**ISO 9001:2015**

**Control of Non-conformity & Corrective Action**

Text

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Approval

The signatures below certify that this management system procedure has been reviewed and accepted, and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensuring their provision.

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Amendment Record

This procedure is reviewed to ensure its continuing relevance to the systems and process that it describes. A record of contextual additions or omissions is given below:

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1. Control of Non-conformity & Corrective Action
   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. Manufacturing Made Easy Ltd.’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. Process Activity Map

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

With what

* NC reporting
* NC report log

With who

* Purchasing
* Quality Manager
* Design Engineers
* CEO
* Senior Engineer

Activity

Non-conformity and corrective action reporting and resolution

Input

* Customer requirements
* Customer complaints
* Supplier non-conformance
* Process non-conformance
* QMS non-conformance
* Product/service/output
  + 1. References

| **Standard** | **Title** | **Description** |
| --- | --- | --- |
| BS EN ISO 9000:2015 | Quality management systems | Fundamentals and vocabulary |
| BS EN ISO 9001:2015 | Quality management systems | Requirements |
| BS EN ISO 9004:2000 | Quality management systems | Guidelines for performance improvements |
| BS EN ISO 19011:2011 | Auditing management systems | Guidelines for auditing |

* + 1. Terms & Definitions

| **Term** | **ISO 9000:2015 Definition** |
| --- | --- |
| Non-conformity | Non-fulfilment of a requirement (3.6.4) |
| Defect | Non-conformity (3.6.9) related to an intended or specified use |
| Conformity | Fulfilment of a requirement (3.6.4) |
| Corrective action | Action to eliminate the cause of a non-conformity (3.6.9) and to prevent recurrence |

* 1. 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. Responsibilities

All employees & Process Owners are required to:

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

TheQuality Manageris 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. Control of Non-conformity
     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. Reworked;
2. Scrapped;
3. Returned to supplier;
4. Customer owned materials are returned;
5. Accepted by concession.
   * 1. Reworked

The Department Manager reviews the method of rework with the Quality Manager. If it is agreed that the product can be reworked the **HOLD** label is joined by a **REWORK** label and the part placed into the quarantine or other area.

If the proposed rework method involves a process not approved for manufacturing, the Quality Manager seeks customer approval via a concession, if deemed required, before continuing. When the rework method has been agreed, the Design Engineer arrange for all rework to be carried out from supplier.

When the rework has been completed the product is re-inspected by the Quality Manager to verify the work is complete and meets the specification. The Quality Manager will verify that any scrap is disposed of and that any revised quantities held in stock are recorded.

* + 1. Scrapped

Known scrap materials are placed in the scrap bins or designated area for recycling. The I Department Manager is responsible for recording all rejects using the reject labels, by entering the data and the rejection details onto a Scrap/Reject sheet. These will be passed to Quality Manager to enter on the non-conformity log. Rejected parts are replaced to allow the order to be satisfied. Reject entries include;

1. Reference number;
2. Quantity rejected;
3. Reason for rejection;

This data is reviewed, analysed, and reduction plans supported by appropriate corrective actions implemented through our continuous improvement and management review meetings.

* + 1. Returned to Supplier

If the product or service is rejected against the supplier the Quality Manager will review such rejections and determine whether to raise a supplier non-conformity report. The Quality Manager will return the product to the supplier using a returns note and a credit note. Free of charge (FOC) replacements are requested from the supplier.

Supplier non-conformity reports are discussed at meetings between the departments involved and the Quality Manager. Where appropriate, some quality problem items require a supplier visit to verify the implementation of any corrective actions.

* + 1. Customer Owned Materials

Customer owned materials either damaged or lost or those found to be non-conforming upon receipt or during processing are recorded on a customer non-conformity report and notified to the customer. The Quality Manager will return the product to the customer using a returns note. Replacements are requested from the customer.

* + 1. Non-conforming Services

In cases where the delivered service is non-conforming by failure to meet customer requirements; but the delivered service can still be utilized by the customer, Manufacturing Made Easy Ltd advises the customer accordingly to seek approval for use of such services.

Concessionary terms are agreed between Manufacturing Made Easy Ltd and the customer and approved as credit notes or fees rebates to the customer as may be applicable. Non-conforming services may also be reworked to meet the specified customer requirements. The disposition and correction decision is made on two different levels depending on the nature of the non-conformity and the decision itself.

When it is obvious that the service must be scrapped or regraded, or when it can be easily reworked without degrading its quality, the Production Manager and the Quality Manager authorized to decide what should be done with the non-conformity.

If the report would in any way affect quality and issues related to policy matters or if there is a possibility for an accept-as-is decision, the evaluation and disposition and corrective action is made in consultation with the customer.

* + 1. Accepted By Concession
       1. Internal Concessions

The Quality Manager will review the nature of any concession request with the Departmental Manager, who will determine the validity of each request. If the request is accepted, the Quality Manager allocates a concession request to the customer. Brief details of the concession request are recorded on the concession request log. The description of the concession includes concise and accurate and the period or quantities covered by the concession accurate.

The Quality Manager considers the concession request. Remarks are made and approvals given where appropriate. If the request impacts on the customer, the Quality Manager will apply for a customer concession. (Using customer designated documentation where appropriate). Once final approval has been given by the appropriate signatories the concession is distributed to the following personnel as appropriate:

1. QA Manager;
2. Technical Sales;
3. Departmental Manager.

All products or services produced under a concession are accompanied by the concession request form and a valid concession reference number. The master is retained by the Quality Manager on the central file.

* + - 1. Supplier Concessions

When a supplier requests a concession, the Quality Manager reviews the request and decides whether to proceed. If the decision is made to reject the request, the Quality Manager informs the supplier of the decision to reject and disposition any material affected.

If the concession request is initially accepted, Quality Manager the raises a concession request. If the concession is accepted all material will supplied under a **Concession** label and a valid concession reference number will accompany the product.

* + - 1. Customer Concessions

In both cases defined above, customer approval is required if the product or service is found to be outside of the specification requirements. In such instances the Quality Manager approaches the customer using a concession request.

Upon approval, the concession is appended to the original concession request which is annotated with the customer’s concession number and will on appear on any delivery documentation. The approved customer concession request is filed by the Quality Manager and copies distributed along with the original concession are issued as per the internal request list.

No product is shipped, or service released until customer approval is received. All shipping or release documentation will quote the customer concession number where customer approval prior to shipment or release is necessary.

A non-conformity report is also raised whenever a customer concession is requested, whether the customer accepts the request or not. The concession log will be held to summarise the status of all concessions by the Quality Manager. This will be held on the central file.

* 1. Control of Corrective Action

The Quality Managerreviews any issues raised by each non-conformity 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:

* Customer concerns, complaints or returns;
* Non-conforming product received from suppliers;
* In-process concerns;
* Concerns about QMS stability;
* Accidents or incidents;
* Environmental incidents.
  + 1. Customer Returns

Upon receipt of notification of a product or service rejection by the Customer, the Goods Inwards Department passes the product and the paperwork onto the Quality Manager for review and disposition. The rejected parts will be placed in the returns bay and the Quality Manager or Quality Inspector will identify the parts with a **Reject Tag** and placed in the quarantine area prior to its disposition and the details are entered onto non-conformity report.

The Quality Manager determines liability with the support of product or service specialists. If the liability is determined, a formal customer complaint report is raised, and an appropriate cross-functional team is assigned to investigate and resolve the problem.

Should the customer require a copy of the corrective action report, the report is kept in the customer’s file located on the central file. Should the customer request a site visit to discuss problems, a visit is arranged to support any actions taken.

* + 1. Supplier Returns

Any product found to be defective due to manufacture with non-conforming purchased material is identified with a **Reject Tag** and placed in the quarantine area or other suitable place whilst it is being reviewed by the Quality Manager. The outcome of the review may result in:

* Rework;
* Accept under concession;
* Rejection to the supplier.

If the product is to be rejected against the supplier, the Quality Manager reviews such rejections and determines whether to raise non-conformity report. The Finance Department is requested to provide a credit note and the product is returned. Supplier related non-conformities are discussed at the monthly management meetings. Where appropriate, some quality problem items require a Supplier visit to verify the implementation of any corrective actions.

* + 1. In-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 non-conformity 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.

* + 1. Corrective Action Impact

Where applicable any corrective action taken and controls implemented to eliminate the cause of non-conformity is applied to other similar processes and is controlled by the Quality Manager in liaison with affected process owners. Significant actions are entered onto the non-conformity log.

* + 1. Corrective Action Review

The Quality Manager will review any issues raised and update the non-conformity report to identify root cause and level of action required. Repeated non-conformities of the same nature or significant deviations from procedures or the policies are reported to Top management for action and resolution. The Quality Manageris responsible for:

* Identifying the root cause(s) of the non-conformity;
* Identifying appropriate corrective actions (including modifying or creating new work practices);
* Planning and implementing corrective actions;
* Verifying the close-out and effectiveness of corrective actions;
* The Quality Manager verifies implementation of corrective actions;
* Where non-compliances are identified outside the audit process, the Quality Manageror designee generates a corrective action request as appropriate.
  + 1. Implementing Containment Action

The Quality Manager should first contain the problem and then determine its root cause in order to take appropriate corrective action to prevent the problem’s recurrence.

* Recording corrective actions using the forms provided;
* Performing an initial review;
* Determining causes and the need to take action;
* Implementing action where required;
* Preventing recurrence and evaluating effectiveness;
* Recording the results;
* Examine the effectiveness of corrective actions.
  + 1. Determining the Causes

Non-conformity and opportunity for improvement may be identified by employees, customer complaints or by management system audit reports. By whichever means a non-conformance is identified, the underlying cause of the non-conformance is investigated. The Quality Managerreviews any issues raised and completes a non-conformance report to identify root cause and evaluate the level of action required. Repeated non-conformances of the same nature or significant deviations from procedures or the policies are reported to Top management for action and resolution.

* + 1. Evaluating the Need for Action

Senior Management will be actively involved in any major corrective actions making sure that all actions agreed by any multi-functional teams are carried out fully. Major corrective actions and improvements are placed onto the continual improvement programme and reported on at Top management meetings. The eventual close-out of any significant action is presented at the management review meeting. All corrective action reports raised are categorized as having major or minor effect:

* **Major**: Where the procedure contradicts working practices and/or working practices do not reflect standard requirements or customer complaints which require additional corrective action
* **Minor**: Where the system procedure or process is not being fully adhered to, equipment breakdown or failures which do not affect operational activities. A non-conformance that does not have an immediate impact upon the stability of the management system
  + 1. Implementing Action

Designated personnel must implement the agreed level of action within an agreed timescale. The Quality Managerwill follow up all corrective actions to ensure effective and timely responses are achieved.

The Quality Managerwill close out the corrective action when satisfactory resolution has been achieved and when objective evidence of close out has been obtained through inquiry or audit. Corrective action such as, implementing, modifying or enforcing procedures or controls will be taken to avoid repetition of the non-conformance where necessary.

* + 1. Verifying the Effectiveness of Actions

The corrective action request originator verifies the effectiveness of the corrective actions taken. Where the originator is also responsible for the implementation of the corrective action, the Quality Managerprovides the verification for each corrective action, and request closure. If corrective actions are determined to be ineffective, the original corrective action request is closed and a new request issued.

* + 1. Review

Corrective actions are reviewed for long-term effects and process improvements during management reviews meetings. The Quality Managerand Top management determine if the action taken could potentially be applied to other areas of the organization.

* 1. Forms & Records

All documentation and records generated by the non-conformity and corrective action processes are retained and managed in accordance with the Control of Documented Information procedure.

|  |
| --- |
| Title & Description |
| Non-conformance Report |
| Non-conformance Log |
| Concession Request |
| Concession Request Log |
| Corrective Action Report |
| Corrective Action Log |

* 1. Non-conformity & Corrective Action Process Map

|  |  |  |  |
| --- | --- | --- | --- |
| **Initiator** | **Approver** | **Implementer** | **Verifier** |
| Update CA Log  Significant or Recurring Issue  Initiate Corrective Action Process | YES  NO  Need Containment Action?  Determine Root Cause(s)  Determine Solution and Verification Method | Implement Containment Action  Implement  Solutions  NO | Action Closed  Was Solution Successful?  Verify Effectiveness of Solutions  YES |