

ANNEX I

PART B

REVISED GUIDANCE FOR THE CONDUCT OF TEST FACILITY INSPECTIONS AND STUDY AUDITS

Storage and retention of records

Purpose: to determine whether the facility has generated adequate records and reports and whether adequate provision has been made for the safe storage and retention of records and materials.

The inspector should check:

- that a person has been identified as responsible for the archive,
- the archive facilities for the storage of study plans, raw data (including that from discontinued GLP studies), final reports, samples and specimens and records of education and training of personnel,
- the procedures for retrieval of archived materials,
- the procedures whereby access to the archives is limited to authorised personnel and records are kept of personnel given access to raw data, slides, etc.,
- that an inventory is maintained of materials removed from, and returned to, the archives,
- that records and materials are retained for the required or appropriate period of time and are protected from loss or damage by fire, adverse environmental conditions, etc.