# IEC 60601-1 ed. 3.2 – Risk Management File (RMF) Checklist

**These 4 pages provides examples on how to complete the RMF Checklist (in total around 25 pages).**

IECEE OD-2044 should be used as support when filling out the RMF Checklist.

Below is RM Results Table 4.2.2, located in the end of the complete Checklist. Each document noted in the table must include the revision date or revision number of the document reviewed as shown in examples.

| 4.2.2 | RM RESULTS TABLE: General requirements for RISK MANAGEMENT | | | |
|---|---|---|---|---|
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. paragraph/clause, version)** | | **Result - Remarks** | **Verdict** |
| | **General process** | **Particular Medical Device** | | |
| **4.1** | **RM Document 123, rev. 2, §2.3** | — | Risk Management Process (excluding production and post-production) | |
| **4.2** | **RM Document 123, rev. 2, §2.5** | — | Evidence of adequate Resources | |
| **4.2** | **RM Document 123, rev. 2, §2.6** | — | Assignment of qualified personnel | |
| **4.2** | **RM Document 123, rev. 2, §2.7** | — | Policy for determining criteria for risk acceptability.<br>Top management shall define and document the policy for determining criteria for risk acceptability; this policy shall ensure that criteria are based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns. | |
| **4.3** | — | **Personnel ABC, rev. 4, §3.5** | Competence of personnel | |
| **4.4a** | — | **RM Plan XYZ, rev. 3, §1.2** | Risk Management Plan - the scope of the planned risk management activities | |
| **4.4b** | — | **RM Plan XYZ, rev. 3, §1.3** | Risk Management Plan - assignment of responsibilities and authorities | |
| **4.4c** | — | **RM Plan XYZ, rev. 3, §1.4** | Risk Management Plan - requirements for review of risk management activities | |

| IEC 60601-1:2005 + A1:2012 + A2:2020 (ed. 3.2) | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| **4.2.2** | **RM RESULTS TABLE: General requirements for RISK MANAGEMENT** | | | |
|---|---|---|---|---|
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. paragraph/clause, version)** | | **Result - Remarks** | **Verdict** |
| | **General process** | **Particular Medical Device** | | |
| **4.4d** | — | **RM Plan XYZ, rev. 3, §1.5** | Risk Management Plan - criteria for risk acceptability, based on policy for determining acceptable risk, including criteria for accepting risks when the probability of occurrence of harm cannot be estimated. | |
| **4.4e** | — | **RM Plan XYZ, rev. 3, §1.6** | Risk Management Plan - a method to evaluate the overall residual risk, and criteria for acceptability of the overall residual risk | |
| **4.4f** | — | **RM Plan XYZ, rev. 3, §1.7** | Risk Management Plan - activities for verification of the implementation and effectiveness of risk control measures | |
| **4.5** | — | **RM FILE ABC, rev. 2** | Risk Management File | |
| **5.1** | — | **Risk Analysis ABC, rev. 7, §1.1** | Risk Analysis – Process (describes device, people performing analysis, date) | |
| **5.2** | — | **Risk Analysis ABC, rev. 7, §1.2** | Risk Analysis - Intended use and reasonably foreseeable misuse | |
| **5.3** | — | **Risk Analysis ABC, rev. 7, §1.3** | Risk Analysis - Identification of characteristics related to safety (list of questions and characteristics) | |
| **5.4** | — | **Hazard table ABC, rev. 4,** | Risk Analysis - Identification of hazards and hazardous situations | |
| **5.5** | — | **Hazard table ABC, rev. 4** | Risk Analysis - Risk estimation (severity & likelihood) pre-mitigation (use max likelihood where can't be estimated) | |
| **6** | — | **Hazard table ABC, rev. 4** | Risk Evaluation (compare against acc. Criteria) of pre-mitigation risks | |
| **7.1** | — | **Risk Control XYZ, rev. 3, §2.2**<br>**Hazard table ABC, rev. 4** | Risk Control - Risk control option analysis (standards requirements or alternate compliance in this context) to make risk acc. (verify hierarchy: a) inherently safe design, b) protective measures, c) information for safety) | |
| **7.2** | — | **Risk Control XYZ, rev. 3, §2.3**<br>**Hazard table ABC, rev. 4** | Risk Control - Implementation of risk control measures | |
| **7.3** | — | **Risk Control XYZ, rev. 3, §2.4**<br>**Hazard table ABC, rev. 4** | Risk Control - Residual risk evaluation | |

| IEC 60601-1:2005 + A1:2012 + A2:2020 (ed. 3.2) | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| **4.2.2** | **RM RESULTS TABLE: General requirements for RISK MANAGEMENT** | | | |
|---|---|---|---|---|
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. paragraph/clause, version)** | | **Result - Remarks** | **Verdict** |
| | **General process** | **Particular Medical Device** | | |
| **7.4** | — | **Risk Control XYZ, rev. 3, §2.5**<br>**Hazard table ABC, rev. 4** | Risk Control - Benefit-risk analysis | |
| **7.5a** | — | **Risk Control XYZ, rev. 3, §2.6**<br>**Hazard table ABC, rev. 4** | Risk Control - Risks arising from risk control measures (new hazards or hazardous situations introduced) | |
| **7.5b** | — | **Risk Control XYZ, rev. 3, §2.7**<br>**Hazard table ABC, rev. 4** | Risk Control - Risks arising from risk control measures (estimated risks for previously identified hazardous situations affected) | |
| **7.6** | — | **Risk Control XYZ, rev. 3, §2.8**<br>**Hazard table ABC, rev. 4** | Risk Control - Completeness of risk control | |
| **8** | — | **RM Document ABC, rev. 4, §3.2** | Evaluation of overall residual risk | |
| **9** | — | **RM Document ABC, rev. 4, §4.2** | Risk management review | |
| **Supplementary Information:**<br>**Document Ref should be with regards to the policy/procedure documents and documents containing Risk Management Process -specific output.** | | | | |

Each clause after 4.2.2 that requires a review of the Risk Management File documents the specific line of the device specific documentation reviewed. In addition, the specific clauses of ISO 14971:2019 reviewed for that items would be entered. Each clause with Risk Management includes the specific clauses from ISO 14971 noted in the IECEE OD-2044 document that need to be reviewed.

The following is an example sub clause for Clause 7.2.2 which shows the ISO 14971 references added to the "Requirement + Test" section which is in line with the OD-2044 Document. When completing the "Result – Remark" section, the specific risk line item reviewed form the particular medical device specific documents would be recorded. In addition, the clauses of ISO 14971 with respect to the specific line item reviewed shall be recorded. Any risk controls or other important information for a Recognizing NCB should be included in the "Result – Remarks" column.

**Requirement as stated in the RMF Checklist**

| **IEC 60601-1** | | | |
|---|---|---|---|
| **Clause** | **Requirement + Test** | **Result - Remark** | **Verdict** |

| IEC 60601-1:2005 + A1:2012 + A2:2020 (ed. 3.2) | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 7.2.2 | RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts.....:<br>(ISO 14971 Cl. 5.2-5.4, 6, 7.3) | RMF Reference to specific RISKS:<br>(ISO 14971 Cl.__) | |

**The following is an example of the line item noted above completed with a "Pass" verdict.**

| **IEC 60601-1** | | | |
|---|---|---|---|
| **Clause** | **Requirement + Test** | **Result - Remark** | **Verdict** |
| | RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts.....:<br>(ISO 14971 Cl. 5.2-5.4, 6, 7.3) | RMF Reference to specific risks: RA-150 to RA-153 –<br>RA 150: (ISO 14971 Cl. 5 to 6)<br>RA 151: (ISO 14971 Cl. 5 to 6, 7.3)<br>RA152: (ISO 14971 Cl. 5 to 6)<br>RA153: ISO 14971 Cl. 5 to 6, 7.3) | **P** |

The following is an example for sub-clause 11.6.3 which shows the ISO 14971 references added to the "Requirement + Test" section; again in line with the OD-2044 Document.
When completing the "Result – Remark" section, the specific risk line item reviewed for the device under investigation in the Risk Management File would be recorded indicating the specific hazard no. Additionally, the clauses of ISO 14971 with respect to the specific line item reviewed shall be recorded. Any risk controls or other important information for an accepting NCB should be included in the "Result – Remarks" column.

| **IEC 60601-1** | | | |
|---|---|---|---|
| **Clause** | **Requirement + Test** | **Result - Remark** | **Verdict** |
| **11.6.3** | **Spillage on ME EQUIPMENT and ME SYSTEM** | | |
| | **ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test .....:**<br>**(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)** | RMF Reference to specific RISK:<br>Hazard No. 22 Spillage of liquids may occur.<br>(ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4) | **P** |
| | **RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill .....:** | Type of liquid: Water<br>Volume: 1 litre<br>Duration of spill: 15 s<br>Location: On top of Equipment (User interface) | **P** |