

<b>SRI</b>	ISO 9001: 2015 Quality Management System Quality Procedure Manual	
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## **11.0 PROCEDURE FOR INTERNAL AUDIT**

### **11.1 SCOPE**

This section of the manual describes the internal quality audit procedure. The objectives of internal quality auditing are;

- To determine the conformity of the Quality System elements with specified requirements.
- To determine the effectiveness of the implementation of Quality System.
- To improve the existing Quality System.

### **11.2 RESPONSIBILITIES**

The Management Representative (MR) is responsible and authorised for planning the Internal Quality Audits, work area for the audits, selection of audit team and also for maintaining and documenting records. He is also responsible for reviewing whether timely corrective actions are taken in case of non-conformities recorded during Internal Quality Audits.

The respective Auditees are responsible for taking corrective action on audit findings and recording same.

### **11.3 AUDIT PLANNING**

MR plans the frequency, audit plan and identifies the auditees. "The internal audit team performs annual audits, while the Head of system compliance and his executive conducts a minimum of six internal audits annually, covering critical areas to ensure regulatory adherence and operational effectiveness." Format of the Plan is shown in **IA-FORM-01**.

### **11.4 AUDIT SCHEDULING**

MR selects the Audit team members, including Audit Team Leader. All members of the Audit team have undergone the Internal Quality Audit training programme.

No employee is allowed to audit his own department. Intimates to the respective auditees about the proposed dates, areas of audit and audit team in writing in Audit schedule. **IA-FORM-02** .

### **11.5 AUDIT PROCESS**

The Audit process is in the following sequence: Carrying out the Audit .

Recording of Audit findings in the form of major / minor non-conformance's and observations in format **IA-FORM-03** and summary of audit is recorded in **IA-FORM-04**. Audits conducted by factory COP personnel record their observations in **IA-FORM-05**.

Closing Meeting with the auditees

Auditee to enter Corrective-actions with time period, in the space provided in **IA-FORM-03**.

If MR signature is absent this will not be a controlled document.	Signature of Management Representative	
	Date	

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- **Major Non-conformance (Category i.)** relates to a Total System Brake down ( not practicing a main element of ISO 9001.2015, Violation of legal requirement, Customer Complaint for failing corrective actions and in-consistency
- **Minor Non-conformance (Category ii.)** relates to lapses in some directions but not a total brake down of the system
- **Observation (Category iii.)** relates to point which is not a Non compliance of the documented system / Procedure, but is made with a view to improve the system. Observation also indicates trends which may cause problems in future.

Auditees must carry-out the Corrective Action and complete the relevant cage in **IA-FORM-03**.

#### **11.6 FOLLOW-UP AUDIT**

Few days before the next audit, the corrective action columns of IA-FORM-03 of the previous audit must be completed.

The adequacy of corrective actions must be reported.

#### **11.7 MR'S COMMENTS**

If the corrective actions are adequate MR will close the audit.

If this audit cannot be closed due to inadequacies of corrective actions, MR must make his remarks in the relevant cage.

If MR signature is absent this will not be a controlled document.	Signature of Management Representative	
	Date	