Medical Equipment Compliance Associates, LLC

ISO 14971:2007 Risk Management Client Completion Form

F 027b (2018-09-28)

ISO 14971:2007 Application of risk management to medical devices
(EN ISO 14971:2012, which adds Annex ZA for the mapping of EU MDD, is not referenced in IEC 60601-1:2012)

MECA Project #	Manufacture, Model Covered

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Experts in the field of medical certification and regulatory compliance with a commitment to quality service

Purpose

The purpose of this client completion form is to document the location of the required objective evidence of compliance with the risk management requirements of ISO 14971:2007 for compliance review.

General Information

The following items outline general rules used throughout this document.

References to clauses within the standard are preceded by the term clause followed by the clause number. References to subclauses within the standard are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

“Shall” means that compliance with a requirement or a test is mandatory for compliance with this standard.

“Should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard.

“May” is used to describe a permissible way to achieve compliance with a requirement or test.

NOTE: This document is not a replacement for the standard, it does not include the full text of any referenced requirements, specifically NOTEs, EXAMPLES and Test Requirements.

Definitions and Acronyms

Definitions

Below are the definitions of terms used within this document.

Table 2: Terms & Definitions

Term	Definition
Clause	One of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 4 includes sub-clauses 4.1, 4.2, etc.).
Subclause	A numbered subdivision of a clause (e.g. 4.1, 4.2 and 4.10.1 are all sub-clauses of Clause 4).
Risk Management Process	A process complying with ISO 14971
Usability Engineering Process	A process complying with either IEC 60601-1-6 or IEC 62366

NOTE: All definitions of IEC 60601-1:2005, IEC 60601-1:1988 + A1:1991 + A2:1995 and ISO 14971:2007 apply.

Acronyms

Below are the acronyms used within this document.

Table 3: Acronyms

Acronym	Term
DHF	Design History File (Technical File)
EP	ESSENTIAL PERFORMANCE
ESL	EXPECTED SERVICE LIFE
IEC	International Electrotechnical Commission
IFU	Instructions for Use
ISO	International Organization for Standardization
MEE	Medical Electrical Equipment
MES	Medical Electrical Systems
MOP	MEANS OF PROTECTION
RI	Reinforced Insulation
RM	Risk Management
RMF	Risk Management File
RMP	Risk Management Process
SDLC	Software Development Life-Cycle (See IEC 62304)

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Instructions for completing Risk Management Tables

The first two columns of the table identify the **Standard** (ISO 14971:2007) and **Clause**.

The "G**uidance**" column identifies general guidance on the applicability of the requirement and/or recommendations on how this requirement should be addressed in specific product designs. There is no user action required on this column.
*NOTE: Any text in **blue font** is taken from the IECEE OD2044 document.*

The **Comment** row is provided for answering to questions (i.e. Service life of equipment is 5 years), or may be a justification of why the clause is not applicable (i.e. no batteries).

The "**RMF Reference(s)**" row is where the location of the required information is entered.
This must include: document/file name, revision, and location (section, Hazard ID, or Row)

All Tables are required for all equipment types where the clause is applicable.

For each applicable clause:
- Review the requirement summary & guidance columns (and standard, as necessary)
- Enter any comments necessary to answer a question or explain a verdict
- Enter the risk management file location(s) where the required evidence can be found

Note: The Clause verdicts will be filled in by MECA in the review of the referenced documents.

All applicable tables are required to be completed for the risk management review.

When completing the tables, the expectation is that the references will be to Quality System Records specific to the Product/Product Family that is under evaluation.

When assessing compliance with IEC 60601-1:2012, only verification of the red text from Table 6 is required, the text in black is not required for assessing compliance with Clause 4.2.2 of IEC 60601-1:2012.

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Table 6: Assessment Results ISO 14971:2007

ISO 14971:2007 Clause	Requirement Guidance	Document/file Reference, Revision	Section Reference
3 General requirements of risk management			
3.1 Risk Management Process	An ongoing process shall be established, documented and maintained for: • Identifying hazards • Estimating, evaluating and controlling the risks • Monitoring the effectiveness of risk controls. The process shall include these elements: • Risk analysis • Risk evaluation • Risk control • Production and post-production information *If a documented product realization process exists, it shall incorporate the appropriate parts of the risk management process.*	Process Specific Document(s):	Section(s):
3.2 Management responsibilities	Evidence that top management is committed to the risk management process: • Ensuring adequate resources • Ensuring the assignment of qualified personnel Top Management shall: • Define & document a policy for determining criteria for risk acceptability • The policy ensures criteria are based on national/regional regulations and international standards also taking into account known stakeholder concerns and accepted state of the art • *Review the risk management process at planned intervals to ensure continuing effectiveness; any decisions/actions are to be documented*	Process Specific Document(s):	Section(s):

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ISO 14971:2007 Clause	Requirement Guidance	Document/file Reference, Revision	Section Reference
3.3 Qualification of personnel	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	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
3.4 Risk management plan	Risk management activities shall be planned. Plans shall be prepared for particular devices/accessories. The plan shall include at a minimum: a) Scope of the planned activities identifying the medical device, including a description of the device and the life-cycle phases covered by the plan b) Assignment of responsibilities & authorities c) Review requirements for risk management activities d) Criteria for risk acceptability, based on the manufacturers policy, including criteria for accepting risks when the probability cannot be estimated e) Verification activities f) *Collection & review of production and post-production information The risk management file shall include changes to the plan made over the life-cycle of the device.*	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
3.5 Risk management file	A risk management file shall be established for each device. The risk management file shall provide traceability for each hazard to: • Risk analysis • Risk evaluation • Implementation and verification of mitigations (control measures) • Assessment of residual risk acceptability	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
4 Risk Analysis			
4.1 Risk analysis process	A risk analysis shall be performed. Implementation of the planned activities and result of the risk analysis is documented. A risk analysis shall include at a minimum: a) Description & identification of the item(s) covered b) Identification of personnel performing the risk analysis c) Scope and date of the risk analysis	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):

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ISO 14971:2007 Clause	Requirement Guidance	Document/file Reference, Revision	Section Reference
4.2 Intended use and identification of characteristics related to the safety of the medical device	The intended use and reasonably foreseeable misuse shall be identified. There shall be a listing of characteristics (qualitative and quantitative) that could impact the safety of the medical device with any appropriate limits. These items shall be documented in the risk management file	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
4.3 Identification of hazards	A list of known and foreseeable hazards shall be compiled for the device in normal and fault conditions and documented in the risk management file.	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
4.4 Estimation of the risk(s) for each hazardous situation	Reasonably foreseeable sequences/combinations of events leading to hazardous situations shall be considered and the hazardous situation 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.	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
5 Risk evaluation	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.	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
6 Risk control			
6.1 Risk reduction	Where risk reduction is required, risk control activities are performed	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):

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6.2 Risk control option analysis	Risk control measures appropriate for reducing risks to an acceptable level shall be identified. 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 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 The selected risk control measure shall be documented in the risk management file. Where further risk reduction is impractical, a risk/benefit analysis of the residual shall be performed.	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
6.3 Implementation of risk control measure(s)	Selected risk control measures shall be implemented. The implementation and its effectiveness shall be verified and documented in the risk management file.	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
6.4 Residual risk evaluation	Risk remaining after the implementation of the risk control shall be evaluated against the criteria in the risk management plan. Further risk control shall be applied where the residual risk is not judged acceptable. For acceptable residual risk, the manufacturer shall determine which residual risks to disclose (including what information is necessary) *Note – this is for each risk individually.*	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):

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ISO 14971:2007 Clause	Requirement Guidance	Document/file Reference, Revision	Section Reference
6.5 Risk/benefit analysis	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) Where the benefit outweighs the residual risk, the manufacturer shall identify any information for safety required to disclose the residual risk. This review shall be documented in the risk management file. That this assessment is performed on individual risks	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
6.6 Risks arising from risk control measures	The impact of risk controls shall be reviewed with regard to: a) Introducing new hazards/hazardous situations b) Effect on the estimated risks for previously identified hazardous situations New/increased risks are subjected to the requirements of this standard. This review shall be documented in the risk management file	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
6.7 Completeness of risk control	An assessment shall be performed to ensure that risks from all identified hazardous situations have been considered. This assessment shall be documented in the risk management file.	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):

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ISO 14971:2007 Clause	Requirement Guidance	Document/file Reference, Revision	Section Reference
7 Overall residual risk acceptability	Following implementation & verification of all risk control measures, the 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 just each risk individually.* Where the overall residual risk is judged to be unacceptable the 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 disclose the overall residual risk in the accompanying documents. This evaluation shall be documented in the risk management file.	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):
8 Risk management report	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 The results of this review are recorded as the risk management report and included in the risk management file. Responsibility for review should be assigned in the risk management plan to persons with appropriate authority.	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):

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ISO 14971:2007 Clause	Requirement Guidance	Document/file Reference, Revision	Section Reference
9 Production and Post-production information	A system shall be established, documented and maintained to collect and review production and post-production information about the device or similar devices. The system should consider at a minimum: a) Mechanism for collecting and processing information generated by the operator, user or those accountable for installation, use and maintenance of the device b) New or revised standards The system should collect and review public information for similar devices. The information shall be evaluated for possible relevance to safety including: • Identification of previously unrecognized hazards/hazardous situations • Estimated risks arising from hazardous situations are no longer acceptable (e.g. if within the boundaries that were accepted during the risk management process...probability & severity) If the above conditions occur: 1. Impact on previously implemented risk management activities shall be evaluated and used an additional input into the risk management process 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 This evaluation shall be documented in the risk management file	Process Specific Document(s): Device Specific Document(s):	Section(s): Section(s):

NOTE: *This table is not intended to be a replacement for the standard, it should not be assumed to contain the full text of any referenced requirements.*