THE ACCREDITATION SCOPE OF A TESTING LABORATORY:

GUIDELINES FOR FORMULATION AND EVALUATION

THIS PROCEDURE IS A SUPPLEMENT TO BELAC 2-002, " ACCREDITATION CERTIFICATE AND CORRESPONDING ACCREDITATION SCOPE: GENERAL GUIDELINES FOR FORMULATION AND EVALUATION "

Whenever it is relevant to a particular conformity assessment activity, the general principles described in this procedure are supplemented with specific provisions in a document from the series BELAC 2-405.

The versions of documents from the BELAC management system, available on the BELAC website (www.belac.be) are considered as the only valid versions.
English translation for information only.
Versions in French and Dutch remain the authoritative documents.

Date of application: 19.03.2024

HISTORY OF THE DOCUMENT

Revision and date of approval	Reason for the revision	Extent of the revision
0 **CC 28.11.2003**	Incorporated into the BELAC documentation. Replaces the document BELTEST L04 and renders it null and void. - The reference to the NBN EN 45001 standard was replaced by a reference to the NBN EN ISO 17025 standard. - Revision of the text defining the concepts "specific testing" and "type of testing".	Full document, as a result of the merger, without any essential changes to the content.
1 **Secr. 31.01.2004**	Optimisation of the format and layout.	Full document
2 **CC 03.05.2016**	Full revision	Full document
3 **CC 27.10.2016**	Amendment of the exceptions governing “own methods”	Item 4.1.2.2.c
4 **CC 29.06.2020**	Updating of the reference to ISO/IEC 17025:2017 Integration of document EA 2/15:2020 Bringing into alignment with BELAC 2-002	Full document
5 **Secr 19.03.2024**	Editorial correction of a translation error in the English version. No changes in the French and Dutch versions.	Point 4.1.2 B c)

THE ACCREDITATION SCOPE OF A TESTING LABORATORY:

GUIDELINES FOR FORMULATION AND EVALUATION- PURPOSES AND REFERENCES TO STANDARDS DOCUMENTATION

The present document is intended to supplement the document BELAC 2-002 «accreditation certificate and corresponding accreditation scope: General guidelines for formulation and evaluation». This document defines specific guidelines for the description and evaluation of the accreditation scope granted to a testing laboratory.

The provisions described in this document explicitly refer to the relevant paragraphs and items contained in the BELAC 2-002 document.

This document refers to and is in accordance with the relevant parts of:

- the legal provisions that determine the functioning of BELAC
- the standard EN ISO/IEC 17011 and EA and ILAC guidance, more specifically documents ILAC G18 and EA 2/15
- the guidelines for the accreditation procedure (documents BELAC 3-11 and BELAC 3-12).

1. RECIPIENTS

With notification of changes:

- The members of the Coordination Committees
- The members of the Accreditation Board
- The Accreditation Secretariat
- The assessors
- The accredited laboratories

Without notification of changes:

- Each applicant

2. TESTING LABORATORIES

BELAC 2-002 ITEM 3: DEFINITIONS

- **Testing or test**

Determining one or more properties of a specific object of conformity assessment according to a procedure.

- **Group of tests**

Set of tests characterised by the use of a single general testing technique or testing principle (*including aspects such as sample preparation*) that apply to a product group and/or can be used to determine a group of parameters.

- **Testing technique or testing principle**

The overall underlying scientific or technical principle of the test method used (e.g. definition of the equipment, such as GC-MS, that is used for testing or a definition of the analytical technique, e.g. gravimetry).

- **Test method**

A test method shall, as a minimum, describe:

- ✓ the applicable scope of application (including details of the working area or measuring range, matrices and parameters)
- ✓ the measuring principles applied or the equipment used
- ✓ the way of execution of the test
- ✓ and, where possible, the performance criteria that apply to the method.

Within the concept of a test method, the following options are possible:

(i) methods standardised on a national or international level

Standard: a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context (ISO/IEC Guide 2:2004)

Testing standard: a standard that is concerned with test methods, sometimes supplemented with other provisions related to testing, such as sampling, use of statistical methods, sequence of tests (ISO/IEC Guide 2: 2004)

(ii) methods published by (inter)national scientific or technical institutions (such as in scientific periodicals) and generally accepted within a specific sector/discipline

(iii) methods published, validated and imposed in the context of a specific regulation by the competent authority

(iv) methods published by the manufacturers of equipment or kits

(v) methods belonging to the categories referred to above, which have been modified by the laboratory (derived methods; for further information, see also below under section 4.1.2.2)

(vi) in house methods developed by the laboratory itself (possibly based on one of the categories referred to above).

The first three categories are generally regarded as **standardised methods** in so far as they are used in unaltered form within the defined scope of application of the method.

On condition they have been validated and officially recognised by a competent body, methods that are included within the fourth category (kits) are also regarded as standardised methods within the defined scope of application of the method (such as kit methods validated and certified by AFNOR, MicroVal, etc. in the nutritional microbiology sector or kit methods validated by nationally or internationally recognised reference laboratories).

Standardised methods must be publicly available.

In the case of standardised methods, the principal performance characteristics have generally been defined and are publicly available; these must also be available during an assessment. In such cases, it is sufficient for the laboratory to carry out testing against those performance criteria (by means of a verification or limited validation), in so far as the laboratory is using the standardised method in unaltered form within the defined scope of application.

If the performance criteria of the standardised method are not publicly accessible, they must be determined by the laboratory itself by means of an extensive validation.

- **Product or matrix**

An item, or a group of items, subjected to a test.

- **Parameter or property**

A characteristic or group of characteristics determined during a test.

- **Flexible scope (of accreditation) (supplementary to the definition in BELAC 2-002)**

For a laboratory, a flexible accreditation scope is a scope which is not limited to specific tests, but is granted for a group of tests. Within the limits of its flexible scope, which have been clearly defined in advance, the laboratory is permitted to make changes to methods or add products or parameters, without any requirement for BELAC to be involved in connection with each specific test. Thispermission is subject

to a number of specific conditions defined in more detail in BELAC 2-002 and in this document.

- **Verification**

The provision of objective evidence that a given item fulfils specified requirements (ISO/IEC 17025, section 3.8).

- **Validation**

Verification, in which the particular requirements for specific intended use are fulfilled (ISO/IEC 17025, section 3.9).

- **Measuring interval**

A set of values of quantities of the same kind that can be measured by a given measuring instrument or measuring system with specified instrumental measurement uncertainty, under defined conditions. (VIM 2012)

BELAC 2-002 § 4 SPECIFIC PROVISIONS

4.1 Accreditation certificate and accreditation scope : concept and rules for presentation

4.1.1 Presentation of the accreditation certificate

a) The accreditation certificate shall state the name, the legal form and the address of the head office of the accredited body. In addition to the name, legal form and the address of the headquarters, the accreditation scope shall also specify all activity centres (BELAC 2-002, section 3.11).

4.1.2 Presentation of the accreditation scope

A. General

a) The accreditation scope for testing laboratories shall unequivocally state the testing activities, along with any sampling activities, for which accreditation has been granted. Instructions on the formulation of these activities are set out in sections 4.1.2.3 (fixed scope) and 4.1.2.4 (flexible scope).

b) If tests are (also) carried out on site, this must be clearly indicated in the accreditation scope. This is also applicable for mobile or semi-permanent laboratories.

c) If the laboratory carries out tests at multiple activity centres, the scope for accreditation will clearly indicate the specific activity centre(s) in which a specific test is carried out for each test in the accreditation scope. In the case of sampling and/or on-site testing, the activity centre(s) from which the activity concerned is coordinated, must be clearly indicated.

d) If sampling activities are included in the accreditation scope, the laboratory must comply with the specific requirements set out in BELAC 1-03, section 4.2.1. The link between the sampling activities and the subsequent (type of) tests will be clearly reflected in the accreditation scope.

e) In principle, **the measuring interval and performance characteristics** are not mentioned in the accreditation scope, but must be available for each accredited test and kept up to date by the laboratory and can be presented on simple request.
Depending on specific requirements in certain sectors, it may be agreed that the measuring interval or specific performance characteristics are explicitly stated on the accreditation scope.

f) The activities stated on the accreditation scope must be carried out by the laboratory to which the accreditation has been granted: **systematic subcontracting** of those activities is not permitted (ISO/IEC 17025, section 5.3). The systematic subcontracting of a step in the execution of a test is subject to the rules set out in BELAC 1-03, section 4.2.2.

g) Wherever possible, the activities in the accreditation scope shall be grouped by discipline (such as chemistry, microbiology, sampling…), by product group and by testing technique or testing principle.

B. Distinction between reference to a standardised (unchanged) test method, reference to a changed (derived) version of a standardised test method or reference to a in house ***method***

a) Reference to a **standardised test method** can only be made if:
   - the method is being used **within the defined scope of application** of the standardised test method
   - there is no deviation from the defined **measuring principle** (or the critical measuring equipment used) or from the described **working method** (with regard to critical components). It is assumed that the variables that are explicitly and specifically stated (such as temperatures, frequencies and time periods) will, in any case, be considered as critical.
   - the laboratory can demonstrate that it is capable of carrying out the test method correctly (ISO/IEC 17025, section 7.2.1) by determining and testing the relevant **performance characteristics** in a statistically significant way against the ones specified in the case of the standardised test method (**verification**). If a standardised method is revised, the verification must be repeated if necessary (ISO/IEC 17025, section 7.2.1).

     Special attention must be paid in this regard to the parameters of accuracy and precision and, if relevant, to the detection limit, the limit of quantification and the measuring interval, and this for those matrices that are most representative of the scope and the laboratory (based on the range of matrices routinely offered to the laboratory).

     If these parameters are not known for the standardised test method concerned, the laboratory must determine them itself by means of preparation of an adequate validation file.

     In the case of test methods that have been published and imposed by the government in the context of a specific regulation, the laboratory must demonstrate its ability to fulfil all **legally imposed requirements relating to specific performance characteristics**.

b) If a laboratory deviates from the method as described in a standardised test method, a reference to **a derived standardised test method ("*derived from*")** is permitted, if:
   - the method is being used **within the defined scope of application** of the standardised test method
   - there is no deviation from the **defined measuring principle** (or from the critical measuring equipment used)
   - the laboratory can demonstrate its ability to meet, in a statistically significant way, the **performance characteristics** associated with the test method, especially those related to accuracy and precision and, if relevant, to

the detection limit, the limit of quantification and the measuring interval, for those matrices that are most representative of the scope and the laboratory (based on the range of matrices routinely offered).

The following **exception** from the aforementioned conditions for derived methods is permitted:

If external requirements regarding performance characteristics are imposed on the laboratory (such as requirements regarding detection limits derived from legislation in a regulated sector), which deviate from those stated in the standardised test method being used, the laboratory may refer to a method derived from the standardised test method concerned provided that a verification has been performed against those externally imposed performance characteristics. The laboratory must, however, demonstrate that those external requirements have been established in consultation with the customers (contract review).

c) In other cases (which do not fulfil the aforementioned conditions for referral to a standardised method or a method derived from a standardised method), only a reference to **an "in house method"** may be included in the accreditation scope.

In such cases, a validation must be carried out by the laboratory. This shall either take the form of a limited validation or a full validation (with determination of all performance characteristics to guarantee the suitability of the method). If any changes are made to a validated in house method, the effect of those changes must be determined and if it is found that they will affect the original validation, the method must be validated again (ISO/IEC 17025, section 7.2.2.2).

If the working method, as described in a standardised test method, is used for a matrix, parameter or measuring interval that falls outside the defined scope of application of the method, it is possible to refer to an "in house method" with specified in brackets that the method is performed according to the standardized test method.

Whenever a standardised test method explicitly makes use of a different technique that is regarded as equivalent (but the application/method of that technique has not been described in detail in the standardised test method), it is possible to make use of the designation "in house method", accompanied, between brackets, by a qualification that the method is equivalent to the standardised test method. In such cases, the laboratory must demonstrate the equivalence of the method.

Whenever a standardised test method A explicitly mentions another method B as equivalent and the 'equivalent' test method B is applied by the laboratory, that method B shall be stated on the scope, but an indication stating that this is equivalent to the standardised test method A can also be included.

4.1.2.1 "Fixed" accreditation scope

a) The formulation of the fixed accreditation scope consists of a detailed list of the specific activities (testing and/or sampling activities) that meet the accreditation criteria. It represents the situation at the time of the assessment.

b) The following items shall be specified for each test (i.e. for each line in the scope):

- **the product** to which the testing or sampling applies
- **the property (or properties) measured** or **the type of sampling**
- **the testing or sampling method** as used by the laboratory
- the **testing principle and/or testing technique or sampling technique or sampling principle employed**
- the **internal method reference** of the laboratory, which unequivocally refers to the test method or testing approach used (especially when using derived or in house methods)
- the applicable **product standard**, if relevant
- details of the applicable **European Directive** in the case of activities carried out in the context of a notification (CE marking).

Changes to a 'fixed' accreditation scope in relation to the products, properties or test methods mentioned in the scope shall only be possible when evaluated and approved by BELAC.

If necessary, a "product group" can also be included in a fixed scope. This shall always be evaluated on a case-by-case basis by BELAC, based upon the nature and complexity of the test method or test technique or according to sector-specific provisions.

Further information can be added to the accreditation scope, according to the specific requirements imposed by certain sectors (e.g. specifying measuring interval, measurement uncertainty, detection limit, etc.). If requested by the competent authority, the valid, applicable regulations will also be mentioned if the activities are being carried out within a legal framework and/or in the framework of an agreement by the competent authority.

When formulating the test method, due attention will also be paid to the formulation of so-called preparatory steps prior to an actual test in the laboratory (purification, extraction, destruction, mineralisation, etc.), if the choice of the preparatory steps may affect the final result, including the measurement uncertainty.
The methods (if different from the actual test method) and/or techniques used in those steps must also be explicitly named in the accreditation scope, especially if they will have a significant effect on the test results.
Any preparatory steps (purification, extraction, destruction, mineralization, etc.) must always be unambiguously linked in the accreditation scope to the subsequent analytical steps. Preferably, these preparatory steps are included and defined in the same test line to which they relate.

c) Whenever **standardised test methods or methods published by the manufacturers of equipment or kits** are used, the accreditation scope will not state the date of issue of the test method used, assuming that the latest version is applied by the laboratory (ISO/IEC 17025, section 7.2.1.3).

The laboratory can apply for accreditation for an 'obsolete' version of the aforementioned methods, provided a thorough argumentation is made. In that case, reference can be made to the standardized test method with an explicit statement

of the year or version number. In accordance with ISO/IEC 17025, section 7.1.2, the laboratory shall inform the customer that it concerns an outdated method (contract review).

The applicable test methods (e.g. testing standards and kit protocols) stated in the accreditation scope must be available in the laboratory.

d) If a **new version** of a standardised test method mentioned in the scope appears, the laboratory must keep records of the measures taken in order to implement and control the new version of the testing standard.

If **the scope of application of the mentioned method or the measuring principles used** change in comparison to the preceding version, the laboratory must immediately inform BELAC of this. BELAC shall then evaluate what measures are to be taken and shall schedule a complementary evaluation, if deemed necessary.

In the case of rather limited changes of the mentioned method, the laboratory shall inform BELAC when requesting the next assessment, during which the records and measures concerning the transition to the new version of the testing standard shall be examined in detail.

e) A laboratory that has been accredited according to a specific testing standard, as issued by a specific standardization institute (e.g. NBN), can also apply testing standards issued by other standardization institutes (e.g. NEN, AFNOR), as long as those testing standards are based on an identical testing principle and scope of application. In order to do that, the laboratory will need to contact BELAC, which shall assess whether (a limited) evaluation will be required for inclusion in the scope.

f) In the case of a specific testing line in the accreditation scope (i.e. a specific combination of matrix and parameter) a reference to several standardised test methods within a single testing line is permitted, on condition that the various methods are based on the same testing principle and area of application.

g) When using **derived methods** (derived from a standardised method), the laboratory shall keep an internal up-to-date overview available for BELAC, listing the points for which deviations from the standardised method are made.

h) When referring **to in-house developed or modified (derived) methods**, the laboratory shall ensure that the (limited) changes or updates to those methods, as well as the reason for updating and the records of the measures taken to control the updated version, are traceable.

In the event of changes in the scope of application of the method or the measurement principles used as compared to the previous version, the laboratory must also immediately inform BELAC.

i) A laboratory may specialize in a group of tests performed on a single **product or a specific group of products** (usually described in general testing standards or product standards).

In the latter case, the scope can state the reference of the general testing standards or product standards, without reproducing the whole list, to the extent that the laboratory can demonstrate its competence to perform all tests in these standards.

j) For examples of accreditation scopes of testing laboratories in a variety of disciplines, reference is made to the BELAC website (www.belac.fgov.be or https://economie.fgov.be/en/themes/quality-and-safety/accreditation-belac/accredited-bodies/testing-laboratories-test).

4.1.2.2. "Flexible" accreditation scope

a) Activities that fall under a flexible scope shall be indicated as such in the accreditation scope.

b) For each test group that forms part of a flexible scope, the following must be specified as a minimum:
   - applied testing technique or testing principle
   - the product or product group
   - the parameter of group of parameters

   In the flexible scope, only reference is made to the testing technique or testing principle. Information regarding the specific test method used must be kept up to date by the laboratory itself for each specific matrix and parameter (in the detailed list of activities, see below). Additional specifications may be mandatory for certain sectors of activity.

c) Within the defined limits of its flexible scope, a laboratory is permitted to make changes or additions in the form of:
   - specific test methods (including methods for the sample preparation extraction, etc.) falling under the testing technique specified in the BELAC accreditation scope
   - specific products and/or specific parameters that fall under the respective group of products or group of parameters mentioned in the BELAC accreditation scope.

   However, a flexible scope will not allow a laboratory to extend the accreditation scope without the intervention of BELAC with regard to:
   - a test method that forms part of a new testing technique or testing principle
   - a different activity centre.

d) For each testing line within the flexible scope (in this case a testing line corresponds to a test group), the laboratory must maintain a detailed, up-to-date list of individual specific tests that fall under that testing line (see section 4.3.1.2).

e) Activities that fall under a flexible scope shall always be accompanied by a specific disclaimer which explicitly states that the laboratory is allowed to carry out the

specific tests that fall under the stated test group with reference to their accreditation, provided that an adapted validation or verification according to a globally documented process as included in the laboratory management system has been performed.

4.1.2.3. Accreditation scope that is partly "fixed" and partly "flexible"

No additional guidelines

4.2 Organisation of assessments in the case of “fixed” scopes

4.2.1 General procedure for evaluation

a) BELAC shall ensure that all disciplines within a accreditation scope are covered during a full accreditation cycle. In that regard, it will be ensured that by means of targeted sampling the main methods within a discipline are evaluated, including aspects such as the competence of the personnel involved and witnessing of the execution of tests.

   During an initial assessment or extension assessment, a sufficient number of methods shall be included in the evaluation of each discipline in the scope. During subsequent surveillance and extension assessments, a selection of disciplines shall be made, based on the assessment programme prepared in advance. This programme may be changed at any time if deemed necessary, taking into account, among other things, changes regarding: the volume of activities, the location, the number of employees or the organisational structure, but also regarding performance when participating in proficiency tests. In that regard, the necessary attention shall be given to any methods that have been changed or updated.

b) The selections of methods for evaluation by the assessment team during an assessment will be based on the laboratory's experience, the technical complexity of the test methods, a risk estimation of possible errors or deviations and (if relevant) a combination of standardised, derived and in house methods. In this regard, a balance shall always be sought between a (complete) witness of the execution of tests on the one hand and the follow-up of reports, validation reports and the performance parameters recorded therein (as well as their compliance with any external and/or legal requirements), quality control reports and the evaluation of the laboratory facilities and equipment on the other hand.

This targeted sampling of evaluation activities must provide sufficient confidence that the activities within the entire accreditation scope will lead to the release of reliable results.

c) The evaluation of the technical competence of the laboratory is an important part of the BELAC assessments and can be demonstrated by means of factors

such as participation in internal and external training courses, collaboration with other organisations working in the same sector and knowledge and experience acquired during the professional career.

Whenever a laboratory is making use of in house or modified (derived) methods, particular attention shall be paid to the technical competence of the responsible personnel designated for this purpose. Alongside the items already listed above, the specific competence relating to method development and validation activities can be demonstrated by means of factors such as participation in standardisation committees, scientific committees or research and development committees.

In this case, technical knowledge relating to the test methods and testing techniques employed, including aspects such as validation and evaluating the suitability of the test methods used and the quality of the results obtained, shall be an important point of attention during the BELAC assessment.

d) Whenever a laboratory refers in its accreditation scope to in house or modified (derived) methods, procedures for the development, validation, approval, implementation and management (including periodic revision) of these test methods shall form a specific point of attention during assessments.

e) Before inclusion in the scope, a laboratory must demonstrate that the relevant test method has been validated and/or that it has been demonstrated through verification that the laboratory is able to perform this method correctly. This validation or verification must be carried out on the basis of a prior selection of the performance characteristics to be determined and the associated well-defined assessment criteria.

The scope of the validation or verification that needs to be carried out will depend on the type of test method (e.g. qualitative versus quantitative methods, quantitative method at high concentration level versus low concentration level…), and already publicly available performance characteristics (e.g. normative test methods).

When a laboratory can demonstrate by means of publicly available performance parameters that the test method has already been sufficiently validated (e.g. for a standardized method), a verification in which an assessment against the available performance characteristics is performed will be sufficient.

For test methods already included in the accreditation scope, the laboratory shall regularly evaluate whether the performance characteristics are still up-to-date (e.g. based on quality control data, after changes in equipment or operating conditions…).

4.2.2 Maintaining a “fixed” scope

See also 4.2.1

4.2.3 "Dormant" activities

Tests that are no longer performed in routine (e.g. due to lack of a sample offer) but for which a laboratory still participates on a regular basis (at least 1/year) in quality controls, which allow a review of the most relevant performance characteristics, are not considered dormant.

4.2.4 Extension of a fixed accreditation scope

a) In order to take into account the technological developments within its field of activity or to be able to respond to the needs of its customers, the laboratory may at any time submit a formal application to BELAC in order to:

- modify or extend test methods, products or parameters already included in its accreditation scope. Based on the proposed modifications, BELAC will examine whether an evaluation (documentary or on site) is required.

  In cases of limited modifications which are closely related to activities for which accreditation has already been granted, BELAC can also make an administrative adjustment of the accreditation scope without a prior evaluation. These activities shall, however, form a point of attention during the next assessment.
- extend its fixed accreditation scope with completely new, specific types of testing
- extend its fixed scope to include other activity centres
- extend or replace its fixed accreditation scope with a flexible accreditation scope (see section 4.3.4 for further details).

b) In each of the aforementioned cases, the laboratory shall submit to BELAC a proposed for the formulation of the new or modified tests or test group(s), based on the valid accreditation scope applicable at that time (a copy of which can be requested at any time from the BELAC file manager).

As part of that submission, the information on activity volume (number of tests on an annual basis), the participation in proficiency tests and results of proficiency tests for these modifications or extensions is completed in the appropriate columns of the accreditation scope.

4.2.5 Sanctions in case of failure to comply with the accreditation conditions

No additional guidelines

4.3 Organisation of assessments in case of a "flexible" accreditation scope

4.3.1 Requirements applicable to conformity assessment bodies that apply for a flexible scope

a) The accreditation for a flexible scope is subject to compliance with special requirements (see below) and the demonstration of an efficient management system and of the acquired experience related to the test group(s) for which a flexible scope is being applied for.

b) In principle, an initial application for a flexible scope will only be possible if the laboratory has already been accredited for a fixed scope in the discipline for which a flexible scope is being applied for. Deviations from this may be allowed, provided that a properly documented and well-founded argumentation is presented.

4.3.1.1 Implementation and management of an accreditation with flexible scope

When applying for a flexible scope, the laboratory shall be required to submit at least the following items for each test group :

- a documented, transparent design/development process for the overall management of the activities that fall under the flexible scope (see BELAC 2-002, section 4.3.1). Specific requirements may be set by BELAC for some sectors of activity.
- validation and/or verification reports of a representative number of specific tests that are exemplary for the test group concerned
- a proposal of formulation for the BELAC scope, in particular with regard to the product group and/or parameter group and the testing technique or testing principle being used. In this regard, the limits of the flexibility must be determined in function of the available competence and resources and the needs of the laboratory and its customers.
- a (concept of a) detailed list of activities belonging to the flexible scope.

The design/development shall define the elements to be taken into account and the steps to be taken to manage an application for a new activity in the context of a flexible scope. As a minimum, the following elements must be taken into account :

- the support from the management for the development of the new activity within the flexible scope
- access to all of the necessary resources to carry out the requested activity
- a description of the implementation modalities for the activity, including an overall, documented validation and/or verification process applicable to the test group
- access to qualified personnel for the development, validation, verification, approval, execution and supervision of the activities; defining the responsibilities for each of the tasks to be performed in the management of a flexible scope, including the management of the detailed list (see below).

4.3.1.2 Detailed list of activities

- The laboratory must have a list of specific tests carried out under accreditation within the framework of the flexible scope.

- This list will detail for each specific test at least the same information as required for the description of a fixed scope. Additional specifications may be mandatory for certain sectors of activity.
- On the basis of this detailed list, it must be possible to demonstrate undeniably from which moment on the specific test has been reported under accreditation; the basis on which this decision was made must also be fully traceable..
- This list must be publicly available and the accreditation scope issued by BELAC must refer to this list.
- This list must be made available to BELAC or any other interested party whenever requested. In any case, this list must be submitted to BELAC before any planned renewal or surveillance audit.
- The inclusion of a new test in the list shall only be possible after all necessary steps to demonstrate that the activity in question is under control and leading to reliable results have been taken and formal approval by management has been obtained.

4.3.1.3 Contract review and service to the customer

The laboratory shall develop, document and implement a contract review process that allows to process an customer request for a test that is included within its flexible accreditation scope but has not been performed before (i.e. not yet included in the detailed list).

The contract review process shall foresee in confirmation to the customer whether or not an application falls within the limits of the organization's flexible accreditation scope.

The contract review process shall also ensure that:

- The customer will be informed that the effective execution of the test and subsequent issuance of a test report under accreditation may only occur after the design/development process has been completed and the formal update of the list of activities has been completed;
- the term of execution and the price are communicated clearly.

4.3.2 Evaluation procedures

The provisions under section 4.2.1 shall also be applicable here. Only additions specific to the flexible scope will be stated here.

a) In addition to the items already listed under section 4.2.1, particular attention during the BELAC assessment shall be paid to:
   - the competence, qualifications and continuous training of staff who bear responsibility with regard to the development, approval and management of test methods within the flexible scope

- the performance level provided by the equipment concerned
- the presence of adequate technical procedures and required legal documents;
- the validation and verification process for modifying or adding methods under the flexible scope and registrations with regard to completion of these processes
- the list of the specific, individual tests that fall under the flexible scope and for which the validation or verification process has been completed, with a special focus on the activities that have been added or modified since the previous assessment. It will also be assessed whether the link between the BELAC scope, the detailed list of the laboratory and what is reported to the customer is sufficiently unambiguous and transparent.
- the performance level of the management system and the overall organisational aspects regarding the management of the activities that fall under the flexible scope. The following aspects shall be taken into consideration in that regard: contract reviews and information provided to the customer, internal audits, management reviews, training and declarations of competency, measurement uncertainty, equipment and traceability, participation in proficiency tests and internal quality controls and reporting to the customer
- the identification of risks associated with laboratory activities covered under the flexible scope
- the supervision of less frequently performed activities.

b) For each test group, the assessor shall make a selection and carry out an evaluation of the most representative and critical tests and the corresponding equipment. The following will be taken into account as criteria for the selection:
   - the degree of complexity of the measurement technique
   - the extent of the consequences associated with an incorrect test result
   - the frequency of execution of the activities

The assessor will evaluate concrete examples of activities for which the laboratory has implemented its flexible scope management process.

4.3.3 "Dormant" activities

With regard to the management of its flexible scope, a laboratory shall also describe how to manage the tests on the detailed list which are no longer performed in routine and should be considered as dormant.

4.3.4 Extending an accreditation with a flexible scope

In order to take into account the technological developments within its field of activity or to be able to respond to the needs of its customers, the laboratory may at any time submit a formal application to BELAC in order to:

- extend its scope to include one or more test groups
- extend its scope to include other activity centres

An initial application for the extension towards a flexible scope shall be followed by the organisation of an on-site assessment, during which, in addition to a technical evaluation, due attention will be paid to the management and control aspects related to the flexible scope.

An application for extension must contain sufficient information regarding the activities for which the extension is being requested (see also the last paragraph under section 4.2.4) and shall be examined by BELAC, which, depending on the nature of the application file, shall organise, as a minimum, a documentary assessment and if applicable, an on-site assessment.

4.3.5 Sanctions in case of failure to comply with the accreditation conditions

No additional guidelines
