Guidance document for the writing of standard operating procedures
(Taken from United States Environmental Protection Agency *Guidance for Preparing Standard Operating Procedures (SOPs) EPA QA/G-6 [EPA/600/B-07/001 April 2007])*

1.0 INTRODUCTION

1.1 Overview

A standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity followed by an organization. The development and use of SOPs are an integral part of a successful quality system as it provides individuals with the information to perform a job properly, and facilitates consistency in the quality and integrity of a product or end-result. The term "SOP" may not always be appropriate and terms such as protocols, instructions, worksheets, and laboratory operating procedures may also be used. For this document "SOP" will be used.

SOPs describe both technical and fundamental programmatic operational elements of an organization that would be managed under a work plan or a Quality Assurance (QA) Project Plan and under an organization's Quality Management Plan.

1.2 Purpose

SOPs detail the regularly recurring work processes that are to be conducted or followed within an organization. They document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. They may describe, for example, fundamental programmatic actions and technical actions such as analytical processes, and processes for maintaining, calibrating, and using equipment. SOPs are intended to be specific to the organization or facility whose activities are described and assist that organization to maintain their quality control and quality assurance processes and ensure compliance with governmental regulations.

If not written correctly, SOPs are of limited value. In addition, the best written SOPs will fail if they are not followed. Therefore, the use of SOPs needs to be reviewed and re-enforced by management, preferably the direct supervisor. Current copies of the SOPs also need to be readily accessible for reference in the work areas of those individuals actually performing the activity, either in hard copy or electronic format, otherwise SOPs serve little purpose.

1.3 Benefits

The development and use of SOPs minimizes variation and promotes quality through consistent implementation of a process or procedure within the organization, even if there are temporary or permanent personnel changes. SOPs can indicate compliance with organizational and governmental requirements and can be used as part of a

personnel training program, since they should provide detailed work instructions. It minimizes opportunities for miscommunication and can address safety concerns. When historical data are being evaluated for current use, SOPs can also be valuable for reconstructing project activities when no other references are available. In addition, SOPs are frequently used as checklists by inspectors when auditing procedures. Ultimately, the benefits of a valid SOP are reduced work effort, along with improved comparability, credibility, and legal defensibility.

SOPs are needed even when published methods are being utilized. For example, if an SOP is written for a standard analytical method, the SOP should specify the procedures to be followed in greater detail than appear in the published method. It also should detail how, if at all, the SOP differs from the standard method and any options that this organization follows.

1.4 Writing Styles

SOPs should be written in a concise, step-by-step, easy-to-read format. The information presented should be unambiguous and not overly complicated. The active voice and present verb tense should be used. The term "you" should not be used, but implied. The document should not be wordy, redundant, or overly lengthy. Keep it simple and short. Information should be conveyed clearly and explicitly to remove any doubt as to what is required. Also, use a flow chart to illustrate the process being described. In addition, follow the style guide used by your organization, e.g. font size and margins.

2.0 SOP PROCESS

2.1 SOP Preparation

The organization should have a procedure in place for determining what procedures or processes need to be documented. Those SOPs should then be written by individuals knowledgeable with the activity and the organization's internal structure. These individuals are essentially subject-matter experts who actually perform the work or use the process. A team approach can be followed, especially for multi-tasked processes where the experiences of a number of individuals are critical, which also promotes "buy-in" from potential users of the SOP.

SOPs should be written with sufficient detail so that someone with limited experience with or knowledge of the procedure, but with a basic understanding, can successfully reproduce the procedure when unsupervised. The experience requirement for performing an activity should be noted in the section on personnel qualifications. For example, if a basic chemistry or biological course experience or additional training is required that requirement should be indicated.

2.2 SOP Review and Approval

SOPs should be reviewed (that is, validated) by one or more individuals with appropriate training and experience with the process. It is especially helpful if draft SOPs are actually tested by individuals other than the original writer before the SOPs are finalized.

The finalized SOPs should be approved as described in the organization's Quality Management Plan or its own SOP for preparation of SOPs. Generally the immediate supervisor, such as a section or branch chief, and the organization's quality assurance officer review and approve each SOP. Signature approval indicates that an SOP has been both reviewed and approved by management. Use of electronic signatures, as well as electronic maintenance and submission, is an acceptable substitution for paper, when practical.

2.3 Frequency of Revisions and Reviews

SOPs need to remain current to be useful. Therefore, whenever procedures are changed, ensure that the policies and procedures remain current and appropriate, or to determine whether the SOPS are even needed. The review date should be added to each SOP that has been reviewed. If an SOP describes a process that is no longer followed, it should be withdrawn from the current file and archived.

The review process should not be overly cumbersome to encourage a timely review. The frequency of review should be indicated by management in the organizations' Quality Management Plan. The plan should also indicate the individual(s) responsible for ensuring that SOPs are current.

2.4 Checklists

Many activities use checklists to ensure that steps are followed in order. Checklists are also used to document completed actions. Any checklists or forms included as part of an activity should be referenced at the points in the procedure where they are to be used and then attached to the SOP.

In some cases, detailed checklists are prepared specifically for a given activity. In those cases, the SOP should describe, at least generally, how the checklist is to be prepared, or on what it is to be based. Copies of specific checklists should be then maintained in the file with the activity results and/or with the SOP.

Remember that the checklist is not the SOP, but a part of the SOP.

2.5 Document Control

Each organization should develop a numbering system to systematically identify and label their SOPs, and the document control should be described in its Quality Management Plan. Generally, each page of an SOP should have control documentation notation, similar to that illustrated below. A short title and identification (ID) number can serve as a reference designation. The revision number and date are very useful in identifying the SOP in use when reviewing historical data and is critical when the need for evidentiary records is involved and when the activity is being reviewed. When the number of pages is indicated, the use can quickly check if the SOP is complete. Generally this type of document control notation is located in the upper right-hand corner of each document page following the title page.

2.6 SOP Document Tracking and Archival

The organization should maintain a master list of all SOPs. This file or database should indicate the SOP number, version number, date of issuance, title, author, status, organizational division, branch, section, and any historical information regarding past versions. The QA Manager (or designee) is generally the individual responsible for maintaining a file listing of all current, quality-related SOPs used within the organization. If an electronic database is used, automatic "Review SOP" notices can be sent. Note that this list may be used also when audits are being considered or when questions are raised as to practices being followed within the organization.

As noted above, the Quality Management Plan should indicate the individual(s) responsible for assuring that only the current version is used. That plan should also designate where, and how, outdated versions are to be maintained or archived in a manner to prevent their continued use, as well as to be available for historical data review.

Electronic storage and retrieval mechanisms are usually easier to access than a hard-copy document format. For the user, electronic access can be limited to a read-only format, thereby protecting against unauthorized changes made to the document.

3.0 SOP General Format

SOPs should be organized to ensure ease and efficiency in use and to be specific to the organization which develops it. There is no one "correct" format; and internal formatting will vary with each organization and with the type of SOP being written. Where possible break the information into a series of logical steps to avoid a long list. The level of detail provided in the SOP may differ based on, e.g., whether the process is critical, the frequency of that procedure being followed, the number of people who will use the SOP, and where training is not routinely available. A generalized format is discussed next.

3.1 Title Page

The first page or cover page of each SOP should contain the following information: a title that clearly identifies the activity of procedure, an SOP identification (ID) number, date of issue and/or revision, the name of the applicable agency, division, and/or branch to which this SOP applies, and the signatures and signature dates of those individuals who prepared and approved the SOP. Electronic signatures are acceptable for SOPs maintained on a computerized database.

3.2 Table Of Contents

A Table of Contents may be needed for quick reference, especially if the SOP is long, for locating information and to denote changes or revisions made only to certain sections of an SOP.

3.3 Text

Well-written SOPs should first briefly describe the purpose of the work or process, including any regulatory information or standards that are appropriate to the SOP process, and the scope to indicate what is covered. Define any specialized or unusual terms either in a separate definition section or in the appropriate discussion section. Denote what sequential procedures should be followed, divided into significant sections; e.g., possible interferences, equipment needed, personnel qualifications, and safety considerations (preferably listed in bold to capture the attention of the user). Finally, describe next all appropriate QA and quality control (QC) activities for that procedure, and list any cited or significant references.

As noted above, SOPs should be clearly worded so as to be readily understandable by a person knowledgeable with the general concept of the procedure, and the procedures should be written in a format that clearly describes the steps in order. Use of diagrams and flow charts help to break up long sections of text and to briefly summarize a series of steps for the reader.

Attach any appropriate information, e.g., an SOP may reference other SOPs. In such a case, the following should be included:

- Cite the other SOP and attach a copy, or reference where it may be easily located.
- If the referenced SOP is not to be followed exactly, the required modification should be specified in the SOP at the section where the other SOP is cited.

4.0 Types of SOPs

SOPs may be written for any repetitive technical activity, as well as for any administrative or functional programmatic procedure, that is being followed within an organization. General guidance for preparing a technical SOP follows:

Technical SOPs can be written for a wide variety of activities. Examples are SOPs instructing the user how to perform a specific analytical method to be followed in the laboratory or field (such as field testing using an immunoassay kit), or how to collect a sample in order to preserve the sample integrity and representativeness (such as collection of samples for future analysis of volatiles organic compounds or trace metals), or how to conduct a bioassessment of a freshwater site. Technical SOPs are also needed to cover activities such as data processing and evaluation (including verification and validation), modeling, risk assessment, and auditing of equipment operation.

Citing published methods in SOPS is not always acceptable, because cited published methods may not contain pertinent information for conducting the procedure in-house. Technical SOPs need to include the specific steps aimed at initiating, coordinating, and recording and/or reporting the results of the activity, and should be tailored only to that activity. Technical SOPs should fit within the framework presented here, but this format can be modified, reduced, or expanded as required.

Examples

The following are a select number of SOPs of scientific nature intended to give the reader an overview of the various formats SOPs can have:

- Chemical Methods – Compendium of Methods for Chemical Analysis of Foods, Health Canada http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/chem/index-eng.php
- Compendium of Methods for the Microbiological Analysis of Foods, Health Canada http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index-eng.php
- Standard Operating Procedure Documents, Leslie Dan Faculty of Pharmacy, University of Toronto http://www.pharmacy.utoronto.ca/sites/default/files/upload/research/SOPs%20-%20Leslie%20Dan%20Faculty%20of%20Pharmacy.pdf
- Effective Vaccine Management Initiative Version 2, World Health Organization (2012) http://www.who.int/immunization_delivery/systems_policy/EVM_model_SOP_manual-April_2012.pdf
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In order to assist with the SOP authoring process, the following sections which are routinely encountered are explained (largely adopted from the United Nations Global Service Centre, Standard Operating Procedure template)

ANNEXURES (or APPENDICES)

Each Annex is to be listed separately. Reference to Annexes should appear in the body of the document. Annexes are not to be embedded in the document but are to be either included at the end of the SOP word document or in a separate PDF documents clearly marked.

PURPOSE (or OBJECTIVE)

This section should provide a succinct summary of the purpose, aims and/or objectives of the Standard Operating Procedure (SOP). An SOP is a standing instruction that provide staff with guidance on how to implement a specific task, process or activity, or to achieve a desired result. It provides institutional recognition of a best practice method or set of steps to be followed.

SCOPE

This section should identify who exactly the SOP shall apply to. This defines the target user group (which may be an individual work unit/section, a category of staff or all staff). This section should also indicate others who should be aware of the SOP. For SOPS, compliance is mandatory.

REFERENCES

This section should include a list of any normative references (such as resolutions, rules and regulations or international standards) or superior guidance from which this SOP derives its authority or which authorizes action in this area, or binds the user to a certain interpretation, understanding or approach.

RATIONALE

This section shall present, if considered necessary, a short background or history to the development of the SOP. The background should provide the rationale for developing the SOP, especially if it is not derived directly from a normative reference or superior guidance or if this is a new SOP on which little pre-existing information or history may be available.

The background rational for the procedure should include any evidentiary reasons that have given rise to the requirement for a new SOP or revision, e.g. emerging international standards, changes in best practices, field practitioner experience and lessons learned.

TERMS AND DEFINITIONS

This section contains a list of terms and their definitions for words and phrases that are required to understand this guidance material. It is in particular important for concepts that are new to the institutional environment, or that have not been defined clearly previously, or may be

potentially confused, or if the concepts are to have a particular meaning in this SOP. The format should be:

Word/Acronym or Phrase: Definition…

PROCEDURES

Procedural Content

- This section is the main body of the SOP. The Procedures section should contain clear and concise statements of how to complete an activity, to execute a task or tasks, or to achieve a result in the particular context. Remember that an SOP is essentially a set of instructions of how to complete an activity, action or process. The focus of the SOP should be on ensuring that the target user can achieve the desired results by following a series of steps.
- Time should be taken before drafting to focus on exactly what information is to be conveyed to the user (the user should be defined in the Scope section) on how to execute a desired activity or process or fulfill a task. It is generally prescriptive in nature.
- Procedures should be written in sufficient detail so that someone with limited experience with the procedure, but with a basic understanding of the subject can successfully reproduce the procedure unsupervised. Ideally, SOPs should be written by staff knowledgeable or the activity and who have performed or do perform the activity that is subject of the SOP.
- A 'classic' simple SOP is written in the form of a serial of technical or administrative activities, or sequential set of steps, to achieve an objective or complete a task. SOPs may, however, vary from this basic style to convey more complex guidance on how to implement an activity or achieve a result.
- In all cases, the SOP should convey clear institutional expectations of how to implement an activity, process or task. The SOP should be as explicit as possible regarding group or individual responsibilities and any timelines as well as the expected outputs or achievements from following the SOP.
- Where applicable, the SOP should include qualitative and/or quantitative measurements to help monitor implementation progress.

Format and Language

- The format should best suit the approved SOP template
- SOPs are, in general, of a binding nature and thus should carry an expectation of compliance. The language of the SOP should be used carefully to indicate the level of compliance expected or the flexibility and discretion allowed of the user.

    - For mandatory activity, the SOP shall use highly prescriptive language (i.e. shall/shall not to impose an obligation).
    - For recommended but not compulsory activity, the SOP shall use less prescriptive language (i.e. should, should not to infer an obligation but not necessity); and
    - For optional activities which a high degree of flexibility in implementation, the SOP shall use discretionary language (use "may/may not" to indicate discretion).
- Consistent and accurate verb usage should help avoid confusion. The verbs recommended above should be used in place of others such as 'could/could not' (which may cause confusion regarding capability to possibility rather than discretion), 'will/will not' (which refers to a future action than a compulsion to act) or "must/must not" (which should only be used to connote a legal obligation).
- Other drafting tips for SOPs:
    - Use short, concise sentences;
    - Present one idea at a time wherever possible;
    - Use active voice verbs. Passive voice sentences can be lengthy and may be misinterpreted;
    - Avoid jargon;
    - Use position titles (rather than personal names of individuals) to reduce maintenance and revision requirements; and
    - Avoid gender nouns and pronouns wherever possible;
    - Use acronyms only when these are included in the Terms and Definitions section.

RESPONSIBILITIES

Any specific staff roles and responsibilities for implementation of the SOP should be identified clearly in the SOP. Responsibilities and accountabilities should be written in an active tense (e.g. "X shall perform the following…").

The SOP should also establish clearly any general staff responsibilities, right, obligations or prohibitions in relation to the activity.

MONITORING AND COMPLIANCE

Where the SOP creates any explicit or implicit expectation of compliance, it should include clear guidance on how implementation of the SOP will be monitored. Is should include a statement of roles and responsibilities for oversight and monitoring of the SOP outlined in the section above. Wherever possible, the monitoring approach should be based on measureable performance criteria for the SOP. These should be listed in this section, if applicable. This section should also identify the consequences of non-compliance with the compulsory aspects of the SOP. The generation of expectations of compliance without the capacity or resources to

enforce it may undermine the credibility of the SOP and guidance system and the authority of the institution.

DATES

An SOP shall be become effective with the date of the Director's approval. Unless otherwise specified, the SOP should be reviewed every two years.

CONTACT

The "……." Is the contact officer of this SOP and should be contacted for queries about this SOP.

HISTORY

This section should contain the date that this SOP was first approved and issued. It should include the dates of each subsequent review and modification. If necessary, a schedule of amendment dates and the amendments made should be added as a table as illustrated below.

This SOP was first approved and issued on XXXX,XX,XX. It was subsequently revised on xxxx,xx,xx and xxxx,xx,xx.

Revision History

Revision No.	Revision Date	Summary of Changes
1.	MNTH, DD, YYYY	List the change in bullet point format. Identify the changes that have given rise to a reissuance of this SOP which could be: Review date (but no changes made to contents) Procedural amendments which are to be summarized Revised Normative, Superior or related SOPs and Guidelines which affect this SOP and which may alter the procedural contents.
2.		