PROCEDURE FOR THE MANAGEMENT OF NONCONFORMITIES AND CORRECTIVE ACTIONS

Code: 

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1. Purpose, scope and users

The purpose of this procedure is to describe all activities related to identifying and managing non-conforming product in order to prevent its unwanted use or shipment and to define responsibilities and authorities related to treatment of non-conforming product.

This procedure is applied to all processes and/or areas (parts of organization) within the QMS (Quality Management System).

Users of this document are [members of top management] of [organization name], as well as the owner of processes in which the non-conformity occurred.

2. Reference documents

- ISO 9001:2015, clauses 8.7; 10.2
- Quality Manual

3. Managing non-conformities and corrective actions

3.1. Process flow

Diagram showing the process flow:

- Reporting and consideration of non-conformities
- Inspection, testing and disposal of non-conforming product
- Dealing with non-conforming output
- Result and withdrawal
- End
3.2. **Nonconformities**

A nonconformity is any failure to meet the requirements of the standards, internal documentation, regulations, conditions, and other relevant arrangements from the owner nonconformities on the objectives, incidents, during normal business operations, or on any other occasion.

An employee who notices a nonconformity must immediately write [job title], who will record it in the Nonconforming Product Record and take action to control it, contain it, and correct it, and to deal with its consequences.

3.3. **Reporting and consideration of nonconformities**

The non-conformity is recorded in the Non-conforming Product Record by [job title]. The report is completed by job title, who gives guidance to ensure that non-conforming products are removed from the workplace where the non-conformity is discovered, and the non-conforming product is placed in the ZONE OF NON-CONFORMING PRODUCTS.

The non-conforming raw materials and the final products are labeled with a sign indicating NON-
CONFORMING PRODUCTS, and they are stored in a separated space labeled as ZONE OF NON-
CONFORMING PRODUCT.

After noting the nonconformity, the responsible [job title] enters data about the non-conformity in the Registry of Non-Conformities and Corrective Actions.

3.4. **Separation, marking and storage of non-conforming products**

[Job title] separates non-conforming product from conforming products. Responsible for separation, marking, and storage of non-conforming products, the status of non-conforming and conforming products is identified.

3.5. **Dealing with non-conforming outputs**

[Top management] selects members of the Team for non-conforming outputs depending on the process to which the nonconformity applies and the nature of the nonconformity.

The Team for non-conforming outputs reviews the non-conforming product or service in order to determine the method for dealing with it.

### Methods for dealing with non-conforming product are:

- **Correction (Rework)** – is performed in cases when it is possible to bring deviations from the requirements of the standards, internal documentation, regulations, conditions, other relevant arrangements. The corrected product is verified (describe the method) and evidence of verification is the report of an authorized body.

- **Segregation, containment, return, or suspension of provision of products and services** – [job title] prepares action of the believed actions will be taken, considering the nature of the nonconformity.

---


Comment [94B]: Write in the person who is responsible for warehousing and storage.

Comment [94C]: This is usually Quality Manager

Comment [94D]: Choose one or more methods

Comment [94E]: This is usually person manager of production.
3.6. **Corrective actions**

A corrective action may be initiated by any employee or (where appropriate) client, supplier or outsourcing partner of the organization. A corrective action may require that changes be made to any document, process or arrangement within the QMS.

Corrective actions must be appropriate to the consequences of occurred non-conformities that can have a negative influence on:

- Business performance of the organization
- Products, processes and/or services
- Customer satisfaction

By reviewing corrective actions, [job title] ensures that consequences of the corrective action don’t have a negative influence on other parts of the system.

### 3.7. Implementation of corrective actions

A corrective action is implemented in the following way:

<table>
<thead>
<tr>
<th>Step</th>
<th>Person responsible for implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Identifying, reviewing and analysis of non-conformity</td>
<td>Anyone with a role in the QMS</td>
</tr>
<tr>
<td>2. Defining the scope of non-conformity by identifying all processes and products affected by non-conformity</td>
<td>Person responsible for process which non-conformity was discovered</td>
</tr>
<tr>
<td>3. Corrective actions that immediately correct non-conformity or prevent non-conformity</td>
<td>Person responsible for process which non-conformity was discovered</td>
</tr>
<tr>
<td>4. Identifying cause of non-conformity</td>
<td>Person responsible for process which non-conformity was discovered</td>
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</table>
5. Deciding if it is needed to initiate corrective action, depending on complexity of non-conformity

Person responsible for resolving non-conformity

6. Planning corrective action

Person responsible for the area/process where the non-conformity has been identified

7. Implementing corrective action

Person responsible for the area/process where the non-conformity has been identified

8. Reviewing whether the action taken resulted in the elimination of causes of non-conformity

Person responsible for the area/process where the non-conformity has been identified

9. Reviewing non and opportunities determined during planning, if necessary

Top management

Each of the above steps must be recorded in the Corrective Action Record.

4. Managing records kept on the basis of this document

<table>
<thead>
<tr>
<th>Record name</th>
<th>Code</th>
<th>Storage Retention time</th>
<th>Location</th>
<th>Responsibility</th>
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<tr>
<td>Non-conformity Record</td>
<td>PR.12.1</td>
<td>2 years</td>
<td>[office of [job title]]</td>
<td>[job title]</td>
</tr>
<tr>
<td>Corrective Action Record</td>
<td>PR.12.2</td>
<td>2 years</td>
<td>[office of [job title]]</td>
<td>[job title]</td>
</tr>
<tr>
<td>Registry and Status of Non-conformities and Corrective Actions</td>
<td>PR.12.3</td>
<td>2 years</td>
<td>[office of [job title]]</td>
<td>[job title]</td>
</tr>
</tbody>
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5. Appendices

- Appendix 1 – Non-conformity Record
- Appendix 2 – Corrective Action Record
- Appendix 3 – Registry and Status of Non-conformities and Corrective Actions