

 <p> Tel +355 4 22 69097 +355 4 22 69325 Fax E-Mail: info@dpa.gov.al </p>	<p>POLICY ON NON-CONFORMITIES</p>	<p>Code DA-PO-013</p>
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Purpose

This document defines the DPA policy regarding nonconformities and comments found during the assessment of the technical competence of the conformity assessment bodies, the root cause analysis as well as the actions taken by the DPA in the case of non-conformities.

References

The standard ISO/IEC 17011:2017, point 7.6.6, “General Requirements on accreditation organizations which accredit the conformity assessment bodies”.

Procedure DA-PT-001 “Procedure for accreditation, surveillance and renewal of accreditation”

Accreditation policy DA-PO-002

Scope

This policy applies to all nonconformities found during the assessment of the technical competence of conformity assessment bodies that have applied for accreditation or have been accredited by the DPA.

Vocabulary

Non-conformity is failure to meet one or more established criteria for accreditation.


Comment is a finding when the established criteria are met but there is room for improvement.

1. THE NATURE OF THE NONCONFORMITIES

When, during the assessment of the technical competence of a conformity assessment body, it has been determined that one or several criteria for accreditation have not been met, the DPA formulates one or several non-conformities. Lack of documented procedures, failure to carry out processes by OVK in accordance with the procedures defined by it itself will also be considered non-compliance. Non-conformity can also be identified in cases where OVK does not respect the rules established by DPA.

The nonconformity would be identified as a result of :

- OVK's documentation does not comply with the requirements of the standard.

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- OVK personnel do not follow documented procedures.
- OVK personnel demonstrate that they are not competent for the work they perform or that they are authorized to perform.
- Operational procedures such as measurement and testing methods, measurement traceability, method validation, etc., lack technical validity
- Non-functioning of the OVK management system
- OVK does not meet the rules established by the DPA.

Comments are findings formulated by the DPA on the possibilities for improving the conformity assessment activity that the conformity assessment body performs within the accreditation program.


2. ACTIONS UNDERTAKEN BY DPA AS RESULT OF NONCONFORMITIES

If the file manager or the assessment team finds non-conformities during the review of the documentation, they are formulated in the relevant forms, DA-FO-006 and DA-FO-007.

If the assessment team finds non-conformities during assessment visits or pre-assessment visits, at the closing meeting of the visit (on site or remotely) they must be formulated according to form DA-FO-003 and must be presented to the conformity assessment body. A copy of the non-conformities is submitted to the assessed OVK. If the non-conformity is formulated after the visit, it must be written in the assessment report. Form DA-FO-003 for non-conformity formulated after the closing meeting is sent to OVK together with the assessment report and the relevant explanation.

In cases where OVK refuses to sign the non-conformity found by the assessment team during the assessment or pre-assessment visit, the Director of the relevant directorate will decide whether the finding is non-conformity or not, or the correct wording of the finding. The Director of the Directorate may also request the opinion of the relevant technical committee.

For any non-conformity found during the assessment visit or recorded in the report, OVK must perform a root cause analysis, the actions it has taken or plans to take to resolve the non-conformity and the time frame for taking the actions. The assessment team analyzes the root cause analysis and the actions proposed by OVK. If the analysis carried out and the proposed actions are not sufficient and appropriate, the assessment team asks OVK to re-perform the analysis of the causes and propose the corresponding actions based on the new analysis. OVK is obliged to send all records of actions taken to DPA. The appropriateness and efficiency of the actions taken by OVK will be assessed by the assessment team either through review of records or an assessment visit or a combination of both. Before giving the recommendation for accreditation in the case of initial accreditation or extension or recommendation for maintenance of accreditation, all non-conformities found must be resolved. Failure to resolve non-conformities in initial

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accreditation or extension leads to the rejection of the request for accreditation or non-extension of the accreditation program. Failure to resolve non-conformities identified in surveillance visits (planned or unplanned) leads to the reduction or suspension or withdrawal of accreditation.

The assessment team can also formulate comments in the areas for possible improvements which should be submitted to the conformity assessment body or in the closing meeting or written in the assessment report. In formulating comments, the assessment team should be careful not to make recommendations for specific solutions. Regarding the formulated comments, DPA does not expect OVK to submit to DPA the records of actions, but they will be assessed in future visits as opportunities for improvement.

assessment report. The assessment group shall be careful in formulation of observations for possible improvement in order to avoid recommendations and specific solutions. Regarding the observations for possible improvements, the CAB is not obliged to take corrective actions, but they will be assessed in the next visits as possibility for improvements.

3. DEADLINE FOR SOLVING THE NONCONFORMITIES

For the solving of non-conformities, the DPA has determined the relevant time limits.

In the case of non-conformities found during the review of the documentation, the maximum term for their resolution is 6 months.

In the case of non-conformities found during pre-assessment visits, the maximum term for their resolution is 6 months.

In the case of non-conformities found in assessment visits for initial accreditation or extension, the maximum term for their resolution is 5 months.

In the case of non-conformities found in surveillance or surveillance visits where the assessment for the extension of the accreditation program is also included, the maximum deadline for resolving the non-conformities is 2 months.

OVK can request, only once, the extension of the deadline for solving the non-conformities found during the assessment visit. The extension must be requested in writing stating the reasons for the postponement. The deadline for extension is approved by the Director of the relevant Directorate if there are objective reasons. The extension may not exceed one month, if justified.

Failure to resolve non-conformities within the time limit in the case of initial accreditation or extension leads to rejection of the application for accreditation or rejection of accreditation for a specific conformity assessment activity or non-extension

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of the accreditation program. Failure to resolve non-conformities within the specified period in the case of surveillance visits (planned or unplanned) leads to the reduction or suspension or withdrawal of accreditation.

Date:28.06.2024

General Director

Pranvera FAGU