2 STANDARD OPERATING PROCEDURES

2.1 Definition

An important aspect of a quality system is to work according to unambiguous Standard Operating Procedures (SOPs). In fact the whole process from sampling to the filing of the analytical result should be described by a continuous series of SOPs. A SOP for a laboratory can be defined as follows:

"A Standard Operating Procedure is a document which describes the regularly recurring operations relevant to the quality of the investigation. The purpose of a SOP is to carry out the operations correctly and always in the same manner. A SOP should be available at the place where the work is done".

A SOP is a compulsory instruction. If deviations from this instruction are allowed, the conditions for these should be documented including who can give permission for this and what exactly the complete procedure will be. The original should rest at a secure place while working copies should be authenticated with stamps and/or signatures of authorized persons.

Several categories and types of SOPs can be distinguished. The name "SOP" may not always be appropriate, e.g., the description of situations or other matters may better designated *protocols, instructions* or simply *registration forms.* Also *worksheets* belonging to an analytical procedure have to be standardized (to avoid jotting down readings and calculations on odd pieces of paper).

A number of important SOP types are:

- Fundamental SOPs. These give instructions how to make SOPs of the other categories.
- Methodic SOPs. These describe a complete testing system or method of investigation.
- SOPs for safety precautions.
- Standard procedures for operating instruments, apparatus and other equipment.
- SOPs for analytical methods.
- SOPs for the preparation of reagents.
- SOPs for receiving and registration of samples.

- SOPs for Quality Assurance.
- SOPs for archiving and how to deal with complaints.

2.2 Initiating a SOP

As implied above, the initiative and further procedure for the preparation, implementation and management of the documents is a procedure in itself which should be described. These SOPs should at least mention:

a. who can or should make which type of SOP;
b. to whom proposals for a SOP should be submitted, and who adjudges the draft;
c. the procedure of approval;
d. who decides on the date of implementation, and who should be informed;
e. how revisions can be made or how a SOP can be withdrawn.

It should be established and recorded who is responsible for the proper distribution of the documents, the filing and administration (e.g. of the original and further copies). Finally, it should be indicated how frequently a valid SOP should be periodically evaluated (usually 2 years) and by whom. Only officially issued copies may be used, only then the use of the proper instruction is guaranteed.

In the laboratory the procedure for the preparation of a SOP should be as follows:

The Head of Laboratory (HoL) charges a staff member of the laboratory to draft a SOP (or the HoL does this himself or a staff member takes the initiative). 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. The author requests a new registration number from the SOP administrator or custodian (which in smaller institutes or laboratories will often be the HoL, see 2.4). 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. Once the writing of a SOP is undertaken, the management must actively support this effort and allow authors adequate preparation time.

In case of methodic or apparatus SOPs the author asks one or more qualified colleagues to try out the SOP. In case of execution procedures for investigations or protocols, the project leader or HoL could do the testing. In this phase the wording of the SOP is fine-tuned. When the test is passed, the SOP is submitted to the SOP administrator for acceptance. Revisions of SOPs follow the same procedure.

2.3 Preparation of SOPs

The make-up of the documents should meet a minimum number of requirements:

1. Each page should have a heading and/or footing mentioning:

   a. date of approval and/or version number;
   b. a unique title (abbreviated if desired);
   c. the number of the SOP (preferably with category);
   d. page number and total number of pages of the SOP.
   e. the heading (or only the logo) of originals should preferably be printed in another colour than black.

Categories can be denoted with a letter or combination of letters, e.g.:

- *F* for fundamental SOP
- *A* or *APP* for apparatus SOP
- *M* or *METH* for analytical method SOP
- *P* or *PROJ* for procedure to carry out a special investigation (project)
- *PROT* for a protocol describing a sequence of actions or operations
- *ORG* for an organizational document

- *PERS* for describing personnel matters
- *RF* for registration form (e.g. chemicals, samples)
- *WS* for worksheet (related to analytical procedures)

2. The first page, the title page, should mention:

a. general information mentioned under 2.3.1 above, including the complete title;

b. a summary of the contents with purpose and field of application (if these are not evident from the title); if desired the principle may be given, including a list of points that may need attention;

c. any related SOPs (of operations used in the present SOP);

d. possible safety instructions;

e. name and signature of author, including date of signing. (It is possible to record the authors centrally in a register);

f. name and signature of person who authorizes the introduction of the SOP (including date).

3. The necessary equipment, reagents (including grade) and other means should be detailed.

4. A clear, unambiguous imperative description is given in a language mastered by the user.

5. It is recommended to include criteria for the control of the described system during operation.

6. It is recommended to include a list of contents particularly if the SOP is lengthy.

7. It is recommended to include a list of references.

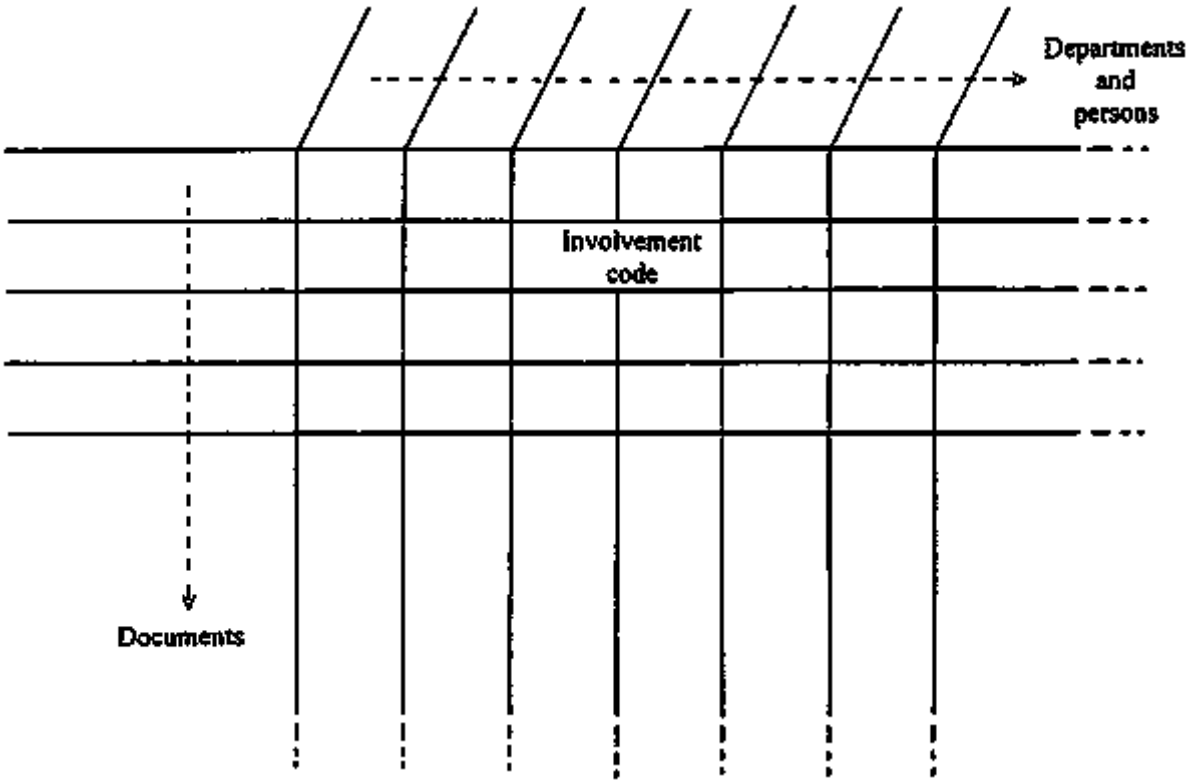
2.4 Administration, Distribution, Implementation

From this description it would seem that the preparation and administration of a SOP and other quality assurance documentation is an onerous job. However, once the draft is made, with the use of word processors and a simple distribution scheme of persons and departments involved, the task can be considerably eased.

A model for a simple preparation and distribution scheme is given in Figure 2-1. This is a relation matrix which can not only be used for the laboratory but for any department or a whole institute. In this matrix (which can be given the status of a SOP) can be indicated all persons or departments that are involved with the subject as well as the kind of their involvement. This can be indicated in the scheme with an *involvement code.* Some of the most usual involvements are (the number can be used as the code):

1. Taking initiative for drafting
2. Drafting the document
3. Verifying
4. Authorizing
5. Implementing/using
6. Copy for information
7. Checking implementation
8. Archiving

Fig. 2-1. Matrix of information organization (see text).



There is a multitude of valid approaches for distribution of SOPs but there must always be a mechanism for informing potential users that a new SOP has been written or that an existing SOP has been revised or withdrawn.

It is worthwhile to set up a good filing system for all documents right at the outset. This will spare much inconvenience, confusion and embarrassment, not only in internal use but also with respect to the institute's management, authorities, clients and, if applicable, inspectors of the accreditation body.

The administrator responsible for distribution and archiving SOPs may differ per institute. In large institutes or institutes with an accredited laboratory this will be the Quality Assurance Officer, otherwise this may be an officer of the department of Personnel & Organization or still someone else. In non-accredited laboratories the administration can most conveniently be done by the head of laboratory or his deputy. The administration may be done in a logbook, by means of a card system or, more conveniently, with a computerized database such as PerfectView or Cardbox. Suspending files are very useful for keeping originals, copies and other information of documents. The most logic system seems to make an appropriate grouping into categories and a master index for easy retrieval. It is most convenient to keep these files at a central place such as the office of the head of laboratory. Naturally, this does not apply to working documents that obviously are used at the work place in the laboratory, e.g., instrument logbooks, operation instruction manuals and laboratory notebooks.

The data which should be stored per document are:

- SOP number
- version number
- date of issue
- date of expiry
- title
- author
- status (title submitted; being drafted; draft ready; issued)
- department of holders/users
- names of holders
- number of copies per holder if this is more than one

- registration number of SOPs to which reference is made
- historical data (dates of previous issues)

The SOP administrator keeps at least two copies of each SOP; one for the historical and one for the back-up file. This also applies to revised versions. Superseded versions should be collected and destroyed (except the copy for the historical file) to avoid confusion and unauthorized use.

Examples of various categories of SOPs will be given in the ensuing chapters. The contents of a SOP for the administration and management of SOPs can be distilled from the above. An example of the basic format is given as Model F 002.

2.5 Laboratory notebook

Unless recorded automatically, raw data and readings of measurements are most conveniently written down on worksheets that can be prepared for each analytical method or procedure, including calibration of equipment. In addition, each laboratory staff member should have a personal Notebook in which all observations, remarks, calculations and other actions connected with the work are recorded in ink, not with a pencil, so that they will not be erased or lost. To ensure integrity such a notebook must meet a few minimum requirements: on the cover it must carry a unique serial number, the owner's name, and the date of issue. The copy is issued by the QA officer or head of laboratory who keeps a record of this (e.g. in his/her own Notebook). The user signs for receipt, the QA officer or HoL for issue. The Notebook should be bound and the pages numbered before issue (loose-leaf bindings are not GLP!). The first one or two pages can be used for an index of contents (to be filled in as the book is used). Such Notebooks can made from ordinary notebooks on sale (before issue, the page numbering should then be done by hand or with a special stamp) or with the help of a word processor and then printed and bound in a graphical workshop.

The instructions for the proper use of a laboratory notebook should be set down in a protocol, an example is given as Model PROT 005. A model for the pages in a laboratory notebook is given.

2.6 Relativization as encouragement

In the Preface it was stated that documentation should not be overdone and that for the implementation of all new Quality Management rules the philosophy of a step-by-step approach should be adopted. It is emphasized that protocols and SOPs, as well as the administration involved, should be kept as simple as possible, particularly in the beginning. The Quality Management system must grow by trial and error, with increasing experience, by group discussions and with changing perceptions. In the beginning, attention will be focused on basic operational SOPs, later shifting to record keeping (as more and more SOPs are issued) and filling gaps as practice reveals missing links in the chain of Quality Assurance. Inevitably problems will turn up. One way to solve them is to talk with people in other laboratories who have faced similar problems.

Do not forget that Quality Management is a tool rather than a goal. The goal is quality performance of the laboratory.

SOPs

F 002 - Administration of Standard Operating Procedures
PROT 005 - The Use of Laboratory Notebooks
Model page of Laboratory Notebook

F 002 - Administration of Standard Operating Procedures

LOGO	**STANDARD OPERATING PROCEDURE**		Page: 1 # 2
	Model: F 002	Version: 1	Date: 95-06-21
	Title: **Administration of Standard Operating Procedures**		File:

1. PURPOSE

To give unambiguous instruction for proper management and administration of Standard Operating Procedures as they are used in the **Regional Soil Survey Institute *(RSSI).***

2. PRINCIPLE

Standard Operating Procedures are an essential part of a quality system. For all jobs and duties relevant operating procedures should be available at the work station. To guarantee that the correct version of the instruction is used copying Standard Operating Procedures is prohibited. Standard Operating Procedures are issued on paper with the heading printed in green.

3. FIELD OF APPLICATION

Generally for use in the quality system of *RSSI* but more specifically this instruction is for use in the Chemistry Department.

4. RELATED SOPs

- F 011 The preparation of SOPs for apparatus
- F 012 The preparation of SOPs for methods
- PROJ 001 The preparation of SOPs for special investigations

5. REQUIREMENTS

Database computer program, PerfectView or Cardbox

6. PROCEDURE

6.1 Administration

The administration of SOPs for the Chemistry Department can be done by the Head of Laboratory.

6.2 Initiating new SOP

(See these Guidelines, 2.2)

6.3 Revision of SOPs

(see these Guidelines, 2.2)

Author:	Sign.:
QA Officer (sign.):	Date of Expiry:

6.5 Distribution of SOPs

When the Sop fulfils all the necessary requirements it is printed. The author hands over the manuscript (or the floppy disk with text) to the SOP administrator who is responsible for the printing. The number of copies is decided by him/her and the author. Make matrix of distribution (see Guidelines for Quality Management Fig. 2-1).

The author (or his successor) signs all copies in the presence of the administrator before distribution. As the new copies are distributed the old ones (if there was one) are taken in.

For each SOP a list of holders is made. The holder signs for receipt of a copy. The list is kept with the spare copies.

Copying SOPs is forbidden. Extra copies can be obtained from the SOP administrator.

Users are responsible for proper keeping of the SOPs. If necessary, copies can be protected by a cover or foil, and/or be kept in a loose-leaf binding.

7. ARCHIVING

Proper archiving is essential for good administration of SOPs. All operating instructions should be kept up-to-date and be accesible to personnel. Good Laboratory Practice requires that all documentation pertaining to a test or investigation should be kept for a certain period. SOPs belong to this documentation.

8. REFERENCES

Mention here the used Standards and other references for this SOP.

PROT 005 - The Use of Laboratory Notebooks

LOGO	**STANDARD OPERATING PROCEDURE**		Page: 1 # 2
	Model: F 002	Version: 1	Date: 95-11-28
	Title: **The Use of Laboratory Notebooks**		File:

1. PURPOSE

To give instruction for proper lay-out, use and administration of Laboratory Notebooks in order to guarantee the integrity and retrievability of raw data (if no preprinted Work Sheets are used), calculations and notes pertaining to the laboratory work.

2. PRINCIPLE

Laboratory Notebooks may either be issued to persons for personal use or to Study Projects for common use by participating persons. They are used to write down observations, remarks, calculations and other actions in connection with the work. They may be used for raw data but bound preprinted Work Sheets are preferred for this.

3. RELATED SOPs

F 001	Administration of SOPs
PROJ 001	The preparation of SOPs for Special Investigations

4. REQUIREMENTS

Bound notebooks with about 100-150 consecutively numbered pages. Any binding which cannot be opened is suitable; a spiral binding is very convenient.

Both ruled and squared paper can be used. On each page provisions for dating and signing for entries, and signing for verification or inspection may be made.

5. PROCEDURE

5.1 Issue

Notebooks are issued by or on behalf of the Head of Laboratory who keeps a record of the books in circulation (this record may have a format similar to a Laboratory Notebook or be part of the HoL's own Notebook).

On the cover, the book is marked with an assigned (if not preprinted) serial number and the name of the user (or of the project). On the inside of the cover the HoL writes the date of issue and signs for issue. The user (or Project Leader) signs the circulation record for receipt.

5.2 Use

All entries are dated and made in ink. The person who makes the entry signs per entry (in project notebooks) or at least per page (in personal notebooks). The Head of Laboratory (and/or Project Leader) may inspect or verify entries and pages and may sign for this on the page(s) concerned.

If entries are corrected, this should be lined out with a single line so that it is possible to see what has been corrected. Essential corrections should be initialed and dated and the reason for correction stated. Pages may not be removed; if necessary, a whole page may be deleted by a diagonal line.

Author:	Sign.:
QA Officer (sign.):	Date of Expiry:

5.3 Withdrawal

When fall, the Notebook is exchanged for a new one. The HoL is responsible for proper archiving. A notebook belonging to a Study Project is withdrawn when the study is completed.

When an employee leaves the laboratory for another post (s)he should hand in her/his notebook to the HoL

6. ARCHIVING

The Head of Laboratory is custodian of the withdrawn Laboratory Notebooks. They must remain accessible for inspection and audit trailing,

7. REFERENCES

Model page of Laboratory Notebook

Date/Signature	SUBJECT

Verified by:

Signature: _____ WO/Test no. _____
Date: _____ File: _____