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FLEXIBLE SCOPE OF ACCREDITATION MANAGEMENT ACTIVITIES

QP 5.0-2 Flexible Scope of Accreditation Management Activities

CHRONOLOGY OF DOCUMENT CHANGES

№	Date of version/date of revision	Version/ Revision	changes made	reason for change / introduction	developed/ made the changes to the document
1	Version date: 08/01/2019 Revision date: 11.09.2020	Version 1/ Revision 1	new document from QS	Required by EA BAS ensuring compliance with the requirements of BAS QR 32 dated 16.04.2020	Eng. Kr. Kalacheva
2	Version date: 08/01/2019 Revision date: 01.12.2020	Version 1/ Revision 2	on page 5 and page 9 marked in Bold	change in the number of the documents referred to in the present procedure	Eng. Kr. Kalacheva
3	Version date: 08/01/2019 Revision date: 08/01/2022	Version 1/ Revision 3	Change the name of documents referred to in the procedure	registered and approved internal proposal by HL	Eng. Kr. Kalacheva
4	Version date: 08/01/2019 Revision date: 30.03.2023	Version 1/ Revision 4	discovered inconsistencies and gaps in the procedures by the State Administration, registered in non-compliance No. 01/30.03.2023: Expanded and specified description of the procedure for review, updating and management of standards by the State Administration and other documents of external origin	detected discrepancies and gaps in the procedures by the QS, registered in discrepancy No. 01/30.03.2023	Eng. Kr. Kalacheva
5	Version date: 08/01/2019 Revision date: 23.10.2023	Version 1/ Revision 5	Clarifications and additions for documenting test results when canceling and replacing a method by Flexible scope	Proposal for amendment of documents from QS registered by PE	Eng. Kr. Kalacheva

CONTENTS

1. GENERAL PRINCIPLES

The purpose of this procedure is to provide a documented process for the analysis, development and implementation of flexible scope, according to the requirements of procedure BAS QR 32 of EA BAS "Procedure for Accreditation of Flexible Scope" dated 04.16.2020.

In accordance with item 4.1.1 of BAS QR 32, LAKOS falls within a flexible scope with a degree of flexibility:

- Application of new (updated) versions (editions) of documents defining the methods used by OOS (standards or other documents) or the documents that replace them.

2. TERMS AND DEFINITIONS

fixed range	The term "fixed scope" means a clearly defined description of the specific conformity assessment activities for which the body is accredited item 2 of EA-2/15 M "EA Requirement for the Accreditation of Flexible Scopes"
Flexible scope of accreditation	Flexible scope, as defined in ISO/IEC 17011, is an accreditation scope expressed to allow conformity assessment bodies to make changes to the methodology and other parameters that fall within the competence of the conformity assessment body, such as has been confirmed by the accreditation body, item 3.2 of BAS QR 32. In cases where a flexible scope is provided in the sense of item 4.1.1 of BAS QR 32, in the accreditation order before the table Type of scope: "flexible scope*" is written, and a note with the following text is added below the table: "The introduction of a new version of the standards or standards that replace them is permitted. The laboratory maintains an up-to-date list of standards with their dated versions."

3. RESPONSIBILITIES

Head of laboratory (HL)	Verification and approval of edited or new documents by the Quality system (QS)
	Approves the distribution of documents (of internal or external origin)
	Manages and controls all documents created and received in LAKOS
	Decides on archiving and destruction of documents
	Performs feasibility review of contracts, offers, inquiries
	Informs clients and EA BAS in case of changes regarding the flexible scope of accreditation
	Gives orders, determines responsible persons and deadline for implementation in case of detected changes in regulatory documents and testing/sampling standards falling within the flexible scope
Quality manager (QM)	Develops MQS(manual of quluty system), QP (quality procedures), QL (qulity lists), WI (work instructions) and QF (quality forms)
	Distributes current documents
	Initiates a proposal to amend or create a document
	Checks for appropriateness to modify or create a document
	Amendment of documents
	Checks the modification or creation of a document
	Controls distribution of documents
	Stores the documents

	Archives and destroys documents
	Downloads and replaces invalid documents
	Trains the staff and documents activities performed to verify new standards replacing canceled ones
	Performs analysis of changes together with OMO when replacing a standard
Staff of laboratory	Prepares comparative tables of repealed and superseded standards
	Responsible for storing, distributing, updating and archiving the documents of external origin - the standards and normative documents included in the flexible scope

4. DESCRIPTION OF THE PROCESS FOR THE ANALYSIS, DEVELOPMENT AND IMPLEMENTATION OF A FLEXIBLE SCOPE, IN ACCORDANCE WITH THE REQUIREMENTS OF ITEM 5.2 OF BAS QR 32

4.1. Determination of entry requirements

The activities listed below include determining the input requirements in maintaining and managing the flexible scope, developing and providing testing and/or sampling services, and verifying that the laboratory has met the requirements.

- Track the relevance of testing/sampling standards, part of the scope of accreditation
  According to the requirements of QP 8.3-1 Management of the documents of the Quality system (option A), all documents of external origin for the laboratory are managed and maintained by the Normative Document Manager (NDM).
  Information on current normative documents (ordinances, rules, etc.) is obtained from the electronic edition of the Bulgarian Governmental Newspaper, and information on current standards is obtained from the subscription for updates to the Bulgarian Institute of Standardization (BIS).
  - All documents of external origin are checked for relevance in a period of 15 days by the National Audit Office according to the following lists:
    QL 7.2-2 List of methods with flexible scope of accreditation
    QL 7.2-3 List of methods relating to sample quality and sample preparation
    QL 8.3-2 List of external documents
  - Each check is documented at the end of the relevant list in the Appendix - a table with the name "Check for the relevance of methods with a flexible scope of accreditation" by hand with a signature from the NDM. After each change, the list is updated and the old one is archived. In cases where there are no changes in the table during the check, the date and text "No revised or new documents/found changes in..." are recorded.

LAKOS demonstrates and provides evidence of competence and compliance with accreditation requirements in maintaining and managing flexible scope. This process includes the following activities:

- In the case of ascertained changes to the methods of the flexible scope of accreditation, the activities related to the change are carefully examined in accordance with QP 7.1-1 Review of inquiries, contracts and offers. HL informs the contracting authorities about the changes that have occurred and requests their confirmation for the continuation of the laboratory activity. This process is documented by written communication via QF 7.1-6 Notification Letter. The signing and return of the Notification Letter is proof that the Employer is informed and agrees to continue the laboratory activity.
- In the case of detected changes, the NDM reflects this in Appendix 1 "Check for the actuality of methods with a flexible scope" from QL 7.2-2 List of methods with a flexible scope of

accreditation, by handwriting the date, the name of the method, describing the change, preparing an information sheet, with which he informs HL about the changes, which in turn takes follow-up actions.

- The head of LAKOS issues Order QF 5.0-2 ordering the termination of all activities affected by the change; gives orders for the specific activities; determines the deadlines and the persons responsible, both for carrying out the activities and for carrying out the inspection, for example:
  - Notifying the contracting authorities of the started orders with the included activities to which the change applies - through QF 7.1-6 Notification letter, the contracting authorities are informed about the change and its consequences / eg. delay in the execution of the assigned laboratory activity, change in the price, etc./. Feedback and consent to continue execution of the order is required from the contracting authority;
  - Intermission of the application of the given method from the date of cancellation/replacement;
  - Purchasing the relevant document and handing it over to competent officials /NDM/ for the preparation of a comparative table QF 7.2-7
  - Carrying out analysis of changes by Metrologist and QM, ending with a proposal for further actions and approval of HL;
  - Informing and, if necessary, training the staff - through information sheet QF 7.11-1;
  - Verification plan - and verification process if necessary (for testing and/or sampling methods) or familiarization (for a regulatory document - Law, Rulebook, Guide or Ordinance);
  - Order to introduce the new document (when it refers to a test/measurement and/or sampling method) ;
  - Update of documents in LAKOS that are related to the change;
  - If necessary (if the test/measurement and/or sampling method has been changed) - applying the changes to the laboratory software product as well. **The test/measurement/sampling protocols shall cite the current test/measurement/sampling method, which supersedes and replaces the old one, part of the LAKOS Accreditation Standard** .

Each staff member declares with his signature that he is familiar with the Order.

Analysis of the changes related to the changes of the new document compared to the previous version starts with the preparation by the NDM and/or the QM of a shortened version of the comparative table containing only the changes. The actual analysis is carried out by the QM and the Metrologist, being documented in QF 7.2-7 "Comparison table" and contains information on:

- Comparison of the requirements of the new document against those of its previous version/revision;
- Assessment of changes – whether they are significant or minor;
- Necessary actions to align with the requirements of the new document and accreditation requirements;
- Change in test and/or sampling method (when applicable to added new product) and whether it falls within the scope of testing under the accredited method;
- Change in the requirements relating to the qualification of the personnel performing the testing and/or sampling;
- Change in the requirements relating to the technical means used within the accredited scope;

- Change in requirements relating to the premises and conditions for conducting testing used within the accredited scope;
- The need for verification of the test and/or sampling method.

The analysis ends with the conclusion of the QM and Metrologyst regarding the need for new technical equipment, RM and/or CRM, personnel and a new method verification procedure or just documenting the change in a new protocol with the old data.

- After implementation and documentation of all these activities related to the ascertained change of method, part of the flexible scope of accreditation, HL documents in QL 7.2-2 the traceability of the implementation of all prescribed activities - "Order No. from date... - for the start of the actions, Order No. of the date of termination of the actions"
- Monitoring the relevance of regulatory documents related to the implementation of laboratory activities.

The process for checking the actuality of all external documents is carried out and documented at certain periods in accordance with the order described in item 4.2 of QP 8.3-1 Management of the documents of the management system (option A).

4.2. Verifying the process to fulfill the requirements

Each canceled and replaced method, part of the scope of LAKOS accreditation, after evaluation of the changes made, is verified according to the procedure described in item 4.2 of QP 7.2-1 Selection and verification of methods.

If the verification process for an activity leads to the conclusion that LAKOS is unable to issue valid protocols, a cause analysis is performed and adequate corrective actions are taken, as described in QP 8.7-1 Corrective Actions. Such actions include:

- Informing the client that while the analysis and all subsequent actions are being carried out, LAKOS will not be able to issue accredited protocols and the reasons for this.
- Revising relevant procedures or methods to resolve the identified problem and ensure that it does not recur in the future.

In cases where the verification process regarding a canceled/replaced method has been completed and the result is that the method is suitable for the intended use and can be put into operation, the head of LAKOS issues Order QF 5.0-2 to put the method into use . **The test/measurement/sampling protocols shall quote the current test/measurement/sampling method, which supersedes and replaces the old one, part of the LAKOS accreditation Flexible scope.**

Each inquiry to LAKOS is subject to review for feasibility, carried out and documented by HL in accordance with the requirements of QP 7.1 Review of inquiries, contracts and offers.

4.3. Determining responsible persons for flexible scope management and for each area of activity

Responsible persons for the management of the documents and for ensuring the fulfillment of the requirements of this procedure and of BAS QR 32 are NDM and QM, authorized by QF 5.0-2 "Order" by the Head of the Laboratory.

4.4. Provide a documented contract and bid review process informing the client/contractor and confirming that the laboratory assignment falls within the flexible scope

All activities related to review of customer inquiries, contracts and offers are regulated in QP 7.1-1 Review of inquiries, contracts and offers.

The current procedure is available on the website of "Eco-Consult-Engineering" Ltd, by which the laboratory ensures publicity and access to its customers. There is also a clause in QF 7.1-2

"Awarding for laboratory activity", through which the Contracting Authority declares with his signature that he is familiar with the current procedure, accepts the conditions and actions of the laboratory in the event that an updated or replaced test method is established and/or taking samples. When the assignment is made in a free text letter, e.g. by e-mail, LAKOS sends an assignment for laboratory work also electronically.

LAKOS does not accept assignments for laboratory activity in the case of established new, updated or replaced testing and/or sampling methods, until it proves competence and compliance with their changed requirements. In this case, the client is notified in writing with QF 7.1-6 Notification letter.

Within 5 working days after identifying the change, HL informs in writing all customers who, at the time of identification of the change, submitted an assignment for laboratory activities based on canceled (outdated) testing and/or sampling methods. In its notification letter, the HL sets a period by which the performance of the service is postponed depending on the time and resources required to fulfill the requirements of the relevant test method and/or sampling (analysis of changes, staff training and verification in cases, when the changes are significant) and informs them of a possible change in the price of the service. The minimum period for this is 20 working days, and it should not be more than 30 working days, unless the circumstances require it (provision of new reagents or CRM related to the requirements of the updated version of the standard, the delivery of which has a longer period than that determined by this procedure).

In cases where the Contracting Authority does not agree with the postponement in time, he has the right to refuse the assignment according to the relevant test method. In such case, LAKOS shall refund the amount paid in full for the activity relating only to the changed or replaced test and/or sampling method. The laboratory does not refund the amounts paid for the remaining activities, regardless of whether the client wants a test report or not. Any correspondence with the client shall be attached to the documentation of the performance of the laboratory work assignment or contract.

In the event that the change of testing and/or sampling method is established at a later stage (up to 10 working days, counting from the delivery of the reports of the performed laboratory activity), when test reports concerning the change have already been issued, then the head of LAKOS immediately sends a notification letter to the respective client. In his letter, he informed him about the change that had occurred, declared the issued and submitted test reports invalid and demanded that they be returned. LAKOS refunds in full the entire amount paid for the changed or replaced testing and/or sampling method, but does not refund the amounts paid for the other activities performed.

In the letter, HL informs the client of the possibility, if he so wishes, of testing and/or sampling activities to be carried out in accordance with the requirements of the updated or replaced method, after the latter provides evidence of competence and compliance with the requirements of the updated or replaced methods for testing and/or sampling. In the event that the customer agrees, he undertakes to provide the necessary conditions for this and access to the object. In this case, a new test and/or sampling report will be issued.

Any written correspondence with the client is attached to the documentation for the performance of the assignment for laboratory activity and/or contract/order. The process of information and coordination with LAKOS customers is also regulated in QP 7.1 Review of inquiries, contracts and offers .

4.5. Maintaining an up-to-date and publicly available list of dated versions of the standards, technical specifications and regulatory documents against which the testing/sampling activities are carried out within the accredited flexible scope

In accordance with the order described in item 4.2 of QP 8.3-1 Management of the documents of the management system (option A), the NDM maintains an up-to-date list of all documents of external origin:

QL 5-0.4 Laboratory activities performed in LAKOS with fixed and flexible scope
QL 7.2-2 List of methods with flexible scope of accreditation
QL 7.2-3 List of methods relating to sample quality and sample preparation
QL 8.3-2 List of external documents

Information about laboratory activities in LASOS with a fixed and flexible scope is publicly available on the company 's website http://www.ecoeng.bg/. Any change in the list is reflected in Italic font and underlining in Bold to show what changes have occurred. This is done after:

- ascertaining changes in the relevance of the standards
- performing an analysis of these changes,
- carrying out the actions prescribed by the HL
- staff training and documentation;
- verification of the method (if necessary) and its documentation;
- conclusion of the HL on using the new version of the standard.

5. DOCUMENTS

5.1 External documents used

BDS EN ISO/IEC 17025:2018	General requirements for the competence of testing and calibration laboratories
BAS QR 32	Flexible Scope Accreditation Procedure
EA-2/15 M	EA Requirement for the Accreditation of Flexible Scopes

5.2 Accompanying internal documents

no accompanying internal documents

5.3 Referenced Internal Documents

QP 8.3-1	Management System Documentation (Option A)
QP 7.1-1	Review of inquiries, contracts and offers
QP 7.2-1	Selection and verification of methods
QP 8.7-1	Corrective actions
QF 7.1-6	Notification Letter
QF 7.2-7	Comparison table
QF 7.2-8	Verification / Validation Plan
QF 5.0-2	Order
QL 7.2-2	List of methods with flexible scope of accreditation
QL 7.2-3	List of methods relating to sample quality and sample preparation
QL 5.0-2	List of laboratory activities in LAKOS
QL 5.0-4	Laboratory activities carried out in LAKOS with a fixed and flexible scope