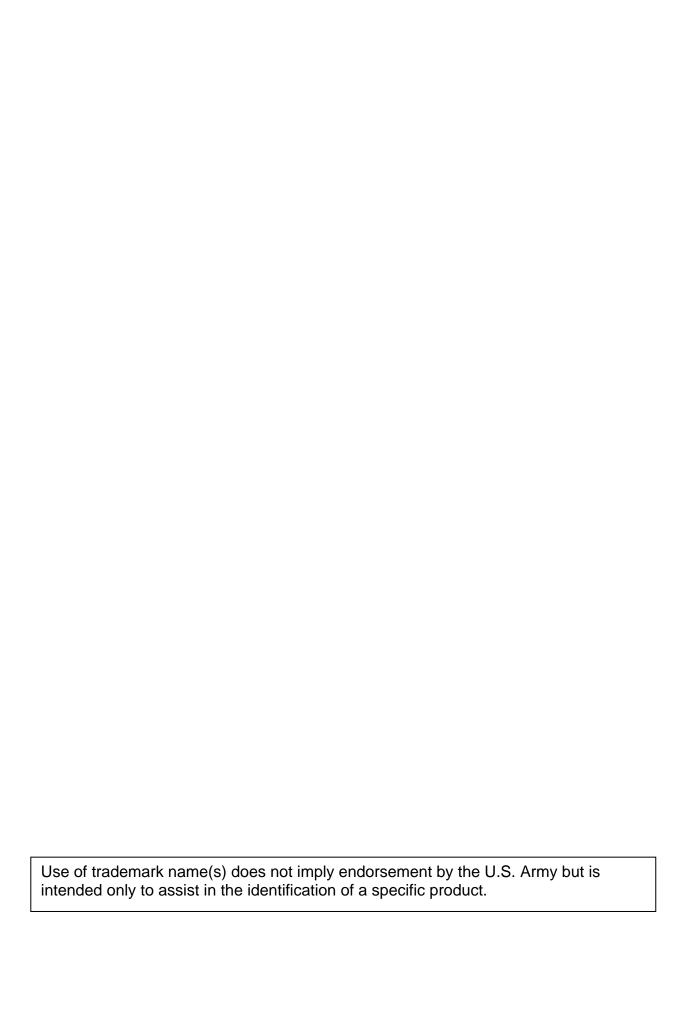# Writing and Managing a Standing Operating Procedure

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October 2010

USAPHC

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WRITING AND MANAGING A STANDING OPERATING PROCEDURE

1. Purpose. Technical Guide (TG) 176 is for the person(s) who must plan, write, revise, publish, or manage Standing Operating Procedure's (SOPs). The guidance is presented generically so that it can be used in any setting, such as administrative, industrial, laboratory, or field operations. This guide addresses both the format and content of administrative and technical SOPs.

2. Definition. An SOP is a clearly written set of instructions or methods detailing the procedures for carrying out a routine or recurring task or study. The use of SOPs describes both administrative and technical tasks.

3. Use.

   a. As a management tool, an SOP—

      (1) Provides a foundation for training new employees by establishing operational procedures.

      (2) Serves as a continuity tool in cases where regular personnel are absent from an operation, enabling others to carry out the function.

      (3) Refreshes the memory of management and experienced employees regarding operational procedures within the organization.

      (4) Helps maintain quality control by providing detailed, step-by-step guidance to personnel who are required to carry out certain procedures.

      (5) Sets forth study methods that are adequate to ensure the quality and integrity of the data generated in the course of a study.

      (6) Provides a documented, historical record of an organization's operating procedures during a specific time period.

b. As an administrative tool, an SOP can be used to—

    (1) Decide where in an organization a procedure should be carried out.

    (2) Decide what material and personnel resources are required.

    (3) Outline the manner in which procedures are to be carried out.

4. Developing and Publishing an SOP.

    a. Review your procedures and decide what needs to be explained in your SOP. Seek the input of personnel who have experience in these procedures.

    b. Gather information on the procedures from reference sources. Contact other organizations performing similar functions to see if they have an SOP. If they do, request a copy to use as a guide or source of ideas. Often, such a document can be modified to serve your needs.

    c. Assemble all blank forms and other documents you will need to reference in the SOP.

    d. Assign the SOP a number and title for identification and reference purposes.

    e. Write a draft of the SOP, following the guidelines in paragraph 5.

    f.   Review the draft SOP for technical adequacy and administrative accuracy. Make sure that the SOP conveys its message clearly, and that it answers the questions "who," "what," "when," "where," and "how."

    g. Submit the draft SOP for peer review and supervisory approval.

    h. Incorporate approved changes into a final version.

    i.   Sign and date the final version; include supervisors signature. On approval, distribute copies as appropriate, and post a copy in the SOP file for reference (see paragraph 6).

5. Structuring the SOP.

    a. Format.

    (1) Figure 1 shows the suggested format for an administrative SOP.

(2) Figure 2 shows the suggested format for a technical SOP.

b. Numbering the divisions and parts of an SOP. The divisions of an SOP (such as paragraphs, sections, and chapters) and certain parts (figures and tables) are numbered to help make referencing easier. Table 1 explains the numbering scheme.

c. Table of Contents.

(1) If the SOP is over 10 paragraphs, include a table of contents.

(2) In preparing the table of contents, list part, chapter, section, paragraph titles (if appropriate), and appendixes exactly as given in the body of the text and in the same order.

d. Content.

(1) Be clear, concise, and thorough when listing the step-by-step procedures. Remember that the person most dependent on your SOP is the employee who may have little or no experience with the procedure in question. Technical phrases requiring special knowledge should be avoided except when no other word or phrase will convey the proper meaning. To better appreciate what you must communicate, place yourself in the position of the employee that will be performing the tasks. Your greatest enemies are vagueness and imprecision. Your SOP will be of little use if no one can understand who is supposed to do what.

(2) Include only those steps that are carried out by the employees in the immediate organization. When procedures include interactions with individuals outside of the organization, indicate this but do not specify the actual steps taken by the other persons.

(3) Be comprehensive in terms of how to get the procedure accomplished, but do not encompass irrelevant matters.
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(4) Be positive in your presentation.

e. Appendices. Include appendices when it is necessary to finish additional or supplemental material (for example, reproduction of an agreement or a sample contract, list of references, sample plan for a maneuver or exercise). Appendices, if used, are placed at the end of the document.

f. Glossary. Provide a glossary if the SOP contains more than 15 abbreviations or terms.

g. Illustrations. Use illustrations only when they are essential, contribute to a clearer understanding of the subject matter, or substantially reduce the narrative portion of the SOP.

6. Filing the SOPs. When a number of SOPs have accumulated in a file, incorporate them into an SOP Manual.

a. Place the individual SOPs into a large binder, sorting the documents into chapters by subject.

b. Arrange these chapters in a logical sequence (for example, all administrative procedures in one section and all laboratory procedures in another).

c. Develop a table of contents, and place it in the front of the binder.

d. Place the manual alongside other references such as Regulations and Pamphlets.

7. Maintaining a Historical Registry for Laboratory Procedures. The supervisor must maintain a historical file of obsolete laboratory SOPS and revisions according to Title 21, Code of Federal Regulations (CFR), Section 58.81, Standard Operating Procedures, and Title 40, CFR, Section 160.81, Standard Operating Procedures.

a. File at least one copy of all discontinued or obsolete SOPS, (perhaps in a binder stored near the SOP Manual).

b. Record the following information and attach it to the SOP cover—

This SOP was in effect for the period XX Month 20XX (original effective date) through XX Month 20XX (date SOP was removed from service). This SOP was replaced by SOP_____ (give the SOP number, effective date, and title of the new SOP).

8. Revising the SOPs. The supervisor should review the SOPs, at least annually, to ensure the procedures are current and accurately reflect changes in the work environment.

a. If no changes are necessary, the reviewing supervisor should sign and date a cover sheet and attach it to the file copy of the SOP. Figure 3 shows an example of a cover sheet.

   b. If procedures change, rewrite the section.

     (1) New material added by a change is identified by an asterisk.

     (2) On rescinding a paragraph, delete the body of the paragraph but keep its number and title in its original place in the text. Mark the paragraph with an asterisk and write "rescinded" in parentheses after the title. The paragraph should appear in the text as follows:

<div align="center">3-1 Requisitioning (Rescinded)</div>

     (3) In any future change, keep the number, the title, and "(Rescinded)," but remove the asterisk. The number and title are not deleted until the publication is revised.

     (4) Prepare a memorandum to transmit the revised SOP to the user. Indicate the number of changes and the number of changed pages. Attach the memorandum to the file copy of the SOP.

   c. If changes are extensive, revise the entire SOP, and follow steps addressed in paragraphs 4g through 4i.

9. Managing the SOPs. One person in your organization should-

   a. Assign SOP numbers for identification purposes.

   b. Know how many copies of SOPs exist for good control, management, and revision.

   c. Verify that all organization SOPs—

     (1) Are evaluated for currency at least annually.

     (2) Contain cover sheets to reflect the supervisor's review (see paragraph 8).

NAME OF ORGANIZATION
(e.g., Division/Branch/Office)

(Office File Symbol)

SOP No._____
Effective Date _____
Date Removed from Service _____

Title of SOP

1. Purpose. A brief statement which outlines the reason for or purpose of the SOP, described in terms of function, applicability, and objective.

2. Authority. References the regulation that calls for procedure to be performed.

3. Abbreviations and Terms: Use a glossary if there are more than 5 terms or more than 15 abbreviations to be explained in the SOP. Otherwise, define them as they are introduced.

4. Procedure.

     a. Procedures are an orderly series of specific actions taken to carry out an assignment (the main contents of the body of the SOP)…

     b. Subheadings a-z are used to break a procedure into sub procedures or major components.

5. Safety Considerations. Include in all SOPs. If none, state that safety was a consideration.

6. References. List other publications that are cited in the text. All such publications must be available to the user of the SOP.

Figure 1. Sample Format for an Administrative SOP

NAME OF ORGANIZATION
(e.g., Division/Branch/Office)

(Office File Symbol)

SOP No._____
Effective Date _____
Date Removed from Service _____

Title of SOP

1. Purpose. Is a brief statement which outlines the reason or purpose of the SOP. It describes terms of function, applicability, and the objective.

2. Authority. References the regulation that calls for the procedure to be performed.

3. Abbreviations and Terms. Uses a glossary if there are more than 5 terms or 15 abbreviations to be explained in the SOP. Otherwise, define them as they are introduced.

4. Restrictions. Indicates who has authority to update the SOP and when.

5. Location. Indicates the area in which the procedures are to be followed, usually a lab name and room number, or a location.

6. Scope. Describes the type of test, the nature of samples (matrix), and the type of program supported. Include linear range, level of quantization (method detection limit), and method of derivation and bias.

7. Sample Handling and Preservation. Focuses the analyst's responsibilities in sample handling.

8. Apparatus and Materials. Describes reagents, standards and equipment used.

9. Analytical Procedures. Describes interferences, preparation, and analysis.

10. Quality Control. Describes the quality control checks including type, frequency, evaluation procedure, acceptance and rejection criteria, and corrective actions.

11. Data Analysis. Describes how raw data is recorded, calculations are made, and results are reported.

12. Documentation. Describes the information which shall be recorded sufficient to permit data validation.

13. Report Requirements. Describes the information to be included in the final report.

14. Safety Considerations. Include in all SOPs. If there is none, state that safety was a consideration.

15. References. List publications that are cited in the text; all such publications must be available to the user of the SOP.

Figure 2. Sample Format for a Technical SOP

Table 1. Numbering the Divisions and Parts of a Publication

1. Parts	Number consecutively, spelling out the part number. For example, Part One, Part Two.
2. Chapters	Number consecutively throughout the publication, using Arabic numbers. For example, Chapter 1 or Chapter 2.
3. Sections	Number consecutively within chapters, using capital Roman numerals. For example, within Chapter 1, Section I, Section II; within Chapter 2, Section I, Section II.
4. Paragraphs[a]	Number consecutively, using two-part Arabic numbers. The first number represent the chapter; the second the numerical sequence of the paragraph within the chapter. For example. 1-1, 1-2; 2-1, 2-2.
5. Subparagraphs	First level: Number consecutively within each paragraph, using lower-case letters in alphabetical sequence. For example, a,b, c…z. aa, ab, ac ... az. ba, bb… bz.
	Second level: Number consecutively within each subparagraph, using Arabic numbers in parentheses. For example, within subparagraph a, (11, (2)); within subparagraph b (111, (2)).
	Third level[b] number consecutively within each subparagraph, using lower-case letters in parentheses, in alphabetical sequence. For example, within subparagraph d(l), (a), (b); within subparagraph a(2), (a), (b).
6. Illustrations and tables	Number consecutively within each chapter, using two-part Arabic numbers. The first number represents the chapter; the second, the numerical sequence of the illustration or table within the chapter. For example, Figure 1-1, Figure 1-2, Figure 2-1, Figure 2-2; Table 1-1, Table 1-2, Table 2-1, Table 2-2.
7. Appendixes	Number consecutively, using capital letters in alphabetical sequence. For example, Appendix A, Appendix B[c]
a. Sections within an appendix	Number consecutively within each appendix as explained in Item 3.
b. Paragraphs within an appendix	Number consecutively, using a capital letter and an Arabic number. The letter represents the appendix; the number, the numerical sequence of the paragraph within the appendix. For example, A-1, A-2, B-1, B-2.
c. Subparagraphs	Same as in item 5.
d. Illustrations and tables	Number consecutively, using a capital latter and an Arabic number. The letter represents the appendix; the number, the numerical sequence of the illustration or table in the appendix. For example, Figure A-I, Figure A-2; Table A-I, Table A-2.
8. Glossary	Unnumbered.

Notes:
[a] This item refers only to paragraphs in the body of the publication. Paragraphs in the foreword and a glossary are not numbered.
[b] A paragraph may not be divided further than the third level.
[c] If there is only one Appendix, call it "Appendix A."

8

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                                                SOP No._____
                                         Effective Date_____
                           Date Removed from Service_____

                              SOP Title


_____                    _____
Submitted by                                          Date

_____                    _____
Approved by                                           Date

                            Reviewed by

_____                    _____
Supervisor                                            Date

_____                    _____
Supervisor                                            Date

_____                    _____
Supervisor                                            Date

_____                    _____
Supervisor                                            Date

_____                    _____
Supervisor                                            Date

_____                    _____
Supervisor                                            Date

_____                    _____
Supervisor                                            Date

_____                    _____
Supervisor                                            Date
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Figure 3. Example of a Review Cover Sheet

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