Quality Procedure

Non-conformity & Corrective Action
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Quality Procedure
Non-conformity & Corrective Action

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 implementing appropriate corrective action(s). Your organization’s management system is geared toward the proactive elimination of actual and potential failures. Non-conformities arising from complaints, product and service outputs, and management system processes are investigated and action implemented to prevent their occurrence.

1.1.1 Process Turtle Diagram

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>
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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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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>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 management system compliance issues, sourced through internal and external audits, customer complaints, or internal reporting. 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. This procedure applies to the following types of non-conformity:

1. Processes producing negative results and defective 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*.
2. 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 Reports*, and *Corrective Action Requests*.

The root causes of process non-conformities, including those arising from complaints are investigated and actions implemented to prevent their recurrence.

1.3 **Responsibilities**

All **Employees** and **Process Owners** are required to:

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

The **Quality Manager** is required to:

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

1.4 **Non-conformities**

1.4.1 **Process & QMS Non-conformities**

Where problems exist in our process or in our management system, employees are authorized to report the issue to the **Quality Manager** via the *Corrective Action Report* or the *Internal Audit Report*. The **Quality Manager** reviews the problem and decides whether to implement any process or system changes necessary using any specialists as required.

The **Quality Manager** reviews any issue raised by the non-conformity, including those arising from complaints to identify root cause and level of action required. Repeated non-conformities of the same nature or which are significant deviations from procedures or the policies are reported to **Top management** for action and resolution. Corrective action is taken as a result of:

1. Customer complaints or returns;
2. Non-conforming product received from suppliers;
3. In-process concerns;
4. Internal and external audits;
5. Concerns about management system stability.