

CORRECTIVE / PREVENTIVE ACTION PROCESS

Any KTMC Employee can initiate an NCR (Non Conformance Document), which is used to record any corrective or preventative actions discovered by any source.

PROCEDURE:

1. Actions can be initiated by, or brought to the attention of, any employee. These actions may be the result of an in-process inspection, customer complaint, receiving activity, internal audit OR ANY OTHER DAY TO DAY ACTIVITY where a nonconformity or opportunity for preventive action is identified. (100% of nonconformities discovered in products (by inspection or otherwise) will result in an action. All actions are documented using a Non Conforming Report, or NCR.

2 Third party audit findings are handled the same as internal audit findings. An NCR (corrective action) is issued and a response is required.

3 Once identified, the initiator will access the NCR form and complete the form through the identification of the issue. The information should include the process where the problem was identified, affected procedures, area(s) involved, and any other pertinent information concerning the problem. The form is then forwarded to Quality Manager.

4 Upon receipt of the, the Quality Manager reviews the information provided for completeness, and shall contact the initiator for additional information, if required. The Quality Manager will determine the responsible person(s), type of corrective action, date sent and date the response is due.

5. The Quality Manager shall log the NCR for tracking purposes, record the NCR in the NCR Log and forward the form to the individual(s) responsible to take Corrective or Preventative Action.

6. The responsible person(s) must complete the rest of the NCR indicating the root cause and actions taken to ensure the nonconformity does not recur (in the case of a non conformity.) The responsible person performs an investigation (again in the case of a non conformity) to determine if previously manufactured or shipped product has been impacted and records the result on the NCR form. For Preventive type actions, a discussion of the improvement goal is included.

The form is to be returned to the Quality Manager by the date indicated on the form. If additional time is required to determine Corrective / Preventive Action, the responsible person(s) shall contact the Quality Manager to make arrangements for an alternate due date.

7. All NCRs are reviewed at each Management Review Meeting to identify trends and also to assist in closing NCRs where the disposition needs review, as determined by the quality manager. Internal Audit findings are always closed at Management Review Meetings.

8. Once the proper resolution has been reached and the Corrective / Preventive Action has been implemented as outlined, the Quality Manager closes the NCR and records the closed status in the NCR log.

9. The NCR Log and completed forms are maintained by the Quality Manager in the Quality office..

ASSOCIATED DOCUMENTS:

NCR Form
NCR Form Work Instructions