

Application of Risk Management to New Medical Devices

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Introducing a new Medical Device onto the market a number of well defined risk analysis and evaluation phases should be undertaken. Risk Management and the performance of Risk Assessment are crucial parts of the design, development and control process.

Risk Assessment is a valuable tool and a regulatory expectation that should be used throughout the whole of the product life cycle to ensure a safe and effective product.

Application of Risk Management to New Medical Devices

The stages required for applying ISO 14971 principles to risk management can be typically broken into 6 steps, these are:

1. Describe the intended purpose or use of the device.
2. Conduct a hazards identification (Profiling)
3. Conduct a risk estimation
4. Conduct risk evaluation and acceptability
5. Document (proposed) risk controls
6. Prepare a risk management report for the device as part of design input or output

Risk management at a high level can be broken down into risk assessment and risk control.

A. Risk Assessment

1. Risk Identification and Analysis (Risk Estimation)

The Manufacturer must first identify the risks associated with the product; for example risks to the operator and risks to the patient. The ISO standard contains risk profile templates that aid in identification of risk elements and analysis. First the risk elements of the product design should be identified by a team made up of subject matter experts that should come from the various areas involved in the organization such as the design, quality, production and business departments. It is vital that a representative mix of ALL these disciplines are involved at this stage of risk identification. Subject matter experts tend to focus on their specific area and do not always have a thorough appreciation of how other elements can have an impact. Once the risk elements of the product design are identified an analysis of each element can be performed.

The use of standard templates simplifies this process.

A simple method is FMEA (Failure Mode and Effect Analysis), this can either use numerical values or colours to demonstrate risk (Example of such assessments figures 1 and 2)

2. Risk Evaluation and associated Risk Acceptability Decisions

Following the identification and analysis of the risk during device design, the results of the analysis should be evaluated and decisions made upon how to proceed. The process can be split into two sections, though these are frequently combined.

2.1 Risk Evaluation

The stage of risk evaluation determines the controls that need to be implemented to mitigate the risks and must be made in the context of the effectiveness of any existing strategies and controls.

2.2 Risk Acceptability Decisions

The Risk Acceptability for the design of the medical device must be then made. The acceptability decisions are prioritised using pre determined assessment criteria. Assessment criteria are usually descriptive, for example:

- High / Critical Risk – should re-design product/processes or not proceed
- Medium /Moderate Risk - should or may mitigate or control the risk eg. increase verification/ testing or other controls

B. Risk Control

The purpose of risk control is to reduce the risk(s) to an acceptable level, e.g. by inherent safety or by design and implemented during the Concept Design Phase and verified during design output. The effort used in reducing the risks to an acceptable level should be proportional to the significance / impact of the risks.

Control should be targeted at answering questions, such as:

- How can the risk be eliminated or reduced?
- What is an acceptable level of risk for the patient?
- Can the risk be controlled? i.e. can the 'severity' be minimised?

Summary

When introducing a new Medical Device onto the market a number of well defined risk analysis and evaluation phases should be undertaken. Risk Management and the performance of Risk Assessment are therefore crucial parts of the design, development and control process. They assist manufacturers to understand the product, ensuring that consideration has been given to user requirements, the patient and the operator. When performed with a multi disciplinary team using the appropriate and consistent rules, problems in the design development and use of the device can often be eliminated. Risk Assessment is a valuable tool and a regulatory expectation that should be used throughout the whole of the product life cycle to ensure a safe and effective product.

Frequency Severity or Product Risk	Rarely (Possible but unlikely to occur)	Occasional	Frequent (Probable – likely to occur)
High (likely patient harm /injury or recall of product)	Moderate	Major	Critical
Medium (Unlikely to cause harm/injury but likely complaints)	Minor	Moderate	Major
Low (Cosmetic defects only low to very low impact on quality)	No Risk	Minor	Moderate

Figure 1 Pictorial Risk Ranking

Classification of the Risk	Severity if it Occurs	Probability of Occurrence	Risk Factor (S x P)
Material Incompatibility	6	1	6
Material Fractures in Use	9	4	36
Allergic response	7	2	14
Product non-Sterile	8	7	56

Figure 2. Numerical Risk Ranking

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