**ISO 9001:2015**

**Control of Internal Audits**

Text

Description automatically generated

XMP House, Starnhill Close,  
Ecclesfield, Sheffield,  
S35 9TG, United Kingdom.

This procedure is the property of Manufacturing Made Easy Ltd It must not be reproduced in whole or in part or otherwise disclosed without prior written consent.

The official controlled copy of this quality manual is the digitally signed PDF document held within our network server and visible to all authorised users. All printed copies, and all electronic copies and versions, except the ones described above, are considered uncontrolled copies which should be used for reference only.

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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Name | Signature | Position | Date |
| Prepared by | Dhairyasheel Ashok Mulik Patil |  | Quality Manager |  |
| Reviewed by | Dr Prveen Bidare |  | Senior Engineer |  |
| Approved by | Jyoti Bidare |  | CEO |  |

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:

|  |  |  |  |
| --- | --- | --- | --- |
| Page No. | Context | Revision | Date |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Company Proprietary Information

The electronic version of this procedure is the latest revision. It is the responsibility of the individual to ensure that any paper material is the current revision. The printed version of this manual is uncontrolled, except when provided with a document reference number and revision in the field below:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Document Ref. |  | | | | | Rev |  |
|  |  |  | | | |  |  |
| Uncontrolled Copy |  |  | Controlled Copy |  |  | Date |  |

# Contents

[1 Control of Internal Audits 3](#_Toc482262489)

[1.1 Introduction & Purpose 3](#_Toc482262490)

[1.1.1 Process Activity Map 3](#_Toc482262491)

[1.1.2 References 3](#_Toc482262492)

[1.1.3 Terms & Definitions 3](#_Toc482262493)

[1.2 Application & Scope 4](#_Toc482262494)

[1.3 Responsibilities 4](#_Toc482262495)

[1.4 Controlling Internal Audits 4](#_Toc482262496)

[1.4.1 Selecting Internal Auditors 4](#_Toc482262497)

[1.4.2 Developing the Audit Programme 4](#_Toc482262498)

[1.4.3 Preparing for the Audit 4](#_Toc482262499)

[1.4.4 Conducting the Audit 5](#_Toc482262500)

[1.4.5 Data Review & Initial Reporting 5](#_Toc482262501)

[1.4.6 Monitoring 5](#_Toc482262502)

[1.4.7 Final Reporting 5](#_Toc482262503)

[1.4.8 Review 5](#_Toc482262504)

[1.5 Conducting Audits 5](#_Toc482262505)

[1.5.1 System Audits 5](#_Toc482262506)

[1.5.2 Process Audits 6](#_Toc482262507)

[1.5.3 Supplier Audits 6](#_Toc482262508)

[1.5.4 Legislation Audits 7](#_Toc482262509)

[1.6 Corrective Action 7](#_Toc482262510)

[1.7 Forms & Records 7](#_Toc482262511)

[1.8 Internal Audit Process Map 8](#_Toc482262512)

1. Control of Internal Audits
   1. Introduction & Purpose

The purpose of this procedure is to define Manufacturing Made Easy Ltd.’s process for undertaking QMS audits, process audits, and supplier and legislation audits in order to assess the effectiveness of the application of our quality management system and its compliance to ISO 9001:2015. This procedure also defines the responsibilities for planning and conducting audits, reporting results and retaining associated records.

* + 1. Process Activity Map

Output

* Process improvement
* QMS improvement
* Conforming processes
* Process corrective actions
* System corrective actions
* Audit reports

How

* NC/CA process
* Internal audit checklist
* Process audit checklist
* Forms & reports

With what measure

* No. of audits conducted
* No. of open audit actions
* Repeated NCs
* Audit score

With what

* Internal audit programme
* Status and importance
* Risk and opportunities

With who

* Quality Manager
* Top Management

Activity

Systematic, independent and documented process to obtain objective evidence and to evaluate it to determine the extent to which audit criteria are met

Input

* Customer requirements
* Statutory or legal requirements
* Areas of concern
* Audit considerations
  + 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** |
| --- | --- |
| Audit | A documented process for obtaining and evaluating evidence |
| 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

The scope of this procedure is focused on assessing the effectiveness of Manufacturing Made Easy Ltd.’s quality management system. Where such processes are found to be deficient, the audit will lead to improvement in those processes. By applying the principles of auditing, outlined by ISO 19011:2011, Manufacturing Made Easy Ltd ensures that all internal audits are conducted with due professional care, integrity and independence. All conclusions derived from the audit are based upon objective and traceable evidence.

* 1. Responsibilities

It is the responsibility of the Quality Managerto coordinate the whole internal audit programme. TheQuality Manageris required to:

* Determine the root causes of non-conformities;
* Maintain a system for reporting audit results;
* Determine conformity to planned arrangements;
* Determine proper implementation and maintenance;
* Provide the results of audits to top management;
* Review the effectiveness of corrective actions taken.
  1. Controlling Internal Audits
     1. Selecting Internal Auditors

To ensure impartiality and objectivity, the audit team will include personnel from departments not directly associated with the area, process or department being audited. The Internal Auditors are selected on the basis of their:

* Education: secondary or higher;
* Work Experience: more than 5 years;
* Relevant Training: provided in-house or externally;
* Audit Experience: demonstrable knowledge/skills.
  + 1. Developing the Audit Programme

The Quality Manageris required to:

* Determine the status and importance of each process;
* Establish audit frequency based on the status and importance of each process;
* Develop and communicate the audit schedule;
* Appoint audit team leader where required;
* Select audit team;
* Assign audit duties to the auditor team.
  + 1. Preparing for the Audit

The Internal Auditors (Quality Manager) are required to:

* Review relevant management system documents and records;
* Determine their adequacy with respect to the audit criteria and with ISO 9001;
* Review and prepare the internal audit checklist;
* Arrange audit appointment;
* Issue the audit checklist to the responsible manager for preview.
  + 1. Conducting the Audit

The Internal Auditors (Quality Manager) are required to:

* Conduct opening meeting;
* Sample and observe process inputs/activities/outputs;
* Record objective evidence to verify process compliance or non-conformance;
* Generate audit findings;
* Close the audit.
  + 1. Data Review & Initial Reporting

The Internal Auditors (Quality Manager) is required to:

* Review the audit evidence and conclusions and discuss recommendations for improvement;
* Decide if process non-conformances observed should be subject to formal corrective action;
* Prepare the audit report;
* Review the audit report with the responsible manager;
* Corrective actions are reviewed by the responsible manager and a close-out action is agreed;
* Finalize the audit report.
  + 1. Monitoring

The Auditee/Process Owner is required to:

* Ensure corrective actions are implemented and are closed-out within the agreed timeframe;
* Ensure non-conformances are closed-out within the agreed timeframe;
* Minor areas of non-conformance are taken care of immediately;
* Ensure the status of corrective actions and any non-conformances are kept up-to-date.
  + 1. Final Reporting

The Quality Manageris required to:

* Review audit conclusions;
* Identify trends;
* Make recommendations for improvement;
* Finalise the internal audit report;
* Issue internal audit report to top management.
  + 1. Review

All internal audit results and any corrective actions are discussed at management review meetings to evaluate their effectiveness and implementation.

* 1. Conducting Audits
     1. System Audits

The Quality Manager prepares the Audit Programme using the Internal Audit Tracker each year in consultation with Top management. The frequency of audits depends on the perceived need for audit, but all processes and areas are audited at least once per year. The frequency is determined using the Process Assessment worksheet in the Internal Audit Tracker. All internal and external non-conformances that are attributable to systems or process failures may result in the audit programme being updated to include additional audits in the area concerned.

Auditors audit areas other than their own but with which they will have some familiarity. Their responsibility for auditing areas rotated from year to year. The Internal Audit Programme is available on the network drive so that time can be scheduled in advance. The internal audit is conducted using the ISO 9001-2015 Internal Audit Checklist.

Before each audit activity the Quality Managermakes arrangements for those concerned to be notified in advance of the time of the audit by email. The audit team then reviews the process inputs and outputs using the Turtle Diagram at the front of this procedure in order to:

1. Identify the purpose of the process under investigation and determine what should be accomplished;
2. What are the Inputs into the process;
3. What are the expected outputs from the process;
4. What are the product and or services provided to the customer;
5. What are risks to the customer;
6. Identify the owner of the process;
7. Determine the objectives of the process;
8. What are the key performance indicators associated with the process;
9. Are there any customer specific requirements;
10. Determine how to obtain information which provides an indication of process performance.

The audit is documented using the Internal Audit Report which documents the performance of the process/procedure and the section of the QMS being audited, identifying all documentation used, and key indicators associated with the process. On completion of the audit the audit team enters the results of the internal audit into the Internal Audit Tracker.

* + 1. Process Audits

Standard operating process audits of the product design and development process realization activities are planned by the Quality Manageron an annual basis in conjunction with the Senior Engineer.

The audit team then reviews the process inputs and outputs using the Turtle Diagram at the front of this procedure. The audit is conducted using the ISO 9001-2015 Process Audit Checklist. Audits are conducted on a monthly/six-weekly/bi-annual basis and cover all product design and development process areas over the year. Any non-conformity found during the audit is agreed with the Senior Engineer and resolution or containments actions agree.

* + 1. Supplier Audits

2nd Party audits of our suppliers are planned by the Quality Managerin conjunction with the Senior Engineer and conducted to determine whether the Supplier’s processes conform to the specified purchase controls and planned arrangements.

The audit team then reviews the process inputs and outputs using the Turtle Diagram at the front of this procedure. The audit is conducted using the ISO 9001-2015 Supplier Audit Checklist.

* + 1. Legislation Audits

At least once per year, audit is conducted on the scope and applicability of the register of applicable legislation in order to verify continued compliance. Using the register of legislation, the auditor determines the most significant legislation applicable to our organization at the time of the audit, by taking a sample and seeking objective evidence that the legislation is current and is being complied with.

Samples of legislation are noted and the register brought up to date as required. The samples taken are selected based on current risks but ensures that the whole register is audited at least once in each 3 year period.

* 1. Corrective Action

The corrective actions are identified on the Internal Audit, Non-conformity & Correct Action Tracker along with the person responsible and the timescales for completion. The process or procedure is re-audited and the issue closed out when all corrective actions are completed. A member of the audit team will then sign off the audit report. An audit summary is prepared for management review.

* 1. Forms & Records

All documentation and records generated by the internal audit process are retained and managed in accordance with the Control of Documented Information procedure.

| Title & Description |
| --- |
| Audit Report |
| Audit Feedback Form |
| Internal Audit Checklists (Form In Internal Audit Folder) |
| Internal Audit, Non-conformity & Corrective Action Tracker (Form In Internal Audit Folder) |

* 1. Internal Audit Process Map

|  |  |  |  |
| --- | --- | --- | --- |
| **Quality Manager** | **Auditor** | **Auditee** | **Top Management** |
| YES  NO  **Audit Considerations**   * Standards * Customer feedback * QMS requirements * Corrective actions * 3rd party audits * Process status * Non-conformances * Process importance   **Audit Considerations**   * Legal requirements * Employee concerns * Management review * Risks * Opportunities * Policies * Objectives * PESTLE * SWOT   Prepare Audit Programme  Assign Audit Duties  Prepare Audit Checklist  Document Review  Non-compliances Found?  Initiate Corrective Actions  Prepare Audit Report  Close-out Corrective Actions  Verify Close-out  Review Audit Findings  Update System Metrics  Submit Audit Report  Review Recommendations |  |  |  |