MEDTECH INSIGHT
CITELINE COMMERCIAL

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Crosswalk: ISO 14971:2007 Vs. ISO 14971:2019

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Here's a crosswalk for recently revised international risk management standard ISO 14971 and its 2007 predecessor.

Below is a crosswalk for the clauses and subclauses in the previous version (2007) of international risk management standard ISO 14971 and the new 2019 edition. (*Check out our related ISO 14971:2019 story* for tips on bringing the retooled standard into quality systems, and more.)

ISO 14971:2007	ISO 14971:2019
1 Scope	1 Scope
(New clause)	2 Normative references
2 Terms and definitions	3 Terms and definitions
2.1 accompanying documentation	3.1 accompanying documentation
(New definition)	3.2 benefit
2.2 harm	3.3 harm
2.3 hazard	3.4 hazard
2.4 hazardous situation	3.5 hazardous situation
2.5 intended use intended purpose	3.6 intended use intended purpose
2.6 *in vitro* diagnostic medical device IVD medical device	3.7 *in vitro* diagnostic medical device IVD medical device
2.7 life cycle	3.8 life cycle
2.8 manufacturer	3.9 manufacturer
2.9 medical device	3.10 medical device
2.10 objective evidence	3.11 objective evidence

2.11 post-production	3.12 post-production
2.12 procedure	3.13 procedure
2.13 process	3.14 process
(New definition)	3.15 reasonably foreseeable misuse
2.14 record	3.16 record
2.15 residual risk	3.17 residual risk
2.16 risk	3.18 risk
2.17 risk analysis	3.19 risk analysis
2.18 risk assessment	3.20 risk assessment
2.19 risk control	3.21 risk control
2.20 risk estimation	3.22 risk estimation
2.21 risk evaluation	3.23 risk evaluation
2.22 risk management	3.24 risk management
2.23 risk management file	3.25 risk management file
2.24 safety	3.26 safety
2.25 severity	3.27 severity
(New definition)	3.28 state of the art
2.26 top management	3.29 top management
2.27 use error	3.30 use error
2.28 verification	3.31 verification
3 General requirements for risk management	4 General requirements for risk management system
3.1 Risk management process	4.1 Risk management process
3.2 Management responsibilities	4.2 Management responsibilities
3.3 Qualification of personnel	4.3 Competence of personnel
3.4 Risk management plan	4.4 Risk management plan
3.5 Risk management file	4.5 Risk management file
4 Risk analysis	5 Risk analysis
4.1 Risk analysis process	5.1 Risk analysis process
4.2 Intended use and identification of characteristics related to the safety of the medical device	5.2 Intended use and reasonably foreseeable misuse 5.3 Identification of characteristics related to safety
4.3 Identification of hazards	5.4 Identification of hazards and hazardous situations
4.4 Estimation of the risk(s) for each hazardous situation	5.5 Risk estimation
5 Risk evaluation	6 Risk evaluation

6 Risk control	7 Risk control
6.1 Risk reduction	(Subclause deleted)
6.2 Risk control option analysis	7.1 Risk control option analysis
6.3 Implementation of risk control measure(s)	7.2 Implementation of risk control measures
6.4 Residual risk evaluation	7.3 Residual risk evaluation
6.5 Risk/benefit analysis	7.4 Benefit-risk analysis
6.6 Risks arising from risk control measures	7.5 Risks arising from risk control measures
6.7 Completeness of risk control	7.6 Completeness of risk control
7 Evaluation of overall residual risk acceptability	8 Evaluation of overall residual risk
8. Risk management report	9 Risk management review
9 Production and post-production information	10 Production and post-production activities 10.1 General 10.2 Information collection 10.3 Information review 10.4 Actions
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 *in vitro* diagnostic medical devices	Moved to ISO/TR 24971
Annex I Guidance on risk analysis process for biological hazards	Deleted
Annex J Information for safety and	Moved to ISO/TR 24971

information about residual risk	