ACCREDIA
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Testing Laboratories Department

Rules for the definition of the scope of accreditation for testing laboratories

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NOTE *The present document represents the English version of the document under reference at the specified revision. In case of conflict, the Italian version will prevail. To identify the revised parts reference must be made to the Italian version only.*

PREPARATION
The Director of Testing Laboratories Department

APPROVAL
The Directive Council

AUTHORIZATION
The President

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1. Introduction

The specific conformity assessment activities for which accreditation is requested and/or granted are defined by the scope of accreditation. In the case of Testing Laboratories, as stated in Clause 7.8.3 of the ISO/IEC 17011:2018 standard, the scope of accreditation shall identify at least the following:

- materials or products subject to testing;
- the item, parameter or characteristic subject to testing;
- the tests or types of tests performed and, where appropriate, the techniques, methods and/or equipment used.

In order to ensure uniformity and consistency in the lists of tests to be accredited/accredited, ACCREDIA has made available the “Atlante” database, which contains the tests currently available for accreditation requests. This is a continuously evolving list. The database is accessible to Testing Laboratories through a web application called “DAonline”, which enables the online completion of the section of the application relating to the scope of accreditation.

To facilitate searches by ACCREDIA and the Institutions for laboratories operating in regulated sectors, the portal also includes a section entitled “Legislative References”, where European and/or national legislative instruments requiring laboratory accreditation for the performance of tests are listed[1].

Once logged into DAonline, the homepage contains a section called NEWS, where operational information concerning the methods/parameters/matrices recorded in the Atlante database is regularly published.

2. Scope and field of application

This document defines the general criteria applied:

- by ACCREDIA, for the compilation and implementation of the Atlante database;
- by Testing Laboratories, for defining accreditation requests under a fixed scope and for compiling detailed lists in the case of flexible accreditation[2], in order to ensure a consistent indication of the product/matrix/item, the designation of the test, and the identification of the methods used.

The description of individual tests in the Atlante database is provided in accordance with the information expressly stated in the individual methods (e.g. identifiers, matrices, parameters, scope of application of the method).

The definitions entered by ACCREDIA in the Atlante database cannot be modified by individual Laboratories, which may only select from the various options available. For the expression of tests in Test Reports, reference

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[1] For the compilation process, please refer to Operating Instruction IO-09-04-DL.

[2] In the case of flexible accreditation, reference shall be made to ACCREDIA Technical Regulation RT-26, “Requirements for the accreditation of flexible scope – Testing Laboratories, Medical Laboratories, Calibration Laboratories, Proficiency Testing Providers”, and to the specific dedicated application.

should be made to the provisions of RT-08 regarding the use of synonyms or wording consistent with the list of tests.

For operational details concerning the use of the “DAonline” application, including the possibility of entering new methods or tests, please refer to Instruction IO-09-04-DL.

3. Normative references

The complete list of reference documents[3] (LS-04) is available on the website www.accredia.it.

4. Terms and definitions

For the purposes of this document, the terms and definitions specified in ISO/IEC 17000, ISO/IEC 17025, UNI CEI 70099, UNI CEI EN 45020, and in the ACCREDIA General and Technical Regulations applicable to Testing Laboratories shall apply.

5. Definition of the scope of accreditation

As an accreditation body, ACCREDIA is responsible for ensuring that Testing Laboratories have the competence to perform the activities defined within the scope of accreditation. For this reason, the description and assessment of the scope of accreditation represent the core of the accreditation process (see ILAC-G18).

The following paragraphs set out the requirements for describing the scope of accreditation for Testing Laboratories.

In general, reference should be made to ACCREDIA Regulation RT-08 regarding the selection of methods and the possibility of making modifications to them, while maintaining references to the official/standardised/non-standardised method, as well as the cases in which validation is required and/or a transformation into a laboratory-developed method (in-house method).

5.1. Standardised, non-standardised and official testing methods

5.1.1. Material/Product/Matrix

In the “Material/Product/Matrix” field, the information specified in the scope of application of the method is reported. Any matrices deemed comparable to those explicitly indicated by the method are recorded in the Atlante database, following a technical assessment, and are identified with the symbol (1).
For example, methods for “natural waters” may also be applicable to “water intended for human consumption”,

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[3] For ILAC documents, where cited or referenced, the subsequent Global version shall also be considered equivalent, unless otherwise indicated.

subject to verification of the compatibility of the LOD and LOQ with the relevant legal limits; methods for "sludges and eluates" may also be applicable to soils.

It is not possible to associate the method with "Material/Product/Matrix" items that are not indicated in the relevant scope of application and are not considered comparable. For example, depending on what is specified in the method itself, the "Material/Product/Matrix" field in Atlante includes:

- the specific item/product under test (e.g. blenders, recessed lighting luminaires, cereals, milk, etc.), or
- the general category of items/products under test (e.g. electrical and electronic equipment, lighting equipment, food, etc.).

When completing the accreditation application via DAonline, both for fixed scope and for the compilation of detailed lists under flexible accreditation, the laboratory may limit the scope of application of the method by indicating only some of the "Materials/Products/Matrices" included in Atlante, or by specifying any exclusions.

Instead, where the laboratory intends to apply a method to "Materials/Products/Matrices" that are not specified within the method's scope of application and are not comparable to those covered by it, it may request accreditation for such use only as a laboratory-developed test method (in-house method).
For example, in the case of methods for "Soil", it is not possible to extend the scope of application to "Waste", as this latter matrix is excessively broad. Similarly, for methods specifically designed for the "Steel" matrix, application to the generic "Metallic materials" matrix is not permitted.

The matrices recorded in Atlante are grouped into homogeneous "macro-matrices" for statistical purposes. Where the same method is applicable to matrices belonging to different macro-matrices, separate entries are provided in Atlante.

5.1.2. Measurand / Measured Property / Test Designation

In the "Measurand/Measured Property/Test Designation" field, Atlante reports in detail the individual analytes/quantities as specified in the scope of the method.

For parameters derived from calculations, see §5.1.2.1.

In order to group certain specific classes of compounds and to facilitate searches within the database, a field entitled "Group" has been introduced.
For example: "Pesticides: Alfametrina, Azinfos-Etile, Azinfos-Metile, Benalaxil, Bromofos-Etile, Captafol, Captano, Carbendazim".

Where the same method is applicable to "Measurand/Measured property/Test designation" belonging to different groups, separate entries are provided in Atlante.

Certain test methods explicitly indicate the possibility of extending the scope to include the determination of additional parameters not originally specified: only in such cases may Laboratories request ACCREDIA to include the additional parameters in Atlante, provided that they fall within the scope covered by the method (see ACCREDIA Regulation RT-08).
For example, for the UNI EN 15662 method, it is possible to add further pesticides, but not PAHs or PCBs.

When completing the accreditation application via DAonline, or when compiling their own detailed lists in the case of flexible accreditation, the laboratory may introduce restrictions or specify exclusions with respect to what is indicated in the scope of the test method under the field “Measurand/Measured property/Test designation”, provided that the stated limitations are compatible with the requirements of the method itself.

Where several parameters may be measured using the same method, the Laboratory shall select all those of interest at the time of choosing the method.

5.1.2.1. Parameters determined by calculation

For parameters determined by calculation, the following situations may arise:

1. parameters derived from calculations described within the method, together with the determination of all parameters involved in the calculation (e.g. Moisture and Dry Residue with UNI EN 12880; Ammonium ion and Ammoniacal nitrogen with ISO 23695).

   In such cases, in Atlante, these are listed among the parameters without the indication “calculation”.

2. parameters derived from calculations not described within a method, but resulting from simple, transparent and universally accepted calculations. In such cases, these parameters are not reported in Atlante, nor is the laboratory required to request them explicitly for accreditation, since the accreditation status is clearly represented by the tests whose results are included in the calculation.

   This category includes, by way of example, sums of substance quantities (for example pesticides, fatty acids, mycotoxins), well-defined stoichiometric calculations, and ratios between parameters whose designation unequivocally clarifies their origin and calculation (for example carbon/nitrogen ratio, fat/dry residue, moisture/proteins, salt/dry matter).

3. parameters derived from calculations which do not fall within the two previous categories, such as those:

   - not attributable to simple, unambiguous or universally recognised formulae,
   - or for which the literature provides different calculation approaches, thereby creating uncertainty as to the origin of the result,
   - or for which it is necessary to explicitly identify the parameter whose designation changes as a result of the calculation, and where the new designation is not directly attributable to the parameter(s) from which the calculation is derived (e.g. energy value, non-reducing extract, number of eggs).

   In such cases, the parameters are included in Atlante.

The designation “by calculation”, when inserted after a parameter, indicates that the calculation is not explicitly described in the specified test method.

In certain specific cases, parameters may be included in Atlante by associating them with the document that contains the calculations as standalone standards. In such cases, the laboratory must select both the reference for the calculation and all test standards related to the tests involved in the calculation.

5.1.3. Measurement range

The measurement range is a free-entry field present in all Atlante records:

- if the laboratory covers the full measurement range of the standard, this field must be left blank;
- if it differs (i.e. is limited or extended)[4] from what is stated in the standard, completion is mandatory and no additional information shall be included (e.g. non-foreseen parameters, techniques, etc);
- if the standard does not specify a measurement range, it is advisable, for greater clarity, to indicate a range consistent with the verification/validation performed.

5.1.4. Test method

Test methods are reported in Atlante in a concise form, as specified by the standardisation bodies. Amendments and corrigenda are all indicated using the symbol "/", regardless of the format adopted by the issuing body, which is not always consistent.

Atlante does not include standards containing only general guidance or guidelines (e.g. IEC 60068-1 for environmental tests, ISO 16474-1 for light-exposure ageing tests, or ISO 7218 for microbiological analyses), nor methods that have not completed the approval process and been formally published[5].

In general, product standards are included in Atlante and associated with the test methods referenced within them for individual tests:

- where the product standard cites dated references only, Atlante includes the combinations with the test methods together with the specific years cited;
- where undated references are used, Atlante includes the combinations with the latest revision of the cited test method.

Only in specific cases may certain product standards, although referencing other standards within them for testing purposes, be included as standalone standards, in order to improve clarity in the listings (e.g. some standards for electrical equipment). In such cases, the laboratory must select both the product standard and all test standards related to the tests (in the revision required by the product standard) that it intends to apply for accreditation.

It is also possible to include Test Specifications or Technical specifications issued by manufacturers or clients (e.g. major contractors) in Atlante, provided that these are made available to ACCREDIA for the preliminary documentary assessment prior to the visit.

Atlante includes standards relating to Classification and Extended Application (EXAP). These may be requested by laboratories, provided that the corresponding test standards for the individual tests referenced within them, or otherwise necessary for performing the test, are also included in the accreditation request or are present within the scope of accreditation.

Where a test is performed in accordance with multiple methods (e.g. preparation, ageing, reading), Atlante provides, in the drop-down menu, all the necessary standards. In any case, the laboratory's selection

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[4] Please refer to RT-08 for the use of methods outside the measurement range.

[5] Accordingly, draft standards are not included in Atlante, even if they have been published (e.g. standards issued as DIS or FDIS versions).

must always include at least one reading standard in each selected entry. The matrix reported is generally that of the first method (e.g. the preparation method) or, in any case, the most restrictive/appropriate among the various methods (e.g. the product standard).

It is not possible to request official or standardised methods for accreditation where each is performed only for certain phases or parts.

Where the method contains only a single test phase (e.g. extraction, ageing), the possible situations are as follows:

a. the method refers within itself to one or more specific methods for carrying out the other phases. Atlante provides combinations including such methods (it is assumed that the overall set of stages has been validated). For the citation of years, in the case of combined methods, the same criterion applies as described above for product standards.
   If the Laboratory uses other methods that are not referenced, the entire sequence must be treated as a laboratory-developed method.

b. the method refers within itself to one or more specific methods for carrying out the other phases, while nevertheless allowing the Laboratory to choose alternative test methods should those referenced prove unsuitable.

c. the method does not refer within itself to any specific methods for carrying out the tests, or it only specifies the type of technique or performance requirements.

For cases b) and c), upon request and subject to technical assessment, Atlante may include different combinations. In such cases, the Laboratory must verify that it is capable of performing the entire sequence, ensuring that the required performance criteria can be achieved.

In all the cases listed above, the Laboratory may not exclude any of the methods within the combination.

Where a method requires confirmations without describing it in detail, but instead refers to a specific standardised test method or allows the Laboratory a broader choice (e.g. ISO method, validated rapid method, alternative medium or another technique), the Laboratory must also request accreditation for the performance of the test according to that method, selecting from the options available in Atlante.

Where the test method also includes sampling instructions, the following situations may arise:

1. The method describes both sampling and test performance.
   In Atlante, both the full method (sampling + test) applied to the matrix specified in the method itself, and the method excluding sampling applied to the matrix “sampling support…” are recorded (e.g. UNI EN 15980 (except sampling), matrix: air sampling supports).
   Therefore, if the laboratory does not wish to request accreditation for sampling, it must select in Atlante the test entry where this exclusion is explicitly indicated.
2. The method describes only the test performance, while sampling is referred to another method.
   In Atlante, the sampling method (see §5.2) and the test method are recorded independently, each linked to its respective standard.
   If the laboratory does not wish to request accreditation for sampling, it must select only the test method, without indicating any exclusions.

If, on the other hand, it intends to include sampling within the scope of accreditation, it must request it separately, selecting it in Atlante (e.g. ISO 19458 for water sampling for microbiological parameters).

5.1.4.1. Superseded test methods

In Atlante, superseded editions are identified by the word “Withdrawn”[6], visible on the portal and on the downloaded DA-02 Annex 1, but not on the list of accredited tests.

In general, such methods are retained in Atlante for three months from the withdrawal date, unless otherwise specified by the issuing body or if they are referenced by mandatory provisions, public administration specifications, product standards, or required by notified bodies.

In addition to the cases above, where the laboratory needs to request accreditation for superseded methods (e.g. due to customer authorisations referring to outdated methods), it must also attach to the accreditation application supporting evidence for such a request (see ACCREDIA Regulation RT-08 for no longer valid methods).

5.1.5. Test technique

For each method recorded in Atlante, the test technique is specified (with the exception of physical-mechanical and electrical tests, where different tests may appear within the same row), according to the following criteria:

- where test methods involve the application of multiple analytical techniques, Atlante includes one row for each technique.
- the reading technique is always indicated, even where multiple preparatory options exist (e.g. digestion, staining, liquid/liquid extraction, etc.).
- in some cases, Atlante reports the underlying principle of the test technique rather than individual measurement instruments, which are included within the broader designation (e.g. HPLC-DAD is included within HPLC-UV-VIS).

It should be noted that where test techniques not foreseen by the methods are used, or where there is a change of detector or culture medium, it is not possible to retain the reference to the official/standardised/non-standardised method; in such cases, it is necessary to convert the procedure into a laboratory-developed method (see ACCREDIA Regulation RT-08).

5.2. Sampling methods

Methods relating exclusively to sampling activities are included in Atlante in specific rows and identified in the “test type” field as “sampling”. This category includes methods that describe only the sampling activity within the method itself (e.g. ISO 18593, UNI 10802).

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[6] The database is periodically updated by ACCREDIA DL. However, it is specified that it has not been developed as a tool for verifying the currency of external reference documents by testing laboratories, which are required to carry out appropriate checks on the official websites of the bodies responsible for issuing the individual methods.

In Atlante, category III is always assigned to these activities and cannot be modified by the Laboratory.

For sampling, the matrix indicated in Atlante corresponds to that stated in the scope of the method (e.g. environmental surfaces in the food sector / sampling supports, and not swab, sponge, etc.).

Atlante does not provide combinations of sampling methods + test methods. In test reports, the laboratory may associate the sampling standard with subsequent analytical methods that have the same scope and applicability as the sampling standard.

5.3. Laboratory-developed test methods (in-house methods)

5.3.1. Material/Product/Matrix

A list of “Material/Product/Matrix” options is available in Atlante for selection. The laboratory may request that the list be expanded with new terms, but not with synonyms.

The laboratory must select, in the “Material/Product/Matrix” field, only the specific matrices for which validation has been carried out and for which the relevant validation data are available. Overly generic matrices (e.g. Waters) must not be indicated, as this could result in flexibility.

If a laboratory-developed method is intended to be applied to multiple macro-matrices (e.g. soils, waters and food products), the laboratory must enter a separate row for each matrix type.

5.3.2. Measurand/Measured Property/Test Designation

A list of “Measurand/Measured Property/Test Designation” options is available in Atlante for selection. The laboratory may request that the list be expanded with new terms, but not with synonyms.

When specifying the measurand, the laboratory must not select generic categories (e.g. Metals, a term intended for flexible tests), but rather the individual analytes/quantities for which the laboratory has carried out validation and for which the relevant validation data are available (e.g. Arsenic, Barium, Cadmium, Chromium, Potassium, Vanadium, Zinc).

5.3.3. Measurement Range

The measurement range is a free-text field available in all rows.

Completion by the laboratory is mandatory (e.g. range, limit of determination, presence/absence, detectable/non-detectable, pass/fail, etc.). No additional information must be entered (e.g. non-selectable parameters, techniques, etc.).

5.3.4. Test Method

Laboratory-developed methods shall be identified by:

- the code and/or alphanumeric designation defined by the laboratory;
- the revision index;
- the revision year.

When selecting the identifier for an in-house method, the laboratory shall not use acronyms, abbreviations or codes that could create confusion with, or overlap with, official/standardised methods.

No other information shall be entered in this field.

Only where a laboratory-developed method has been drafted complement a non-exhaustive standardised method, it is permissible to report the combination of the standardised method and the laboratory-developed method (RT-08). In all other cases, the laboratory-developed method shall be complete and self-contained; therefore, no other combinations are permitted (e.g. in-house method + in-house method).

5.3.5. Test Technique

For each laboratory-developed method submitted for accreditation, the laboratory shall select the test technique from those available in Atlante, in accordance with the criteria set out in Section 5.1.5 above.

5.4. Flexible Scope of Accreditation

In the case of flexible accreditation, each test (the so-called “master test”) shall be entered in the test list via the DAonline portal in accordance with the following requirements:

- The entry must remain within the scope of flexibility requested by the laboratory. Consistently with the fixed scope, the laboratory may also select broader matrices and parameters (e.g. Waters/Metals; Metallic Materials/Hardness).
- Where matrices belong to different macro-matrices, a separate row must be entered for each macro-matrix (e.g. Waters and Urine shall be entered on two separate rows)
- Overly broad parameters (e.g. contaminants, chemical parameters, microorganisms, chemical analysis) shall not be entered. Instead, “families” of analytes with similar chemical characteristics must be specified (such as PCBs, organochlorine pesticides, PAHs, PFAS, etc.). Furthermore, different classes of parameters shall be entered on separate rows (e.g. allergens and GMOs; pesticides and PCBs).
- The laboratory shall select a test technique for each row and shall also specify the detector (e.g. HPLC-MS, HPLC-FLD). Tests involving the 'culture method' technique cannot be entered, even if followed by another confirmatory technique (e.g. Culture Method + PCR). For rows where it is not possible to identify a specific technique, the details of the reference standard must be entered in the measurement field (e.g. IEC 60335-1, which implies that the only techniques included are those provided for by the indicated reference standard).
- In the case of a first application for a flexible test, in the 'test method' field the laboratory must indicate, even in simplified form, all the methods it intends to transfer from the fixed scope.

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