ABN 84 816 063 155
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Example Procedure

NON-CONFORMANCE

1. PURPOSE

[Insert Company Name] shall establish and maintain a documented non-conformance program to ensure that product not meeting specification is isolated and controlled, is not available for release to customers. Or, in the instance that non-conforming product has been released to a customer(s), it is recalled (if required) and isolated from any further release.

This process description describes the procedures at the appearance of all nonconformities. Those are documented, reviewed, controlled and handled in a cause-specific manner.

All reported non-conformance shall form the basis for corrective actions and also for the potential of improvement of the Management System.

The aim of this procedure is the elimination of the cause of nonconformities as well as the prevention of reoccurrence.

2. SCOPE

This process description is valid for all sections and products of [Insert Company Name].

Customer complaints will be handled within this GMP, and any product returned from customers will be managed under this GMP.

The [insert relevant positions] are directly responsible for this procedure.

3. TERMS & DEFINITIONS

Corrective Action - Action to eliminate the cause of a detected non-conformity or other desirable situation. Corrective action is taken to prevent or eliminate the recurrence of non-conformity.

FMEA: Failure Mode Effects Analysis, a method to identify potential problems and their subsequent effect

Non-Conformance: Any non-fulfilment of required specification. Any defect, imperfection or failing against specifications, procedures and/or processes.

Preventative Action: Any action to eliminate the cause of a potential non-conformity or other undesirable outcome. Preventative action is taken to prevent the occurrence whereas corrective action is taken to prevent recurrence.

Non-conforming goods: Nonconforming goods are goods or products, which do not conform to COMPANY or customer expectations or determinations.

Returned goods: Returned goods are goods, which return from storages and customers. A delivery note of returned goods has to be added to the goods (incl. reasons). Reasons for returned goods are:

- Goods have expired from recommended shelf-life.
- Goods are not as per Product Specification.

Urgent actions: Urgent actions are preventive actions to eliminate the causes of nonconformities.

4. PROCESS

4.1 GENERAL

Each employee is responsible to document and forward all presumed, recognized and identified nonconformities to the QUALITY MANAGER.

If raw products, temporary products or finished products do not fulfil specified quality criteria, following requirements become effective:

- Labelling of the non-conforming products
- Record of identification, nonconformities and quantity
- Forwarding the information to responsible departments
- Decision about further use

4.2 DISABLE STATEMENT

Nonconforming products shall be marked as “Not for Use” to avoid further use. Further use of the disabled product depends on the kind of the nonconformity. Therefore the product can:

- be reworked to fulfil defined quality standards after a new review
- be categorized for another use
- returned to supplier
- obtain a release under concession, whereby customers are informed about facts and possible special actions
- disposed of in an appropriate manner

If a non-conformity of a product only occurs after leaving the [Insert Company Name], a product recall may be considered. This decision is made by the QUALITY MANAGER. An already imposed disable statement can only be cancelled by the QUALITY MANAGER.

4.3 OCCURRENCE/EVENT

Regardless whether products, service, quality, etc. are concerned, all occurrences of a non-conformance must be documented within the Non-Conformance register.

Where applicable, the occurrence can be forwarded to a responsible person (such as the Operations Manager or the Administration Manager), who then has to take required actions.

When only insignificant claims are happening, the documentation must not occur in the register but nevertheless must be documented in another format so that its occurrence can be tracked and corrective or preventative action applied, if required.

4.4 CUSTOMER COMPLAINTS

All complaints will be entered into the Non-Conformance Register by the Administration Manager.

Complaints should preferably be written, addressed to the QUALITY MANAGER and signed by the complainant, complete with [Insert Company Name] name, address and product details.

Telephone, email and verbal complaints will be entered into the Register, but wherever possible should be confirmed in writing.

In order to deal with complaints effectively and efficiently so as to resolve the complaint/problem, customer complaints shall be dealt with in the following manner:

- All complaints will be responded to in writing within 5 working days of receipt.
- Upon receipt of a complaint, it will be logged in Register and identified by the NCR Number

Complaints entered into Register shall record on the NC Report;

- Name and address of customer
- Date complaint first received
- Product details
- Nature of the complaint
- Initial complaint response and time.
- Complaint resolution
- Final response to customer.
- Any corrective or preventative actions required

All complaints for products and staff service/ behaviour will be handled by the QUALITY MANAGER.

Serious complaints involving personal injury, a breach of the law or financial implications shall be addressed by the QUALITY MANAGER directly.

Corrective and preventative actions in response to the complaint will be recorded in NC Report.
All customer complaints will be reviewed in the quarterly review of the Integrated Management System.

4.5 CORRECTIVE ACTIONS

Corrective actions are reactive – a process, product, service or management has gone wrong and these are the actions taken to deal with this issue/problem.

Non-conformance is resolved through corrective actions:

- Corrective actions can be identified through;
- Conducting internal audits and general inspections
- Testing and monitoring
- Consulting with staff
- Customer feedback and complaints
- Hazard reporting
- Non-conformance
- System failures
- Regulatory requirements

Steps to be taken with corrective action:

- Review and document the issue/problem
- Contain or temporarily resolve the problem. This may include removing and isolating the affected product or replacing the service.
- Investigate the cause of the problem. [Insert Company Name] shall use a root cause analysis process to identify the cause of a problem.
- Propose an appropriate and suitable solution that will prevent the issue/problem from re-occurring. This may include a change to the process.
- Report actions taken in the Corrective Actions report
- Corrective Actions shall be reviewed at Management Reviews or on an immediate basis if urgent in nature.

The Management Committee is responsible for close out of corrective actions and ensuring that effectiveness has been resolved appropriately.

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4.6 PREVENTIVE ACTIONS

Preventative actions are proactive – something could go wrong and actions are taken to stop it happening or to reduce its severity.

In contrast if something has gone wrong, then it is a non-conformance and is addressed as corrective action Preventative actions are identified through the continual monitoring and verification of the management and quality system.

Preventative actions provide the evidence that an effective quality system is established and is able to anticipate, identify and eliminate potential issues/problems before they cause harm to product quality and safety, or affect customer satisfaction.

Preventative actions can be identified in the following manner:

- Management review process
- Process monitoring
- Trend analysis
- Process analysis
- FMEA analysis
- Risk assessment
- Staff suggestions for improvement
- Contingency planning
- Marketplace trends
- Regulatory or legislation changes
- New technology
- Internal and external audits
- Observation

Preventative actions shall be identified in the Corrective Action Register. This register shall include;

- Identification of potential problem
- Suggested investigation
- Action decided to be taken
- Effectiveness of action taken
- Close out.

The Management Committee will review and manage all preventative actions**.**

4.7 PRODUCT RECALL.

The management committee shall act as the Product Recall Team.

The key actions to be taken in conducting a successful product recall are:

A. Obtain and consolidate all necessary information about the product involved:
    a. Nature of the problem (including testing results)
    b. Product description (including name and batch identification)
    c. Quantity involved
    d. Location of the product
B. Determine the level of recall required;
    a. Depending on the extent of distribution
    b. Notification to all relevant parties;
    c. Internal staff
    d. Customers
C. Notification information shall include;
    a. Name and batch code of product covered by the recall
    b. Why the product is being recalled

   c. Where and how to return the product
   d. Contact at [Insert Company Name] for further information

D. To concisely identify all product affected both internally and despatched to customers;
   a. Internal stock control
   b. Customer despatch records
   c. To ensure total removal of product from the market place;
   d. Recall distribution register

E. To isolate all product involved;
   a. Product to be clearly identified as **"DO NOT USE"**
   b. Product to be isolated from all other products in store
   c. To determine the appropriate corrective action with the affected product

F. To determine appropriate disposal of the affected product (if required);
   a. To implement appropriate preventative action to avoid a recurrence

G. To report on the product recall;
   a. Circumstances leading to the recall
   b. Copies of communication to distributors and customers
   c. Details of all actions taken
   d. Extent of distribution
   e. Result of the recall (quantity of stock recovered)
   f. Corrective actions
   g. Disposal methods
   h. Preventative actions
   i. Difficulties experienced and suggestions for improvement.

5. DOCUMENTATION & RECORDS

The following records shall be maintained to assure this program was conducted according to the Quality Policy.

- Non-Conformance Reports
- Non- Conformance Register
- Product Recall Report
- Management Review

6. DOCUMENT HISTORY

Version No.:			
Last saved by:		Date:	
Original Author:		Date:	
Approved by:		Date:	

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