Risk identification of calibration laboratories

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Abstract. The article is devoted to the identification, ranking and quantitative analysis of the risks that affect the quality of calibration work in the calibration laboratory. The paper used the brainstorming technique, the Ishikawa chart, and the ranking method for research. The results are represented by the Pareto chart. The ranked list was compiled based on the statistical data of the calibration laboratory. The ranked list was used as assessment criteria of risk.

1. Introduction

The new version of the GOST ISO / IEC 17025-2019 standard was adopted in 2019. A feature of the implementation of the requirements of the standard in the new edition is the addition of a new process - risk management, to the usual version of the organization's QMS. Moreover, all calibration laboratories must adopt a risk-based mindset, which will affect how laboratories approach calibration processes. Previously, the risk was mentioned only as the need to take it into account when making decisions, no more. That is, it was mainly advisory in nature. In connection with these changes, it became necessary to organize and implement risk management in the QMS [1].

The risk management policy also affects the laboratory policy, it dictates [2]:

- Statement of the fact of focus on risk management on the part of the laboratory management in relation to the stated goals.
- Intention to implement risk management.
- Determining the authority of the personnel in relation to risk management [3].
- Obligation to ensure access of those responsible for risk management to the necessary resources (personnel, time, training, finance).
- Commitment to maximum involvement of the company in maintaining risk management [4].
- Establishing indicators of the effectiveness of risk management.
- Allocation of resources for risk management.
- Ways to resolve conflicts.
- Striving to revise and improve the risk management system [5-7].

The purpose of the study is to identify the most common risks affecting the calibration process. The relevance of the study is due to the need of the calibration laboratory to minimize the risks arising during the calibration process.
Research problem:

- Identify risks and their consequences using the brainstorming method and Ishikawa diagram.
- To rank quantitative indicators of risks arising within one year.
- Identify the most common risks.

The process of calibration of measuring instruments in the calibration laboratory of OOO «Laboratorno-issledovatel'skij centr» was chosen as the object of research.

2. Identification of risks
Risk is the factor that affects the final result, and influence will mean the deviation of events from the expected result of the events that were influenced. Regarding to the calibration process, the end result is understood as obtaining a reliable result with a given, i.e. certain accuracy [8].

To form the most complete list of risks, the brainstorming method was used, for this an expert group of six people was created (GOST R 58771-2019 Risk management. Risk assessment technologies), namely:

- Quality Director - Chief Metrologist.
- Director of the Department of Measuring Technology.
- Leading Metrology Engineer.
- Quality specialist.
- Head of the laboratory of precision mechanics and measuring instruments for geometric quantities.
- Metrology engineer.

Brainstorming allows you to establish the relationship between the end result and the problems that affect the ability to produce a valid calibration result.

To enhance the effectiveness of the application, the brainstorming method was used simultaneously with the construction of the Ishikawa chart. This made it possible not only to identify risks, but also to make a preliminary ranking of factors. With a causal diagram, it is easy to visualize the root causes that generate specific consequences and are manageable [9], [10].

The Ishikawa chart is shown in figure 1.

![Ishikawa chart](image)

**Figure 1. Ishikawa chart.**

Data analysis has identified five main groups of risk factors [8], [11]: Calibrating instruments, Calibrator, Working place, Item of calibration, Quality measurement. These groups are shown in figure 2.
3. Enumeration of risk register

Further according to the provided diagram during the year, the identified risk factors were counted and their further registration in the register. The frequency of occurrence and possible consequences on the calibration process and the issuance of a calibration document to the customer were determined. The proportion of cases of occurrence of adverse factors was calculated. Table 1 shows the quantitative risk indicators obtained after observations [12-15].

Table 1. Ranked list of risks, according to the frequency of occurrence.

| №  | basic risk                                           | consequences of risk                                           | incident count | percentage of cases, % |
|----|-----------------------------------------------------|----------------------------------------------------------------|---------------|------------------------|
| 1.1| Equipment failure                                   | Temporary inability to perform calibration of measuring instruments | 86            | 10.54                  |
| 1.2| Depreciation of equipment, functional obsolescence  | Temporary inability to perform calibration of measuring instruments | 179           | 21.94                  |
| 1.3| Contaminating impurity of equipment                 | Equipment failure                                              | 41            | 5.02                   |
| 2.1| Substandard work servicing                          | A high probability of a negative result of the calibration of measuring instruments | 49            | 6.00                   |
| 2.2| Late performance servicing of equipment             | A high probability of a negative result of the calibration of measuring instruments | 84            | 10.29                  |
| 2   |                                                     |                                                                | 35            | 4.29                   |
3.1 Violation of calibration schedules of equipment

- Temporary inability to perform calibration of measuring instruments
- Failure to meet deadlines calibration was performed
- User dissatisfaction

3 Non-compliance of metrological characteristics of measuring instruments in the scope of accreditation

- Temporary inability to perform calibration of measuring instruments
- Failure to meet deadlines calibration was performed
- User dissatisfaction

3.2 Supply downtime or poor in quality consumable products

- A high probability of a negative result of the calibration of measuring instruments.

| Calibrator |
|-------------|
| 1.1 Technical problems in the operation of information systems |
| 1.1.1 Technical problems in the operation of information systems |
| 1.1.2 Loss of data (calibration status of measuring instruments) |
| 2.1 Outage along deficiency of standard test conditions (temperature, humidity, pressure, power supply voltage) |
| 3.1 Contamination of the room |

| Working place |
|---------------|
| 1.1 Technical problems in the operation of information systems |
| 1.1.1 Technical problems in the operation of information systems |
| 1.1.2 Loss of data (calibration status of measuring instruments) |
| 2.1 Outage along deficiency of standard test conditions (temperature, humidity, pressure, power supply voltage) |
| 3.1 Contamination of the room |
3.2 Emergency condition of the service room

| Item of calibration                                                                 | Temporary inability to perform calibration of measuring instruments |
|------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| 1.1 Increase in the time required to prepare measuring instruments for calibration | 56                                                                  |
| 1.2 User dissatisfaction                                                              | 23                                                                  |
| 1.3 Refusal to provide calibration services                                           | 9                                                                   |
| 1.4 Quality measurement                                                              |                                                                    |
| 2.1 Non-compliance of the purchased equipment (measuring instruments, consumables,    | 46                                                                  |
| 2.2 Ineffectiveness of control of human resources system / equipment                 |                                                                    |
| 2.3 Negative result of inter-laboratory comparison in the field of ensuring the       |                                                                    |
| 2.4 Lack of regulatory documents for calibration work                                 | 19                                                                 |
| 2.5 Insufficiency of calibration methods due to changes in regulatory documents        | 12                                                                 |
| 2.6 Increased calibration time due to the search for the necessary documentation      |                                                                    |
| 2.7 Compliant costs. Temporary inability to perform calibration of measuring instruments | 8                                                                   |
| 2.8 Increased calibration time due to making changes to the quality management system |                                                                    |
| 2.9 Increased risk of non-valid result                                               | 7                                                                  |
| 2.10 Increased calibration time due to making changes to the quality management system | 14                                                                 |
| 2.11 Lack of verification of calibrators’ qualifications. Possibility of incorrect    |                                                                    |
| 2.12 Possibility of incorrect calculations and calibration results                    | 19                                                                 |
| 2.13 Re-entry into participation in inter-laboratory comparison. Reporting of negative result to the accreditation body | 0                                                                 |
| 2.14 Reporting of negative result to the accreditation body                            | 0                                                                  |

The processing of the information received made it possible not only to group particular risk factors around the main ones, but also to identify patterns of manifestation.

4. Recommendations and conclusions

After completing the risk ranking process, it is necessary to identify the risk groups that have the greatest impact on the calibration process. This task is solved by constructing a Pareto chart (figure 3), which allows you to demonstrate the quantitative ratios of various groups of risks in descending order of...
frequency of occurrence. The 80/20 Pareto Principle clearly shows which factors are key in managing emerging risks.

![Figure 3. Pareto chart.](image)

It can be seen from the Pareto chart that the most common risks will be the risks of the «Calibration resources» and «Personnel (Calibrator)» groups. In further researches, a system for influencing the risk group «Calibration resources» will be developed, which includes the development of a corrective action plan for risk management in the calibration laboratory, and the determination of the numerical characteristics of the identified risks.

As a result of the study, the risks that may arise during the calibration process were identified and ranked. Identified those that have the greatest impact on the process. The results obtained will be useful not only for calibration laboratories but for any organizations working in the field of ensuring the uniformity of measurements, because the assessment methods used are available and allow them to be effectively applied in the transition of calibration laboratories to risk-based thinking.

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