1. SCOPE

This guideline only applies to accredited test laboratories and medical laboratories that require flexible accreditation scope. This guideline does not apply to calibration laboratories. This guideline regulates the NBE policy for a more flexible way of identifying the accredited test scopes, and does not lead to the possibility of publication of the uncertain accreditation scopes. Where special and / or additional requirements are stipulated by legal authorities (regulations, standards, etc.), these requirements shall be complied with.

2. RELATED DOCUMENTS

- ISO/IEC 17025 General Requirements For the Competence of Testing and Calibration Laboratories
- ISO 15189 Medical laboratories –Requirements For Quality and Competence
- EA-2/15 EA Requirements For the Accreditation of Flexible Scopes
- ILAC-G18 Guideline for the Formulation of Scopes of Accreditation for Laboratories
- JGM 200:2012 VIM, International Vocabulary of Metrology – Basic and General Concepts and Associated Terms
- ISO/IEC 17011 Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies
- PR-7-01 Procedure for the Accreditation of Conformity Assessment Bodies
- G-2-43 Guideline on Accreditation of Laboratories

3. DEFINITIONS AND ABBREVIATIONS

3.1 Definitions

Fixed (non flexible) accreditation scope: Scope parameters (tested materials/products, name of test, testing method) are fixed in the fixed (non flexible) accreditation scope however, it can be changed based on application and after NBE assessment is carried out and the scope is approved by NBE.

Flexible accreditation scope: Flexible accreditation scope means that a laboratory can make changes in accreditation scope without performing an additional assessment by NBE. The relevant changes can be performed to apply permanently or on a single work.

Non-standard methods or in-house methods: Methods developed by a laboratory or by a third party or validated by adapting standard methods.

Standard methods: Methods developed by a standardization organization or an expert

organization in their field and adopted by the relevant sector (e.g. TS, EN, ISO, IEC, FAO, AOAC, SM, NMKL, EPA, FDA, ASTM etc.).

Verification: Obtaining clear evidence that an element meets the requirements

Example 1 Confirmation that a reference material is homogeneous to a mass of 10 mg, for a given measurement procedure and size value.

Example 2 Confirmation that a measuring system meets performance characteristics or legal requirements.

Example 3 Confirmation of accessibility to a targeted measurement uncertainty.

Example 4 The medical laboratory using the commercial kit proves that the measurement system performance characteristics of the commercial kit manufacturer organization are provided under its own laboratory conditions.

Validation: Verification of suitability of specified conditions for intended use

Example 1 The measurement procedure for measuring the mass concentration of nitrogen in water can be validated for use in measurements in the serum.

Example 2 If a laboratory has configured the measurement system itself or has made modifications to the measurement system of the commercial kit it has purchased, it must validate all performance characteristics of the measuring system according to the accepted target dimensions.

3.2 Abbreviations

LAAT: List of Additionally Accredited Tests
VIM: International Vocabulary of Metrology
JCGM: Joint Committee for Guides in Metrology
ISO: International Organization for Standardization
IEC: International Electrotechnical Commission
FAO: Food and Agriculture Organization
AOAC: Association of Official Agricultural Chemists
FDA: Food and Drug Administration
NMKL: Nordic Committee on Food Analysis
EPA: Environmental Protection Agency
ASTM: American Society for Testing and Materials

4. INTRODUCTION

Fixed accreditation scope includes a definitive description of the laboratory's proficient tests and the competence of the laboratory for each new experiment to be included in the scope shall be evaluated with an assessment. On the other hand it is seen that there is a need to establish mechanisms that allow laboratories to expand their scope based on the method development and validation/verification competencies of the laboratories assessed before.

This guideline sets out the general requirements within NBE to enable an accredited laboratory to assume responsibility for the management of all or part of its scope of accreditation without the necessity of an on-site assessment by the accreditation body for each new activity. In doing so not only the responsibilities of the accreditation body and the laboratory at the same time it also takes into consideration the needs of customers who benefit from the accredited activity.

Laboratories will be asked to analyze their flexible scope needs before requesting accreditation of flexible scope. Additional work required to develop, implement and maintain an expanded management system required by flexible scope will be evaluated only if the need for such flexibility is clearly demonstrated by the laboratory.

Accreditation of flexible scope permits a laboratory to perform certain tests and to declare accreditation for these experiments, even if it is not explicitly stated in the scope of accreditation. NBE determines that the accreditation of flexible scope will be given in which areas/sectors in test and medical laboratories.

This guideline describes how laboratories that require flexible aaccreditation scope control the management system and how the tests added to List of Additionally Accredited Tests (LAAT) that validated/verified and approved according to the defined system shall be shown. It also explains how NBE evaluates laboratories that want to accredited with flexible scope. The laboratory requesting flexible scope will be asked to prove the followings:

- Fixed scope is very restrictive in terms of the work already undertaken by the laboratory
- The management system will check the flexible scope in accordance with all the requirements specified in this guide, all tests are performed in accordance with accreditation requirements
- The laboratory has the technical competence and sufficient experience to support flexible scope

This system is based on the List of Additionally Accredited Tests (LAAT) used in conjunction with the accredited scope of the laboratory. Additional experiments that the laboratory declares for accreditation through flexible scope are recorded from the last NBE assessment. Experimental materials / products and parameters / analytes, test or examination technique and method for

the test laboratories and medical laboratories are recorded in this document.

5. FIXED ACCREDITATION SCOPE AND FLEXIBLE ACCREDITATION SCOPE

5.1 Fixed Accreditation Scope

All sub-items in the scope are fixed within the fixed accreditation scope and it can only be changed by NBE depending on the application.

5.2 Flexible Accreditation Scope

Fixed accreditation scope is generally sufficient to meet the requirements of laboratories that make routine analysis of certain test materials. However, although some laboratories have routinely used methods / procedures, these applications will not always be known in advance. For example, a customer may request a method for the new material/product or measured matter that is not verificated/validated. Under these circumstances, when a consistent request is made within the limits of flexible accreditation scope, the laboratory may apply the development/ explication and verification/ validation process of present accredited methods. This process must follow a predefined protocol to confirm the fitness for purpose of the new application.

Flexible accreditation scope means that the laboratory can declare accreditation for changes in accreditation scopes without making assessment. These changes may be carried out either permanently or for a single study.

The changes to be made within the framework of the flexible scope can only be carried out based on the flexibility parameter which has been previously assessed and accredited by NBE. The use of flexibility requires that the laboratory perform validation or verification activities for each change. The laboratory presents all validation or verification activities and the current LAAT to NBE and informs the case officer before making any changes in the scope of flexible accreditation. The laboratory may prepare reports in accredited scope after the LAAT is published on websites of NBE and the laboratory.

5.3 Definition of Scope Parameters

The accreditation scope of the laboratory is attached to the accreditation certificate and refers to the following items.

5.3.1 Flexibility for Materials and Products Tested

The flexibility in this area allows changes in tested product or material in product group that is currently accredited, by using the same experimental techniques. For example, cadmium

analysis in fruit and fruit products by using atomic absorption spectroscopy can be changed to cadmium analysis in grain and bakery products by using the same method. Another examples is mechanical tests for the various components of automotive applications (eg wheels and tire suspensions).

5.3.2 Flexibility for Test Parameters

Flexibility in this field allows to make changes in the test parameters and the test field that the laboratory accredited by using the same test techniques and test types. For example, a laboratory that is accredited in cadmium determination in food products by using atomic absorption spectroscopy can add the determination of other trace metals in food products to LAAT.

5.3.3 Flexibility for Method Performance

Flexibility in this field allows to make changes in a given test parameter (feature/analytical parameter) or a method performance for test parameters and a specific test field that the laboratory accredited by using the same test techniques and test types. When there is a change in the method performance of a specific parameter in medical laboratories, this change is expected to meet the medical requirements of the test. Flexibility allows changes related to method performance. The variation of the measurement range is a sample method performance change.

The change in pipe diameters tested in the determination of the resistance to the inner pressure in polyethylene pipes can be given as an example for flexibility in method performance.

5.3.4 Flexibility for Test Method

Flexibility in this field allows to add technical equivalent standard methods to the standards currently in the accreditation scope. In some sectors, laboratories specialize in certain tests according to standard methods determined by the customer. In fixed accreditation scope laboratory shall prove its competence for each standard method. However, in some cases, the customer may request that the test be carried out according to a national or a similar standard, altough it is not accredited by NBE. Even if there are one or more minor differences in the parameters (time, temperature, pressure, etc.), the test requested by the customer may be considered as technical equivalent to the accredited test of the laboratory, although there are possible exceptions. When such a situation occurs, the laboratory shall determine the key differences between the tests by properly reviewing the new standard method corresponding to

the method to which it is accredited and shall show that they are within the flexible scope. After this stage, the laboratory can perform the authorization required for the use of the test. The using of ISO 10523 test method can be given as an example of the addition of technical equivalent standard methods.

Note: The names of parameters in the field of test and medical test may vary due to the differences in methodology in the field of Test and Medical Test.

6. REQUIREMENTS FOR ACCREDITATION OF LABORATORIES FOR FLEXIBLE SCOPE

There is a need for a complete technical understanding of the methods and techniques used to develop new or modified methods. This understanding can be achieved by taking part in relevant research and development projects, by participating in method development studies, or by gaining extensive experience in the relevant field of tests. In addition to the general requirements for accredited tests, the laboratory shall extend and adapt the quality system in accordance with the desired accreditation by taking into account the complexity of the test technique and the number of test parameters expressed in Clause 6.

The laboratory shall prove that it has sufficient reliability related to the technical capacity in the areas to perform the test in accordance with all requirements of the related accreditation standard and NBE rules.

6.1 Accreditation Requirements for Flexible Scope

The laboratory's quality management system must meet the following requirements to be accredited for flexible scope:

a) The laboratory shall have at least 4 years of experience in the field of desired flexible scope in performing tests which adequately represent the test areas intended to be accredited. The laboratory shall have sufficient experience in validating the test methods.

b) The laboratory shall be able to obtain acceptable test results in internal and external quality assurance controls and NBE assessments.

c)The laboratory shall have the necessary testing equipment to be able to work in the test areas intended to be accredited.

d) Laboratory management shall assigned staff with technical competence to key responsibilities, including the development and revision of test methods, validation of methods, and the obligation to implement new and revised methods. Staff shall have at least 4 years experience in the field of flexible scope. All changes in the critical personnel (Laboratory manager, quality manager, authorized personnel in the field of flexible scope) shall be notified to NBE within 15 days. In the cases where the laboratory is authorized in the relevant flexible accreditation scope and the technical competence of the laboratory has been compromised as a result of the change, the relevant flexible accreditation scope of the laboratory may be suspended and/or withdrawn.

e) The laboratory shall establish a validation and verification strategy in accordance with the technical nature and the magnitude of the areas of required flexible accreditation. The laboratory shall establish criteria for the acceptance of validation / verification results, shall approve that the method is suitable for the intended purpose and shall document how to inform the customer about the results of validation / verification.

Note: The above strategy may consist of more detailed validation / verification procedures for certain classification groups or parameters as well as a general procedure of validation / verification.

f) The laboratory may define different testing fields and determine different validation levels. In some cases, validation can be more comprehensive to determine all method characteristics and may require different degrees of partial validation when a new product is added to a previously validated product group. Similarly, the size of the additional scope may require a validation study that is less comprehensive than the original one.

g) Validation plans shall be prepared for all method changes applied within the scope of flexible accreditation. The validation results shall be documented in a report. The report shall be approved by personnel responsible for the validation.

h) The laboratory shall record all changes under the flexible accreditation scope. These records shall also include unapproved studies, and shall be comprehensive and detailed enough for the evaluation of the processes followed and the decisions taken in internal and external audits. These records shall demonstrate that the laboratory has carried out all the necessary activities efficiently before publishing the test reports.

i) There shall be at least one person responsible for all validation / verification study. The responsible person or persons shall submit evidence that they have experience of developing

independent methods in the field of study and have competence in the theoretical fields and application areas of the following items:

i. Being able to control the appropriateness of the method, including the aspect of meeting the customer needs,
ii. Being able to prepare a specific validation / verification plan,
iii. Being able to determine the method performance and create an uncertainty budget for measurement.

6.2 Laboratory Records

The records of the laboratory shall include as a minimum;

a) Evidence of activities carried out for revision, adaptation and extension of test methods in flexible scope,

b) Changes made in flexible scope,

c) Whether the change is permanent or not,

d) The date on which the change will be applied,

e) For which work it will be applied, if the change is not permanent,

f) Validation and / or verification reports,

g) Name and position of personnel responsible for validation / verification,

h) Authorization and application records for the test,

i) **Critical personnel** training.

j) Approve of legal authority, if applicable

The laboratory may issue reports under the accreditation following the sending e-mail of the above records to NBE website and publishing the current version of LAAT on NBE and the websites of the laboratory.
In case of LAAT is not published on the NBE website because of confidentiality requirements, the laboratory may issue reports after informing NBE case officer and making necessary editings in LAAT.

6.3 Request, Proposals and Contracts within the Flexible Scope of Accreditation

The procedure for evaluating requests, proposals and contracts shall include features that could be applied to flexible scope of accreditation. In the absence of a program

for the requested test, the laboratory shall inform its customer about:

a) The requirements for test request (turnaround time, price, etc.)

b) The possibility that the laboratory may not be able to issue an accredited test result depending on the outputs of the validation studies.

6.4 Flexible Scope Procedure

A procedure indicating the steps to be followed when an application is submitted to the experiments not previously done by the laboratory shall be established. Such a procedure must meet the following requirements:

a) All reference materials, equipment and other means necessary for carrying out the test shall be available in the laboratory.

b) Personnel with appropriate qualifications and experience to perform the test shall be available in the laboratory.

c)Responsibilities for each activity shall be assigned.

d) The necessary validation and / or verification activities shall be carried out according to the procedures established by the laboratory.

e) Appropriate test procedures shall be approved.

f) New tests must be added to the LAAT after approval.

g) A test report shall be prepared, after the related documents and the current version of LAAT are published on the website of NBE and the laboratory,

h) New methods or procedures for changing and replacing existing methods shall not include new measurement principles which are not included in the scope of flexible accreditation of the laboratory. In such additions, the laboratory shall apply to NBE for on-site scope extension assessment.

i) If there is no qualification for publishing the laboratory's accredited test reports as a result of the validation / verification process, the report shall not be prepared, the cause / reason analysis and examinations shall be made and sufficiency of the corrective actions shall be ensured. These activities shall cover:

i. The laboratory shall inform the customer that it is not being able to publish an accredited report in the relevant examination and subsequent activities.

ii.Revisions of the relevant procedures or methods shall identify the technical problem associated with this experiment.

iii. The details of the problem, details of the examination and the results of the examination shall be kept by the laboratory.

All tests of the laboratory's management system within the flexible scope of accreditation shall include internal and external quality control activities:

i. The internal audit carried out in the applied system must meet all the requirements of this guideline and also ensure implementation records and effectiveness.

ii. Procedures and plans for activities to develop test methods, to create new methods or to revise methods, related responsibilities and risks shall be included in internal audit.

iii. Management review shall include the effectiveness and relevance of the system established to control flexible scope.

iv. External quality control studies (Proficiency Tests, Interlaboratory Comparison etc.) shall comprise the change made in the scope.

7. APPLICATION AND PRE-EVALUATION PROCESS FOR FLEXIBLE ACCREDITATION SCOPE

Laboratories that complying with the requirements of this guideline and meeting all the following requirements related to the test field intended to be accredited may apply for flexible accreditation.

The laboratory presents the following documents to NBE;

- The laboratory presents a summary of its experience and competence for method development and validation that has carried out in the field which wants to apply.

This summary shall contain the list of validated/verified products/materials/matrix and tests in the application field.

- The laboratory shall present the number of samples analyzed and experience time for each year to demonstrate the experience of the flexible scope in the test fields requested.

- The laboratory shall submit internal and external quality control results, including results of proficiency testing and / or interlaboratory comparisons for experiments in fields where flexible scope is requested.

- The laboratory shall establish a document that demonstrates the necessity of flexible scope. In this document the laboratory expresses that the fixed scope is restrictive in serving the needs of its customers and flexible accreditation shall be able to express the needs better. NBE examines the documents presented and evaluates the compliance of the flexible scope fields requested with the requirements of this guideline. NBE determines the suitability of the

flexible accreditation scope for the needs of the laboratory and its customers, whether the laboratory has adequate experience on the requested scope flexibility or not and informs the laboratory about the result of the application.

8. IMPLEMENTATION

When the laboratory's preliminary evaluation is found successful by NBE, the laboratory is informed. The laboratory fills out the application form for flexible scope and offers the following documents together with the form:

- The documents defines how the process is carried out by the laboratory in order to meet the demands from the customer for the tests in the requested flexible scope that have not been carried out by the laboratory before
- Validation / verification procedures for the test field applied
- Test procedures and instructions
- List of assigned critical personnel for test method development, validation, revision, expansion and authorisation

Application documents must be delivered to NBE at least 3 months before the on- site assessment. Evaluation of all technical documentation, including those listed above, is carried out before the assessment. Revisions or deficient aspects are requested by NBE if necessary. NBE evaluates the conditions of the laboratory and gives essential information about the organization's flexible scope application.

9. FLEXIBLE SCOPE ASSESSMENT

Additional time is required for NBE assessment for laboratories that apply for flexible accreditation. On regular visits and in all cases where it is necessary, NBE evaluates the adequacy of the laboratory in relation to the flexible scope.

NBE monitors the following activities in the assessment:

- Implementation of management system
- Evaluation of the personnel competency responsible for the validation of methods pplied in flexible scope, including interview and curriculum vitae
- Performing selected tests carried out in flexible scope (The selection criteria of tests are the level of complexity of the test techniques, the frequency of the test methods, etc.)

10. PUBLISH THE FLEXIBLE ACCREDITATION SCOPE

The flexible accreditation scope can be given alone or with fixed scope by NBE. The flexible

accreditation scope is published on the NBE website. Scope examples are given in Appendix-A.

The laboratory send e-mail the related records, informs the NBE case officer and the current status of the List of Additionally Accredited Tests on the NBE website before making any changes in flexible accreditation scope and the current version of LAAT is published on the NBE website.

In case LAAT covers information that shall not be shared with the public due to the confidentiality principle considering the requirements of international institutions and organizations, it may be possible to block access the relevant document from the NBE website.

11. MAINTAINING THE ACCREDITATION

The implementation and effectiveness of the management system established by the laboratory on flexible scope issues are assessed in accreditation assessments. The laboratory shall provide evidence of its technical competence and the established management system.

The laboratory shall send the following documents to the NBE e-mail before making changes in the flexible scope.

- List of Additionally Accredited Tests (LAAT)
- Validation records of test or method changes in flexible accreditation scope after the on-site assessment,
- Pivot table showing validation studies for each method change

This table shall include at least;

- Method title and reference number
- Date of change
- Name and title of the personnel authorized to make changes
- Descriptive summary information for the change (for example; “copper added”, “fruit product added” etc.)

The following method performance characteristics which are applicable shall be used for the method changes and modifications. If these characteristics are not used, the reasons for not being used shall be stated:

- Precision
- Accuracy
- Limit of Detection
- Limit of Quantification

- Linearity
- Selectivity
- Robustness
- Analytical reference range (for medical laboratories)

In the following process, NBE examines the validation records of the added tests to the LAAT and the implementation in accordance with the relevant procedures of the management system, if NBE finds them appropriate, the scopes are included in the approved scope of the laboratory. If it is determined that; the laboratory can not maintain the management system, flexible scope changes are not made properly or are not declared without complying with the conditions in this guideline; the accreditation decision shall be submitted to the decision board in order to decide partial or complete suspension, withdrawn or reduction of the flexible accreditation scope and/or the the entire accreditation scope in accordance with the written proposal of the assessment team and/or the relevant case officer,

12. LIST OF ADDITIONALLY ACCREDITED TESTS (LAAT)

LAAT is the additional tests that the laboratory serves within the flexible scope after the necessary checks are performed by the laboratory. An example of List of Additionally Accredited Tests is given in appendix-C.

The list is publicly available and includes the following information:

- Name and address of the laboratory
- NBE file number of the Laboratory
- Title: List of Additionally Accredited Tests
- LAAT's revision number
- Test areas which the laboratory is authorized to implement within the scope of flexible accreditation
- Categories of additional tests and properties of the analyte (eg trace metals, pesticides) in all test areas requested through laboratory scope
- Date of addition of material, product, analyte, or method to LAAT
- Test technique for each test area or reference method or measured property corresponding to each test method
- Measuring range and / or detection limit (when applicable)
- For Medical Laboratories "Reportable Range" between Quantitation Limit and Linearity Limit, (if applicable)
- Date of publication on NBE website

APPENDIX A (INFORMATIVE)

Various flexible scope examples are given below:

TABLE 1: FLEXIBLE SCOPE EXAMPLE FOR TESTED MATERIALS AND PRODUCTS

TESTED MATERIALS / PRODUCTS	NAME OF TEST	TESTING METHOD (NATIONAL, INTERNATIONAL STANDARDS, IN HOUSE METHODS)
[1]Milk Powder	Detection of *Cronobacter* spp.	ISO/TS 22964
[1]Hazelnut Paste	Determination of Aflatoxin B1 and total aflatoxins (B_1, B_2, G_1, G_2)	AOAC 991.31

Flexible Scope: In accordance with approved and documented procedures and in accordance with the same measurement technique, the laboratory can use flexible scope parameters below that are marked on its scope. For details, see the List of Additionally Accredited Tests fort he laboratory on NBE website www.nbeglobal.org.

[1]Laboratory may add new materials/products on its scope.

[2]Laboratory may add new test parameters on its scope.

[3]Laboratory may do modifications on test method performance.

[4]Laboratory may add equivalent test methods on its scope.

TABLE 2: FLEXIBLE SCOPE EXAMPLE FOR TEST PARAMETERS

TESTED MATERIALS / PRODUCTS	NAME OF TEST	TESTING METHOD (NATIONAL, INTERNATIONAL STANDARDS, IN HOUSE METHODS)
[2]Food	Determination of lead and cadmium	NMKL 186
[2]Feed	Determination and quantification of Pesticides 2,4'-DDT, 4,4'-DDD, 4,4'-DDE, 4,4'- DDT	AOAC 2007.01

Flexible Scope: In accordance with approved and documented procedures and in accordance with the same measurement technique, the laboratory can use flexible scope parameters below that are marked on its scope. For details, see the List of Additionally Accredited Tests fort he laboratory on NBE website www.nbeglobal.org.

[1]Laboratory may add new materials/products on its scope.

[2]Laboratory may add new test parameters on its scope.

[3]Laboratory may do modifications on test method performance.[4]Laboratory may add equivalent test methods on its scope.

TABLE 3: FLEXIBLE SCOPE EXAMPLE FOR METHOD PERFORMANCE CHANGE

TESTED MATERIALS / PRODUCTS	NAME OF TEST	TESTING METHOD (NATIONAL, INTERNATIONAL STANDARDS, IN HOUSE METHODS)
[3] Thermoplastics pipes	Determination of the resistance to internal pressure Ø 16mm- Ø 1000mm	ISO 1167-1
[3] Thermoplastics corrugated pipes	Determination of ring stiffness Ø100 mm- Ø1400 mm	ISO 9969

Flexible Scope: In accordance with approved and documented procedures and in accordance with the same measurement technique, the laboratory can use flexible scope parameters below that are marked on its scope. For details, see the List of Additionally Accredited Tests fort he laboratory on NBE website www.nbeglobal.org.

[1]Laboratory may add new materials/products on its scope.

[2]Laboratory may add new test parameters on its scope.

[3]Laboratory may do modifications on test method performance.

[4]Laboratory may add equivalent test methods on its scope.

TABLE 4: FLEXIBLE SCOPE EXAMPLE FOR TEST METHOD (TECHNICAL EQUIVALENT STANDARD)

TESTED MATERIALS / PRODUCTS	NAME OF TEST	TESTING METHOD (NATIONAL, INTERNATIONAL STANDARDS, IN HOUSE METHODS)
[4] Food and Feed	Detection of *Salmonella* spp.	ISO 6579 AOAC 2013.02
[4] Cereals and Cereal Product	Determination of Humidity	ISO 712

Flexible Scope: In accordance with approved and documented procedures and in accordance with the same measurement technique, the laboratory can use flexible scope parameters below that are marked on its scope. For details, see the List of Additionally Accredited Tests fort he laboratory on NBE website www.nbeglobal.org.

[1]Laboratory may add new materials/products on its scope.

[2]Laboratory may add new test parameters on its scope.

[3]Laboratory may do modifications on test method performance.

[4]Laboratory may add equivalent test methods on its scope.

TABLE 5: FLEXIBLE SCOPE EXAMPLE FOR TESTED MATERIALS/PRODUCTS AND TEST PARAMETERS

TESTED MATERIALS / PRODUCTS	NAME OF TEST	TESTING METHOD (NATIONAL, INTERNATIONAL STANDARDS, IN HOUSE METHODS)
[1,2]Food Cereal products Meat and meat products Fish and fish products Dairy products Fruits and vegetables Beverages Bottled water Fats and oils	Determination and quantification of some selected pesticides GC-MS or GC-MS/MS, LC-MS/MS Method (Active substances analyzed….)	1) AOAC 2007.01 2) SOP No:…. if the method is modified ; SOP No: (Modified from AOAC 2007.01)
[1,2]Fruits and vegetables High water content (Drupe, pome fruit, citrus fruits, fruity vegetable, grape, tuberous vegetable, tiny fruits, legumes, leafy vegetables, fresh grass, miscellaneous (including tropical fruits according to EC 396/ 2005, EC 187/2006 regulations)	Defining Residue: GC/ NPD/ ECD/MS method Categories: Orgonophosphates, amides, triazoles, organochlorides, pyrethroids, triazines, dinitroanilines, strobilourinl Pesticides: bromopropylate, carbaryl fenarimol	In-house Chromatographic Multicile Method Rev.03
[1,2] Cereals and Bakery Products	Determination of Lead and Cadmium (GF-AAS method)	In house method (ENS16) Rev.02
[1,2] Meat and animal based products (Not processed, processed)	Qualitative Analysis Determination of presence/ absence of genomic DNA by using Real Time PCR species identification Cattle, Pig, Sheep, Horse, Chicken, Turkey, Goat	Real Time PCR amplification method Rev.03 as documented in house
[1,2] Food / Food Products / Feed Ground soybean, rapeseed oil and grain based food and feed material	GMO Species identification and Quantification	Methods, published for GMO analyses by JRC and verified by using ABI 7900HT RT-PCR on flexible scope

Flexible Scope: In accordance with approved and documented procedures and in accordance with the same measurement technique, the laboratory can use flexible scope parameters below that are marked on its scope. For details, see the List of Additionally Accredited Tests fort he laboratory on NBE website www.nbeglobal.org.

[1]Laboratory may add new materials/products on its scope.

[2]Laboratory may add new test parameters on its scope.

[3]Laboratory may do modifications on test method performance.

[4]Laboratory may add equivalent test methods on its scope.

TABLE 6: FLEXIBLE SCOPE EXAMPLE FOR TESTED MATERIALS/PRODUCTS, TEST PARAMETERS, TEST METHOD PERFORMANCE AND TEST METHOD (TECHNICAL EQUIVALENT STANDARD) CHANGE

TESTED MATERIALS / PRODUCTS	NAME OF TEST	TESTING METHOD (NATIONAL, INTERNATIONAL STANDARDS, IN HOUSE METHODS)
[1,2,3,4] Baby formula	Detection of Vitamine B_2 HPLC-FLD Method	In-house method (ENS13) Rev.00
[1,2,3,4] Any material/product	DNA Isolation	Manuel or automated isolation and documented as in-house method - Qiagen (Qiasymphony) - Qiagen DNA Invesitgator - Qiagen Maxi Kit - Chelex - Phenol Chloroform
[1,2,] Cereal and bakery products	Determination of lead and cadmium (GF-AAS method)	In-house method (ENS16) Rev.01

Flexible Scope: In accordance with approved and documented procedures and in accordance with the same measurement technique, the laboratory can use flexible scope parameters below that are marked on its scope. For details, see the List of Additionally Accredited Tests fort he laboratory on NBE website www.nbeglobal.org.

[1]Laboratory may add new materials/products on its scope.

[2]Laboratory may add new test parameters on its scope.

[3]Laboratory may do modifications on test method performance.

[4]Laboratory may add equivalent test methods on its scope.

TABLO 7: FLEXIBLE SCOPE EXAMPLE FOR MEDICAL LABORATORIES

PRODUCTS OR SUBSTANCES TESTED / EXAMINED	EXAMINATION / TESTING TYPES, TECHNICAL FIELD, PARAMETERS / ANALITIC METHODS	TESTING METOHOD (NATIONAL, INTERNATIONAL STANDARDS, IN-HAUSE METHODS (SOP) / USED TECHNICS, EQUIPMENTS
Clinical Biochemistry		
[2]Blood, Serum, Plasma, Urine	Glucose BUN Creatine Kinase Ammonia	Enzymatic, photometric
[2]Serum, Plasma, Urine, CSF	Total protein Inorganic phosphorus	Photometric
[1,2]Serum, Plasma	ApoB Digoxin IgM Kappa light chain	Immunochemical (Immunoturbidimetric)
Hematology		
[1,2,3]Blood, EDTA-Blood, Citrate-Plasma, CSF	HLA-B27	Flow cytometry Blood cell count
Immunology		
[2,3]Serum, Urine, Liquid	Anti Gliadin IGA	Enzyme immunoassay Particle agglutination
Microbiology (bacteriology, mycobacteriology, mycology, parasitology)		
[1,2,3,4] Body fluid, Serum, Saliva, Gaita, Blood culture	Total beta - hCG	PCR, ELISA, Microscopy

Flexible Scope: In accordance with approved and documented procedures and in accordance with the same measurement technique, the laboratory can use flexible scope parameters below that are marked on its scope. For details, see the List of Additionally Accredited Tests fort he laboratory on NBE website www.nbeglobal.org.

[1]Laboratory may add new materials/products on its scope.

[2]Laboratory may add new test parameters on its scope.

[3]Laboratory may do modifications on test method performance.

[4]Laboratory may add equivalent test methods on its scope.

ANNEX-B (INFORMATIVE)

TABLE 8: COMPARATIVE TABLE OF FLEXIBLE AND FIXED SCOPE

ACCREDITATION SCOPE	FLEXIBLE	FIXED
Adding new material / product / sample / sample type add (vegetable, fruit, cereal, blood, plasma, urine, CSF, cell)	Yes	No
Applying new measurement technique / principle (e.g. using LC- MS instead of GC-MS in a test or using the HPLC method instead of immune measurement for an analysis)	No	No
Adding new analytes / parameters to the method used	Yes	No
Replacement or renewal of analyzer/instruments	Yes	No
Switching tests between instruments / analyzers	Yes	No
Replacing reagents, control samples and calibrators (for medical laboratory)	Yes	No
Using technical equivalent method	Yes	No

ANNEX-C

LIST OF ADDITIONALLY ACCREDITED TESTS

NBE New Business Education ACCREDITED BODY NBE-TL-000	**LAB.** **PRIVATE FOOD CONTROL LABORATORY** **Accreditation Nr: NBE-TL-000** **LAAT Revision Nr: 00** **Date: 17 June 2017**
As a Testing Laboratory	
Address:	**Phone :** **Fax :** **E-Mail :** **Website :**

TESTED MATERIALS / PRODUCTS	NAME/CATEGORY OF TEST AND ANALYTE SPECIFICATIONS	TESTING METHOD (NATIONAL, INTERNATIONAL STANDARDS, IN HOUSE METHODS), TEST TECHNIQUES/ MEASURED CHARACTERISTICS
[2]Food	**(Date:xx/xx/20xx) Determination of copper is added.**	NMKL 186
[1,2]Food **(20.11.2014)** **Dietary products are added.**	Determination and quantification of some selected pesticides LC-MS/MS Method **(Date:yy/yy/20xx) (Amethryn, Atrazine) are added.**	QuEChERS Method Journal of AOAC international Vol: 90, No: 2

Flexible Scope: In accordance with approved and documented procedures and in accordance with the same measurement technique, the laboratory can use flexible scope parameters below that are marked on its scope. For details, see the List of Additionally Accredited Tests fort he laboratory on NBE website www.nbeglobal.org.

[1]Laboratory may add new materials/products on its scope.

[2]Laboratory may add new test parameters on its scope.

[3]Laboratory may do modifications on test method performance.

[4]Laboratory may add equivalent test methods on its scope

REVISION HISTORY:

PAGE NO:	REVISION NO:	CAUSE OF REVISION: