Assessment of adequacy of the monitoring method in the activity of a verification laboratory

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Abstract. Questions of assessing adequacy of a risk monitoring technique for a verification laboratory operation concerning the conformity to the accreditation criteria, and aimed at decision-making on advisability of a verification laboratory activities in the declared area of accreditation are considered.

Key words - risk assessment, laboratory, accreditation criteria.

1. Introduction

In modern conditions of market relations, an urgent task is to assess and identify risks in the activities of laboratories. Risks assessment and identification is one of the main requirements in the quality management system in accordance with Russian state Standard GOST R ISO 9001-2015 [1]. The need for identifying and assessing risks in the verification laboratory should be met with a view to improving the quality of the laboratory activities.

The main risks in the verification laboratory are: confirmation of the competence of the accredited party, the risk of obtaining unreliable results, the risk of "not being" certified.

At present, a lot of methods for assessing and identifying risks are developed [2]. One of the most promising of them is the method of constructing and analyzing the risks probability tree. To assess the risks of not satisfying the criteria, in particular accreditation criteria in the verification laboratory, expert methods can be used if it is impossible to find the frequency of not satisfying the accreditation criteria.

2. Statement of the problem

For the successful operation of the calibration laboratory, it is necessary to monitor the risks of not satisfying the accreditation criteria in the declared area of the verification laboratory accreditation. One of the main tasks is to check the adequacy of the methodology for monitoring risks in the laboratory. To verify the adequacy of the methodology for monitoring risks in the verification laboratory, it is necessary to check the adequacy of the received risk assessments for non-compliance with the accreditation criteria.

3. Theory

Order No. 326 of the Ministry of Economic Development of Russia on May 30, 2013 regulates the requirements for the applicant and accredited party when carrying out activities in a certain area of accreditation.
The accreditation criteria for legal bodies or entrepreneurs performing work and (or) providing services for ensuring the uniformity of assessment measurements include [3]:

1) general criteria for accreditation, which are a set of requirements that all applicants and accredited parties must satisfy [3];

2) additional criteria for accreditation that provide for special requirements of the quality management system in certain areas of work performance and (or) provision of services to ensure the uniformity of measurements [3].

Assessment and identification of risk consists in identifying adverse events and assessing their likelihood of occurrence, as well as assessing possible consequences. One way to identify and evaluate risks is the event tree. On the basis of this technique, a method for monitoring the risk for the operation of a verification laboratory was developed [5].

In accordance with Order No. 326 of the Ministry of Economic Development of the Russian Federation (May 30, 2014), the following accreditation criteria are established, which can be grouped into the following blocks:

1. An integral generalized criterion characterizing the overall risk in the refusal or discontinuation of a verification laboratory accreditation.
2. General criteria required for accrediting a verification laboratory are those corresponding to paragraphs 42-49, 55 [3].
3. Particular criteria with a digital index are No. 44.1-44.2, 49.1-49.21, 55.1-55.8 [3].
4. Particular criteria with an alphabetic index [3].

To assess the adequacy of the risk monitoring methodology for a verification laboratory [4], it is necessary to assess the likelihood of the risk of failure to fulfill the accreditation criteria in several ways and compare the results obtained.

The assessment of the probability of the risk of non-fulfillment of the accreditation criteria was carried out by expert methods by three groups of experts, using the following ways:

1. The method of direct determination of risk probability, based on the method of direct ranking (MDR).
2. The method of paired comparisons [5] (MPC).
3. The method of analytical hierarchy [6] (MAH).

4. Experimental results
In accordance with the selected methods for assessing the likelihood of non-fulfillment of the accreditation criteria risks, an expert survey was conducted on the basis of which the probability trees were compiled in accordance with the results obtained using the direct risk probability method (figure 1), the paired comparisons method (figure 2), and the analytical hierarchy method (figure 3).
Figure 1. Probability ree of events occurrence by the method of direct ranking of risk probability.
Figure 2. Probability tree of events occurrence by the method of paired comparison.
In accordance with the presented results of the expert survey and their subsequent processing, the following estimates of the likelihood of adverse consequences in the form of refusal of accreditation in the declared area of a verification laboratory accreditation are presented in tables 1-3.
Table 1. Assessment of risk probability by method of direct definition

| Events | Criteria groups | A   | B   | C   |
|--------|----------------|-----|-----|-----|
| 42     |                | 0.92| 0.01| 0.07|
| 43     |                | 0.97| 0.01| 0.01|
| 44     |                | 0.91| 0.03| 0.06|
| 45     |                | 0.91| 0.09| 0.00|
| 46     |                | 0.98| 0.00| 0.02|
| 47     |                | 0.96| 0.03| 0.01|
| 48     |                | 0.98| 0.01| 0.01|
| 49     |                | 0.64| 0.10| 0.27|
| 55     |                | 0.92| 0.02| 0.05|
| Total  |                | 0.41| 0.27| 0.32|

Table 2. Assessment of risk probability by the method of pair comparison

| Events | Criteria groups | A   | B   | C   |
|--------|----------------|-----|-----|-----|
| 42     |                | 0.92| 0.01| 0.07|
| 43     |                | 0.97| 0.01| 0.01|
| 44     |                | 0.92| 0.03| 0.05|
| 45     |                | 0.91| 0.09| 0.00|
| 46     |                | 0.99| 0.00| 0.01|
| 47     |                | 0.96| 0.03| 0.01|
| 48     |                | 0.99| 0.01| 0.00|
| 49     |                | 0.62| 0.13| 0.25|
| 55     |                | 0.91| 0.02| 0.07|
| Total  |                | 0.40| 0.30| 0.30|

Table 3. Assessment of risk probability by the analytic hierarchy method

| Events | Criteria groups | A   | B   | C   |
|--------|----------------|-----|-----|-----|
| 42     |                | 0.93| 0.01| 0.06|
| 43     |                | 0.97| 0.01| 0.01|
| 44     |                | 0.91| 0.05| 0.04|
| 45     |                | 0.90| 0.09| 0.01|
| 46     |                | 0.98| 0.00| 0.02|
| 47     |                | 0.95| 0.04| 0.01|
| 48     |                | 0.99| 0.00| 0.01|
| 49     |                | 0.62| 0.16| 0.23|
| 55     |                | 0.89| 0.05| 0.05|
| Total  |                | 0.38| 0.35| 0.27|

The assessment of the obtained risk probability results adequacy is carried out on the basis of testing the hypothesis on the dispersion homogeneity of events probabilities obtained by different methods using the Cochran’s Q Test:
\[
G_p = \frac{\max(S\{p\})}{\sum_i S\{p\}},
\]

where \(S\{p\}\) is the dispersion of the risks probability assessment of not being accredited by the criterion \(p\).

If the calculated value of the Cochran’s Q Test is less than the one given in a table, then the hypothesis of dispersion homogeneity is accepted and it can be considered that the probabilities of the risks of not being accredited are adequate.

The results of the dispersions \(S\{p\}\) calculation are given in table 4.

**Table 4. Disperse evaluation of events probabilities**

| Criteria groups | Methods | \(S\{p\}\) |
|-----------------|---------|-------------|
| Event | MDR | MPC | MAH A | |
| 42 | 0.92 | 0.92 | 0.93 | 0.000033 |
| 43 | 0.97 | 0.97 | 0.97 | 0 |
| 44 | 0.91 | 0.92 | 0.91 | 0.000033 |
| 45 | 0.91 | 0.91 | 0.90 | 0.000033 |
| 46 | 0.98 | 0.99 | 0.98 | 0.000033 |
| 47 | 0.96 | 0.96 | 0.95 | 0.000033 |
| 48 | 0.98 | 0.99 | 0.99 | 0.000033 |
| 49 | 0.64 | 0.62 | 0.62 | 0.000133 |
| 55 | 0.92 | 0.91 | 0.89 | 0.00233 |
| Event | B | |
| 42 | 0.01 | 0.01 | 0.01 | 0 |
| 43 | 0.01 | 0.01 | 0.01 | 0 |
| 44 | 0.03 | 0.03 | 0.05 | 0.000133 |
| 45 | 0.09 | 0.09 | 0.09 | 0 |
| 46 | 0.00 | 0.00 | 0.00 | 0 |
| 47 | 0.03 | 0.03 | 0.04 | 0.000033 |
| 48 | 0.01 | 0.01 | 0.00 | 0.000033 |
| 49 | 0.10 | 0.13 | 0.16 | 0.0009 |
| 55 | 0.02 | 0.02 | 0.05 | 0.0003 |
| Event | C | |
| 42 | 0.07 | 0.07 | 0.06 | 0.000033 |
| 43 | 0.01 | 0.01 | 0.01 | 0 |
| 44 | 0.06 | 0.05 | 0.04 | 0.0001 |
| 45 | 0.00 | 0.00 | 0.01 | 0.000033 |
| 46 | 0.02 | 0.01 | 0.02 | 0.000033 |
| 47 | 0.01 | 0.01 | 0.01 | 0 |
| 48 | 0.01 | 0.00 | 0.01 | 0.000033 |
| 49 | 0.27 | 0.25 | 0.23 | 0.0004 |
| 55 | 0.05 | 0.07 | 0.05 | 0.00133 |
The hypothesis of the dispersion homogeneity in assessment of risk probabilities is determined by
the formula $G_p = 0.32$, comparing with the value given in a table $G_p = 0.51$, it can be concluded that the dispersion is homogeneous, and therefore the adequacy of the obtained risk probability estimates does not correspond to the verification laboratory criteria for accreditation.

5. Discussion of the results
When identifying and assessing the risks of non-fulfilling verification laboratory accreditation criteria in the declared area of accreditation, one can use the following methodology:
1. Identification of risks based on the requirements for verification laboratory accreditation.
2. Assessment of risk probability by expert methods, in particular MDR, MPC, MAH
3. Checking the adequacy of the resulting risk assessment.
4. Determination of the expediency of the verification laboratory accreditation [4].

6. Conclusion
Thus, the suggested methodology for assessing the adequacy of the methodology for monitoring risks in the verification laboratory allows to determine the adequacy of assessing the probability of risk to not fulfill the accreditation criteria in the declared area of a verification laboratory accreditation.

References
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