Quality Procedure

Non-conformity & Corrective Action
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1 Non-conformity & Corrective Action

1.1 Introduction & Purpose

The purpose of this procedure is to establish the process for identifying, documenting and analyzing non-conformities and mitigating their impacts by implementing appropriate corrective actions. Your organization's quality management system is geared toward the proactive elimination of actual and potential deficiencies. Non-conformities in products, services, processes and our management system are investigated and action implemented to prevent their occurrence.

1.1.1 Process Activity Map

With what

- NC reporting
- NC report log

With who

- Production team
- Quality Inspector
- Purchasing
- Technical Sales
- Quality Manager
- Customer Services

Input

- Customer requirements
- Customer complaints
- Supplier non-conformance
- Process non-conformance
- QMS non-conformance
- Product/service/output

Activity

Non-conformity and corrective action reporting and resolution

Output

- Customer satisfaction
- Control of supplier NCs
- Continual improvement
- Conforming processes
- Reduction in open NCs
- Conformance/concessions

How

- NC/CA process
- Specifications
- Forms & reports
- Work instructions
- Inspection checklists

With what measure

- Concerns about suppliers
- Customer concerns

1.1.2 References

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BS EN ISO 9000:2015</td>
<td>Quality management systems</td>
<td>Fundamentals and vocabulary</td>
</tr>
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<td>BS EN ISO 9001:2015</td>
<td>Quality management systems</td>
<td>Requirements</td>
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<td>BS EN ISO 9004:2000</td>
<td>Quality management systems</td>
<td>Guidelines for performance improvements</td>
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<tr>
<td>BS EN ISO 19011:2011</td>
<td>Auditing management systems</td>
<td>Guidelines for auditing</td>
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1.1.3 Terms & Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>ISO 9000:2015 Definition</th>
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<tbody>
<tr>
<td>Non-conformity</td>
<td>Non-fulfilment of a requirement (3.6.4)</td>
</tr>
<tr>
<td>Defect</td>
<td>Non-conformity (3.6.9) related to an intended or specified use</td>
</tr>
<tr>
<td>Conformity</td>
<td>Fulfilment of a requirement (3.6.4)</td>
</tr>
<tr>
<td>Corrective action</td>
<td>Action to eliminate the cause of a non-conformity (3.6.9) and to prevent recurrence</td>
</tr>
</tbody>
</table>

1.2 Application & Scope

This procedure is applicable to all non-conforming products, services, processes and any aspect of our quality management system. Any corrective action taken to eliminate the cause of non-conformity is appropriate to the magnitude of the problem whilst also being in proportion to the risks presented by the non-conformity. Root causes of process non-conformities, including those arising from complaints are investigated and actions implemented to prevent their recurrence. This procedure applies to:

1. **Processes producing negative results and defect outputs.** Any process which does not produce an acceptable product or services should be reported by any employee through the initiation of the Corrective Action Request Form.

2. **Incoming products from suppliers or customers.** Product received from suppliers which is found to be non-conforming are identified, reported and returned to the supplier. Recurring problems with discrepant materials from a vendor are reported to the Purchasing Department.

3. **Services provided by external sources.** If a service provided from an external source does not comply with the requirements of the purchase order and/or contract, then the Corrective Action Request Form is completed and submitted.

4. **Internal issues and quality audits.** During the process of conducting internal quality audits, processes may be identified as being non-conforming. These are documented on the Internal Audit Checklist, Internal Audit Report Form, and the Corrective Action Request Form.

1.3 Responsibilities

All employees & Process Owners are required to:

- Follow this procedure upon detecting non-conformities.
- Implement necessary actions to achieve resolution;

The Quality Manager `<amend as appropriate>` is required to:

- Determine the root causes of non-conformities;
- Maintain a system for reporting and record keeping;
- Raise and record concessions;
- Review the effectiveness of corrective actions taken.

1.4 Non-conformity Process

1.4.1 Discovering a Non-conformity

Any product, material or service that is found to be suspect or non-conforming at any point during the manufacturing or development process is removed from work in progress, and is clearly identified with a REJECT label. The product or material will either be held in the Quarantine Area to await disposition. Disposition of a non-conforming product, service or output will either be:
1.7 Non-conformity & Corrective Action Process Map

<table>
<thead>
<tr>
<th>Initiator</th>
<th>Approver</th>
<th>Implementer</th>
<th>Verifier</th>
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<tbody>
<tr>
<td>Significant or Recurring Issue</td>
<td>Update CA Log</td>
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<tr>
<td>Initiate Corrective Action Process</td>
<td>Need Containment Action?</td>
<td>Implement Containment Action</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Determine Root Cause(s)</td>
<td></td>
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<tr>
<td></td>
<td>Determine Solution and Verification</td>
<td>Implement Solutions</td>
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<tr>
<td></td>
<td>Yes</td>
<td>Verify Effectiveness of Solutions</td>
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<td>Was Solution Successful?</td>
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