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Supervision of measuring equipment based on risk management and ISO 9001

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Abstract
The study presents the results of analysis of the possibilities of measuring equipment supervision, taking into account the requirements of the ISO 9001: 2015 standard and risk management present there. As it has been shown, it is possible to use (mentioned in point 6.1 of indicated standard) a risk management method for skilfully managing a measuring equipment. Orientation of business to risk is one of the elements of the ISO 9001 standard, which does not specify exactly how the method of its implementation should looks like. Generally, it orders to manage risk wherever goals appear. The targets also appear in the field of supervision of measuring equipment. Therefore, in the elaboration, apart from the requirements analysis, the concept of a five-stage methodology for implementing a risk-based approach to management of measurement equipment was presented. The matrix method was used to assess the risk. Within this method two elements were assessed: probability and potential effects of the risk occurrence. Application of the proposed concept may contribute to a more efficient and effective management of measuring instruments.

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1. Introduction

Each organization seek to optimize the mechanisms of its activity. This may mean increasing market share, reducing costs, implementing more efficient risk factors management or increasing customer satisfaction. Another action can be a continuous (as in the system) change in the production parameters of products, such as in (Korzyński et al., 2009; Pacana, et al. 2014). The quality management system is a structure enabling monitoring and increasing the efficiency of operations in every area. ISO 9000 series standards follow these aspirations. The ISO 9001 standard is undoubtedly the most-respected standard in the world regarding system quality management (Boiral, 2011).

Risk management in ISO 9001 is a consequence of the update of the standard in 2015, which result-ed, among other things, from the need to ensure greater concentration on the client's needs.

One of the important elements of providing the customer with products of the desired quality is proper measurements. To do this it is important, among others, to properly supervise the measuring equipment. This is mentioned in the ISO 9001: 2015 standard in section 8.5.

To ensure a demand of traceability, the concepts related to monitoring and measurement have been standardized in the standard. Calibration and / or checking of measuring equipment should take place at set time intervals or immediately before use in the case of standards related to international or national standards. The basis for calibrating or checking of equipment that does not have standards is a documented information. Measuring equipment should also be secured and marked (Zwinkels, 1996). Measuring instruments should not only be checked but also calibrated. In turn, the ISO 10012 standard proposes in this respect not to exceed the period of 24 months. Practice shows that the most frequent calibration is carried out once a year (Krajewski et al., 2010; Saito et al., 2010). In order to skillfully select the calibration time, the already mentioned standard ISO 9001 can be used and in the field of risk management the requirements of point 6.1 can be used to determine the calibration period of measuring equipment.

2. Risk management in ISO 9001:2015

The ISO 9001: 2015 standard has been prepared in an innovative form (HSL ANNEX, 2013), which is common to all new standards of management systems. The said annex imposes a common text, common structure and terminology in all amended till now standards: ISO 9001, ISO 14001, OHSAS 18001 (ISO 45000) and ISO 27001 (Pacana et al., 2017). The current list of chapters of ISO 9001 is presented as follows (PN-EN ISO 9001, 2015):

1. The scope of the standard.
2. Normative references.
3. Terms and definitions.
4. The context of the organization.
5. Leadership.
6. Planning.
7. Support.
8. Operational activities.
9. Evaluation of the effects of action.
10. Improvement.

Annex A (informative) Explanation of the new structure, terminology and concept.

Annex B (informative) Other International Standards on quality management and quality management systems developed by ISO / TC 176.

Bibliography.

The standard introduces a set of requirements that are relatively general, but are strongly related to modern management (Biazzo et al., 2003). Keeping the emphasis on effective process management, the standard also requires to pay attention to the risk that is present at all accompanies. The standard imposes risk management in a systemic way, rather than treating it as a single element of the quality management system, as it was before. In previous editions of ISO 9001, the risk appeared in the point concerning preventive actions, that are not longer present in the current issue of the standard. The ISO 9001: 2015 standard did not specify a methodology in its requirements as it did not ordered to comply with specific risk standards, i.e. for example:

- PN-ISO 31000:2012 Risk management - Rules and guidelines (see (PN-ISO 31000, 2012)),
- Risk management standard FERMA 2002,
- ISO 22301 Continuity management system,
- ISO 19600 Compliance of management systems - Guidelines,
- Corporate risk management - an integrated framework, COSO 2004.

ISO 9001, however, put great emphasis on necessity to consider by organizations the understanding of the general risk level present in their processes and activities. One of such processes is a supervision over measuring equipment (Jarysz-Kamińska, 2006). Knowing the risks and discovering opportunities, the organization gets the chance to become better e.g. to improve itself. While speaking about a risk, it should be emphasized that the standard requires attention not only to these so-called negative risks, but also for opportunities (potential benefits). Both, avoiding unfavorable events as well as using opportunities, is the foundation of risk management.

3. Focusing on risk assessment in the supervision of measuring equipment

Orienting business to risk is one of the most difficult to interpret elements of ISO 9001. Especially since it does not specify exactly how the risk management implementation should look like. It is true that it mentions in comments about the ISO 31000 standard, but in some situations the application of all the recommendations of this standard would be an overgrowth of form. Similarly, it could be in the case of the supervision process over measuring equipment, e.g. in a small or medium-size enterprise (Bošnjaković et al., 2017). Nevertheless, the methodology based on five stages should be used to manage the risk:

1. Process analysis.
2. Identification of risk (threats) and chances (opportunities).
3. Assessment and validation of risks and opportunities.
4. Developing a plan of action in response to threats and opportunities.
5. Implementation of the action plan.

The method of managing the risk of achieving the goal will be proposed as a simplified form. The main purpose of supervision over measuring equipment is to prevent incorrect measurements.

Identification of the risk related to failure to achieve the goal is the most important stage of risk management. It is not limited to the area of threats, but also to looking for opportunities. To identify the risks connected with the supervision over measuring instruments, the metrologists' knowledge can be used as well as the brainstorming method (Zhou et al., 2016; Zwinkels, 1996).

Risk assessment and validation is a stage based on 2 documents: the risk register and the risk map. For the risk assessment, the use of the matrix method was proposed, within which two elements would be assessed:

- probability of risk occurrence and
- potential effects of a risk.

It was proposed that each element be graded on a 5-point scale and with the assignment of different weights. For example, the assessment of the probability of occurrence of a given risk consists in assigning to each of the risk types a score from 0 to 1 (every 0.25), and the impact assessment would take place on a scale from 1 to 6. Examples are shown in tab. 1 and 2.

The risk method was also adopted in the proposed methodology (Figure 1), which took the form of a probability matrix and the effects of the occurrence.

It assigns values to particular fields (ratio of probability and effect), and negligible values, temperate and important risks are established by color and description. The register should be created on the basis of the risk map adopted in the organization. It describes identified risks in operational areas related to the functioning of the organization. Subsequently the risk management team prioritize the risks.

Table 1. Exemplary generalized table of selection of probability of risk occurrence.

Probability	Name	Description of effects
0	Minimal	The risk of changing the accuracy of the measurement does not occur or may occur in completely exceptional, sporadic situations.
0,25	Low	The risk probably will not occur. Over the last year, the measuring instrument practically does not change the accuracy of the measurement.
0,5	Medium	Risks are likely to occur over the next year. Over the past year, the measuring instrument has been subject to small changes in the accuracy of the measurement.
0,75	High	There is a high probability of risk occurring within the next year. Over the past year, the measuring instrument has been subject to changes in the accuracy of the measurement.
1,0	Important	The risk will certainly occur within the next year. Over the last year, the measuring instrument has already undergone significant changes in measurement accuracy.

Table 2. Exemplary generalized table of selection of potential effects of a risk occurrence.

Points	Name	Description of effects
1	Minimal	Possible effects are mitigated by existing control mechanisms.
2	Small	Existing control mechanisms should limit the effects of possible disruptions.
3	Medium	Existing control mechanisms can to some extent limit the effects of possible disruptions.
4	Important	Existing control mechanisms can only minimize in small extent the effects of possible disruptions.
4	Serious	Low efficiency of existing control mechanisms.
5	Disastrous	Lack of proper control mechanisms or existing mechanisms are ineffective - serious disruptions in the unit's operation; threats will cause lack of continuity.

The effect of work related to analysis, assessment and risk hierarchy is to rank them according to the importance criterion, and as it usually occurs in accordance with the principle of 20/80, planning activities in relation to the most important ones. The next task is proceeding with a risk. For each of the risks, the monitoring mechanism in use should be analyzed and described and it should be checked whether it provides sufficient control over the risks. For the most important types of risk or those that may pose a particular threat to the achievement of quality objectives, appropriate measures should be taken. The form from tab. 2.9 can be used for this purpose. These activities are strongly dependent from the specificity of the organization and from the identified threats.

Effects / Probability	Minimal 1	Small 2	Medium 3	Important 4	Serious 5	Critical 6
Sure – 1,0	**1,0**	**2,0**	**3,0**	**4,0**	**5,0**	**6,0**
High – 0,75	**0,75**	**1,5**	**2,25**	**3,0**	**3,75**	**4,5**
Medium – 0,50	**0,5**	**1,0**	**1,5**	**2,0**	**2,5**	**3,0**
Low – 0,25	**0,25**	**0,5**	**1,0**	**1,5**	**2,0**	**2,5**
Minimal – 0,0	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**

- non-significant risk (N), results from 0.0 to 1.0 - measuring equipment can be calibrated once every two years
- moderate (U) risk, results from 1.0 to 2.5 - the measuring equipment can be calibrated once a year
- significant risk (I), results from 3 to 6,0 - measuring equipment should be calibrated once every six months or more often

Fig. 1. Risk matrix

Table 3. An example of a risk treatment form

Goal:							
	Risk type	Probability of occurrence	Effects	Importance	Responsible person	Method of operation	Necessary resources
1	2	3	4	5	6	7	8
1							
2							
:							

Proceeding with risk is also the control of the implemented solutions. Correct communication as well as monitoring and controlling of the implemented solutions in the field of monitoring of measuring equipment is recommended (Zelenkova et al., 2015). This can be done before management reviews or before periodic management reviews. The basic condition for the effectiveness of the risk management system to supervise measuring equipment is its suitability to the organization. It may be difficult to undertake a thorough risk assessment process. The risk is an effect of uncertainty on the expected result.

4. Summary and conclusion

The changing environment and economic conditions induce the organizations to undertake systemic actions aimed at preventing any incompatibilities, the nature of which may be internal or external. Risk management becomes an inherent element of management. This aspect of management has been strongly exposed in the ISO 9000 quality management standards amended in 2015, which should be verified by appropriately monitored control and measurement equipment. To skilfully, and on the basis of real factors, choose the period of calibration of measuring instruments, the risk management in the area of supervision over control and measurement equipment was proposed in the article (based on the six-stage methodology). Its purpose is to prevent defective measurements. Particular attention has been paid to the risk assessment method. A risk matrix and a form for gradation of risk importance and for preparation of reaction plans have been proposed. Applying to these proposals can be the key to preventing incorrect measurements in many organizations.

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基于风险管理和ISO 9001的测量设备监督

關鍵詞
控制和测量设备
ISO 9001
风险管理

摘要
该研究介绍了测量设备监督可能性的分析结果，同时考虑了ISO 9001：2015标准的要求和存在的风险管理。如图所示，可以使用（在指定标准的第6.1点中提到）用于熟练地管理测量设备的风险管理方法。企业对风险的定位是ISO 9001标准的要素之一，该标准没有具体说明其实施方法应该如何。通常，它会命令在目标出现的任何地方管理风险。目标也出现在测量设备的监督领域。因此，在详细说明中，除了需求分析外，还提出了实施基于风险的测量设备管理方法的五阶段方法的概念。矩阵方法用于评估风险。在这种方法中，评估了两个要素：风险发生的概率和潜在影响。应用所提出的概念可有助于更有效和更有效地管理测量仪器。