

Procedure for Control of Documents

Objective: To ensure that every person in the organization uses the correct versions of the correct documents.

Scope: Applicable to all the types of documents used for references in the organization, including quality manual sections, procedures, work instructions and formats for records.

Definition: Control of documents is a process by which it is ensured that documents required by the quality management system are under Top management's control.

Responsibility: Management Representative

Internal Documents

Document approval:

The approving authority prior to issue or release for use shall approve all documents of the quality management system.

The document is approved by stamping "Approved Document" on the backside of the paper and signed by the approving authority.

"Document Approval and Revision Control Register M-01" is maintained by MR containing index of all approved documents including sections of quality manual, documented procedures, reference documents and forms.

Original or First version of the document is assigned revision "00".

Legibility of documents shall be ensured while approving documents.

Approving Authority:

Any Partner will have authority to approve Quality manual and Factory Manager will have authority to approve Procedures, Work Instructions, Reference documents and forms.

Document Review, update (amendments) and re-approve:

All the documents of quality management system should be reviewed by the approving authority for its applicability and possibility of update after two years of its revision, if the document is not modified or updated in two years.

If the document is found appropriate not updated or modified after review, it should be stamped "Re-approved" on the backside and signed by approving authority.

Documents can be amended during the course of implementation or during planned review of documents.

Amendments can be issued in two ways:

1. Issuing "Document Amendment Note Form M-02". This can be done when amendment is being issued temporarily or there is an urgency to

issue an amendment and revising the whole document can take some time or the revision may affect (references given in) several other documents, which needs to be verified.

2. Document is revised to next revision level (01 after 00 and so on). Approving authority as stated in "Document approval" above should approve the revised document.

Whenever a document is revised, all pages of the documents bearing same unique number are revised and a new issue date is marked. For the purpose of revision, document shall mean a section of quality manual, a procedure, a work instructions or a single form.

If amendment issued in "Document Amendment Note Form M-02" issued earlier is incorporated in a revision than they are considered withdrawn. Management representative records the identification of "Document Amendment Note Form M-02" withdrawn in the "Document Issue Record Form M-03", while issuing a revised document.

Any employee of the company can request amendments to the documents verbally or in writing.

Identifying changes and current revision status:

Nature of changes and reason for changes are recorded in "Document Approval and Revision Control Register M-01" maintained by MR.

"Rev. No." and "Rev. Date" identifies the revision status of a document. Versions of currently applicable documents can be verified from "Document Approval and Revision Control Register M-01".

All documents are identified at the bottom as below:

Document ID: Document Number/ Page 1 of 3 /Rev.: 00/ Rev. Date: 01-04-2002

Forms are identified as below:

Form ID: Form Number/ Rev.: 00/ Rev. Date: 01-04-2002

In some cases instead of "Rev. No. and Rev. Date", "Issued on *Date*" is given, which shall mean original issue Rev. 00 and Rev. Date.

Document issue:

Approved copies of the documents are issued to all the concerned persons. Document wise issue details are given in "Document Approval and Revision Control Register M-01"

Record of issue should be maintained in "Document Issue Record Form M-03". Where appropriate, evidence of receipt can be taken on appropriate covering letter of issue.

Copies of a document when distributed as per distribution list are considered as controlled copies and are stamped "Controlled" and copy number is identified and signed by the management representative.

Copies of forms used for records are made available at point of use but not issued as per this procedure i.e. record of issue is not maintained and they are not stamped "Controlled".

For all practical purposes "Date of Issue", "Date of Revision" "Effective Date for implementation" and "Date of implementation" is considered same.

All the controlled copyholders are issued a revised document and/or "Document Amendment Note Form M-02" whenever there is an amendment.

Documents issued for display are also controlled and distribution is recorded in "Document Issue Record Form M-03".

Legibility of documents should be ensured at the time of issue of documents as well as during all internal audits.

Identifying obsolete documents:

After receiving the latest edition of any document, the receiver of the document should destroy the old copies. If they prefer to retain old copies, they should identify the document by stamping them "OBSOLETE" in "RED" colour. MR should keep one copy of previous version of document by appropriately identifying the document as "OBSOLETE" in "RED".

External Origin Document:

Standards and other documents, which are release by the external agencies including customer, are external origin documents. External origin documents used by the organization require periodic verification of their applicability (current revision status etc) with its owner.

MR verifies the applicability (current revision status) of these documents with its owner once in a year and re-affirms this document or revises as necessary.

List of external origin documents and record of verification is maintained in document R-4.2.3

References:

Document Approval and Revision Control Register M-01

Records

Document Approval and Revision Control Register M-01

Document Amendment Note M-02

Document Issue Record M-03

Master List of secondary Documents

Control of External Origin documents R-4.2.3

Note: Leaflets containing product information shall be treated as documents.