Main nonconformities revealed during the assessment of compliance of testing laboratories with the accreditation criteria

A A Vinogradova¹, S M Leontyuk¹, M O Silivanov¹

¹Saint-Petersburg Mining University, 2, 21st Line, St Petersburg 199106, Russia

E-mail: vinogradova_aa@pers.spmi.ru

Abstract. The process of accreditation in national accreditation system is carried out in order to ensure confidence in the results of conformity assessment and create conditions for mutual recognition of the results of conformity assessment by the states - trading partners of the Russian Federation. Federal Service for Accreditation of the Russian Federation is a federal executive body performing the functions of the national body of the Russian Federation for accreditation. It makes a decision on accreditation or on denial of accreditation on the basis of the applicant's compliance with the accreditation criteria. The assessment of the applicant's compliance with the accreditation criteria is carried out in the form of a documentary and off-site conformity assessment conducted at the place (or places) of applicant’s activities. The assessment of the applicant's compliance with the accreditation criteria is based on the principles of legality, protection of the rights of a legal entity or individual entrepreneur, independence, fairness and competence of experts, objectivity, comprehensiveness and completeness of assessment, responsibility of accreditation experts and technical experts for the conduct and quality of assessment. The Appeals Commission is included in the list of participants in national accreditation system. The consideration of complaints against decisions, actions (inaction) of Federal Service for Accreditation of the Russian Federation and its officials in connection with the refusal of accreditation, suspension and termination of accreditation, reduction of the scope of accreditation upon applications from applicants, accredited persons or federal executive bodies fall within the powers of the Appeals Commission. In the period from 2016 to 2019 there has been a uniformity in the practice of the Appeals Commission under Federal Accreditation Service (hereinafter referred as the Commission), therefore it is advisable to consider the most common reasons for the solution and denial of complaints.

1. Introduction
During the accreditation procedures, competence confirmation, expansion of the scope of accreditation, testing laboratories (centers) must meet certain criteria. In increasingly competitive conditions, an organization must respond quickly to the changes in the requirements of external environment. Nowadays, quality management, as the leading management of an organization [1-5], can contribute to the prevention of the most common nonconformities identified during compliance assessment of testing laboratories (centers) with accreditation criteria within the framework of accreditation procedures, expanding the scope of accreditation, confirming the competence of testing laboratories (centers), which we will discuss further. The relevance of the topic is explained by the constancy of the above mentioned procedures.
2. Problem statement

The Appeals Commission under the Federal Accreditation Service [6] (hereinafter referred to as the Commission) carries out its activities in accordance with:

- the Article 10 of the Federal Law of December 28, 2013 No. 412-FL “On accreditation in national accreditation system” [7] (hereinafter FL No. 412);
- the Provisions on the Appeals Commission under the Federal Accreditation Service, approved by the Government of the Russian Federation of May 15, 2014 No. 436 [8] (hereinafter - the Provisions);
- the Commission Regulations approved by the Commission's decision of January 16, 2017 [9] (hereinafter - the Regulations).

According to Part 2 of the Article 10 of Federal Law No. 412-FL, the powers of the Appeals Commission include consideration of complaints against decisions, actions (inaction) of national accreditation body and its officials in connection with the denial of accreditation (including the denial to the declared scope of accreditation, expansion of the scope of accreditation), suspension or termination of accreditation, reduction of the scope of accreditation at the request of applicants, accredited persons, federal executive bodies.

According to part 5 of the Article 10 of Federal Law No. 412-FL, the Appeals Commission includes representatives of federal executive bodies authorized to exercise state control (supervision), the officials of the national accreditation body and the federal executive body responsible for the development of state policy and regulatory regulation in the field of accreditation, the members of the accreditation council, accreditation experts, representatives of scientific organizations, public organizations (Figure 1).

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**Figure 1.** Complaints consideration scheme

There has been a significant decrease in the total number of complaints considered by the Commission from 2016 to 2018 (Figure 2).
Fig. 2. Dynamics of changes in the number of complaints considered by the working groups of the commission

Over three years, there had been a uniformity in the work of the Commission. Thus, it is advisable to consider the most common reasons for acceptance and denial of complaints.

For the period from 2016 to 2018, the working group on accreditation considered 35 complaints about decisions of the Federal Accreditation Agency on refuse of accreditation or expansion of the scope of accreditation, in respect of which the Commission made decisions to refuse acceptance due to the applicant's non-compliance with the accreditation criteria approved by the order of the Ministry of Economic Development of Russia, 30.05.2014 № 326 “On approval of the accreditation criteria, the list of documents confirming the compliance of applicants, accredited party with accreditation criteria and the list of documents in the field of standardization, compliance with the requirements of which ensure compliance with the accreditation criteria” [10] (hereinafter - Accreditation Criteria) established during the on-site and (or) documentary examination.

Over three years, the working group on accreditation considered 15 complaints about the decision of the Federal Accreditation Agency on refuse of accreditation, in respect of which the Commission made decisions to refuse due to the decision to terminate the accreditation in respect of a legal entity or individual entrepreneur who applied for accreditation to a national accreditation body earlier than after two years from the date of such a decision, as a result of which accreditation was denied on the basis of Part 9 of Article 22 of Federal Law No. 412.

Most of the accepted complaints, considered by the working group on accreditation over three years, are related to the applicants' appeals against the decisions of the Federal Accreditation Agency on refusal of accreditation in the part of the declared scope of accreditation due to the applicants' disagreement with the conclusions of the expert group, reflected in the on-site examination certificate. The Commission made decisions on acceptance of complaints, in connection with the establishment of the possibility of accreditation with the reduction of the declared scope of accreditation at the Commission on the establishment of facts of violations by accreditation expert, technical expert and expert organization of the requirements of the legislation of the Russian Federation on accreditation in the national accreditation system, or in connection with the establishment of groundlessness of the conclusions contained in the certificate of the on-site examination.
Most of the complaints considered by the control working group during three years and refused, were related to the applicants’ appeals about the decisions of the Federal Accreditation Service of the Russian Federation. This number included the complaints:

- on the termination of the accreditation due to the establishment of the fact of non-elimination of revealed violations after the suspension of the accreditation following the results of unscheduled documentary or on-site inspection, which entails a decision by the Federal Accreditation Agency to terminate the accreditation. Therefore, the Commission’s decisions are recognized as legal and reasonable.

- on the suspension of the accreditation due to the fact that revealed violations do not belong to the List of violations that, when exercising federal state control over the activities of accredited persons, do not entail suspension of accreditation, approved by the order of the Ministry of Economic Development of Russia of May 30, 2014 No. 322.

Most of the accepted complaints, considered by the working group for control over three years, were related to the applicants’ appeals about the decisions of the Federal Accreditation Service of the Russian Federation on termination of the accreditation due to the applicants’ failure to receive notifications on the suspension of the accreditation with the indication of time period for eliminating the revealed violations.

According to the results of consideration, the Commission decided to accept the complaints, since the notifications were sent to a non-existent e-mail address, due to incorrect data in the register of accredited parties.

According to statistics, the main reason of negative decisions by the Federal Accreditation Service of the Russian Federation on public services in relation to applicants, is the non-compliance with the accreditation criteria approved by the order of the Ministry of Economic Development of Russia of May 30, 2014 No. 326 “On Approval of Accreditation Criteria, List of Documents Confirming Compliance of Applicants, Accredited Parties with the Accreditation Criteria, and a list of documents in the field of standardization, compliance with the requirements of which ensures compliance with the accreditation criteria” (hereinafter referred as the Accreditation Criteria) established during the on-site and (or) documentary examination.

During the period from January to September 2019, about 1300 government services were completed in relation to testing laboratories (centers) with the participation of expert groups.

During the studied period, the current accreditation experts analyzed more than 140 acts of on-site examination / examination certificate containing non-compliance of testing laboratories (centers) with the accreditation criteria within the framework of accreditation procedures, expanding the scope of accreditation and confirmation of competence, which comprised 13.7% of the total number of public services for testing laboratories (centers) with the participation of expert groups.

According to the results of the research, it is possible to name the most common non-conformities with the requirements of the Accreditation Criteria, which are established during the conformity assessment in testing laboratories (centers). The most common non-compliance are with the following criteria:

- the availability of regulatory legal acts, documents in the field of standardization, rules and methods of research (testing) and measurements, including rules for sampling and other documents specified in the field of accreditation or in the register of accredited persons and the laboratory’s compliance with the requirements of these documents (the requirements of part 18 of Accreditation criteria);

- the availability of rules for quality management of research (test) and measurement results, including rules for planning and analyzing the results of quality control of studies (tests) and measurements, which may provide for interlaboratory comparison tests, the use of reference materials and (or) internal quality control with the use of standard samples, retesting (the requirements of part 23.11. of Accreditation criteria).
In addition, according to the accreditation from these acts of on-site examinations / acts of examinations containing inconsistencies of testing laboratories (centers) with the Accreditation Criteria the experts identified and analyzed inconsistencies that were directly or indirectly related to quality management of the results of work in the field of accreditation of testing laboratories (centers).

Despite the fact that there is a tendency to reduce inconsistencies in the quality management of the results of accreditation activities, accreditation experts believe that this factor is one of the most important elements of laboratory activities and a parameter for compliance assessment of an applicant / accredited party with the Accreditation Criteria.

According to the results of the received data, the accreditation experts developed the “Draft Guidelines for Compliance with the Accreditation Criteria in terms of quality management of research results, tests, measurements for testing laboratories (centers)”, containing recommendations on quality management of research (test) results, measurements, namely, the formation of a plan of intralaboratory control, the organization of intralaboratory control, the registration of intralaboratory control results, the volume of intralaboratory control and data analysis.

3. Conclusion

As a result of a comparative analysis of revealed violations in the acts of expertise for 2018 and 2019 we established a tendency to reduce the inconsistencies associated with quality management of the results of work in the field of accreditation. The percentage of inconsistencies revealed in the implementation of the internal laboratory quality management procedures remains quite high (more than 40%). During the studied period, the current accreditation experts analyzed more than 140 acts of on-site examination / examination certificate containing non-compliance of testing laboratories (centers) with the accreditation criteria within the framework of accreditation procedures, expanding the scope of accreditation and confirmation of competence, which was 13.7% of the total number of public services for testing laboratories (centers) with the participation of expert groups.

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