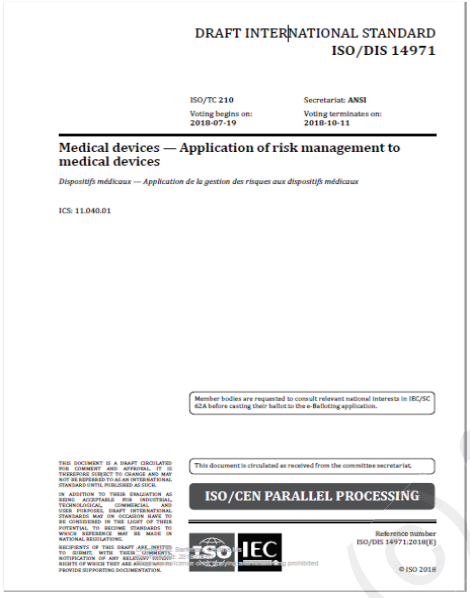
QAdvis

Timeline



QAdvis

Main changes in ISO/DIS 14971



DRAFT INTERNATIONAL STANDARD
ISO/DIS 14971

ISO/TC 210 — Secretariat: ANSI
Voting begins on: 2018-07-19 — Voting terminates on: 2018-10-11

Medical devices — Application of risk management to medical devices

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

ICS: 11.040.01

Member bodies are requested to consult relevant national interests in IEC/SC 62A before casting their ballot to the e-Balloting application.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 14971:2018(E)

© ISO 2018

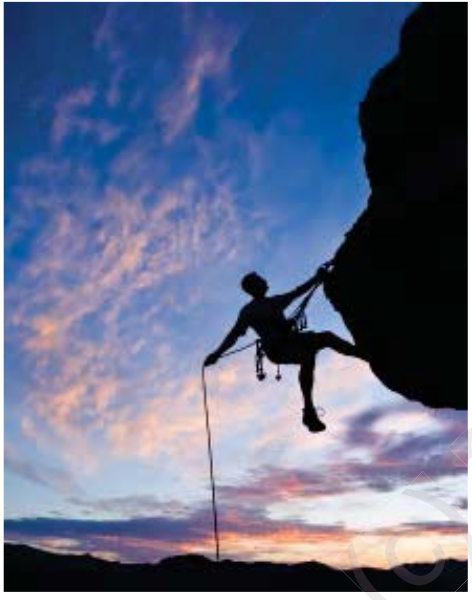
- Clauses restructured and revised
- Most annexes moved to ISO/TR 24971
- Process applicable for all types of medical device risks
- Defined terms updated
- Normative clause added

Key changes: Benefit-Risk

- Definition of benefit added
- Aligned terminology
- Benefits expected from use

QAdvis

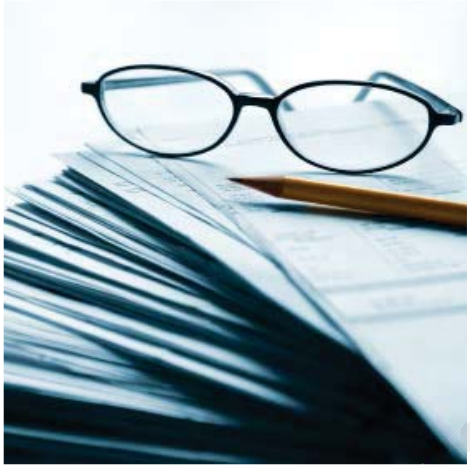
Key changes: Overall residual risk



- Method to be defined in the plan.
- Criteria for its acceptability defined in the plan.
- Criteria can be different from the criteria for acceptability of individual risks.
- Disclosure of residual risk

QAdvis

Key changes: Risk management review



- Clarified that the review concerns the execution of the risk management plan.
- The results documented as the risk management report
- Plan for subsequent reviews and updates of RMR

Key changes: Production and post-production activities

- More detail on information to be collected and reviewed.
- More detail on actions to take when the information is determined to be relevant to safety.

QAdvis

Key changes: Annexes

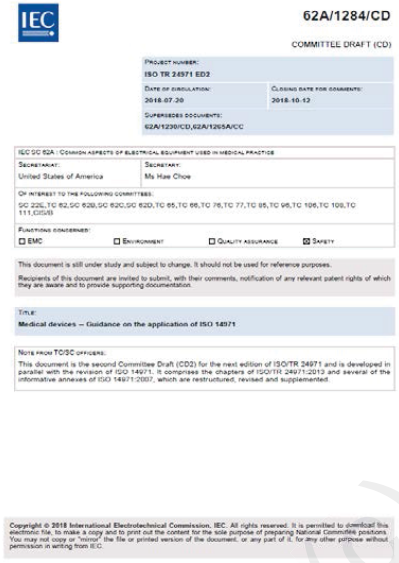
ISO 14971:2007	ISO 14971:2019
Annex A Rationale for requirements	**Annex A** Rationale for requirements
Annex B Overview of the risk management process for medical devices	**Annex B** Overview of the risk management process for medical devices
Annex C Questions that can be used…	Moved to ISO/TR 24971
Annex D Risk concepts applied to medical …	
Annex E Examples of hazards, …	**Annex C** Fundamental risk concepts
Annex F Risk management plan	Moved to ISO/TR 24971
Annex G Information on risk mgm techniques	
Annex H Guidance on risk mgm for in-vitro …	
Annex I Guidance on risk analysis process…	
Annex J Information for safety and about …	

QAdvis

Harmonization with European directives and regulations

- Harmonization done by the European Commission
- No timeline for harmonization yet
- Proposal for Annexes Z by JWG 1

Main changes in ISO/TR CD2 24971



62A/1284/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:
ISO TR 24971 ED2

DATE OF CIRCULATION: 2018-07-20

CLOSING DATE FOR COMMENTS: 2018-10-12

SUPERSEDES DOCUMENTS:
62A/1230/CD,62A/1265A/CC

IEC SC 62A: COMMON ASPECTS OF ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE

SECRETARY: United States of America

SECRETARY: Ms Hae Choe

OF INTEREST TO THE FOLLOWING COMMITTEES:
SC 22E,TC 62,SC 62B,SC 62C,SC 62D,TC 65,TC 66,TC 76,TC 77,TC 95,TC 96,TC 106,TC 109,TC 111,CISPR

FUNCTIONS CONCERNED:
☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

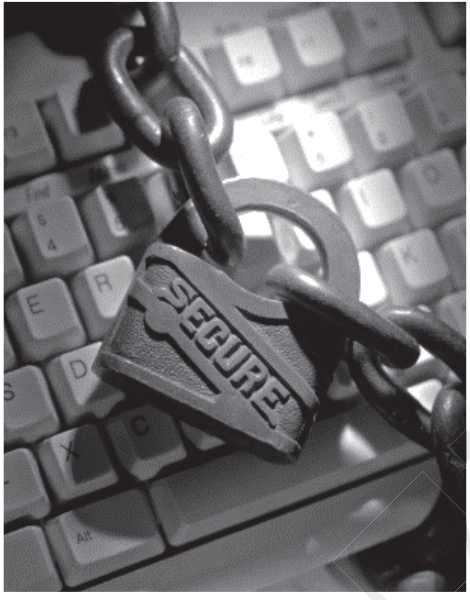
TITLE:
Medical devices – Guidance on the application of ISO 14971

NOTE FROM TC/SC OFFICERS:
This document is the second Committee Draft (CD2) for the next edition of ISO/TR 24971 and is developed in parallel with the revision of ISO 14971. It comprises the chapters of ISO/TR 24971:2013 and several of the informative annexes of ISO 14971:2007, which are restructured, revised and supplemented.

- Developed in parallel with the revision of ISO 14971.
- Comprises the chapters of ISO/TR 24971:2013
- Includes most annexes of ISO 14971:2007
- Entire document restructured, revised and supplemented.
- NEW Annex on risks related to cybersecurity

QAdvis

Cybersecurity risks



- Process also suitable for cybersecurity risks
- Correspondence between terms
- Overlapping between health risks and cybersecurity risks

QAdvis

Main changes: Overview of new structure

CONTENT	
1 Scope	**10** Production and post-production activities
2 Normative references	**Annex A** Identification of hazards and characteristics for safety
3 Terms and definitions	**Annex B** Risk analysis techniques
4 General requirements for risk management	**Annex C** Risk acceptability considerations
5 Risk Analysis	**Annex D** Information for safety and information on residual risk
6 Risk Evaluation	**Annex E** Role of international standards in risk management
7 Risk Control	**Annex F** Guidance on risk related to cybersecurity
8 Evaluation of residual risk	**Annex G** Components and devices designed not using ISO 14971
9 Risk management review	**Annex H** Guidance for in-vitro diagnostic devices

Take away notes

- **No risk management revolution!**
- Keep informed
- Train
- Prepare your processes & files

QAdvis

QAdvis services

- **Implementation of QMS**
- **Development of product documentation**
- **Risk management/Clinical evaluation**
- **Software validation**
- **Training**
- **Implementation of tools**

QAdvis