1.0 Objectives

- To ensure that the organization is continuously complying with the planned requirements of the existing quality management system based on ISO 9001:2015 Standards.

2.0 Scope

- This procedure covers all activities from the preparation of an audit plan/ program up to the monitoring and review of the audit process.

3.0 Definition of Terms

- Auditee refers to the person being audited.
- Auditor refers to a person with the competence to conduct an audit.
- Audit findings refer to the results of the evaluation of the collected audit evidence against audit criteria.
- Audit evidence refers to records, statements of fact or other information which are relevant to the audit criteria and verifiable.
- Audit conclusion refers to the outcome of an audit team after consideration of the audit objectives and all audit findings.
- Audit Program refers to a set of one or more audits planned for a specific time frame and directed towards a specific purpose
- Audit Criteria refers to set of policies, procedures or requirements used as a reference.
- Audit Team refers to one or more person auditors conducting an audit.
- Lead Auditor refers to a person who has the qualifications to lead the audit team.
- Audit Cycle refers to all audit activities from planning to follow up.
- Nonconformity is a non-fulfillment of a requirement (ISO 9000:2005)
- Minor Nonconformity is when a particular requirement of ISO 9001:2008 is not applied to the process consistently or when there is a single observed lapse in following one item of a company procedure.
- Major Nonconformity is the absence, or the total breakdown of a system to meet the requirements of ISO 9001:2008 or other reference documents.
- Observation refers to both strength and areas for improvement in system implementation.

4.0 Records

- R-BAI-04 Attendance File
- R-BAI-05 Audit Conclusion File
- *R-BAI-06 Auditor Qualification Matrix File*
- R-BAI-30 Internal Audit Checklist File
- R-BAI-31 Internal Audit Itinerary File
- R-BAI-32 Internal Audit Program File
- R-BAI-44 Notice of Audit File
- R-BAI-50 Performance Evaluation of Auditors File
- R-BAI-76 Status of Corrective Action Implementation on IQA Findings File
- R-BAI-77 Summary of Audit Findings File

5.0 References

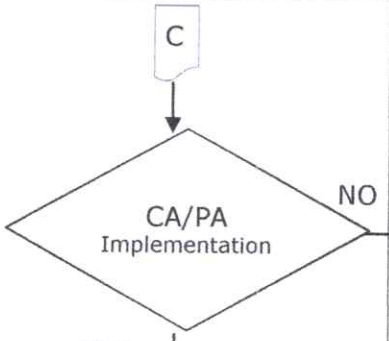
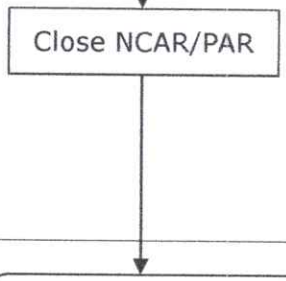
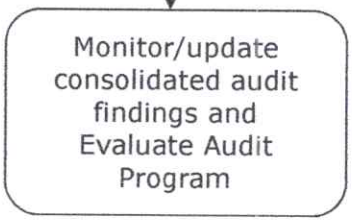
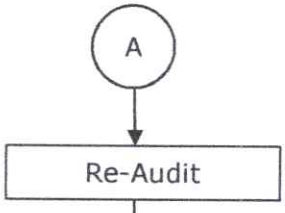
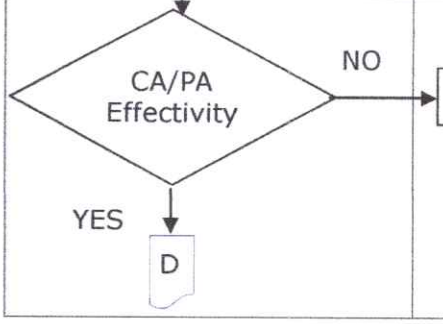
- ED BAI-01 PNS ISO 9001:*2015*, Quality Management Systems- Requirements
- ED BAI-02 PNS ISO 9000:2005, Quality Management Systems – Fundamentals and Vocabulary
- ED BAI-03 PNS ISO IEC 17020:2012 Inspection Body Requirements
- PL BAI-13 List of Internal Auditors
- GP BAI-19 Corrective Action
- PL BAI-08 Risk Register (FMEA)
- PL BAI-09 Risk Register (PPA)

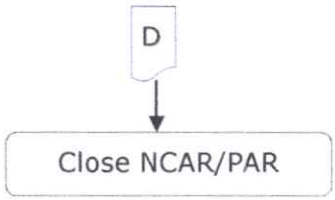
6.0 Process Flow

FLOW	RESPONSIBILITY	DETAILS
Prepare Audit Program	Lead Auditor	• Audit program contains the following information ○ Objectives ○ Responsibilities ○ Resource requirement ○ Procedure ○ Audit team selection • Approved by the QMR
Organize the Audit Teams	Lead Auditor	• Select the Audit Team *Use form GF BAI-09 Auditor Qualification Matrix* • Refer to PL BAI-13 List of Internal Quality Auditors
Prepare the Audit Plan	Lead Auditor	• Audit plan includes the following: ○ The audit objectives ○ The audit criteria and any reference documents ○ The audit scope, including organizational and functional units and processes to be audited
Conduct Document Review A	Audit Team/s	• Relevant Management System documents, including records to determine their adequacy with respect to audit criteria • Refer to R-BAI-50 Performance Evaluation of Auditors File • Use GF BAI-44 Internal Audit Checklist

A → Prepare Audit Documents	Audit Team/s	• Prepare the following work documents ○ Check list ○ Forms for recording information, such as supporting evidence, audit findings and records of meetings
Notify Auditee/s	Lead Auditor	• Sent one week before conduct of audit. Refer to GF BAI-61 Notice of Audit. • Auditees return Notice of Audit indicating confirmation or non-confirmation
Conduct Internal Quality Audit	Audit Team/s	• Conduct Opening Meeting ○ Introduction of the participants and their roles ○ Confirmation of the audit objectives, scope and criteria ○ Confirmation of the audit timetable ○ Methods and procedures to be used to conduct the audit ○ The method or reporting, including any grading of non-conformities ○ Conduct audit interview, use audit checklists as guide
Prepare Audit Findings	Audit Team/s	• Conduct of wash-up meetings to review audit findings and categorize nonconformities • Evaluate audit evidence against audit criteria
B	Lead Auditor	• Categorized findings as: ○ Major nonconformity ○ Minor nonconformity ○ Observation

B → Report Audit Findings	Lead Auditor/Audit Team Leaders	• Agenda of the closing meeting includes: ○ Acknowledgment of the participation of auditees ○ Audit findings and conclusions to include positive observations ○ Agreement on the time frame for the auditee to present a corrective and preventive action plan. Use GF BAI-60 NCAR for Nonconformity ○ Participants include Top Management, auditees, auditors ○ Attendance of the Meeting is recorded (R-BAI-04 Attendance File)
Prepare and Submit Audit Report	Audit Team Leaders	• Prepare Summary of Audit Findings (GF BAI-104) • Submit to the Lead Auditor one week after the conduct of the audit
Prepare Corrective/Preventive Actions	Concerned Process Owners	• Refer to: ○ GP-BAI 19 Corrective Action ○ GP-BAI-04 Risks and Opportunities Management • Corrective (CA) action reports must be submitted within the week after receipt of audit report
Conduct Follow-up Audits → C	Concerned Auditor/ Lead Auditor	• Refer to the GF BAI-60 NCAR for the implementation date/s of CA/PA • Follow up a day after the implementation date of agreed CA/PA

	Concerned Auditor/ Lead Auditor	• Corrective Action is closed if implemented • The Lead Auditor shall be audited after the audit findings have been consolidated
	Lead Auditor	• When closed, verify the effectiveness of action taken within three months. • If not effective, re-investigate the root cause of non-conformity and implement the appropriate corrective action.
	Lead Auditor/QMR	• Update consolidated audit findings GF BAI-104 Summary of Audit Findings • Report updates during the Management Review/ Management Committee (ManCom) meeting
	Concerned Auditor/ Lead Auditor	• If findings remain open, Auditee is re-audited to determine real root cause of non-conformance then agree for corrective action/s and date of completion • Follow up a day after the implementation date of agreed CA/PA
		• Issue NCAR against CA/PA using GF BAI-60 NCAR

	Lead Auditor	• When closed, verify the effectiveness of action taken within three months. • If not effective, re-investigate the root cause of non-conformity and implement the appropriate corrective action.

Prepared by:	Approved by:
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Lead Auditor	Top Management