| **ISO 14971:2019**  **Clause** | **Documentation**  **Requirement** | **Document**  **Reference**  <this will be the Doc ID in your system> | **Notes** |
| --- | --- | --- | --- |
| 4.1: Risk management process | Document a process for risk management which includes 4 required elements |  | Generally, a risk management process and requirements are documented in a risk management procedure |
| 4.2 Management responsibility | Evidence of resources, personnel, policy, and review of risk management process |  | * Evidence of resources/personnel is provided in the risk management plan. * Policy for risk acceptability needs to be a stand-alone record. It can be integrated within your Quality Policy. * Minutes of management reviews can be used to show evidence of review of risk management process |
| 4.3 Competence of personnel | Evidence of competence based on education, training, skills, and experience |  | Job descriptions are a good source to show competence requirements. Make sure job descriptions are current and job titles match those in the risk management plan where you outline roles/responsibilities. You don’t need to physically include job descriptions in the RMF, but you should be able to provide them if requested during an audit. |
| 4.4 Risk management plan | Evidence that a plan has been established with the 7 required elements and documented in the RMF |  | A risk management plan is a stand-alone record in the RMF |
| 5.1 Risk analysis process | Evidence that risk analysis activities have been planned and documented in the RMF |  | Planned risk analysis activities are documented in the risk management plan. |
| 5.2 Intended use and reasonably foreseeable misuse | Evidence that intended use and reasonably foreseeable misuse have been documented in the RMF |  | * Intended use is documented in the Scope section of the risk management plan. * Reasonably foreseeable misuse is documented in a use-error analysis. Use-error analysis is a type of risk analysis; it should be included in your plan. Although we are using the term “use error”, this analysis is also expected to include foreseeable misuse. |
| 5.3 Identification of characteristics related to safety | Evidence that qualitative and quantitative characteristics affecting safety are documented in the RMF |  | Industry practice is to use the list of questions provided in Annex A of ISO/TR 24971:2020 to document the identification of these characteristics and associated hazards. Note that it is not a mandatory requirement to use this questionnaire. You can use a baseline hazard analysis as a starting point. You can also include a column in your design/process FMEA to indicate relationship to safety. |
| 5.4 Identification of hazards and hazardous situations | 1. Evidence that all known and potential hazards in the context of intended use and reasonably foreseeable misuse have been identified and documented in the RMF. 2. Evidence that for each hazard, sequence of events leading to hazardous situation have been identified and documented in the RMF. |  | Hazards, sequence of events and hazardous situations are documented in a stand-alone hazard analysis. |
| 5.5 Risk estimation | 1. Evidence that for each hazardous situation, risk of applicable harms has been estimated and documented in the RMF. 2. When probability of harm cannot be estimated, evidence that the consequences have been identified for those hazardous situations and documented in the RMF. 3. Evidence that approach used for estimating risk (SxPOH) has been documented in the RMF |  | * Risk estimation (assigning a value to severity and probability) is part of risk analysis. However, it is not the same as failure risk in FMEA. * Consequences in a hazardous situation are generally documented in hazard analysis. * Document your approach to risk estimation (qualitative or quantitative) in the risk management plan. |
| 6.0 Risk evaluation | Evidence that risk level for each hazardous situation has been evaluated for acceptability and documented in the RMF |  | * This is the “initial” risk evaluation. It is not necessary to estimate and evaluate the risk level in a state of “no controls”, especially for a device that is substantially like an existing device. However, you should define what you mean by the “initial” state of the product for which each risk is estimated and evaluated. * Note also that this is not the same as failure risk in an FMEA. * A best practice is to use a stand-alone risk assessment document in the RMF. |
| 7.1 Risk control option analysis | 1. Evidence that risk control options have been considered in the priority listed (design – protective measures – information for safety) and the selected risk control options are documented in the RMF. 2. Evidence that relevant standards have been considered (this is a “should”, not a “shall”; however, it is a best practice to document it in your RMF). 3. If the selected risk control measures are not practicable (note: this does not include cost considerations), the benefit-risk analysis of the residual risk is documented in the RMF. |  | * A best practice is to clearly identify the type of risk control (design – protective measure – information for safety). It can be documented in the stand-alone risk assessment document. * A best practice is to use a column to cite relevant standards, including product-specific safety standards, wherever applicable. This can be done in the stand-alone risk assessment document. * A column for benefit-risk can be used to indicate a reference to a separate analysis for each residual risk. Alternately, a simple statement “benefit exceed the residual risk” may be used. This can be done in the stand-alone risk assessment document. |
| 7.2 Implementation of risk control measures | 1. Evidence that each risk control measure selected per clause 7.1 is implemented and verified, and documented in the RMF 2. Evidence that implementation of each risk control measure is effective and documented in the RMF |  | * A column to provide a reference to the implementation of each risk control measure can be used in the risk assessment document. Note that this evidence supports the implementation of a risk control measure (example: raw material specs, product specs, test methods, operating procedures, inspection methods/criteria etc.) * A column to provide a refence to the effectiveness of each implemented risk control measure can be used in the risk assessment document. Note that this evidence supports effectiveness with respect to pre-defined criteria in your protocols. It is a best practice to use statistically valid methods and acceptance criteria to verify effectiveness (examples: test method validations, process validation, design verification/validation, usability studies, internal audit reports, supplier qualification reports, training effectiveness etc.) |
| 7.3 Residual risk evaluation | 1. Evidence of evaluation of each individual residual risk after effective implementation of risk control measures is documented in the RMF. 2. If the individual residual risk is not acceptable, then additional risk control measures are identified and implemented, or if they are not practicable, then a benefit-risk is documented in the RMF. |  | * This is the “final” risk level estimation and evaluation for each individual risk identified earlier. You need to estimate the change in POH and/or S, and the resulting risk level. This can be done in the risk assessment document. * A column to show residual risk acceptability can be added in the risk assessment document. * A column for additional risk control measures (Y/N) can be added in the risk assessment document. * Additional columns to show evidence of verification of implementation and effectiveness are also added in the risk assessment document |
| 7.4 Benefit-risk analysis | Evidence that each individual residual risk, when judged to be not acceptable, is analyzed for benefit-risk and documented in the RMF |  | * A column for benefit-risk analysis for each individual residual risk can be added in the risk assessment document. * Note that this benefit-risk is in the context of the specific individual residual risk and not the overall residual risk. If you use a benefit-risk analysis to continue with a specific risk that remains unacceptable, make sure your analysis is very specific and detailed for that specific residual risk. Generally, this is documented in a separate document. You can use a reference to this benefit-risk analysis in the risk assessment document. |
| 7.5 Risks arising from risk control measures | Evidence that any new hazards or hazardous situations, or changes in previously estimated risk levels due to implementation of risk control measures is documented in the RMF |  | * Generally, a column to indicate if new hazards are introduced by each risk control measure can be added in the risk assessment document. Alternately, a summary of the overall analysis based on an aggregated review of all risk control measures may be included in the risk management report. |
| 7.6 Completeness of risk control | Evidence that risks from all identified hazardous situations have been sufficiently addressed by the risk control activities and documented in the RMF. |  | * There are two ways to address this requirement, and both may be used in your RMF to support completeness of risk control activities. * Both completeness and traceability can be demonstrated in a stand-alone risk trace matrix document * A summary statement regarding completeness can be included in the risk management report. |
| 8.0 Evaluation of overall residual risk | 1. Evidence of the review of overall residual risk evaluation in the context of the benefits of the intended use is documented in the RMF. 2. If overall residual risk is judged acceptable, disclosure of significant residual risks is made and included in accompanying documentation. 3. If overall residual is judged not acceptable, then additional risk controls may be considered or the device and/or its intended use may be modified. 4. Documentation requirement is for a review of this evaluation. |  | * Generally, a statement about the overall residual risk in relation to the benefits of the intended use is documented in the risk management report. * Disclosure of residual risks considered significant is provided through the Instructions for Use (IFU) documents. Note that EU-MDR requires disclosure of all residual risks, not just significant residual risks. * As added evidence of this documentation, you can add a column for residual risk disclosure (Y/N) in the risk assessment and/or risk trace matrix |
| 9.0 Risk management review | Evidence of the review of all planned risk management activities and their results is documented in the RMF |  | * The risk management report is the most important output of the risk management process. It summarizes the overall results, decisions and plans for the production and post-production phase of the lifecycle. * A risk management report is meant to be used as an external facing document. It should be written well, with the goal of persuading key stakeholders that your plan has been executed effectively, the overall residual risk is acceptable and that you are ready for the production and post-production phase. |
| 10.1 General requirements for production and post-production activities | Evidence that a system to collect and review production and post-production information has been established |  | * Generally, production and post-production activities and requirements are documented in a post-market surveillance procedure. * In some cases, a product-specific post-market surveillance plan (PMS Plan) may be required. * Note that post-market surveillance activities are different from complaints handling and adverse event reporting. Therefore, it is best to separate the two processes. * A best practice is to use statistically valid methods and action limits whenever possible. Decision making criteria and responsibilities for action should be clearly identified |
| 10.2 Information collection | Evidence that relevant sources of information and type of information collected during the production and post-production phase have been identified |  | * Generally, this is outlined in the post-market surveillance procedure. * In some cases, a product-specific post-market surveillance plan (PMS Plan) may be required to collect additional information for a particular product |
| 10.3 Information review | Evidence that a review of information with relevance to safety has been completed and documented in the RMF. |  | * Generally, this is documented in records resulting from the implementation of the post-market surveillance procedure. * When a product-specific PMS plan is in place, additional records are required to document the results of this review. * These records are required to be referenced in your RMF to support the continuing execution of your plan and actions identified in the risk management report. Generally, periodic post-market surveillance reports, or product-specific PMS plan reports become a part of the device RMF. * These may also be required to comply with regulatory requirements such as EU-MDR or EU-IVDR |
| 10.4 Actions | Evidence that appropriate decisions and actions following the review of production and post-production information are documented in the RMF |  | * Note that two different types of actions are required: 1) actions related to changes in the risk levels, or related to newly identified risks; and 2) actions related to suitability and effectiveness of the risk management process. * Evidence for item 2 above may be documented in other places such as management review. * Gaps in documentation of evidence related to production and post-production activities are likely to present a significant challenge in audits. It is very important to be specific in your plan, especially as part of the lifecycle aspects. |