

NAME OF THE ORGANIZATION		Doc.No. ABC/BRC/005
TITLE	INTERNAL AUDIT	ISSUE NO : 1.0 REVISION NO.: 00
		Issue Date: 01 Sept. 2022

Procedure for Internal audit

	Prepared by	Reviewed By	Approved by
Name			
Function			
Date			
Signature			

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1. PURPOSE:

- Describe the procedure for planning and conducting internal audit (IA) to verify whether PMS activities and related results comply with the planned arrangement and to determine the effectiveness of the Product safety management system”.

2.SCOPE

- Procedure is applicable to all processes / elements of PMS. This procedure covers all Divisions, their documentation and processes.

3.0 RESPONSIBILITY

- FSTL is responsible for planning, scheduling and conducting periodic audit and maintenance of this procedure.

4.0 PROCEDURE:

4.1 Planning and scheduling:

- FSTL prepares an Annual Internal Audit Plan based on the status and importance of the activity being audited and results of previous audits conducted. Minimum of one internal audit covering all the functions is conducted based on risk.
- Internal Audit Schedules are prepared based on the Annual internal Audit Plan. Audits are scheduled based status and importance of the process and on results of audit, further audits may be scheduled by FSTL.

4.2 Conduct of audit and collecting evidence:

- Trained and qualified personnel carry out internal audit. It is ensured that the auditor is independent of the activity/ function/ process being audited. MR maintains a list of trained internal auditors
- Internal auditor audits all the processes / activities of the company. Audit criteria will also be the procedures applicable to the Function. Scope of internal audit includes HARA, PRPs, Product defence, Product fraud .Compliance to the applicable procedures is ensured when the process plans are audited. Other procedures are specific to processes and are audited when the specific process is audited.
- Collection of evidence of compliance is carried out by logical sequence of enquiry using (Where, When, What, Who, Why & How) interview, observation of activities, asking to show records and detailed examination of records to seek evidence. Auditor chooses the sample size and adopts random selection.

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4.3 AUDIT REPORTING AND FOLLOW UP :

- Non conformities, if any, are reported using Audit NC format. Auditee signs the non-conformance report (NCR) form along with auditor and also commits to carry out corrective action with time frame indicated for ensuring compliance. Internal auditor allots NC serial number after consolidating all NC's of a particular auditee. The original NCR is given to auditee for taking necessary corrective action and a copy is retained by FSTL for follow up.
- Auditee completes corrective action within the time frame indicated by him/her, records it on the NCR and forwards to FSTL. Action regarding verification of corrective action and closing of NCR will be completed by FSTL within about two weeks after receipt of NCR. FSTL will contact the auditee to fix time and date for verification and also for name of the person and phone number of the person to be contacted for verification of the corrective action.
- FSTL or auditor nominated by FSTL will contact the auditee's representative and examine the evidence and verify the corrective action carefully, record the details of verification with evidence verified and endorse the NCR. FSTL will close the NC after verifying the effectiveness of corrective action taken.

REFERENCE

NONE

Records:

Sl. No.	Record Name	Minimum Retention time
1.	Annual Audit Schedule	3 years
2.	Audit Schedule	3 years
3.	Internal Audit - NC Report	3 years
4.	Audit Summary report	3 years
5.	List of Trained Auditors	3 years