Guidelines for Addressing and Clearing Nonconformities

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HISTORY OF THE DOCUMENT

Version number	Reason(s) of revision	Scope of the revision
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1. PURPOSE

This document provides guidance to assessors and conformity assessment bodies on how to address and clear nonconformities.

The clearance of nonconformities can often be a difficult and drawn out process as a result of different factors. This document seeks to identify some of the sticking points and seeks to propose how these can be alleviated to make the entire process of clearing nonconformities as painless for the assessors and the conformity assessment bodies (CABs).

2. SCOPE

These guidelines apply to all accreditation schemes

3. REFERENCES

ISO/IEC 17011:2017 Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

PAC-G-01 Assessors Handbook

4. DEFINITIONS

Conformity Assessment Body CAB

A body that performs conformity assessment activities and that can be the object of accreditation.

Finding:

a result of the evaluation of the collected evidence against the assessment criteria. The finding can show if the assessment criteria are being met (conformity) or not being met (nonconformity) and can lead to the identification of opportunities for improvement or good practices.

Nonconformity

A nonconformity is defined as a non-fulfillment of the requirements

Observation

An observation is defined as an opportunity for improvement or a case that may develop into nonconformity in the future but it is currently not a nonconformity.

Correction:

Action to eliminate a detected nonconformity

Corrective action:
Action to eliminate the cause of a nonconformity and to prevent recurrence

5. RESPONSIBILITIES

Assessor	To classify and record nonconformity/observation during assessment according to this document
CAB	To respond to nonconformity/observation according to this document.
Accreditation manager	To coordinate between assessment team and assessed CAB

6. GUIDELINES

6.1 INTRODUCTION TO ASSESSMENT FINDINGS

The International standard ISO/IEC 17011 requires the assessment team appointed by the accreditation body to bring to the attention of the CAB undergoing an assessment any findings raised during the assessment.

During the assessment the CAB must be provided with the opportunity to ask questions to seek clarity concerning the findings and any nonconformity. The assessed CAB must also be provided with copies of the findings.

After the assessment the CAB is required to first identify and propose corrective action within two weeks which once acceptable shall be implemented and evidence provided for implementation which in turn shall be cleared by the assessors within 2 months after the conduct of the assessment. The accreditation body and its assessors or experts are then required to review the corrective action taken including where applicable appropriate evidence of the corrective action taken.

The process of identifying, recording findings, taking corrective action and reviewing the corrective action for adequacy is relatively straight forward but often these findings take long to clear.

6.2 RECORDING AND ADDRESSING NONCONFORMITIES

6.2.1 RECORDING THE NONCONFORMITY

The first cause of delay occurs when there is a misunderstanding concerning what the assessor has recorded and the understanding of the assessment team and the CAB on the nonconformity raised. This could be as a result of a poorly worded nonconformity or the interpretation of the nonconformity.

Form PAC-F-14 is used to cite nonconformities. The findings that can be recorded are:

i. **Nonconformities:**
Finding where the CAB does not meet a requirement of the applicable standard(s) e.g.

ISO/IEC 17025, ISO/IEC 17020 and ISO 15189, its own management system or the PAC requirements.

The assessed CAB shall respond to each non-conformity by taking appropriate corrective action and providing the assessment team with evidence of effective implementation.

ii. Observation:

Finding about the CAB's documents or practices with a potential of improvement or may turn to nonconformity in the future but still fulfilling the requirements. Not all Comments need to refer to a clause in a standard or other requirements document. The assessed CAB is required to respond to comments.

Assessors are encouraged to ensure when recording the nonconformity that the description of the nonconformity:

- refers to the specific requirement not being met.
- depicts the nonconforming practice of the CAB.
- makes reference to the equipment, procedure or record to which the nonconformity relates.

If however, a CAB is in the process of transforming to a new standard, the finding does not need to be converted into nonconformity during the transition stage and can remain as an observation. This observation must be followed up at the next assessment and if still the case, it must then be converted to a nonconformity.

The CAB in turn should question the assessor to ensure that they understand the nonconformity and where necessary ask for the wording of the nonconformity to be amended so that it adequately reflect what the actual nonconformity is.
The nonconformity recorded must be factual, clear and concise.

6.2.2 INVESTIGATION INTO THE CAUSES OF THE NONCONFORMITY

Once the assessed CAB has conducted a thorough investigation into the causes (including the root cause) of the nonconformity they are required to take appropriate corrective action. Each of the applicable key accreditation standards e.g. ISO/IEC 17021-1, or ISO/IEC 17025 requires that the corrective action taken shall be to a degree appropriate to the magnitude and risk of the problem, or in layman's terms the corrective action should be fit for purpose.

Example:
Nonconformity: The laboratory is operating outside the required environmental conditions.

Possible corrective action:
✓Having the air conditioner serviced or repaired, or
✓Relocating the entire laboratory to a building with appropriate environmental conditions

Whilst relocation of the entire laboratory may solve the problem, it is not necessarily fit for purpose. The root cause analysis should examine why the out of specification environmental conditions had not been previously noted.

When investigating appropriate corrective action to be taken, the CAB must remember to look widely and not focus only on the area in which the nonconformity was raised. Remember that the assessment is a sampling exercise and will not reveal all possible nonconformities in a facility, for example if an omission was found in one measurement procedure the investigation should extend to other procedures to confirm that similar short comings are not present in these procedures as well.

6.3 CORRECTIVE ACTION TIMELINES

The assessed CAB must take cognizance of the timeline for the submission of the completed and signed off nonconformities. The timeline provided by PAC in the annex of PAC-PR-08 for clearance of nonconformities includes the following activities:

1. Root cause analysis;
2. Submission of proposed corrective action by CABs;
3. Acceptance of proposed corrective action by assessors;
4. Submission by CABs of evidence of implementation of corrective action; and
5. Clearance of the accepted evidence by the assessment team.

Note: By the end of the timeline (3-months for initial accreditation & 1-momth for continuation of accreditation) all nonconformities should have been cleared and signed off by the assessment team. Unless there is justification, and this period should not be longed than 2 weeks.

6.4 ELECTRONIC SUBMISSION OF CORRECTIVE ACTION

The CAB should submit the corrective action electronically to the Accreditation Manager. Completed nonconformities and evidence should not be submitted directly to the assessor as this can cause unnecessary delays with the administration of the assessment pack, and this is done, the accreditation manager should be copied.
All the forms and corrective action submitted shall be legible as these documents need to be scanned or photocopied. Therefore if the information is illegible, the CABs are so often requested to resubmit which can result in unnecessary delays during the process of clearing of nonconformities.

6.5 SUBMISSION OF EVIDENCE

Another cause of unnecessary delays in the review of completed corrective actions is the manner in which evidence is submitted by the assessed CAB. The submission of evidence often tends to extremes, where either the assessed CAB submits no evidence (the trust me syndrome), or where they submit copious volumes of irrelevant information (the enjoy reading my entire quality manual syndrome).

An assessed CAB may have chosen corrective action that has both elements of immediate action and long term corrective action. In such cases the CAB should submit evidence confirming that the problem that resulted in the nonconformity has been addressed whilst necessary action to prevent recurrence is in progress.

The evidence attached to clear a nonconformity should be specific, for example where a calibration/testing/examination /inspection procedure is modified to correct for a shortcoming, the facility may choose to submit a copy of the revised procedure, clearly showing the changes that were made, or where appropriate the relevant pages from the procedure. It is not appropriate to submit the entire quality manual where only one procedure has been amended.
Please do not submit numerous excel spreadsheets with an expectation that the assessor will go through each one until they find the relevant information. All spreadsheets submitted as evidence must be suitably identified.

Where an assessed CAB submits completed corrective actions and the evidence separately, these facilities must clearly link the evidence related to each nonconformity by referencing the attachment with the related nonconformity number. By ensuring that each nonconformity is distinctly linked to its evidence, the PAC accreditation manager is able to ensure that each assessor receives the correct evidence to support the clearance of the nonconformity that they have raised.

The assessed CAB may not always be sure on how to submit appropriate evidence. Where an item of equipment has been calibrated/recalibrated as part of the corrective action process, a calibration certificate should suffice a copy of a quotation for a calibration is an indication of intended corrective action rather than completed corrective action.

The proliferation of digital cameras provides a simple method of recording corrective action taken and submitting the evidence in support of the clearance of the nonconformity. An example may be a case when the corrective action included the relocation of an item of equipment. Taking of a digital photograph of appropriate resolution showing the relocated item is a manner in which evidence can be recorded that would not be difficult to demonstrate.

6.6 THE BENEFITS OF TAKING CORRECTIVE ACTION

Nonconformities are often viewed in a very negative light by the management of an assessed CAB whilst the inherent positive aspects are largely ignored. Nonconformities provide the CAB with the opportunity to improve their own systems and procedures which is to their own benefit.

Seeing the positive side of a finding and approaching the investigation with a positive attitude will result in the corrective action being of great benefit to the CAB. 'Band-Aid' fixes will ultimately result in nonconformities recurring and the opportunity to derive benefit by the CAB will be lost.

7. RELATED FORMS

PAC-F-14 "Nonconformity Form"