STANDARD OPERATING PROCEDURE
PREPARING AND APPROVING STUDY MEMORANDA AND REPORTS

KEY WORDS

Document review, preliminary findings presentation, formatting, executive summary, abstract, review panel

APPROVALS

Original signed by: 7/12/07
APPROVED BY: _____ DATE: _____
John Sanders, Ph.D.
Environmental Monitoring Branch Management

7/12/07
APPROVED BY: _____ DATE: _____
Lisa Quagliaroli
Environmental Monitoring Branch Senior Scientist

7/12/07
APPROVED BY: _____ DATE: _____
Carissa Ganapathy
Environmental Monitoring Branch Quality Assurance Officer

7/12/07
PREPARED BY: _____ DATE: _____
Joy Lyn Dias
Environmental Scientist

Environmental Monitoring Branch organization and personnel, such as management, quality assurance officer, project leader, etc., are defined and discussed in SOP ADMN002.01.

The procedures for preparing and approving protocols are outlined in SOP ADMN003.01.

STANDARD OPERATING PROCEDURE
PREPARING AND APPROVING STUDY MEMORANDA AND REPORTS

1.0 INTRODUCTION

1.1 Purpose

This Standard Operating Procedure (SOP) provides guidance for preparing, reviewing, and approving study memoranda and reports. Additional guidance is provided for studies conducted under Good Laboratory Practices (GLP) (U.S. EPA 40 CFR Part 160.120 and 160.185).

1.2 Application

Environmental Monitoring Branch management expects study staff to understand and apply the guidance provided by this SOP to all study memoranda and reports, including contractual activities where DPR will be responsible for study documentation. If project staff cannot apply this guidance to their study memoranda or reports for practical reasons, Branch management expects them to discuss and develop appropriate alternatives with their Project Supervisor.

The Branch Chief may authorize deviations from this SOP when:

- Emergency monitoring is needed.
- The target audiences for the memorandum or report are not scientists.
- Requested by an external sponsor for studies conducted under grants, contracts, or other cooperative agreements.

2.0 PRELIMINARY FINDINGS PRESENTATION

2.1 Purpose

Establish a process that allows the Project Leader to share preliminary study results with key staff and management before developing the draft report. Management and key staff participation in this discussion will:

- Allow early technical review of study execution, validity of results, statistical analysis, preliminary findings, and conclusions.
- Identify deficiencies and solutions to reduce time spent on formal report reviews.
- Provide Project Leader or study team members with an opportunity to practice presentation skills.

2.2 Scope

All studies for which a study memorandum or report is required, especially those that will be published in scientific journals.

2.3 Participants

Minimum:

- Participants from the protocol review panel
- Study team members
- Key scientific staff and management

Optional but encouraged:

- Any Branch and DPR staff interested in the study

2.4 Procedure

The Project Leader is responsible for initiating and following the procedure shown below:

Step	Action
1	Prepare presentation, report outline, and summary of findings. • Project Supervisor reviews and suggests non-technical edits.
2	Schedule seminar and distribute presentation and additional documentation to the protocol review panel. Other Branch and DPR staff or external stakeholders may be invited as appropriate. • Allow adequate time for presentation and discussion. • Assign note-taker to capture verbal feedback. • Invite review panel to provide written feedback.
3	Review feedback with Project Supervisor and study team members. • Significant technical deficiencies[1] noted during seminar or in written comments must be addressed before the draft study memorandum or report is produced. This may involve meetings between study team members and comment author(s), or arbitration by Project Supervisor.
4	Project Leader drafts study memorandum or report.

3.0 STUDY MEMORANDUM DEVELOPMENT

3.1 Overview

A study memorandum summarizes the results of a study and is written prior to or in place of a report. A study memorandum is generally written when there is a need to make the data available to the public or a contractor before all of the data analysis and interpretation can occur. It is generally preferable to follow a study memorandum with a report to ensure that all of the information pertaining to the study is documented.

1 Significant technical deficiencies are flaws in study execution, laboratory analysis, or statistical analyses that are severe enough to call findings into question or present serious logic problems between analysis and conclusions.

The Project Leader is responsible for memorandum development and must ensure that the memorandum has been approved through the review process described in *Section 5.0* before distributing the memorandum to persons or organizations outside of DPR.

A study memorandum is not an acceptable final document for a GLP study. A final report must be written for all GLP studies.

3.2 Format and Content

This section describes the standard study memorandum format and content. Formatting generally follows the *Publications Handbook & Style Manual*. The Project Leader may elect to add other sections as appropriate. However, significant departures from this SOP must be discussed with the Project Supervisor in advance.

3.2.1 *Header* – The final study memorandum should be written to the Project Supervisor or Program Manager on DPR letterhead. The subject should concisely describe the study and the text must be single-spaced and uppercase. Provide the header information to the office staff for the proper formatting and dispersal of the memorandum.

3.2.2 *Sections* – A study memorandum provides a brief, but broad idea of the study and its results. It may contain the sections listed in the table below:

Section Heading	Section Description
Summary	Provide a brief overview of the study and results. The summary may only be a one-page summary of the study.
Introduction	Follow *Section 4.2.5 Introduction*. As an alternative to the introduction, two sections titled *Scope of this Memorandum* and *Background* may be used.
Scope of this Memorandum	Briefly describe the information that will be presented in the memorandum. If a report will be written, describe the additional information that will be available in the report.
Background	Provide relevant background information regarding the study.
Materials and Methods	Follow *Section 4.2.5 Materials and Methods*. SOPs for procedures and methods should be referenced, but do not need to be included with the document.
Results	Follow *Section 4.2.5 Results*. State the findings observed in the study. Clearly present the text, tables, and figures.
Discussion	It is typical to omit this section since the final report will contain this information. If this

	section is included, follow *Section 4.2.5 Discussion*.
Conclusions	It is typical to omit this section since the final report will contain this information. If this section is included, follow *Section 4.2.5 Conclusions*.
References	Follow *Section 4.2.5 References*.
Appendices	Follow *Section 4.2.5 Appendices*.

4.0 STUDY REPORT DEVELOPMENT

4.1 Overview

A report presents a detailed account of a completed study and a thorough discussion of the study team members' conclusions. The final report should be concise, comprehensive, and clear enough to allow another scientist to reproduce the study without having to seek additional information. Thorough study reports ensure program continuity in the event essential study information is lost (e.g., due to a fire) or becomes unrecoverable (e.g., due to network failure).

The Project Leader is responsible for report development and must ensure that the report has been approved through the review process described in *Section 5.0* before distributing the report to persons or organizations outside of DPR.

Project Leaders are encouraged to obtain input from the field coordinator, statistician, or others involved with the study.

4.2 Format and Content

This section describes the standard report format and content for GLP and non-GLP studies. Formatting generally follows the *Publications Handbook & Style Manual*. All reports contain distinctive component parts such as the title, executive summary, abstract, introduction, materials and methods, results, discussion, conclusions, references, and appendices. The Project Leader may elect to add other sections as appropriate. However, significant departures from this SOP must be discussed with the Project Supervisor in advance.

4.2.1 *Title Page* –

4.2.1.1 *Title*: The title should concisely describe the study (10 to 12 words) and the text must be single-spaced, uppercase,

bolded, and centered. Report titles should not contain chemical formulas or proprietary names.

4.2.1.2 *Authorship*: The authors' names appear on the cover page of the report below the title. Authors include those persons who actively participated in or contributed to the design and execution of the study. Author order should parallel the individual overall contribution to study conception, design, conduct, data analysis, and write-up.

4.2.1.3 *Art*: Consider cover art as appropriate. Example: EH 05-01

4.2.1.4 *Department Logo and Identification*: Include department, branch and program name (if applicable), and full address. Date and report number should appear directly below the address. Text should be single-spaced, bolded, and centered. The DPR logo is optional, but if used should be centered as shown below:

California Environmental Protection Agency
Department of Pesticide Regulation
Environmental Monitoring Branch
1001 I Street, PO Box 4015
Sacramento, CA 95812

<Date>
<Report Number>

4.2.2 *Summary* – Each report must include an Abstract and/or an Executive Summary as described below:

4.2.2.1 *Abstract:* A concise summary of the important points of the study which discusses scope, objective, methodology, results, and main conclusions. Abstracts differ from Executive Summaries in the amount of detail provided. They should not exceed 250 words or include references, tables, or figures.

4.2.2.2 *Executive Summary:* An Executive Summary describes the study in lay terms and provides a context for the results, such as comparing pesticide residue concentrations to health or environmental standards. Possible regulatory actions, mitigation measures, or other Departmental recommendations should be discussed where applicable.

Not all studies require an Executive Summary. Branch management will determine the necessity of an Executive Summary. If required, the Contact Person will write the summary for the Branch Chief's approval.

4.2.3 *Acknowledgements and Disclaimers* – Start on a new page.

4.2.3.1 *Acknowledgements:* Use this section to acknowledge the contributions of personnel not listed on the title page which may include program staff or those who participated in the subjects listed below:

- Field Monitoring and Sampling
- Study Design and Statistical Analysis
- Method Development and Chemical Analysis
- Soil Composition and Water Quality Analysis
- Quality Assurance and Quality Control
- Modeling
- Executive Summary
- Graphics

4.2.3.2 *Disclaimers:* The author may add a disclaimer below the acknowledgements such as:

"The mention of commercial products, their source, or use in connection with material reported herein is not to be construed as an actual or implied endorsement of such product."

4.2.4 *Contents* – Consider using hyperlinks in long reports for reader accessibility.

4.2.4.1 *Table of Contents*

4.2.4.2 *List of Tables*

4.2.4.3 *List of Figures*

4.2.4.4 *List of Appendices*

4.2.5 *Sections* – GLP and non-GLP study reports typically include the section headings shown in the table below. Author(s) may opt to organize the sections differently, combine similar sections, or add new sections provided the final report adequately addresses the topics discussed below. Significant departures from this SOP should be discussed with the Project Supervisor in advance.

Section Heading	Study Type	Section Description
Introduction	Both	Provide enough relevant background information regarding the study so the reader can follow the discussion and interpret the results without needing to refer to previously written articles on the subject. The last segment of the introduction should describe the need for the study and the objective as listed in the approved protocol.
Testing Facilities and Personnel	GLP	List all testing facilities (name and address) and personnel involved in the study such as the Project Leader (study director), other scientists or professionals, and all supervisory personnel involved in the study. List study sponsor, if appropriate. May be organized as in SOP *ADMN003.01 Section 3.2.3 Personnel*.

Section Heading	Study Type	Section Description
Materials and Methods	Both	Provide the necessary information to repeat the testing procedures used in the study. Describe why and how the results were obtained. The information should be similar to SOP *ADMN003.01 Section 3.2.3 Study Plan and Sampling Methods*. Include the following: • Technical specifications of equipment used (instrument names and model number) • Stability of pesticides (test substances), if applicable • Quality control procedures • Statistical procedures, if not under their own heading • Reference any relevant SOPs pertaining to methods and procedures used • **Required for GLP studies:** o Include description of the transformations, calculations, or operations performed on the data o Place all relevant SOPs in the appendices
Results	Both	Describe the overall study without repeating the experimental procedures in detail. • Clearly state the findings in the text, tables, and figures. • Tables and figures should be presented such that the reader can simply look at a table and understand what data were collected. • If adjusted results are mentioned in the report, include all necessary supporting data in the main body of the report or in an appendix. Supporting data should be adequate to allow the reader to derive the adjusted results. • The report must address the objectives stated in the written protocol.
Discussion	Both	Clearly describe what the results mean. • The data should support the principles, relationships, and generalizations stated in the discussion. • Show how the results and interpretations are either similar or dissimilar to previously published work. • Describe all circumstances that may have affected the quality or integrity of the data. • Describe any uncertainties in the results. • Present new ideas and speculations if there are data to support them. The results and discussion sections may be combined instead of having two separate headings.
Conclusions	Both	Clearly and succinctly state the conclusions. Emphasize the main points brought out in the discussion. Do not present any new information.
Archiving	GLP	List the location where all specimens, raw data, and the final report are to be stored. Citing that SOP ADMN005 will be followed for archiving is generally adequate.

Section Heading	Study Type	Section Description
References	Both	Format references according to the guidelines in *Publications Handbook & Style Manual* and list them on a separate page. Include a reference and hyperlink to the approved study protocol.
Appendices	Both	Include supplemental material such as: • Illustrations and tables to elaborate or support the text, but not distract the reader from the text's main ideas • Raw data • Quality control data • SOPs • Statistical procedures • Deviations from the approved study protocol and/or SOPs and their potential affect(s) on the study results • Contract information – see SOP *ADMN003.01 Section 3.2.3 Contract Information* for details to include or provide hyperlink to contract information on external website, if posted. • **Required for GLP studies:** • A statement prepared and signed by the Quality Assurance Officer that includes inspection dates and findings reported to management and the Project Leader. **NOTE:** If there are two or more appendices, they must be numbered with Roman numerals or lettered consecutively.

5.0 REVIEW AND APPROVAL PROCEDURES

5.1 Overview

Prior to publishing the findings of a study all study memoranda and reports must undergo a comprehensive review to ensure the appropriateness of the science, materials and methods, analytical methods, chemistry, quality assurance and control, statistics, policy, editorial accuracy, and any additional categories as needed. The review procedures are intended to provide staff with the opportunity to produce the best study possible and to utilize the available technical resources early in the project.

In general, Project Supervisors and Project Leaders will follow normal chain-of-command (e.g., Program Supervisor, Branch Chief, Assistant Director) once they complete the review procedures outlined in this SOP for study memoranda and reports. At each step, the management reviewer may return the document for revision, pass the document to the next management level, or give final approval.

The Project Supervisor should consult with management to determine which, if any, external entities (e.g., other agencies, universities, stakeholders) should review the study memorandum or report and whether the external review will occur before, concurrently, or after management review. If management requires external review, the Project Supervisor and/or Contact Person will coordinate the reviews and compose a cover letter that briefly describes the document and sets a deadline for comments. Depending on the timing and outcome of the external review, management may opt to conduct a second review. DPR policies or legal requirements may require additional review or supercede this SOP (e.g., scientific documents used to support rulemaking).

5.2 Purpose

- Identify significant deficiencies that would be barriers to management approval and subsequent publication.
- Ensure that all branch reports are “journal-ready” regardless of where they will be published.

5.3 Scope

All study memoranda or reports that may be made public (e.g., published, posted to the web, available through public information act requests).

5.4 Participants

Minimum:

- Participants from protocol review panel
- Appropriate study team members
- Assorted management

Optional but encouraged:

- EM Research Scientists from beyond the media-specific group
- External scientists or statisticians (e.g., other Branches, UC)
- Interested staff – selected based on current assignments, professional interest, or beneficial knowledge

5.5 Procedure

The Project Leader is responsible for initiating and following the document review procedure shown below:

Step	Action
1	Provide the draft document to Project Supervisor for non-technical review.
2	Select the review panel participants.

	• Project Supervisor coordinates staff assignments with other supervisors. • **Note:** If possible, the same panel participants should review the protocol, study memorandum (if produced) and report. Additional reviewers can be assigned as needed to address technical issues that arise throughout the study.
3	Submit edited document to review panel with due date for written comments.
4	Evaluate panel's written comments with the Project Supervisor[2] and respond to comments in writing. • Project Supervisor reviews comments for significant technical disagreements between panel members. • Program Supervisor or Branch Chief, in consultation with the Project Supervisor, will settle significant technical disagreements between panel members or the panel and Project Leader before continuing the process. • **Required for GLP studies:** o A copy of the reviews and responses must be included in the appendix.
5	Revise the document according to panel's and Project Supervisor's comments. • *For documents with significant deficiencies*: Review process will be repeated until the panel and Project Supervisor approve the document. • Minor amendments will not require further technical review unless requested by panel members.
6	Project Supervisor will submit approved draft document to Branch management for final approval. • If an Executive Summary is required, the Project Supervisor will have the Project Leader and/or Contact Person write the summary for the Branch Chief's approval. • Project Supervisor will submit the report and Executive Summary for management review.
7	Send the approved document to the Branch webmaster for posting to DPR's websites.

5.6 GLP Study Requirements

5.6.1 *Signature page* – GLP Study Reports must be signed and dated by the Project Supervisor, Project Leader, and Quality Assurance Officer. The signature page should follow the template used in EM Branch SOPs.

5.6.2 *GLP Study Report Corrections or Additions* – Corrections or additions to a signed final report shall be in the form of an amendment by the Project Leader. A copy of the final report and of any amendment shall be maintained by the sponsor and by the test facility.

2 The panel's comments, whether individual or group, will clearly identify significant technical deficiencies and minor amendments. Significant technical deficiencies are flaws in the study that are so great that, if uncorrected, would warrant management denial of the project.