INSTITUTE FOR ACCREDITATION OF THE REPUBLIC OF NORTH MACEDONIA

Grading of nonconformities

PR 05 - 06

1. **Nature of nonconformities**

If an assessment identifies that certain requirements of the standard have not been met, this constitutes nonconformities in the activities of the CAB and requires corrective action. Failure by the CAB to carry out its activities in accordance with its prescribed procedures also constitutes a nonconformity. Nonconformity may also arise where the organisation does not comply with IARNM's rules.

The cause of non-conformities may be:

- Documentation does not meet the requirements of the standard for the relevant accreditation scheme and conformity assessment scheme, or the accreditation criteria;
- Personnel do not operate in accordance with their own prescribed procedures (except where such practices do not contravene the requirements of the relevant standard);
- Personnel, or some personnel, do not demonstrate competence in the work they perform;
- Failure of the quality system in the organization;
- The conformity assessment body does not operate in accordance with IARNM's rules.

2. Grading of nonconformities

- **Critical nonconformity:** A nonconformity so serious that it jeopardises the credibility of the accreditation granted.

- **Nonconformity:** Corrective action shall be taken within the time limit specified in this procedure, and the CAB shall submit documentation of the corrective action implemented. Corrective action addressing certain nonconformities may need to be verified on site to confirm successful implementation, particularly where the validity of results or the integrity of the accreditation body has been put at risk.

- **Observation:** Observations are comments/recommendations made by the assessment team to improve the quality system of the conformity assessment body. Their implementation is recommended to make the quality system function more effectively. Observations do not constitute potential or actual failure to meet the requirements of the standards applicable to particular accreditation schemes or other mandatory requirements (technical standards, guidelines, standard conformity assessment schemes, etc.).
  When defining observations, the assessment team shall ensure that they do not constitute nonconformities, i.e. that they do not indicate a failure to meet the requirements of the standards.
  Taking appropriate action in response to observations should only add value to the management system of the conformity assessment body.

3. Measures taken by IARNM as a result of nonconformities

If the assessment team identifies nonconformities, it defines their nature in Form OB 05-14 at the final meeting of each assessment.
The grading of nonconformities shall be based solely on the findings established during the assessment.
The grading of nonconformities is determined by the lead assessor and/or assessor.
Grading shall be carried out during the assessment.
Nonconformities shall be stated precisely enough to determine whether they are isolated occurrences or recurring issues for which corrective action shall be taken across the entire organisation.

If the CAB accepts the nonconformities at the final meeting, it shall, within 14 days at the latest (10 days for a critical nonconformity), submit proposed corrective actions for their elimination, together with an analysis of their causes and the extent of each nonconformity, specifying the parts of the CAB's overall operational system in which it occurs. The conformity assessment body enters this information in form OB 05-15. Once the CAB submits OB 05-15 to the coordinator, it is forwarded to the assessment team, and each relevant team member is required to give an opinion on whether the information provided is satisfactory.

4. Time limits for elimination nonconformities

- For a **critical nonconformity**, the time limit for completing and submitting the form OB 05-15 and obtaining the assessment team's approval is 10 days from the final day of the assessment. The time limit for the CAB to implement and submit corrective action is 30 days from the final day of the assessment. IARNM will verify the corrective action implemented as soon as possible to establish whether it is appropriate and sufficient to resolve the nonconformity.

- For **nonconformity**, the time limit for completing and submitting form OB 05-15 and obtaining the assessment team's approval is 14 days from the final day of the assessment. The time limit for implementing and submitting corrective action is 90 days from the final day of the assessment. IARNM will verify the corrective action implemented as soon as possible to establish whether it is appropriate and sufficient to resolve the nonconformity.

  NOTE: If the assessment is carried out in several stages or the period between the first and final day of the assessment exceeds 7 days, the time limits for submitting OB 05-15 and corrective actions are calculated from the date on which the nonconformity is recorded.

  If the Assessment Team considers that the maximum time limit of 3 months for elimination certain nonconformities is too long (this applies to surveillance assessment of an already accredited scope), it may set a shorter time limit. This applies particularly where the reliability and accuracy of the results provided to the conformity assessment body's end customer are at risk.

  For initial assessment and extension of scope, corrective action addressing nonconformities and its verification shall be completed before accreditation is granted or the scope is extended, respectively.

  The maximum time limit for elimination a nonconformity may be extended to 6 months from the assessment date in exceptional cases where there are objective reasons, for example an interlaboratory comparison, participation in proficiency testing or external quality assessment, or attendance at externally organised training, which objectively cannot take place within 3 months. The Director decides on an extension of the time limit on the basis of a request from the conformity assessment body and recommendations from the assessment team and the Accreditation Commission. During that period, the conformity assessment body shall not, through its activities, jeopardise confidence in the accreditation granted. Extensions of the time limit for elimination nonconformities do not apply to critical nonconformities or to the third surveillance assessment.

EXAMPLES OF GRADING OF NONCONFORMITIES

To improve the effectiveness of this procedure, examples of nonconformities with different grading levels are provided. The proposed grading levels serve only to illustrate this procedure, as in actual cases, depending on the circumstances, a different grading level from that given in the example may be more appropriate.

1. Nonconformities that may be classified as critical nonconformities

- The laboratory has lost the key technical manager for a particular activity and no longer has competent personnel to perform it. It continues to issue testing/calibration reports in that field. The accreditation body has not been informed, and the activity within the accredited scope has not been discontinued.

Note: The same may apply to premises and equipment.

- Even after the laboratory has been warned about issuing testing/calibration certificates bearing the accreditation mark and including methods outside the scope of accreditation, these methods are still not appropriately identified.

- The laboratory has found serious errors in the calibration records for measuring equipment that affect testing results. The errors have not been corrected, nor have customers been informed of the erroneous testing results caused by the equipment.

- There is no equipment calibration information, so the calibration status of the equipment cannot be verified. Maintenance plans and records cannot be found, and there are no records of the reference materials/standards used for the calibrations in question.

- The calibration/testing laboratory has not provided reference standards, and it is unclear what was used as reference standards.

- A new internal procedure has been developed for a single type of testing included in the scope of accreditation. The procedure has not been validated, and there is no evidence that it produces the same results as the standard method.

- There is evidence that the body's quality management system is not functioning. The body has not carried out an internal audit for more than 18 months (contrary to its procedure). Personnel also state that customer complaints have been received by telephone or email, but they have not been recorded in the complaints registration form, nor has any action been taken in response to them.

- During the surveillance assessment, it was established that the certification body had lost the personnel with the necessary competence to carry out evaluation/auditing and make decisions.

- A product certification body uses subcontractors and has assigned responsibility for planning and decision-making to them.

- The Assessment Commission has identified a breach of the inspection body's independence (for example, a Type A inspection body simultaneously carrying out inspection and conflicting activities such as the design, manufacture, supply, installation, ownership, use or maintenance of the items inspected).

2. Nonconformities

Critical equipment is overdue for calibration and has not been recalibrated. An internal check of the device in the laboratory shows that the equipment meets the specifications.

The standard method has been modified without the customer's prior approval and without validation of the modification (further information would be needed to determine the seriousness of the problem).

The advertised scope of accreditation is wider than the actual scope.

No management review has been carried out.

Errors have been found in the transcription of information from the standard method into the laboratory's internal instructions.

Competence records for some technical personnel do not demonstrate that they are competent to perform activities within the accredited scope (if the problem extends beyond the records, the nonconformity may be more serious).

There is no procedure for managing nonconformities.

The laboratory has no records of implementation of the training programme (plan). There is also no evidence from the past year of personnel competence assessment or identification of training needs. These shortcomings were not identified during the internal audit.

The method for determining measurement uncertainty is not fully aligned with EA 4/02 or the GUM, but the calculated measurement uncertainty values are not lower than expected.

A management systems certification body has prepared an internal audit plan that does not cover all types of management systems included in its accredited scope.

During the assessment of a certification body, it was found that IARNM had not been informed of changes within the organisation.

During the initial assessment of a product certification body, it was established that no internal audit or management review had been carried out.