Corrective action and preventive action

1.0 Purpose

The purpose of this procedure is to establish a system for analyzing the nonconformities and to initiate corrective actions to avoid recurrence of nonconformities.

2.0 Application

This procedure is applicable for all the activities covered under QMS at **KSPH&IDCL**.

3.0 Responsibility

All process owners are responsible to ensure that timely action is taken to eliminate the causes of nonconformities thereby improve the performance of the process.

4.0 Terms and definitions

Conformity – Fulfillment of a requirement.

Continual Improvement – Recurring activity to increase the ability to fulfill the requirements.

Corrective Action – Action to eliminate the cause of a detected nonconformity or other undesirable situation.

Correction – Action to eliminate a detected nonconformity.

Nonconformity: Non-fulfillment of a requirement

Preventive action – Action to eliminate the cause of a potential nonconformity or other undesirable potential situation

5.0 Procedures

5.1 Corrective action

1) Need for corrective action arises when nonconformity identified in Product, Process, and Systems.

2) Nonconformity in product, process and systems may get identified during;

- Inspection & testing,
- Process performance results

- Internal audits,
- External audits, and
- Through customer complaints and customer feedback.

3) Concerned functional head shall analyze the nonconformities to find out the cause for Nonconformity (**NC**). This can be done either through brainstorming or through using Cause & Effect Diagram. More importance and stress to be given to analysis of various checks & controls adapted in the system for their effectiveness.
4) On arriving at conclusion with regard to cause for NC, all probable corrective actions should be discussed among personnel responsible for implementation as well as personnel of processes that will be affected by it. The impact of corrective action should help in eliminating or reducing the recurrence of NC; it should not lead to occurrence of any new nonconformity. Review of causes of identified nonconformities may help in identifying potential nonconformities and there by preventive action can be initiated.
5) Concerned functional head shall implement, monitor and control the effectiveness of the corrective action taken.
6) Concerned functional head shall maintain records of Nonconformities analyzed, details of NC analysis, corrective action initiated and their effectiveness.
7) Corrective actions planned, implemented and the subsequent effectiveness should be discussed in the Management review meetings.

5.2 Preventive action

1) Need for preventive action arises when **potential nonconformity** identified in

- Product,
- Process, and
- Systems.

2) Generally, nonconformity in product, process and systems may be identified by

- Analysis of data
- Quality objectives
- Trends of process performance

4) Concerned functional head shall analyze the one or more of above to find out the potential nonconformity (**NC**) and their causes.. This can be done either through brainstorming or through using Cause & Effect Diagram. More importance and stress to be given to analysis of various checks & controls adapted in the system for their effectiveness.

4) On arriving at conclusion with regard to cause for NC, all probable preventive actions should be discussed among personnel responsible for implementation as well as personnel of processes that will be affected by it. The impact of preventive action should help in eliminating or reducing the occurrence of NC; it should not lead to occurrence of any new nonconformity.

5) Concerned functional head shall implement, monitor and control the effectiveness of the preventive action taken.

6) Concerned functional head shall maintain records of Nonconformities analyzed, details of NC analysis, preventive action initiated and their effectiveness.

8) Preventive actions planned, implemented and the subsequent effectiveness should be discussed in the Management review meetings.

6.0 Records

Sl. No	Name of the Record	Authorizing Personnel	Custodian of record	Retention Time
1	Corrective action report	Concerned functional Head	Concerned functional Head (Copy with M.R)	3 years

7.0 Reference

a) ISO 9001: 2008 Clause Number 8.5.2 and 8.5.3

b) IMS Manual Clause Number 9.3 and 9.4

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8.0 Associated Documents

1) Procedure for control of records IMSP 02
2) Management review IMSP 28

Approved by : Managing Director