

Chapter 1: Executive Procedures

Environmental Assessment Procedure 1-08

Resource Contact: Ecology Quality Assurance Officer

Established: July 6, 2007

Reference: EAP SOP for Technical SOPs
(Attachment 1)

Approved/Revision Effective: December 21, 2012

Development, Adoption, Use, and Revision of Technical Standard Operating Procedures

Goal: To ensure major program technical activities are documented by SOPs. This procedure requires that SOPs are written to a standard format, archived in both electronic and hard-copy formats, and kept in a convenient location easily accessed by Program staff.

1. Definitions

EIM: Environmental Information Management System. This is an Ecology database that is a major repository for the Agency's environmental data.

MEL: Manchester Environmental Laboratory.

QAPP: Also known as a Quality Assurance Project Plan. It is a key planning document for projects producing environmental data.

PMT: Program Management Team.

Procedure: Steps taken by program staff to accomplish an objective.

Reference: Authority which dictates the procedure's form, content, or scope.

Resource Contact: The person most knowledgeable about the activity or procedure.

SOP: Also known as a standard operating procedure. It is a document which describes in organized detail a standardized business activity of the Environmental Assessment Program (EAP).

2. Program SOPs will Follow a Standard Format

The Ecology Quality Assurance (QA) Officer will retain a master copy of the approved format for SOPs and will be responsible for ensuring that all SOPs conform to that format. The approved format is documented in the SOP entitled "Standard Operating Procedure for the Documentation of Technical Standard

Operating Procedures," provided as an attachment to this policy. MEL uses a slightly different SOP format, which is documented in both the MEL QA Manual and the MEL SOP for Analytical Methods. The actual template for technical SOPs can be found at:

<X:\EA PROGRAM\ECYEAPSOP\SOP Template.dotx>

3. SOPs will be Prepared for all Important Technical Activities

SOPs will be developed for all Program technical activities, including sampling and field measurement techniques. SOP development for a technical activity is required when an activity involves:

- Hazardous waste generation
- Personal hazard
- Use of toxic reagents
- Data entry into EIM
- Data published in any manner
- Regulatory requirement for SOP
- Potentially controversial data

Additionally, SOPs will be developed for technical activities such as data validation and verification.

4. SOP Use is Mandatory

Once SOPs are developed for a defined technical activity, their use is mandatory. Additionally, no deviations from the SOP are allowed without timely approval by the QA officer. For technical activities that may involve decision trees or that may require flexibility in the field, the SOPs will be prepared to indicate the allowable range of decisions and/or options. If for some rare reason the deviations cannot be documented in the SOP, use the QAPP and report process to document ad hoc changes to a technical activity.

5. All EAP Sections will Develop SOPs for their Important Technical Activities

SOPs are applicable Program-wide. This includes Manchester Environmental Laboratory, Lab Accreditation Unit, Western Operations Section, Statewide Coordination Section, Eastern Operations Section, and Program Administrative Group. However, the immediate applicability of this procedure is to the technical activities of the EAP technical staff. Additionally, the various units and sections will

identify technical activities that overlap or apply to several groups, and develop one SOP to meet the needs of all users.

6. SOP Development Process

Typically, program staff, the QA officer, or PMT will identify technical activities that require SOP development. The initiator will request development of a new SOP through the program's Activity Tracker database system. PMT will prioritize development of those SOPs. The QA Officer will maintain the master list of SOPs, both finalized and in development.

7. SOP Adoption Process

SOP adoption consists of a signature approval process. As per the U.S. Environmental Protection Agency (EPA) SOP guidance, typical signatories will include:

- SOP author.
- SOP reviewer.
- Agency QA Officer.

If an SOP applies to more than one section, then signature approval may include all managers impacted by the SOP.

SOP status will be tracked. SOPs will be in one of five statuses:

- Draft- The SOP is being prepared, under revision, or needs signature approval.
- Provisional- Provisional status designates an SOP that has been through signature approval, but is being held pending comparison with other program SOPs on the same or similar subject areas.
- Final - Final SOP status designates signature approval, SOP number assignment, and when appropriate, posting on the internet.
- Withdrawn -Withdrawn status means the document has been removed from use, and is stored as a historical record only.
- Advisory – Over three years since publication, and will not be recertified.

8. SOP Revision/Certification Process

SOP revisions will occur as needed; primarily as technical activities change or new instrumentation is deployed. Revisions will go through the same development process as new SOPs (Step 6).

SOPs will be reviewed and certified every three years. The QA officer will coordinate these document reviews. The Ecology SOP Recertification Form will be utilized to document review and approval. This form can be found at:

<X:\EA Program\ECYEAPSOP\EcologySOPRecertForm.doc>.

9. SOP Archiving and Naming Conventions

SOPs will be archived in both electronic and hard-copy formats. Hard-copy archiving is detailed in Sections 10 and 11 of this policy. SOPs will be electronically archived on the x- drive at X:\EA PROGRAM\ECYEAPSOP\.

SOPs will be archived in both read-only pdf and word document formats.

SOPs will be named in the following manner. Originating Agency-level organization i.e. ECY; then Agency Program i. e. EAP; then SOP; then SOP abbreviated title i. e. FreshWaterFecalColiformSampling; then version number i.e. v1_0, then EAP SOP number. So in this case the full SOP name is -

ECY_EAP_SOP_FreshWaterFecalColiformSampling_v1_0EAP###

Use underscores to separate SOP naming elements. Use this SOP designation in the SOP footer.

SOPs will be numbered sequentially as they reach final approval. The Ecology QA Officer is responsible for numbering the SOPs, which will be designated EAP###, where the number sign stands for a digit.

10. SOP Manual

The Agency QA Officer will maintain a master SOP manual which contains current versions of all HQ SOPs, and will post appropriate final and provisional SOPs to the QA internet website. Approved or provisional SOPs having only internal Ecology use will be posted on the EAP intranet site.

11. SOP Retention

SOPs are intended to be permanently linked to Program Project activities, i e. "what happened when and where." Retention of all Program SOPs and revisions will be indefinite. Under no circumstances are approved SOPs or versions to be discarded or deleted.

12. Withdrawn SOPs

SOPs are frequently revised, and in some cases, completely removed from use. These SOPs are termed "withdrawn," and are archived at Ecology.

13. Referencing SOPs

The appropriate format for referencing SOPs in QA Project Plans or other documents is shown below. Note that the version number of the SOP must be included in the reference.

Swanson, T., 2007. Standard Operating Procedure (SOP) for Hydrolab® DataSonde® and MiniSonde® Multiprobes, Version 1.0. Washington State Department of Ecology, Olympia, WA.
http://www.ecy.wa.gov/programs/eap/qa/docs/ECY_EAP_SOP_Hydrolab_v1_0EAP###.pdf

Attachment 1 -SOP for Technical SOPs

Washington State Department of Ecology

Environmental Assessment Program

Standard Operating Procedure for the Documentation of Technical Standard Operating Procedures

Version 1.5

Author-

Date-

Reviewer -Date -

QA Approval- William R Kammin, Ecology Quality Assurance Officer

Date-

EAP###

Please note that the Washington State Department of Ecology's Standard Operating Procedures (SOPs) are adapted from published methods, or developed by in-house technical experts. Their primary purpose is for internal Ecology use, although SOP's may have a wider utility. Our SOPs do not supplant official published methods. Distribution of these SOPs does not constitute an endorsement of a particular procedure or method.

Any reference to specific equipment, manufacturer, or supplies is for descriptive purposes only and does not constitute an endorsement of a particular product or service by the author or by the Department of Ecology.

Although Ecology follows the SOP in most instances, there may be instances in which Ecology uses an alternative methodology, procedure, or process.

SOP Revision History

Revision Date	Rev number	Summary of changes	Sections	Reviser(s)
12/5/2005	1.0	Rewrite of Lab SOP for HQ use	all	BillKammin
1/4/200?	1.1	Added revision page, disclaimer page, safety language, reagent	0.5 0.6 5.1 9.1	BillKammin
11/17/2006	1.2	Changed title to "technical" SOP; replaced admin/sampling with technical thru-out document	title	Bill Kammin
3/23/2006	1.3	Removed P Brake as signatory	0	BillKammin
8/8/2006	1.4	Removed other signatures	0	Bill Kammin
10/20/2009	1.5	Updated as part of procedure revision; added EAP SOP number to footer	footer	Bill Kammin

Environmental Assessment Program

Standard Operating Procedure for the Production of Technical SOP's

1.0 SOP Format

- 1.1 The guidelines in this SOP will apply to all technical SOPs.
- 1.2 All Program SOP's will be prepared, approved and archived according to the EAP Policy on SOP Development and Use.
- 1.3 The cover page will consist of organization headers, the title of the SOP, the name of the author, the date completed by the author, the names of the approvers/reviewers, and the dates of approval or review.
- 1.4 The disclaimer language page is always Page 2 of an SOP. The disclaimer language is derived from language used in Manchester Environmental Laboratory SOPs, and has been reviewed by the State Attorney General's office. See Page 2 of this document for the disclaimer language.
- 1.5 The SOP will consist of a cover page, disclaimer page, revision history page, and the SOP body, which are specified in Sections 1-10 of the SOP document.
- 1.6 The revision history page contains a table with the following information:
 - 1.6.1 Date of revision approval
 - 1.6.2 Revision number
 - 1.6.3 Summary of changes
 - 1.6.4 Sections revised
 - 1.6.5 Revision author editor
- 1.7 Track minor editing changes in the decimal i. e. 1.1 to 1.2. Major SOP changes, such as the introduction of new sampling equipment, merit a change in the version number i. e. 1.2 to 2.0.
- 1.8 The revision history page will always be Page 3 of the SOP.
- 1.9 Use Times New Roman 10 as the font for the revision page.
- 1.10 All pages except the Title page will contain a footer with the following information: drive file location and file name, the abbreviated title of the SOP, version number, EAP SOP number format EAP###), date of publication, and page number. See the page footer for this SOP for an example of appropriate page footer.

- 1.11 Use legal type outlining, i.e., 1.0, 1.1, 1.1.1, 1.1.2, ad infinitum.
- 1.12 Use a non-indented outline format, as demonstrated in this SOP.
- 1.13 Use a Times New Roman 12 point boldface font for outline headers, and Times New Roman 12 point regular font for SOP body. Use Times New Roman 12 point regular font for all text on the title page. Use Times New Roman 8 point regular for the footer text.

2.0 Margins specifications

- 2.1 Use a top and bottom margin of one inch.
- 2.2 Use left and right margins of 0.8 inch. If less than 0.8 inch is used, holes punched in the hard copy will obliterate some text.
- 2.3 Use normal rather than mirror margins, which could interfere with Acrobat conversion.
- 2.4 Use a one-inch tab between the SOP text and the outline number. Print SOPs in double-sided format.

1.0 Purpose and Scope

- 1.1 This document is the Environmental Assessment Program (EAP) Standard Operating Procedure (SOP) for the preparation of technical SOP's.
- 1.2 Expand on the description of the procedure name for the beginner or casual reader.

2.0 Applicability

- 2.1 Identify when the procedure is to be followed.

3.0 Definitions

- 3.1 Define any words, phrases, or acronyms having special meaning or application. Do not assume the reader has special knowledge of acronyms. Fully state all acronyms before further use.

4.0 Personnel Qualifications/Responsibilities

- 4.1 Identify any special qualifications users must have such as certification or training experience.
- 4.2 List job class(es) to indicate typical level(s) performing the SOP.

5.0 Equipment, Reagents, and Supplies

- 5.1 Provide a list of all materials and equipment used in the procedure. Include descriptions of specialized equipment, sampling bottles, preservation reagents, and other items used in the technical process. For reagents, state final concentration, preparation techniques, and expiration dates. Include explicit descriptions of any health and safety concerns with reagents, including toxicity, carcinogenicity, and teratogenicity. Also include relevant Material Safety Data Sheets (MSDS) for any toxic materials handled in sampling or field activities.

6.0 Summary of Procedure

- 6.1 If the procedure is performed in several discrete steps, describe the steps or outline the procedure succinctly.
- 6.2 Provide a procedure flow chart if necessary or appropriate.
- 6.3 Attach example forms if necessary or appropriate. Label as attachments and number sequentially.
- 6.4 Use the active voice for describing step-by-step procedures. Using active voice is instructional; e.g.: "Add ___", "Dilute ___" or "Perform _____".
- 6.5 Acronyms: Write out all abbreviations the first time each is used.
- 6.5.1 e.g.: Manchester Environmental Laboratory (MEL), Hydrochloric acid (HCl).
- 6.6 Use Microsoft conventions for keyboard command typeface:
- 6.7 Use small font capital letters when spelling out the names of keys on the keyboard.
- 6.7.1 e.g.: "Press ENTER." "Press" is font size 12, while ENTER is font size 10.

- 6.8 Use capital letters and a plus sign (+) when pressing two keys simultaneously.
6.8.1 e.g.: "Press SHIFT+X."
- 6.9 Use **BOLD** text for words or characters that the user is to type. Use lowercase letters unless capital letters must be typed.
- 6.10 Use *italicized* text for specialized text and placeholder names.
6.10.1 e.g.: "Name the file using the parameter and today's date: *parameter/date*. Thus, a TKN analyzed on March 31, 1997, would be '**TKN033197**'."
- 6.11 Instruct the user to "Press keys"; not "Hit", "Punch", etc.
- 6.12 Instruct the user to "Press ENTER[or RETURN]" rather than instruct the user to "Enter" after typing in data.
- 6.13 Instruct the user to "Press ESC to escape" to exit a program, etc.
- 6.14 Mouse Conventions: "Click" means to press and then immediately release the mouse button without moving the mouse. "Double Click" means to press and release the mouse button twice in quick succession.
- 7.0 Records Management**
- 7.1 Specifically list forms to be used and locations of files.
- 8.0 Quality Control and Quality Assurance Section**
- 8.1 Describe any control steps and provisions for review or oversight prior to acceptance of the product or deliverable. This can include test plans such as verification and validation plans for software or running a "spell-check" program on the finished document.
- 9.0 Safety**
- 9.1 Identify products, supplies, reagents, and activities that pose a safety hazard of any kind. Reference to EAP HQ Safety Manual when appropriate.
- 10.0 References**
- 10.1 List references on which the procedure is based. Include references to all EAP safety documents.