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Design of a risk register for an accredited laboratory according to the ISO/IEC 17025

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Abstract The main aim of this article is to analyse the possibilities of risks and the introduction of the methodology for work with risks in accredited laboratory according to the ISO/IEC 17025. The effort is to sufficiently meet all the requirements of the standard and set up risk assessment process so that is understandable for accredited laboratory and easy to use for subsequent analyses. The aim of this article is to provide complex view into the given issue and these conclusions could be used as an informational source for laboratories, which will start the certification of the implementation the quality system management.

Keywords ISO/IEC 17025, accreditation, processes, risks, FMEA

1. INTRODUCTION INTO THE ISSUE

In the 2018 was released the revised version of the standard ČSN EN ISO/IEC 17025:2018. In this version the general requirements on eligibility of testing and calibration laboratory was revised. This standard was reorganized and severe requirements were modified. Continuous risk investigation and work with them are the newest requirements of this standard. The purpose of this requirement is to deal within the planning with weaknesses, which are necessary to identify to ensure sustainable development, and also treat them.
The main idea is to focus on the identification of possible risks which are related to all activities in accredited testing laboratory. All these identified risks will be evaluated and the register and the work methodology with given risks will be designed. This step will fulfil the new requirement of the standard ČSN EN ISO/IEC 17025:2018 [1].

The standard ČSN ISO 31000:2018 – Management of risks is the key standard to control the process of risks, where the risk assessment is described and it is collected from three parts, see Fig. 1. The first part of the process control is the identification, which is considered as the most important and this article is focused right on this issue. [2]

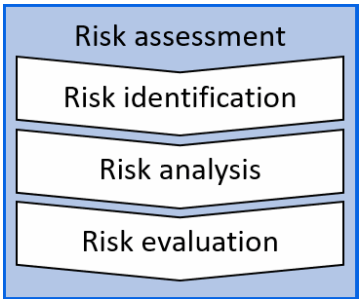

Fig. 1: Risk assessment [2]

1.1 The decision about the risk identification
1.2

There are many approaches how to treat the risks in an organisation. But these methods are mostly general and they are not targeted directly on requirements of accredited subjects. FMEA is one of the most known methods how to analyse risks. Method of analysis of causes and defect results is one of the possible techniques to perform risk analysis. In general, it is characterized as a method to investigate the system with demand to uncover the causes of defects, their causes and their impacts. It could be applicated on broad spectrum of areas. [3]

In this article we are mainly focused on identification of risks, because it is a central task in the field of risk assessment. Our basic idea to identify all potential risks is that accredited laboratory has to fulfil all requirements of the standard ISO/IEC 17025. Based on this idea it is not necessary to set a team, which will realize the first design of the risks register. It is not also necessary to use any of the common used methods. The aim is to identify risks according to the individual requirements of each chapter of the ISO/IEC 17025 standard in order to address the given normative requirements.

It is accurate to give concise name of the risk and a brief description what the risk deals with for the following evaluation of each designed risks. This model simulates possible impact of the risk on the laboratory and it could be used as a next to evaluate this risk because it demonstrates its own possible consequence. It is necessary to design a precaution for every risk to eliminate it. Some of requirements of the standard follows the need of documentation and records and just these records and documentation could be used as the measure itself.

1.3 Risks to the ISO/IEC 17025

The most important document of the standard ISO/IEC 17025 to keep given approach contains requirements of accredited laboratories. These requirements demonstrate their authority and ability to provide valued results. It performs as a basis for possible accreditation of the laboratory. This standard could be applicated for all organizations, which realize laboratory activity, with no demand on their size. It is also consistent with the standard ISO 9001.

Both standards, as ISO 9001 as ISO/IEC 17025, require to consider risks and opportunities for increasing the effectiveness of the management system and to reduce negative impacts by the prevention of them. It is only general requirement on laboratory to decide and to be responsible itself which risks and opportunities are necessary to identify, analyse and treat. [1] [4]

1.4 Risks in chapters ISO/IEC 17025

Chapter 4: General requirements
First mention about risks and how to consider them is stated in the subchapter 4.1.4, which is dealing with impartiality of laboratory. Impartiality is explained as an existence of objectivity in this standard. Objectivity means that the laboratory is not in any conflict of interest. The conflict of interest may be eventually resolved that it does not interfere into the activity of laboratory. Such risks and measures must be found to reduce any potential threat to the impartiality of the laboratory. These risks could be found with respect to the activities and relates of the laboratory or it could result from the relationships of its employees. The laboratory must provide by the identification and treat of risks that it is not exposed to any financial conditions which could impact its impartiality. [1]

Chapter 8.5: Measures with respect to risks and opportunities
The need to solve risks and opportunities is explicitly described in chapter 8.5, which is dealing only in general with need to respect risks and opportunities. According to this chapter and its subchapters, the laboratory is obliged to respect risks and opportunities according to its activities to:

- Provide that the management system reaches given results;
- increase opportunities to reach intentions and targets of the laboratory;
- prevent undesirable impacts and potential failures of laboratory activities or to decrease them;
- reach an improvement.

In addition to the need to plan measures for identified risks, the laboratory must integrate the proposed measures into the management system and analyse their effectiveness. According to the standard ISO/IEC 17025, the laboratory is obliged to solve risks and opportunities, but there is no accurate methodology. The laboratory can use any of methods to assess them. There is also no requirement on the documentation of the process management risks in the standard. In the subchapter 8.5.3, there is defined the need to use such measures to eliminate an influence on the validity of laboratory results.

In the case the results are not influenced by the risk or by its measure, it can be used as an occasion, for example: increasing the range of laboratory activities, reaching new customers, etc. Risk avoidance, elimination of a source, change of probability, decreasing costs, risk sharing or withholding by an informative decision are the main tasks of designed measures. [1]

It is necessary to continuously update the risks, especially when the dissension occurs. It is also necessary to use the risk analysis as an input for a regular review of the management system. [1]

Evaluation of the standard ISO/IEC 17025
Based on the detailed research, the risks can be identified in individual chapters of the standard. In the standard ISO 9001 and also in the standard ISO/IEC 17025 the method, how to solve the risks, is not described. Also, the particular risks which are necessary to involve are also not specified. In these documents is only the need of an application how to consider the risks and opportunities to improve the management quality system described.

2. CURRENT STATE OF EVALUATION THE RISKS IN ACCREDITED LABORATORIES

In our laboratories, risks are currently set and identified according to the implemented projects without the use of any method.

In order to meet the approaches of the accreditation standard, it is appropriate to identify new risks which will be connected to all processes in laboratories. According to the standard ISO 31000 which defines the solution of risks as a cycle, the re-identification is appropriate. That means repeatedly review and seek new risks.

Close range and low amount of identified risks are the main disadvantages of a current state. In terms of meaning, the risk “Sources for metrological traceability” highlights only the need to keep metrological traceability but there is no definition for the possibility of measures to decrease the chance of damage or influence on the equipment and cause its calibration impairment. There is also absence of the definition for the possibility to unintentionally use the damaged or uncalibrated equipment. All areas of ISO/IEC 17025 are not involved in current risks, for example like environmental control where are laboratory activities realized.

It is necessary to set new risks for laboratories according to the standard for the accreditation. It is also necessary to respect different aspects of laboratory processes due to the diversity of activities.
This solution is currently sufficient because the need of the detailed evaluation is not described in the standard ISO 31000 and the responsibility to choose the method has the organisation. This only criterion is not appropriate to understand the risk and it should be expanded.

3. NEW DESIGN HOW TO EVALUATE THE RISKS IN ACCREDITED LABORATORIES

3.1 Method of identification

Risks were identified based on the requirements of each chapter of the standard ISO/IEC 17025 chronologically according to their sequence. See the Tab. 1 as a brief illustration.

Tab. 1: Example of identified risks from chapter 4

ID	Chapter	Risk	Description
1	4.1 Impartiality	Financial, commercial and other forces	Existence of any forces which could influence the impartiality of the laboratory
2	4.1 Impartiality	Relations of the laboratory	Existence of external/internal relations of the laboratory which could influence the impartiality

3	4.1 Impartiality	Internal/external relations of employees	Internal/external relations of employees which could influence the impartiality of the laboratory
4	4.2 Confidentiality	Access to secret informations about laboratory activities	Loss of laboratory reliance, legal sanction, financial sanction.
ID	**Chapter**	**Risk**	**Description**
5	4.2 Confidentiality	Access to secret information about a customer	Loss of laboratory reliance, loss of a customer, legal sanction, financial sanction.
6	4.2 Confidentiality	Violence confidentiality of information caused by human factor	Informational leakage caused by human factor

3.2 Design of an evaluation

Current state respects the determination of a simple meaning of the risk, but it is recommended to use more criteria to obtain a more complex view on a risk. The first design of the new concept to evaluate the risks comes from FMEA analysis. This concept use evaluation of three criteria, namely Occurrence, Severity and Detection. [5]

Each criterion is scored by the range 1 – 3 points and they are then. The meaning of the risk or RPN (Risk Priority Number) is calculated as a point of product evaluation O*S*D. It´s meaning and need of measure can be obtained according to the classification of a result. In the case the measure is already set, the criteria are re-evaluated and it can conduct to the reduction of the risk as a result. After this evaluation on some criteria was tested, it was found out that in this issue it is not possible to use criteria of traceability or it is completely irrelevant.

As a more appropriate way how to evaluate the risks is not to consider the criteria of traceability and on the other hand to extend the criteria of probability and consequences. Due to the decrease of the number of criteria, the risks will be more efficiently evaluable. Their meaning can be rated as a product of two criteria and according to the RPN intervals recorded in the risk evaluation matrix, see Tab.2. The modification of the number and range of criteria is not in conflict with any standard. The standard ISO 31000 points on the possibility to set own system to evaluate risks. [2][6]

Tab. 2: Risk evaluation matrix

Risk evaluation matrix		**Severity**				
		1 Minor Injuries	2 Significant Injury	3 Serious Injury	4 Major Injury	5 Fatality
Likelihood	1 Very unlikely	**1**	**2**	**3**	**4**	**5**
	2 Slight	**2**	**4**	**6**	**8**	**10**
	3 Feasible	**3**	**6**	**9**	**12**	**15**
	4 Likely	**4**	**8**	**12**	**16**	**20**
	5 Very likely	**5**	**10**	**15**	**20**	**25**

Risk rating	**Likelihood (L) * Severity (S)**
1-4	Acceptable
5-10	Unfavourable
12-25	Unacceptable

As you can see in the table 3, there are few examples how to evaluate the risks according to two mentioned criteria and their resulting meaning. Evaluation is mentioned as a design because it should be objective all the time and realized by competent team which has knowledge and experiences with processes of an organization.

Tab. 3: Examples of risks with rating

ID	**Chapter**	**Risk**	**L**	**S**	**Risk rating**
4	4.2 Confidentiality	**Disclosure of confidential information about laboratory activities**	**2**	**5**	**10**
7	5. Structural requirements	**Organisational changes**	**3**	**2**	**6**
10	5. Structural requirements	**Deviation from given procedures of laboratory activities**	**2**	**4**	**8**
20	6.1 Resource requirements	**Unsatisfactory environment from the view of human factors**	**2**	**2**	**4**
30	6.6 Externally provided products and services	**Inconsistent selection of an external provider**	**3**	**3**	**9**
43	7.4 Handling of test or calibration items	**Identification of test item**	**3**	**3**	**9**
58	7.11 Control of data and information management	**Inadequate operation and security of the information management system**	**4**	**3**	**12**

4. EVALUATION OF THE APPROACH TO THE SOLUTION OF OPPORTUNITIES

The opportunities are considered as a next subject to improve the quality management because they are classified as a positive aspect of the risk. The opportunities as opposed to risks can´t be evaluated and their classification is difficult. We designed possible approaches how to improve the search of the risks in this analysis. Analysis SOAR and NOISE are designed as an alternative to the current SWOT analysis which could be replaced or extended about new approaches into the opportunity management issue. In a current state, these are only suggestions for identifying areas where opportunities can be identified. [7]

5. CONCLUSION

The aim was to set the process for evaluation of the risks for accredited laboratories. The need to primary identifies new risks was

determined based on the review of a current situation. Risks are identified in accordance with the requirements of the standard ISO/IEC 17025 on the basis of determination that the risk may be non-compliance of the requirement. The list was significantly extended against current risks. The risks which can lead to the identification of product and services conformity with requirements were determined. They can be also used for accreditation. Risks are in accordance to the standard requirements. Measures of these risks will be used as measures to meet the requirements of each chapter of the standard.

Identification was realized according to each chapter of standards to determine risks for all of their sections. The register of risks, as the result is, will be divided according to risks for each laboratory with respect to easier evaluation of the laboratories. There is possibility that the identified risk is not in relevant to the specific laboratory activity and it will not occur in the laboratory register of risks.

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