

Procedure for control of records and documents

Purpose: To establish the procedure for document and record control.

Scope and responsibility:

- a) This procedure applies to all records generated, gathered and handled by the laboratory.
- b) Quality Manager is responsible for implementation for this procedure.
- c) Every employee is responsible for implementation of this procedure for the records under their custody.

Procedure:

- a) The laboratory has developed a procedure for records and documents control and adheres to the procedure as documented.
- b) The laboratory possesses two manuals viz. Quality Manual and Operating Manual. Quality Manual is abbreviated as QM whereas Operating Manual as OM.
- c) The laboratory has developed a complete set of operative documents for the certification system. A list of master documents is maintained by the laboratory for easy retrieval and identification of the documents. The identification numbers are mentioned in the list of master format.
- d) As and when required revisions are made in the procedures and documents as per the advice of ISO-17025 accreditation provider and changes in the certification requirements. Revision number is denoted by a number advancing serially for each procedure or document to be revised. Each revision is maintained with a revision date for easy retrieval.
- e) For every revision in any of the procedure or documents approval of Managing Director is to be taken. The obsolete copy of any of the document or procedure is retrieved and the same is made superseded with consent of Managing Director.
- f) The changes made in the documents are communicated to the staff members and the interested parties in the form of circulars.
- g) Quality Manager is responsible for:
 - i) Reporting to Managing Director in case of any revision.
 - ii) Making available relevant issues of appropriate documentation at required locations,

- iii) Effecting changes with the consent of the concerned official and the Managing Director and maintaining records of the changes.
 - iv) Notifying approved changes to concerned operators and other parties, if any,
 - v) Getting the documents approved/re-approved by the Managing Director.
 - vi) Removing superseded documents from use and identifying them as “superseded” with the consent of Managing Director, maintaining a register/record of documents with respective issues/ revision.
- h) All the records are stored in a safe and confidential way by the laboratory.
- i) Records obtained by the operator for certification and certified operations are retained for at least 5 years beyond its creation and records created by the laboratory regarding the operators for certification and certified operations are kept for at least 10 years beyond its creation.
- j) Computerized records will be backed up at regular interval of every three months. If the legal obligation requires a longer period then the records can be retained for a longer time.
- k) Signatures of the authorized personnel are taken on the records as and when required.
- l) Records are not disclosed to any of the party outside the organization or to the staff members who are not part of the operation without consent of Managing Director.
- m) Records are disclosed to the accreditation body as and when required by them.
- n) Records are maintained in such a manner to facilitate easy retrieval of the records. Client's records are maintained in a separate and dedicated file for each client.