Guidelines for the Identification and Classification of Nonconformities in the Assessment Process of CABs

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1. SCOPE AND FIELD OF APPLICATION

These guidelines are applied to provide direction in the determination, identification, and classification of nonconformities in the assessment process of Conformity Assessment Bodies (CABs).

2. ABBREVIATIONS AND DEFINITIONS

2.1 Abbreviations

ATCG – Accreditation Body of Montenegro
CAB – Conformity Assessment Body

2.2 Definitions

Nonconformity – non-fulfilment of a requirement of a reference standard and/or other applicable documents.

Assessment – an activity performed by a conformity assessment body (3.4) when assessing conformity.

Note 1: In the context of this document, activities covered by accreditation include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, as well as validation and verification. For simplicity, these are referred to as conformity assessment activities performed by conformity assessment bodies.

3. RELATIONSHIP WITH OTHER DOCUMENTS

- ISO/IEC 17011, Conformity Assessment — Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies
- ISO/IEC 17000, Conformity Assessment — Vocabulary and General Principles
- ILAC G3:08/2020, Guidelines for Training Courses for Assessors Used by Accreditation Bodies

4. PURPOSE OF THE GUIDELINES FOR HANDLING NONCONFORMITIES

The main purpose of the classification of nonconformities is to determine the severity of a nonconformity identified during initial accreditation, re-accreditation (reassessment), regular surveillance within the accreditation cycle, or extraordinary assessment, as well as to define and implement appropriate corrective actions.

5. CLASSIFICATION OF NONCONFORMITIES

Type A – A deviation from the accreditation criteria which has led or may lead:

- incorrect or unreliable conformity assessment results; or
- improper use of the ATCG accreditation symbol or any other way of unjustified reference to ATCG accreditation; or
- to a specific threat to human health or safety or to the environment, or
- to a deviation that calls into question the fundamental effectiveness of the quality management system, or
- to the repeated occurrence of a Type B nonconformity related to the same standard requirement.

Type B – A deviation from the accreditation criteria which, by its nature and significance, does not indicate a systemic problem and is not expected to lead to the situations described under the definition of a Type A nonconformity.

Examples illustrating Type A nonconformities for different types of CABs are provided in Annex 1 of these Guidelines.

6. CORRECTIVE ACTIONS

Identified nonconformities shall be documented in the Nonconformity Report (ZPR.01.21-1) in full compliance with Procedure PR.01 – Assessment of CABs.

The CAB is required, within the defined deadlines, to submit a proposal for corrective actions, which shall include: root cause analysis of the nonconformity, its extent and impact, and the proposed corrective action. The extent and impact imply that the CAB shall analyse where else within the system the identified problem occurs. Furthermore, the analysis of the root cause and extent shall demonstrate the impact of the identified nonconformity on previously performed activities and clearly define the need and possibility for correction of previously completed work.

ATCG shall confirm the closure of nonconformities once the CAB has taken appropriate actions to eliminate the root cause. This means that the CAB shall demonstrate that it has:
a) performed an analysis identifying the root cause, extent, and impact of the nonconformity;
b) where necessary, immediately suspended activities when conformity assessment results may be considered incorrect or unreliable due to the identified nonconformities;
c) taken all necessary actions based on the root cause analysis to correct or withdraw issued results (reports, certificates, etc.) that do not meet requirements, and, where applicable, informed relevant parties of the consequences of the identified nonconformities;
d) implemented actions aimed at eliminating the identified root cause.

Within the defined timeframe, the conformity assessment body shall notify ATCG in writing of the elimination of identified nonconformities and provide evidence of the actions taken. The assessment team shall verify whether the identified nonconformities have been effectively resolved. Verification may be carried out through review and evaluation of submitted documentary evidence and/or through a follow-up assessment, of which the CAB shall be informed during the evaluation of the proposed corrective actions.

If the assessment team, during the evaluation of the proposed corrective actions, recommends a follow-up on-site assessment at the CAB premises, such activities shall be approved by the Head of the relevant Department or, where applicable, by the Head of the Accreditation Department if the Department Head conducted the assessment, based on the recommendation of the assessment team.

7. CLASSIFICATION OF NONCONFORMITIES AND TIMEFRAMES FOR IMPLEMENTATION OF CORRECTIVE ACTIONS

Type B nonconformity – The period for the closure of nonconformities shall not exceed three (3) months for all types of assessments (initial, surveillance, and reassessment).

Type A nonconformity – In the case of initial assessment, the defined timeframe for corrective actions shall not exceed three (3) months.

During surveillance, reassessment, and extraordinary assessments, the timeframe for corrective actions shall not exceed two (2) months.

Depending on the nature and significance of the nonconformity, shorter timeframes for the implementation of appropriate corrective actions may be set, except in the case of initial assessment.

The applicable deadlines shall be documented in each Nonconformity Report.

Annex 1: Examples of Type A Nonconformities

LABORATORIES

a) The laboratory has reported incorrect results.
b) The body cannot demonstrate the competence of personnel performing testing/calibration.
c) Adequate quality control measures are not in place; therefore, it is not possible to demonstrate the validity of results.
d) The accreditation symbol is used in a manner that suggests accreditation for activities for which the body is not accredited.
e) Required records for one or more tests/calibrations are missing, making it impossible to determine whether the activities were performed correctly.

INSPECTION BODIES

a) The body cannot demonstrate the competence of inspectors.
b) A finding raises doubts about the independence of the inspection body (e.g. demonstrable involvement in activities such as design, manufacturing, etc., or dependency on a design organization).
c) Key observations were missed during inspection, or observations were incorrectly evaluated, leading to unreliable inspection results.
d) The accreditation symbol is used in a manner that suggests accreditation for activities for which the body is not accredited.
e) Required records are missing from one or more inspection files, making it impossible to determine whether a reliable inspection was carried out.

CERTIFICATION BODIES

a) The body cannot demonstrate the competence of its assessor.
b) A finding raises doubts about the impartiality or independence of the body (e.g. demonstrable involvement of certification activities with consultancy services or dependency on a consultancy organization).
c) The body has issued a certificate (a positive decision has been made), while its client has not corrected identified nonconformities.
d) Inconsistencies have been identified in certification activities or in certification decision-making.
e) Key observations were missed during certification activities, or observations were incorrectly evaluated, in a manner that has led or could lead to an incorrect decision by the CAB.
f) The accreditation symbol is used in a manner that suggests accreditation for activities for which the body is not accredited.
g) Required records are missing in one or more files, making it impossible to determine whether a reliable certification decision has been made.