Jordanian Accreditation System
نظام الاعتماد الأردني
Accreditation Unit

ACCREDITATION UNIT

POLICY ON GRADING OF NON-CONFORMITIES

Purpose

Explain to the assessors working with AU, its policy for the grading of the nonconformities discovered during the assessment against the assessment criteria.

Scope

This policy is implemented on all the nonconformities discovered during the assessment which is conducted on the **CABs** through the accreditation course.

Authorship

This publication has been written by AU staff, approved by the Accreditation Director.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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Further information

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Policy on Grading of Non-conformities

The Accreditation Unit (AU) has adopted **ILAC G3:08/2012 Appendix A**

1. Determining the nature of the nonconformities

The definition of the nonconformities and their categories found during an assessment shall be implemented in the following manner:

a- Determine the nature of the non conformity resulting from the assessment or the surveillance conducted on the lab, which maybe listed as follows:

- Documentation is not conforming to the requirements of the standard.
- Staff are not following documented procedures.
- Technical managers, Quality Manager or other key staff are not demonstrating competence in the work they are doing
- Operational procedures such as test or measurement methods, Traceability, etc., are lacking technical validity.
- Breakdown in the operation of the quality management system of the lab.
- The lab is not conforming to the accreditation rules.

b- Determine the seriousness of non-conformities taking into consideration that the accreditation is primarily concerned with providing assurance to the customers of lab that the staff of the labs are competent and their procedures and results are technically valid, then non-conformities related to technical activities would normally be viewed as more serious than those related to management requirements where the validity of results may not be in question

2. Grading of Nonconformities

A typical grading of seriousness of non-conformities, based on the actions taken by the AU, shall be:

1. Critical / "very serious indeed":

The credibility of the accreditation program is seriously threatened.

In this case the laboratory has to correct such nonconformities immediately otherwise the lead assessor shall immediately inform the AU relevant staff for immediate action regarding the accreditation of the laboratory which shall be suspended immediately, or shall not be granted before closure of such nonconformities.

Example:

- Equipment that is important to conduct tests has failed and cannot be fixed or replaced in the near future.
- A serious breakdown in the quality management system, such as:

  Many complaints, in a serious category, being received but no actions were taken.

  No internal audit has been conducted since the last assessment.

In some cases a series of non-conformities, each in themselves being classified as a "Deviation" may add up in combination to what is considered a serious overall problem "Critical" non-conformity.

In general in the case of "Critical" nonconformities:

For non-accredited laboratories undergoing their first assessment, the accreditation is delayed until corrective actions are taken and effectively implemented within five months.

For accredited laboratories undergoing their surveillance or reassessment, and the non-conformities affecting specific area in the scope of the accreditation or the whole scope, the Lead Assessors in this case, are obliged to inform the AU immediately with any "Critical" nonconformities found during assessment, so as the accreditation is immediately suspended partially or totally (respectively) until corrective actions are taken and effectively implemented within three months.

Otherwise the Accreditation Unit is proceeding in the withdrawal procedure (if the scope was totally suspended) or shrinking procedure (if it was partially suspended).

2. Deviation.

Non conformities found against the technical and/or management requirements that are threatening the validity of test or measurement results.

Corrective action must be completed within the agreed time interval as follows:

- Within (5) months to close the deviations raised from the first on-site assessment.
- Within (3) months to close the deviations raised from the additional assessment visit or surveillance visit or re-accreditation visit.

If all non-conformities were not closed, the applicant is requested to submit new and appropriate corrective actions, and all non-conformities shall be closed within (1) month, and if the applicant or the accredited lab did not close all non-conformities appropriately and in the agreed period, the following actions will be taken:

- In case of first on-site assessment, an additional (extra) on-site assessment will be conducted.
- In case of additional (extra) assessment, and whether the lab under assessment closed the corrective actions or not, the assessment reports will be submitted to the Accreditation Committee for a decision regarding accreditation and no further chance will be given.
- In case of surveillance or re-accreditation visit, the assessment reports will be submitted for the Accreditation Committee for a decision regarding accreditation.

Such non-conformities may need a follow up on-site assessment to ensure they have been effectively corrected especially if the validity of results or the integrity of the accreditation body is threatened.

Example:

A reference standard is not calibrated in time but the deviation from the assigned due date is relatively short (up to 10% of the re- calibration interval)

3. “Observation”

Non conformities that do not affect test or calibration results or certificates, and corrective action would not improve the operation of the laboratory but could seriously damage the relationship between the laboratory and the accreditation body.

In such cases the non-conformities could be noted in the assessment notes, for checking at the next assessment.

Example:

Wrong reference to other document.

One of the dates in the sample reception notebook was incomplete in that month

> Regardless of the nature of the non-conformities, the assessor(s) shall evaluate the effect on the quality of the results of the lab within the circumstances presented so that a fair grading may be established and the actions taken against the laboratory will be appropriate.