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1. Subject

1.1 Purpose

The purpose of this procedure is to define the rules for the identification, analysis, evaluation and reduction of risk. The goal is to increase the overall performance of the company by focusing on its core business and not on emergencies.

1.2 Scope

We do not forget that zero risk does not exist and that any activity includes risks related to:

- the safety of products
- satisfaction of interested parties
- control of documents
- data analysis (obtaining false measurements by non-calibrated equipment)
- staff competence (inadequate training)
- staff safety
- environmental protection
- the degradation of the company's image

The relevant internal and external issues for the QMS and actions to address risks identified and improvements opportunities found are taken into account.

1.3 Glossary

QMS – quality management system

Risk – likelihood of occurrence of a threat or an opportunity

FMEA – Failure Mode and Effects Analysis

2. Responsibility

Top management at its highest level is responsible for ensuring the strict application of this procedure in accordance with the company's risk management policy. Any project manager, as risk owner, is responsible for the risk management of their product or process. Each department of the company contributes to the treatment (reduction) of the identified risks.

3. Documents

3.1 Procedures

Control of documents

Management review

Control of the work environment

Design and development

Transfer

Control of changes

Purchasing

Control of production

Servicing activities

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Identification and traceability
Feedback
Internal Audit
Analysis of data

3.2 Instructions and records

List of risks
Internal report
Action plan
List of control measures

4. Requirements of standards

4.1 Requirements of ISO 31000:2018

§ 6.4 Risk assessment

§ 6.5 Risk treatment

4.2 Requirements of ISO 14971 version 2019. Note: ISO 14971 "Medical Devices - Application of Risk Management to Medical Devices" is specialized for medical devices, but most requirements are generic and can be used for any management system.

§ 4.1 Risk management process

§ 4.4 Risk management plan

§ 4.5 Risk management file

§ 5.1 Risk analysis process

6 Risk evaluation

§ 7.1 Risk control option analysis

§ 7.2 Implementation of risk control measures

§ 7.3 Residual risk evaluation

§ 7.4 Benefit-risk analysis

§ 7.5 Risks arising from risk control measures

§ 7.6 Completeness of risk control

8 Evaluation of overall residual risk

9 Risk management review

10 Production and post-production activities

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5. Development

5.1 Planning

5.1.1 General

The involvement of top management is an essential condition for the success of the risk management project.

On the basis of existing information and documents, project planning is started. The risk management process is part of the overall management system of the company and is adapted to our specificities.

The annual objectives of identification, analysis, evaluation and treatment of risks are set. Responsible persons, roles and deadlines are established, recorded and communicated (see "Internal Report", paragraph 5.1.3).

Compliance of our company's processes with legal and regulatory requirements is checked by the quality manager.

5.1.2 Resources

Top management plans and ensures the resources required for each step of the risk management activities.

The training, knowledge, skills and experience of the staff are crucial.

Resources include methods, process, documentation and equipment used.

5.1.3 Internal communication

Internal communication and consultation of information on risk management activities is recorded in internal reports.

Reports help staff understands accountability and risk appropriation.

For each risk identified as unacceptable, a control measure is chosen (see "Action Plan").

5.1.4 External communication

External communication and consultation of information on risk management activities is recorded in external reports with the active participation of interested parties (feedback, consultation, emergency plan).

5.2 Context

To establish the external context, first and foremost, we take into account the satisfaction of the requirements of external interested parties.

To establish the internal context, we take into account the strategy and culture of our company, the policy, the risk management objectives, the skills and perceptions of the staff.

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The necessary resources are established and ensured (see paragraph 5.1.2).

The activities of the "manage risks" process are determined (see paragraphs 5.3 to 5.7).

The risk criteria are determined:

- types of causes
- types of consequences
- measurement method
- likelihood (probability) of occurrence of effects
- acceptable level of risk
- combination of several risks

5.3 Identification

The list of all identified risks (potential and actual) is recorded and updated at least twice a year (see "List of risks").

The active participation of all is essential because it is the field persons who know best the real and potentially dangerous situations.

This list is the result of the work of the multidisciplinary team having reviewed the sources, causes, impacts, effects and consequences of the risks that may appear in our company.

5.4 Analysis

Determining the causes and consequences of the risks allows us to gather the necessary data to evaluate the risks (see paragraph 5.5) and to make the risk treatment decisions (see paragraph 5.6).

A risk analysis method used is FMEA - failure mode, effects and analysis. This analysis allows us to identify and evaluate potential failures and to eliminate or reduce the risks associated with appropriate actions. FMEA is used by the design department to analyze risks at different stages of design.

We use the following table to determine the likelihood of occurrence of a risk:

| Likelihood of occurrence (O) | | |
|------------------------------|-----------|--------------------|
| | Detection | Frequency |
| 1 | Unlikely | Never occurred |
| 2 | Very weak | Once a year |
| 3 | Low | A few times a year |
| 4 | Likely | Once a month |
| 5 | Strong | Once a week |

We use the following table to determine the severity of impacts of a risk:

| Severity of impacts (I) | | |
|-------------------------|---------|------------|
| | Degree | Impact |
| 1 | Minimal | Negligible |

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|---|----------|----------|
| 2 | Minor | Low |
| 3 | Moderate | Moderate |
| 4 | Major | High |
| 5 | Strict | Critical |

Each risk is quantified as to its likelihood of occurrence (O) and the severity of impacts (I) it can exert. The level of risk (L) is the result of the multiplication of the occurrence by the impact:

$$L = O \times I$$

In some cases we can add factors such as exposure time (increased risk) and difficulty of risk detection.

5.5 Evaluation

We classify the risks according to their level in three categories (see figure risk level):

- acceptable (1 ÷ 4) - green
- unacceptable (5 ÷ 9) - yellow
- intolerable (10 ÷ 25) – red

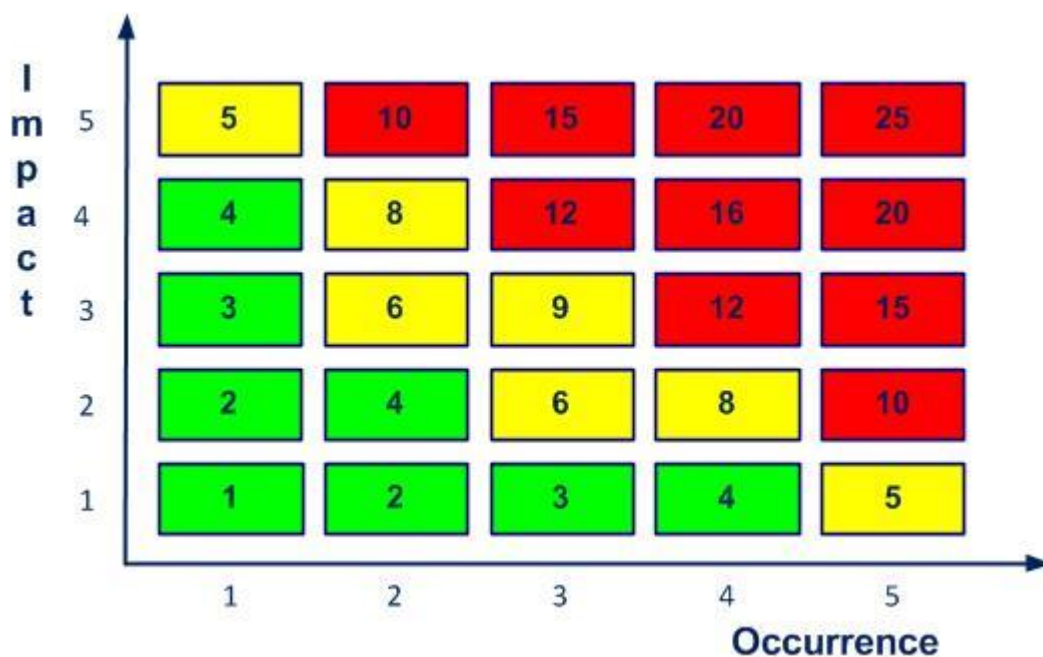


Figure Risk level

This allows us to make decisions about prioritizing and implementing control measures to address risks (see paragraph 5.6).

The financial consequences play an important role in the risk evaluation and the decision to implement the actions.

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The risk evaluation allows us to determine when a risk is acceptable and can be tolerated by the risk owner (level 1 to 4). Depending on the importance of the risk, the existing means of control remain unchanged.

For an unacceptable level of risk (level 5 to 9) we seek balanced control opportunities with reasonable and realistic costs (benefit-risk ratio).

When the level of risk is intolerable (level above 10) risk treatment is unavoidable, regardless of its cost.

Control measures to address unacceptable and intolerable risks comply with the legal, regulatory and other requirements to which our company has subscribed.

The risk assessment is based on:

- data review
- the benefit-risk ratio
- the participation of interested parties
- taking into account the worst case (extreme limits)

5.6 Treatment

When the potential or actual risks are unacceptable or intolerable they are reduced, avoided or transferred.

The priority of the actions is carried out on the risks with the highest level.

When the source of the risk is identified our efforts are directed towards the elimination of the source.

Risk treatment is evaluated by verifying that residual risks are tolerable and reviewing the effectiveness of control measures. Record of the "List of control measures" is retained.

A comparison is made on the financial impact of setting up and not implementing each control measure. After this cost analysis the control measures are selected and responsibilities are assigned.

The risk treatment actions are regular and are described in the treatment plans. Each plan is registered, dated, verified and validated by the person designated by top management (see job descriptions).

A combination of several risk treatment options is often used.

Communicating and consulting with interested parties when choosing options for treating a risk is a guarantee that a new risk will not be created as a result of the treatment of the old risk.

5.7 Monitoring

The purpose is to verify the relevance of the analysis, the effectiveness of the control means put in place and the level of residual risks.

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The persons responsible for the risks (see job descriptions) regularly monitor the situation.

Feedback (incidents, claims, results of preventive and corrective actions) is the database to drive continual improvement.

Monitoring records are kept in the reports and are an input element of the management review.

The data obtained after the marketing of the products allow us to:

- identify new risks as unplanned use
- update the analysis, evaluation and treatment of risks
- update the benefit-risk ratio
- improve the risk management process

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