What Is ISO-14971 & MDD/93/42/EEC Risk Analysis For Medical Devices?

In this article we will attempt to explain ISO-14971 Risk Analysis. For complex medical devices risk analysis is sometimes required to be in compliance with ISO-14971 and/ or MDD/93/42/EEC (Medical Device Directive for the European Economic Community). This applies for medical devices requiring the CE Mark in Europe. When considering the medical device, the criteria for risk acceptability is based on ATL's policy for determining acceptable risk, including criteria for accepting risks when the probability of occurrence of harm cannot be estimated (such as end user misuse of the product). ATL's risk management process must include the risk acceptability criteria (RPN's) (Risk Priority Numbers).

ATL Risk analysis is performed (when required) for the particular medical device as described in ISO-14971 paragraphs 4.2 to 4.4. The implementation of the planned risk analysis activities and the results of the risk analysis is recorded in the risk management file (FMEA or Control Plan or other ATL documentation).
In addition to the records required in ISO-14971 paragraphs 4.2 to 4.4, the documentation of the conduct and results of the risk analysis include at least the following:

a) a description and identification of the medical device that was analyzed;
b) identification of the person(s) and ATL organization who carried out the risk analysis;
c) scope and date of the risk analysis.

Intended Use and Identification of Characteristics related to safety. For the particular medical device being considered, ATL documents the intended use (if this information is available from the design organization) and reasonably foreseeable misuse. ATL shall identify and document those qualitative and quantitative characteristics that could affect the safety of the medical device and, where appropriate, their defined limits. This documentation is maintained in the appropriate ATL risk management file.

Hazard Identification. ATL compiles documentation on known and foreseeable hazards associated with the medical device in both normal and fault conditions. ATL process all of the 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 as to who or what is harmed.

Estimation of Risk (RPN's). ATL determines and documents reasonably foreseeable sequences or combinations of events that can result in a hazardous situation and records the resulting hazardous situation(s). This is generally expressed as an RPN for product conformity. For each identified hazardous situation, ATL 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 are listed for use in risk evaluation and risk control (via RPN's). Any system used for qualitative or quantitative categorization of probability of occurrence of harm or severity of harm is recorded in the appropriate ATL risk management file/ function (e.g., FMEA, Control Plan, hypothesis testing, other).

Risk Evaluation. For each identified hazardous situation, ATL decides if risk reduction is required. The detail of the risk reduction efforts are listed in the Control Plan/ Performance Qualification/ Quality Traveler/ Batch Record/ or other. For risk reduction, one or more of the above paragraphs apply.

Risk Reduction. ATL identifies risk control measure(s) that are appropriate for reducing the risk(s) to an acceptable level. ATL shall use one or more of the following risk control options in the priority order listed:
a) inherent safety by design (by contacting design organization);
b) protective measures in the medical device itself or in the manufacturing process;
c) information for safety.

Implementation of Risk Control Measures. ATL shall implement the identified risk control measure(s). ATL verifies the implementation of each hazard based risk control measure.

The effectiveness of the risk control measure(s) are verified and the results are recorded in the appropriate risk management file (FMEA/ Control Plan/ NPD Test Run Form/ Quality Traveler/ Batch Record/ Other).

Risks Arising From Risk Control Measures. ATL 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.

ATL processes newly identified hazards or hazardous situations through risk management (FMEA/ Change Control/ Other).

ISO-14971:2012 and MDD (Medical Device Directive) Gaps: All risks, regardless of their dimension, need to be reduced as much as possible and need to be balanced, together with all other risks, against the benefit of the device (Annex I, Sections 1 and 2). All risks, regardless of any “acceptability” assessment, must be reduced as far as possible and must be balanced, together with all other risks, against the benefit of the device (Annex I, Sections 1 and 2). Risks are required to be reduced “as far as possible” without room for economic considerations (Annex I, Section 2).

An overall risk-benefit analysis must take place, regardless of the application of criteria established in the management plan of the manufacturer (Annex I, Section 1). Undesirable side effects must “constitute an acceptable risk when weighed against the performance intended.” (Annex I, Section 6). These gaps shall be addressed by ATL unless they are not applicable (because they are needed to be addressed by the design function).
Risk Numbers & Their Meanings:

Severity Rankings (Failure Mode) For Medical Devices (ISO-14791:2012, MDD/93/42/EEC)

Severity Ranking	Severity Level	Severity Definitions (possible actions associated with potential failure)
1-2	Very Low	Minor nuisance, may effect product appearance, not used in patient; no patient safety concern, possible performance degradation *E.g. Cannot prep device/system, not used in patient, select another device/system*
3-4	Low	Degraded performance, may remove and replace device/system, may extend invasive procedure time; no patient safety concern, degraded performance *E.g. Used in patient, removed due to degraded performance, select another device/system*
5-6	Moderate	Requires unplanned but not uncommon medical management, with or without degraded performance; moderate patient safety concern *E.g. Filler remnant in parent artery, additional anticoagulant medication given* *E.g. Distal emboli, attempt to retrieve emboli*
7-8	High	Requires unplanned medical intervention with or without prolonged hospital stay to prevent or mitigate serious injury or death; high safety concern *E.g. Rupture of aneurysm or parent artery*
9-10	Very High	Likely to cause death or serious permanent injury; catastrophic safety-related effects *E.g. Catastrophic aneurysm rupture with hemorrhagic and/or ischemic stroke and/or permanent neurological deficit*

Failure mode likelihood levels (frequency of occurrence)

1 or 2	1/10,000 or less frequent
3 or 4	between 1/1000 and 1/10,000
5 or 6	between 1/100 and 1/1000
7 or 8	from 1/10 to 1/100
9 or 10	more frequent than 1/10

Failure mode detectability levels

1 or 2 or 3 or 4 **High detectability**

- Failure is visually evident and likely to be noticed by a trained operator

5 or 6 or 7 **Medium detectability**

- Product or process is specifically tested or monitored for this failure mode

8 or 9 or 10 **Low detectability**

- Failure mode is neither visually evident nor specifically tested or monitored

The Overall Risk Level/ Hazard Levels (defined with RPN's) are detailed below:

Overall Hazard Priority Number (RPN)	Risk Level
< or = 100	Very Low
100 through 200	Low
201 through 300	Moderate
301 through 400	High
401 through 500 +	Very High

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