




AKREDITACIONO TIJELO CRNE GORE
ACCREDITATION BODY OF MONTENEGRO

Reference/Date:
PR.12-3/07.04.2026.

FLEXIBLE SCOPE OF ACCREDITATION

	Name and surname	Function	Date	Signature
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1. SCOPE

This document defines general principles applied by the Accreditation Body of Montenegro regarding the flexible scope of accreditation, determines the requirements for conformity assessment bodies requesting a flexible scope of accreditation, and prescribes the accreditation procedure that shall be applied by the Accreditation Body of Montenegro to grant a flexible scope of accreditation.

2. ABBREVIATIONS AND DEFINITIONS

2.1 ABBREVIATIONS

ATCG - Accreditation body of Montenegro

CAB - Conformity Assessment Body

2.2 DEFINITIONS

Conformity assessment - process by which it is demonstrated that specified requirements relating to a product, process, service, system, person, or body are fulfilled

Conformity assessment body (CAB) - the body that performs conformity assessment activities and that can be the object of accreditation

scope of accreditation - specific conformity assessment activities for which accreditation is sought or has been granted

flexible scope of accreditation - scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body as confirmed by the accreditation body

Other relevant terms and definitions given in MEST EN ISO/IEC 17011:2018 and MEST EN ISO/IEC 1700:2022 also apply.

3. RELATIONSHIP WITH OTHER DOCUMENTS

MEST EN ISO/IEC 17011:2018, Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies

MEST EN ISO/IEC 17000:2022, Conformity assessment - Vocabulary and general principles

EA 2/15 M: 2023, EA Requirements for the Accreditation of Flexible Scope

PA.01 - Rules of Accreditation

PR.01 - Assessment of conformity assessment bodies

PR.11 - Procedure for expression of the scope of accreditation


Note: For documents without the stated year of publication, the latest valid version of document applies.

4. DESCRIPTION OF TASKS AND RESPONSIBILITIES

4.1 GENERAL PRINCIPLES

4.1.1. Introduction to “flexible” scope of accreditation

Accreditation is a third-party attestation related to a conformity assessment body (CAB) conveying formal demonstration of its competence, impartiality, and consistent operation in performing specific conformity assessment activities. It follows that a description of the competence of a CAB must be clearly visible to all interested parties. This is currently done through the scope of accreditation. It is

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important to define the scopes in such a way that it is possible to establish accurately and unambiguously the range of activities covered by a CAB's accreditation.

Historically, accreditation has been based on so-called "fixed" scopes of accreditation, published by the national accreditation body (e.g., ATCG). This system for defining the scope permits on one hand, an accurate description of the accredited activities of the CAB and on the other ensures that an appropriate evaluation of its competence is carried out each time an additional or modified activity is included in the scope.

However, this method of describing a scope can be considered restrictive by some CABs for the following reasons:

- There is a difference between listing specific activities that a CAB is competent to carry out and defining its competence to apply its knowledge, skills, and experience to different activities. It is important not to let the limitations of describing the scope determine what is accredited, instead of determining what a CAB is competent to do and then describing that.
- The fixed scope does not readily enable additional or modified activities to be added to a body's scope without further assessment, even where competence in this general area has already been demonstrated. Although existing CABs may apply for an extension to scope at any time throughout the assessment cycle, the timescales involved may prevent tenders or contracts being met within their customer's timeframe.
- In practice, end-users are not always experienced in the conformity assessment standards. They are often faced with significant difficulties in understanding the content of very long, detailed, and technical scopes of activities. A more generic approach might help to promote the use of the scope of accreditation by the end-users.

Accreditation bodies (e.g. ATCG) therefore need to establish mechanisms that permit, in defined circumstances, CABs to include additional or modified activities in their scope of accreditation on the basis that their competence has been evaluated not only to carry out activities following previously evaluated procedures, but also for the development and validation of their procedures following a pre-established system. This kind of scope is called "flexible scope".

4.1.2 ATCG's policy on flexible scope of accreditation


ATCG offers "flexible scopes" of accreditation to interested CABs.

During the first accreditation cycle (ATCG accreditation cycle lasts for 4 years), ATCG shall grant only fixed scopes of accreditation to CABs.

Upon request, ATCG may grant a flexible scope of accreditation to an accredited CAB (for all or part of its conformity assessment activities) at the earliest, at the beginning of the second accreditation cycle.

There is no unique way of establishing and applying a flexible scope of accreditation. It is the responsibility of each CAB to determine how it will implement flexible scope (i.e., what its requirements are) in the framework of the standard used for accreditation, and how it can demonstrate that this approach is fit for its intended use and capable of being maintained and controlled.

The technical capability for a CAB to manage itself within a flexible scope becomes the key to introducing flexible scopes. A flexible scope shall only be awarded when the CAB has demonstrated it has a design/development process that it can apply for any additional or modified conformity assessment activity or to expand into new areas covered by the flexible scope, but not previously undertaken. The design process shall determine the requirements, develop the conformity assessment service, validate that the planned activities will meet the requirements, and verify that the activities have met the requirements. Without a demonstrated design process, it would not be possible to extend flexibility beyond the current fixed scope position. CAB's competence to manage conformity assessment activities within the flexible scope of accreditation shall be the basis for awarding such

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scope.

The flexible scope of accreditation shall be valid only for the particular accreditation scheme and within the defined limits of flexibility, meaning that the CAB may not extend conformity assessment activities to other accreditation schemes or beyond the defined boundaries of the flexible scope of accreditation without prior assessment by ATCG. Furthermore, a flexible scope of accreditation shall be granted only for those locations that were assessed during the accreditation process.

CABs shall explain to (potential) customers the boundaries of their accredited scope.

ATCG or CAB shall not imply in any communication that holding a flexible scope is an overt sign that it is more competent than a CAB holding a fixed scope. ATCG considers the reliability of reports/certificates issued by accredited CABs to be the same regardless of whether the CAB has a fixed or flexible scope of accreditation.

Types of flexibility:

1) For **laboratories** (testing/calibration/medical), the flexibility of the scope of accreditation can refer to:

a) test/calibration item (object/material/product)

This type of flexibility allows changes to be made in the scope of accreditation within the test object/item, provided that the new test item is still within the intended area of application of the accredited test method.

b) type of test/characteristic being tested/measured

This type of flexibility allows changes to be made in the scope of accreditation within the characteristic being tested/measured, provided that it can be tested/measured using an existing test method on a test item that is already within the scope of accreditation. This flexibility can also include changes in the measurement range.

c) reference document (test/calibration method)

This type of flexibility allows reference document to be changed, provided that the the reference document remains within the framework of the same test/measurement principles for which the laboratory already holds accreditation.

Note: The above also includes the possibility of using new versions of standards/reference documents that prescribe the test/measurement method

d) combination of the above-stated elements.


Note: The scope of accreditation for calibration laboratories is defined as a fixed scope, and any extension thereof is subject to the procedure for extending the scope of accreditation.

4.2 REQUIREMENTS FOR CABs

CAB is obliged to fulfil the requirements established by ATCG for the flexible scope of accreditation, within the framework of the reference harmonized standard for accreditation. On a continuous bases, CAB must be capable of demonstrating to ATCG that its approach to flexible scope is fit for intended use and capable of being maintained and controlled.


In order to perform conformity assessment activities within the flexible scope of accreditation, CAB shall:

- Design a system for managing the flexible scope of accreditation within the framework of the reference harmonized standard for accreditation. The design process shall determine the requirements, develop the conformity assessment service, and validate that the planned activities will meet the requirements, and verify that the activities have met the requirements.
- Document the design and implementation process for managing the flexible scope of accreditation and integrate it into the CAB's management system. The CAB's policy in relation to the flexible scope of accreditation shall be clearly stated (e.g. in the Quality Manual) and relevant management

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system documents for flexible scope of accreditation shall be updated/developed (for example to cover: review of requests/contracts, competences and responsibilities of CAB's personnel, monitoring and reporting, etc.).

- Define the limits (boundaries) of flexibility clearly and unambiguously. Within the documented system for managing the flexible scope of accreditation, there shall be clear and precise information about which conformity assessment activities are included in the flexible scope of accreditation, what is the scope of possible changes (types of flexibility), which new activities can be additionally included in the flexible scope of accreditation.
- Determine procedures for validation and/or verification of new activities within the flexible scope of accreditation. CAB shall document procedures that specify the extent of validation and/or verification to be carried out before changes to the flexible scope of accreditation are made. Validation shall be as extensive as necessary to meet the needs of the intended application area. A validation plan shall be prepared for any change in the flexible scope of accreditation. The results of the validation shall be documented in an appropriate report approved by an authorized person.
- Assign responsibilities and authorities to personnel for all aspects of managing the flexible scope of accreditation. Among other things, the CAB shall define and document competence criteria, and shall designate persons responsible for validation and/or verification of changes and persons authorized to decide whether the changes shall be implemented. For laboratories, the personnel shall meet the requirements for adequate qualifications and experience in development of test methods or research within the relevant technical area (as a minimum, the authorized person shall have the competence to evaluate the suitability of the method, to prepare a validation plan, to carry out necessary estimation of measurement uncertainty (random and systematic errors), to evaluate calibration data and measurement range, when relevant).
- Determine and apply request/contract review procedure on how it processes a request which is within the boundaries of its flexible scope, but also where the activity has not been undertaken before (i.e. not on the List). In such cases the CAB needs to ensure the following:
 - It informs the customer that it will not be able to issue a report/certificate under accreditation until the activities have been established and authorized within its system under its flexible scope process;
 - It informs the customer of the appropriate implications (e.g. turnaround time, price, etc);
 - It has access to all necessary resources and other means required for the completion of the specific requested activity;
 - It has suitably qualified personnel for the completion of the specific activity and its validation or verification;
 - The necessary validation or verification has been carried out;
 - Updating of the List is made only after appropriate technical activities have been properly performed as per the design and implementation process and duly authorized by the CAB;
 - All locations of the CAB involved in the additional or modified conformity assessment activity have been previously declared to the ATCG. Moreover, an additional or modified conformity assessment activity shall not be included in the locations of the CAB until the ATCG has assessed and added the locations to the accreditation information.
- Should the established validation process of an activity result in the conclusion that the CAB is not capable of issuing valid reports/certificates, the CAB shall carry out an analysis of the cause and take adequate actions. Such actions include:

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- to inform the client that it is not possible to issue a reliable report/certificate under the accreditation (with an explanation);
 - the revision of the relevant procedures/methods (if it is determined that the reason is a specific technical problem);
 - If necessary, redefinition of the boundaries within which the scope is flexible, about which the CAB is obliged to immediately inform ATCG to consider the need for an extraordinary assessment.
- Ensure that reports/certificates issued under accreditation contain a clear indication of whether the method/procedure in question is within the flexible scope of accreditation.
 - Establish and regularly update the List of changes, documenting all changes implemented within the flexible scope of accreditation. The list shall contain at least:
 - a) a brief description of the change;
 - b) the date from which the change became effective;
 - c) reference to the validation and/or verification report.
 - Establish and regularly update a detailed List of activities that are carried out within the flexible scope of accreditation, which must be publicly available on the CAB's web portal. Activities must be expressed in the manner prescribed for the fixed scope of accreditation. This List must contain information as a minimum to that detailed in section 7.8.3 a-h of MEST EN ISO/IEC 17011:2018.
 - Continuously monitor the effectiveness of the system for managing the flexible scope of accreditation (during internal audits of the management system, management reviews, etc.).

4.3 CAB APPLICATION AND ASSESSMENT PROCEDURE


From the beginning of the second accreditation cycle and onward, CAB may submit to ATCG the corresponding Application for accreditation (forms ZPR.01.01, ZPR.01.06), with a request for the flexible scope of accreditation. Application shall clearly indicate for which part of the scope of accreditation the flexibility is requested (full scope or part of the scope), as well as what that flexibility refers to (see types of flexibility in section 4.1.2 of this document).

In similar way, an accredited CAB that has previously been granted a flexible scope of accreditation may request an extension of the flexible scope (for a part of the remaining scope of accreditation, or for the entire scope of accreditation), as well as for a new scope of accreditation.

Along with the Application for accreditation, CAB shall submit the following supporting documentation:

- clear information about the limits (boundaries) of flexibility, stating which part of the scope is under the flexible scope of accreditation, what are possible changes in flexible scope (types of flexibility), which new activities can be additionally included in the flexible scope of accreditation;
- all relevant documentation of the CAB's management system describing the procedure for design, implementation and managing the flexible scope of accreditation;
- documented criteria for the competence of the personnel responsible and authorized to manage all aspects related to the flexible scope of accreditation;
- records on the qualifications, experience and training of the personnel responsible/authorized for managing the flexible scope of accreditation;
- current List of activities that would be included within the flexible scope of accreditation.

Responsibility: CAB applying for flexible scope

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When reviewing the Application for accreditation, ATCG shall take into account the results of previous assessments of the CAB, as well as any previous experience with the use of the flexible scope of accreditation by the CAB (if applicable). In determining the level of risks associated with the activities, to accept the application of a CAB for a flexible scope and design a suitable assessment process, the ATCG shall consider, in addition to the usual risks associated with accreditation processes and operation, the following aspects (risk factors):

- Extent of flexibility requested by the CAB;
- Robustness of the process (including extent of controls) designed by the CAB for managing its flexible scope;
- Stability of technical personnel within CAB, responsible for the management of flexible scope and for the different activities relating to flexible scope;
- Complexity and level of familiarity of the ATCG with the conformity assessment activities. For example, with new and emerging activities, the competency requirements may not yet be fully known;
- Ability of the CAB to demonstrate that the way that it operates is suitable and valid, and is undertaken impartially, competently and consistently;
- Stakeholders/regulatory expectations;
- Reputational risks for ATCG.

Responsibility: Head of the competent Department/Head of the Accreditation service/ATCG director

4.3.1 Access to Initial Assessment


The assessment will include:

- (a) The competence and capability of the CAB to perform each activity included within the flexible scope of accreditation
- (b) The management system and controls implemented by the CAB to maintain the flexible scope of accreditation
- (c) The process of reviewing, validating, approving, and authorizing new and/or modified activities used within the framework of the flexible scope of accreditation, including risk assessment
- (d) The contract review process to ensure clarity of understanding between the customer and the CAB regarding expectations related to the flexible scope of accreditation

To assess the competence of the CAB in managing the flexible scope of accreditation, ATCG will use the following assessment techniques, through a combination of remote and on-site visits, as appropriate:

Techniques for flexible scope assessment are:

- a) Review of documentation:
 - Verification that the CAB has a clear, flexible scope management system in place, including procedures for approving and updating new activities.
- b) Assessment of technical competence:
 - Verification of the ability of the CAB staff to apply the requirements of the standard to the activities to be added to the flexible scope.
 - Analysis of technical documentation and records related to extended activities.
- c) Risk analysis:
 - Assessment of the CAB approach to identifying and managing the risks associated with flexible scope.
- d) Sample of extended activities:
 - Verification of a representative sample of the activities included by the authority in the flexible scope, in order to determine whether all new activities are carried out in accordance with the requirements.
- e) On-site observation:
 - Observation of the work of the staff of the CAB while carrying out activities covered by the flexible scope, to ensure the practical application of policies and procedures.

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- f) Staff Training and Competence:
 - Verification of the training and qualification system of the CAB staff for activities that were not originally covered by the scope of accreditation.
- g) Traceability and Change Management:
 - Verification of the traceability of all changes within the flexible scope of accreditation, including compliance with the latest versions of relevant standards and regulations.
- h) Effectiveness of Internal Audit and Management System:
 - Verification of whether the internal audit of the CAB covered activities related to the flexible scope.

As part of the assessment, ATCG will require a discussion with authorized personnel responsible for managing the flexible scope process to confirm the competence of the CAB. When the application includes multiple locations, such evaluations may be conducted on a sampling basis, taking into account risk assessment and the extent to which the CAB has demonstrated its ability to effectively control its locations.

4.3.2 Post-Accreditation Processes

After the accreditation for the flexible scope has been granted, ATCG may require records of the first processes/activities authorized by the CAB within its flexible scope, outside the usual accreditation assessment activities, to confirm the effective implementation of relevant management controls.


The implementation and effectiveness of the CAB's management system in controlling its flexible scope of accreditation will be monitored as part of the regular accreditation assessment cycle. Sufficient time will be allocated for future surveillance and reassessments to evaluate the CAB's ongoing competence in managing the flexible scope. This will include an examination of the CAB's records related to decisions on new and/or modified activities since the last assessment visit, based on an appropriate sample. The time required for these assessment activities will depend on the approach used, the activities involved, the risks associated with those activities, and the number and complexity of new/modified activities. In some cases, this may require an additional visit or visits to the CAB's premises; this will be agreed upon before granting the flexible scope of accreditation and subsequently reviewed on an ongoing basis. Before each scheduled assessment, ATCG will require a list of activities conducted under the flexible scope arrangements since the last visit and may request the CAB to provide relevant records related to some or all of these activities for review.

In general, during the assessment and decision-making process, ATCG shall consider the following aspects:

- Degree of understanding of the CAB in the rules and procedures for implementing and managing a flexible scope;
- Performance and robustness of the CAB's management system for the defined boundaries;
- Knowledge of the CAB and its compliance to the relevant standards and activities;
- The planned frequency with which the CAB intends to update the List of activities relating to the flexible scope;
- Proofs of the performance of the full process including the extent of controls implemented by the CAB for managing a flexible scope;
- Extent of flexibility given to CAB.

During the assessment of the flexible scope of accreditation, ATCG shall (in addition to general relevant accreditation criteria) verify the fulfillment of the requirements specified in point 4.2 of this document. Findings on the fulfillment of those requirements shall be given in the assessment report. Any ATCG refusal to grant accreditation for a flexible scope shall be in relation to CAB's failure to fulfill one of the requirements given in section 4.2 of this document.

ATCG shall verify the competence of a CAB for managing the flexible scope of accreditation by evaluating the documentation and procedures applied by the CAB, by evaluating the performance of

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the CAB in connection with the introduction of new activities in the flexible scope of accreditation in the previous period, as well as by evaluating the competence of the personnel responsible and authorized for managing of the flexible scope of accreditation. In general, the verification process should include the examination of real examples where a CAB has implemented a flexible scope.

Based on the findings of the on-site assessment, ATCG assessment team shall clearly and unambiguously determine CAB's flexible scope of accreditation.

If, during the assessment, non-conformities are identified in relation to the implementation of the flexible scope of accreditation, ATCG (i.e. ATCG's assessment team) shall undertake the activities according to documents *PA.01 – Rules of Accreditation* and *PR.01 - Assessment of conformity assessment bodies*.

Responsibility: ATCG assessment team

The scope of accreditation issued by the ATCG shall make clear the extent of flexibility given and make reference to the List of activities that are included within the flexible scope of accreditation.

Responsibility: ATCG Accreditation Committee/ATCG director

When developing the Assessment program for the CAB with flexible scope, the ATCG will take a risk-based approach, taking into account previously mentioned risk factors detailed to determine the appropriate level of sampling to confirm ongoing controls and effective implementation are in place in areas such as:

- All additional/modified activities
- Validation
- Metrology assessment (where applicable) / Quality assurance mechanisms
- Competence and training of personnel involved with the additional/modified activity
- Availability of working instructions, legal requirements, etc.
- Comparisons with other activities
- Risk assessment

Responsibility: Assessment team/Head of the competent Department

During regular assessment of the CAB, performed according to the Assessment program, ATCG shall verify the fulfillment of requirements related to the flexible scope of accreditation. For preparing of the assessment, CAB shall present to ATCG all the relevant information related to implementation of flexible scope of accreditation in the period between two assessments. The information shall be submitted to the ATCG in a timely manner, no later than one month before the planned on-site assessment.


Should the CAB have issued any reports/certificates under accreditation that do not comply with the requirements of this document, the ATCG shall take the measures it deems appropriate.

In the same way, depending upon the nature, implications and severity of the possible non-conformity identified in terms of the management of a flexible scope, and without prejudice to other actions (for example, suspension of accreditation), the ATCG may decide to revise the scope such as to reduce or even withdraw the flexibility, thus limiting the specific activities included in the List of activities that are included within the flexible scope of accreditation.

4.4 EXPRESSING THE FLEXIBLE SCOPE OF ACCREDITATION

Granted scope of accreditation to any CAB is presented (expressed) within the Addendum to the accreditation certificate (hereafter: Addendum) in accordance with document PR.11 - Procedure for expression of the scope of accreditation

In the Addendum, ATCG shall express the scope of accreditation granted to a CAB, defining the CAB's demonstrated competence to carry out conformity assessment activities. The CAB's flexible scope of accreditation, when relevant, shall also be stated within the granted scope of accreditation (in the Addendum). The flexible scope of accreditation shall be indicated.

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In addition to the indication of the flexible scope of accreditation, the flexible scope shall be accompanied by a reference to where the interested parties may find the detailed list of activities carried out by the CAB under the flexible scope of accreditation.

Note: The list of activities is maintained by the accredited CAB.

4.4.1 Laboratories

As provided in section 4.1.2, flexibility of scope, concerning a "fixed" scope of accreditation, can refer to the following elements:

- “Test item/material/product”, “Measurand/Calibration object” or “Subject of examination (materials, sample)” - this type of flexibility allows changes to be made in the scope of accreditation within the object of testing/calibration/medical examination, and/or
- “Measuring characteristics/ Examination technique”, “Measurement range” or “Measuring characteristics/ Examination technique” - this type of flexibility allows changes to be made in the scope of accreditation within the characteristic to be tested/measured, and/or
- "Reference document" - This type of flexibility allows for changing the reference document.

If the entire granted scope of accreditation is flexible, in front of the table provided in the Addendum to the accreditation certificate, the text "Flexible scope of accreditation" is stated. If the scope includes both fixed and flexible activities, the text "Combined fixed and flexible scope of accreditation" is stated, and then expressed through specially defined tables of the scope of accreditation.


For different types of flexibility, the following text is added below the table in the Addendum:

- If flexibility refers to all elements of the Scope of accreditation, the text "Flexibility is allowed within all elements of the Scope of accreditation" is indicated below the table;
- If the flexibility refers only to certain elements of the Scope of accreditation, the text "Flexibility is allowed within the elements <Test item/material/product> and/or <Measuring characteristics/ Examination technique> and/or <Reference document> is indicated below the table;
- If there is flexibility in relation to the reference document, the year of publication of the standard/other relevant document is not stated (nor the corresponding annexes and clauses of the standard), because it is considered that the laboratory applies the valid edition; in this case under the table of the scope of accreditation it is stated: "Flexibility refers to the application of new editions of standards/internal methods without reference of the year of edition".

In all above cases, below the table presenting the scope of accreditation, the text "The full list of accredited conformity assessment activities within the flexible scope of accreditation is available on the website of the accredited laboratory <website name>"

Assessment team, during the assessment, has to check and report on the following issues:

- Are **competence requirements** determined for personnel who are authorized to modify or develop, to verify or validate test methods?
- Are **responsibilities** for the modification or new development of test methods and validation or verification documented (authorization granted)?
- Are the laboratory's **procedures** for the introduction of new or modified test methods considered in the management system and documented to the required extent?
- Are modifications to test methods or development activities, including all underlying validation and verification results and other relevant data, fully **recorded**?
- Is the process for implementing new or modified test methods considered in the **audit programme**?
- Is the process for incorporating new or modified test methods considered as input to the **management review**?

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- Are **verified** and/or **validated** test methods applied within the limits specified in the flexible scope of accreditation?
- Is the development, evaluation, validation and approval of new or modified test methods regularly documented with suitable measures to **ensure the validity** of the results?
- Does the laboratory maintain a **publicly available list** of accredited activities performed within its flexible scope? Is this published list up to date?
- Does this list of all test methods within the (flexible) scope of accreditation contain at least the following information for each test method?

4.4.2 Inspection and certification bodies

Due to the nature of inspection and certification activities, which require clearly defined methods and regulatory requirements, ATCG does not apply a flexible scope of accreditation for inspection and certification bodies. The scope of accreditation is defined as a fixed scope, and any extension thereof is subject to the procedure for extension the scope of accreditation.

5. FORMS

This procedure has no accompanying forms