Text

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**ISO 9001:2015**

**Control of Documented Information**

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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| --- | --- | --- | --- | --- |
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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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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:

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1. Control of Documented Information
   1. Introduction & Purpose

The purpose of this procedure is to ensure that all relevant documented information and organizational knowledge which forms an integral part of our quality management system is managed under controlled conditions and that all documented information is reviewed and approved by authorized personnel prior to issue.

* + 1. Process Activity Map

Output

* Document approval
* Process control
* Continual improvement
* Document changes
* Record control

How

* Documented information register
* Disaster recovery

With what measure

* No. of incorrect documents
* No. of document errors
* No. of document changes

With what

* Retained information
* Maintained information

With who

* Document Control
* Quality Manager

Activity

Controlling documented information and organizational knowledge

Input

* Revised QMS documents
* Standards
* Customer drawings
* Specifications
* Process changes
  + 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** |
| --- | --- |
| Documented Information | Information (3.8.2) Required to be Controlled and Maintained |
| Record | Document (3.8.5) Stating Results Achieved or Providing Evidence |
| Quality Manual | Specification (3.8.7) for the Quality Management System |
| Specification | Document (3.8.5) Stating Requirements |
| Objective Evidence | Data (3.8.1) Supporting The Existence or Verity of Something |

* 1. Application & Scope

Documented information is retained to demonstrate compliance with ISO 9001:2015, customer requirements, and the effective operation of our Quality Management System (QMS). Standardized templates and forms are used and accessed via our secure company network.

This procedure outlines controls to ensure that:

1. Documents are reviewed and approved before issue;
2. Revisions are identified and managed;
3. Current versions are accessible where needed;
4. Documents are clear, identifiable, and easy to use;
5. External documents are tracked and controlled;
6. Obsolete documents are removed or marked clearly.

This process applies to all QMS documents and must be followed by all relevant personnel.

* 1. Requirements

Top management ensures all documented information is clearly identified (e.g. title, date, author) and available in the correct format and media (paper or electronic).

Our electronic document system is regularly updated and backed up to ensure only current versions are available. Each department is responsible for creating, maintaining, and securing records relevant to their processes.

* 1. Creating, Updating & Controlling Documented Information

Manufacturing Made Easy Ltd applies the following criteria to all types of ‘documented information’ in order to assess whether the information is necessary for demonstrating the effectiveness of our QMS, and whether it should be formally controlled.

1. Communicates a message internally or externally;
2. Provides evidence of process and product conformity;
3. Provides evidence that planned outputs were achieved;
4. Provides knowledge sharing.
   * 1. General

Authorized personnel review and approve all documents before release. Each department is responsible for maintaining its own current documents, which must be available at the point of use.

Controlled documents include:

1. Specifications and drawings;
2. Quality management manual;
3. Operational procedures, reports and forms;
4. Management review and design review minutes;
5. External documents.
   * 1. Document & Data Identification, Approval and Use

All documents are identified with a title, revision level, and where needed, a reference code. They are reviewed and approved by authorized personnel before issue.

Key controls include:

* Documents are checked for accuracy and compliance before release.
* Multi-signature approvals clearly indicate required signatories.
* The Quality Manager ensures the Quality Manual is reviewed, approved, and issued under controlled distribution.
* Uncontrolled copies are marked “UNCONTROLLED” and may be shared externally. Controlled copies can be issued to customers if requested.
* Customer and external documents are reviewed by the Quality Manager. Any discrepancies are communicated back to the customer.
* Only approved documents are used for operations.
* Departments maintain their own documents and a master index of revisions.
* Current versions must be available at the point of use.
* When sending documents externally, the sender must inform the Quality Manager, who will issue a document control sheet.
  + 1. Revising a Controlled Document

Controlled documents may be temporarily amended by authorised personnel through a red-lining process and includes hand-written amendments which are initialled and dated by the authorised person. Current revisions of appropriate documents are available at locations where they are used by staff.

* + 1. External Documents

The Quality Manager periodically verifies the current revision of external documents (e.g. international standards, customer specifications, etc.) and amends the documents and master document index accordingly when new revisions are available. Notification of revision changes is given to those departments shown in the distribution list.

* + 1. Uncontrolled Documents

Copies of documents issued to personnel and outside parties for information only (are not affected by the documents) are stamped ‘**UNCONTROLLED**’ across the front page. Such documents are not under revision control. Uncontrolled copies of documents may not be issued to personnel or outside parties who manage, perform, or verify work that is directly affected by the document.

* + 1. Document Change Requests

Changes to a document are requested using the document change request form if a document is found to be deficient. Any employee can request a change to a document but the review and approval must be performed by the same functions that performed the original review and approval.

* + 1. International Standards & Specifications

The Quality Manager maintains a controlled and up to date set of relevant International Standards and Specifications, relevant to our operations, for the purpose of reference and to assist compliance to company and client requirements. Controlled copies of such standards maybe distributed as required and/or placed on the company website.

* + 1. Obsolete Documents

Obsolete documents are removed from use and clearly marked as **“OBSOLETE.”** They are stored separately for reference or legal purposes, following this procedure.

Hard copies are kept in labeled cabinets; electronic versions are removed from active systems but stored securely for access if needed. If reactivated, documents must be reviewed, approved, and reissued like new documents.

* 1. Management System Records

Records are retained to attest to the proper implementation of various aspects of the integrated management system. Records are stored as secured computer files or in designated filing cabinets to prevent deterioration and damage. Such records are easily accessible for use and are made available for review upon request.

Master forms are be signed by the initiator and date indicated to evidence their authority. Forms are controlled via their document number and revision status. Standard forms, e.g. pre-printed material are listed in the appropriate procedure or work instruction.

Archival records and data retained for legal or knowledge preservation purposes or both are suitably identified. All records must contain sufficient data to attest to satisfactory completion of the recorded activity and at minimum, must be signed and dated by the individual responsible for completing the record. The following documents are acceptable records:

* + 1. Protection, Storage and Retrieval of Documented Information

Documented information may exist in either hard copy of electronic formats. Hard copies are stored where they are protected from physical deterioration, loss and damage due to environmental conditions. Electronic back up data and contract documents are stored in a lockable which is located Company Office.

Documented information is labelled and indexed for ease of retrieval and for proper referencing. All filing cabinets, containers, and devices are clearly marked and labelled to identify their contents. Retained documented information is indexed and grouped for expedient retrieval. Retained documented information must not be stored on personal storage drives or files.

* + 1. Retention Period for Records

| **Document** | **Retention Period** |
| --- | --- |
| Management Reviews | 2 Years |
| Audit Reports | 5 Years |
| Process Monitoring Records | 5 Years |
| Legal & Compliance Records | 10 Years |
| Risk & Opportunity Assessments | 10 Years |
| Business Plans | 5 Years |
| Corrective Action Reports | 5 Years |
| Complaint Records | 2 Years |
| Inspection and Test Reports | 5 Years |
| Non-conformance Reports | 5 Years |
| Design Review Records | 5 Years |
| Training Records | 10 Years |
| Calibration Records | 5 Years |

* + 1. Disposal of Records

Upon expiration of the retention period, Quality Manager will dispose of such records in an appropriate manner. Confidential records are shredded.

* + 1. Register of Documented Information

Manufacturing Made Easy Ltd **maintains** the following Documented Information:

| **ISO 9001:2015** | **Description** |
| --- | --- |
| 4.3 | The scope of the quality management system |
| 4.4 | Information necessary to support the operation of QMS processes |
| 5.2 | The quality policy |
| 6.2 | The quality objectives |

Manufacturing Made Easy Ltd **retains** the following Documented Information:

| **ISO 9001:2015** | **Description** |
| --- | --- |
| 4.4 | Information necessary to support the operation of QMS processes |
| 7.1.5.1 | Evidence of fitness for purpose of monitoring and measuring resources |
| 7.1.5.2 | Evidence of the basis used for calibration of the monitoring and measurement resources |
| 7.2 | Evidence of competence of people doing work under the control of the organization that affects the performance and effectiveness of the QMS |
| 7.5.1b | Documented information required by the QMS |
| 8.2.3 | Results of the review and requirements for the products and services |
| 8.3.2 | Records to demonstrate compliance with design and development requirements |
| 8.3.3 | Records of design and development inputs |
| 8.3.4 | Records of the activities of design and development controls |
| 8.3.5 | Records of design and development outputs |
| 8.3.6 | Design and development changes, including the results of the review and the authorization of the changes and necessary actions |
| 8.4.1 | Records of the evaluation, selection, monitoring of performance and re-evaluation of external providers and any actions arising |
| 8.5.2 | Evidence of the unique identification of outputs when traceability is a requirement |
| 8.5.3 | Records of property of the customer or external provider that is lost, damaged or non-conforming and of its communication to the owner |
| 8.5.6 | Results of the review of changes for production or service provision, the persons authorizing the change, and necessary actions taken |
| 8.6 | Records of authorized release of products for delivery to the customer including acceptance criteria and traceability to the authorizing person(s) |
| 8.7 | Records of non-conformities, actions taken, concessions and the identity of the authority deciding the action in respect of the nonconformity |
| 9.1.1 | Results of the evaluation of the performance and the effectiveness of the QMS |
| 9.2.2 | Evidence of the implementation of the audit programme and the audit results |
| 9.3.3 | Evidence of the results of management reviews |
| 10.2.2 | Evidence of the nature of the nonconformities and any subsequent actions taken |
| 10.2.2 | Results of any corrective actions |

* 1. Organizational Knowledge
     1. General

Manufacturing Made Easy Ltd recognizes that organizational knowledge is a valuable resource that supports our quality management activities and ensures continual product and service conformity. There is a strong link between organizational knowledge and the competence of our people, the latter being peoples’ ability to apply knowledge to their work.

* + 1. Sources of Organization Knowledge

Sources of internal knowledge often include the organization’s intellectual property; knowledge gained from experience; lessons learned from failures and successes; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services.

Sources of external knowledge often include other ISO standards; research papers; conferences; or knowledge gathered from customers or external parties. Your organization considers internal and external sources, such as:

* Lesson learnt from non-conformities and corrective actions, near miss situations and successes;
* Gathering knowledge from customers, suppliers and partners;
* Capturing knowledge that exists within the organization, e.g. through mentoring, succession planning;
* Benchmarking against competitors;
* Sharing organizational knowledge with relevant interested parties to ensure sustainability of the organization;
* Updating the necessary organizational knowledge based on the results of improvement;
* Knowledge from conferences, attending trade fairs, networking seminars, or other external events.
  1. Forms & Records

Master forms are be signed by the initiator and date indicated to evidence their authority. Forms are controlled via their number and revision status. Standard forms, e.g. pre-printed material are listed in the appropriate procedure or work instruction.

|  |
| --- |
| Title & Description |
| Master Document & Record Index |
| Document Issue Sheet |
| Document Change Request |