Document ID: OAK-CAPA-PR

Corrective and Preventive Action Process

Version 1.5.1

01-Aug-11

#27, NGEF Lane, Off 100 Feet Road,
Indiranagar 1st Stage,
Bangalore-560 038
Ph: +91 80 4126 7681
e-mail: asmita@oaksys.net
http://www.oaksys.net

Owner: **Asmita P. Oak Management Representative-MR**

Approvals
Name: Pradeep P. Oak **Designation:** Director

Signature: **Approved On: 01-Aug-11**

Distribution List: Director, MR, Library

Abstract: This document describes the process to be established for implementing corrective and preventive action, to ensure that the non-conformances are not repeated.

CHANGE HISTORY

Version	Release Date	Authors	Review team	Description
1.0a		Asmita	Pradeep Pai	Draft
1.0	15-Jul-03	Asmita	Pradeep, Pai Bala, Swati, Asmita, Santosh, Ben, Manik	Changes incorporated in Sec.1.5, Sec 5.3
1.1	15-Sept-04	Asmita	Pai	changes as per CR 129 to incorporate consolidation of CAPA in section 5.1. Appendix now includes OAK-CAPA-FR-CCA
1.2	13-Apr-05	Prashant S.O	Shashidhar Joshi	Address, Phone number & email-ID was changed as per CR151 in the first page of the process.
1.3	15-Jun-06	Deepa G C	Asmita	The Phone Number was changed as per CR 262 in the first page of the process.
1.4	10-Feb-09	Asmita	Asmita	As per CR 380, review of effeciveness of each CA is done in QMR
1.5	10-Aug-09	Asmita	Pai	As per CR 386 ISO 9001:2008 As per CR 388, Address change
1.5.1	01-Aug-11	Vinoth	Pai	As per CR 406 , Address change

TABLE OF CONTENTS

1.0 CORRECTIVE AND PREVENTIVE ACTION PROCESS

1.1 Purpose

The purpose of this process is to establish a process for implementing corrective and preventive action, to ensure that the non-conformances are not repeated.

1.2 Scope

This Process is applicable to all groups in Oak Systems Pvt Ltd.

1.3 Target Audience

All members of OAKSYS

1.4 Glossary

BD—Business Development
CAPA—Corrective And Preventive Action
C or P—Corrective or Preventive Action
HR—Human Resource
IQA—Internal Quality Audit
ISO—International Organization for Standardization
MR—Management Representative
NC—Non Conformance
OAKSYS—Oak Systems Pvt Ltd
PMR—Project Management Review
QMR—Quality Management Review
QMS—Quality Management System
SCM—Software Configuration Management
w. r. t. —With respect to

1.5 References

- ISO 9001:2008 standard Clause 8.5.2, 8.5.3
- BD Process OAK-BD-PR

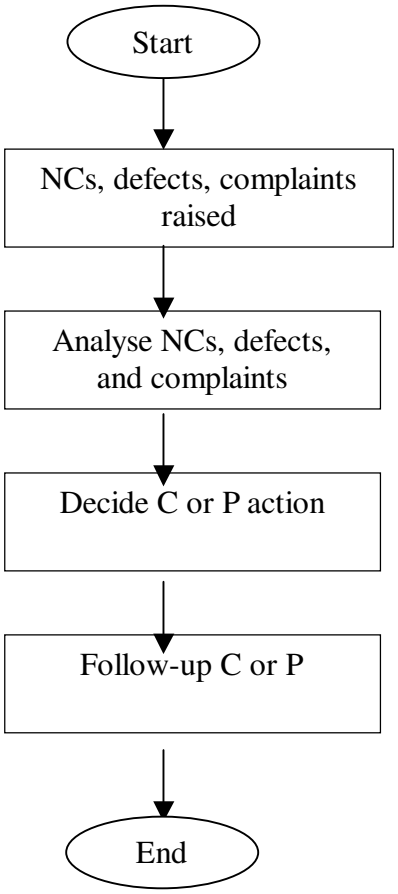
2.0 ENTRY CRITERIA

- NCs raised in IQA
- Defects found
- Customer complaints

3.0 RESPONSIBILITY

- Concerned persons for defect or NC or Customer complaint

4.0 PROCESS FLOW DIAGRAM



5.0 PROCESS DESCRIPTION

5.1 Corrective Action

NCs, defects and complaints arise throughout project execution. Peer Review Process, IQA process BD process and QMR process shall suggest the necessary corrective action to take care of NCs, defects, and customer complaints. All corrective actions related to NCs, customer complaints shall be consolidated by Org SQA. The project shall consolidate all their corrective actions in Post Project Reports. All post project reports are under the repository of Org SQA. Org SQA may consolidate all corrective actions at process level as well as at project level, once in six month. The format attached in Appendix ***Consolidation of CA - OAK-CAPA-FR-CCA*** can be used for the purpose. All the corrective actions taken and their effectiveness is discussed in each QMR referring to the consolidated Corrective Actions (***OAK-CAPA-FR-CCA)***

5.2 NCs, Defects, Complaints have been raised

The need for initiating corrective and preventive actions shall be identified based on the following situations:

- NCs are raised through IQA
- Defects are found through reviews and test execution
- Customer complaints are received

5.3 Analyze and follow-up of NC, defects, customer complaints

The NCs, defects are analyzed through IQA process and Peer Review Process respectively. If defect finding through testing is a part of the project scope, then its CAPA shall be defined in the life cycle sections of the project plan. Whenever a decision is made to take corrective / preventive actions, the action taken shall be recorded in the respective form which shall reflect the

- Action proposed
- Target date & Responsibility

The follow up is done according to respective process.

The customer complaints can arrive during project execution or through business development process. All customer complaints are recorded in customer response sheet, complaints that require immediate attention are analyzed on priority and resolved as per the business development process. The other complaints, feedback and suggestions from customer are taken care in PMR and in QMR processes as issues and concern.

5.4 Preventive Action

Each project shall identify the potential non-conformities as Risks and shall manage the risks as per Project Management Process. All the project risks are reviewed during Project Management Reviews. Potential non-conformities in QMS are identified through IQAs and appropriate preventive actions are planned and incorporated. All the preventive actions are reviewed through QMRs.

6.0 DELIVERABLES AND QUALITY RECORDS

- Respective deliverables of Peer Review, IQA and QMR process w. r. t. Corrective and preventive action
- Consolidation of CAPA

7.0 VERIFICATION

- Approval of CAPA by MR
- Review of CAPA by MR
- Item log from Peer review process
- Customer response sheet
- PMR
- QMR

8.0 EXIT CRITERIA

- NCs, defects and customer complaints are closed or escalated

9.0 APPENDIX

9.1 Consolidation of CA - OAK-CAPA-FR-CCA