

GUIDANCE FOR ADDRESSING AND CLEARING NONCONFORMITIES

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1. PURPOSE AND SCOPE

This document provides guidance to assessors, technical experts and Conformity Assessment Bodies (CABs) on how to address and clear nonconformities.

The clearance of nonconformities can often be a difficult and drawn-out process due to 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 effective for the assessors and the conformity assessment bodies (CABs).

2. DEFINITIONS

2.1 **Conformity Assessment Body** : A body that provides assessment services such as testing, calibration, inspection and certification.

2.2 **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.

2.3 **Nonconformity** : Nonfulfilment of a requirement.

Nonconformities are graded into two categories:

- ✓ **Major** – A nonconformity which directly affects the quality management system and the results of tests/verification.
- ✓ **Minor** – A nonconformity which does not affect the results of tests/verification.

2.4 **Observation** : A finding raised which may prejudice a CAB's ability to meet the SADCAS accreditation requirements. A representative of the CAB must acknowledge (by signature) that the observation has been accurately recorded.

3. 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 representative is provided with the opportunity to ask questions and to seek clarity concerning the findings raised which may be nonconformities or observations. The assessment visit is concluded by a closing meeting with the management of the CAB and other relevant personnel to present the recommendation report and findings following which the CAB representative is requested to make copies of the recommendation report and findings.

During the closing meeting, the assessed CAB is reminded to conduct root cause analysis, identify and propose the corrective actions to address the raised nonconformities within one (1) month after the initial assessment and have the corrective actions cleared within three (3) months after the assessment. For periodic on-site assessments, reinstatements and re-assessments the assessed CAB is required to address the findings raised and to have the corrective actions cleared within two (2) months after the assessment. SADCAS and its assessors or technical 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.

4. RECORDING AND ADDRESSING NONCONFORMITIES

4.1 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. Assessors are encouraged to ensure that when recording the nonconformity adequate reference must be made to the equipment, procedure or record to which the nonconformity relates. The CAB in turn should seek clarification with 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 reflects what the actual nonconformity is.

The nonconformity recorded must be factual, clear and concise.

4.2 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 ISO 15189, ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17025 and ISO/IEC 17065 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 shortcomings are not present in these procedures as well.

4.3 Corrective Action Timelines

The assessed CAB must take cognizance of the timeline for the submission of the completed and signed off nonconformities. The 3-months timeline for initial assessments and 2 months' timeline for periodic on-site assessments, reinstatements and reassessments provided by SADCAS for clearance of nonconformities includes the following activities:

1. Root cause analysis;
2. Submission of proposed corrective action by CABs, where applicable;
3. Acceptance of proposed corrective action by assessors, where applicable;
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 stipulated timelines, all nonconformities should have been cleared and signed off by the assessment team.

4.4 Electronic Submission of Corrective Action

Where corrective action is submitted electronically the CAB should ensure that it knows the correct email address at SADCAS to which the submission must be made. Refer to AD 01: SADCAS Contact Details for Communicating with Clients. Completed nonconformities and evidence **must not** be submitted directly to the assessor as this can cause unnecessary delays with the administration of the assessment pack.

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 often requested to resubmit which can result in unnecessary delays during the process of clearing of nonconformities.

4.5 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/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. Submitting copious volumes of irrelevant information may lead to unnecessary delays in the review of completed corrective action.

Please do not submit numerous attachments or excel spreadsheets with an expectation that the assessor will go through each one until they find the relevant information. All information 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 SADCAS responsible person 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 what to submit as 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 and not 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.

4.6 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.

5. REFERENCES

- ISO/IEC 17011 : Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
- ISO 15189 : Medical laboratories – Requirements for quality and competence
- ISO/IEC 17020 : Conformity assessment - General criteria for the operation of various types of bodies performing inspection
- ISO/IEC 17021-1 : Conformity assessment – Requirements for bodies providing audit and certification of management systems ; Part 1 - Requirements
- ISO/IEC 17025 : General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17065 : Conformity assessment – Requirements for bodies certifying products, processes and services
- SADCAS AD 01 : SADCAS Contact Details for Communicating with Clients

ANNEX – AMENDMENT RECORD

Revision Status	Change			Approved by	Effective Date
	Page	Clause/ Sub clause	Description of change		
Issue 1	-	-	-	CEO	2016-06-15
Issue 1	3	1	Line 1 : Inserted "technical expert "between "assessor" and "conformity assessment bodies" Line 3 : Substituted "as a result of" with "due to". Line 6 : Deleted "as painless" and substituted with "effective".	CEO	2019-08-27
		3	Title : Deleted " introduction to". Paragraph 2- Deleted Paragraph 2 and substituted with "During the closing meeting, the assessed CAB is reminded to conduct root cause analysis, identify and propose the corrective actions to address the raised nonconformities within one(1) month after the initial assessment and have the corrective actions cleared within three(3) months after the assessment. For periodic on-site assessments, reinstatements and re-assessments the assessed CAB is required to address the findings raised and to have the corrective actions cleared within two(2) months after the assessment. SADCAS and its assessors or technical experts are then required to review the corrective action taken including where applicable appropriate evidence of the corrective action taken."		
	4	4.1	<u>Line 7</u> : Deleted "question" and substituted with "seek clarification with".		
	5	4.3	<u>Line 2</u> : Inserted "for initial assessment and 2 months timeline for periodic on- site assessments, reinstatements and re-assessments "between "timeline" and "provided by". <u>Lines 6 and 7</u> : Added "where applicable" at the end of bullet points 2 and 3. <u>Line 10</u> : Deleted "3 months" and substituted with "stipulated"		
	5	4.4	Paragraph 2, Line 2 : Deleted "so" between "the CABs are" and "often requested".		
	6	4.5	<u>Paragraph 3, Line 5</u> : Added at the end of sentence "Submitting copious volumes of irrelevant information may lead to unnecessary delays in the review of completed corrective action". <u>Paragraph 4</u> : • Line 1 : Added : "attachment or" between "numerous" and "excel spreadsheet" • <u>Line 2</u> : Deleted "spreadsheets" and substituted with "information" <u>Paragraph 6</u> : • <u>Line 1</u> : Deleted "how" and substituted with "what". Inserted "as" between "submit" and "appropriate"		

Revision Status	Change			Approved by	Effective Date
	Page	Clause/ Sub clause	Description of change		
			<ul style="list-style-type: none"> Line 4 : Deleted "rather than" and substituted with "and not". 		