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Instruction for Identification and Classification of Nonconformities in the Conformity Assessment Body Evaluation Process

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1. SUBJECT AND SCOPE

These guidelines apply to providing directions for determining, identifying, and classifying nonconformities during the assessment process of the Conformity Assessment Body (TOU).

2. ABBREVIATIONS AND DEFINITIONS

2.1 Abbreviations

- **ATCG** – Accreditation Body of Montenegro
- **CAB** – Conformity Assessment Body

2.2 Definitions

- **Nonconformity** – Failure to meet the requirements of the reference standard and/or other documents.
- **Assessment** – Conformity assessment activity carried out by a conformity assessment body (CAB).


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

3. REFERENCE DOCUMENTS

- **ISO/IEC 17011** – Conformity assessment – General 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 NONCONFORMITY CLASSIFICATION INSTRUCTION

The primary purpose of classifying nonconformities is to determine the severity of nonconformities identified during initial accreditation, re-accreditation (reassessment), regular assessments within the accreditation cycle, or extraordinary assessments, as well as to define and implement appropriate corrective actions.

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5. CLASSIFICATION OF NONCONFORMITIES

Type A - Finding that is regarded as not conforming to an accreditation requirement and that may lead, is leading, or has led:

- to incorrect or unreliable (not demonstrably correct) conformity assessment results, or
- to the improper use of the ATCG accreditation mark or in some other way an improper claim of ATCG accreditation, or
- to a concrete threat to the health or safety of persons or the environment.

Type A nonconformities in some cases, may lead to the suspension of part or all of the scope. Resolving the non-conformities, by the rule, requires corrective actions to be verified on-site in a subsequent assessment to confirm their resolution, especially when the validity of results or the integrity of the accreditation body is at risk.

Type B – Finding that is regarded as not conforming to an accreditation requirement but that is not leading, has not led, or may not lead to one of the situations specified under the definition of Type A above.

Appendix 1 of this instruction contains examples to illustrate Type A nonconformities for different types of CAB.


6. CORRECTIVE ACTIONS

Identified nonconformities have to be documented in the Report on Nonconformities (ZPR.01.21-1) as described in Procedure PR.04, Assessment of CABs.

Corrective actions must be submitted within the defined time. It has to include: cause analysis, the extent of the finding and its impact, and a corrective action proposal. The term extent means that the CAB analyses where else in the organization or the system the problem identified as nonconformity occurs. Furthermore, the cause analysis and extent will also have to demonstrate the impact of the problems on work done previously and set out clearly the need and possibility of repairing work done previously.

The ATCG will close a non-conformity when the CAB has taken appropriate action to eliminate the root cause of the nonconformity. This means that the CAB can demonstrate that it:

- a) has carried out an analysis showing the root cause and the extent of the non-conformity;
- b) where necessary, has immediately ceased activities as long as results may have to be regarded as incorrect or unreliable as a consequence of the findings found;
- c) has taken action based on the extent analysis by which results delivered (reports, certificates, etc.) that do not meet the requirements have been rectified or withdrawn and where necessary persons concerned have been informed about the consequences of the findings found;
- d) has taken action based on the cause analysis aimed at eliminating the root cause.

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7. CLASSIFICATION OF NONCONFORMITIES AND TIMELINES FOR CORRECTIVE ACTIONS

For Type B nonconformities identified during the initial accreditation assessment, accreditation will not be granted without corrective actions, which must be resolved within 3 months.


The period for resolving non-conformity is three months when it is identified during the regular surveillance assessment. In this case, the accreditation will be suspended if the non-conformity is not resolved within the defined period.

Non-conformity Type A - in the case of initial assessment, accreditation will not be granted until the identified non-conformity is resolved, and its resolution confirmed in the follow-up assessment at the CAB location.

In the case of initial assessment, the defined deadline for resolution of nonconformities is no longer than 3 months.

During regular and extraordinary assessments, in case of identification of Type A non-conformities, the deadline for corrective actions may not exceed 3 months, assuming that the activity within that accredited scope is not performed during that period.

In case of re-evaluation, the deadline for corrective actions is 3 months, assuming that the activity within that part of the accredited scope is not performed during that period.

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Appendix 1 : Type A nonconformities -examples

LABORATORIES

- a. The laboratory has reported erroneous results.
- b. In the absence of adequate quality controls it is not demonstrable that results are correct.
- c. The accreditation mark is used in a way that suggests that the body is accredited for an activity where this is not the case.
- d. In one or more files so many of the records required are lacking that it is no longer possible to see that tests/calibrations have been carried out correctly.

INSPECTION BODIES

- a. The body cannot demonstrate that the inspector is competent.
- b. The finding raises doubts about the independence of the body (for example, in the case of demonstrable mixing of inspection and conflicting activities such as design, production, etc, or demonstrable dependence on a design organisation).
- c. During an inspection essential observations are missed or observations are rated incorrect causing the results of the inspection to be unreliable.
- d. The accreditation mark is used in a way that suggests that the body is accredited for an activity where this is not the case.
- e. In one or more files so many of the records required are lacking that it is no longer possible to see that a reliable inspection has been carried out.

CERTIFICATION BODIES

- a. The body cannot demonstrate that the person who performs the certification activity is competent.
- b. The finding raises doubts about the impartiality or independence of the body (for example, in the case of demonstrable mixing of certification and consultancy or demonstrable dependence on a consultancy organisation).
- c. The body has wrongly provided a certificate; there were still some non-conformities not yet closed by the CAB's client.
- d. Inconsistencies are observed in audits or decisions.
- e. During the performing of certification activities essential observations are missed or observations are rated incorrectly, in such a way that the CAB has made or would make an incorrect decision.
- f. In one or more files so many of the records required are lacking that it is no longer possible to see that a reliable certification decision has been made.
- g. The accreditation mark is used in a way that suggests that the body is accredited for an activity where this is not the case.