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Research Article

IDENTIFICATION OF RISKS IN ANALYTICAL TESTING LABORATORIES

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Masharipov Shodlik Masharipovich
PhD, Tashkent state technical university, Uzbekistan

Erkaboyev Abrorjon Khabibullo ogli
PhD student, Namangan engineering-construction institute, Uzbekistan

ABSTRACT

This article provides information on a study on the identification of risks in analytical testing laboratories. The process of "acceptance of applications for testing, examination of samples and formalization of test results" in the quality analytical laboratory of the research object was obtained.

KEYWORDS

Analytical testing laboratory, risk, risk management, risk identification, "brainstorming" method.

INTRODUCTION

Risk management in analytical laboratories where the object of testing is food, chemical and other fields, according to the previous interpretation of the international standard ISO/IEC 17025 points 4.12.2 and 5.4.5.3, it is necessary to consider the risk consideration in its context when making decisions. In the last interpretation of the standard, it was determined the need to develop a full-fledged procedure for risk management [1, 3].

The risk management process should begin with an attempt to understand the external and internal factors that may affect the laboratory's success in achieving its objectives. The greater the number of factors that make up the external and internal context, the greater the number of risks to be considered.

Context is the external or internal environment in which the testing laboratory works: legal requirements, customers, management, availability of resources, direction and density of information flows, management system of the organization, etc. For example, putting occupational safety requirements into context involves risk management in this area. It is customary for testing laboratories (in addition to the tests themselves) to consider risks in the field of

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accreditation, keeping state and commercial secrets, working with highly toxic and radioactive substances, ensuring industrial, fire, environmental, sanitary safety, etc. [5].

METHOD

The purpose of identification of risks is to find, recognize, and describe risks that may help or hinder the laboratory from achieving its goals. The relevance, appropriateness and relevance of the information used in the identification of risks is important.

A laboratory may use a number of methods to identify uncertainties that may affect one or more objectives. In particular, in the "brainstorming" method, the list of risks is identified in a meeting with 10-15 people. This meeting is also a requirement of the ISO 31000:2018 standard, which constitutes the initial - communication and consultation stage of the risk management process. Each participant can propose their own risks, and risks can be expanded or detailed during the joint discussion. The risks are then categorized and defined. This article also used the "brainstorming" method [2, 4].

RESULTS AND DISCUSSION

In this article, we developed a model of the process of "Acceptance of applications for testing, examination of samples and formalization of test results" in analytical laboratories, in accordance with the "process approach", which is one of the principles of the ISO 9001:2015 standard (Fig. 1).

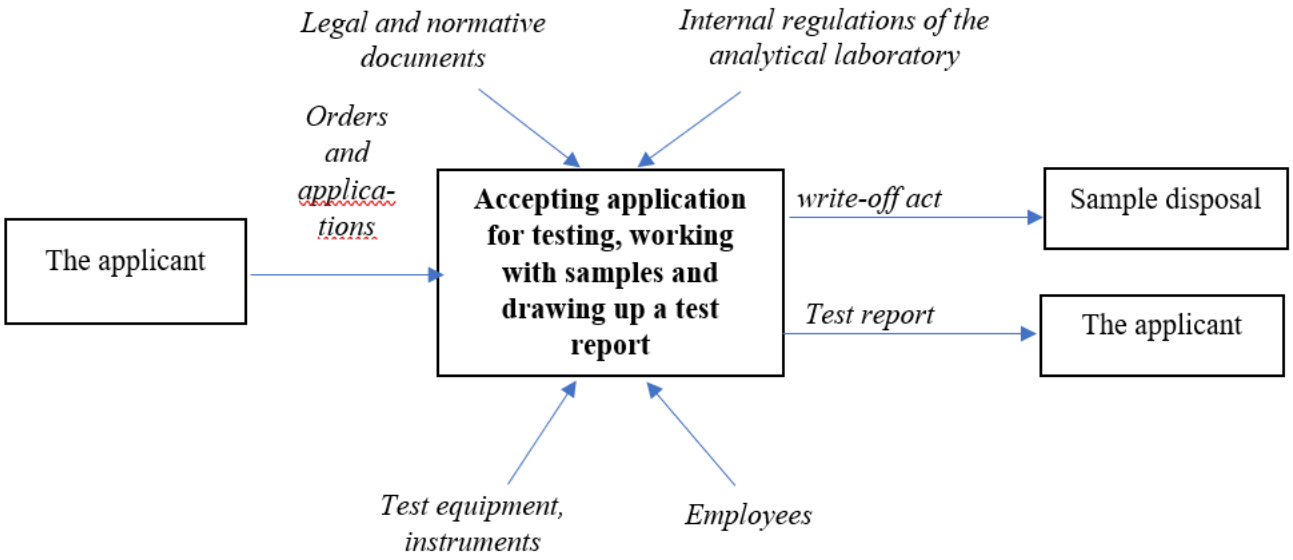

Figure 1. Model of the process of "Acceptance of applications for testing, examination of samples and formalization of test results".

Risk management for this model (Figure 1) identified possible risks for each step of the process (Table 1).

Table 1.

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Identified risks for the process of "Acceptance of applications for testing, examination of samples and formalization of test results".

Process step	In charge	The result of the process	Identified risk event
Formalization of application	Specialist of the reception department	Correctly filled out application	1. Error in filling out the application by the applicant. 2. Unsigned application. 3. A set of incorrectly attached documents.
Acceptance of samples, submission for testing	Specialist of the reception department	Sample registration and sending to the testing department	1. Operator error when entering data. 2. Violation of the requirements in sample selection and separation.
Inspection and storage of samples	Specialist of the test department	Sample test	1. Lack of necessary reagents and substances for testing. 2. Testing with out-of-date regulatory documents. 3. Incompetence of the employee.
Forming a test report	Specialist of the test department	Signed test report	1. Violation of report in model formation. 2. Include incorrect information in the results.
Issuing the test report	Specialist of the department	Signed test report	1. Customer dissatisfaction with the result.

CONCLUSION

Whether the sources of potential risks are under the control of the organization or not, the organization must identify (determine) them. In addition to the "brainstorming" methods that we have discussed, there are other methods of this identification process, such as "FMEA analysis", "Bow-tie analysis", "Delphi method" and "Crawford maps"

Thus, each organization has the right to decide for itself how to identify risks, how to manage them and what methods to use for this. Correct identification of risks allows the organization to eliminate or minimize

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the probability of an undesirable event, reduce losses and improve the quality management system of the organization as a whole.

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