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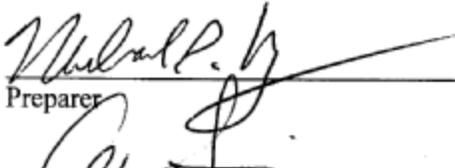
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U. S. Army Center For Health Promotion and Preventive Medicine (USA HPPM)
Quality Assurance Team

STANDING OPERATING PROCEDURE (SOP)
for

THE PREPARATION OF STANDING OPERATING PROCEDURE


Preparer

Supervisor Approval

12/20/2000
Date
12/20/2000
Date

Annual Review

Preparer 12/20/2001 Date Due Date Comp.
Supervisor 12/20/2001 Date Due Date Comp.

Preparer _____ Date Due Date Comp.
Supervisor _____ Date Due Date Comp.

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**U. S. Army Center For Health Promotion and Preventive Medicine (USACHPPM)
Quality Assurance Team**

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Army Center For Health Promotion and Preventive Medicine (USACHPPM) and may not be specifically applicable to the activities of other organizations.

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I. <u>PURPOSE:</u> To specify the minimum requirements for SOPs and how to plan, write, publish, and manage them. Good quality assurance requires that all routine activities having an impact on data quality or process operations shall be documented explicitly so that activities are performed consistently and effectively by all personnel. SOPs are used in training new employees and encourage uniformity among and between personnel performing the same task. When reviewed and updated on an annual basis SOPs ensure that methods and procedures remain current and in compliance with regulations and agency policy.	
II. <u>APPLICABILITY:</u> This SOP applies to all personnel in the U.S. Army Center for Health Promotion and Preventive Medicine's (USACHPPM) Quality Assurance Team (QAT). The original hard copy of the SOP will be maintained in the QAT.	
III. <u>DEFINITION:</u> An SOP is a clearly written set of instructions or methods detailing the procedures for carrying out a routine or recurring task or study. SOPs are used to describe both administrative and technical tasks.	
IV. <u>QUALITY CONTROL:</u>	
A. Identification - Each SOP will be assigned an identification number (i.e. SOP # QAT1.0) for tracking purposes, as well as to facilitate referencing. The following information will be	

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contained in the SOP:

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1. The cover page (See Appendix A) will contain the following information:
 - a. SOP title -

**U. S. Army Center For Health Promotion and Preventive Medicine (USACHPPM)
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for**

- b. Date removed from service.
- c. Approval signatures and dates to include:
 - 1) Author/Preparer
 - 2) Supervisor
- d. Annual review signatures and dates top include:
 - 1) Author/Preparer
 - 2) Supervisor
- e. SOPs should contain a disclaimer such as:

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2. All pages including the cover page and excluding appendices will have the following information in the upper right corner:
 - a. SOP NUMBER WITH REVISION NUMBER
 - b. EFFECTIVE DATE
 - c. PAGE ___ OF
 - d. COPY #

B. Policies:

1. It is the responsibility of the immediate supervisor to ensure that all procedures and processes are documented using SOPs, and that the SOPs are approved and reviewed. All SOPs must be approved by the immediate supervisor prior to use.
2. It is also the responsibility of the immediate supervisor to designate an SOP custodian for his/her directorate, division, and/or program.
3. The SOP custodian is responsible for developing and maintaining a listing of all organizational SOPs.

4. Approved SOPs must be made available to and used by workers who perform those procedures:
 - a. Hard copies in all areas performing the procedure,
 - b. Electronic copies on Intranet.
5. Deviations from current SOPs are permitted with documented approval of the approving supervisor.
6. Minor corrections and changes to SOPs may be made in pen and ink by drawing a single line through the change, entering the updated information, then initialing, dating, and specifying the reason for the change. The out of service versions of SOPs will be archived in a historical file.
7. All current SOPs must be reviewed no less than annually by the author/preparer or someone who is proficient in the procedure to ensure that the SOP is accurate and up-to-date.

V. PROCEDURE:

A. Steps for Developing and Publishing an SOP.

1. Review the procedure and decide what information is required in the SOP.
2. Gather information on the procedure from reference sources.
3. Assemble all blank forms and other documents to be referenced in the SOP.
4. Write a draft SOP. Review the draft for technical adequacy and administrative accuracy. Make sure the SOP conveys its message clearly, and that it answers the questions "who," "what," "when," and "how."
5. Submit the draft SOP for peer review and supervisory approval. Structure of an SOP - See Appendix B for administrative SOP format and Appendix C for technical SOP format. All paragraphs noted in either format shall be addressed even if they are not applicable to the SOP being developed.

B. Be clear, concise, and thorough when listing the step-by-step procedures. Remember that the person most dependent on this SOP is the employee who may have little or no experience with the procedure in question. Technical phraseology requiring special knowledge should be avoided except when no other wording will convey the intended meaning. Definitions should be provided as necessary.

C. Include appendices when it is necessary to furnish additional or supplemental material. Appendices, if used, are placed at end of the document and are not subject to the

requirements listed in paragraph IV.A.2. of this SOP. When appendices are used to supply blank forms, the form must have an official form number and an effective date (i.e., SIO Form #1.0, effective date 10/1/96). A list of all current forms used in an organization and a historical file of out-of-service forms shall also be maintained.

1. Provide a glossary if the SOP contains more than 15 abbreviations or terms.
2. An SOP of 10 paragraphs or more should have a Table of Contents to identify major subdivisions and their locations.
3. 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.
4. Use warnings to indicate an operation that, if not followed strictly, could result in personal injury or loss of life. Warnings shall always precede associated text. For example:

WARNING

This is a warning. Avoid contact or spilling solution of this chemical on any parts of the body. Clean up spills and discard waste as described (give reference).

5. A note is an item of information added to highlight an operating procedure, condition, or practice that is independent of the main thought sequence.

NOTE: Notes do not require action and are written in the third person indicative.

6. The proper use of "shall", "will", "should", and "may". Whenever the words "shall" or "will" are used, they will be defined as a mandatory requirement. The word "should" is normally used to express a preferred method of accomplishment. The word "may" is normally used to express an acceptable or suggested means of accomplishment.

- D. SOP Revision and Correction - Procedures will change with time as better ways to do things are discovered and procedures are refined. Ideally SOP changes will keep pace with actual procedures but this is not always the case.
1. Minor corrections and changes to SOPs will be done in accordance with paragraph IV.B.4. of this SOP. If this method is used, all controlled copies of that version must also reflect the pen and ink change. SOPs that have minor pen and ink changes will be totally revised during the annual review process described in paragraph V.D.2. below.
 2. Total revision is the preferred method of correcting errors in or changing an approved SOP. The SOP is amended with the desired changes and a new version

is created (i.e. SOP# QAT1.1 becomes QAT1.2). The immediate supervisor must approve the new version of the SOP. The new SOP replaces the old version and the “date removed from service” is indicated on the original copy of the SOP. All out-of-service SOPs will be removed from common access to avoid inadvertent use. Minor changes to and total revision of SOPs must be publicized to appropriate personnel.

E. SOP Review.

1. All SOPs will be reviewed no less than annually by the author/preparer or someone proficient in the procedure.
2. If no changes to the SOP are needed, the reviewer signs and dates the cover page under “Annual Review”. The approving supervisor also signs and dates the cover page under “Annual Review” acknowledging the authors review and acceptance that the SOP accurately describes the procedure or process.
3. If the SOP is deemed as being inconsistent with existing procedures and/or processes, it must be revised in accordance with paragraph V.D.2. above.

F. SOP Control – The distribution and control of SOPs is critical to ensure that only current approved procedures are in use. USACHPPM’s mail distribution system is not sufficient for document control.

1. Hard Copies.

- a. The original hard copy of an approved SOP should be kept in the organizations main office.
- b. All other controlled copies must have an identifying copy number located in the top right hand corner of each page.
- c. When the pen and ink change method is used to modify an SOP, the designated SOP custodian is responsible for ensuring that all controlled copies of the SOP are updated to reflect the changes.
- d. When the total revision method is used to modify an SOP, the designated SOP custodian is responsible for ensuring that all controlled copies of out-of-service SOPs are collected and replaced with the current revision.
- e. The organizational listing of current SOPs must be updated when a total revision occurs.

2. Electronic Copies.

- a. Electronic copies of approved SOPs may be placed on the USACHPPM network on:
 - 1) The organization's "Homepage"
 - 2) Or, on the organization's directory on the "P Drive".
 - b. Electronic copies of approved SOPs must contain the review and approval signatures and dates.
 - c. Organizational personnel will have read only access to the electronic SOPs to ensure changes are made by authorized personnel only.
 - d. The SOP custodian and/or the immediate supervisor will have read/write access to electronic SOPs.
 - e. The SOP custodian is usually designated by the immediate supervisor as the responsible person for maintaining the electronic copies of SOPs.
 - f. Electronic copies of SOPs that are printed from the network are considered to be uncontrolled documents and must contain the date that the SOP was printed.
 - g. An SOP that is printed from the network is considered to be a current version only for the day it was printed.
- G. Recordkeeping - Indicate what records will be kept and where they will be kept to ensure that the project may be completely reconstructed.
- H. SOP Archiving
- 1. When all copies of an out-of-service SOP are collected, the original copy is archived and all others copies are destroyed to avoid inadvertent use.
 - 2. The out-of-service SOPs will be placed in a historical file and archived in accordance with the Modern Army Recordkeeping System (Marks), AR 25-400-2.
- VI. SAFETY CONSIDERATIONS: SOPs must address all safety precautions that may affect personnel performing the procedure. Safety was a consideration in developing this SOP; however, there are no requirements at this time.
- VII. REFERENCES:
- A. US Army Environmental Hygiene Agency. How to Write and Manage Standing Operating Procedures (SOP). TG No. 176. Maryland: Aberdeen Proving Ground. June 1990.

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- B. US Environmental Protection Agency. Guidelines for the Preparation of Standard Operating Procedures. Quality Assurance Workshop Manual. Washington D.C. July 1990.

APPENDIX A - Cover Sheet Format

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Quality assurance team
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Preparer

Date

Supervisor Approval

Date

Annual Review

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APPENDIX B - Format for an Administrative SOP.

- I. PURPOSE: A brief statement which outlines the reason for or purpose of the SOP, described in terms of function, applicability, and objective.
- II. APPLICABILITY: Identify the activity(ies) to which the procedure applies. Include the distribution list and how the control of copies will be handled.
- III. DEFINITIONS: Words or phrases (including acronyms) having a special meaning or application within the procedure are defined.
- IV. QUALITY CONTROL: This will include any control steps and provisions or review or oversight prior to acceptance of the product or deliverable.
- V. PROCEDURE: This will identify the step-by-step sequence of activities to be followed. Be specific in the content and scope. Recordkeeping and archiving must also be addressed here
- VI. SAFETY CONSIDERATIONS: This is to be included in all SOPs. If there are none, state that safety was a consideration.
- VII. REFERENCES: This is a list of other publications that are cited in the text. All such publications must be available to the user of the SOP.

APPENDIX C - Format for a Technical SOP

- I. PURPOSE: A brief statement which outlines the reason for or purpose of the SOP, described in terms of function, applicability, and objective.
- II. SCOPE: This describes the type of test, nature of samples (matrix), and environmental program support. Include linear range, level of quantitation (method detection limit) and method precision and bias.
- III. APPLICABILITY: Identify the activity(ies) to which the procedure applies. Include the distribution list and how the control of copies will be handled.
- IV. DEFINITIONS: Words or phrases (including acronyms) having a special meaning or application within the procedure are defined.
- V. QUALITY CONTROL: This will include any control steps and provisions or review or oversight prior to acceptance of the product or deliverable. Describe the QC checks including type, frequency, evaluation procedure, acceptance and rejection criteria, and corrective actions.
- VI. INTERFERENCES: List any known or possible compounds or classes of compounds that can create a false positive or negative response.
- VII. EQUIPMENT: This should be as complete as possible without getting too detailed in listing all equipment required by the procedure. For special or unusual equipment give the manufacturer and model number. Address special glassware cleaning requirements, as appropriate.
- VIII. REAGENTS AND CHEMICALS: List desired purity of the neat chemicals. Describe how reagents and standards are prepared and stored (include shelf life, traceability, water quality, etc.) Describe labeling requirements.
- IX. PROCEDURE:
 - A. Safety Considerations. Include use of safety equipment, precautions on hazardous materials handling and safe use of instruments.
 - B. Sample Preparation. Give a step-by-step procedure on how to process samples for analysis. For existing SOPs, a reference may be cited.
 - C. Instrument Set-up. List all instrument settings and operating parameters. Include pre-analysis checks.
 - D. Analysis. A step-wise procedure should be given rather than lengthy paragraphs. Provide a complete listing of steps required to accomplish the analysis.

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APPENDIX C - Format for a Technical SOP (cont.)

- E. Instrument Shutdown. Instructions for returning equipment to "standby" upon work completion.
- F. CALCULATIONS: This section should be used to explain how experimental data is handled to obtain accurate results. Include formulas for all calculations with explanation of symbols used. Indicate the units for which results will be reported.

- X. DATA HANDLING: This section describes how the data are to be stored archived and retrieved. Also address recordkeeping and archiving.

- XI. REFERENCES: This is a list of other publications that are cited in the text. All such publications must be available to the user of the SOP.

