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OPERATIONAL & RULING DOCUMENTS

Evaluation of Risk Management in medical electrical equipment according to the IEC 60601-1 & IEC/ISO 80601-1 Series of Standards

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Contents

1 Scope

The scope of this procedure is to provide a uniform approach to the CBTL and Manufacturer on how to assess and document compliance with the relevant clauses of IEC 60601 standard series related to the standard ISO 14971.

2 Reference documents

IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1:2005 Incl. Am 1:2012 Medical equipment – Part 1: General requirements for basic safety and essential performance (Also known as IEC 60601-1:2005 + A1:2012)

IEC 60601-1-2:2007 Medical electrical equipment - Collateral standard: Electromagnetic compatibility - Requirements and tests

Note: The RM requirements are addressed through the IEC 60601-1:2005

IEC 60601-1-3:2008 Medical electrical equipment - Collateral Standard: Radiation protection in diagnostic X-ray equipment

IEC 60601-1-6:2010 Medical electrical equipment - Collateral Standard: Usability

IEC 60601-1-8:2006 Medical electrical equipment - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-10:2007 Medical electrical equipment - Collateral Standard: Requirements for the development of physiologic closed-loop controllers

IEC 60601-1-11:2010 Medical electrical equipment - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 62366:2007 Medical devices – Application of usability engineering to medical devices

IEC 62304:2006 Medical device software – Software life cycle processes

ISO 14971:2000 Medical devices – Application of risk management to medical devices

ISO 14971:2007 Medical devices – Application of risk management to medical devices

IEC60601_1G – IECEE Test Report Form - IEC 60601-1: 2005 + CORR. 1(2006) + CORR 2 (2007)

IEC60601_1H – IECEE Test Report form - IEC 60601-1: 2005 + AM1 (2012)

3 Terms and definitions

For the purposes of this Operational Document, the terms and definitions of ISO 14971 standard and IEC 60601 standard series apply.

For the purpose of this document, the Risk Management Process is a management system intended to address all activities related to ISO 14971.

For the purpose of this document, unless otherwise specified, the following conventions are used:

- IEC 60601-1:2005 or IEC 60601-1:2005 + A1:2012 designates "the general standard" alone;
- IEC 60601-1 designates reference to IEC 60601-1:2005 and IEC 60601-1:2005 + A1:2012
- IEC 60601-1-nn designates a specific collateral standard (this applies for all the collateral standards stated in this document where “nn” is the number of the collateral)
- IEC 60601 series designates the combination of the general standard IEC 60601-1:2005/IEC 60601-1:2005 + A1:2012 and the collateral standards IEC 60601-1-nn.
- ISO 14971 designates references to ISO 14971:2000 and ISO 14971:2007

4 Application of Risk Management Principle for IEC 60601 series CB Scheme investigations

4.1 General

The third edition of IEC 60601-1:2005 is the primary standard in a series of standards that covers safety and essential performance of medical electrical equipment. It is the first IEC standard in the scope of the CB Scheme that incorporates risk management principles according to ISO 14971:2000. The introduction of Risk Management is the reason for this Operational Document.

The existence of a CB Test Certificate does not solely establish legal market entry. However, it could be used to help substantiate a request for legal market access.
This Operational Document is related solely to the IECEE CB Scheme and is intended for use by those individuals with a working knowledge of risk management for medical electrical equipment and the provisions of the IEC 60601 series.

NOTE: IEC 60601-1:2005 + A1:2012 incorporates risk management principles according to ISO 14971:2007.

5 Assessment of Risk Management principles in the IEC 60601 series CB Scheme investigations

5.1 General principles

There is a general requirement to perform the risk management process as specified in ISO 14971:2000 (IEC 60601-1:2005, Clause 4.2.) or ISO 14971:2007 (IEC 60601-1:2005 + A1:2012, Clause 4.2.2).

The registration to ISO 13485 is not sufficient to demonstrate that a risk management process compliant with ISO 14971 requirements is performed. There can be no investigation to IEC 60601 series without the manufacturer’s Risk Management File being available, unless specifically permitted by the rules of the CB Scheme.

The CB Test Report and Certificate confirms that there is a Risk Management Process performed which complies with the risk management requirements of IEC 60601 series and the applicable requirements of ISO 14971. This does not mean that a complete Risk Management System in compliance with ISO 14971 is in place. The CB Test Report is only a snapshot in time and does not necessarily assess all top management responsibilities.

Several clauses of ISO 14971 define the requirements for the application of the Risk Management Process to “the particular medical device being considered”. When those clauses of ISO 14971 are used to address Risk Management requirements in IEC 60601-1, the verification shall confirm whether the Risk Management Process is correctly applied to the particular Device Under Evaluation/Test.

A separate certification of registration to ISO 14971 indicates that a risk management system conforming to ISO 14971 is in place, but does not necessarily provide the risk management device specific documentation to meet the requirements of IEC 60601 series. IEC 60601 series requires specific Risk Management activities to be done and the CB Test Report requires objective evidence that these activities have been performed for the Device Under Test.

A CB Scheme Test Certificate does not imply that an audit of the manufacturer's Risk Management System was conducted.

In view of the above and similar to the second edition, the CB Test Report according to IEC 60601- 1 is not necessarily a guarantee of certification by an accepting NCB.

A certificate of registration may be requested for local or regional certification to IEC 60601 series as it relates to follow-up services. There may be differences in requirements that are the subject of local legal market entry requirements.

5.2 Implementation of ISO 14971 into the IEC 60601 series

In the clauses of IEC 60601-1 series there are three types of references to ISO 14971 Risk Management requirements:

a) Direct reference to Risk Management Process as specified by ISO 14971 (for example clause 4.2 or 4.2.2).

b) Test related references to give appropriate alternative to the application of laboratory testing with specific pass/fail criteria or to select appropriate tests to be performed on the specific product (for example clause 5.7).

c) Indirect reference to offer additional elements to be considered in the implementation of the Risk Management Process specified by ISO 14971 for the specific product. (for example clause 14.1)

The manufacturer can also identify alternative means to provide an equivalent safety level to IEC 60601 series. The manufacturer may implement new and original approaches to developing effective means of protection against unacceptable risks. The manufacturer must verify that the residual risks that result from applying the alternative means are equal to or less than the residual risks that result from applying the requirements of IEC 60601 series. All these activities must be performed in accordance with the requirements of ISO 14971.

Clause 4.2 of IEC 60601-1:2005 and Clause 4.2.2 of IEC 60601-1:2005 + A1:2012 do not require post market monitoring (e.g. clause 9 of ISO 14971) of the effectiveness of the risk control measures

Tables appended in Clause 6 of this Operational Document provide mapping with all the clauses of IEC 60601-1 and the IEC collaterals standards which require risk management, and the applicable clauses in ISO 14971. These tables provide guidance and considerations for application and assessment of RM criteria.

5.3 ISO 14971:2000 (1st edition) and ISO 14971:2007 (2nd edition)

The process of standards development progresses over a significant length of time. The IEC 60601 series of standards to which this Operational Document refers were published between 2005 and 2010. When IEC 60601-1:2005 was published and consequentially its collateral standards published, the risk management standard used as reference was the ISO 14971:2000.

This situation is not valid when referring to IEC 60601-1-6:2010 which includes a direct link to IEC 62366:2007. The IEC 62366:2007 also refers directly to ISO 14971:2007. This situation is also not valid when referring to IEC 60601-1:2005 + A1:2012 which also makes a direct reference to ISO 14971:2007.

For this reason, in the tables appended that provide mapping with all the clauses of IEC 60601 series, the following references have been made:

- ISO 14971:2000 clauses are used to address the risk management process required by IEC 60601-1 series aligned with IEC 60601-1:2005;
- ISO 14971:2007 clauses used to address the risk management process required by IEC 60601-1 series aligned with IEC 60601-1:2005 + A1:2012;
- ISO 14971:2007 clauses are used to address the risk management process required by IEC 62366:2007 (IEC 60601-1-6:2010).

5.4 Description of ISO 14971 clauses application in regards to IEC 60601-1 standard

The following Table is a guidance document. Refer to standard ISO 14971 for more detailed requirements and supporting rationales. This table explains what action or evidence is required for each clause of ISO 14971.

IEC 60601-1 TRF – RM RESULTS TABLE 4.2 – Risk Management Process

4.2	RM RESULTS TABLE: Risk Management Process for ME Equipment or ME Systems		P
Clause of ISO 14971	**Document Ref. in RMF (Document No. and paragraph) – Main topic of clause**	**Result – Remarks - What type of objective evidence would be required in the Document Ref.**	**Verdict**
3.3a (2000) or 3.2 (2007)	**Management responsibilities**	Requires that the manufacturer define and document the policy for determining criteria for risk acceptability; this policy ensures that criteria are based upon applicable national or regional regulations and relevant International Standards, and takes into account available information such as the generally accepted state of the art and known stakeholder concerns. The CBTL must review the manufacturer's policy and verify that it meets these requirements. This review is done once, as is recommended to be completed early in the risk management review process. **ISO 14971:2007, additionally requires an assessment to ensure the manufacturer will allocate sufficient resources and assign trained personnel to the risk management process**	**P**
3.3 (2007 only)	**Qualification of personnel**	Requires the personnel performing risk management tasks to have the appropriate knowledge and experience for the tasks assigned to them. This includes knowledge and experience related to the medical device(s), their use, technologies involved and risk management techniques. The manufacturer is required to maintain qualification records	**P**
3.5e (2000) or 3.4 (2007)	**Risk management plan**	The criteria for risk acceptability are based on the manufacturer's policy for determining acceptable risk, including criteria for accepting risks when the probability of occurrence of harm cannot be estimated. The manufacturer's risk management process must include the risk acceptability criteria. The CBTL must review the manufacturer's risk acceptability criteria and verify that it meets established requirements. This review is done once, as is recommended to be completed early in the risk management review process	**P**

Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph) – Main topic of clause	Result – Remarks - What type of objective evidence would be required in the Document Ref.	Verdict
3.5 (2007 only)	**Risk management file**	Requires the manufacturer to estabilish and maintain a file containing the results of the risk management activities including all documentation requirements specified in ISO 14971 and traceability for each identified hazard to: the risk analysis, the risk evaluation, risk control measures and acceptance of residual risks	**P**
4.1	**Risk analysis process**	Risk analysis shall be performed for the particular medical device as described in 4.2 to 4.4. The implementation of the planned risk analysis activities and the results of the risk analysis shall be recorded in the risk management file. In addition to the records required in 4.2 to 4.4, the documentation of the conduct and results of the risk analysis shall include at least the following: a) a description and identification of the medical device that was analyzed; b) identification of the person(s) and organization who carried out the risk analysis; c) scope and date of the risk analysis	**P**
4.2	**Intended use and identification of characteristics related to the safety of the medical device**	For the particular medical device being considered, the manufacturer documents the intended use and reasonably foreseeable misuse. The manufacturer identifies and documents those qualitative and quantitative characteristics that could affect the safety of the medical device and, where appropriate, their defined limits. This documentation shall be maintained in the risk management file. The CBTL must review the risk management file and verify that based on the device, the manufacturer has complied with these requirements. Note that the identification of characteristics that could affect safety, needs to include those hazard based requirements from the IEC 60601 series of standards where clause 4.2 of ISO 14971 is a required element. This review repeats for each IEC 60601 series hazard based risk management requirement.	**P**
4.3	**Identification of hazards**	The manufacturer compiles documentation on known and foreseeable hazards associated with the medical device in both normal and fault conditions. The manufacturer processes identified risks through hazard identification→event(s) or circumstance(s) leading to a hazardous situation→hazardous situation→event(s) or circumstance(s) leading to harm→harm→who or what is harmed. For those hazard based requirements that are applicable to the medical device, the CBTL uses this information for completing clause 4.3 and 4.4 of the IECEE Risk Management Results Tables. The CBTL reviews and verifies compliance for all of the applicable hazard based risk management requirements.	**P**

Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph) – Main topic of clause	Result – Remarks - What type of objective evidence would be required in the Document Ref.	Verdict
4.4	**Estimation of the risk(s) for each hazardous situation**	The manufacturer determines and documents rreasonably foreseeable sequences or combinations of events that can result in a hazardous situation and records the resulting hazardous situation(s). For each identified hazardous situation, the manufacturer estimates the associated risk(s) using available information or data. For hazardous situations for which the probability of the occurrence of harm cannot be estimated, the possible consequences shall be listed for use in risk evaluation and risk control. The results of these activities shall be recorded in the risk management file. Any system used for qualitative or quantitative categorization of probability of occurrence of harm or severity of harm shall be recorded in the risk management file. The CBTL reviews the risk analysis and risk estimation and enters verification of each of the hazards based risk management analysis and risk estimation in the test results table.	**P**
5	**Risk evaluation**	For each identified hazardous situation, the manufacturer shall decide, using the criteria defined in the risk management plan, if risk reduction is required. If risk reduction is not required, the requirements given in 6.2 to 6.6 do not apply for this hazardous situation. The results of this risk evaluation shall be recorded in the risk management file. The CBTL reviews the manufacturer's risk evaluation for each hazard based risk required by the IEC 60601 series of standards and enters a verdict in the Risk Management Results Table. The CBTL uses this information for test plans and conducting tests.(e.g. unacceptable performance becomes essential performance).	**P**
6.1	**Risk reduction**	When risk reduction is required, risk control activities, as described in 6.2 to 6.7, shall be performed.	**P**
6.2	**Risk control option analysis**	The manufacturer identifies risk control measure(s) that are appropriate for reducing the risk(s) to an acceptable level. The manufacturer uses one or more of the following risk control options in the priority order listed: a) inherent safety by design; b) protective measures in the medical device itself or in the manufacturing process; c) information for safety The manufacturer records the risk control measure(s) in the risk management file. If, during risk control option analysis, the manufacturer determines that required risk reduction is not practicable, the manufacturer shall conduct a risk/benefit analysis of the residual risk (proceed to 6.5). The CBTL reviews the manufacturer's chosen risk control measure(s) for each hazard based requirement from IEC 60601 series of standards and documents their findings in the Risk Management Results Tables in the TRF.	**P**

Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph) – Main topic of clause	Result – Remarks - What type of objective evidence would be required in the Document Ref.	Verdict
6.3	**Implementation of risk control measure(s)**	The manufacturer implements the identified risk control measure(s). The manufacturer verifies the implementation of each hazard based risk control measure. The effectiveness of the risk control measure(s) shall be verified and the results shall be recorded in the risk management file. The CBTL reviews manufacturer's implementation, verification and effectiveness of risk control measure(s) for each hazard based requirement from IEC 60601 series of standards and documents their findings in the Risk Management Results Tables in the TRF.	**P**
6.4	**Residual risk evaluation**	After the risk control measures are applied, the manufacturer evaluates any residual risk using the criteria defined in the risk management plan. The results of this evaluation are recorded in the risk management file. If the residual risk is not judged acceptable using these criteria, then the manufacturer applies further risk control measures. For residual risks that are judged acceptable, the manufacturer decides which residual risks to disclose and what information is necessary to include in the accompanying documents in order to disclose those residual risks. The CBTL reviews the manufacturer's residual risk analysis, risk control looping where necessary, and their determination of information to be included in the accompanying documents. The CBTL verifies compliance with these requirements and records their findings in the Risk Management Results Tables of the TRF for each hazard based risk management from the IEC 60601 series of standards.	**P**
6.5	**Risk/benefit analysis**	If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the residual risk, then the risk remains unacceptable. If the medical benefits outweigh the residual risk, then proceed to 6.6. For risks that are demonstrated to be outweighed by the benefits, the manufacturer shall decide which information for safety is necessary to disclose the residual risk. The CBTL is responsible for carefully reviewing the manufacturers' risk management file and entering their findings in the Risk Management Results table.	**P**

Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph) – Main topic of clause	Result – Remarks - What type of objective evidence would be required in the Document Ref.	Verdict
6.6	**Risks arising from risk control measures**	The manufacturer reviews the effects of the risk control measures with regard to: a) the introduction of new hazards or hazardous situations; b) whether the estimated risks for previously identified hazardous situations are affected by the introduction of the risk control measures. The manufacturer processes newly identified hazards or hazardous situations through their risk management process and reprocesses risks that are affected by the introduction of risk control measures through initial risk estimation, risk evaluation and if necessary, risk control. The CBTL reviews the manufacturers' risk management file and records their findings in the TRF Risk Management Results Table.	**P**
6.7	**Completeness of risk control**	The manufacturer ensures that the risk(s) from all identified hazardous situations have been considered. The results of this activity are recorded in the risk management file. The CBTL reviews the manufacturers' risk management file and records their findings in the Risk Management Results Table	**P**
7	**Evaluation of overall residual risk acceptability**	After all risk control measures have been implemented and verified, the manufacturer decides if the overall residual risk posed by the medical device is acceptable using the criteria defined in the risk management plan. If the overall residual risk is not judged acceptable using the criteria established in the risk management plan, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the overall residual risk. If this evidence supports the conclusion that the medical benefits outweigh the overall residual risk, then the overall residual risk can be judged acceptable. Otherwise, the overall residual risk remains unacceptable. For an overall residual risk that is judged acceptable, the manufacturer shall decide which information is necessary to include in the accompanying documents in order to disclose the overall residual risk. The CBTL reviews the manufacturers' risk management file regarding their overall residual risk and records a verdict in the TRF Risk Management Results Table.	**P**
8 (2007 only)	**Risk management report**	Requires the manufacturer to prepare a report prior to commercial release documenting a review of the risk management process (specific to activities on specific devices). The report is intended to ensure that the risk management plan was properly implemented, the overall residual risk is acceptable and there are appropriate methods in place to collect and analyze production and post-production information. The portion of the requirement related to production and post-production information is outside the scope of assessment under the IECEE CB Scheme	**P**

5.5 Evaluating RISK - HAZARDS identified in the IEC 60601-series

The requirements of this standard shall be applied in the following way when evaluating RISK:

a) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS, together with specific acceptance criteria, compliance with these requirements is presumed to establish that the RESIDUAL RISKS have been reduced to acceptable levels unless there is OBJECTIVE EVIDENCE to the contrary.

EXAMPLE 1: Sub-clause 8.5.1.2, MEANS OF PATIENT PROTECTION (MOPP)

EXAMPLE 2: Sub-clause 9.4.2.1, Instability in transport position

Compliance is checked by satisfying the relevant requirements of this standard and its collateral and particular standards.

b) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS but do not provide specific acceptance criteria, the MANUFACTURER shall provide the acceptance criteria for which the RESIDUAL RISK shall be acceptable according to the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan.

EXAMPLE 3: Sub-clause 9.8.3.3, Dynamic forces due to loading from persons *(Note:* IEC 60601-1:2005 + A1:2012 *removes reference to unacceptable RISK and replaces the text with reference to maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE)*

EXAMPLE 4: Sub-clause 11.6.3, Spillage on ME EQUIPMENT and ME SYSTEM

Compliance is checked by confirming that the documentation in the RISK MANAGEMENT FILE demonstrates that after applying the specific requirements of this standard and the acceptance criteria determined by the manufacturer the RESIDUAL RISK is acceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan, i.e. no unacceptable RISK remains. Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. MANUFACTURER'S calculations or test results, or the determination of RISK

c) Where this standard or its collateral or particular standards identify particular HAZARDS that have to be investigated without providing specific technical requirements:

– The MANUFACTURER shall determine whether such HAZARDS exist for the particular ME EQUIPMENT or ME SYSTEM, and

– where such HAZARDS exist for the particular ME EQUIPMENT or ME SYSTEM, the MANUFACTURER shall evaluate and (if necessary) control these RISKS following the RISK MANAGEMENT PROCESS specified in 4.2/4.2.2.

EXAMPLE 5: Sub-clause 10.2, Alpha, beta, gamma, neutron and other particle radiation *Compliance is checked by confirming that the documentation in the RISK MANAGEMENT FILE demonstrates that the RESIDUAL RISK is acceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan, i.e. no unacceptable RISK remains.*

Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

NOTE: When ME EQUIPMENT or an ME SYSTEM has been designed in such way that for a certain type of HAZARD no HAZARDOUS SITUATION exists, no further RISK ASSESSMENT for that HAZARD is necessary. This can be verified by tests or inspections.

5.6 Evaluating RISK - HAZARDS not identified in the IEC 60601-series

For HAZARDS that are identified for the particular ME EQUIPMENT or ME SYSTEM but are not specifically addressed in the Standard IEC 60601-1 or its collateral or particular standards, the MANUFACTURER shall address those HAZARDS in the RISK MANAGEMENT PROCESS as specified in 4.2.2.

EXAMPLE 6: ME EQUIPMENT or an ME SYSTEM for which there are particular RISKS but no particular standard

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Clause 4.2 of ISO 14971 has caused confusion when used with the IEC 60601 series of standards. The manufacturers Intended Use statement is information that the CBTL can use to understand the intended purpose of the product. The manufacturer must identify and document a list of qualitative and quantitative characteristics that could affect safety. Where clause 4.2 of ISO 14971 is called out in the hazard based clauses of IEC 60601 series, the CBTL must use the manufacturers' list of qualitative and quantitative characteristics that could affect safety. For example, high humidity for extended period of time, the manufacturer should have identified and documented the intended use environment.

One of the IEC 60601-1:2005 risk management requirements is process based and not hazard based. This requirement will not be found in the manufactures hazard identification. The process based clause is 4.2 and it is expected that the manufacturer will have implemented appropriate system procedures to address this clause.

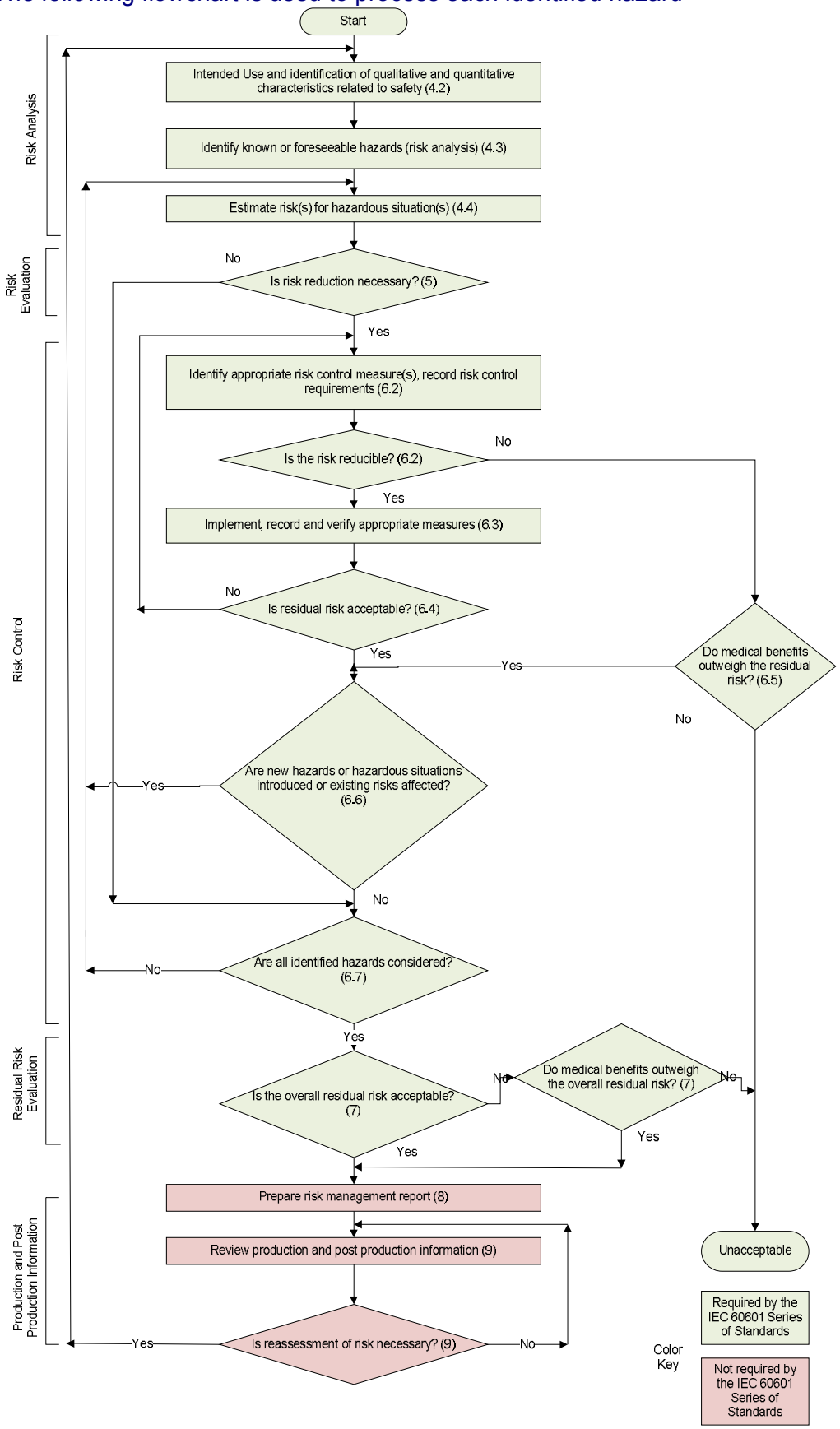
Four of the elements (requirements) of ISO 14971 only require single use/review including 3.3 a), 3.5 e), 6.7 and 7 since they are process requirements rather than hazard based requirements. Note that not all of the elements (requirements) of ISO 14971 are required by the IEC 60601 series of standards.

The manufacturer addresses the hazard based clauses of the IEC 60601 series of standards according to the ME Equipment. The Risk Management Results Tables in the TRFs are based on the requirements of the IEC 60601 series of standards. For a specific hazard, a manufacturers' risk management file may go beyond the specific Risk Management Results Table, or the manufacturers' risk management file may use only a portion of the risk management elements and, therefore, it is acceptable to enter NA into some of the identified ISO 14971 Risk Management Results Table clauses based on the specific risk for the ME Equipment.

For hazard based risk management requirements, the flow diagram below shows the steps that the manufacturer must consider. For example, if they complete risk evaluation with an acceptable level of risk, they may not proceed to risk control.

5.7 Risk Management Flowchart (Reference to the ISO 14971:2007, 2nd edition – Figure B.1)

The following flowchart is used to process each identified hazard



5.8 IEC 60601-1 Test Report Form (TRF)

To assess the requirements for Risk Management process required by IEC 60601 series, the CB Scheme utilizes Risk Management Results tables within the IEC 60601 series TRF in conjunction with the test data tables, containing reference to the manufacturer's documents intended to support objective evidence of compliance.

For a clause from IEC 60601-1 which makes reference to the RM file refer to TABLE 1 - IEC 60601- 1 / ISO 14971 CLAUSE MAPPING GUIDE to identify which clauses from ISO 14971 need to be documented.

For example, IEC 60601-1:2005 Clause 9.2.4 which requires reference to the RM file; Table 1 of this OD 2044 specifies that documents demonstrating compliance with clauses 4.2 to 6.6 of ISO 14971:2000 shall be provided for evaluation.

9.2.4	Emergency stopping devices	- Does the MEE use emergency stopping devices? - Are risks caused by mechanical hazards which are reduced by the use of the emergency stopping devices reduced to an acceptable level?	4.2 to 6.6

The actual clauses that are to be used to provide evidence are referenced in the Risk Management Results Tables of the TRF; the ISO 14971 range of clauses in table 1 is given for reference only.

After evaluation, the 9.2.4 Risk Management Results Table shall be filled in appropriately.

9.2.4	**Risk Management Results Table: Emergency stopping devices**		Pass
Clause ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result- Remark**	**Verdict**
4.2	See document 453627 rev 1 Product Specifications	The Treadmill is intended to make a patient walk on a moving belt.	Pass
4.3	See document 1234567 rev 1 clause 13.1a	The possible hazard of the patient tripping has been identified.	Pass
4.4	Document 7654321 – rev 2 Refer to clause 13.1a	The probability of occurrence of the harm has been estimated in “ProbRange C”. The severity of the harm has been estimated as “SevRange B”	Pass
5	Document 7654321 – rev 2 Refer to clause 13.1a	The risk has been evaluated as “TBR = To Be Reduced”	Pass
6.2	Document 7654321 – rev 2 Refer to clause 13.1a	The measure that has been identified to control the risk is the use of an emergency stopping device.	Pass
6.3	Document 1726354 – rev 3 Design Verification	The Treadmill is provided with an emergency stopping device.	Pass
6.4	Document 1726354 – rev 3 Design Verification	The emergency stopping device works as intended. The probability of occurrence of the harm has been reduced to “ProbRange A”. The residual risk has been evaluated as “acceptable”.	Pass
6.5		Not deemed necessary	N/A
6.6		No other hazards generated	Pass

IEC 60601-1:2005 Clause 11.6.3 which requires reference to the RM file; Table 1 of this OD 2044 specifies that documents demonstrating compliance with clauses 4.2 to 6.5 of ISO 14971:2000 shall be provided for evaluation.

11.6.3	**RM RESULTS TABLE: Spillage on ME equipment and ME system**		**Pass**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	See document 453627 rev 1 Product Specifications	The Treadmill is provided with a cup holder. Spillage of liquids may occur.	Pass
4.3	See document 1234567 rev 1 clause 7.1	The possible hazard of electric shock to the patient caused by the insulation breakdown has been identified. For the purpose of the test, the following test conditions have been identified: Type of liquid: mineral water Volume: 1 liter Duration of spill: 15 s Point of contact: on the end of the belt above the drum motor from a height not exceeding 5 cm	Pass
4.4	Document 7654321 – rev 2 Refer to clause 7.1	The probability of occurrence of the harm has been estimated in “ProbRange C”. The severity of the harm has been estimated as “SevRange A”	Pass
5	Document 7654321 – rev 2 Refer to clause 7.1	The risk has been evaluated as “TBR = To Be Reduced”	Pass
6.2	Document 7654321 – rev 2 Refer to clause 7.1	The measure that has been identified to control the risk is a protective cover to the motor.	Pass
6.3	Document 1726354 – rev 3 Design Verification	The Treadmill is provided with a protective cover	Pass
6.4	Document 1726354 – rev 3 Design Verification	No wetting of uninsulated electrical parts or electrical insulation of parts could result in a Hazardous Situation. The probability of occurrence of the harm has been reduced to “ProbRange A”. The residual risk has been evaluated as “acceptable”.	Pass
6.5		Not deemed necessary	N/A

Compliance with those sub-clauses in IEC 60601-1 that refer to "minimizing risk" are deemed satisfied if the manufacturer can show that the particular condition or event does not result in an unacceptable risk.

Compliance with those sub-clauses in IEC 60601-1 that require protection against a particular condition or event that "could result in a hazardous situation" are deemed to be satisfied if the manufacturer can show that the particular condition or event does not result in an unacceptable risk.

5.9 Workflow

1. Based on the latest TRF version, establish the relevant clauses of IEC 60601 series that have to be supported by RM documentation.

2. Verify the required documentation and identify the relevant reference points to be listed in the TRF. To initiate the assessment process of a manufacturer, the CBTL may use attachment 1, from this Procedure (ISO 14971:2000 Checklist), attachment 2 from this Procedure (ISO 14971:2007 Checklist) or equivalent. The form is intended to facilitate an understanding of the manufacturer's risk management procedures. The completion of this form documents the assessment of the manufacturer's risk management process. (Note: It is not necessary to maintain a copy of the risk management file).

3. In case the use of RM influences the tests (see clause 5.2)

   3.1 Identify the test to be conducted

   3.2 Identify the test parameters and conditions to be used performing the tests

   3.3 Identify the RM Pass/Fail criteria. The Pass/Fail criteria and the rationale for acceptance shall be reported in the TRF.

4. Perform verification and report the results in the TRF tables.

5.10 Application of Risk Management to the General and Collateral Standards

The evaluation of clauses and sub-clauses of IEC 60601-1 containing risk management requirements are provided in Table 1 of this document, Clause Mapping Guide.
The evaluation of clauses and sub-clauses in IEC 60601-1-nn, Collateral standards containing risk management requirements are provided in Tables 1-3 through 1-11 of this document.

Note: Guidance has not yet been developed by the task force for IEC 60601 3rd edition particular standards IEC 60601-2-nn. The collateral standard IEC 60601-1-2:2007 does not contain any risk management requirements, the RM requirements are addressed through the IEC 60601-1 (Clause 17).
There is no planned guidance for IEC 60601-1-9:2007.

6 Clause mapping guide IEC 60601 / ISO 14971

6.1 Application of ISO 14971:2000 in IEC 60601-1:2005 product evaluation

IEC 60601-1:2005 (Ed.3) Medical electrical equipment, Part 1: General requirements for basic safety & essential performance - Guidance for the application of ISO 14971:2000 (Ed.1)

Clause 4 – General requirements

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
4.2	Risk Management Process for ME Equipment or ME Systems	Compliance is checked by inspection of the risk management file. The requirements of this clause and all requirements of this standard referring to inspection of the risk management file are considered to be satisfied if the manufacturer has: – established a risk management process; and – established acceptable levels of risks; and – demonstrated that the residual risk is acceptable Does the manufacturer have a risk management process according to ISO14971:2000 in place? Was this process used for the device being considered? If so, a limited number of more detailed questions can be addressed at this point: • Are all risk management procedures (that meet the requirements of ISO14971:2000, including acceptability criteria) developed and applied for the device considered (clauses 3.3 a), 3.5 e), 4 to 7 of ISO14971:2000)? • Is there a risk management plan (including resources and commitment) for the device considered (clause 3.3 a), 3.5 e) of ISO14971:2000)? • Is the overall residual risk for the device considered acceptable (clause 7 of ISO 14971:2000)?	3.3 a), 3.5 e), 4 to 7
4.3	Essential performance	Compliance is checked by inspection of the risk management file. Have, apart from the essential performance identified in the particular standards, hazardous situations been identified whereby the residual risk is unacceptable due to the absence of performance of the device? If so, has this performance been identified as essential performance for the device during the risk assessment process? If so, have risk control measures or particular tests been identified to check whether this performance is maintained? If so, has this been checked by inspection or by functional test?	4.2 to 5
4.5	Equivalent safety for ME Equipment of ME System	Compliance is checked by inspection of the risk management file. Are there particular risks for which alternative means of controlling these risks are applied such that the resulting risk level is acceptable for these risks? If so, have these risks been identified as such during the risk assessment process? If so, is the resulting risk level equal or less than the residual risk that results from applying the requirements of this standard?	4.2 to 5, 6.2 to 6.5

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
4.6	ME equipment or ME system parts that contact the patient	Compliance is checked by inspection of the risk management file. Have parts been identified during the risk management process which can come into contact with the patient but fall outside the definition of applied parts? If so, are all the relevant requirements and tests of this standard applied? If so, are there residual risks which are not acceptable? If so, are risk controls measures implemented that make the residual risk acceptable?	4.2 to 6.5
4.7	Single Fault Condition for ME Equipment	Compliance is determined by applying the specific requirements and tests associated with the single fault conditions identified in 13.2, and tests for the failures identified from evaluation of the results of the risk analysis. Compliance is determined if the introduction of any of the single fault conditions described in 13.2, one at the time, does not lead directly to the hazardous situations described in 13.1, or any other outcome that results in an unacceptable risk. Are there single fault conditions which lead directly to hazardous situations described in 13.1 or to risks that are unacceptable?	4.2 to 4.4
4.8	Components of ME Equipment	Compliance is checked by inspection and, where necessary, by test. The tests of this standard for motors (see 13.2.8 and 13.2.13.3) and transformers (see 15.5.3) are considered to be comprehensive and together with the evaluation of the motor or transformer insulation system according to Table 22 represent all testing required by this standard. ME system components that provide isolation from non-ME equipment are evaluated to clause 16. Are specific exceptions made for any component of the device under investigation to allow it to be used not in accordance with its specified rating? If so, are these exceptions formulated as the result of the risk management process? If so, have inspection or test requirements been formulated to make the hazardous situations acceptable?	4.2 to 6.5
4.9	Use of components with high-integrity characteristics in ME	Compliance is checked by inspection of the risk management file and the selection criteria for the components with high-integrity characteristics. Are components with high-integrity characteristics applied? If so, have the risks associated with its use been identified as such during the risk assessment process, or in other words are they selected and evaluated consistent with their conditions of use and reasonably foreseeable misuse during the expected service life of the ME equipment?	4.2 to 6.5

Clause 5 – General requirements for testing MEE

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
5.1	Type Tests	The tests to be performed are determined taking into consideration the requirements of clause 4, in particular 4.2. For the selection of the tests to be performed, is a risk management process according to ISO14971:2000 applied? If so, this requirement is fulfilled. The results of the risk analysis are used to determine which combination(s) of simultaneous faults are to be tested. For the determination of which combination(s) of simultaneous faults have to be tested, is a risk assessment applied?	4.2 to 4.4
5.4 a)	Other conditions	Unless otherwise specified in this standard, ME equipment is to be tested under the least favourable working conditions as specified in the Instructions for Use that are identified during the risk analysis. For testing of the ME equipment, have the least favourable working conditions been identified via the risk analysis?	4.2 to 4.4
5.7	Humidity preconditioning treatment	Where the risk management process suggests that the ME equipment can be exposed to high humidity for extended periods, the period is extended appropriately. Has it been determined via the application of the risk management process whether the ME equipment can be exposed to high humidity for extended periods? If so, is the period for testing been extended appropriately following the conclusions of the risk management process?	4.2 to 6.5
5.9.2.3	Actuating mechanisms	Inspection of the risk management file demonstrates that the relevant part is unlikely to become detached unintentionally during the expected service life of the ME equipment. Has the result of the risk analysis demonstrated that the relevant part is unlikely to become detached unintentionally during the expected service life time of the ME equipment and that an acceptable residual risk results?	4.2 to 6.5

Clause 7- MEE Identification, markings and documents

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
7.2.2	Identification	ME Equipment and its detachable parts not marked with the name or trademark of the manufacturer and with a Model or Type reference does not present an unacceptable risk?	4.2 to 5, 6.4
7.2.5	ME Equipment intended to receive power from other equipment	Are the model or Type reference of the specified other equipment marked if this could result in an unacceptable risk?	4.2 to 5, 6.4
7.2.13	Physiological effects (safety signs and warning statements)	Do the instructions for use describe the nature of the HAZARD and the precautions for avoiding it or minimizing the associated RISK?	4.2 to 5, 6.3

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
7.2.17	Protective packaging	Can premature unpacking of ME Equipment or its parts result in an unacceptable RISK? Is the packaging marked with a suitable safety sign?	4.2 to 5, 6.3, 6.4
7.3.3	Batteries	Are there lithium batteries or fuel cells which are incorporated where incorrect replacement could result in an unacceptable RISK? If so, is there a warning indicating that replacement by inadequately trained personnel could result in a HAZARD?	4.2 to 5, 6.3
7.3.7	Supply terminals	Are Terminals for supply conductors marked adjacent to the terminals? If not, does the identification of known or foreseeable hazards (risk management file) demonstrate that no HAZARDOUS SITUATION can result if connections are interchanged?	4.3
7.4.2	Control devices	In normal use, can the change of the setting of a control result in an unacceptable RISK to the patient? If so, review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control.	4.2 to 5, 6.2, 6.3
7.5	Safety signs	Is marking used to convey a warning, prohibition or mandatory action that mitigates a RISK that is not obvious to the operator? If so, review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control.	4.3 to 5, 6.3
7.9.1	General accompanying documents format. (see also Table C.4)	Compliance is checked by inspection of the risk management file. Has the manufacturer applied the risk management process to determine which information also needs to be provided as hard copy or as marking on the ME equipment?	4.2 to 5, 6.2, 6.3
7.9.2.4	Electrical power source	If leakage from a battery would result in an unacceptable RISK, do the instructions for use include a warning to remove the battery if the ME Equipment is not likely to be used for some time? If so, review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control. If loss of power would result in an unacceptable risk, do the instructions for use include a Warning that the ME Equipment must be connected to an appropriate power source? If so, review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control.	4.2 to 5, 6.3
7.9.3.2	Replacement of fuses, power supply cords and other parts	Where replacement of a component could result in an unacceptable RISK, is there appropriate warnings to identify the nature of the HAZARD and, if the Manufacturer specifies the component as replaceable by service personnel, is all information necessary to safely replace the component? Review the manufacturers risk management file for risk analysis, risk evaluation and where necessary risk control measures.	4.2 to 6.5

Clause 8 - Protection against electrical hazards from MEE

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
8.1 b	Fundamental rule of protection against electric shock	1. Has the manufacturer identified in their risk analysis if the interruption of any one power carrying conductor between MEE parts in separate enclosures might cause permitted limits (voltage, current, energy) to be exceeded? If so, then during product safety verification, this must be one of the SFC's tested. 2. Has the manufacturer identified in their risk management process that a component's movement must be considered as a SFC because its lack of securement (8.10.1) over the expected service life of the MEE may cause permitted limits (voltage, current, energy) to be exceeded? If so, then during product safety verification, this must be one of the SFC's tested. 3. Has the manufacturer identified in their risk management process accidental detachment of conductors and connectors? If so, then during product safety verification, this must be one of the SFC's tested	b(1) 4.3 & 4.4 b(2) 4.2 to 6.5 b(3) 4.3
8.2.2	Connection to an external d.c. power source	Does ME Equipment specified for power supplied from an external d.c. power source, have no HAZARDOUS SITUATION, other than absence of essential performance, develop when a connection with the wrong polarity is made? Review the manufacturers risk management file for risk analysis and risk evaluation. Does the ME Equipment, when connection is subsequently made with the correct polarity, provide freedom from unacceptable RISK? Review the manufacturers risk management file for risk analysis and risk evaluation.	4.2 to 5
8.3 d	Classification of applied parts	Has the manufacturer identified in their risk management process the need for parts (not being applied parts) to be subject to the requirements for an applied part of Type BF or Type CF? If so, then during product safety verification, these parts are to be tested accordingly.	6.2
8.4.2 c	Accessible parts including applied parts	Has the manufacturer identified parts (not being applied parts) where a current exceeding the allowable touch current could flow, either directly or through the body of an operator, however, the risk analysis determined that the probability in normal use is negligible? If so, then during product safety verification, these identified parts do not require touch current testing. Inspect the instructions for use includes instructions for the operator not to touch the relevant part and the patient simultaneously.	4.2-4.4
8.5.2.2	Type B applied parts	Has the manufacturer identified in their risk management file, unearthed Type B applied parts that are not separated from unearthed conductive accessible parts, however, determined that the level of risk that the unearthed accessible part will make contact with a source of voltage or leakage current above permitted limits is acceptably low? If so, accepted. If not, then one means of protection is required.	4.2 to 5

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
8.5.2.3	Patient Leads	Has the manufacturer identified in their risk management process connectors for electrical connections on a patient lead at the end of the lead remote from the patient and that contains a conductive part that is not separated from all patient connections by one MOPP for a working voltage equal to the maximum mains voltage, that will not present an unacceptable risk from contact with objects other than a mains socket or a flat surface (e.g. corners or edges)? If so, during product safety verification, the test using a straight, rigid test finger with a force of 10 N is not required, however, the remaining inspections of this clause are required.	4.2 to 5
8.6.3	Protective earthing of moving parts	Does the manufacturer's risk management file indicate the need to bond moving parts to the protective earth connection? If so, has the manufacturer demonstrated the reliability of the connection during the expected service life?	4.2 to 6.5
8.8.4.1	Mechanical strength and resistance to heat	Has the manufacturer identified in the risk management file the need for insulations of all types, considering its resistance to heat in the application and the expected service life? Has the manufacturer identified any specific test protocols that must be performed during product safety verification? If so, conduct the tests required in this clause and any additional tests or inspections identified in the risk management file.	4.2 to 6.5
8.10.1	Fixing of components	Has the manufacturer identified components the movement of which could result in an unacceptable risk in their risk management file? If so, verify that such identified components are securely mounted and will remain so for the expected service life.	4.2 to 6.5
8.10.2	Fixing of wiring	Has the manufacturer identified in their risk management file the need to restrain by double securement any conductors and connectors where if they were to break free and touch circuit points this could result in a hazardous situation? If so, inspect the construction and restraint of these conductors and connectors to ensure that they are held in place by use of double securement.	4.3 to 6.5
8.10.5	Mechanical protection of wiring	Has the manufacturer identified in the risk management file the need to protect against contact with moving parts, friction at sharp corners and edges or damage during assembly or the opening or closing of access covers of internal cables, wiring, cord forms or components, where the damage or insulation damage could result in a hazardous situation? If so, inspect these parts carefully considering their location and potential damage during assembly, disassembly, contact with moving parts and friction at sharp corners and edges.	4.3 to 6.5
8.11.5	Mains fuses and over-current releases	Has the manufacturer provided justification for omission of fuses or over-current releases in the risk management file? If so, inspect the circuit according to the requirements of this clause ensuring double insulation and acceptable fault condition tests results.	4.3 to 6.5

Clause 9 - Protection against mechanical hazards of MEE and MES

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
9.2.1	Hazards associated with moving parts - General	Are protective measures used to reduce the risk from contact with moving parts? Considering use as indicated in the Accompanying Documents or reasonably foreseeable misuse and bearing in mind the ease of access, the ME Equipment function, the shape of the parts, the energy and speed of the motion and the benefits to the patient, is this risk reduced to an acceptable level? Is exposure to moving parts needed for MEE to perform its intended function? Have all reasonable protective measures including warning markings on the MEE where the hazards persist been implemented?	4.2 to 6.5
9.2.2.4.3	Movable guards	Are the risks caused by mechanical hazards associated with moving parts and reduced by use of the movable guards addressed?	4.2 to 6.5
9.2.2.4.4	Protective measures	Are the risks caused by mechanical hazards associated with moving parts and reduced by the use of protective measures incorporated in the control system addressed?	4.2 to 6.5
9.2.2.5 c	Continuous activation	Are the risks caused by mechanical hazards associated with accessibility to a trapping zone and reduced by use of the continuous activation of the movement control addressed?	4.2 to 6.5
9.2.2.6	Speed of movement(s)	Are the risks caused by mechanical hazards associated with the speed of movement addressed?	4.2 to 6.5
9.2.3.2	Over travel	Are the risks caused by mechanical hazards associated with the over travel addressed?	4.2 to 6.5
9.2.4	Emergency stopping devices	Does the MEE use emergency stopping devices? Are risks caused by mechanical hazards which are reduced by the use of the emergency stopping devices reduced to an acceptable level?	4.2 to 6.6
9.2.5	Release of patient	Are the risks caused by mechanical hazards associated with release of patient addressed?	4.2 to 6.5
9.3	Hazards associated with surfaces, corners and edges	Are the risks caused by mechanical hazards associated with surfaces, corners and edges addressed?	4.3 to 6.5
9.4.2.4.3	Movement over a threshold	Are the risks caused by mechanical hazards associated with movement over a threshold addressed?	4.2 to 6.5
9.5.1	Protective means	Have the risks caused by mechanical hazards associated with expelled parts been addressed?	4.3 to 6.5
9.6.1	Acoustic energy - General	Have the risks caused by mechanical hazards associated with acoustic energy and vibration been addressed?	4.2 to 6.5
9.6.2.2	Infrasound and ultrasound energy	Have the risks caused by mechanical hazards associated with infrasound and ultrasound energy been addressed?	4.2 to 6.5

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
9.7.2	Pneumatic and hydraulic parts	Have the risks caused by mechanical hazards associated with pneumatic and hydraulic parts been addressed?	4.3 to 6.5
9.7.4	Pressure rating of ME equipment parts	Have the risks caused by mechanical hazards associated with pressure rating of MEE parts been addressed?	4.3 to 6.5
9.7.6	Pressure-control device	Have the risks caused by mechanical hazards associated with pressure – control device been addressed?	4.3 to 6.5
9.7.7	Pressure-relief device	Have the risks caused by mechanical hazards associated with a pressure-relief device been addressed?	4.3 to 6.5
9.8.1	Hazards associated with support systems - General	Have the risks caused by hazards arising from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions been addressed? Were all of the following failures considered: excessive deflection, plastic deformation, ductile or brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep, and material deterioration? Were the following residual stresses resulting from the manufacturing process, e.g. machining, assembling, welding, heat treatment or surface coating considered?	4.2 to 6.5
9.8.2	Tensile safety factor	When not according to Table 21, what alternative method was used to determine the tensile safety factor? Have the risks related to the value of the tensile factor been addressed?	4.3 to 6.5
9.8.3.1	Strength of patient or operator support or suspension systems - General	Have the risks caused by mechanical hazards associated with support or suspensions of the patient (including particular applications) been addressed?	4.2 to 6.5
9.8.3.2 a, b	Static forces due to loading from persons	Have the risks caused by mechanical hazards associated with static forces due to loading from persons been addressed?	4.3 to 6.5
9.8.4.1	Systems with mechanical protective devices- General	Does the MEE use mechanical protective devices? Does the mechanical protective device activate before travel (movement) produces an unacceptable risk?	4.3 to 6.5
9.8.4.3	Mechanical protective device intended for single activation	Does the MEE use mechanical protective devices intended for single activation? Where risks caused by mechanical hazards which have been reduced by the use of mechanical protective devices intended for single activation:	4.3 to 6.5
9.8.5	Systems without mechanical protective devices	Has the manufacturer determined that the use of mechanical protective devices in the MEE is not required? Has the manufacturer justified the reasons not to use mechanical protective devices?	4.3 to 6.5

Clause 10 - Protection against unwanted and excessive radiation hazards

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
10.1.2	ME equipment intended to produce diagnostic or therapeutic X-radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of X-radiation in the risk management file?	4.2 to 6.5
10.2	Alpha, beta, gamma, neutron and other particle radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of alpha, beta, gamma, neutron or other particle radiation in the risk management file?	4.2 to 6.5
10.3	Microwave radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of microwave radiation in the risk management file?	4.2 to 6.5
10.5	Other visible electromagnetic radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of visible electromagnetic radiation in the risk management file?	4.2 to 6.5
10.6	Infrared radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of infrared radiation in the risk management file?	4.2 to 6.5
10.7	Ultraviolet radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of ultraviolet radiation in the risk management file?	4.2 to 6.5

Clause 11 - Protection against excessive temperatures and other hazards

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
11.1.1	Maximum temperature during normal use		
	Table 23	Has the manufacturer identified parts of the ME Equipment that are likely to be touched in normal or foreseeable misuse that can contact more than 10% of the surface area operator or patient's body or 10% of the surface area of the patient's or operator's head? Has the manufacturer identified the duration of continuous or aggregate contact? Has the manufacturer identified and addressed such risks? Has the RM process determined suitable limits for temperature based on the risk acceptability criteria and risk benefit analysis in association with patient state of health and whether adult, pediatric or neonate?	4.2 to 6.5
	Table 24	Has the manufacturer identified applied parts of the ME Equipment that can contact more than 10% of the surface area operator or patient's body or 10% of the surface area of the patient's or operator's head during normal or foreseeable misuse? Has the manufacturer identified the duration of continuous or aggregate contact of these applied parts? Has the manufacturer identified and addressed such risks? Has the RM process determined suitable limits for temperature based on the risk acceptability criteria? If the temperature limits exceed the values in table 24 has a favorable risk benefit analysis in association with patient state of health and whether adult, pediatric or neonate been documented?	4.2 to 6.5
11.1.2.1	Applied parts intended to supply heat to a patient	Is any part of the ME Equipment intended to supply heat or otherwise intended to cool a patient? Has the manufacturer identified and addressed the clinical risks associated with hazards? Has the manufacturer disclosed such risks?	4.2 to 6.5
11.1.2.2	Applied parts not intended to supply heat to a patient	Does the ME equipment have any applied parts that are not intended to heat or cool the patient that could in normal or foreseeable misuse exceed 41 °C or cool below ambient temperature?	4.2 to 6.5
11.1.3 e	Measurements	Has the manufacturer identified hazardous situations that relate to maximum heating effect of nearby surfaces? If no hazardous situations are apparent has the manufacturer made appropriate declarations in the RMF? Has the manufacturer identified all conditions of intended use and foreseeable misuse to determine occurrence and duration of contact with parts and applied parts that could be touched?	4.2 to 6.5
11.2.2.1	Risk of fire in an oxygen rich environment	Has the manufacturer identified that there is a risk of fire from an oxygen rich environment? Where scenario number 3 is applicable, has the manufacturer conducted a risk assessment to determine hazards associated with leaks or component failures causing a source of ignition been conducted?	4.2 to 6.5

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
11.3	Constructional requirements for fire enclosures of ME equipment	Have the specific requirements of this clause been employed to comply with cl 13.1.2? Has the manufacturer analyzed and addressed risks of not complying with the constructional requirements and showed than an equivalent level of risk / benefit has been provided?	4.2 to 6.5
11.5	ME equipment and ME systems intended for use in conjunction with flammable agents	Is the ME Equipment intended to (or can it through foreseeable misuse) come into contact with flammable agents?	4.2 to 6.5
11.6.2	Overflow in ME Equipment	Does a HAZARDOUS SITUATION or unacceptable risk due to overflow develop if transportable ME Equipment is tilted through an angle of 15°? Review the manufacturers risk management file for risk analysis and risk evaluation. Does wetting of uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION occur? Review the manufacturers risk management file for risk analysis and risk evaluation.	4.2 to 5
11.6.3	Spillage on ME equipment and ME system	Does the ME Equipment require the handling of liquids in normal or foreseeable misuse? Could the wetting of the ME equipment result in a hazardous situation? Has the manufacturer identified hazardous situations relating to the worst case volume and type of liquid? Has the manufacturer identified hazardous situations relating to the worst location for the equipment to spill?	4.2 to 6.5
11.6.5	Ingress of water or particulate matter into ME Equipment and ME Systems	Does the ME Equipment show no signs of bridging of insulation (or electrical components) that could result in a HAZARDOUS SITUATION in normal condition or in combination with a single fault condition? Review the manufacturers risk management file for risk analysis and risk evaluation.	4.2 to 5
11.6.6	Cleaning and disinfection of ME equipment and ME systems	Has the manufacturer identified the parts of the ME equipment which may be subject to cleaning or disinfection in normal or foreseeable misuse and the type of cleaning or disinfection? Based on the ESL of the ME equipment has the manufacturer extrapolated the number of cleaning processes to which the equipment will be subjected? Has the manufacturer identified all related hazards and addressed such risks in the RMF?	4.2 to 6.5
11.6.7	Sterilization of ME equipment and ME systems	Has the manufacturer identified the parts of the ME equipment which may be subject to sterilization in normal or foreseeable misuse and the type of sterilization?	4.2 to 6.5
11.6.8	Compatibility with substances used with the ME equipment	Has the manufacturer identified all substances to which the ME Equipment may come into contact with in normal or foreseeable misuse?	4.2 to 6.5

Clause 12 - Accuracy of controls & instruments; protection against hazardous outputs

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
12.1	Accuracy of controls and instruments	Has the manufacturer identified all controls and instruments contained on the ME Equipment? Has the manufacturer conducted a hazard analysis to identify the risks associated with the accuracy of the above identified controls and instruments?	4.2 to 6.5
12.3	Alarm systems	Has the manufacturer considered in their option analysis the inclusion of alarms as a means to mitigate the risk of accuracy of controls and instruments for controlling hazards against hazardous outputs? If yes, has the use of alarms been implemented as a means of mitigating the risk of accuracy of controls and instruments for controlling hazards against hazardous outputs? If yes, has the manufacturer in their risk analysis explored and addressed the hazards of operation or failure of the alarm systems? Does the residual risk of such hazards meet IEC 60601-1-8?	4.2 to 6.5
12.4.1	Intentional exceeding of safety limits	Has the manufacturer identified risks associated with the intentional exceeding of safety limits? Has the manufacturer addressed such risks to comply with the manufacturer's risk acceptability criteria?	4.2 to 6.5
12.4.2	Indication of parameters relevant to safety	Has the manufacturer identified all functions related to the delivery of energy or substances to the patient? Has the manufacturer explored such functions for hazardous situations in which these functions can produce an output to the patient?	4.2 to 6.5
12.4.3	Accidental selection of excessive output values	Has the manufacturer identified all features of the ME Equipment that provide an output to the patient for therapeutic purposes? Has the manufacturer identified which of these features have multiple purposes that require different intensities for different treatments? Has the manufacturer identified hazards associated with accidental selection of excessive output values?	4.2 to 6.5
12.4.4	Incorrect output	Has the manufacturer identified all features of the ME Equipment that provide an output? Has the manufacturer identified hazards associated with incorrect output?	4.2 to 6.5
12.4.5.2	Diagnostic X-ray equipment	Has the manufacturer identified if the product emits intentional X-ray radiation for diagnostic purposes? Has the manufacturer identified and explored risks associated with emission of X-Ray radiation for diagnostic purposes?	4.2 to 6.5
12.4.5.3	Radiotherapy equipment	Has the manufacturer identified if the product is intended for radiotherapy purposes? Has the manufacturer identified and explored risks associated with emission radiation for therapeutic purposes?	4.2 to 6.5

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
12.4.5.4	Other ME equipment producing diagnostic or therapeutic radiation	Has the manufacturer identified if the product is intended for radiotherapy purposes? Has the manufacturer identified and explored risks associated with emission radiation for therapeutic purposes?	4.2 to 6.5
12.4.6	Diagnostic or therapeutic acoustic pressure	Has the manufacturer identified if the equipment emits an acoustic pressure output? Has the manufacturer identified and explored risks associated with emission of such acoustic pressure?	4.2 to 6.5

Clause 13 - Hazardous situations and fault conditions

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
13.2.6	Leakage of liquid	Has the manufacturer determined the appropriate test conditions for the evaluation of liquid leakage?	4.2 to 6.5

Clause 14 - Programmable Electrical Medical Systems (PEMS)

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
14.1	Programmable electrical medical systems - General	Does the application of ISO 14971 demonstrate that the failure of the PEMS does not lead to an unacceptable risk?	4.2 to 5
14.6.1	Identification of known and foreseeable hazards	Has the manufacturer considered those hazards associated with the software and hardware aspects of the PEMS including those associated with Network/Data coupling and legacy subsystems?	4.3
14.6.2	Risk control	Has the manufacturer identified suitable tools and procedures to implement risk control measures? Are these tools and procedures appropriate to ensure that each risk control measure effectively reduces the identified risks?	6.1
14.7	Requirement specification	Does the requirement specification include and distinguish any risk control measures?	6.3
14.8	Architecture	Does the architecture specification reduce the risk to an acceptable level, where appropriate, using levels a) – f)? Does the architecture specification take into consideration allocation of risk control measures?	6.3
14.9	Design and Implementation	Is descriptive data regarding the design environment included in the risk management file?	6.2, 6.3
14.10	Verification	Is the result of the verification activity documented? Have all functions that implement risk control measures been verified?	6.3

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
14.11	Programmable electrical medical systems - PEMS validation	Has the manufacturer documented the professional relationships of the members of the PEMS Validation team with members of the design team? Is a reference to the methods and results of the PEMS Validation included in the risk management file?	6.3
14.13	Connection of PEMS by network/data coupling to other equipment	Is there a list of the HAZARDOUS SITUATIONS resulting from a failure of the network/data coupling provided with the specified characteristics? Review the manufacturers risk management file for any risk analysis, risk evaluation and any necessary risk control measures. Does a connection of the PEMS to a network/data coupling that includes other equipment result in previously unidentified RISKS to patients, operators or third parties? Review the manufacturers risk management file for any risk analysis, risk evaluation and any necessary risk control measures.	4.2 to 5, 6.2, 6.3

Clause 15 - Construction of MEE

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
15.1	Construction of ME equipment - Arrangements of controls and indicators of ME equipment	Has the manufacturer identified in the risk management process the risks associated with the arrangement of controls and indicators? If so, inspect for the arrangement of controls and indicators.	4.2 to 6.5
15.3.2	Push test	After the push test, were damages sustained that result in an unacceptable risk identified?	4.2 to 5
15.3.3	Impact test	After the impact test, were damages sustained that resulted in an unacceptable risk identified?	4.2 to 5
15.3.4.2	Portable ME equipment	After the drop test, were damages sustained that resulted in an unacceptable risk identified?	4.2 to 5
15.3.5	Rough handling test	After the rough handling test, were damages sustained that resulted in an unacceptable risk identified?	4.2 to 5
15.4.1	Construction of connectors	Has the manufacturer identified electrical, hydraulic, and pneumatic or gas connection terminals and connectors removable without the use of a tool where incorrect connection to other outlets intended for other functions would not result in unacceptable risks? If so, ensure that incorrect connection does not result in an unacceptable risk. (Gas connectors must comply with item b) of this clause).	4.2 to 6.5
15.4.2.1 a	Temperature and overload control devices - Application	Has the manufacturer identified in the risk management file, any automatic resetting thermal cut-outs or over-current releases where their use would not result in an unacceptable risk? If so, ensure that the resetting of these devices does not result in unacceptable risks.	4.2 to 5

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
15.4.2.1 b	Application	Has the manufacturer identified in the risk management file the use of thermal cut-outs with a safety function? If so, ensure that such components are not of the types that have to be reset by a soldering operation that can affect the operating value.	4.2 to 4.4
15.4.2.1 c	Application	Has the manufacturer identified the use of a thermostat in the MEE in the risk management file? If so, inspect for an independent non-self-resetting thermal cut-out with a setting outside the maximum range of the thermostat but within the safe temperature limit for its intended function.	4.2 to 4.4
15.4.2.1 d	Application	Has the manufacturer identified that loss of function of the MEE could result in a hazardous situation? If so, ensure that the operation of a thermal cut-out or over-current release does not result in an unacceptable risk.	4.2 to 4.4
15.4.2.1 h	Application	Has the manufacturer identified the need for fusing each lead for the use of tubular heating elements in the risk management file? If so, inspect for fuses in both leads and fault either lead to ground and ensure over-heating does not occur.	4.2 to 4.4
15.4.3.1	Housing	Has the manufacturer identified the need for ventilated battery housings where gases that could result in a hazard can escape during charging or discharging? If so, inspect the battery housings for proper ventilation. Has the manufacturer identified the need for battery polarity connection construction such that short-circuiting is not possible? If so, inspect the battery connection and ensure that incorrect connection is not possible.	4.2 to 4.4
15.4.3.2	Connection	If a HAZARDOUS SITUATION might develop by the incorrect connection or replacement of a battery, verify the ME Equipment is fitted with a means of preventing incorrect polarity of connection. Review the manufacturers risk management file for any risk analysis.	4.2 to 4.4
15.4.3.3	Protection against overcharging	Does overcharging of any battery of ME Equipment result in an unacceptable RISK, the design shall prevent overcharging? Review the manufacturers risk management file for any risk analysis.	4.2 to 4.4
15.4.3.4	Lithium batteries	Do lithium batteries used in ME EQUIPMENT that could become a HAZARD comply with the requirements of IEC 60086-4? Review the manufacturers risk management file for any risk analysis.	4.2 to 4.4
15.4.3.5	Excessive current and voltage protection	Has the manufacturer provided justification for the omission of fuses or over-current releases in the risk management file? If so, protection against fire caused by excessive currents is by inspection of the design and the risk management file and no additional testing is required.	4.2 to 6.5

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
15.4.4	Indicators	Are indicator lights provided on ME Equipment incorporating non-luminous heaters to indicate that the heaters are operational, if a HAZARDOUS SITUATION could exist unless it is otherwise apparent to the operator from the normal operating position? Review the manufacturers risk management file for any risk analysis. Are indicator lights provided on ME Equipment to indicate that an output exists where an accidental or prolonged operation of the output circuit could constitute a HAZARDOUS SITUATION? Review the manufacturers risk management file for any risk analysis.	4.2 to 4.4
15.4.5	Pre-set controls	Where applicable, has the manufacturer addressed the risk associated with pre-set controls?	4.2 to 6.5
15.4.7.3 b	Entry of liquids	Has the manufacturer conducted risk analysis for foot operated control devices during their risk management process? If so, is the probability of occurrence of the intended normal use in areas where liquids are likely to be found low enough such that foot-operated control devices that contain electrical circuits do not have to be classified IPX6 according to IEC 60529? If so, then perform testing at the manufacturer's lesser IPX_ rating. Note IPX1 is the minimum rating. If not, then verify compliance to IPX6 classification.	4.2 to 4.4

Clause 16 – ME Systems

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
16.1	General Requirements for ME Systems	After installation or subsequent modification, does the ME system result in an unacceptable risk? Have hazards arising from combining various equipment to constitute an ME system been considered? Is the level of safety equivalent to ME system complying with this standard IEC 60601-1 within the patient environment? If the ME System is reconfigurable, have risk management methods been used to determine which configurations constitute the highest risks and which measures are needed to ensure that the reconfiguration does not constitute an unacceptable risk?	4.2 to 5
16.9.1	Connection terminals and connectors	Are the design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors such that incorrect connection of accessible connectors, removable without the use of a tool, can be prevented where a HAZARDOUS SITUATION could otherwise exist? Review the manufacturers risk management file for any risk analysis, risk evaluation and risk control measures. Are plugs for patient leads designed to prevent connection to other outlets of the same ME System that are likely to be located in the patient environment unless no hazardous situation can result? Review the manufacturers risk management file for any risk analysis, risk evaluation and risk control measures.	4.2 to 6.5

Clause 17 – Electromagnetic compatibility of MEE and MES

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
17	Electromagnetic compatibility of ME equipment and ME systems	Does the risk management process address the risks associated with the electromagnetic phenomena existing at the locations where the ME equipment or ME System is intended to be used as indicated in the accompanying documents? Does the risk management process address the risks associated with the introduction by the ME equipment or ME system of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment, and systems?	4.2 to 6.5

Notes:

Clauses 3.3a, 3.5e, and 7 shall be included in the complete RM file which has been addressed through clause 4.3. Numbering above is inclusive as applicable. This document includes clauses from IEC 60601-1 which have guidance for inspection requirements of the manufacturer's risk management file, risk control measures and risk management process. The document does not address other clauses from IEC 60601-1 which include key terms for example RISK (with or without qualifying words such as unacceptable, acceptable and significant), HAZARD, HAZARDOUS SITUATION. These clauses do not necessarily require the manufacturer to include them in their risk management process.

6.2 Application of ISO 14971:2007 in IEC 60601-1:2005 + A1:2012 product evaluation

IEC 60601-1:2005 + A1:2012 (Ed.3 + Am. 1) Medical electrical equipment, Part 1: General requirements for basic safety & essential performance - Guidance for the application of ISO 14971:2007 (Ed.2)

Clause 4 – General requirements

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
4.2.2	General requirements for RISK MANAGEMENT	Compliance is checked by: – inspection of the MANUFACTURER'S policy for determining criteria for RISK acceptability; – inspection of the RISK MANAGEMENT plan for the particular ME EQUIPMENT or ME SYSTEM under consideration; and – confirming the MANUFACTURER has prepared a RISK MANAGEMENT FILE containing the RISK MANAGEMENT RECORDS and other documentation required by this standard for the particular ME EQUIPMENT or ME SYSTEM under consideration. Does the manufacturer have a risk management process according to ISO14971:2007 in place? Was this process used for the device being considered? If so, a limited number of more detailed questions can be addressed at this point: • Are all risk management procedures (that meet the requirements of ISO14971:2007, including acceptability criteria) developed and applied for the device considered (clauses 3.3, 3.4, 3.5, 4 to 8 of ISO14971:2007)? • Is there a risk management plan (including resources and commitment) for the device considered (clause 3.4 of ISO14971:2007)? • Has the manufacturer established requirements for maintaining a Risk management file (clause 3.5 of ISO 14971:2007)? • Is the overall residual risk for the device considered acceptable (clause 7 of ISO 14971:2007)? • Has the manufacturer established requirements for creating a Risk management report to document the review of Risk management activities (clause 8 of ISO 14971:2007)?	3.3, 3.5, 4.1 to 8

NOTES:

The table shown above is a modified version of Table 4.2 from Section 6.1 of this document used when applying IEC 60601-1:2005 + A1:2012 and ISO 14971:2007. For all other Risk management requirements in IEC 60601-1:2005 + A1:2012, use the corresponding guidance from section 6.1 of this document for completing the RM Tables in Revision H of the TRF. Where no RM Table exists in Revision H of the TRF, no assessment of the Risk management file is required.

IEC 60601-1:2005 + A1:2012 modified the Risk management requirements now summarized in Table 4.2.2 and removed the need to assess the Risk management file for many other clauses. No new Risk management requirements were added above those already described in IEC 60601-1:2005..

Clauses 3.3, 3.4, 3.5, 7 and 8 shall be included in the complete RM file which has been addressed through clause 4.3. Numbering above is inclusive as applicable. This document includes clauses from IEC 60601-1 which have guidance for inspection requirements of the manufacturer's risk management file, risk control measures and risk management process. The document does not address other clauses from IEC 60601-1 which include key terms for example RISK (with or without qualifying words such as unacceptable, acceptable and significant), HAZARD, HAZARDOUS SITUATION. These clauses do not necessarily require the manufacturer to include them in their risk management process.

6.3 IEC 60601-1-3:2008 / ISO 14971:2000

IEC 60601-1-3:2008 Collateral standard: Radiation Protection in Diagnostic X-Ray Equipment - Guidance for the application of ISO 14971:2000

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
6.3.2	Reproducibility of the RADIATION output	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, does the RISK MANAGEMENT FILE determine the reproducibility of the RADIATION output relative to fixed LOADING FACTORS required for the INTENDED USE?	4.2 to 6.4
6.4.3	Indication of LOADING FACTORS and MODES OF OPERATION	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, has the Manufacturer determined the accuracy of the LOADING FACTORS required for the INTENDED USE?	4.2 to 6.4
6.5	AUTOMATIC CONTROL SYSTEM	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, does the RISK MANAGEMENT FILE determine the constancy of AUTOMATIC EXPOSURE CONTROLS required for the INTENDED USE?	4.2 to 6.4
6.7.2	System performance	Has the Manufacturer defined and specified metrics describing imaging performance for the INTENDED USE?	4.2 to 6.6
6.7.3	Nominal focal spot value	Has the Manufacturer defined The nominal focal spot values of the X-RAY TUBE(s) FOCAL SPOTS in the EQUIPMENT according to IEC 60336?	4.2
6.7.4	RADIATION DETECTOR or X-RAY IMAGE RECEPTOR	If a RADIATION DETECTOR or X-RAY IMAGE RECEPTOR is integrated in the X-RAY EQUIPMENT, has the Manufacturer specified the contribution to the metrics of imaging performance? Is this contribution sufficient to ensure the efficient use of RADIATION? If no X-RAY IMAGE RECEPTOR is integrated in the system, has the Manufacturer described in the ACCOMPANYING DOCUMENTS examples of X-RAY IMAGE RECEPTOR types or performance?	4.3 to 6.6

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
7.2	Waveform of the X-RAY TUBE VOLTAGE	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, has the Manufacturer define the characteristics of The X-RAY TUBE VOLTAGE waveform, taking in consideration: • the rising phase of the X-RAY TUBE VOLTAGE; • the falling phase of the X-RAY TUBE VOLTAGE; and • the shape and amplitude of the X-RAY TUBE VOLTAGE RIPPLE. which, in conjunction with the TOTAL FILTRATION in the XRAY EQUIPMENT, results in an acceptable RADIATION dose for the INTENDED USE?	4.2 to 6.4
8.1	Limitation of the extent of the X-RAY BEAM (General)	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, does the risk management file consider all the risk associated not to limit the RADIATION FIELD not contributing to the formation of the image?	4.4 to 6.4
8.5.3	Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, does the Manufacturer identify and provide means to adjust the X-RAY FIELD such that its position and size correspond to the EFFECTIVE IMAGE RECEPTION AREA? Is this means designed with an acceptable accuracy? *Note: For clause 4.4 and 5.0 of ISO 14971, see also 8.5.1.*	4.4 to 6.4
9.1	FOCAL SPOT TO SKIN DISTANCE	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, has the Manufacturer identified The FOCAL SPOT TO SKIN DISTANCES in NORMAL USE sufficiently large to keep the RADIATION dose to the PATIENT as low as reasonably achievable? Has the Manufacturer defined a minimum FOCAL SPOT TO SKIN DISTANCE?	4.4 to 6.4
10.1	ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, has the manufacturer designed the X-RAY EQUIPMENT in such a way that the ATTENUATION of the X-RAY BEAM by material interposed between the PATIENT and the X-RAY IMAGE RECEPTOR is kept as low as reasonably achievable in order to avoid unnecessarily high doses to the PATIENT and, through STRAY RADIATION, to the OPERATOR. Does the risk management file determine the values of ATTENUATION EQUIVALENT and RADIATION CONDITIONS for testing required for the INTENDED USE?	4.2 to 6.4

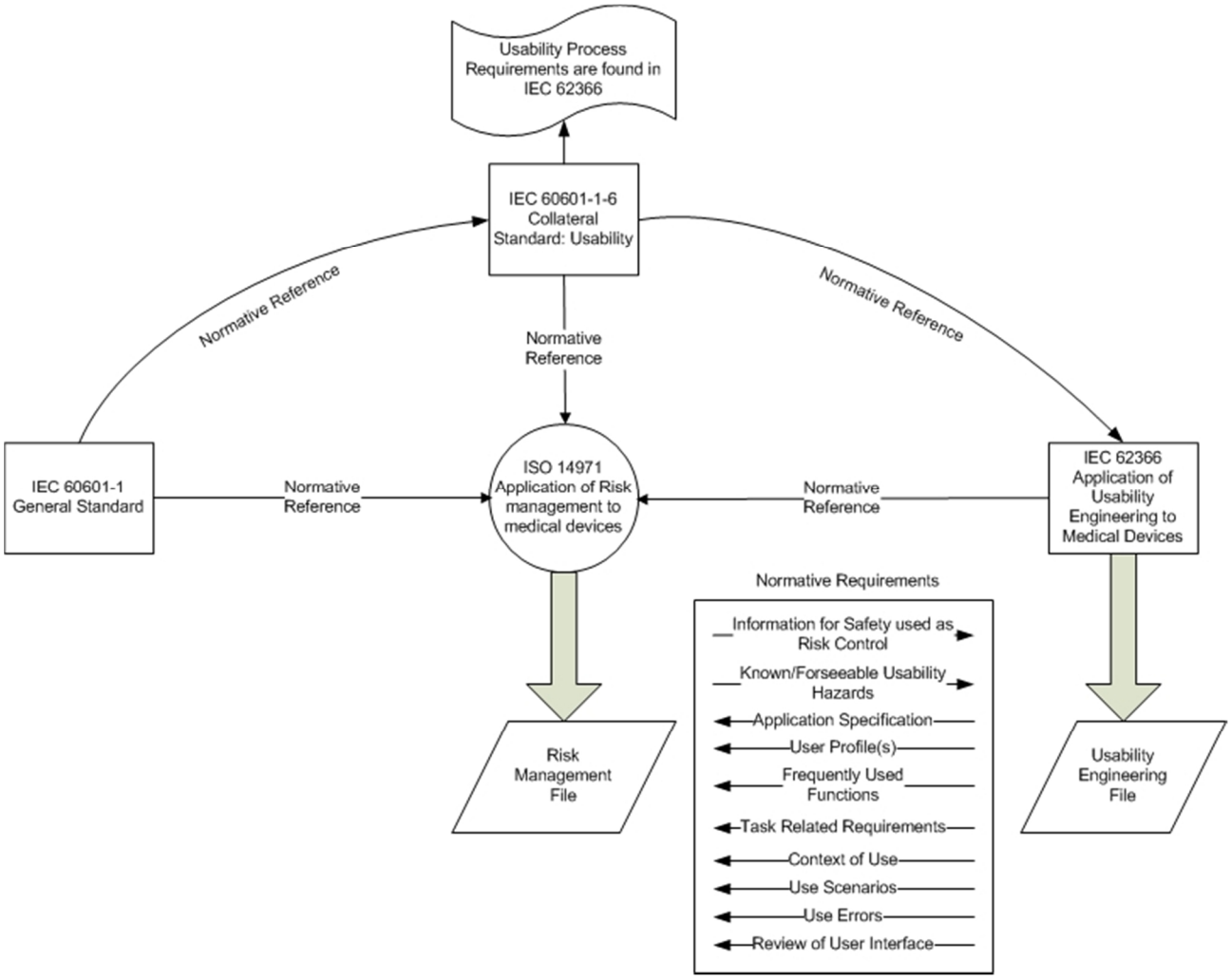
IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
11	Protection against RESIDUAL RADIATION	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, does the RISK MANAGEMENT FILE evaluate the RADIATION dose resulting from the RESIDUAL RADIATION: • for the PATIENT, relative to the RADIATION dose resulting from the examination, and • for other persons, relative to the dose resulting from X-RADIATION scattered off the PATIENT? Does the Manufacturer identify the need to incorporate in the X-RAY EQUIPMENT a PRIMARY PROTECTIVE SHIELDING? Is this PRIMARY PROTECTIVE SHIELDING taking into account the RESIDUAL RADIATION which contribute significantly to the RADIATION dose received by: • OPERATORS, • other persons present in the examination room during the LOADING (e.g. parents holding a child, other PATIENTS or personnel), • parts of the PATIENT other than from those being currently imaged?	4.3 to 6.6
12.1	Protection against LEAKAGE RADIATION	Has the manufacturer addressed this risk by applying and applicable particular standard? If yes, this requirement does not apply. If no, does the RISK MANAGEMENT FILE evaluate the RADIATION dose resulting from the LEAKAGE RADIATION: • for the PATIENT, relative to the RADIATION dose resulting from the examination, and • for other persons, relative to the dose resulting from X-RADIATION scattered off the PATIENT? Does the RISK MANAGEMENT FILE consider the LEAKAGE RADIATION which contribute significantly to the RADIATION dose received by: • OPERATORS, • other persons present in the examination room during the LOADING (e.g. parents holding a child, other PATIENTS or personnel), • parts of the PATIENT other than from those being currently imaged?	4.2 to 6.6
12.2	Mounting of X-RAY SOURCE ASSEMBLIES and X-RAY IMAGING ARRANGEMENTS	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, does the RISK MANAGEMENT FILE included exceptions to justify that the X-RAY SOURCE ASSEMBLIES and/or the X-RAY IMAGE RECEPTOR need to be hand held during LOADING in NORMAL USE?	4.2 to 6.6

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
13.2	Control of X-ray equipment from a protected area	Has the manufacturer addressed this risk by applying an applicable particular standard? If yes, this requirement does not apply. If no, does the RISK MANAGEMENT FILE cover exceptions related to the following control functions: • selection and control of MODES OF OPERATION; • selection of LOADING FACTORS; • actuation of the IRRADIATION SWITCH; • other necessary controls for the OPERATOR during LOADING, where the control functions are to be implemented from a PROTECTED AREA after installation, for X-RAY EQUIPMENT specified exclusively for examinations that do not need the OPERATOR or staff to be close to the PATIENT during NORMAL USE? *Supplementary information: See also 13.3*	4.2 to 6.6
13.3	Protection by distance	Has the manufacturer addressed this risk by applying an applicable particular standard or some exception applies? If yes, this requirement does not apply. If no, does the RISK MANAGEMENT FILE determine, for the INTENDED USE, the distance required and the RADIATION dose resulting from the STRAY RADIATION? Is this distance sufficiently long to protect operator? *Supplementary information: See also 13.2*	4.2 to 6.6

6.4 IEC 60601-1-6:2010 / ISO 14971:2007 / IEC 62366:2007

When evaluating compliance with IEC 60601-1-6:2010, it is important to understand the relationships that exist between this standard, IEC 60601-1:2005, IEC 62366:2007 and ISO 14971:2007.
Figure 1 below provides a graphical representation of this relationship. IEC 60601-1-6:2010 is a collateral standard in the IEC 60601-1 series covering the requirements for the Usability Engineering Process. IEC 60601-1:2005 makes a normative reference to IEC 60601-1-6 for requirements related to usability. Currently, IEC 60601-1-6:2010 links the IEC 62366:2007 which contains requirements for the usability engineering process.

Figure 1: Relationship between USABILITY (IEC 60601-1-6 & IEC 62366) and RISK MANAGEMENT (ISO 14971)



IEC 60601-1-6:2010 makes a normative reference to IEC 62366:2007 for the Usability Engineering Process requirements: In turn, IEC 62366:2007 makes a normative reference to ISO 14971:2007 for the requirements related to Risk Management.

When performing the usability engineering process and the risk management process there are deliverables from each process that are used as inputs into the other process. Figure 1 indicates in which process these deliverables are generated and which deliverables are necessary for completing the other process.

When complying with IEC 60601-1:2005, IEC 60601-1-6:2010, IEC 62366:2007 and ISO 14971:2007 are all required to satisfy the requirements for the Usability Engineering Process.

IEC 60601-1-6:2010 Collateral standard: Usability
Guidance for the application of ISO 14971:2007 and IEC 62366:2007

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
4.2 (60601-1-6)	General Requirements – Conditions for application to ME EQUIPMENT	Compliance is confirmed through application of IEC 60601-1-6:2010, IEC 62366:2007 and ISO 14971:2007 Equipment provides adequate USABILITY such that RISKS resulting from NORMAL USE and USE ERROR are considered acceptable Has the USABILITY ENGINEERING PROCESS adequately addressed all RISKS associated with NORMAL USE and USE ERROR?	3.2, 3.4d, 4-7
4.1.2 (62366)	RESIDUAL RISK	Compliance is checked by inspection of the USABILITY ENGINEERING FILE Has compliance with Clause 5.9 of IEC 62366:2007 been demonstrated? Has the USABILITY ENGINEERING PROCESS integrated all elements of RISK MANAGEMENT as required by this standard? Have all design changes related to USABILITY been reviewed to determine if any new HAZARDS or HAZARDOUS SITUATIONS have been generated? Has the manufacture adequately addressed all risks related to usability, and have all the risk been mitigated to an acceptable level?	6.4
4.1.3 (62366)	Information for SAFETY	Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the USABILITY ENGINEERING FILE Has the MANUFACTURER identified any information for SAFETY as a RISK CONTROL MEASURE? • If yes, has this information been subject to the USABILITY ENGINEERING PROCESS to determine acceptable USABILITY? • If yes, has this information been subject to the RISK MANAGEMENT PROCESS when determining the appropriate RISK CONTROL measure?	5, 6.2
4.3 (62366)	Scaling of the USABILITY ENGINEERING effort	Compliance is checked by inspection of the USABILITY ENGINEERING FILE Has the MANFACTURER scaled the USABILITY ENGINEERING PROCESS? • If yes, has the MANUFACTURER taken into account the nature of the MEDICAL DEVICE, the intended USER and the INTENDED USE? • If yes, does the RISK ANALYSIS indicate the scaling was based on the significance of the modification?	4.2-4.4
5.3.1 (62366)	Identification of characteristics related to SAFETY	Compliance is checked by inspection of the USABILITY ENGINEERING FILE When applying ISO 14971:2007, clause 4.2, has the MANFACTURER identified all characteristics related to SAFETY related to USABILITY (or poor USABILITY)? Has the MANUFACTURER included the application specification, USER PROFILE(s), and list of frequently used functions as inputs?	4.2

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
5.3.2 (62366)	Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS	Compliance is checked by inspection of the USABILTY ENGINEERING FILE When applying ISO 14971:2007, Clause 4.3, has the MANUFACTUER identified all known or foreseeable HAZARDS and HAZARDOUS SITUATIONS related to USABILITY (or poor USABILITY)? Has the MANUFACTURER adequately identified reasonably foreseeable sequences or combinations of events involving the USER INTERFACE? When identifying HAZARDS and HAZARDOUS SITUATIONS related to USABLITY, has the MANUFACTURER considered (used as inputs) the following: • Application specification, including the USER PROFILE(S) • Task related requirements (user) • Context of use • Known HAZARDS and HAZARDOUS SITUATIONS from USER INTERFACES of similar MEDICAL DEVICES • USE SCENARIOS • Foreseeable USE ERROR(S) • A review of the USER INTERFACE	4.3
5.5 (62366)	USABILITY SPECIFICATION	Compliance is checked by inspection of the USABILITY ENGINEERING FILE Does the USABILITY ENGINEERING FILE contain specific criteria for determining the adequacy of RISK CONTROL measures related to USABILITY? Does the USABILITY SPECIFICATION included the following minimum items: • Application specification • PRIMARY OPERATING FUNCTIONS • HAZARDS/HAZARDOUS SITUATIONS related to USABILITY • Known and foreseeable USE ERRORS At a minimum, does the USABILITY SPECIFICATION describe the following: • USE SCENARIOS related to the PRIMARY OPERATING FUNCTIONS (frequent USE SCENARIOS, reasonably foreseeable worst case USE SCENARIOS) • USER INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS including those used as RISK MITIGATIONS • Requirements for determining if the PRIMARY OPERATING FUNCTIONS are easily recognized by the USER	3.4 d), 4.3, 5, 6.2-6.4
5.6 (62366)	USABILITY VALIDATION plan	Compliance is checked by inspection of the USABILITY ENGINEERING FILE Does the plan for validation of the PRIMARY OPERATING FUNCTIONS include the criteria for RISK acceptability determined through ISO 14971:2007, clause 3.4 d) as acceptance criteria?	3.4 d)

IEC 60601-1 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
5.9 (62366)	USABILITY VALIDATION	Compliance is checked by inspection of the USABILITY ENGINEERING FILE If the criteria of the USABILITY VALIDATION plan have not been met, and the MANUFACTURER has determined that further improvement of the USER INTERFACE is not practical; has the MANUFACTURER done the following: • Estimated RISKS arising from USABILITY problems • Gathered and reviewed data and literature to determine that the medical benefit of the INTENDED USE outweighs the RISKS arising from the USABILITY problems • Determined that all RISKS are acceptable?	4.4, 5, 6.4-6.5

6.5 IEC 60601-1-8:2006 / ISO 14971:2000

IEC 60601-1-8:2006 Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems Guidance for the application of ISO 14971:2000

IEC 60601-1-8 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
4	Alarm System – General requirements	Compliance is checked by inspection of the risk management file. As a means of risk control, has the manufacturer provided an alarm system that is used to notify the operator that a hazardous situation can exist? • If so, then an alarm system complying with this standard is used for this purpose. • If not, continue with other risk management requirements. Does the manufacturer's risk assessment identify hazards to patients, operators and other persons arising from the alarm system? • If so, verify that the resulting risk is an acceptable level before or after risk control measures are implemented as applicable based on the manufacturers criteria for acceptable risks. • If not, and the medical electrical equipment has an alarm system, then this is an unacceptable result.	6.2-6.6 4.3-5
6.1.2	Alarm condition priority	Compliance is checked by inspection of the risk management file. Does the manufacturer's risk management file include the assignment of alarm priorities based on Table 1 or in accordance with relevant particular standards? • If so, then verify by testing them accordingly. • If not, then this is an unacceptable result. Review the manufacturer's risk management file in regards to the assignment of alarm condition priorities	4.2 – 5, 6.2 – 6.6

IEC 60601-1-8 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
6.3.1	Generation of Alarm Signals	Compliance is checked by inspection of the risk management file. Does the manufacturer's risk management file, risk assessment considering the environment in which the ME Equipment is intended, identify the need for additional alarm signals (audio, verbal, vibratory or produced by other means)? • If so, then verify the implementation according to the manufacturer's risk management file; • If not implemented, then this is an unacceptable result, unless the risk assessment shows no need for additional alarm signals.	4.2-5, 6.2-6.5
6.3.4	Characteristics of verbal alarm signals	Compliance is checked by inspection of the risk management file. Does the manufacturer's risk management file, consider the risks associated with verbal alarm signals? • If so, verify the implementation of verbal alarm signals in accordance with the risk management file; • If not, and the ME Equipment has provisions for verbal alarm signals, then this is an unacceptable result; • If not, and the ME Equipment does not have provisions for verbal alarm signals, then proceed to other risk management requirements.	4.2-5, 6.2-6.6
6.8.3	Global indefinite Alarm Signal inactivation states	Compliance is checked by inspection of the risk management file. Has the manufacturer's risk management file, risk assessment, considered the intended environment of use, and accepted the Alarm System function of global Alarm Off or global Audio Off? • If so, follow the requirements of the standard. • If not, then this is an unacceptable result.	4.2-5

6.6 IEC 60601-1-10:2007 / ISO 14971:2000

IEC 60601-1-10:2007 Collateral standard: Requirements for the development of physiologic closed-loop controllers - Guidance for the application of ISO 14971:2000

IEC 60601-1-10 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
4	General requirements	Compliance is checked by inspection of the risk management file. Has the risk analysis considered HAZARDS from a PCLC? • If so, then they shall be included in the RISK MANAGEMENT PROCESS. • If not, then this is an unacceptable result.	4.3-4.4
6.1	Accuracy of controls and instruments and protection against hazardous outputs - Usability	Compliance is checked by inspection of the risk management file. Has the indication over time not lead to an unacceptable RISK? • If so, then the indication over time may be omitted. • If not, then the information indication over time shall be indicated continuously or by OPERATOR action. Have the presentation format and the choice between indicating the information continuously or by OPERATOR action based on the USABILITY ENGINEERING PROCESS? • If so, then they shall be included in the RISK MANAGEMENT PROCESS. • If not, then this is an unacceptable result.	4.3 – 4.4, 6.2 -6.3 See USABILITY ENGINEERING FILE assessment per IEC 60601-1-6
8.2.1	RECORDS and PROCESS scaling	Compliance is checked by inspection of the risk management file. Have the RECORDS and documents produced from application of the PCLC development PROCESS been established and maintained to provide evidence of conformity to requirements of this collateral standard? • If so, then they shall form part of the RISK MANAGEMENT FILE • If not, then this is an unacceptable result. Have the results of the RISK ANALYSIS based on significance of the modification of a PCLC design been documented? • If so, then the PCLC development PROCESS shall include the scaling up or scaling down of that modification. • • If not, then this is an unacceptable result.	4.3-4.4
8.2.2.3	FALLBACK MODE	Compliance is checked by inspection of the risk management file. Has the MANUFACTURER specified all FALLBACK MODES of the PCLCS? • If so, then the FALLBACK MODE shall have no unacceptable RISK. • If not, then this is an unacceptable result.	4.3-4.4, 5, 6.2-6.5

IEC 60601-1-10 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
8.2.2.5	Limitation of the MANIPULATED VARIABLE	Compliance is checked by inspection of the risk management file. If necessary, have the measures been taken or means provided to eliminate, control, or decrease RISKS to acceptable levels by controlling of the following? – the range of the MANIPULATED VARIABLE; – the integral over a period of time of the MANIPULATED VARIABLE; or – the rate of change of the MANIPULATED VARIABLE. • If so, follow the requirements of the standard. • If not, then this is an unacceptable result.	4.3-4.4, 5, 6.2-6.5
8.2.2.6	Responses of the PCLCS	Compliance is checked by inspection of the risk management file. If the PCLC changes its mode of operation, does the PCLCS have a means of notifying and indicating to the OPERATOR of its change in mode of operation? • If so, the RISK ANALYSIS shall determine the choice between an INFORMATION SIGNAL and an ALARM CONDITION and its priority. • If not, then this is an unacceptable result.	4.3-4.4, 5, 6.2
8.2.2.7	Range limitation of PHYSIOLOGIC VARIABLE	Compliance is checked by inspection of the risk management file. Does the PCLCS provide the means to monitor the value of the PHYSIOLOGIC VARIABLE within its acceptable range? Or limit the value of the MANIPULATED VARIABLE, or CONTROLLER OUTPUT VARIABLE? • If so, follow the requirements of the standard and if the value of the PHYSIOLOGIC VARIABLE exceeds its specified range, the PCLCS shall switch into a FALLBACK MODE. • If not, then this is an unacceptable result.	4.3-4.4, 5, 6.2-6.5
8.2.3.1	General	Have measures been taken or means provided in the PCLC to eliminate unacceptable RISK to the PATIENT that could be caused by unfavourable response of the PCLCS to DISTURBANCE VARIABLES including PATIENT DISTURBANCE VARIABLES? • If so, follow the requirements of the standard. • If not, then this is an unacceptable result.	4.3-4.4, 5, 6.2-6.5

IEC 60601-1-10 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
8.2.3.2	Disturbance analysis	Compliance is checked by inspection of the risk management file. Has the analysis of the effect of DISTURBANCE VARIABLES on the PCLCS in NORMAL USE included the following activities? a) identification of foreseeable DISTURBANCE VARIABLES; b) characterization of those DISTURBANCE VARIABLES; c) analysis of the potential responses of the PHYSIOLOGIC VARIABLE to those DISTURBANCE VARIABLES in any mode of operation; and d) analysis of the response of the PCLCS to those DISTURBANCE VARIABLES in any mode of operation • If so, follow the requirements of the standard. • If not, then this is an unacceptable result.	4.3-4.4, 5, 6.2-6.5
8.2.4	PCLC Verification	Compliance is checked by inspection of the risk management file. Has the PCLC undergone VERIFICATION against all Risk Management specifications required by this collateral standard? • If so, follow the requirements of the standard. • If not, then this is an unacceptable result.	6.3
8.2.5.1	PCLCS Validation	Compliance is checked by inspection of the risk management file. Has the Validation plan been based on the RISK ANALYSIS and knowledge of the RESIDUAL RISKS? • If so, follow the method selection requirements of the standard. • If not, then this is an unacceptable result.	4.3-4.4, 5, 6.2-6.5

6.7 IEC 60601-1-11:2010 / ISO 14971:2000

IEC 60601-1-11:2010 Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment - Guidance for the application of ISO 14971:2000

IEC 60601-1-11 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
4.2.1	Environmental conditions of transport and storage between uses	Do the instructions for use state a more restricted range of environmental transport and storage conditions between uses? If yes, the range of environmental conditions shall be justified in the Risk Management file.	4.2-4.4
4.2.2	Environmental operating conditions	Do the instructions for use state a more restricted range of environmental operating conditions of the ME Equipment? If yes, the range of environmental conditions shall be justified in the Risk Management file	4.2-4.4

IEC 60601-1-11 Clauses	Subject	Considerations for application of RM criteria	ISO 14971 Clauses
7.4.1	Additional requirements for warning and safety notices	For each warning and safety sign, the instructions for use shall describe the nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK. Review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control.	4.2-4.4, 5, 6.2-6.4
7.4.5	Additional requirements for operating instructions	Where the instructions for use include a description of generally known conditions in the HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT and the steps that can be taken by the LAY OPERATOR to identify and resolve these conditions, review the manufacturers risk management file for risk analysis, risk evaluation and implementation of risk control.	4.3-4.4, 5, 6.2-6.4
8.4	Additional requirements for interruption of the power supply/supply mains to ME Equipment and ME System	When loss or failure of the SUPPLY MAINS or INTERNAL ELECTRICAL POWER SOURCE would result in an unacceptable risk, do the time or number of PROCEDURES remaining allow for alternative life-supporting methods to be employed? If so, review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control, as well as whether an acceptable residual risk results.	4.2-4.4, 5, 6.2-6.7
9	Accuracy of controls and instruments and protection against hazardous outputs	Have the RISKS associated with USABILITY in the HOME HEALTHCARE ENVIRONMENT included consideration of all factors identified by the Standard, placing particular emphasis on the limited training of a LAY OPERATOR with respect to the ability to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE? If so, review the manufacturer's USABILITY ENGINEERING FILE for risk analysis, risk evaluation and where necessary implementation of risk control, as well as whether an acceptable residual risk results.	See USABILITY ENGINEERING FILE assessment per IEC 60601-1-6:2010
11.0	Protection against strangulation or asphyxiation	Have means been provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level? If so, review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control, including whether other hazards may have been generated.	4.3-4.4, 5, 6.2-6.6

6.8 IEC 62304 Edition 1.0 2006-05

Medical device software –Software life cycle processes

When the requirements for software apply for the medical devices, 60601-1 requires compliance with applicable clauses of IEC 62304 that makes normative reference to ISO 14971. In fact in the evaluation of a device with respect to the requirements of 60601-1 which employs PEMS and PESS, a risk management process is required to be followed.

According to IEC 60601-1, when the requirements in 14.2 to 14.13 apply, the requirements in subclause 4.3, Clause 5, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 shall also apply to the development or modification of software for PEMS and for each PESS.

IEC 62304 makes a normative reference to ISO 14971. However, some minor additional RISK MANAGEMENT requirements are identified for software, especially in the area of identification of contributing software factors related to HAZARDS. These requirements are summarized and captured in Clause 7 of IEC 62304 as the software RISK MANAGEMENT PROCESS.

The CBTL needs to ensure the manufacturer has taken into account the additional requirement for the Software Risk Management.

Annex 1 ISO 14971:2000 Checklist (Informative)

Clause	Subject	Item	References
3.3 a)	Management Responsibilities	a. Policy for determining acceptable risk.	
3.5 e)	Risk Management Plan	e. Evidence of risk acceptability criteria.	
4.1	Risk Analysis Procedure	Procedure for risk analysis.	
4.2	Intended use/intended purpose and/or identification of characteristics related to the safety of the medical device	Record of safety issue analysis.	
4.3	Identification of known or foreseeable hazards	Record of hazard analysis	
4.4	Estimation of the risk(s) for each hazard	a. Definition of methods used for estimating risks.	
		b. Description of method(s) used.	
		c. Result of risk estimation activities.	
5.0	Risk evaluation	a. Result of risk evaluation activities.	
6.1	Risk reduction	Procedure for risk control activities	
6.2	Option analysis	Record of risk control option analysis (including risk-benefit analysis, if appropriate).	
6.3	Implementation of risk control measures	Inputs from risk management activities	
6.4	Residual risk evaluation	Final results of the residual risk evaluation and, if necessary, information necessary to explain the residual risk(s) in the appropriate accompanying documents	
6.5	Risk-Benefit Analysis	Evidence as necessary.	

Clause	Subject	Item	References
6.6	Other generated hazards	Record of results of review of all risk controls for to identify if other hazards are introduced by any risk control measures and the associated risk(s) assessment(s)	
6.7	Completeness of risk evaluation	Record of assessment to assure that the risk(s) from all identified hazards have been evaluated	
7	Overall residual risk evaluation	Records of related meetings, analysis, and overall results.	

Note: The ANNEX 1 above is for ISO 14971 1st edition, if ISO 14971 2nd edition is used ANNEX 2 is applied.

Annex 2 ISO 14971:2007 Checklist (Informative)

Clause	Subject	Item	References
3.2	Management responsibilities	– provision of adequate resources – assignment of qualified personnel – Policy for determining acceptable risk	
3.3	Management Responsibilities	Persons performing work have appropriate knowledge and experience	
3.4	Risk management plan	a) Scope of risk management activities b) Assignment of responsibilities and authorities c) Requirements for review of activities d) Evidence of risk acceptability criteria e) Verification activities	
3.5	Risk management file	Criteria for the establishment of a risk management file providing traceability for each identified hazard	
4.1	Risk Analysis Procedure	Procedure for risk analysis.	
4.2	Intended use/intended purpose and/or identification of characteristics related to the safety of the medical device	Record of safety issue analysis.	
4.3	Identification of known or foreseeable hazards	Record of hazard analysis	
4.4	Estimation of the risk(s) for each hazard	d. Definition of methods used for estimating risks. e. Description of method(s) used. f. Result of risk estimation activities.	

Clause	Subject	Item	References
5.0	Risk evaluation	b. Result of risk evaluation activities.	
6.1	Risk reduction	Procedure for risk control activities	
6.2	Option analysis	Record of risk control option analysis (including risk-benefit analysis, if appropriate).	
6.3	Implementation of risk control measures	Inputs from risk management activities	
6.4	Residual risk evaluation	Final results of the residual risk evaluation and, if necessary, information necessary to explain the residual risk(s) in the appropriate accompanying documents	
6.5	Risk-Benefit Analysis	Evidence as necessary.	
6.6	Other generated hazards	Record of results of review of all risk controls for to identify if other hazards are introduced by any risk control measures and the associated risk(s) assessment(s)	
6.7	Completeness of risk evaluation	Record of assessment to assure that the risk(s) from all identified hazards have been evaluated	
7	Overall residual risk evaluation	Records of related meetings, analysis, and overall results.	
8	Risk management report	Documented review of risk management process prior to commercial distribution	