Content

...

...

3.0 General

Risk - effect of uncertainty on an expected result.

Actions to address risks in QMS process includes four phases:

- risk identification,
- risk analysis,
- risk evaluation,
- risk treatment.

4.0 Risk Identification consists of revealing, classification and description of the risk. The ultimate goal of **risk identification** is to draft a comprehensive Risk list.

In order to ensure a unified approach to management, risk should be defined as an event that can occur with a certain likelihood, and that may have adverse (more often) or favorable (less frequently) consequences.

NOTE. Any of the possible risk wording can be accepted when identifying a risk. The main idea is that the risk wording is clearly understood by the group of experts and convenient when analyzing the causes and consequences.

…

…

5.0 Risk analysis consists of determination of level of risk for each risk included into the Risk list.

5.1 For QMS Processes the level of risk (**R**) is calculated using the ratio:

$$R = C \cdot L$$

Where **C** – consequences,

L – likelihood.

Consequences and likelihood are defined via expert evaluation.

Expert evaluation is done by a team of experts (5 or 7 people). Process owner appoints the experts. To facilitate the process, the expert evaluation is carried out in quality categories, for example, in the case of determining the likelihood: 'very high' – 'high' – 'medium' – 'low' – 'very low'. It is very important to agree on the recommendations for the evaluation conditions.

Next, the results are digitized. Table 1 provides an example of such expert opinion digitization when determining the consequences. Table 2 provides an example of expert opinion digitization when determining the likelihood.

The maximum and minimum values are discarded and the average value is calculated based on the remaining values – this is the evaluation result.

Table 1

Expert evaluation	Evaluation recommendations (if applicable)	Consequences, C
Very severe consequences	The event represents a danger to life and health of users of the product or service, process operators.	**10**
Severe consequences	The loss of functional properties of the product or service (the inability to use as intended). Stopping the process. The necessity cull more than 50% of the product.	**7.5**
Medium severity consequences	Partial loss of functional properties of the product or service (the ability for intended use is limited). Increase of process cycle duration by more than twice. The level of product rejection exceeds the target.	**5**
Insignificant consequences	Loss or limitation of the secondary function of the product or service. Inconvenience in use, loss of aesthetic appearance. Observed by over 20% of customers.	**3**

Expert evaluation	Evaluation recommendations (if applicable)	Consequences, C
Very insignificant consequences	Observed by less than 20% of customers.	**1**

*NOTE 1. Experts can find more convenient the use of a three-level scale: **1 - 5 - 10** (for example, in the case of insufficient information).*

...