STANDARD OPERATING PROCEDURE
Preparing, Approving and Implementing Standard Operating Procedures

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KEY WORDS

SOP numbering; SOP creation; SOP modification; SOP archiving

APPROVALS

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Environmental Hazards Assessment Program (EHAP) organization and personnel such as management, senior scientist, quality assurance officer, project leader, etc. are defined and discussed in SOP ADMN002.

1.0 INTRODUCTION

1.1 Purpose

This Standard Operating Procedure (SOP) discusses the organization and numbering system for SOPs; preparing and revising SOPs; and the procedure for reviewing, approving and archiving SOPs.

1.2 Definitions

A **Standard Operating Procedure** is a set of guidelines that describe routine procedures for studies conducted by the EHAP.

2.0 ORGANIZATION AND NUMBERING SYSTEM OF SOPs

2.1 SOP Categories

The EHAP SOPs are organized by subject in the following categories. Approval by a quality assurance officer is necessary to add other categories or subcategories; approval of a senior scientist or management is not required.

ADMN - administrative: these describe personnel and responsibilities, document formats, archives and general policy

DATA - data handling: these describe the analysis and reporting of data

EQAI - equipment (air): these describe routine maintenance, cleaning, storage and calibration of air sampling equipment

EQOT - equipment (other): these describe routine maintenance, cleaning, storage and calibration of miscellaneous or other types of equipment

EQSO - equipment (soil): these describe routine maintenance, cleaning, storage and calibration of soil sampling equipment

EQWA - equipment (water): these describe routine maintenance, cleaning, storage and calibration of water sampling equipment

EQWE - equipment (weather): these describe routine maintenance, cleaning, storage and calibration of weather equipment

FSAI - field sampling (air): these describe air sampling procedures

FSOT - field sampling (other): these describe miscellaneous or other types of sampling procedures

FSSO - field sampling (soil): these describe soil sampling procedures

FSWA - field sampling (water): these describe water sampling procedures

METH - methods: these describe analytical procedures

QAQC - quality assurance/quality control: these describe field and laboratory quality assurance and quality control procedures

SAFE - safety: these describe safety procedures during field sampling

2.2 SOP Numbering

Each SOP is assigned a number by the quality assurance unit with the following format:

category abbreviation, 3-digit SOP number, 2-digit revision number

For example: ADMN001.02

ADMN is the category
001 is the SOP number
the decimal point serves as a separator
02 indicates the second revision (00 indicates original version)

3.0 PREPARING AND REVISING SOPs

The project leader is responsible for insuring that all applicable SOPs are prepared or revised and that all study-specific decisions (see 3.5) are documented prior to the initiation of a study. When it is inappropriate to prepare SOPs prior to the initiation of a study, the procedures followed during the study should be well-documented. The SOPs should be prepared within a reasonable period of time.

The following format should be followed for all SOPs. The quality assurance officer has a template.

3.1 Font: Arial, 12-point is the usual size, but others may be used.

3.2 Header: This contains the name and address of the program, the SOP number, the number of the SOP of the previous version, page number, and title (bold and italicized). A line separates the header from the main body. See this header as an example.

3.3 Key Words: The first section of the main body is Key Words. This section acts as a cross-reference so that related SOPs can be identified. Key words should be some characteristic words or phrases that are not already mentioned in the title.

3.4 Approvals: The second section is the Approvals. A SOP cannot be officially used until the management, a senior scientist and a quality assurance officer approve.

3.5 Main Text: The main text should contain the following critical elements in a legal outline format (e.g., 1.2.3). Use these headings only if applicable. Additional headings can be used. The following major headings should be given in order, using all capital letters with bold type (e.g. **1.0 INTRODUCTION**). Subheadings should be lower case with bold type.

INTRODUCTION
- **Purpose**
- **Definitions**

MATERIALS
PROCEDURES
CALCULATIONS
REPORTING REQUIREMENTS
STUDY-SPECIFIC DECISIONS - see below for description
REFERENCES
APPENDICES (including forms referenced in the SOP)

Generic SOPs should be written whenever possible. Each SOP should apply to as many studies as possible. For example, an air sampling procedure should apply to all air studies, not just malathion or some other specific study. Study specific information should be included in the study protocol, a separate document describing a specific study. For example, a procedure may specify that a water sample be collected in a glass container. The decision regarding the container size should be made in each study protocol.

4.0 REVIEW AND APPROVAL OF SOPs

The supervisor of the author or project will coordinate the review of the SOP. Each SOP should be reviewed by the following EHAP personnel: one or more peers, the quality assurance unit and a senior scientist. The peers will review the SOP for completeness and clarity. Part of the review should consist of the peers performing or simulating the procedure as written. The quality assurance unit will review the SOP for format, organization and applicable QA requirements. The SOP will be returned to the author for revision after peer and QA review.

The senior scientist will review the method for validity, applicability and adherence to proper scientific principles. The senior scientist should determine if the methodology achieves the objective of the procedure. The senior scientist should also make sure that the SOP is specific enough to carry out the procedure consistently and flexible enough to apply to other studies. The SOP will be returned to the author for revision after senior scientist review.

The final draft should be sent to the quality assurance officer and senior scientist for approval and then routed to the EHAP program supervisor. The program supervisor or a higher ranking person must give final approval. The effective date of the SOP is the date management signs the SOP.

5.0 IMPLEMENTATION AND USE OF SOPs

Procedures outlined in SOPs are meant to assure conformity between personnel in sampling, laboratory analysis, data analysis, etc. All SOPs are to be used as guidance documents. They are not meant to be a collection of rigid rules. Deviations from SOPs are allowed, but must be documented and approved by the project leader.

The project leader is responsible for disseminating all appropriate SOPs to all appropriate personnel for a specific study. The project leader is responsible for insuring that all applicable SOPs are followed and any deviations are documented and approved.

6.0 ARCHIVING SOPs

The quality assurance officer is responsible for maintaining complete sets of SOPs. The original, signed SOPs will be stored at the EHAP headquarters office. Complete sets of SOPs will also be stored at all EHAP field offices. Electronic copies of all SOPs will also be stored on the branch server. However, a database will not be maintained. The electronic copies may or may not have the appendices included. In addition, the electronic copies will not have the signatures and cannot be disseminated as approved SOPs.