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TITLE **REQUIREMENTS FOR ACCREDITATION WITH FLEXIBLE SCOPE - TESTING LABORATORIES, MEDICAL LABORATORIES, CALIBRATION LABORATORIES, PROFICIENCY TESTING PROVIDERS (PTPs)**

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THE DIRECTORS OF THE DEPT. OF TESTING LABS & THE DEPT. OF CALIBRATION LABS

APPROVAL

THE DIRECTIVE COUNCIL

AUTHORIZATION

THE PRESIDENT

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1. INTRODUCTION

The description of the activities for which accreditation has been granted to a testing laboratory or to a medical laboratory, or to a PTP (hereafter also referred to as CAB) is reported in the field of accreditation, which shall be available to the client, to other interested parties and to the market in general.

The field of accreditation shall be defined clearly and precisely in order to identify the activities covered by it. In order to do this, the accreditation field is defined by ACCREDIA in detail and is reported in the document attached to the accreditation certificate. In particular:

- **For testing laboratories**, the test is fully reported in terms of test material/matrices/products, measurands/parameters to be determined, test methods and test categories.
- **For medical laboratories**, the test is fully reported in terms of the sample on which it is performed, the specific name of the test, the technique on which the test procedure is based, the reference to the test procedure/method with relative update status or, if the procedure/method can be fully inferred, the specific name/model of the diagnostic system used, and finally, an indication of whether the procedure is validated or not by the laboratory.
- **For calibration laboratories**, the measurement and calibration capacity is fully reported in terms of measurand or reference material, method or procedure of measurement or calibration, type of instrument or material to be calibrated or measured, measuring range, conditions of measurement (additional parameters important for defining capacities), measurement uncertainty, location.
- **For PTPs,** the proficiency test is reported in full, in terms of: identification code of the scheme (e.g., unique code of the round, name, or specific reference), sector of the proficiency test, materials/products/matrices/objects to be submitted for testing, measurands/properties/quantities to be determined, typology of scheme.

If the description of the accreditation field is detailed and unambiguously defined for each of the elements in question (so-called fixed accreditation, for which reference is made to the definition in §4 below), any variation or extension must be previously evaluated and approved by ACCREDIA. This may lead to limits for the CAB, especially timelines, related to the presentation of the application to ACCREDIA, to the evaluation and issuance of the attachment to the accreditation certificate.

The introduction of the flexible scope of accreditation (see definition in § 4) enables labs in the accredited area of competence, to respond more rapidly to the requests of clients and of authorities to determine new measurands/properties measured on new materials/products/matrices/instruments/samples by the laboratory and to conduct calibrations of devices which are not specifically provided for and to plan and provide PT schemes on new specimens, for different properties or for different typologies of scheme.

In fact, in the flexible accreditation field, the information reported is similar to that of the fixed accreditation field, but a part of it, which varies according to the degrees of flexibility granted to the CAB, is defined by the CAB itself, which can make changes over time without an evaluation beforehand by ACCREDIA.

In particular, the flexible field of accreditation makes the description of the accreditation field issued by ACCREDIA less detailed, but requires its integration by the CAB, under its own responsibility and always within the limits defined by the ACCREDIA list, with a list of publicly available details. In this way, the overall information on the CAB's accreditation field derives from the combination of the ACCREDIA list and the detailed list of the CAB.

The possibility of introducing new activities such as tests, exams, calibrations, PTs, within the flexible field of accreditation is limited to activities requiring the same competences and resources already included within the limits of the accredited field (e.g., personnel, equipment, work areas). However, it is not possible to introduce new activities based on test techniques and methodologies other than those indicated in the flexible accreditation field granted to the laboratory.

2. SCOPE AND FIELD OF APPLICATION

This document defines the requirements for the application of the flexible field of accreditation in accordance with the requirements of UNI CEI EN ISO/IEC 17011 § 7.8.4.

This document is applicable by calibration laboratories, testing laboratories, medical laboratories and PTPs with ACCREDIA accreditation.

3. NORMATIVE REFERENCES

Vengono di seguito riportati i principali documenti/standard di riferimento:

- UNI CEI EN ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories;
- UNI EN ISO 15189: Medical laboratories - requirements for quality and competence;
- UNI EN ISO 22870: Point-of-care testing, POCT) - requirements for quality and competence;
- UNI CEI EN ISO/IEC 17043: Conformity assessment – General requirements for proficiency testing;
- UNI CEI EN ISO/IEC 17011: Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies;
- EA-4/17: EA Description of scopes of accreditation for medical laboratories;
- EA 2/15: EA Requirements for the Accreditation of Flexible Scopes;
- EA 2/18: Guidelines for Accreditation Bodies on the Contents of the scopes of Accreditation for Proficiency Testing Providers;
- ILAC G18: Guideline for the Formulation of Scopes of Accreditation for Laboratories;
- RG-02: Regulation for the accreditation of testing and medical laboratories;
- RG-02-01: Regulation for the accreditation of multisite laboratories;
- RG-09: Regulations for use of the ACCREDIA accreditation mark;

- RG-13: Regulation for the accreditation of calibration laboratories;
- RG-14: Regulation for the accreditation of PTPs;
- RT-08: Provisions for the accreditation of testing laboratories;
- RT-23: Provisions for the definition of the scope of accreditation;
- RT-25: Provisions for the accreditation of calibration laboratories;
- RT-27: Provisions for the accreditation of PTPs;
- RT-35: Provisions for the accreditation of medical laboratories.

For all the above documents the current revision is applicable. ACCREDIA documents can be downloaded free of charge from the documents area and/or the reserved area of the ACCREDFIA website.

4. TERMS AND DEFINITIONS

Field of application of accreditation: Specific conformity assessment services for which accreditation is requested or has been granted (UNI CEI EN ISO/IEC 17011, point 3.6). In the text of this document "field of accreditation" and "scope of accreditation" have the same meaning.

Fixed field of accreditation: description of the scope of accreditation in a detailed, unambiguous, unequivocal manner of each element (descriptor) of the scope of accreditation. For example, including the year and revision index of the test/examination/calibration methods and reporting the individual measurands and not the categories (e.g., "cadmium, thallium, vanadium" and not "metals").

Field of application of flexible accreditation: field of application of accreditation expressed in such a way as to allow conformity assessment bodies to make changes to the methodology and other parameters that come within the competence of the conformity assessment body, as confirmed by the Accreditation Body (UNI CEI EN ISO/IEC 17011, point 3.8).

- **For testing labs and medical labs** this involves a more generic description of the scope of accreditation as concerns testing materials/matrices/products or concerning the parameters/measurands/exams/ to determine, accepting the possibility for the laboratory on the basis of possessed and positively evaluated competences for accreditation, to modify the field of application of the accredited testing/exam methods, to use new revisions of methods (where the testing technique is the same as the previous revision) or to add new methods based on the same testing techniques as those already accredited.

  For calibration laboratories it means the scope of the accreditation expressed in such a way as to allow changes to the methodology and other parameters that could influence the Calibration and Measurement Capability (CMC) and provided that the measurand, measurement range and uncertainty range do not vary and fall within the competence recognized to the laboratory.
- **For PTPs** with flexible scope of accreditation, this involves a more generic description of the scope of accreditation regarding materials/products/matrices/specimens to be tested, materials/products/matrices/specimens to be tested and the measurands/properties/quantities to be determined.

The possibility of introducing new activities (e.g., tests, exams, calibrations, proficiency tests) within the flexible scope of accreditation is limited to activities which require the same competences and resources as those included within the limits of the scope of accreditation.

For example:

- to implement updates and amendments of standardized methods such as the use of UNI EN ISO 3960:2017 instead of UNI EN ISO 3960:2010 for determining the number of peroxides in animal and vegetable oils and fat;
- to add other standardized methods issued by different standardization bodies with the same field of application (chlorides in conformity with APAT CNR IRSA 4020 Man 29 2003 and chlorides in conformity with UNI EN ISO 10304-1:2009) and the same testing or calibration technique;
- to add other measurands associated with different testing methods from those accredited with the fixed scope but similar in terms of the measuring or instrument technique used (e.g., electromagnetic compatibility tests with EN and MIL-STD standards) – not applicable for calibration labs;
- for calibration labs to prepare and apply the same calibration methodology to instruments, samples or measuring systems within the same family or typology;
- for labs conducting tests in line with the requirements of technical product standards, to add new products (and the relative applicable standards) where the testing technique is the same with respect to other products (and the relative applicable standards) already covered by the accreditation;
- for PTPs, the possibility of providing PTs for different parameters belonging to the same category (e.g., metals) or on similar matrices (e.g., surface or potable water). Specifically, it is possible to add materials or measurands which do not involve new competencies from those related to the preparation of the sample or related to homogeneity/stability tests, or the determination of the assigned value or the evaluation of performance.

Laboratories: term used in this Regulation referring to testing laboratories, medical laboratories and calibration laboratories.

Proficiency testing providers (PTPs): an organization which takes responsibility for all tasks in the development and operation of an proficiency testing scheme (UNI CEI EN ISO/IEC 17043, §3.9). In this document it is also briefly indicated as organizer or organization or as a Proficiency Testing Provider PTP.

Conformity assessment body (CAB): body performing conformity assessment activities including calibrations, tests, certifications and inspections (Reg. 765/2008, Ch. 1, art. 2, par. 13). For the purpose of this Regulation, a CAB is a testing lab, a medical lab, a calibration lab or an proficiency testing provider (PTP).

For other definitions see ACCREDIA documents RT-08, RT-25, RT-27, RT-35 and other applicable ones.

5. PROVISIONS FOR ACCREDITATION WITH FLEXIBLE SCOPE

5.1. GENERAL REQUIREMENTS

As set out in EA-2/15, in the processes of planning, assessment and granting of accreditation with flexible scope to a CAB, ACCREDIA adopts a risk based approach, taking the following considerations into account:

- the CAB's knowledge of and ability to implement the requirements and procedures for the management of flexible scope accreditation;
- the stability of the CAB's MS;
- the typology and complexity of accreditation activities;
- the limits of flexibility;
- risks relating to ACCREDIA's or the CAB's reputation or risks to the market;
- turnover of staff involved in management of flexible scope;
- results of previous assessments and degree of conformity with the accreditation requirements;
- frequency of recourse to flexible accreditation (e.g. updating the detailed lists);
- stakeholders' and competent authorities' expectations;
- range of controls proposed by the CAB for the management of flexible scope accreditation;
- sites and geographical areas.

5.1.1. Responsibilities

Accreditation in the flexible field requires a greater responsibility of the CAB in demonstrating that the way in which it operates is valid, fit for purpose, and that the management system supports the activities covered by accreditation with regularity and consistency and in line with the requirements of the reference standard.

It is the applicant CAB's responsibility to precisely define the limits of the flexibility in terms of similarity of competences and resources and to demonstrate to ACCREDIA the validity and effectiveness of such choices.

The technical ability of the CAB to manage the flexible scope independently is the key element. For this reason flexible scope accreditation may be granted only when the CAB has demonstrated that it has a planning and development process able to manage its affairs (tests/exams/calibrations/ PTs) within the flexible scope requested (see EA - 2/15 § 5.1 and 5.2).

Flexible scope accreditation is not determined only by the technical competence of the CAB but it is also determined by its ability to manage this accreditation process and its commitment to provide accredited activities in this area.

It is the CAB's task to keep updated the detailed list of activities covered by flexible accreditation (see §5.5.1).

5.1.2. Definition of the limits of the flexible scope of accreditation (boundaries of flexibility)

The CAB defines the limits of the flexible accreditation field (flexibility perimeter) with the completion of the accreditation application. In fact, the perimeter depends on how generic the description of the requested accreditation field is, assuring the homogeneity of the skills and resources required. For example, in the case of a testing laboratory, by requesting the generic 'food' matrix, the perimeter is defined by the 'food' category, therefore in the detailed list different matrices belonging to the food category may be specified. Conversely, by requesting

the generic matrix 'honey', different types of honey may be specified in the detailed list, but not other food matrices not coming within the 'honey' category.

The definition of the limits of flexibility is the responsibility of the CAB at the time of presenting the application, but is subject to evaluation by ACCREDIA which, according to the CAB's competences and the relative risk assessment in line with the criteria referred to in §5.1, may require a more precise formulation.

By adopting the flexible accreditation field, the CAB can insert tests/examinations/calibrations/proficiency tests in its detailed list, provided that they come within the scope of the flexibility granted.

In general, the definition of the scope of flexibility must follow a criterion of homogeneity of the required skills and clarity of the scope of application. The perimeter must therefore precisely identify the families/categories of activities and must not be excessively broad (for example, 'chemical parameters' or 'contaminants' cannot be requested, but the families, such as 'metals', 'PCBs', must be specified).

Reported below are the conditions for managing the detailed lists within the scope of flexibility, for the different accreditation schemes, once flexible accreditation has been obtained.

For testing laboratories adopting the flexible accreditation field, it is possible to add new methods developed by the laboratory or standardized, based on the same testing technique or applied to matrices and measurands within the limits of the scope of flexibility. It is specified that this possibility does not include the introduction of new techniques (e.g., if flexible accreditation is granted for metals on a water matrix, with methods based on the atomic absorption technique, it is not possible, in the context of flexible accreditation to introduce a method based on the ICP technique). The testing technique, in fact, does not come within the flexibility granted.

It is also possible to manage within the flexible accreditation the normative updates as long as this does not involve a change in the testing technique. However, in cases where the normative update, despite retaining the same technique, involves major changes to the method and/or requires new competences, ACCREDIA may communicate to the lab that it is not possible to manage the update within the flexible scope.

If the need for flexibility does not concern matrices and/or parameters/measurands, but only the normative update (e.g., mechanical sector), it is possible to request flexibility relating to the latter, without 'expanding' the matrix indication and parameters/measurands with respect to fixed accreditation, but subject to the above conditions.

Flexibility does not apply for:

- the test category (ref. RG-02), because different competences are required for each category;
- test methods that require specific competences/abilities of the operator for individual determinations (e.g., culture test methods for microbiology). Flexibility can only be applicable in cases of automated instrumental systems (e.g., PCR, TEMPO, VIDAS).

For medical laboratories it is allowed to include activities in its flexible accreditation field, based on the lab's own verifications and validations, without assessment by ACCREDIA before the conduct of such activities, as long as they do not include new technical principles not previously covered by the accreditation field.

For calibration laboratories, it is possible to modify the methodology and other parameters but it is not possible to recognize flexibility that modifies the metrological area, the measurand, the measuring range and the uncertainties because different metrological areas require completely different measurement techniques and calibration methods (see ILAC G18).

For PTPs it is possible to introduce the determination of new properties/quantities and/or to propose new specimens for proficiency testing as long as they belong to the same generic category defined in the scope of accreditation. Changes to the management modalities of the sample/specimen do not come within the flexibility for determining the attributed value (change of statistical techniques) with regard to the validation of performances (e.g. change of statistical model) or typology of scheme (e.g. qualitative, quantitative or interpretative scheme).

For multisite labs/organizations (see RG-02-01) flexibility among sites is not possible: flexible scope accreditation must be requested by each site, and the site must possess the requirements of access as set out in this Regulation. A site which does not possess the requirements for flexible accreditation cannot make the application, also if other sites of the same multisite lab possess these requirements.

5.1.3. Procedure for management of the flexible scope of accreditation

The CAB shall demonstrate that it has applied the specific procedures for the management of the flexible scope of accreditation with respect to the requirements of ILAC G-18, EA-2/15 and EA-2/18 and of this document which includes, at least, the following:

- the conditions of applicability/non-applicability of flexible accreditation;
- definition of the responsibility of the decision to apply flexible accreditation;
- modalities for defining the input requirements;
- modalities of development, validation and verification of activities for inclusion in the flexible accreditation;
- modalities for performing the contract review, including information for clients regarding the application of flexible accreditation;
- modalities for the management of the detailed list of flexible accreditation so as to provide precise information concerning the activities covered by the accreditation.

With regard to the contract review, the procedure shall also specify the process to follow in cases of a request from the client for an activity which, despite coming within the flexible accreditation, is not on the detailed list managed by the CAB (information for the client, timeframes, review of resources, activation of the process of entry of a new activity in the flexible accreditation, update of the detailed list, management of any cases in which the process of validation is not concluded successfully, including communications with the client and the CAs adopted.

For laboratories the procedure shall also:

- provide details of the modalities for the planning and performance of the various phases of the validation, the modalities for the formalization of parameters and frequency with which a lab carries out the validation reviews. The adoption of flexible accreditation does not allow for a 'simplification' of the validation activities, because the requirements of UNI CEI EN ISO 17025 and UNI EN ISO 15189 apply;
- specify the criteria for the definition of the performance characteristics of the method and of acceptance/non-acceptance of the values determined for each parameter against which the next declaration of validation will be made;
- describe the modalities and responsibilities for the validation of methods with respect to flexibility;
- regulate the modalities and responsibilities for updating the detailed list;
- give evidence that the verification/validation activities of the procedures for the test, calibration or exam are performed before entry on the list;
- for medical labs, enable them to understand - regarding the type and the aim of the exam – what performance characteristics will be investigated and the approach to use for determination (for these issues, if considered necessary, the procedure may include reference to other documents such as sector guidelines issued by recognized organizations or the lab's instructions, as long as the lab's policy with regard to the extension of the validation/verification is made clear).

In the case of PTPs, this procedure shall also:

- define, in the design and planning phase of the scheme, the choice of test specimens and quantities to be determined;
- regulate the modalities and responsibilities for updating the list of proficiency tests;
- regulate the modalities and responsibilities regarding sub-contracted activities with respect to the limits imposed by the scope of accreditation;
- define the modalities and responsibilities of the evaluation of the competences of personnel involved in activities, including the requirements concerning the statistical part.

5.2. FIRST APPLICATION FOR THE FLEXIBLE FIELD OF ACCREDITATION

5.2.1. Testing laboratories

For testing labs the application for extension for the flexible scope shall be considered an extension for generic measurands/matrices only if the lab has accredited with fixed filed of accreditation, and for at least two years, testing methods with the same testing/measuring technique for measurands/matrices coming within the limits of the requested flexibility.

For testing labs the application for extension for the flexible scope shall describe the field of application and it shall be accompanied by:

- a description of the typology of application of the flexible field of accreditation (e.g., flexibility by matrix and/or measurand and/or method, respecting the test technique);
- the methods developed by the lab accompanied by the declaration of validation if relevant to the request for flexible accreditation and revised (if revision has been made) with respect to those already sent to ACCREDIA for fixed accreditation;

- from the evidence of having accredited, for at least 2 years, test methods conducted with the same test technique for matrices and parameters coming within the scope of the requested flexibility. The completion of the accreditation application, as indicated below, provides evidence of this;
- the procedure prepared and made available by the lab for the management of flexible accreditation.

In the first application for extension for the flexible accreditation, testing labs shall complete the individual fields of the DA-online system:

- specifying the required flexibility limits, by indicating (in a generic way) the material/product/test matrix and measurand/property measured/name of the test;
- listing the test methods that the laboratory has already accredited with fixed accreditation field for at least 2 years, for matrices/measurands coming within the scope of the requested flexibility (including any methods developed by the laboratory); these methods will become the basic "core" for granting flexible accreditation and shall be included by the laboratory in the detailed list after granting flexible accreditation.

The first application for extension for the flexible scope of accreditation for testing labs will be evaluated by the member of the Sector Accreditation Committee with, if necessary, the assistance of experts and, subsequently, during the assessment the Committee will decide with regard to the accreditation.

5.2.2. Calibration laboratories

For calibration labs the first application for flexible scope accreditation is to be considered as an extension and flexibility can only be requested if the lab has accredited with fixed accreditation scope the CMC to which it is applied since at least two years.

For calibration laboratories, the extension application must report the type of flexibility required in the module DA-05, and attach the documentation relating to the management of flexible accreditation, including the description of the validation of methods.

For example:

- a calibration lab accredited for the calibration of a particular instrument requests accreditation in the flexible scope for calibrations within the family to which the accredited instrument belongs, modifying its procedures by generalization in order to include new ones without an assessment by the ACCREDIA-DT;
- the lab shall apply this flexibility for the calibration of a new instrument;
- the lab shall validate this flexibility applying its procedure PT-xxx.

5.2.3. Medical laboratories

Following the principles indicated in EA 4/17 and taking into account the activities most frequently carried out by the medical laboratories requesting accreditation, the degrees of freedom of flexibility for the materials, the tests (analytes/parameters) are defined [with the involvement of the main associations of clinical laboratory health professionals] and the principles on which the procedures for carrying out the tests are based. These flexibilities have

been defined taking into account the risk assessment aspects listed in the motivations of this document and the flexibility limits specified in § 5.1.2.

Together with the application, the lab can request flexible scope accreditation by completing the relevant module, only if:

a) at least one test comes within each flexibility requested is managed in conformity with the requirements of UNI EN ISO 15189 and the ACCREDIA rules;
b) the lab has participated with positive outcome of the proficiency test (PT/EQA) for at least one exam regarding each flexibility requested. For exams where the offer of external quality assessments is on an ongoing basis, participation must extend over a period of at least 4 rounds; for those that are not ongoing, participation must extend over a period of at least 2 years. If the laboratory proves that there are no commercially available PT/VEQ programs (at national or European level) to participate in, it can request accreditation in the flexible field, giving evidence of the implementation of alternative approaches *(*point 5.6.3.2 of UNI EN ISO 15189 *Alternative approaches).*

In cases of multisite labs the scope of accreditation shall include the location where the accreditation for flexible scope accreditation is granted. With this it is understood that the flexibility regards only the tests performed at that location: it is not possible to add tests carried out at another location.

In the case of accreditation of tests that require the validation of the method/procedure by the laboratory (such as in the case of "home-made" tests), the flexible field of accreditation reports this eventuality. Flexibility for this typology of test can only be granted after evaluating the laboratory's competence in conducting the validation process. By this it is intended that there is no flexibility for adding a test validated by a laboratory unless this is expressly indicated in the flexible accreditation field.

For POCTs, flexibility is provided using the same modalities established for the tests performed at the laboratory facilities, with the addition of the department/unit (the delivery point) where the POCT is delivered. By this we mean that there is no flexibility for adding a POCT in a new department/unit, unless expressly indicated, in the flexible accreditation field granted to the laboratory, as in cases of POCTs belonging to the same cluster.

According to the rules set out in par. 5.5.1 the lab shall manage the detailed list of tests within the flexible scope of accreditation.

If the laboratory is also responsible for the pre-testing activities of sample gathering and transport, this activity is indicated in the flexible accreditation field with a brief description of the nature of the primary sample, the methodology and/or the sampling technique employed, and the place where the activity of collection and sampling is performed, which means that there is no flexibility as regards the typology of primary sample, the sampling methodology and the place of performance of the sampling.

The application for accreditation for the flexible field must be accompanied by the procedure for managing the tests in the flexible field, from which the methods and responsibilities of managing the detailed list of examinations must be deduced.

The first application for flexible scope accreditation will be evaluated by the member of the Sector Accreditation Committee with the support of experts where necessary, and following the assessment the Committee will decide regarding accreditation.

5.2.4. Proficiency Testing Providers

For providers of proficiency tests it is possible to seek flexible scope accreditation also without having previously obtained fixed scope accreditation. This is to guarantee that PTPs can offer, with continuity, schemes proposing various different matrices/testing specimens and/or quantities to be determined but still belonging to the same generic category.

For PTPs, the first flexible scope application for accreditation shall describe the scope of application and shall include:

- a letter containing a description of the typology of application of the flexible scope (e.g. flexibility for matrices and/or measurands);
- the procedure for the management of the flexible accreditation;
- a detailed list of the schemes of the proficiency tests which the PTP can offer;
- the last report issued for the schemes for which accreditation is requested;
- in cases of calibration PTs, from a list of qualified suppliers for the purchase or renting of instruments used for flexible scope accreditation which the PTP intends to manage.

In completing the application for accreditation using the appropriate modules, the provider of PTs must specify the scope of flexibility required by indicating (in a generic way) the material/product/matrix/test specimen and/or the or misurand/measured property/test name.

5.3. MAINTENANCE, VARIATION, EXTENSION AND RENEWAL OF THE FIELD OF FLEXIBLE ACCREDITATION

The procedures for maintenance, variation and extension of the scope of accreditation are covered by the ACCREDIA General Regulations for the specific accreditation scheme (RG-02, RG-13, RG-14). The details for flexible scope accreditation are set out below.

5.3.1. Testing laboratories

Maintenance of flexible scope of accreditation is verified during the surveillance assessment at the lab's premises as described in point 5.4 below.

Variation to flexible scope of accreditation may be requested by the lab at any time by means of the DA-online system. The variation may concern a modification of the indication of the generic test already accredited, correction of small errors, incorporation of flexible tests already accredited and similar to each other.

If a testing lab, already holding flexible scope accreditation, applies for extension in the flexible scope for non-similar matrices/measurands or analytical techniques which are different from those already present in the flexible scope on the list, or if it wishes to enlarge the flexibility perimeter for an accredited test with flexible scope, two years of accreditation of the same measuring technique in the fixed scope for matrices/measurands coming within the generic wording. For the application for extension, the modalities are similar to those of the first

application (see §5.2.1), with the exception of the procedure for the management of flexible accreditation, which must be attached only if revised.

For the evaluation of the variation or extension the ACCREDIA Director of Department, after having (when necessary) discussed with the technical officer and/or member of the Sector Accreditation Committee, or (if necessary) technical expert/s shall decide whether or not to carry out an assessment at the lab.

In cases of renewal of accreditation, if the lab does not intend to add other tests in the flexible scope, it does not need to send any other documents outside of those foreseen by the application in the fixed scope. If, however, during the renewal process, the lab wishes to seek accreditation for new tests in the flexible scope, it shall complete the application for accreditation (DA-02 Annex 1) as for extension, described above.

5.3.2. Calibration laboratories

Maintenance of flexible scope accreditation is verified during the surveillance assessments at the lab's premises, performed as described in point 5.4 below. The laboratory, at least 2 (two) months before the surveillance deadline, must send the module DA-05 to the ACCREDIA-DT secretariat with attached documented procedures that describe the methods developed and the evidence of their validation for the performance of the document review.

If a calibration laboratory, already accredited for the flexible field, requests the extension of calibrations other than those already present in the list, it shall send the extension application (DA-05), completed according to the indications of point 5.2.2, provided that the laboratory has been accredited for the same measuring technique in the fixed field for at least 2 years.

In cases of renewal of accreditation the calibration lab shall present the application DA-05 in accordance with the regulation, taking care to specify, also with regard to the flexible part, if there any changes have been made. Any extensions of flexibility to calibrations already present in the scope shall be presented as extensions, not related to renewal.

5.3.3. Medical laboratories

Maintenance of flexible scope accreditation is assessed during the surveillance assessment at the lab's premises and conducted in accordance with point 5.4 below.

Variation to flexible scope accreditation may be requested at any time. Variation may regard a modification to the indication of the already accredited generic test, the correction of small errors, and the incorporation of accredited and accredited tests which are similar with each other.

For medical laboratories already accredited for the flexible field, it is possible to request an extension for new typologies of exams. In this case, the procedure to be followed is similar to the procedure for the initial granting of flexible accreditation, except for the sending of the procedure prepared by the laboratory for the management of flexible accreditation, which must be sent only if modified with respect to the one already sent to ACCREDIA.

The enlargement of the description in the flexible field is considered as an extension, including the possibility of accrediting exams that require validation, if not already present in the flexible field of accreditation already granted.

For assessment of the extension the ACCREDIA Director of Department, after having (when necessary) discussed with the technical assessor and/or rapporteur member of the Sector Accreditation Committee, or (if necessary) technical expert/s shall decide whether or not to perform an assessment at the lab's premises.

5.3.4. Proficiency Testing Providers

Maintenance of flexible scope accreditation is verified during the surveillance assessment at the PTP's premises and it is conducted as set out in point 5.4.

Variation to this accreditation with flexible scope may be requested by the PTP at any time by means of the module DA-06 Annex 1. The variation can regard a modification to the indication of the accredited generic scheme, the correction of errors, the incorporation of already accredited flexible schemes which are similar to each other.

For the PTPs already accredited for the flexible scope, the application for extension/renewal (DA-06 Annex 1) shall be completed according to the indications of point 5.2.4 together with the following documents, regarding the specific activities concerning the extension of the scope of accreditation:

- procedure prepared and made available by the lab for the management of flexible accreditation, if modified;
- the revisions issued of the detailed lists of PTs managed in the flexible scope (with respect to the previous assessment);
- the last report issued for schemes for which extension is requested.

For the assessment of the extension the ACCREDIA Dept. Director, after consulting (when necessary) with the technical assessor and/or the Sector Accreditation Committee or with the technical experts, shall establish the necessity (if one exists) to carry out an assessment at the PTP.

In the case of renewal, if the PTP does not intend to add other schemes in the flexible scope, it is not necessary to send further documentation than provided for by the fixed scope application for accreditation. If, during the renewal process, the PTP intends to request accreditation for new schemes in the flexible scope, it shall complete the application (DA-06 Annex 1), as for extension, described above.

5.4. PERFORMANCE OF ASSESSMENTS

Assessment of the scope of flexible accreditation requires an assessment of tests/calibrations/exams/PTs sampled against the requirements of ISO/IEC 17025, ISO 15189, ISO/IEC 17043 and the applicable ACCREDIA documents.

In cases of flexible scope accreditation, great attention shall be paid to:

- agreements with clients and contract review;
- competence and responsibilities of personnel involved in the management of accredited activities in the flexible scope;
- choice of testing/calibration/performance of exam/test method, validation of the method, assessment of measurement uncertainties, updating of the method;

- information contained in the test reports, calibration certificates and/or reports including, when necessary, the measurement uncertainty;
- for testing labs, the type of activity undertaken, with particular reference to the performance of official controls – the nature of the owner of the lab (e.g., AASSLL, ARPA, IZS, etc.);
- the lab's conduct of the management process of the flexible scope, of validation, of the list of tests/calibrations/exams with flexible scope accreditation (responsibilities, modalities for the inclusion, modifications to and/or cancellations of tests/exams/calibrations, application date etc.);
- for PTPs: the management of the sub-contract, with regard to the necessary competence concerning sub-contracted activities.

During the assessment, the assessors shall verify the records regarding the verification and validation of the methods, the evaluation of measurement uncertainty and (in the case of calibration labs) respect for the CMC declared in the accreditation template currently in force. The completion is necessary of the validation records (where applicable: LOD, LOQ, linearity, strength etc.) and conformity with the applicable mandatory requirements.

The assessment may also regard records concerning methods/PT schemes which have been included or eliminated updated detailed list managed by the lab or PTP.

ACCREDIA may carry out, at any time, a remote assessment of the detailed list published by the CAB.

The plan of the assessment carried out at a CAB shall include checking the updating of the detailed lists managed in the flexible scope of accreditation.

For multisite labs the sampling shall be planned taking into consideration the locations which are intending to seek flexible scope accreditation and, for medical laboratories, sampling points and POCTs. Also, following the decision regarding accreditation with flexible scope at one or more of the multisite lab's locations, the Sector Accreditation Committee shall define any modifications to the four-year sampling plan for surveillances at head office and secondary locations (see RG-02-01).

In general, assessment duration times will be set according to the activities necessary to fulfill the requirements of this document.

After the assessment ACCREDIA informs the CAB regarding the decision of the Sector Accreditation Committee for the maintenance and/or extension of the flexible scope of accreditation.

The tests accredited in the flexible field are entered in the appropriate field of the annex to the accreditation certificate (list of tests/exams/laboratory data sheet) issued by ACCREDIA.

If the accreditation in the flexible scope of calibrations requires a list of instruments, types of instruments or measuring systems, this may be done by accessing the lab's website.

5.5. OBLIGATIONS OF THE LABORATORY/ PTP

5.5.1. Detailed list of the flexible field of accreditation

The laboratories shall keep un updated list of methods and relative ranges of application managed under flexible scope of accreditation which is similar to the list of tests/exams/calibrations related to the fixed accreditation and, for testing labs, in conformity with RT-23 and with the body of tests available in the DA-online system and, for calibrations, in conformity with the accreditation table.

PTPs shall keep an updated list of schemes managed under the flexible scope, specifying unambiguously, the detail of material/product/matrix/specimen to be tested and measurand/measured property/name/quantities of the test.

For testing labs the list shall be completed in the reserved area of the ACCREDIA website directly by the lab which is responsible for the contents and the update status and the list shall contain at least:

- material/product/testing matrix;
- measurand/measured property/name of the test;
- testing technique;
- testing method with code, year and (only for methods developed by the lab) revision status.

The search modalities in the ACCREDIA website's database enable the identification, for each lab, of the accredited tests in both the flexible and in the fixed scopes contemporarily.

In this database the tests for which ACCREDIA issues flexible scope accreditation are indicated "Flexible field" and they are a generic description of the scope of accreditation with regard to testing materials/matrices/products, whilst each specific test performed by the lab is indicated as a "Related test".

In order to avoid duplication it is better practice if the lab – at the same time as the inclusion of the tests on the list it manages – requests the renunciation of accreditation with respect to the same tests in the fixed scope.

It is also necessary that, for each flexible scope test accredited by ACCREDIA, the lab manages, in its list, at least one related representative test of the flexible scope requested (in terms of testing materials/matrices/test products), thereby guaranteeing the maintenance of the lab's competence.

At the granting of flexible accreditation and after obtaining access to the reserved area of ACCREDIA's website the lab shall prepare its detailed list, entering the test/s given in the application for accreditation supporting the application for flexible scope (tests which have been accredited for at least two years for a determined technique on matrices/measurands within the flexible scope).

For the entry of new tests on the detailed list the lab:

- shall remain within the limits of the flexibility granted as indicated in the scope of accreditation given in the annexes of the certificate issued by ACCREDIA;

- shall not, within every flexible scope, include tests which are not in common with the flexible scope (generic) matrices/parameters/technique;
- before entering the detailed tests, it shall make sure through the body of tests available in the DA-online system that the test is accreditable and that any combinations are allowed (not applicable for the methods developed by the laboratory, except for the indication to consult the DA-online portal for general information on the tests).

For calibration laboratories the updated list of calibrations performed in the flexible scope shall be provided by ACCREDIA upon request and at the opening of the file concerning maintenance, extension or renewal, attached to DA-05. The list shall be available to the clients of the calibration lab and published in the revised status in the website. The lab shall communicate the address of the web page to ACCREDIA, authorizing disclosure.

This shall contain as follows:

- the instrument
- the measurand
- the measurement range
- uncertainties
- reference to standardized procedures (if any)
- internal calibration procedures

Medical laboratories shall keep an updated list of tests managed under the flexible scope, both for tests at the lab's premises and POCT exams. The list shall be submitted to ACCREDIA upon request and in all cases at the opening of the surveillance or renewal file. The list shall be made available to the lab's clients and published in the revised status on its website.

Superseded versions of the detailed list issued by the lab shall be kept for at least 4 years.

The list shall be managed by the lab in accordance with §4.3 of UNI EN ISO 15189 and shall be referable to the ACCREDIA document giving the description of the scope of accreditation, for example, using the following wording: "*Detail of tests and blood sampling points within the scope of UNI EN ISO 15189 accreditation of issued by ACCREDIA as in Annex rev. X to the certificate of accreditation MED number WXYZ*).

The list shall contain – as a minimum – the following information:

- medical rules/requirements;
- sub-rules/requirements;
- name of the test as reported by the lab when it communicates its test results;
- nature of the sample to which the test procedure is applicable (e.g., serum, plasma, urine, urethral swab);
- principle of the method/technique on which the test procedure is based and – if important – if it is a qualitative or quantitative method, manual or automated;
- reference to the document containing the test procedure (code assigned by the lab to the test procedure and relative update status (e.g., PE-01 rev. 3). If the test is carried out entirely according to the instructions defined by the producer of an in vitro medical device

(IVD-MD) in place of the reference to the procedure, the lab may refer to the specific IVD-MD;

- indication if it is a recognized test procedure, i.e. subject to verification by the lab (see § 5.5.1.2 of UNI EN ISO 15189), or internal – i.e. subject to validation by the lab (see 5.5.1.3 of UNI EN ISO 15189);
- the address of the test location and, if relevant, the internal location of the site – building number, floor etc.;
- if it is a POCT, provide a clear indication that it is a POCT, the location's address and, if applicable, the name of the department or unit (or other indication used by the organization) where the POCT is situated;
- in the case of accreditation of pre-test phases of acquisition of primary samples at sampling points, the nature of the sample, reference to the documented sampling/collection/transport procedures (with relative update statuses), methodology and/or technique, location of sampling point/gathering point;
- the indication of the modifications made to the list, with particular reference to those regarding the above information.

Upon granting flexible accreditation, the laboratory must promptly publish its detailed list, entering the tests and pre-test phases of sample acquisition at sampling test points that it is able to offer with flexible accreditation.

For the inclusion of new tests, POCTs and samples in the list or modification of procedures in the list, including their application on new typologies of samples, the lab must comply with the limits of the flexibility granted, as indicated in the accreditation field reported in the annexes of the certificate issued by ACCREDIA. The laboratory will not be able to enter, for example, tests that are not based on the technical principles listed in the flexible field. It will also not be able to insert tests and samples that are not carried out on the same nature of sample or in the places indicated.

PTPs shall keep an updated list of tests managed under the flexible scope of accreditation. The list shall be submitted to ACCREDIA upon request and in all cases at the opening of the surveillance or renewal process. The list shall be made available to the PTP's clients and published in the revised status on its website.

Superseded versions of the detailed list issued by the PTP shall be kept for at least four years.

The list shall be managed by the lab in accordance with §4.3 of UNI EN ISO 15189 and shall be referable to the ACCREDIA document giving the description of the scope of accreditation, for example, using the following wording: "*Detail of tests and blood test points within the scope of UNI EN ISO 15189 accreditation of issued by ACCREDIA as in Annex rev. X to the certificate of accreditation MED number WXYZ*).

The list shall give, at least, the following information:

- identification code of the scheme;
- proficiency testing sector (e.g., microbiology, environment, medical);
- material/product/matrix/specimen to be tested;
- measurand/property/quantity to determine;
- scheme typology.

At the granting of flexible scope accreditation the PTP shall promptly make available its detailed list, entering the schemes which it offers with flexible accreditation.

For the inclusion of new schemes on the list, the PTP shall adhere to the limits of the flexibility granted as indicated in the annexes of the certificate issued by ACCREDIA. Within each typology of flexible (generic) PT the PTP shall not include schemes which do not have in common with the flexible test: the specimens to be tested, the quantities to be determined, the statistical approach and the modalities for determining the assigned value.

Also, the PTP shall not include different scheme typologies.

5.5.2. Preparation of test reports, calibration certificates and reports

Test reports, calibration certificates and reports shall carry details of the quantities and/or single measurands to be determined; they shall be prepared in conformity with the requirements of UNI CEI EN ISO/IEC 17025, and with ACCREDIA Regulations RT-08 and RT-25.

The calibration certificates shall follow the indications provided in IO-09-DT.

For medical labs, the reports shall be written in conformity with point 5.8 of UNI EN CEI ISO 15189 and with ACCREDIA Regulation RT-35.

The proficiency testing reports shall be prepared in conformity with point 4.8 of UNI CEI EN ISO/IEC 17043 and with ACCREDIA Regulation RT-27.

5.5.3. Management of NCs and the imposition of sanctions

In cases of the raising of NCs which could influence the results of tests, calibrations, of exams or of PTs, managed in the flexible scope, the CAB shall inform, in writing, its clients/participants and ACCREDIA within no more than 10 days. The corrective actions shall not be limited to the NC alone but shall be applied to all areas which could be affected.

Apart from the motivations contained in the regulations in force, failures in validation or in the evaluation of measurement uncertainty with respect to the flexible scope of accreditation may lead to the imposition of sanctions consisting of the reduction or suspension of accreditation.