MP 05-03

NONCONFORMITIES AND CORRECTIVE ACTIONS

Prepared by:	Okechukwu Ejiofor, Quality Manager
Reviewed by:	Lawrena Okoro, Director of Accreditation
Approved by:	Celestine Okanya, DG/CEO
Date of Approval	21/02/2023
Date of Implementation:	21/02/2023

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1.0 Purpose/Scope

This procedure is to ensure that nonconformities are identified,corrected and their cause eliminated in NiNAS operations as well as identifing opportunities for improvement and taking action to prevent nonconformities before they arise. This procedure applies to the control of all non-conformities that may arise in the operation of NiNAS accreditation activities.

2.0 Defintions/References

For the purpose of this procedure a non-conformity is defined as:
a deviation from a specification, a standard, or an expectation; or the nonfulfilment of a requirement.

i) ISO/IEC 17011 – *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.*
ii) ISO/IEC 17000 – *Conformity assessment – General vocabulary*
iii) QM-01 – *NiNAS Quality Manual*

3.0 Procedure

The Quality Manager has the overall responsibility to ensure the suitability of this procedure for its intended use. It is the responsibility of all staff to ensure that this procedure is followed and any non-conformities or potential non-conformities are brought to the notice of management.

3.1 Corrective Action

Non-confomities to international requirements and the NiNAS QMS are usually identified through internal and external audits and through the investigation of customer complaints. Once identified and logged the following actions are taken:

a) The Non-conformity is logged onto a Corrective Action Request (CAR) form and filed in the Internal CAR file on the Server.

b) Root cause analysis to determine the source of the problem is conducted and recorded on the CAR form. (The 5-Why technique is generally the simplest and easiest technique to apply to be sure that one has found the true cause of the problem. This is a technique whereby one asks why five times and determines the answer, continuing to ask why until there are no further explanations). However, any other method for the conduct of root cause analysis may be used as necessary.
c) Action is documented to fix the problem
d) Action is documented that once taken will prevent re-occurance of the problem
e) Necessary staff training as part of the correction is included and documented.
f) Results of the corrective actions are reviewed at the next Internal Audit, at which time the effectiveness of the action is also judged.
g) Corrective actions taken should be appropriate to the impact of the issue being addressed and taken in a timely manner appropriate to the severity of the problem.

3.2 Preventative Actions Including Improvement

Preventative actions are implemented when there is an increased risk for a potential nonconformity. The need is identified on the basis of information regarding capability and performance of processes and operations, service and user feedback, customer complaints, and effectiveness of the quality system.
The individual responsible for Quality must collect, compile and review pertinent information to include:

- Staff suggestions
- Customer complaints; and
- Quality system and other audit records.

➢ Preventive actions are initiated when quality performance indicates that there are trends of decreasing effectiveness of the quality system. For example: increasing incidence of service nonconformities traceable to the same common cause or increasing number of audit findings against the same quality system process or department.

- Improvement actions are taken when an opportunity to make changes for example making a process more efficient are identified even when the threat of a non-conformity is not present.

3.3 CAR and PA Process

- When a problem requiring preventive action is identified, the process of dealing with the problem follows the same steps that apply to corrective actions, as described above.
- In subsequent processing stages both types of actions are referred to as corrective actions. Corrective and preventive actions are requested using the CAR form.
- The requests include description of the unsatisfactory condition that needs to be corrected and are addressed to the Director of the area responsible for the condition.
- The responsible Director then proposes a corrective action to be taken, and indicates the date by which the corrective action will be fully implemented.
- Corrective CAR forms that result from a nonconformance found during an audit shall take priority and be resolved within 45 days of issuance.
- Preventative CAR forms that result from an audit will be resolved as soon as possible with progress monitored every quarter during Executive Meetings.
- The causes of the nonconformity and the proposed corrective action are documented in the CAR form.
- The CAR form is then forwarded to the Executive for review and approval of the proposed action and implementation timeline.
- Any implemented changes are reviewed with respect to their impact on current documentation, and the documentation is updated as appropriate. Documentation changes, if any, are recorded in the CAR form and follow all Document Control Policies and Procedures.
- On, or immediately after the due date for the implementation of the corrective action, the Director or competent delegate follows up with an inquiry to determine if the CAR has been implemented and sufficiently effective.

- Nonconformity reports are closed out by the auditor, only when there is objective evidence that the corrective action is effective.
- If more work/time is needed to fully implement the corrective action, then a new follow-up date is agreed upon.

4.0 Forms

Table: 5-1 Forms in use with Procedure 5	
Form Number	Title
F-6-01	Corrective Action Requisition and Clearance

5.0 Document History

Modification No/Date	Proposed by	Page No.	Summary of Modification
30/04/2020	Quality Manager		Updated to reflect the requirements of ISO/IEC 17011:2017
04/07/2021	Quality Manager	Approval page	Change in the name and designation of the personnel reviewing document
21/02/2023	Qualit y Manager	All	Updste resulting from Internal Audit
