

GUIDANCE FOR ADDRESSING AND CLEARING NONCONFORMITIES

Prepared by : Technical Manager	Reviewed by : Quality Manager	Approved by : Chief Executive Officer	Date of Approval: 2026-09-07 Effective Date: 2026-09-07
--	--------------------------------------	--	--

Table of Contents

	Page
1. PURPOSE AND SCOPE	3
2. DEFINITIONS.....	3
3. ASSESSMENT FINDINGS	4
4. RECORDING AND ADDRESSING NONCONFORMITIES.....	5
4.1 Recording of Nonconformity	5
4.2 Investigation into the Causes of the Nonconformity.....	5
4.3 Corrective Action Timelines.....	6
4.4 Electronic Submission of Corrective Action	7
4.5 Key Principles of Submission of Evidence	8
4.6 The Benefits of Taking Corrective Action.....	10
5. REFERENCES.....	11
ANNEX - AMENDEMENT RECORD	12

1. EXECUTIVE SUMMARY PURPOSE AND SCOPE

This guideline provides practical guidance to Conformity Assessment Bodies (CABs), assessors, and technical experts on the effective identification, documentation, submission, review, verification, and closure of nonconformities arising from SADCAS assessments. It establishes a consistent approach to nonconformity management to ensure timely resolution, maintain confidence in accredited services, and support fulfilment of accreditation requirements.

The guideline emphasizes:

- Accurate, objective, and evidence-based recording of nonconformities.
- Effective root cause and extent analyses to address underlying issues.
- Risk-based planning and implementation of corrective actions.
- Timely submission of corrective actions and supporting evidence.
- Use of secure and approved communication channels for correspondence and evidence submission.
- Objective verification of the implementation and effectiveness of corrective actions.
- Promotion of continual improvement and enhanced organizational performance.

The objective of this guideline is to improve the quality and consistency of corrective action responses, reduce delays in nonconformity closure, and strengthen the effectiveness, integrity, and credibility of the accreditation process.

The closure of nonconformities can be a challenging and time-consuming process due to factors such as inadequate root cause analysis, insufficient supporting evidence, ineffective corrective actions, and delays in communication and review. This document identifies common challenges encountered during the nonconformity management process and provides practical guidance to address them.

The aim is to promote a consistent, efficient, and effective approach to nonconformity closure, thereby improving the quality of corrective actions, reducing delays, and supporting the continual fulfilment of accreditation requirements and the integrity of the accreditation process.

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 **Corrective Action**: Action taken to eliminate the cause of a nonconformity and prevent recurrence.

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

Nonconformities are graded into two categories based on their significance and potential impact on the conformity assessment body's ability to fulfil applicable requirements:

Major nonconformity – A major nonconformity typically:

- Affects the ability of the management system to effectively control processes or consistently deliver valid results, products, or services;
- Creates an actual or potential risk to the validity of results, product quality, safety, customer confidence, or regulatory fulfilment;
- Demonstrates a significant failure in the implementation or maintenance of the management system; or
- Represents a pattern of repeated minor nonconformities indicating a systemic issue.

Minor nonconformity – A minor nonconformity is an isolated deviation from specified requirements that does not significantly affect the effectiveness of the management system or the organization's ability to deliver valid results, products, or services. It does not pose a significant risk to the fulfilment of accreditation, regulatory, or customer requirements and is not indicative of a systemic failure within the management system.

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 and extent 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 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 RECORDING AND ADDRESSING NONCONFORMITIES

4.1 Recording the Nonconformity

One of the primary causes of delay in the corrective action process is a lack of common understanding between what the assessor has documented as a nonconformity and how it is interpreted by the assessment team and the CAB.

This lack of understanding may result from unclear or ambiguous wording of the nonconformity, or from differing interpretations of the issue raised. A lack of common understanding can lead to:

- Delays in responding to the nonconformity;
- Incorrect/ineffective corrective actions;
- Disputes over the validity of the finding; and
- Inefficiency in the closing of the assessment.

To mitigate this:

- **Assessors** must ensure that all recorded nonconformities are:
 - Clearly and concisely worded;
 - Factual and objective; and
 - Referenced specifically to the relevant equipment, procedure, record, or requirement to which the nonconformity pertains.
- **CABs** are responsible for:
 - Seeking clarification from the assessor where any ambiguity exists; and
 - Requesting amendments to the wording of the nonconformity, if necessary, to ensure it accurately reflects the actual issue observed.

All nonconformities must be documented in a manner that is factual, unambiguous, and easily understood by all relevant parties.

4.2 Investigation into the Causes of the Nonconformity

Once the assessed CAB conducted a thorough investigation into the causes - including the identification of the root cause of the nonconformity and extent analysis - it is 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, ISO/IEC 17043, ISO/IEC 17024 and ISO/IEC 17065 specifies that corrective actions must be proportionate to the magnitude and risk associated with the nonconformity. In practical terms, this means that the corrective action must be "fit for purpose", effectively addressing both the cause and the potential consequences of the issue.

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 facility with appropriate environmental conditions.

While relocating the laboratory may appear to be the solution, it may not be fit for purpose if it does not address the root cause of the issue. A meaningful root cause analysis should investigate why the out-of-specification environmental conditions were not identified or addressed earlier, indicating potential gaps in monitoring, maintenance, or awareness of environmental requirements.

Following identification of the root cause, the CAB shall conduct an extent analysis to determine whether the nonconformity may exist in other areas of the management system, processes, activities, locations, personnel, records, or technical operations. Extent analysis should consider:

- Similar processes or activities.
- Related procedures and work instructions.
- Other departments or locations.
- Comparable equipment or methods.
- Historical records and previous findings.
- Potential impacts on validity of results, impartiality, competence, or regulatory compliance.

The outcome of the extent analysis shall be documented and considered when determining corrective actions

Corrective actions should be prioritized using a risk-based approach. Higher-risk nonconformities should receive priority attention and enhanced monitoring to ensure effective resolution. When determining the appropriate corrective action, the CAB must adopt a broader, system-wide perspective rather than focusing solely on the specific area where the nonconformity was identified. It is important to recognize that assessments are based on sampling and may not uncover every instance of nonconformance within the facility

4.3 Corrective Action Timelines

The following timelines apply to the submission and closure of nonconformities identified during assessments:

Assessment Type	Submission of Root Cause & Proposed Corrective Action	Submission of Evidence of Corrective Action Implementation	Deadline to Clear Nonconformities

Initial Assessment	Within 1 month of the assessment date	Within 2 months of the assessment date	Within 3 months of the assessment date
Periodic Assessments, Reinstatements and Reassessments	N/A	Within 1 month of the assessment date	Within 2 months of the assessment date

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

1. Root cause analysis;
2. Extent analysis
3. Submission of proposed corrective action by CABs, where applicable;
4. Acceptance of proposed corrective action by assessors, where applicable;
5. Submission by CABs of evidence of implementation of corrective action; and
6. 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 must ensure it uses the correct email address designated by SADCAS. Where available, CABs are encouraged to utilize approved secure electronic submission platforms or portals designated by SADCAS. Secure portals should protect confidentiality and integrity of information. CABs remain responsible for ensuring submissions are complete, accurate, and submitted within the required timelines.

To safeguard impartiality and ensure efficient processing, all nonconformity responses and supporting evidence must be submitted through the SADCAS office, not directly to individual assessors. Submitting documentation directly to assessors may compromise impartiality and lead to unnecessary delays in the administration of assessment packs and finalization of the assessment process. CABs are therefore required to adhere strictly to the official communication channels as outlined by SADCAS. All forms and corrective action submissions shall be clearly legible, as these documents are scanned or photocopied for record-keeping and further processing.

Illegible submissions may lead to the CAB being requested to resubmit the information, which can result in unnecessary delays in the clearance of nonconformities. To facilitate efficient processing,

CABs shall ensure that all handwritten or typed content is clear, readable, and professionally presented.

4.5 Key Principles for Submission of Evidence

- Submit evidence directly relevant to the nonconformity.
- Demonstrate completed implementation, not planned actions.
- Clearly identify links between evidence and nonconformity numbers.
- Avoid excessive documentation.
- Label and organize all submissions.
- Provide photographs where physical changes have been made.
- Demonstrate both correction and prevention of recurrence.

Another common cause of unnecessary delays in the review of completed corrective actions is the manner in which evidence is submitted by the assessed CAB. Submissions often fall into two extremes:

- Providing insufficient evidence, where no or minimal supporting documentation is included, making it difficult to verify the effectiveness of the corrective action.
- Submitting excessive irrelevant information, which can overwhelm reviewers and obscure the key evidence needed for review of the corrective action.

CABs are encouraged to provide **clear, concise, and relevant evidence** that directly supports the corrective actions taken. This focused approach facilitates a timely and effective review process.

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. This approach demonstrates that the CAB is taking timely action to mitigate risk while also working toward sustainable improvement.

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 search through them to locate the relevant information

Each document or piece of evidence submitted should be:

- Clearly labelled with a reference to the related nonconformity,

- Organized logically, and
- Focused on demonstrating how the specific issue has been addressed.

This facilitates efficient and accurate review by the assessor.

When an assessed CAB submits completed corrective actions and supporting evidence in separate documents, it is essential that each piece of evidence is clearly linked to the corresponding nonconformity. This should be done by referencing the relevant nonconformity number on each attachment.

Clear linkage allows the SADCAS responsible person to accurately allocate evidence to the appropriate assessor, ensuring that each nonconformity can be efficiently and properly reviewed.

Guidance on Submitting Appropriate Evidence

Assessed CABs may sometimes be uncertain about what constitutes appropriate evidence of corrective action. The following guidance is provided to support effective and relevant submissions:

Completed vs. Intended Action:

Evidence must demonstrate that the corrective action has been completed, not merely planned.

-  *Acceptable example:* A calibration certificate showing that a piece of equipment has been calibrated/recalibrated.
-  *Unacceptable example:* A quotation for calibration, which only indicates intent and not completion.

Use of Photographic Evidence:

The widespread availability of digital cameras and smartphones provides a simple and effective way to document physical corrective actions.

- For example, if an item of equipment has been relocated as part of the corrective action, a digital photograph (with adequate resolution) clearly showing the new location can serve as valid supporting evidence.
- Ensure that photos are appropriately labelled and referenced to the corresponding nonconformity.

4.6 The Benefits of taking Corrective Action

Taking appropriate and well-considered corrective action offers several important benefits to the Conformity Assessment Body (CAB), including:

1. Improved System Effectiveness

- Corrective actions address the underlying root causes of nonconformities, preventing recurrence.
- Strengthens the overall management system by closing gaps, ensuring requirements are consistently met.

2. Enhanced Compliance

- Ensures continued conformity with accreditation standards (e.g., ISO/IEC 17025, ISO 15189, ISO/IEC 17020, etc.) and regulatory requirements.
- Reduces the risk of suspension, withdrawal, or reduction of accreditation due to unresolved issues.

3. Risk Reduction

- Identifies and mitigates risks that could affect product/service quality, safety, impartiality, or customer satisfaction.
- Prevents escalation of minor issues into major nonconformities or systemic failures.

4. Continuous Improvement

- Encourages a culture of learning and improvement within the CAB.
- Leads to stronger processes, clearer procedures, and more reliable outputs.

5. Operational Efficiency

- Prevents recurring problems that consume staff time and resources.
- Improves process efficiency and reduces costs associated with rework, errors, and delays.

6. Customer Confidence and Satisfaction

- Demonstrates commitment to quality and reliability.
- Builds trust with clients and stakeholders by showing that issues are addressed effectively and proactively.

7. Positive Organisational Culture

- Promotes a proactive and constructive approach to challenges.

- Helps staff see nonconformities as opportunities rather than failures, boosting engagement and accountability.

8. Sustainability of Improvements

- Well-documented corrective actions provide a reference for future staff and audits.
- Contributes to long-term organisational resilience and adaptability.

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 17043 : General requirements for the competence and impartiality of proficiency testing providers.
- ISO/IEC 17065 : Conformity assessment – Requirements for bodies certifying products, processes and services
- SADCAS AD 01 : SADCAS Contact Details for Communicating with Clients

ANNEX – AMENDEMENT 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		
			• <u>Line 4</u> : Deleted “rather than” and substituted with “and not”.		
Issue 2	3	2.3	Refined the definitions of Major and Minor nonconformities	CEO	2026-09-07
	3	2.4	Deleted : 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.		
	4	4.1 and 4.2	Reworded to improve clarity on recording nonconformities, emphasising the need for clear, factual, and unambiguous wording, and the responsibilities of both assessors and CABs. Expanded to enhance guidance on investigating causes of nonconformities and carrying out root cause analysis and extent analysis, with practical examples provided.		
	5				
	6	4.3	Included separate timelines for submission of proposed corrective actions, provision of evidence of corrective action implementation and clearance of nonconformities.		
	7	4.4	Updated to include explicit reference to safeguarding impartiality.		
	8	4.5	Expanded to enhance understanding of what constitutes appropriate evidence.		
	9	4.6	Clause rewritten and expanded –		