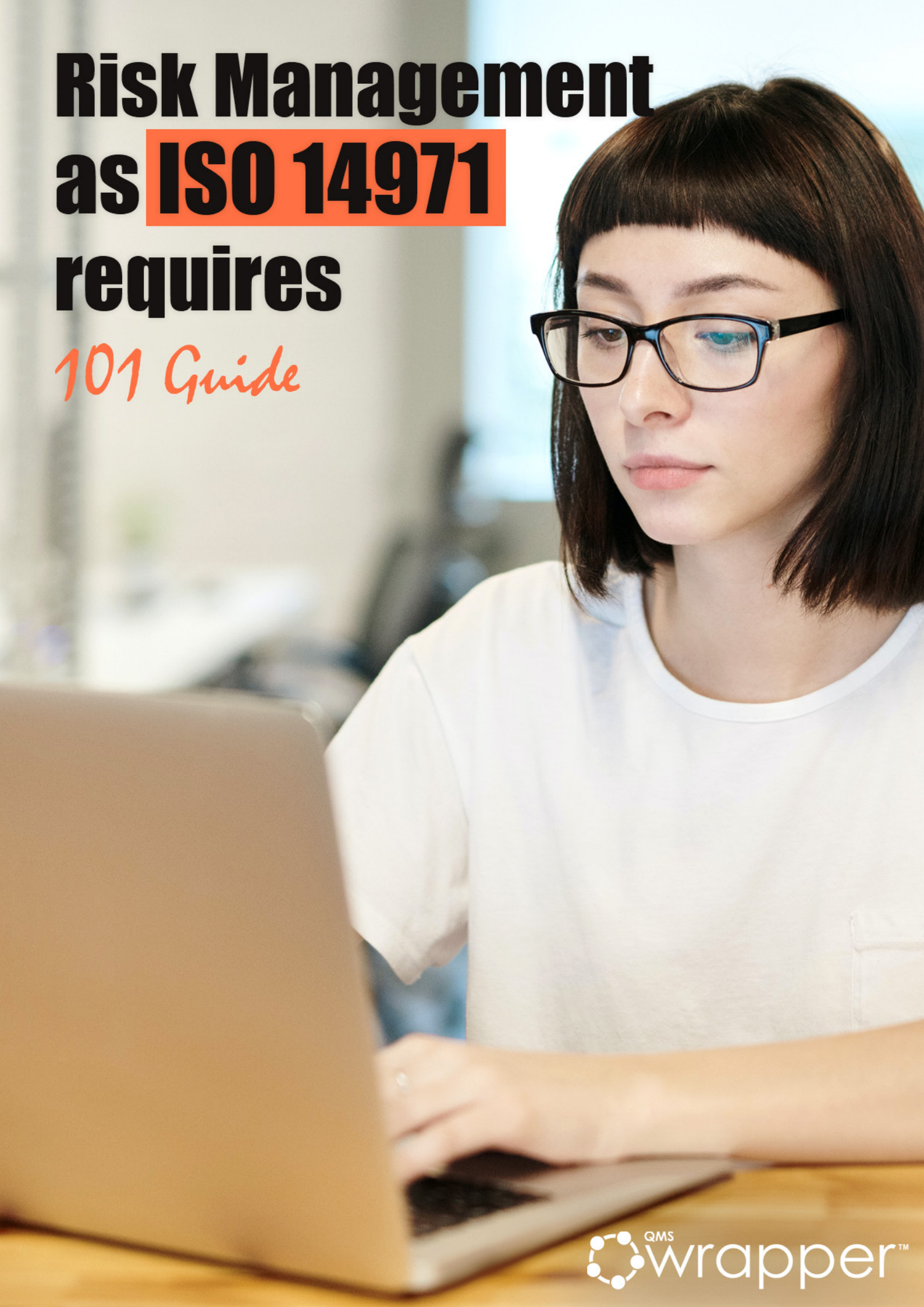
# Risk Management as ISO 14971 requires

*101 Guide*



QMS wrapper™

# Risk Management as ISO 14971 requires

ISO 14971 provides a process for managing risks associated with medical devices. Compliance with normative clauses will ensure that a process is in place to address general risk management aspects related to medical devices.

## Risk Management process

It's important to think about **risk management as a process** that you must define and manage in your quality management system just **like any other QMS process**.

The risk management process shouldn't be looked at as a single step to be performed throughout the development of the medical device.  It is an ongoing activity that is constantly and consistently applied throughout the entire life of the medical device. From the beginning of drawing the medical device all the way to the market.

Risk Management is a systematic approach of identifying, analyzing, evaluating, controlling, and monitoring all kinds of risks associated with a medical device from its design stage to the end of life. This is exactly what all of the above represents throughout the

lifecycle of all the devices you make. Risk management is a never-ending task.

The management has to provide evidence of its commitment to the risk management process, ensuring the provision of adequate resources and assigning qualified personnel for risk management.

## Risk Management Plan

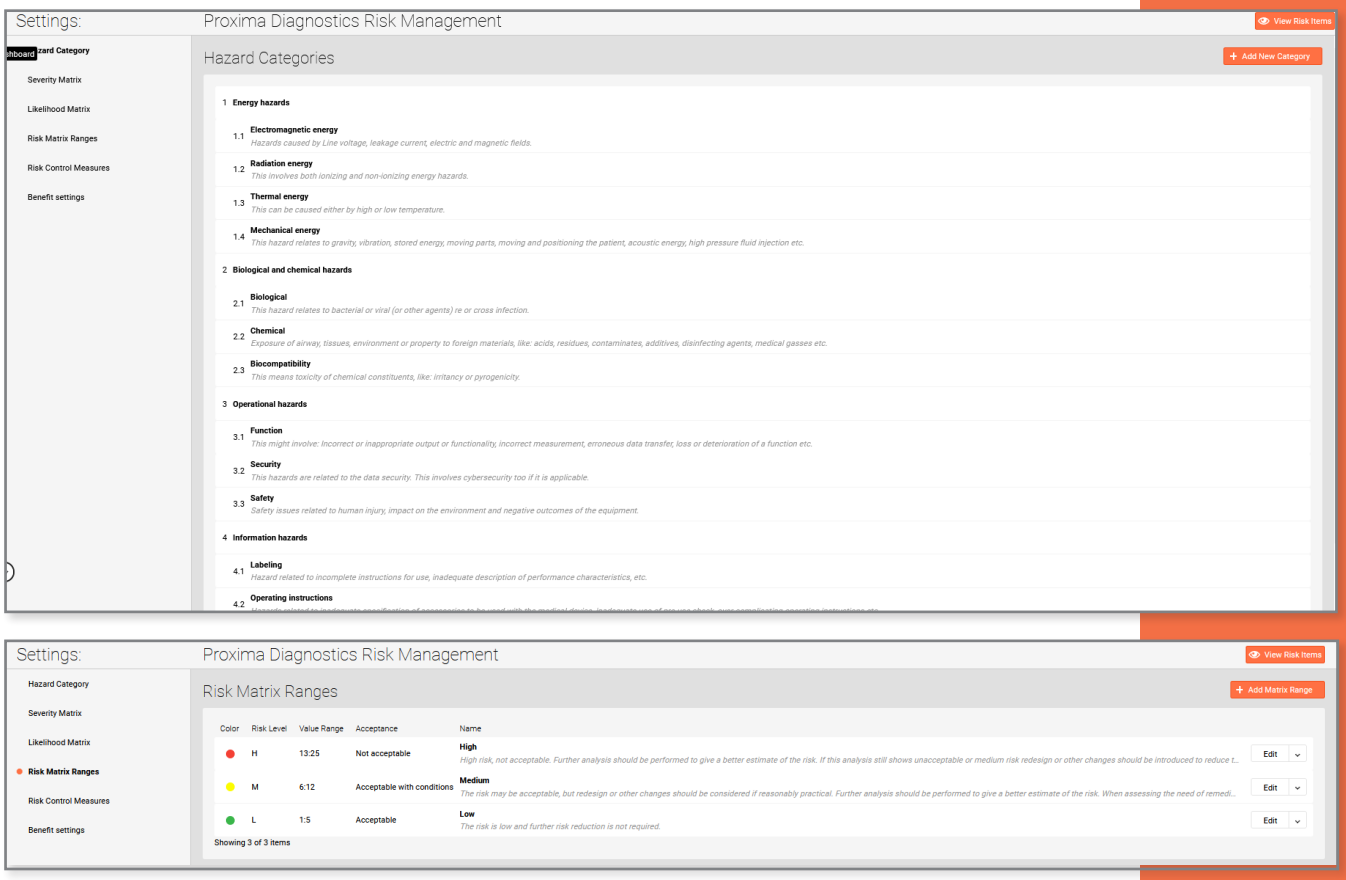
Just like any process, a risk assessment should start with a plan. The plan provides a roadmap for the activities to be conducted during the life cycle of the medical device. Among all criteria, a risk management plan must include the criteria for risk acceptability for the medical device to be developed.

The plan determines precise steps for risk management for a specific device, including all the risk analysis, evaluation, control, review, and reporting. Having a plan guarantees a systematized approach to risk management and prevents crucial activities from being forgotten.

Elements of the risk management plan MUST include:

1. Scope of the activities
2. Roles and responsibilities – assignments of responsibilities and authorities
3. Requirements for review of risk management activities
4. Risk acceptance criteria
5. Risk control measures verification methods
6. Methods to evaluate overall residual risk and criteria for acceptability

7. System to collect and review information in production and post-production phase







## Risk Management File

A risk management file must be created and maintained. Important parts of the risk management file are the risk management plan and the risk management report, which is created after the review of the implementation of the plan.

The risk management file should refer to all records and other documents that are produced during the risk management process. It should provide traceability for each identified hazard to the risk analysis, the risk evaluation, and the implemented risk control measures, including the evaluation of the residual risks.

It makes sure the risk management process is complete,

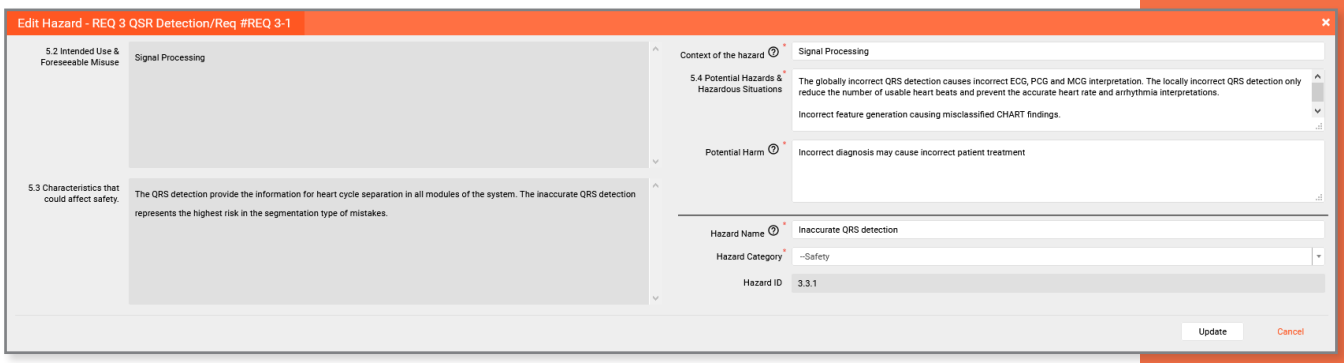
demonstrating that all hazards are accordingly handled and that every risk is suitably controlled.

## Risk analysis

Risk analysis is a sequence of the process with the use of available information to **identify** hazards and **estimate** risk for each hazardous situation of a medical device in its normal use and faulty state.

Risk Analysis shall be carried out in three phases:

1. Intended use and identification of characteristics related to the safety of the medical device
2. Hazard Identification
3. Estimation of Risk for each Hazardous situations




Risk estimation comprises the analysis of the probability of occurrence of harm and its severity.

Various methods can be used to estimate risk:

- the circumstances in which a hazardous situation is present

- the sequence of events leading to a hazardous situation,

- the probability of a hazardous situation occurring,

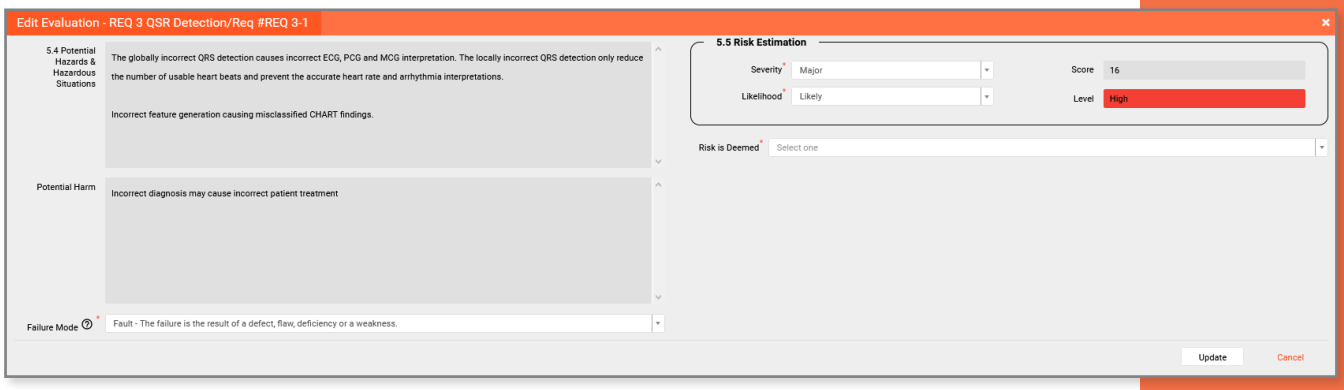
- the probability of a hazardous situation leading to harm,

- the type of harm that could result.

## Risk evaluation

Using the criteria defined in the risk management plan, the estimated risks should be evaluated for each identified hazardous situation, determining whether a risk is acceptable or not, and if risk reduction is required.

During this phase in the risk management process, the estimated risks are compared to the risk acceptance criteria.




## Risk Control

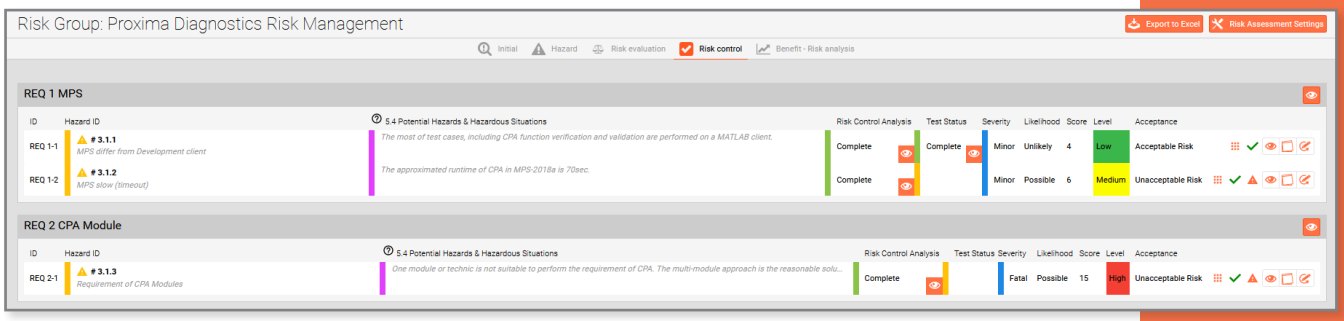
Risk control is one of the key steps in the risk management process of ISO 14971. The company should explore different options to reduce the risk to acceptable levels in a reasonable practical way.

There are several risk control options for eliminating or reducing risks to an acceptable level:

1. inherently safe design and manufacture - this is often related to the operating principle of the medical device.

2. measures of precaution in the medical device itself or the production process - such measures can minimize the probability of an event of a hazardous situation or harm and/or the level of the harm.

3. information for safety and training of users - this information can concern particular actions that the user needs to take or to avoid to prevent the occurrence of a specific hazardous situation or harm.

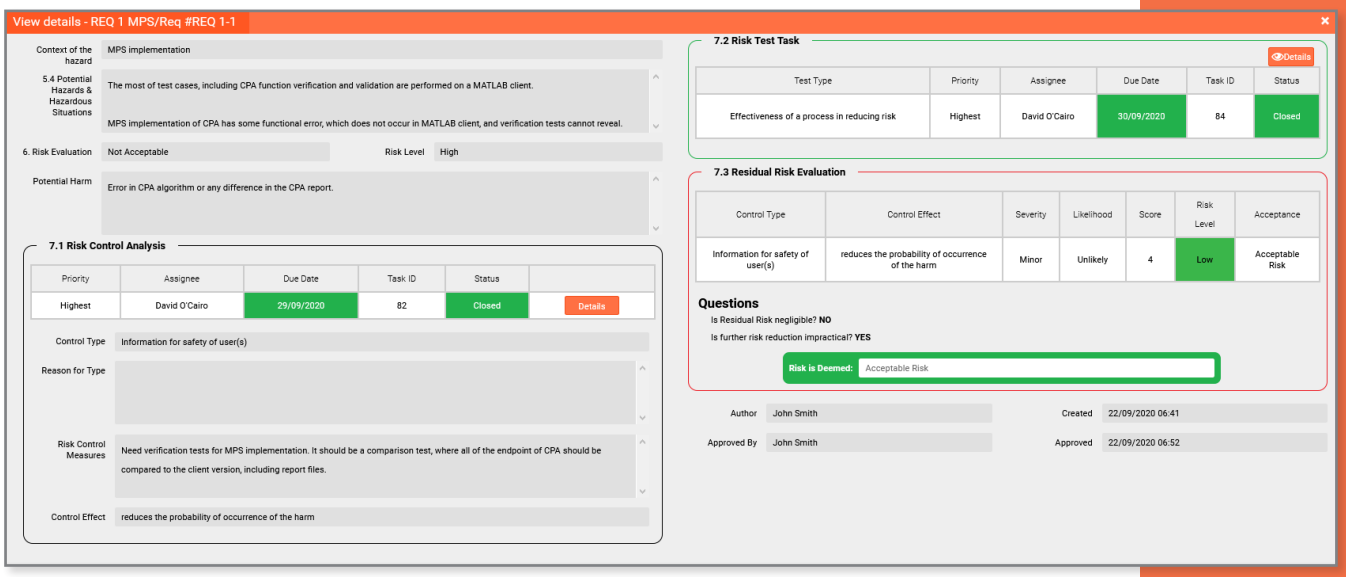



## *Implementation of risk control measures*

The selected risk control measures have to be implemented, and the implementation must be verified as part of D & D verification in a QMS. The same applies to the effectiveness of the implemented measures check.

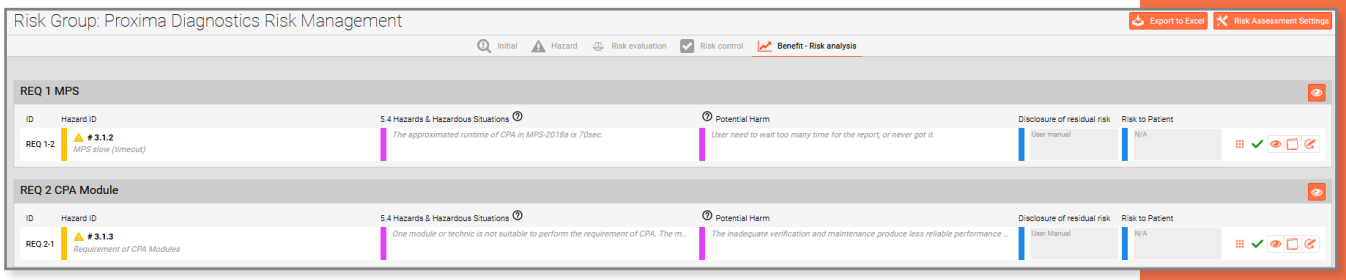
## *Residual risk evaluation*

After the implementation of the risk control measures, the residual risk must be estimated and evaluated again using the criteria for risk acceptability. If the risk is not judged acceptable, it is necessary to consider more risk controls.




## *Benefit-risk analysis*

If it is concluded that further risk control is not practicable, a benefit-risk analysis should be performed. Data and literature may be gathered and analyzed to determine if the benefits of using the medical device outweigh the residual risk. If this is not the case, the manufacturer needs to go back to the process and consider modifying the medical device or to restrict the intended use. Otherwise, the risk remains unacceptable.




## *Risks arising from risk control measures*

The effects of risk control measures should be reviewed since it can introduce new risks or increase other risks.

***Completeness of risk control***

Completeness is an important aspect of risk management. Therefore, it is required to check that all identified hazardous situations have been addressed and all risk control activities have been completed. Also, it must be checked that the selected and implemented risk control measures do not introduce new risks and do not affect other risks.

## Evaluation of overall residual risk

It is not only about the acceptability of individual risks but of evaluating whether the combination of all individual risks related to the device exceeds acceptable levels.

Even when all individual risks are considered acceptable, the cumulative effect of those risks may be unacceptable. The combination of several small risks could pose an unanticipated big risk.

The evaluation method and the criteria for acceptability of the overall residual risk are required to be documented in the risk management plan. This ensures an objective evaluation.

## Risk management review

As part of the risk review process, an assessment of the risk management activities need to be conducted against the risk management plan:

1. Has the plan been implemented appropriately?
2. Is the overall residual risk acceptable?
3. Is the production and post-production information collection methods implemented?

The summation of answers to these questions becomes a risk management report, which is part of the risk management file.

It will summarize all risk management activities and include any benefit-risk analyses and explanation of overall risk acceptability. The report documents the conduct and results of risk management activities.

## Production and post-production activities

Risk management should be looked at as an ongoing process for as long as the device serves. So it is essential to establish, document, and maintain a system to collect and review information relevant to the medical device in the production and post-production phases.

### *Information collection*

A system to collect and review relevant production and post-production information should be established. A list of sources is included in the standard, some of them are data from complaints, post-market surveillance data, supply chain, information available about the predicate device, etc. The aim is to actively gain data rather than passively wait for the data to be available.

### *Information review*

One of the analysis aims is to determine if any potential hazard exists. Also, it has to be identified if control measures were not effective. Any residual risks previously identified can be mitigated now or that it is no longer acceptable and if the risk-benefit analysis is still acceptable.

***Actions***

Appropriate analysis and data trends will help to take the necessary action, whether those actions are to implement additional risk control measures or actions regarding medical devices in the field. This data analysis provides valuable input for management to review the suitability of the risk management process for the organization.

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Risk management should be an essential part of every step in the development of a medical device, and everyone should know how to integrate risk management.

A risk assessment is not about creating enormous amounts of paperwork, but rather about identifying practical actions to control the risks related to a medical device.  By merging the risk management process throughout QMS, organizations can repair points that expose them to risk. Especially because it's less expensive and time-consuming to do so.

Every company must able to precisely assess risk levels across product lines, business processes, and business units in real-time. If the risk assessment systems in use are manual, it is hard to track, record, and preserve up-to-date documentation. A streamlined risk management solution can bring all risk activities and documentation together.

qmsWrapper's Risk Management Module is built based on ISO 14971 guidance and it is combined with a flexible system where the company can create own Risk

processes, including approval workflows, and define risk varieties and action plans. It provides a step-by-step sequence of task with appropriate explanations and cautions that makes it possible for risk or quality managers even with little experience to appropriately perform their risk-related tasks.

qmsWrapper's Risk Management Module increases the effectiveness, where the company will spend limited time and energy tracking risks and planning mitigations instead of managing a tool.

The automated risk management system allows companies to evaluate critical events more carefully and help them properly evaluate whether or not corrective measures are effective. Effectively managed risks help companies achieve their goals!