

Internal Audits

1.0 Purpose

The purpose of this procedure is to establish a system for conducting internal quality audits in order to determine whether the quality management system

- a) Conforms to the planned arrangements, to the requirements of ISO 9001:2000 QMS established by **KSPHC** and,
- b) Is effectively implemented and maintained.

1.1 Application

This procedure is applicable for all the activities covered under QMS at **KSPHC**.

1.2 Responsibility

Management representative and the Chief Coordinator-QMS shall be responsible for implementation of this system.

1.3 Terms and definitions

Audit Programme: Set of one or more audits planned for a specific time frame and directed towards a specific purpose.

Audit criteria: Set of policies, procedures or requirements used as a reference

Audit evidence: Records, statements of fact or other information, which are relevant to the audit criteria and verifiable. *Audit evidence can be qualitative or quantitative.*

Audit findings: Results of the evaluation of the collected audit evidence against audit criteria. *Audit findings can indicate either conformity or nonconformity with audit criteria, or opportunities for improvement.*

Audit conclusion: Outcome of an audit provided by the audit team after consideration of the audit objectives and all audit findings.

Auditee: Organization being audited

Auditor: Person with competence to conduct an audit.

Audit team: One or more auditors conducting an audit.

Nonconformity: Non-fulfillment of a requirement.

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2.0 Procedures**2.1 Characteristics of the audits**

- 1) Every internal quality audit shall be a compliance audit with requirements of ISO 9001: 2000 and the quality management system established and implemented by **KSPHC**.
- 2) All functions covered under quality management system of **KSPHC** are subject to internal audits.

2.2 Planning of audits

- 1) Periodicity (Audit Programme) of Quality Management System audits shall be once in 4 months and are conducted in the Month of February, June and October of every year.
- 2) M.R. **may plan for additional audits** based on the necessities and requirements.
- 3) M.R. shall prepare the audit schedule for each audit as per Form # MR F 01. Audit schedule shall be communicated at least one week in advance.
- 4) M.R shall ensure that the Internal audits are synchronized with management review meeting, i.e., MRM should be preceded by internal audits. *If required, conducting special MRM may be considered*
- 5) Trained and qualified internal quality auditors (those who have undergone ISO 9001:2000 Internal auditor's training and have passed the examination conducted by a certified ISO 9000 QMS Auditor) shall conduct the audit. For this purpose, M.R. shall maintain list of trained and qualified auditors.
- 6) Auditors shall not audit their own work.

2.3 Conducting and reporting of audit results

- 1) All functional heads shall ensure their availability on the scheduled date. In case of exigencies changes may be allowed with prior intimation to M.R.
- 2) The internal auditors should make effort to surface-out facts other than nonconformities which may include information related to:
 - a) Effective and efficient implementation of processes,
 - b) Opportunities for continual improvement,
 - c) Capability of processes,
 - d) Effective and efficient use of resources,
 - e) Analysis of quality cost data.

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Initially, Audit findings should be recorded in Audit Observation sheet Form # MR F 02.

Each observation is classified under the following heading:

O+ → Observation Positive

Observations conforming to ISO 9001:2000 requirements and the documented Quality System

OI → Opportunity for Improvement

Nor a nonconformance or the results evidenced could have been better (eg. More time taken to demonstrate compliance, higher variability within specification, documents are not user friendly, no logical flow, improper document/record maintenance, etc)

OBS → Observation (comment)

A case, which has not affected the effectiveness of the process or the product but may have a bearing on fineness of the system. *For example, a document not having a good legibility; a report does not bear the date; details recorded using unusual abbreviations.*

NC → Nonconformity

Non-fulfillment of a requirement. This can be classified as MAJOR and MINOR:

Major: Nonconformity is classified as major if:

- The company does not meet the requirements of the standard.
- The company does not meet the requirements of the contract.
- The company does not do what it claims
- There is a significant gap in the system
- Problem of similar kind is observed through out the company
- The product is (will be) highly affected

Minor: Nonconformity is classified as minor if:

- It is occasional, insignificant lapses are noted
- It has no impact on product
- It is an isolated incident

3) Non-conformities should be then transferred to Nonconformity Report Form # MR F 03.

4) M.R Shall prepare the audit conclusion (audit summary) of each cycle of audit, which will be an input for the management review.

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- 5) Concerned functional heads shall analyze reports of audit and initiate suitable corrective action.
- 6) The Management review committee shall review the audit findings and it shall assign the responsibility of implementation, monitoring of suitable corrective action to the concerned heads of department.
- 7) The implementation of action associated with audit report is to be followed-up by functional heads by means of continuous monitoring. The result of the follow-up should be made available to the MR Committee. Effectiveness of the actions taken shall be reviewed in the ensuing MR meeting and necessary action be taken.

3.0 Records

Sl. No	Name of the Record	Form No.	Authorizing Personnel	Copy distribution to	Retention time
1	Audit schedule (for each audit)	MR F 01	M.R.	All Auditees and Auditors	3 Years
2	Internal Audit Observations	MR F 02	Internal Auditor	Concerned Auditees	3 Years
3	Internal audit NC report	MR F 03	Internal Auditor		3 Years
4	List of trained Internal Auditors	-	M.R.	Nil	3 Years
5	Audit Conclusion (Audit summary)	MR F 04	M.R.	Concerned Auditees	3 Years

4.0 Reference

- 1) ISO 9001:2000 clause number 8.2.2
- 2) Quality Manual clause number 8.2.2

5.0 Associated documents

- 1) Procedure for control of documents QSP 01
- 2) Procedure for control of records QSP 02
- 3) Procedure for Management review QSP 05
- 4) Procedure for corrective action QSP 26
- 5) Procedure for preventive action QSP 27
- 6) List of Internal Quality Auditors.

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6.0 Revision details

Revision "0" – First issue.

7.0 Distribution of procedure

Chief Coordinator-QMS shall issue this procedure to all the functional heads.

* Approved by	Top Management Committee
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* Board of Directors of KSPHC in its 107th meeting held on 04-12-2004 vide resolution No. 2004 / 047 has constituted a Top Management Committee consisting of CMD, ED, CE and FA with MR and CC as co-opted members. Further the Board has authorised CMD to approve and issue the QSPs after review by the Top Management Committee.