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Analysis and Systematization of Non-conformities Regarding Accredited Testing Laboratories Operations

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***Abstract*—This article provides analysis and systematization of factors causing non-conformities of testing laboratories operations with the established regulations. The research was conducted based on analysis of expert examination results, in the course of verification of testing laboratories competence as regards the accreditation criteria and GOST ISO/IEC 17025 standard requirements. The sampling provided consists of fifty expert reports of testing laboratories engaged in food products quality compliance assessment.**

Keywords—Testing laboratory, Non-conformities, Accreditation criteria, Scattering method, Multicomponent system, Frequency diagram.

I. Analysis and Systematization of Non-conformities Regarding Accredited Testing Laboratories Operations

Within the frames of technical regulation reform in Russia, a new system of accreditation and competence verification for testing laboratories was established. In the course of reform, legal and methodological framework was created for the purposes of competence verification of testing laboratories. However, a large number of non-conformities detected in the process of competence verification calls for special attention to these issues and their further systematization in order to improve the testing laboratories operations [1, 2].

Accreditation is an effective marketing tool for testing laboratories and a reliable indicator of their technical competence both on the national and international level.

Technical competence of laboratory depends on multiple factors, including:

- requirements to organization carrying out testing operations;

- requirements to management system;

- requirements to staff qualification, training and experience;

- requirements to testing premises and environment conditions;

- available testing and calibration methods, as well as their acceptability appraisal;

- requirements to equipment;

- requirements to treatment of testing and calibration objects.

The purpose of this research is analysis of factors of testing laboratories operations, which cause non-conformities with the established requirements.

As a source material to carry out analysis, the authors used the sampling data of fifty on-site expert examination reports (expert reports) to carry out accreditation and competence verification of testing laboratories engaged in research (testing) in the area of assessment (verification) of food products compliance at the Russian Federation territory [1-6].

In the course of analysis, we measured specific weight of non-conformities detected in the operations of testing laboratories engaged in food products quality compliance assessment, according to the following formula:

$$\text{Specific weight of non-conformities} = \frac{\text{Number of non-conformities per each unit of Accreditation Criteria}}{\text{Total number of non-conformities}} * 100\%$$

This formula made it possible to find out percentage of detected non-conformities per each unit of accreditation criteria for testing laboratories to the total set of detected non-conformities, taking into account the frequency of their detection.

For each non-conformity shown, we generalized the facts of non-compliance with the established requirements and carried out analysis of possible reasons for emerging non-conformities.

To analyze the data collected, the factors had to be coded; those controlled criteria, to which the numeric values can be assigned, were taken for the factors. Results of coding are shown in the Table 1.

TABLE 1. CODING OF FACTORS

Factors affecting the testing laboratories operations	Representation symbol
requirements to organization carrying out testing operations	a1
requirements to management system	a2
requirements to staff qualification, training and experience	a3
requirements to testing premises and environment conditions	a4
available methods of testing and calibration, as well as their acceptability appraisal	a5
requirements to equipment	a6
requirements to treatment of testing and calibration objects	a7

Results of generalized analysis of on-site expert examinations of testing laboratories are shown on the Fig. 1.

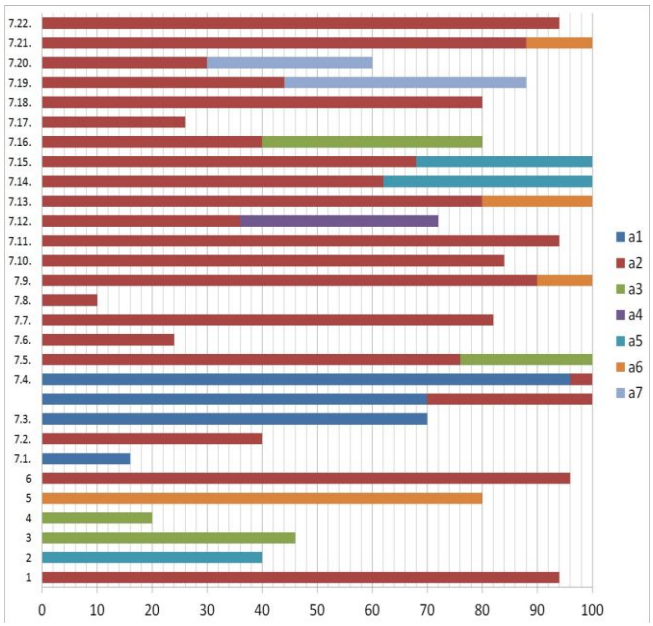

Fig. 1. Generalized analysis of on-site expert examinations of testing laboratories.

The Fig. 1 shows multicomponent system; the most suitable descriptive method for its analysis is scatter diagrams together with frequency diagrams. Applying standard statistical analysis methods is constrained by normal distribution requirement, which is not possible in our situation. For analysis, we used the successive screening algorithm; according to this algorithm, based on a priori established conditions, all factors under research are divided into groups, each of the groups is being viewed as a separate and complex factor. Such an approach makes it possible for us to visually evaluate the character of parameters value distribution and to separate fixed factors from random ones. Frequency distribution diagram makes it possible to carry out a quantitative assessment of how many times totally the factor under research occurs [6-15].

Based on the data obtained for the factors affecting the laboratory operations, scatter diagrams were built. We singled out tentatively significant factors under the η-rule, for our research it is a2; others, according to the rule of successive screening, should be deemed insignificant (refer to Fig. 2).

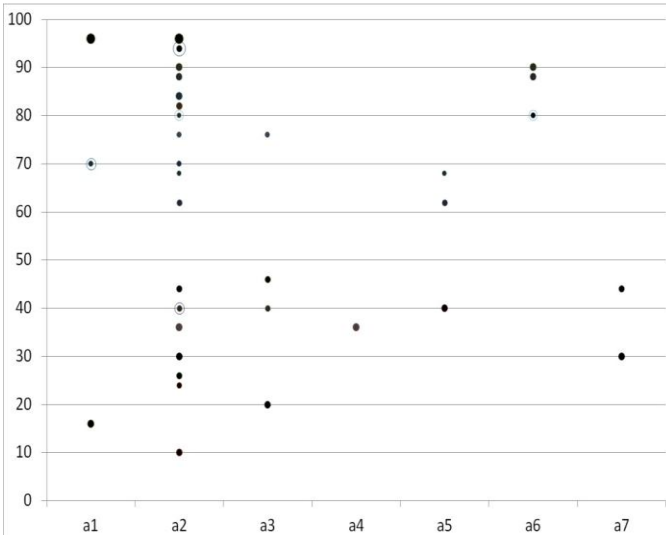

Fig. 2. Scatter diagram for the factors affecting the laboratory operations.

Before making a conclusion whether the factor is significant or not, let us build the frequency diagram, and based on this diagram, let us determine the number of projecting points for the scatter diagram, Fig. 3.

Use of successive screening algorithm, frequency diagram and Pareto Principle made it possible for us to single out significant factors a2, a3, a1, and a6 (requirements to management system; requirements to staff qualification, training and experience; requirements to organization carrying out testing operations; and requirements to equipment) [15-20].

At the same time, the "requirements to management system" factor stands out against the other factors and amounts to 52% of the total level of occurrence of all the factors.

However, it is not the only factor causing non-conformities. The frequency diagram made it possible to visually represent the factors, which, along with the quality management system, cause non-conformities [1, 21-25].

Ranking the factors according to the Pareto Principle and building the cumulative curve made it possible to identify the primary factors, which are as follows:

- requirements to management system;

- requirements to staff qualification, training and experience;

- requirements to organization carrying out testing operations;

- requirements to equipment.

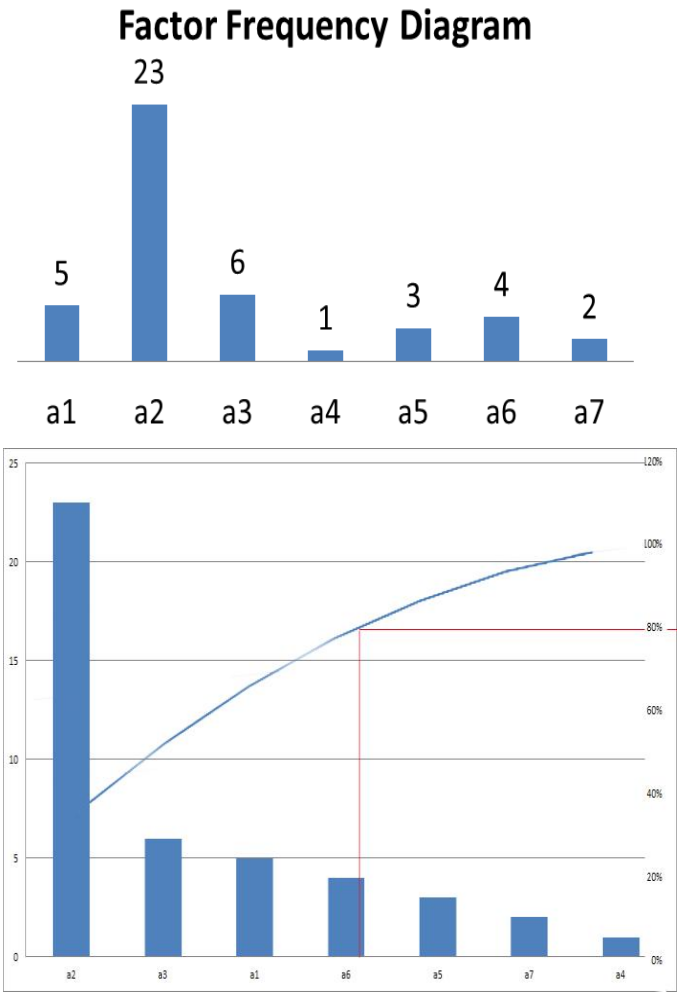

Fig. 3. Frequency diagram for the factors affecting the laboratory operations.

II. Conclusion

Therefore, when preparing to accreditation and carrying out their operations, testing laboratories should focus their attention on development of adequate quality management system and its intensive implementation. Besides, when outlining the area of accreditation, the testing laboratory should pay special attention to:

- maintaining adequate staffing with highly-qualified specialists constantly improving their skills;

- meeting the accreditation criteria as regards independency from commercial, financial and administrative influence, avoidance and settling conflicts of interest in each particular area;

- availability of equipment and its working condition, which make it possible to carry out testing in accordance with the methods declared in the area of one's accreditation.

References

[1] ILAC-G20:2002 Guidelines on Grading of Non-conformities.

[2] GOST ISO/IEC 17025-2009 General requirements for the competence of testing and calibration laboratories, Regional Standard.

[3] Decree of the Ministry of Economic Development No. 326 dated May 30, 2014 "On approval of accreditation criteria, list of the documents confirming the applicant's compliance, accredited person with the accreditation criteria, as well as the list of documents in the area of standardization, which compliance ensures for the accredited persons their compliance with the accreditation criteria".

[4] Middlebrook, K. Accred Qual Assur, Do accredited laboratories perform better in proficiency testing than non-accredited laboratories. (2017) 22: 111.

[5] Okrepilov, V.V. Stud. Russ. Econ. Dev., Role of standardization in the sustainable development of communities) (2015) 26: 1.

[6] Žel, J., Mazzara, M., Savini, C. et al. Food Anal. Methods, Method Validation and Quality Management in the Flexible Scope of Accreditation: An Example of Laboratories Testing for Genetically Modified Organisms (2008) 1: 61.

[7] Schimke, I. Anal Bioanal Chem, Quality and timeliness in medical laboratory testing, (2009) 393: 1499.

[8] Koch K.H. (1999) Chemical Process Analytics as Part of Quality Management and Quality Assurance, Chemical Process Analytics as Part of Quality Management and Quality Assurance Springer In: Process Analytical Chemistry., Berlin, Heidelberg.

[9] Mario Plebani, Laura Sciacovelli, Biol Sci, Ada Aita, Biol Sci, Clinics in Laboratory Medicine, Quality Indicators for the Total Testing Process, March 2017 Volume 37, Issue 1, Pages 187–205.

[10] Kaus R. (2010) Accreditation – ISO/IEC 17025. In: Wenclawiak B., Koch M., Hadjicostas E. (eds) Quality Assurance in Analytical Chemistry. Springer, Berlin, Heidelberg.

[11] Groboth, G. Journal of Thermal Analysis and Calorimetry, Quality Assurance in Testing Laboratories (1999) 56: 1405.

[12] James A.Rodger, David J.Paper, Parag C.Pendharka, Volume 9, Issue 1, Spring 1998, Pages 131-156, The Journal of High Technology Management Research, An empirical study for measuring operating room quality performance attributes.

[13] Ponomareva, O.B. & Shpakov, S.V. Meas Tech, Testing the proficiency of analytical laboratories by means of inter-laboratory comparison tests – an important element in assurance of the uniformity of measurements (2012) 54: 1427.

[14] Kleindienst, D. Electron Markets, The data quality improvement plan: deciding on choice and sequence of data quality improvements (2017) 27: 387.

[15] Vasiliev, V.A, Alexandrova, S. V. Quality Management under Current Conditions ISSN 0036 0295, Russian Metallurgy (Metally), Vol. 2015, No. 13, pp. 1161–1167.

[16] Burak P., Zvorykina T., Ivanova G., Inanov A., Aladin V. International Guidelines for Standardization of Sustainable Development of the Administrative and Territorial Entites: Russian Experience of Implementation //Journal of Advanced Research in Law and Economics, Winter. –2015.

[17] V.V. Miroshnikov Perfection of enterprise management on the basis of application of integrated management technology / Logistics in innovative economy. 2014. P. 23-26.

[18] Levina IA The motives of managers, the management model and the results of the firm's activity / The Economic Journal of the Higher School of Economics. 2014. T. 18. No. 3. P. 429-453

[19] Kakulia IA, Musharapova N.I., Quality control of products, 01.07.2016, No. 7/2016. Accreditation of testing laboratories: standard inconsistencies.

[20] Bardonov I.V. Quality management system according to the requirements of GOST ISO / IEC 17025-2009 and the criteria of the Ministry of Economic Development of Russia / Quality and life. No. 2, 2014. P. 78-0.

[21] Bykova N.G. The concept of continuous improvement / Standards and quality, No. 7/2017.

[22] Reference and legal information and search system NormaCS. Available at: http://www.normacs.ru (viewed on 21.04.18)

[23] Mozhaeva TP The concept of human resource management in the quality management system / T.П. Mozhaeva // Bulletin RGATU behalf PA. Solovyov - 2014. - № 4. - P. 48-56.

[24] Ageev A.V. Evaluation of the choice of suppliers of products / / Economic analysis: theory and practice. № 21. 2007. P. 42-47.

[25] Ivanova GN, Okrepilov VV, Okrepilova IG. Development of the theory of quality management for the purpose of sustainable development and improving the quality of life // Quality and life. -2016.