

Concepts

For better understanding further material, get acquainted with basic concepts of analyzing safety and reliability.

Risk terms

Concept	Description
Risk	Combination of the probability of occurrence of harm and the severity of that harm.
Hazard	A potential source of harm. A hazard is any source of potential damage, harm or adverse health effects on something or someone under certain conditions at work.
Hazardous situation	Circumstance in which people, property, or the environment are exposed to one or more hazard(s).
Harm	Physical injury or damage to the health of people, or damage to property or the environment.
Severity	Measure of the possible consequences of a hazard.
Probability	Quantitative evaluation of a event happening. There are two types of probabilities emphasized in ISO 14971:2012: <ul style="list-style-type: none">• P1 – probability of foreseeable sequence of events leading to hazardous situation.• P2 – probability that harm will occur when exposed to hazard.
Detectability	Hazard detection index accounts for the likelihood of discovering and correcting a hazard or failure mode prior to harm occurrence.
Hazard Correctability	Factor rates the relative ease of mitigating a certain risk. It accounts for the associated feasibility and effort required in reducing a particular risk to the lowest practicable level.
Product Utility	Factor is meant to integrate clinical benefit into the risk score.

FMEA terms

Concept	Description
Item	Enter the items, interfaces, or parts which have been identified through block diagrams, P-diagrams, schematics and other drawings, and other analysis conducted by the team.
Failure Mode	Potential failure mode is defined as the manner in which a component, subsystem, or system could potentially fail to meet or deliver the intended function described in the item column.
Effect of Failure	Effects of failure are defined as the effects of the failure mode on the function, as perceived by the customer(s).
Severity	Severity is the value associated with the most serious effect for a given failure mode.
Cause of Failure	Potential cause of failure is defined as an indication of how the design process could allow the failure to occur, described in terms of something that can be corrected or can be controlled.
Occurrence	Occurrence is the likelihood that a specific cause/mechanism will occur resulting in the failure mode within the design life.
Current Design Controls	Current Design Controls are those activities conducted as part of the design process that have been completed or committed to and that will assure the design adequacy for the design functional and reliability requirements under consideration.
Detectability	Detection is the rank associated with the best detection control listed in the Current Design Control Detection column.
Recommended Action	The intent of recommended actions is to improve the design. Identifying these actions should consider reducing rankings in the following order: severity, occurrence, and detection.
Responsibility Target Completion Date	The name of the individual and organization which is responsible for completing each recommended action including the target completion date.
Action taken	A brief description of the action taken and actual completion date.

Hazard Analysis Reference	Reference to Risk.
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Related pages

- [Getting started](#)
 - [Process description](#)
 - [Project templates](#)