MECA ISO 14971 Risk Management Guidance-Review Document (for IEC 60601-1, Clause 4.2.2 Requirements)

See examples of compliant risk management sections after tables.

The purpose of this document is to identify the ISO 14971 requirements to meet Clause 4.2.2 of IEC 60601-1, and to specify where each item is located in your risk management documentation (document and section or page). Each of the specified required items must be in your risk documentation. Since these process requirements are not device-specific, all must be considered applicable. Your risk management documentation must specify how you address each of these requirements. For a specific device, some may not be applicable (such as risk-benefit analysis), but there needs to be a documented process of how it would be applied if it were applicable.

External References:
IEC 60601-1:2012, Edition 3 + Amendment 1 (Edition 3.1); ISO 14971:2007 Medical devices - Application of risk management to medical devices
Note: For IEC60601-1 clause requirements, see separate MECA IEC 60601-1 Risk Management Guidance-Review Document
Note: Differences in the European National Standard EN ISO 14971:2012 are not applicable to the compliance to IEC 60601-1
Note: This document is not a replacement for the ISO 14971 or IEC 60601-1 standard, and does not include the full text of any referenced clauses or requirements, so a purchased copy of the standards should also be used.

Enter the location for each of the required risk management items (document number and page or section). This will be used in the IEC 60601-1 evaluation to verify the required risk management information is provided, and to document the location in the compliance report (IECEE TRF).

ISO 14971 Clause	ISO 14971 RM Document: Location:	Clause Requirement
3.1	-	Risk Management Process (IEC 60601-1 excludes production and post-production)
	-	The following items shall be documented in the risk management procedure:
	-	That an ongoing process is established, documented and maintained for:
		- Identifying hazards
		- Estimating, evaluating and controlling the risks
		- Monitoring the effectiveness of risk controls
	-	That the process shall include these elements:
		- Risk analysis
		- Risk evaluation
		- Risk control
	-	That if a documented product realization process exists, it shall:
		- Incorporate the appropriate parts of the risk management process
3.2	-	Management Responsibilities
	-	The following items shall be documented in the risk management procedure:
		Evidence that top management is committed to providing adequate Resources
3.2	-	Management Responsibilities
	-	The following items shall be documented in the risk management procedure:
		Evidence that top management is committed to the assignment of Qualified Personnel
3.2	-	Management Responsibilities
	-	The following items shall be documented in the risk management procedure:
	-	That a policy is designed and documented for:
		- Determining Criteria for Risk Acceptability
	-	That management policy ensures criteria based on:
		- National/regional regulations and international standards
		- Takes into account known stakeholder concerns and accepted state of the art

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3.3	-	Qualification of Personnel
	-	Specify that the following items shall be documented in the device risk management file:
	-	Risk management tasks are completed by persons having:
		- The knowledge and experience appropriate to the tasks they are assigned, including
		* Device experience
		* Technical experience
		* Risk management techniques, as appropriate
		- Qualification records are maintained
3.4	-	Risk Management Plan
	-	Specify that the following items shall be documented in the device risk management file:
	-	That risk management activities shall:
		- Be planned
		- Include changes to the plan made over the life-cycle of the device
	-	That plans shall be prepared for particular medical devices/accessories, and shall include at a minimum:
3.4a	-	Scope
	-	Specify that the following items shall be documented in the device risk management file:
	-	Scope of the planned activities identifying the medical device, including:
		- Description of the device
		- Life-cycle phases covered by the plan
3.4b	-	Assignment of Responsibilities and Authorities
	-	Specify that the following items shall be documented in the device risk management file:
		Specification of the assignment of responsibilities and authorities
3.4c	-	Review Requirements for Risk Management Activities
	-	Specify that the following items shall be documented in the device risk management file:
		Specification of the review requirements for risk management activities
3.4d	-	Criteria for Risk Acceptability
	-	Specify that the following items shall be documented in the device risk management file:
		Criteria based on the manufacturers policy
		Criteria for accepting risks when the probability cannot be estimated
3.4e	-	Verification Activities
	-	Specify that the following items shall be documented in the device risk management file:
		Specification of the verification activities
3.4f	-	Production and Post-Production
	Not required by IEC 60601-1 Ed.3.1	Collection & review of production and post-production information
3.5	-	Risk Management File
	-	Specify that the following items shall be documented in the device risk management file:
		That a risk management file shall be established for each device
	-	That the risk management file shall provide traceability for each hazard to:
		- Risk analysis

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		- Risk evaluation
		- Implementation and verification of mitigations (control measures)
		- Assessment of residual risk acceptability
4.1	-	Risk analysis process
	-	Specify that the following items shall be documented in the device risk management file:
		That a risk analysis shall be performed
		That implementation of the planned activities and result of the risk analysis shall be documented
	-	That the risk analysis shall include at a minimum:
		a) Description & identification of the items covered
		b) Identification of personnel performing the risk analysis
		c) Scope and date of the risk analysis
4.2	-	Product Specifications (Intended Use and Characteristics Related to the Safety)
	-	Specify that the following items shall be documented in the device risk management file:
		- Intended use and reasonably foreseeable misuse identified
		- Listing of characteristics (qualitative and quantitative) that could impact the safety of the medical device
		- Any appropriate limits
4.3	-	Identification of Hazards
	-	Specify that the following items shall be documented in the device risk management file:
		- List compiled of known and foreseeable hazards for the device in normal and fault conditions
4.4	-	Estimation of the Risk(s) For Each Hazardous Situation
	-	Specify that the following items shall be documented in the device risk management file:
		- Reasonably foreseeable sequences/combinations of events leading to hazardous situations considered
		- The hazardous situation is recorded
		- Risk(s) for each hazardous situation shall be estimated using available data or information
		- Where the probability of occurrence cannot be estimated, the resulting consequences shall be identified for use in the risk evaluation/control
		- Activities are recorded in the risk management file
		- Any systems used for qualitative/quantitative categorization of probability/severity shall be documented in the risk management file
5	-	Risk Evaluation
	-	Specify that the following items shall be documented in the device risk management file:
		- All identified hazardous situation shall be evaluated to determine if risk reduction is required, based on the criteria defined in the plan
		- The results of the evaluation are recorded in the risk management file
6.1	-	Risk Reduction
	Not required by IEC 60601-1 Ed.3.1	- Where reduction is required, risk control activities are performed
6.2	-	Risk Control Option Analysis
	-	Specify that the following items shall be documented in the device risk management file:
		That risk control measures appropriate for reducing risks to an acceptable level shall be identified
	-	That one or more risk control measures shall be applied in the following priority:
		a) Safety by design (inherent) - elimination of the hazard or hazardous situation

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		b) Protective measures in the device or manufacturing process
		- Prevent the hazard or hazardous situation from occurring
		c) Information for safety
		- Provide warnings related to the hazard or hazardous situation
		That the selected risk control measure shall be documented in the risk management file
		That where further risk reduction is impractical, a risk/benefit analysis of the residual shall be performed
6.3	-	Implementation of Risk Control Measure(s)
	-	Specify that the following items shall be documented in the device risk management file:
		That selected risk control measures shall be implemented
		That the implementation and its effectiveness shall be verified and documented in the risk management file
6.4	-	Residual Risk Evaluation
	-	Specify that the following items shall be documented in the device risk management file:
		That risk remaining after the implementation of the risk control shall be evaluated against the criteria in the risk management plan
		That further risk control shall be applied where the residual risk is not judged acceptable
		That for acceptable residual risk, the manufacturer shall determine which residual risks to disclose (including what information is necessary)
	-	*NOTE: this is looking at each risk individually*
6.5	-	Risk/Benefit Analysis
	-	Specify that the following items shall be documented in the device risk management file:
		That for residual risk not meeting the criteria for risk acceptability where further risk control is impractical, the manufacturer may gather data/literature to determine if benefit of the device outweighs the residual risk (If not, the risk remains unacceptable)
		That where the benefit outweighs the residual risk, the manufacturer shall identify any information for safety required to disclose the residual risk
		That this review shall be documented in the risk management file
		That this assessment is performed on individual risks
6.6	-	Risks arising from risk control measures
		That the impact of risk controls shall be reviewed with regard to risks arising from control measures:
6.6a	-	Introducing New Hazards/Hazardous Situations
	-	Specify that the following items shall be documented in the device risk management file:
		That the impact on risk controls are reviewed for **introducing new hazardous situations**
		That any new/increased risks are subjected to the requirements of this standard and documented in the risk management file
6.6b	-	Effect on the Estimated Risks for Previously Identified Hazardous Situations
	-	Specify that the following items shall be documented in the device risk management file:
		That the impact on risk controls are reviewed for **the effect on the estimated risks for previously identified hazardous situations**
		That any new/increased risks are subjected to the requirements of this standard and documented in the risk management file
6.7	-	Completeness of Risk Control
	-	Specify that the following items shall be documented in the device risk management file:
		That an assessment shall be performed to ensure that risks from all identified hazardous situations have been considered
		That this assessment shall be documented in the risk management file

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7	-	Overall Residual Risk Acceptability
	-	Specify that the following items shall be documented in the device risk management file:
	-	That following implementation & verification of all risk control measures:
		- Manufacturer shall determine if the overall residual risk of the device is acceptable, based on the criteria defined in the risk management plan
	-	*NOTE: this is looking at the overall risk profile, not each risk individually*
	-	Specify that where the overall residual risk is judged to be unacceptable:
		- Manufacturer may gather data & literature on the medical benefit of the device (intended use / purpose) to determine if they outweigh the overall residual risk
		- If not, the residual risk remains unacceptable
		- Where acceptable, the manufacturer shall determine what information is necessary to include in the accompanying documents to disclose residual risk
		That this evaluation shall be documented in the risk management file
8	-	Risk Management Report
	-	Specify that the following items shall be documented in the device risk management file:
	-	That prior to commercial distribution of the device, a review of the risk management process shall be performed to ensure:
		- Risk management plan was appropriately implemented
		- Overall residual risk is acceptable
		- Appropriate methods in place to obtain relevant production/post-production information
		That the results of this review are recorded as the risk management report
		That the results of this review are included in the risk management file
		That responsibility for review assigned in the risk management plan to persons with appropriate authority
9	-	Production and Post-Production Information
	Not required by IEC 60601-1 Ed.3, 3.1	A system shall be established, documented and maintained to collect and review production and post-production information about the device or similar devices
	Not required by IEC 60601-1 Ed.3, 3.1	The system should consider at a minimum:
	Not required by IEC 60601-1 Ed.3, 3.1	a) Mechanism for collecting and processing information generated by the operator, user, or those accountable for installation, use and maintenance of the device
	Not required by IEC 60601-1 Ed.3, 3.1	b) New or revised standards
	Not required by IEC 60601-1 Ed.3, 3.1	The system should collect and review public information for similar devices
	Not required by IEC 60601-1 Ed.3, 3.1	The information shall be evaluated for possible relevance to safety including:
	Not required by IEC 60601-1 Ed.3, 3.1	- Identification of previously unrecognized hazards/hazardous situations
	Not required by IEC 60601-1 Ed.3, 3.1	- Estimated risks arising from hazardous situations are no longer acceptable
	Not required by IEC 60601-1 Ed.3, 3.1	* e.g. if within the boundaries that were accepted during the risk management process.
	Not required by IEC 60601-1 Ed.3, 3.1	(probability & severity)
	Not required by IEC 60601-1 Ed.3, 3.1	- If the above conditions occur:
	Not required by IEC 60601-1 Ed.3, 3.1	1) Impact on previously implemented risk management activities shall be evaluated and used an additional input into the risk management process
	Not required by IEC 60601-1 Ed.3, 3.1	2) Review the risk management file for the device to determine if residual risk(s) or acceptability has changed and the impact on previously implemented control measures
	Not required by IEC 60601-1 Ed.3, 3.1	This evaluation shall be documented in the risk management file

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Enter the risk management document numbers cited above, with revision or issue dates:

Risk Management Document (all those referenced in the requirements above)	Revision or Issue Date

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RISK MANAGEMENT EXAMPLES

ISO 14971, Clause 3.1 Compliant Risk Management Policy:

RISK MANAGEMENT POLICY:
Company name is committed to risk management as an integral part of its corporate quality management system and operation. All company employees shall help to develop strategies and systems to minimize the risk of physical injury and damage to the health of people, property, or the environment, that are caused by the company's products, services, or operations. Risk management is essential to success of the company, and identification and management of risk will be undertaken in the systematic process, using the principles as set out in the international standard for risk management, ISO 14971:2007, relating to medical devices, IEC 60601-1:2005 with A1:2012, medical electrical equipment, and as a function of ISO 13485:2003 Quality Management System.

Purpose:
The purpose of the company name's risk management policy is to ensure that sound risk management practices and procedures for products and services are integrated into the company's quality system, including the design, development, manufacture, use, service, and end of life of the company's products.

Objectives:
- Promote and support risk management practices across the organization through the implementation of a framework that provides a process to identify, analyze, assess, and prioritize areas of risk.
- Include in the company's party management system a risk management plan for the company's products. This will include product risk analysis, risk summary, and post market surveillance.
- Provide adequate information, training, and supervision to staff in the quality management system, and ensure resources and operational capabilities are identified and deployed.
- Develop and maintain the quality management system to comply with relevant standards and regulatory requirements.

Risk management process:
The main elements of the company's risk management process shall at a minimum include the following activities:
- Risk analysis
- Risk evaluation
- Risk control
- Residual risk valuation
- Risk reporting
- Ongoing to risk monitoring and evaluation

Roles and responsibilities:
All employees are responsible for effective risk management practices and ensuring that management is aware of risk associated with company name's products and operations.

Company name's quality representative is accountable for implementing this policy and ensuring that personnel conducting risk management tasks have the appropriate competencies.

Company name's CEO is responsible for risk management performance, including implementation of the strategy, ensuring appropriate resources are made available, and that there is effective monitoring and reporting.

Product development is tasked with the risk analysis specifically related to company name's medical devices.

Signature
Name, Title
Date

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