Nonconformity

1. Introduction & Purpose

The purpose of this procedure is to establish the process for identifying, documenting and analyzing nonconformities and mitigating their impacts by implementing corrective and preventive actions. Your Company’s quality management system is geared toward the proactive elimination of actual and potential deficiencies. Nonconformities in products, services or the management system are investigated and action implemented to prevent their reoccurrence.

2. References

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title &amp; Description</th>
<th>Clause</th>
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<tbody>
<tr>
<td>ISO 9001:2008</td>
<td>Quality management components</td>
<td>8.3</td>
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3. Terms & Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Nonconformity</td>
<td>Non-fulfilment of a requirement</td>
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<td>Preventive Action</td>
<td>Action taken to eliminate a potential non-conformity</td>
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<td>Corrective Action</td>
<td>Action taken to eliminate the cause of a non-conformity</td>
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4. Application & Scope

This procedure is applicable to all corrective and preventive actions that are related to non-conformities in products, services and audit results. Any corrective action taken to eliminate the causes of actual non-conformities is appropriate to the magnitude of the problem whilst also being in proportion to the risks presented by the non-conformity. Root causes of non-conformities in products and services, as well as, management system process defects are investigated and actions implemented to prevent their recurrence.

5. Requirements

**Personnel & Process Owners** are required to:

- Report potential and actual non-conformities to their Line Manager/Supervisor
- Follow this procedure upon detection of a non-conformity

The **Management Representative** is required to:

- Determine the causes of non-conformities
- Maintain a system for reporting and record keeping
- Implement necessary actions to achieve resolution
- Review the effectiveness of corrective actions taken

6. Process

6.1 Identifying Nonconformities

It is the responsibility of all employees to bring suspected nonconformities to the attention of the Management Representative or their Line Manager or Supervisor, or other nominated representative. Nonconformities are identified through the following activities:

- Product nonconformities are identified through inspection activities; subsequent reporting details the nature of the nonconformity as per 8.3. This is done quickly to allow containment and correction action.
• Process nonconformities are based on the analysis of trends in monitoring and measurement data as per 8.2.3. Corrective action is taken and the process is monitored for stability.

• Management system and process nonconformities are identified by auditing as per 8.2.2. Competent auditors describe the nature of the problem, the requirement, including its source and appropriate evidence.

• Potential nonconformities trigger the preventive action process as per 8.5.3. Any potential problem is described in terms of its nature, the requirement and evidence that the requirement will not be fulfilled unless the system is changed.

6.2 Controlling Nonconformities

By whichever means nonconformity is identified, the underlying cause(s) of the nonconformity is investigated and appropriate corrective action(s) are taken according to the nature of the nonconformity.

1. Any non-conforming materials are immediately quarantined in a segregated area
2. Subsequent investigation and verification activities are undertaken to determine the cause(s)
3. Any nonconforming materials maybe disposed of to prevent delivery to the customer or re-worked where it is deemed appropriate by the Management Representative
4. Preventive action, such as implementing modifying or enforcing procedures or other controls, is taken to avoid repetition of the nonconformity
5. Any corrective or preventive action taken to address the causes of the nonconformity must be appropriate to the magnitude of problems and commensurate with the impact encountered is documented
6. The organization has implemented and maintained a system for reporting and record keeping for nonconformity, corrective and preventive action
7. Any changes to quality management system procedures, as a result of corrective or preventive action, are recorded
8. The nonconformity report details the nature and scale of the nonconformity as well as proposals for corrective and preventive actions, as appropriate
9. A repeated nonconformity of the same nature or significant deviations from procedures (e.g. disregard of the procedures or absence of required verification documentation) are reported to the Management Representative for action and resolution

6.3 Review

A report is submitted by the Management Representative as part of the management review process where any significant deviations from the policies and objectives are reported. Where preventive actions involve long term programming, these are considered in the setting of objectives or targets.

6.4 Forms & Records

All records that are generated by this process are managed in accordance with the document and data control and the control of records procedure.

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Title &amp; Description</th>
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<tr>
<td>F04-1</td>
<td>Nonconformity Report</td>
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<tr>
<td>F04-2</td>
<td>Nonconformity Report Log</td>
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7. Process Map

- **Production Team**
  - Product/material non-conformity detected
  - Quarantine product/material
  - Generate non-conformity report
  - Investigate nature of non-conformity
  - Investigate causes
  - Verify non-conformity & determine impact
  - Re-work material/product
  - Validate re-work
  - Identify batches as scrap & dispose of

- **Management Representative**
  - Is disposition of material/product required?
  - Yes
    - Offer return, refund or replacement
  - No
    - Close-out non-conformity report and update log

- **Customer**
  - Product non-conformity reported
  - Update customer with status
  - If material/product conforms ‘use as is’