

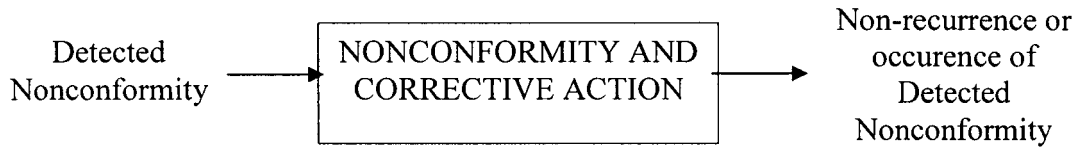


QUALITY SYSTEM PROCEDURE

TITLE	NONCONFORMITY AND CORRECTIVE ACTION PROCEDURE
PURPOSE	To ensure that all QMS identified nonconformities (NCs) are properly addressed with needed action to prevent the recurrence of the NC and their root causes.
SCOPE	This procedure starts from the identification of nonconformities to closure of the nonconformity.
DEFINITION OF TERMS	<ol style="list-style-type: none"> CAR – Corrective Action Report is a form used to record the detected nonconformity, identified root causes and formulated correction and corrective action. Correction – immediate and short-term action to eliminate the detected nonconformity to stop it from continuing Corrective Action (CA) – a long-term action to eliminate the root cause of the nonconformity to prevent it from recurrence.

PROCESS DESCRIPTION

The process is triggered by a detected nonconformity by any process owner. It ensures that the nonconformity is properly addressed by a timely corrective action to eliminate the root cause to prevent recurrence and potential occurrence elsewhere in the QMS.



PROCESS FLOW

STEP NO.	PROCESS / STEPS	DETAILS	RESPONSIBLE PERSON	REFERENCE / INTERFACE
	START			
1.	Identification of nonconformity	Possible sources of nonconformity are the following: <ul style="list-style-type: none"> Internal Audit findings unmet quality objectives and OPCR targets or work programs process deviation client complaint nonconforming services unfulfilled directives from the Management Review other lapses or deviation in the QMS 	Internal Audit Service (IAS) / Concerned Process Owner	Corrective Action Report



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		Record the nonconformity in the CAR Form.		
2.	Review of nonconformity	Identified nonconformity is reviewed and confirmed if valid. a) Audit-related nonconformity b) Other nonconformity	Concerned Division Chief / Process Owner	Corrective Action Report
3.	Formulation and implementation of correction	Correction is an immediate action to stop the nonconformity from continuing. Deal with the potential or actual consequences of the detected nonconformity. Record the correction and the actions taken in dealing the consequences in the CAR Form.	Concerned Division Chief / Process Owner	Corrective Action Report
4.	Root Cause Analysis	Review the risk registers for any controls that may have failed or is not yet recognized which resulted to the nonconforming situation. Check or scan elsewhere in the QMS for any possible occurrence elsewhere, or any existing similar nonconformities, if any. Use appropriate technique in the identification of root causes of the nonconformity and effect of the deviation. Record of the root cause analysis to CAR.	Concerned Division Chief / Process Owner	Corrective Action Report
5.	Establishment of CA	CA are based on the following: <ul style="list-style-type: none">• identified root causes• persons responsible• time of implementing the action plan	Concerned Division Chief / Process Owner	Corrective Action Report



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		<ul style="list-style-type: none"> adequacy to prevent recurrence of root causes 		
6.	Implementation of CA	CA should be implemented in a timely manner as specified in the CAR.	Concerned Division Chief / Process Owner	Corrective Action Report
7.	Submission of Status Report	Concerned process owner/division chief submits status report to IQA	Concerned Division Chief / Process Owner	CAR Status Report
8.	Verification of CA	<p>Verify if corrective action is implemented as planned and evaluate its effectiveness.</p> <p>a) IQA nonconformity b) Other nonconformity</p> <p>Result of corrective action should prevent the recurrence of the root causes of the identified nonconformity.</p> <p>Independence in verification of the CA effectiveness must be demonstrated.</p> <p>Update the risk registers to reflect the risk controls which are validated to be effective. Conduct risk re-rating.</p>	IAS DC/Process Owner	<p>Corrective Action Report</p> <p>Risk Register</p>
9.	Recording of verification results	<p>If CA is verified effective, close the CA. Closure of Nonconformity must be based on objective evidences.</p> <p>Check if the nonconformity can potentially occur elsewhere in the QMS.</p> <p>If the CA is not effective or if it can potentially occur elsewhere, maintain the status of the corrective action as "Open" and</p>	IAS	Corrective Action Report



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		subject for further verification. Record the results of verification in the in CAR.		
10.	Retention of documented information	Retain all records generated in accordance with the Control of Retained of Documented Information Procedure.	IAS / Concerned Division Chief / Process Owners	Control of Retained Documented Information Procedure
	END			
RECORDS GENERATED		1. Duly Accomplished Corrective Action Reports		

Prepared by:	Reviewed by:	Approved by:
 NELIA L. MERCADO	 ROWEENA M. DALUSONG	 JOSE MIGUEL R. DE LA ROSA
Division Chief/Process Owner	Director IV, Internal Audit Service	Undersecretary and Deputy Quality Management Representative