1. Introduction

This master SOP explains exactly which types of SOPs exists, the outline of each type of SOP and how each SOP must be written. It ensures that all other SOPs in the laboratory are written in the same way, standardizing the laboratory procedures and assuring the quality of the procedures.

2. Objectives and Scope

This SOP describes the development of all quality documents namely; SOPs, Laboratory job aids, forms, work sheets, checklists and annexes. It is applicable to all employees of the laboratory. Uniformly developing, changing and controlling SOPs, forms and annexes will lead to clarity and recognition.

3. Abbreviations and definitions

- SOP Standard Operating Procedure
- QM Quality Manual
- User Person who uses the quality document
- Author Person who writes the quality document
- LM laboratory management

4. Tasks, responsibilities and accountabilities

Task	Authorized	Responsible
Determining verifiers of documents	LM	LM
Verification content-wise	User	Authorizer of document
Developing quality documents	User	Authorizer of document

5. Procedure

5.1 SOPs

The laboratory uses six types of SOPs and two types of laboratory job aids:

- Fundamental SOPs.
  These give instructions how to make and manage SOPs of other categories.
- SOPs for receiving, logging, processing, archiving and disposal of samples.
- Analytical methods SOPs.
  These are SOPs on how to perform a laboratory test. For every test a SOP must be written explaining how to make the reagents, how to prepare the sample, step by step instructions on how to perform the tests and how to perform the quality controls.
- Equipment SOPs.
  These are SOPs on how to calibrate, operate and maintain equipment. For every piece of equipment an SOP must be written on how to calibrate, use and maintain that piece of equipment.
- SOPs for Quality assurance.
- SOPs for Safety precautions.
- Laboratory job aids (Bench aids for equipment and workflows for analysis SOPs respectively).
  A short version of the SOP designed to supplement the SOP and designed for use directly at the testing site. It is placed in a visible location as a reminder of the steps that need to be completed. The job aid and the SOP must include the same instructions.

Other documents associated with SOPs include laboratory policy documents, service manuals, safety manuals, annexes, checklists and forms. There is a specific framework on how to write SOPs for each category (see annexes1 to 8).

5.2 Initiating a SOP

Every employee can take the initiative in writing SOPs, in discussion with the LM. In the laboratory the procedure for the preparation of a SOP should be as follows:

1. The Head of Laboratory (LM) charges a staff member of the laboratory to draft a SOP (or the LM does this himself or a staff member takes the initiative).

2. The author writes the SOP. In principle, the author is the person who will work with the SOP, but he or she should always keep in mind that the SOP needs to be understood by others. This person should have the appropriate knowledge and expertise regarding the procedure for which an SOP is written.

3. The author requests a new registration number from the SOP administrator or custodian (LM). The administrator verifies if the SOP already exists (or is drafted). If the SOP does not exist yet, the title and author are entered into the registration system.

4. The writing of the SOP is undertaken, with the LM actively supporting this effort and allowing authors adequate time.

5. Verification of quality documents is done by:
   - At least one user of the quality document for compliance with practice
   - The LM for compliance with the quality standard.

   In this phase the wording of the SOP is fine-tuned.

6. When the test is passed, the SOP is submitted to the SOP administrator for acceptance. Authorization of SOP for use and distribution is done by the LM.

7. Review and revisions of SOPs follow the same procedure and is managed in the document control system. The process consists of reading the document, including its appendixes, forms by the author, checking if the references to the other documents, locations and equipment are correct and whether the SOP still describes the procedures as they are in practice.

5.3 General SOP outline

SOPs shall be developed in a standardized format so staff can easily recognize the flow of information and quickly note the pertinent information.

1. The all pages of each SOP will consist of the following complete standardized header.

	STANDARD OPERATING PROCEDURE	Page
World Agroforestry Centre / Soil-Plant Spectral Diagnostics Lab	Code:	Date:
	Title:	Author:

2. The make-up of the other sections of the documents should meet a minimum number of requirements as follows:

- Information on scope and application of the SOP
- Principle of the SOP
- The abbreviations, definitions, and terms used in the SOP
- The documents related to the SOP (SOPs, workflows, Bench aids,)
- The forms related to the SOP (checklists, work sheets)
- Safety and environment
  The measures that need to be taken to protect the safety and environment.

- Requirements
  - Equipment, Apparatus, Materials and Reagents
- The procedure
  Divided in the sections:
  - Step by step description of the procedure
  - Method of data processing and calculation of results
- Quality Control procedures
- The references
- The appendixes
  Appendixes can include forms, additional instructions, manufacturer manuals, checklists, etc.

For Equipment SOPs generally a section is added describing the method for calibration and for maintenance, divided into preventive and corrective maintenance procedures.

5.4 Coding of quality documents

To keep oversight, all SOPs need to be coded. Our coding system assigns each SOP a unique code in the header of the first page in which, one part of the code on indicates the category SOP group to which a document belongs, the second part which, number the document has in this group, and another part indicates the version number of the document.

Categories are denoted with a letter or combination of letters as follows:

- *F* for fundamental SOP
- EQUIP for equipment SOP
- *APP* for apparatus SOP
- *METH* for analytical method SOP
- *PROT* for a protocol describing a sequence of actions or operations
- QC for Quality assurance SOP
- HS for Safety precautions
- WF for analysis workflows
- BA for equipment bench aids
- *RF* for registration form (e.g. chemicals, samples)
- *WS* for worksheet (related to analytical procedures)
- LOG for laboratory logs
- *ORG* for an organizational document
- *PERS* for describing personnel matters
- OT for other quality documents useful in the laboratory

An example may best explain this:

The code of the **MIR SOP** is **E06v02**:

- The SOP describing Use, Operations and Maintenance of the MIR equipment is an Equipment SOP, this is indicated by the **"EQUIP".**
- It is the fourth SOP in the group of Equipment SOPs: **"EQUIP06".**
- It has not been revised, thus the current version is version 1: **"EQUIP06v01".**

5.5 Administration, Distribution and implementation of a SOP

When the current or new version of the document is reviewed and authorized for release, the LM replaces all copies of the old version with the new version at all locations as indicated in the document control log/or the cover page of the SOP. One copy is stored in the archive section of the laboratory documents control systems. The previous version of the SOP in the archive is clearly marked as "replaced" with the date on which it was replaced and the initials of the LM. Other copies of the previous version of the SOP are destroyed. The quality document control system provides

procedures for standardizing the format and/or numbering, approval, distribution and revision process, master logging and accessibility of documents and will also:

- ensure that the most current version of any document is the one that is in use;
- ensure availability and ease of use when a document is needed;
- provide for the appropriate archiving of documents when they need to be replaced.

Two systems will be used; a paper system (log book) and an electronic system. In each system the factors to consider will include:

- Performance: long lasting paper records and backup systems.
- Accessibility: information is easily retrieved whenever needed
- Security: for confidentiality, environmental hazards, access codes, fires, floods etc.
- Traceability: setting up record systems for tracing and tracking.

For all SOPs a controlled document cover page (Annex 7) should be completed and submitted to the document administrator (LM).

6. Related Documents

- F 01 SOP for documents control

7. Related Forms/Lists

Therefore, each sheet must receive the same code as the SOPs of which they will be part. E.g. if a sheet will be attached to Equipment SOP E04, the code for the sheet will be E04F1 (F1=form 1). This way you can see that the sheet is part of Equipment SOP number 4.

- List of all SOPs in the laboratory
- Document control log

8. References

Reeuwijk, L. P. and V.J.G. Houba. 2001. Guidelines for quality management in soil and plant laboratories. Food and Agriculture Organization of the United Nations FAO Soils Bulletin 74. Daya Publishing House, Shastrinagar Delhi, India.

9. Attachments

- Annex 1: Framework for developing Analytical Methods SOPs
- Annex 2: Framework for developing Equipment SOPs
- Annex 3: Framework for developing …….. SOPs
- Annex 4: Framework for developing …… SOPs
- Annex 5: Framework for developing …….SOPs
- Annex 6: Framework for developing …….SOP
- Annex 7: Cove page for controlled document.
- Annex 8: Framework for developing Annexes and Forms