
 <p><b>AKREDITACIONO TIJELO</b> Crne Gore</p>	<p>AKREDITACIONO TIJELO CRNE GORE ACCREDITATION BODY OF MONTENEGRO</p>	<p><b>Oznaka/Datum:</b> UP.05 /03.12.2024.</p>
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## Instructions for Including Opinion and Interpretation in the Accredited Scope of the Laboratory and the Difference from the Declaration of Conformity

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## 1. SUBJECT AND SCOPE OF APPLICATION

This instruction applies to providing guidelines for the inclusion of opinions and interpretations in the accredited scope of the laboratory.

## 2. ACRONYMS AND DEFINITIONS

### 2.1 Acronyms

ATCG – Accreditation body of Montenegro

### 2.2 DEFINITIONS

**Opinion and Interpretation** is defined as the outcome of the testing and calibration process that extends the application of the obtained results. It is formulated by technically qualified personnel (or organization) based on the obtained results of testing or calibration, their knowledge, and professional judgment in the technical field in which the results were obtained. Opinion and interpretation must be technically correct and supported by evidence.

**Note 1:** This definition is taken from the document EA-4/23 INF:2019, but it is known that there are other definitions of the terms opinion and interpretation. For the purposes of this document and to ensure consistent application for accreditation, the definition above is used.

**Note 2:** It is important to differentiate between opinions and interpretations and declarations of conformity (according to the ISO/IEC 17020 standard) and product certification (according to the ISO/IEC 17065 standard), as well as declarations of conformity (ISO/IEC 17025, clause 7.8.6). Opinion and interpretation must exclusively relate to the tested/calibrated items and should not imply that they refer to a series or future batches of products (which is the subject of product certification). Additionally, opinion and interpretation must include professional judgment to distinguish them from a declaration of conformity.


## 3. CONNECTION WITH OTHER DOCUMENTS

MEST EN ISO/IEC 17011:2018, Conformity Assessment - Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies

MEST EN ISO/IEC 17011:2018 Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies

EA-4/23 INF:2019 The Assessment and Accreditation of Opinions and Interpretations using ISO/IEC 17025:2017

MEST EN ISO/IEC 17025:2018 General Requirements for the Competence of Testing and Calibration Laboratories (6.2.6 b, 7.8.7)

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#### 4. GENERAL

The ATCG policy stipulates that the accreditation of laboratories in accordance with the MEST EN ISO/IEC 17025:2018 standard may include the expression of opinions and interpretations of testing/calibration results in reports.

In most cases, it is the responsibility of laboratories to decide whether to include statements of opinions or interpretations in test reports or calibration certificates, whether to seek accreditation for this activity, and to act accordingly. This decision must be clearly stated in the laboratory's quality system documentation.

In some scenarios, the analysis of opinions and interpretations is an integral part of the process (e.g., they cannot be accredited under ISO/IEC 17025:2017 without expressed opinions and interpretations). When such methods are evaluated, criteria for assessing opinions and interpretations will be included as a standard practice. This should be specified in the application form (Accreditation Request) and considered during the review of the Request.

The expression of opinions and interpretations related to results is considered an integral part of testing/calibration activities, and ATCG will not accredit the expression of opinions and interpretations in reports as a standalone activity. It is essential to ensure that the scope of the use of opinions and interpretations is clearly defined.

The main criterion applied is as follows: Opinions and interpretations expressed in test/calibration reports must be based on results obtained concerning the tested/calibrated item.

Reports that include opinions and interpretations must explicitly state that they relate to the specific item that has been tested or calibrated. They must not be used for product certification, as they represent only an input to that process.


A laboratory already accredited for testing/calibration may submit a request to ATCG for an extension of the accreditation scope to include the expression of opinions and interpretations related to result reports.

When an accredited laboratory reports a statement of compliance or non-compliance alongside the test results, this is not considered part of opinions and interpretations.

Reporting compliance/non-compliance with specific requirements is a general reporting activity covered in detail under ISO/IEC 17025:2017 (section 7.8.6).

##### 4.1 STATEMENT OF CONFORMITY

Providing **statements of conformity** with requirements and/or specifications is a standard part of laboratory activities. Such statements are not considered opinions or interpretations.

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When a laboratory includes statements of conformity in its reports or calibration certificates, they must be appropriately labeled (e.g., as "statement of conformity" or "conclusion," but not as "opinion," "interpretation," or "opinion and interpretation").

When a **statement of conformity** to a specification or standard is provided, the laboratory must document the applied decision rule, taking into account the level of risk (such as false acceptance or false rejection and related statistical assumptions) associated with the chosen decision rule.

The decision rule must be agreed upon with the customer during the contractual phase.

In a **statement of conformity**, the laboratory must clearly specify:

- a) The results to which the statement of conformity applies.
- b) The specifications, standards, or specific parts that are fulfilled or not fulfilled.
- c) The applied decision rule (unless the decision rule is an integral part of the required specification or standard).

If a laboratory includes **statements of conformity** in reports or calibration certificates for testing or calibration activities conducted within the accredited scope, the statement of conformity must not be labeled as outside the scope of accreditation.

In such cases, providing statements of conformity is considered an activity within the accredited scope and is subject to evaluation during the accreditation process.

Statements of conformity with requirements and/or specifications must not be presented in a manner that could create confusion or suggest that they pertain to product control or certification.


If statements of conformity are provided for results that fall outside the scope of accreditation, it is essential that this is clearly indicated. This distinction ensures that the scope of the laboratory's accredited activities is not misrepresented, and that the statement is appropriately aligned with the accredited capabilities.

#### **4.2 REQUIREMENTS FOR THE INCLUSION OF OPINIONS AND INTERPRETATIONS IN THE ACCREDITED SCOPE**

The applicant must specify the accredited testing/calibration/verification activities for which the laboratory intends to express opinions and interpretations. New applicants, when applying for accreditation for testing/calibration (verification), should indicate in the application whether they want the accredited scope to include opinions and interpretations, as well as specify the testing/calibration (verification) activities for which they plan to express opinions and interpretations.

It is unlikely that expressing opinions and interpretations of calibration/verification results will be necessary for most calibration/verification activities. However, ATCG will accredit the expression of opinions and interpretations in calibration reports if it is demonstrated that it is necessary or appropriate.

The following documentation must be submitted to ATCG for review at least three months before the planned evaluation date or within a timeframe agreed upon between ATCG and the laboratory, in order for ATCG to have sufficient time to assemble the evaluation team and plan the assessment:

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- (a) Documentation reflecting the process (procedures and practices) for including opinions and interpretations in reports;
- (b) Criteria for the competence of personnel authorized to express opinions and interpretations;
- (c) Records of qualifications, experience, and training of personnel authorized to express opinions and interpretations;
- (d) Previous (or sample) reports that include opinions and interpretations;
- (e) Internal audit plan and records that demonstrate the organization robustly monitors the process of expressing opinions and interpretations.

### 4.3 OBLIGATIONS OF ATCG

ATCG will evaluate the processes that the laboratory has established for providing statements of opinions or interpretations in order to assess the laboratory's ability to perform these activities, but it will not accredit or otherwise approve the statements themselves. When necessary, ATCG will seek advice from relevant professional bodies regarding the appropriate level of competence for performing such work.

The laboratory's documented quality system must reflect whether the laboratory expresses opinions and interpretations, and if so, for which activities. The process of interpreting the results of testing/calibration/verification for the purpose of expressing opinions and interpretations must be documented.

ATCG will evaluate the laboratory's ability to express opinions and interpretations through:


- (a) Reviewing the implementation of procedures and practices;
- (b) Reviewing the adequacy of the competence criteria for personnel;
- (c) Reviewing the adequacy of mechanisms for monitoring personnel competence;
- (d) Verifying the qualifications, experience, training, and knowledge of personnel;
- (e) Reviewing reports in which opinions and interpretations are expressed;
- (f) Using other appropriate evaluation techniques.

Providing opinions and interpretations should not exceed the scope of those based on the results of control assessments or replace other characteristics required in a product certification scenario. Therefore, opinions and interpretations cannot serve as product certification.

A test report may be one of several inputs into the product certification process. The document EA-4/23 INF contains information on acceptable and unacceptable scenarios for opinions and interpretations.

The output document from ATCG should reflect the testing or calibration/verification activities for which the laboratory has been successfully evaluated and accredited to provide opinions and interpretations. Document EA-4/23 INF (Appendix B) outlines two ways in which the scope of accreditation can be clearly marked to show the testing activities accredited for opinions and interpretations.

If reports include expressions of opinions and interpretations that are not covered by ATCG accreditation, the report must clearly indicate these activities that are not within the scope of ATCG accreditation with an appropriate disclaimer, such as: "These opinions and interpretations are outside the scope of ATCG accreditation."

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As an accreditation body, ATCG has the obligation to ensure that opinions and interpretations in testing and calibration reports are not perceived as a substitute for product certification. The results of a single test sample, even with an opinion, can never serve as a valid substitute for factory production.