



Research article

## ANALYZING AND ASSESSING RISKS FOR ACCREDITED INSPECTION BODIES

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*The legislation of the Russian Federation stipulates the necessity for accreditation within the national system that encompasses organizations engaged by control (surveillance) bodies to accomplish inspections. Activities performed by inspection bodies have strategic importance and provide necessary support for surveillance over implementation of national development projects. It is especially relevant to provide uninterrupted functioning of accredited inspection bodies. Contemporary conditions require improvement of the existing legal and organizational approaches used by federal budgetary institutions in their activities as well as developing and implementing new ones.*

*Statistical data on the research object of the present study and relevant mathematical models are non-existent; given that, we applied an expert approach to risk identification using the Delphi method and expert judgment. The aim of this study was to analyze and assess risks in activities performed by an accredited inspection body and suggest ways to minimize them. Two groups took part in the study. The first one included experts (18 technical directors of three inspection bodies); the second group was made of analysts. The most competent specialists in the analyzed field of activity where risks would be identified were selected as experts. Their functional duties covered responsibility for risks associated with activities of an inspection body as well as for responses to them. To obtain ideas of analyzed risks, we used a questionnaire to collect experts' answers and to distribute them into specific categories for further analysis. A risk level was identified by using the risk analysis diagram. Any response measures were taken relying on this level. We created a register of risk levels and responses to them. A high risk was identified in activities performed by an inspection body as regards external influence of new changes in the legislation. Reformation of the accreditation system for organizations operating in the sphere of providing sanitary-epidemiological welfare may be a potential solution to the existing problem.*

**Keywords:** accreditation, inspection body, hygiene and epidemiology center, risk analysis, risk assessment, Delphi method, risk analysis diagram, a register of risk levels.

The legislation of the Russian Federation stipulates the necessity for accreditation within the national system that encompasses organizations engaged by control (surveillance) bodies to accomplish inspections. This requirement is fixed in the Clause 42 of the

Federal Law issued on March 30, 1999 No. 52-FZ On Sanitary-Epidemiological Welfare of the Population<sup>1</sup>. Also, in accordance with Clause 33 of the Federal Law issued on July 31, 2020 No. 248-FZ On State Control (Surveillance) and Municipal Control in the

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<sup>1</sup> О санитарно-эпидемиологическом благополучии населения: Федеральный закон № 52-ФЗ от 30.03.1999 (с изменениями на 24 июля 2023 года) [On Sanitary-Epidemiological Welfare of the Population: the Federal Law No. 52-FZ issued on March 30, 1999 (as of edited on July 24, 2023)]. *KODEKS: electronic fund for legal and reference documentation*. Available at: <https://docs.cntd.ru/document/901729631> (May 02, 2024) (in Russian).

Russian Federation<sup>2</sup>, bodies that are authorized to conduct state control (surveillance) can engage expert organizations to take part in control activities. The latter should be accredited within the national accreditation system in conformity with the legislation of the Russian Federation on accreditation.

Activities performed by accredited inspection bodies are in high demand and are employed actively in various branches in many countries across the globe [1]. External inspection and accreditation are a good example of external evaluation methods that are widely used all over the world. The existence of inspection bodies is very strategic and needed in assisting the supervision over the implementation of national development projects, especially with large potential benefits [2]. Inspection services also significantly contribute to raising the security system to a higher level [3]. Different countries apply various national policies and mechanisms developed specifically for conducting external expert evaluations. Although there is growing attention to the impact and effects on quality and safety from external evaluation in various spheres, there is still a gap in knowledge to how structures and processes influence its outcomes [4]. Centers for Hygiene and Epidemiology are bodies supervised by Rospotrebnadzor; still, they act as institutions authorized to perform mandatory (regulated) actions aimed at establishing compliance within mandatory evaluation of product safety [5]. Given that, it is becoming especially relevant to provide uninterrupted functioning of accredited inspection bodies. A mandatory condition for any organization to be able to accomplish tasks it is responsible for is preserving a necessary capacity to perform its activities [6]. Contemporary conditions require improvement of the existing legal and organizational approaches as well as developing and implementing new ones that

include optimization of a structure and personnel as well as adequate organization of activities performed by federal budgetary institutions [7]. Risk analysis, assessment and management are necessary for identifying challenges and reducing their effects. Risk management widely relies on obtaining, analyzing and subsequent practical use of relevant data. Insufficient or incomplete data on a given event create uncertainty and risk [8]. The risk management cycle encompasses the following processes: risk management planning, risk identification, qualitative analysis of risks, risk quantification, planning a response to identified risks, risk monitoring and management<sup>3</sup>. Risk analysis should underlie activities performed by any organization since risk identification prevents large financial losses [9]. Risk assessment and risk-based thinking are both key aspects considering the multi-faceted activities inherent in Conformity Assessment [10]. The choice of risk management methods involves using both stereotypical and original solutions containing economically sound recommendations and measures aimed at reducing the initial level of risk to an acceptable level [11].

Statistical data on the research object of the present study and relevant mathematical models are non-existent; given that, we deemed it advisable to employ an expert approach to risk identification using the Delphi method (it is commonly used when only insufficient initial data are available as regards frequency and consequences of unfavorable events [12]). Relevance of using the method is based on a possibility to predetermine probable long-term problem situations [13]. The Delphi technique holds a special place among methods employed in studies with their focus on foresight and future as well as in general empirical studies in various disciplines where uncertainty represents a challenge (administra-

<sup>2</sup> O gosudarstvennom kontrole (nadzore) i munitsipal'nom kontrole v Rossiiskoi Federatsii: Federal'nyi zakon № 248-FZ ot 31.07.2020 (s izmeneniyami na 25 dekabrya 2023 goda) [On State Control (Surveillance) and Municipal Control in the Russian Federation: the Federal Law No. 248-FZ issued on July 31, 2020 (as of edited on December 25, 2023)]. *KODEKS: electronic fund for legal and reference documentation*. Available at: <https://docs.cntd.ru/document/565415215> (May 02, 2024) (in Russian).

<sup>3</sup> Shkurko V.E. Upravlenie riskami proektov [Project risk management]: manual. Ekaterinburg, Urals University Publ., 2014, 184 p. (in Russian).

tion, for example) [14]. Expert judgment is a useful tool for making risk assessment possible in situations when data are scarce and uncertainty is high. Expert judgment is necessary to answer questions associated with policy and decision-making as well as making conclusions [15]. Results obtained by expert risk assessment give grounds for implementing the next stage in risk management, which is regulation (responding to innovative risk) based on selecting risk optimization methods [16].

**The aim of this study** was to analyze and assess risks in activities performed by an accredited inspection body and suggest ways to minimize them.

**Materials and methods.** The study included three stages:

- Creating a group of experts;
- Stating a problem for experts and handing out questionnaires to fill in;
- Analytical stage.

Two groups took part in the study. The first group included experts who presented their point of view regarding the analyzed problem anonymously in writing; the second organizational group was made of analysts (the authors of the present article) who summarized expert opinions into one generalized outcome.

Experts were 18 technical directors of three inspection bodies of the Center for Hygiene and Epidemiology in the Rostov region as the most competent specialists in the analyzed sphere of activity where risks would be identified. Their functional duties covered responsibility for risks associated with activities of an inspection body as well as for responses to them. The following criteria were used for including experts into the first study group: they had tertiary medical education and specialized in medical prevention as well as post-graduate education specializing in common hygiene or epidemiology; they took skills development courses with their focus on functioning of the quality management system over the last 5 years; their relevant work experience was not shorter than 5 years.

The research process included direct communication with the experts by individual questioning of all group members using a

questionnaire. The aim was to learn their opinions based on personal experience and knowledge about hypothetically probable negative events that might occur in functioning of an inspection body.

Expert answers were collected by using a questionnaire in order to get an insight into their ideas of risks. The employed questionnaire met such demands as simplicity and unambiguity in understanding the questions in it; brevity; completeness; good illustrative capacity [17]. The experts relied on their own practical experience in order to establish all likely events that might occur in activities of an accredited inspection body and lead to negative consequences. The questionnaire had an open question that went as follows: ‘Please, enumerate all potential risks associated with activities of an accredited inspection body’ (Table 1).

Table 1

A questionnaire given to the experts

Please, enumerate all potential risks associated with activities of an accredited inspection body	Evaluate a risk factor that has been enumerated (according to suggested evaluation criteria)	
	Likelihood	Severity of consequences

Each mentioned risk had to be evaluated considering its likelihood and severity of its possible consequences. Risk significance and likelihood of a risk event were identified by using criteria specifically developed by the authors of the present article. Likelihood of an unfavorable event was taken in its evaluation based on cycles of activities performed by accredited bodies. These cycles are stipulated by the legislation to determine how often external or internal evaluation should be performed as regards activities performed by accredited bodies: once a year (periodicity of analysis accomplished by supervisors); once every four years (includes two cycles of competence confirmation); once every two years (corresponds to one cycle of competence confirmation); once every five years (covers a 5-year period of competence confirmation). Severity of con-

sequences was identified based on legally established power of the Federal Accreditation Service in case any inconformity was identified in activities of accredited bodies as well as scope of the influence these consequences might have on ability of an inspection body to continue its activities in a sphere determined by its accreditation (Tables 2 and 3).

Table 2

Criteria to evaluate likelihood of an unfavorable event in activities of an inspection body

Likelihood evaluation, score	Likelihood of an unfavorable event
1 – practically non-existent	No unfavorable event has occurred for 5 years
2 – insignificant	An unfavorable event occurred with frequency between once over 5 years and once over 4 years
3 – significant	An unfavorable event occurred with frequency between once over 3 years and once over 2 years
4 – high	An unfavorable event occurred once a year or more frequently

Table 3

Criteria to evaluate severity of consequences that resulted from an unfavorable event in activities of an inspection body

Severity evaluation, score	Severity of consequences
1 – mild	Does not result in inconformity with accreditation criteria
2 – medium	Warning has been made to avoid violation of mandatory requirements
3 – severe	Accreditation validity has been suspended as regards a certain accreditation sphere
4 – critical	Accreditation validity has been suspended as regards the total accreditation sphere

The experts evaluated effects that might be produced by enumerated risk events; each risk was given a score value based on four possible variants of evaluating likelihood (practically non-existent, insignificant, significant, and high) and severity of consequences (mild, average, severe, and critical).

Experts' answers were analyzed and distributed into specific categories by analysts. An

average value (score) was calculated for identical risk events enumerated by the experts.

The next stage involved using a technology for identifying likelihood of risks and scope of their influence on activities. A risk level was identified by using the risk analysis diagram. Any response measures were taken relying on this level. A risk matrix was chosen as a risk management tool; projects are usually placed within relevant squares in such matrix in accordance with risk likelihood and severity of its negative consequences (Figure). Risk matrices are commonly used in various researches. Moreover, they provide relevant support in cases when it is impossible to agree upon a precise quantification [18]. Boundaries of an acceptable risk were built on a qualitative diagram with the following coordinates: likelihood of a hazardous factor realization – severity of consequences (Figure). If a given point was located at the boundary or higher, an event was taken into consideration; if it was below these boundaries, an event was not considered.

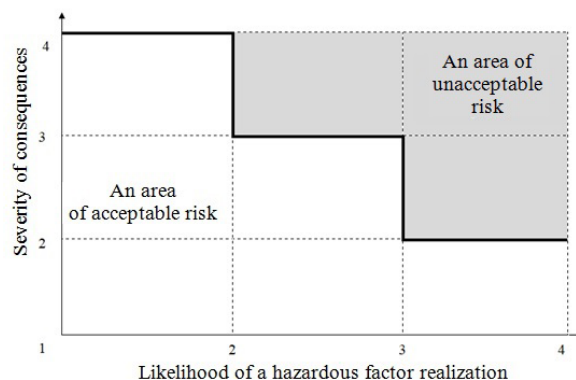


Figure. Risk analysis diagram

**Results and discussion.** The questioning aimed at identifying risks provided answers that were combined into the following categories: personnel, technical devices and equipment and external influence. The 'Personnel' category included the following risks: absence of relevant education, training, technical knowledge and skills, work experience; workers of an inspection body authorized to work with a given request being temporarily absent at the moment; violation of execution terms; errors made by workers in executing a request. The 'Tech-

nical Devices and Equipment' category included the following risks: absence of relevant and sufficient technical devices and equipment necessary to conduct an inspection. The 'External Influence' category included the following: changes in the legislation on accreditation (accreditation criteria<sup>4</sup>); new documents coming into force, which stipulate the requirements to inspection objects or inspection methods (sampling techniques included).

Following the results obtained at this stage in the research, a register of risks was created that contained the total list of identified risks and their quantification (Table 4).

All uncertain events that can have negative influence on uninterrupted execution of a state task by an inspection body (risks) are identified in Table 5. The risks are classified as per groups depending on their source: personnel of

an inspection body, external influence, technical devices and equipment available to an inspection body. Options that could mitigate a given risk were formulated by the authors of the present article based on examining documented procedures within the existing quality management system applied by all three inspection bodies (HR Management; Inspection Management; Equipment Management) as well as valid spheres they were accredited in.

Various branches adopt different approaches to creating an organizational structure for risk management. Risk management in healthcare organizations defines risks associated with patient safety as priority ones [19]. Organizations operating in other branches develop and implement risk management strategies in order to prevent financial losses [20]. One of very few studies focusing on contemporary

Table 4

The results obtained by questioning: experts' risk quantification

Potential risks associated with activities of an accredited inspection body	The number of experts who mentioned a potential risk	Likelihood (average score)	Severity of consequences (average score)
1	2	3	4
<i>Personnel</i>			
– absence of relevant education, training, technical knowledge and skills, work experience	12	1.3	3.8
– workers of an inspection body authorized to work with a given request being temporarily absent at the moment	16	1.1	3.9
– violation of execution terms	15	2.1	2.0
– errors made by workers in executing a request	14	2.1	1.9
<i>Technical devices and equipment</i>			
– absence of relevant and sufficient technical devices and equipment necessary to conduct an inspection	16	1.3	4.0
<i>External influence</i>			
– changes in the legislation on accreditation (accreditation criteria), new documents coming into force, which stipulate the requirements to inspection objects or inspection methods (sampling techniques included)	18	3.0	4.0

<sup>4</sup> Об утверждении критериев аккредитации и перечня документов, подтверждающих соответствие заявителя, аккредитованного лица критериям аккредитации: Приказ Минэкономразвития России № 707 от 26.10.2020 (с изменениями на 23 января 2023 года) [On Approval of the accreditation criteria and the list of documents that certify conformity of an applicant or accredited person with the accreditation criteria: the Order by the RF Ministry for Economic Development No. 707 dated October 26, 2020 (as of edited on January 23, 2023)]. *KODEKS: electronic fund for legal and reference documentation*. Available at: <https://docs.cntd.ru/document/566305944?section=text> (May 02, 2024) (in Russian); GOST R ISO/MEC 17020-2012. Conformity Assessment. Requirements for the operation of various types of bodies performing inspection: National Standard of the Russian Federation. *KODEKS: electronic fund for legal and reference documentation*. Available at: <https://docs.cntd.ru/document/1200097436?section=text> (May 02, 2024) (in Russian).

Table 5

The register of risk levels in activities of an inspection body and responses to them

No.	Risk identification	Risk assessment			An option to mitigate a given risk (a response action)
		Likelihood	Severity of consequences	Risk level*	
<i>Personnel</i>					
1.	Absence of relevant education, training, technical knowledge and skills, work experience	1.3	3.8	average	Possible allocation of additional resources, monitoring: procedures for hiring and initial training, monitoring of education and personnel's activities, qualification check-ups
2.	Workers of an inspection body authorized to work with a given request being temporarily absent at the moment	1.1	3.9	average	Possible allocation of additional resources, monitoring: a procedure of accepting requests by an inspection body that considers analysis of available manpower to execute a request
3.	Violation of execution terms	2.1	2.0	average	Possible allocation of additional resources, monitoring: a procedure of accepting requests by an inspection body that considers analysis of feasible terms of executing a request
4.	Errors made by workers in executing a request	2.1	1.9	average	Possible allocation of additional resources, monitoring: a procedure for monitoring inspection quality, insurance of inspection body liability
<i>Technical devices and equipment</i>					
1.	Absence of relevant and sufficient technical devices and equipment necessary to conduct an inspection	1.3	4.0	average	Possible allocation of additional resources, monitoring: a procedure of accepting requests by an inspection body that considers analysis of technical resources available to an inspection body
<i>External influence</i>					
1.	Changes in the legislation on accreditation (accreditation criteria), new documents coming into force, which stipulate the requirements to inspection objects or inspection methods (sampling techniques included)	3.0	4.0	high	Both likelihood and severity of consequences identified for this risk are high. The risk can have considerable outcomes. Conditions that can bring about realization of this risk are beyond control of top management of an inspection body

Note: \* High, average or low risk levels were established depending on likelihood and severity of consequences. Risks with the highest likelihood and severity of consequences are considered to have a high level; risks with the lowest likelihood and severity of consequences will have a low level. Intermediate risk levels are labeled as average.

challenges in activities of Centers for Hygiene and Epidemiology and ways to tackle them on the example of Primorsky Krai, Sverdlovsk, Arkhangelsk, and Lipetsk regions [7] does not include any analysis of activities performed by such institutions from the point of view of an accredited inspection body. By the moment the present article was being written, the authors

had not found any available studies that focused on assessing risks associated with activities of an inspection body as a part of a Center for Hygiene and Epidemiology.

The present study identified a high risk associated with external influence of new changes in the legislation including those related to accreditation. This risk requires either

changes in the existing quality management system of an inspection body or substantial material resources and time to enlarge an accreditation sphere.

In our opinion, difficulty in implementing new documents on accreditation is related to specificity intrinsic to setting their requirements. Namely, such requirements are usually substantial and invariant and do not consider specific features of different organizations, in particular, in the sphere of providing sanitary-epidemiological welfare. It is not easy for accredited bodies to use the said documentation system since it is very difficult to implement general (non-specific) postulates into practical activities. These requirements are often understood in a different way by accredited bodies and experts on accreditation; in some cases, this leads to conflicts arising in the process of competence confirmation and even to accreditation suspension. The existing accreditation procedure and procedure for competence confirmation are based on using State Standards (GOSTs) that are word-for-word translations of European standards into Russian. They fail to consider national peculiarities intrinsic to conducting sanitary-epidemiological surveillance in Russia.

Bearing in mind that this identified risk can have considerable consequences and its realization cannot be controlled by top management of an inspection body, we can say that it is really necessary to develop the second system of documents. It should contain concrete requirements to accredited bodies that correspond to goals and specificity of activities performed by an organization which includes a given inspection body as well as a certain stage in the development of hygiene and epidemiology. Essentials stipulate in these documents should clearly correspond to this stage

as well as experience accumulated by organizations operating in the sphere. They should be open to dynamic changes if necessary.

In addition to that, the existing system for confirming competence of inspection bodies accredited within the national accreditation system does not permit Centers for Hygiene to promptly use new regulatory documents that have just come into force and are extremely essential for conducting inspections in the sphere of providing sanitary-epidemiological safety under dynamically changing sanitary-epidemiological conditions. Thus, for example, the Sanitary Rules SP 3.1/2.4.3598-20 ‘Sanitary-epidemiological requirements to the structure, maintenance and operations of educational establishments and other social infrastructure objects for children and youth during the spread of the new coronavirus infection (COVID-19)’<sup>5</sup> were never used by inspection bodies of the Center for Hygiene and Epidemiology in the Rostov region during any sanitary-epidemiological inspection. The reason for that was that the document came into force on July 03, 2020 but the competence confirmation procedure that enlarged the accreditation sphere for the inspection body had already been finished before that. The document ceased to be valid on December 31, 2023, which was prior to the next competence confirmation procedure with new prospective enlargement of the accreditation sphere. It did not seem reasonable to submit a separate application to Rosaccreditation to enlarge the accreditation sphere for one regulatory document since the competence confirmation procedure is time-consuming and requires substantial material resources that were in such a high demand by the Center for Hygiene and Epidemiology during the COVID-19 pandemic.

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<sup>5</sup> Ob utverzhdenii sanitarno-epidemiologicheskikh pravil SP 3.1/2.4.3598-20 «Sanitarno-epidemiologicheskie trebovaniya k ustroystvu, soderzhaniyu i organizatsii raboty obrazovatel'nykh organizatsii i drugikh ob"ektov sotsial'noi infrastruktury dlya detei i molodezhi v usloviyakh rasprostraneniya novoi koronavirusnoi infektsii (COVID-19)»: Postanovlenie Glavnogo gosudarstvennogo sanitarnogo vracha RF ot 30.06.2020 № 16 [On Approval of the Sanitary-Epidemiological Rules SP 3.1/2.4.3598-20 ‘Sanitary-epidemiological requirements to the structure, maintenance and operations of educational establishments and other social infrastructure objects for children and youth during the spread of the new coronavirus infection (COVID-19)’: the Order by the RF Chief Sanitary Inspector dated June 30, 2020 № 16] (became invalid on January 01, 2024). *KODEKS: electronic fund for legal and reference documentation*. Available at: <https://docs.cntd.ru/document/565231806> (May 02, 2024) (in Russian).

**Conclusions.** This study identified the most significant legal risk in activities performed by accredited inspection bodies of the Center for Hygiene and Epidemiology in Rostov region. This risk is impossibility to rapidly adapt to changes in the legislation on accreditation and implement new documents establishing requirements to either inspection objects or procedures (including sampling techniques) into practical activities. It may result in financial losses in case of failure to execute a state takes given by Rospotrebnadzor in its full scope; impossibility to meet, fully or partially, a request by a customer who operates in a commercial sphere. This risk also disrupts uninterrupted functioning of an inspection body, including situations when overall sanitary-epidemiological conditions become worse; creates preconditions for forced violation of the legislation on accreditation due to impossibility to rapidly adapt to new ac-

creditation criteria that have just come into force.

In such circumstances, reformation of the accreditation system for organizations operating in the sphere of providing sanitary-epidemiological welfare may be a potential solution to the existing problem. This reformation should include creation of unified and clear departmental requirements to inspection bodies that simultaneously consider accreditation criteria and specific activities performed by bodies under the Rospotrebnadzor supervision. It is also necessary to develop their ability to give rapid responses and work within the legal framework in case of a sanitary-epidemiological emergency.

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