Quality Procedure

Documented Information

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software version, graphics, etc.) and on appropriate media (e.g. paper, electronic). All documented information is reviewed and approved for suitability and adequacy.

An electronic document management system, which is backed up and updated as required, is used to retain documented information ensuring only the current versions are available to users. Records from process outputs are generated and maintained by the departments responsible for their creation. For electronic records, back up procedures are established, employees are responsible for backing up their data.

Your Organization 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.

1.4.1 General

All documents and data are reviewed and approved by authorized personnel prior to issue. Each department issues and maintains its own documents. Current revisions of appropriate documents are available at locations where they are used. A *Master Document & Record Index* is maintained and circulated. Documents controlled by this procedure include but are not limited to the following:

1. Specifications and drawings;
2. Quality management manual;
3. Operational procedures, reports and forms;
4. Management review and design review minutes;
5. External documents.

1.4.2 Document & Data Identification, Approval and Use

All documents are identified with a title, revision level and where applicable, a code or part number. Certain work instructions have a revision level. Only original forms, which are stored on file, are identified with the issuing authority. All documents are reviewed and approved (signed and dated) prior to issue. Documents are reviewed by the issuer prior to release. Release on to the network confirms that they have been reviewed and approved.

1. Prior to issue and release, documents are reviewed for correctness and compliance to quality requirements.
2. Documents that require more than one approval signature indicate how many and which signatures are required for approval and issue.
3. The Quality Manager is responsible for ensuring that the quality manual is reviewed, approved and distributed as required. Copies of the manual will be serialized and issued on a controlled distribution basis.
4. Uncontrolled copies will be marked 'UNCONTROLLED' and will be provided for use outside of the company, although a controlled copy can be issued to customers upon customer request.
5. Customer documents (e.g. standards, specifications & drawings) and external documents (e.g. changes received from customers) are reviewed by the Quality Manager.

6. If any ambiguities or errors are detected, the customer is notified.
7. Only documents approved may be used for production and service operations.
8. Each department issues and maintains its own documents and produces a master document index of all documents and their current revision.
9. Current revisions of appropriate documents are available at locations where they are used.
10. When documented information is transmitted external parties; the initiating person identifies its distribution to the Document Control Department who will generate a document issue sheet.

1.4.3 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.

Where permanent changes to a document are required, a *Document Change Request* form is completed and submitted for the document owner to consideration and implementation.

1.4.4 External Documents

The Document Controller 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.

1.4.5 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.

1.4.6 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.

1.4.7 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.

1.4.8 Obsolete Documents

Obsolete documents are removed from points of use and may be retained for reference or for legal obligations are marked '**OBSOLETE**' and kept separate from active documents. Obsolete documents are stored and retained in accordance this procedure.

Filing cabinets containing obsolete documents are segregated and labelled '**OBSOLETE**'. Obsolete electronic documents are removed from the network and are stored in media that is accessible upon request. Any

obsolete documents that need to be reactivated must be reviewed, approved and released in the same manner as newly established documents.

1.5 Management System Records

1.5.1 General

Records are retained to attest to the proper implementation of various aspects of the quality 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 is 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:

1.5.2 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, fire resistant cabinet which is located [Define your safe storage and back-up methods]. The Document Control Manager and the IT Manager ensures that computer backups are made, that virus protection is in place, and that access to the network is via a secure portal.

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.

1.5.3 Retention Period for Records

Document	Suggested Retention Period
Management Review Minutes	2 Years
Internal and External Audit Reports	5 Years
Context & Interested Party Analysis	3 Years
Process Monitoring and Inspection Records	5 Years
Legal and Compliance Records and Registers	10 Years
Risk and Opportunity Assessments and Registers	10 Years
Business Plans	5 Years
SWOT Analysis Records	5 Years
PESTLE Analysis Records	5 Years