Quality and assurance control management of analytical data in the case of biomonitoring

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Abstract. The industrial development of the Arctic is steadily increasing, which leads to the degradation of the ecosystems of the region. In case of ecological biomonitoring of fragile Arctic nature, the quality of the analytical work and the accuracy of the results obtained come to the fore. Accreditation of analytical laboratories provides confidence and recognition of its results. Verification of the qualifications of analytical laboratories through interlaboratory comparison tests conducted under international programs allows an objective assessment of the quality of the analysis results, compare the data with other laboratories, demonstrate technical competence, and provide additional confidence in the quality of research results obtained by the laboratory.

1. Introduction
The Arctic is the most important region not only for the Russian Federation, but also for a number of other countries due to the enormous natural wealth, potential oil and gas resources, as well as transit opportunities. The role of the Arctic in this regard is steadily increasing. However, intensive industrial development leads to negative consequences for the fragile Arctic nature, that is, degradation of ecosystems. This necessitates a careful study of problems related to the environment, as well as a policy aimed at the maximum preservation of the natural habitat.

The source of information necessary for making environmentally significant decisions is environmental monitoring, which allows to judge the state of the environment with an assessment of the past and the present, as well as with future prediction of environmental parameters. It is known that one of the promising areas of environmental monitoring is biomonitoring, which monitors not just the quality indicators of the environmental components, but the response of biota to the quality of the environment and its changes. Therefore, the tasks of biomonitoring include the regularly conducted assessment of environmental quality with the help of living objects specially selected for this purpose.

Various types of studies can be used to organize biomonitoring, but in order to obtain reliable data, the same measurement methods are applied to the same objects for a long time. The data obtained from temporal dynamics are compared with the control backgrounds, on the basis of which assessments of the object contamination and a forecast for the future are subsequently made.

One of the tasks of bioanalysis is the adaptation and development of the methodological base of environmental and analytical control, which is based, in turn, on conducting research (testing) and measurements in an accredited laboratory for chemical analysis of soil, water, bottom sediments, biological objects, and microbiological analysis of the same samples.

Accredited analytical laboratories allow control in areas of influence of potentially hazardous objects in the area of low maximum allowable concentrations (MAC), which will make it possible to
reliably predict the behavior and trends of specific pollutants accumulation in natural environments and biological objects. The status of an accredited laboratory allows us to ensure both the accuracy of the determination of the elemental composition of the samples studied and the recognition of research results.

2. Discussion
Laboratory accreditation may be conducted at the level of regional, national or international accreditation systems. In order to develop common rules for all participants in this type of activity and simplify the procedure for recognizing laboratory results, common international standards for laboratory accreditation are used [1-3]. In this regard, the accreditation procedure in various systems is unified and includes:
- preparation of the application and submission of documents proving the compliance of the laboratory with the accreditation criteria;
- verification of the application and the documents submitted by the laboratory (documentary check);
- assessment of the laboratory at the place of its activity (on-site inspection);
- preparation of a conclusion on the results of the on-site inspection (examination);
- granting accreditation;
- periodic inspection of the laboratory after the set time (procedure for confirming competence, inspection control, etc.).

In the Russian Federation, laboratories are accredited in the national accreditation system by the Federal Accreditation Service (RuAccreditation) of the Ministry of Economic Development of the Russian Federation in accordance with Federal Law No. 412-FZ of December 28, 2013 “On Accreditation in the National Accreditation System”.

According to the requirements of the Russian legislation, an accredited laboratory must follow in its activities the international standard ISO / IEC 17025 General requirements for the competence of testing and calibration laboratories [1] and meet the accreditation criteria approved by the Order of the Ministry of Economic Development of May 30, 2014 No. 326 [4]. The general scheme for the preparation of documents for the accreditation of testing laboratories in the national accreditation system is shown in Figure 1.

| Documents to RusAccreditation with accreditation application |
|---------------------------------------------------------------|
| **Declared area of accreditation (AA)**                        |
| (Clause 18, Order of the Ministry of Economic Development No. 326, Order of the Ministry of Economic Development No. 288) |
| **Documents of the quality management system (QMS)**           |
| (Clauses 17, 23, Order of the Ministry of Economic Development No. 326, ISO / IEC17025) |
| **Information about the laboratory equipment**                 |
| (Clauses 19, 20, 21, Order of the Ministry of Economic Development No. 326) |

Figure 1 - Documents for submission to RusAccreditation, confirming compliance with the requirements of the Accreditation Criteria.

Agreements on the recognition of accreditation results exist between the national accreditation systems of many countries, which allows laboratories to carry out their activities at the international
level. The most well-known and recognized organizations for laboratory accreditation at the international and regional levels are:

- ILAC (International Laboratory Accreditation Cooperation) - International organization for accreditation of laboratories. The largest organization, comprising more than 90 member countries, is a cooperation whose goal is to ensure the recognition of the results of the accreditation of laboratories of the countries participating in the cooperation;
- APLAC (Asia Pacific Laboratory Accreditation Cooperation) - Organization for accreditation of laboratories in the Asia-Pacific region. It is a regional laboratory accreditation organization that includes a large number of countries in Southeast Asia;
- EA (European Cooperation for Accreditation) - European association for accreditation. This regional organization ensures recognition of the results of accreditation of laboratories in the EEC countries;
- IAAC (Inter American Accreditation Cooperation) – Inter American association for accreditation. The organization was established on the basis of agreements of accrediting bodies of American countries.

As a rule, the participants of these organizations (cooperations) are national accreditation bodies or authorized organizations. RusAccreditation officially joined APLAC in 2017, which was a consequence of the subsequent entry of RusAccreditation in ILAC, and RusAccreditation became the 92nd member of ILACMRA. In June 2018, the Pacific Accreditation Cooperation (PAC) officially announced the inclusion of the Federal Accreditation Service among its members, which allowed RusAccreditation to join the International Accreditation Forum (IAF) in October 2018. [5].

Accreditation of a laboratory in one of the national systems may mean recognition in the specified international and regional agreements, but not always. Sometimes accreditation is required by authorized organizations that have the right to conduct accreditation on behalf of these associations.

One of the key points in assessing the performance of analytical laboratories is to check their qualifications. From a practical point of view, a universal way to demonstrate the technical competence of a laboratory is to check for compliance with predetermined criteria by means of interlaboratory comparison (comparative) tests (ICT) [6]. Another way is, as stated above, accreditation, but its essence lies in the overall assessment of the work organization (QMS, staff competence, availability of necessary resources, etc.). Proficiency testing by means of ICT allows an objective assessment of the reliability of the research (performance) in the laboratory.

Currently, the areas of interlaboratory comparison tests cover a wide range of studies. Figure 2 shows the directions of the ICT, implemented to test the qualifications of analytical laboratories operating in the field of environmental biomonitoring.

![Figure 2](image-url)

**Figure 2.** Directions for conducting interlaboratory comparison tests (ICT): PCR1-polymerase chain reaction.
The competence requirements of the providers of proficiency testing programs, as well as to the development and implementation of these programs are governed by the international standard ISO / IEC 17043 [7].

When choosing quality control programs (competence, qualifications) of laboratories, it is highly desirable to have international laboratories that also participate in competency testing programs, international ICT programs.

FAPAS is a reputable internationally recognized provider, which implements international programs FAPAS, FEPAS, GeMMa, LEAP, PhytoPas, QSE, GD Animal health service. There are a number of other international ICT programs: IAEA, LGC Standards, EPTIS database. The EPTIS database lists hundreds of ICTs, and it can select the appropriate scheme for each specific laboratory. EPTIS is a non-profit joint publication of 20 international organizations, headed by the German Federal Institute for Materials Research and Testing (BAM) with the support of EA, Eurachem, Eurolab, IAAC, IRMM and ILAC.

Participation in the proficiency testing programs allows laboratories to obtain reliable information about the quality of analysis results (assess the accuracy of the results, ensure traceability compared with reference (basic) values), identify methodological errors and eliminate them, determine strengths and weaknesses of the activity, compare the results of research and statistical parameters with the results of other laboratories, demonstrate technical competence, provide additional confidence in the quality of the research results obtained by the laboratory.

3. Conclusion

Thus, obtaining a certificate of accreditation and periodic proficiency testing of analytical laboratories is a significant tool in ensuring the quality and reliability of the research. The results of studies of such laboratories are recognized at the national, regional and international level, which is of paramount importance in the implementation of environmental biomonitoring and assessment of the ecological status of the Arctic territories.

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References
[1] ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.
[2] ISO 15189 Medical laboratories — Requirements for quality and competence.
[3] ISO 9001 Quality management systems – Requirements.
[4] Order of the Ministry of Economic Development of May 30, 2014 No. 326 “On approval of accreditation criteria, the list of documents confirming compliance of an applicant, an accredited person with the accreditation criteria, and the list of standardization documents, compliance of which by applicants, accredited persons ensures their compliance with accreditation criteria” http://fsa.gov.ru/ Official website of the Federal Accreditation Service of the Ministry of Economic Development of the Russian Federation.
[5] ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities In the accreditation process for inspection bodies.
[6] ISO/IEC 17043 Conformity assessment - General requirements for proficiency testing.