



**US Environmental Protection Agency
Office of Pesticide Programs**

**Office of Pesticide Programs
Microbiology Laboratory
Environmental Science Center, Ft. Meade, MD**

**Standard Operating Procedure for
Preparation and Review of
Standard Operating Procedures (SOPs)**

SOP Number: ADM-02-03

Date Revised: 08-20-08

EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Preparation and Review of Standard Operating Procedures (SOPs)

SOP ADM-02-03

Date Revised: 08-20-08

Initiated By: _____ Date: ___/___/___

Print Name: _____

Technical Review: _____ Date: ___/___/___

Print Name: _____

Technical Staff

QA Review: _____ Date: ___/___/___

Print Name: _____

QA Officer

Approved By: _____ Date: ___/___/___

Print Name: _____

Branch Chief

Effective Date: ___/___/___

Controlled Copy No.: _____

Withdrawn By: _____ Date: ___/___/___

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1.0 <u>SCOPE AND APPLICATION:</u>	

1.1 The purpose of this procedure is to provide guidance in the development, revision, and oversight of Standard Operating Procedures (SOPs) used by the Microbiology Laboratory staff, quality assurance unit, and Branch Chief. The Microbiology Laboratory Branch of the Office of Pesticide Programs is located at the Environmental Science Center, Fort Meade, Maryland.

2.0 DEFINITIONS:

2.1 Standard Operating Procedure (SOP): A document which gives a step-by-step description of how a specific operation, method or procedure is performed.

2.2 BEAD: Biological and Economic Analysis Division

3.0 HEALTH AND SAFETY: Not applicable

4.0 CAUTIONS:

4.1 Official SOPs are issued and tracked by the Quality Assurance Officer (QA Officer). The Quality Assurance Officer maintains a log of all official copies. Photocopying of SOPs is discouraged due to tracking issues. If a temporary copy is used (for training purposes etc.), it must be appropriately marked as a "Copy" and destroyed after use.

4.2 Changes to the SOP are made through the official revision process (see 10.2) or by filing an SOP amendment (see 10.3). Handwritten changes are not permitted.

5.0 INTERFERENCES:

5.1 New SOPs and revisions to SOPs should be issued promptly after being approved by the Branch Chief.

5.2 SOP addenda should be issued promptly after being reviewed (by the Team Leader and Quality Assurance Officer) and approved by the Branch Chief or designee.

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable of the procedures in this SOP. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS:

7.1 Hard and/or electronic copies of the SOPs and addenda are prepared using the Agency's acceptable software in use at the time of their preparation.

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE: Not applicable

10.0 PROCEDURE AND ANALYSIS:

10.1 Developing New SOPs.

10.1.1 Summary. Each SOP shall be written in the standard laboratory format. The following procedure describes the organization and format of SOPs, their review and approval, distribution, and storage.

10.1.2 SOP Identification. SOPs are organized into groups according to subject area. Each SOP shall be assigned a unique number. An example of the identification format is presented below:

ADM-01-01 (Group ID - SOP No. - Revision No.)

The first two to three alphabetical characters identify the grouping. The middle two-three digit number is the assigned SOP number in that group. The last two-digit number is the revision number for that SOP. Revision A00" is the original version of the SOPs.

The following group letters shall be used to identify SOP categories:

ADM Administrative
COC Chain-of-Custody
QC Quality Control
EQ Equipment Calibration and Maintenance
MB Microbiology
QA Quality Assurance

The SOPs for the Plant Incorporated Program include the prefix "PIP" prior to the standard SOP designation. This prefix is necessary to distinguish the PIP group of SOPs from other operational and procedural SOPs.

A set of comprehensive SOPs may be developed for BEAD Laboratories to address issues related to the ISO 17025 accreditation of the laboratories. The basic information identified in the table of contents will be included in the comprehensive inter-laboratory SOPs.

- 10.1.3 Title Page. Every SOP shall have a title page (see 16.0) which shall identify it as an SOP for the OPP Microbiology Laboratory. The title page contains the title of the SOP, the SOP identification number, and the date revised. The title page also contains fields for entry of the effective date, the controlled copy number, and withdrawal signature and date. Except for the QA-series of SOPs, the title page also identifies who initiated and reviewed the SOP, and contains the review signature for QAO and approval signature for the Branch Chief.

The QA group SOP title page contains the dates of review/approval and signatures of the Quality Assurance Officer and the Branch Chief.

- 10.1.4 Page Identification. The top right corner of each page, including the title page (Page 1), shall contain the following information:

SOP No. __-__-__
Date Revised: __-__-__
Page __ of __

- 10.1.5 All SOPs shall contain a Table of Contents (Page 2) and the following sections and format:

10.1.5.1 1.0: SCOPE AND APPLICATION: This section describes the reason for writing the SOP, with its intended use and effect.

10.1.5.2 2.0: DEFINITIONS: This section lists definitions of terms, acronyms, and abbreviations relevant to this SOP, or with which the reader may be unfamiliar. When there are no terms to define, the format shall read:

DEFINITIONS: None

10.1.5.3 3.0: HEALTH AND SAFETY: This section will highlight any unique health or safety issues pertaining to the specific SOP. All SOPs will refer to the most recent version of SOP MB-01, Lab Biosafety, for comprehensive health and safety procedures and policy. When there are no health and safety practices to define, the format shall read:

HEALTH AND SAFETY: Not applicable.

10.1.5.4 4.0: CAUTIONS: This section will identify any known activities that may result in equipment damage or degradation of sample, critical control points, or technique sensitive procedures (e.g., inoculum production, timing of transfers of carriers, etc.) found in the protocol. If there are no cautions identified, the format shall read:

CAUTIONS: None

10.1.5.5 5.0: INTERFERENCES: This section discusses any potential or known problems that may be encountered during the performance of a method or procedure that may complicate interpretation or validity of results (e.g., incomplete neutralization, contamination of pre-sterilized supplies, etc.). If there are no known interferences, the format shall read as follows:

INTERFERENCES: None

10.1.5.6 6.0: PERSONNEL QUALIFICATIONS: This section identifies the minimal education or training that is required to carry out the procedure covered by the SOP. Modify standard text as necessary for the specific SOP. The standard text is:

“Personnel are required to be knowledgeable of the procedures in this SOP. Documentation of training and familiarization with this SOP can be found in the training file for each employee.”

10.1.5.7 7.0: SPECIAL APPARATUS AND MATERIALS: Lists special or unique instruments and supplies needed to perform the method. If there are no special apparatus or

materials specified, the format shall read:

SPECIAL APPARATUS AND MATERIALS: None

10.1.5.8 8.0: INSTRUMENT OR METHOD CALIBRATION: Describes the method and frequency of calibrating an instrument or piece of equipment. If this is not applicable to the SOP, the format shall read:

INSTRUMENT OR METHOD CALIBRATION: Not applicable

10.1.5.9 9.0: SAMPLE HANDLING AND STORAGE: Describes the conditions of preservation and storage required to maintain the integrity of the sample. Holding times shall be specified. If this is not applicable to the SOP, then the format shall read:

SAMPLE HANDLING AND STORAGE: Not applicable

10.1.5.10 10.0: PROCEDURE AND ANALYSIS: Provides a step-by-step description of the operation. Method SOPs will include a statement indicating that the staff must demonstrate (e.g., through documented training) that they can perform a method before implementing it in the laboratory. If the procedure changes, confirmation of ability to perform the method must be repeated. If relevant to the topic of the SOP, add a statement at the end of the section on "Resource Management". For example:

"10.X Resource Management.

10.X.X Water Conservation. Laboratory Personnel should be mindful of water consumption, and whenever possible, employ practices that minimize water use."

10.1.5.11 11.0: DATA ANALYSIS/CALCULATIONS: Provides instructions for equations and formulae necessary to produce the results of the method. If there are no analyses or calculations, the format shall read:

DATA ANALYSIS/CALCULATIONS: None

10.1.5.12

12.0: DATA MANAGEMENT/RECORDS

MANAGEMENT: This section describes calculations to be performed and the procedures that will be used to meet Agency, OPP, and GLP data management/records management requirements. Insert standard text, modified as necessary, to fit the specific SOP. The standard text is:

“Data will be recorded promptly, legibly, and in indelible ink on the appropriate forms. Completed forms are archived in notebooks kept in secured file cabinets in the file room D217. Only authorized personnel have access to the secured files. Archived data is subject to OPP=s official retention schedule contained in SOP ADM-03, Records and Archives. Before electronic transmission of official reports and associated documents such as raw data sheets and data summary tables, the files should be converted to pdf format. Each file should be annotated with document control information such as the date the document was finalized, laboratory identification information, and version number.”

10.1.5.13

13.0: QUALITY CONTROL: This section describes the Procedures used to meet GLPs. Insert standard text, modified as necessary to fit the specific SOP. The standard text is:

“Appropriate quality control measures are integrated into each SOP. For quality control purposes, the required information is documented on the appropriate forms (see 16.0).”

10.1.5.14

14.0: NONCONFORMANCE AND CORRECTIVE

ACTION: When a non-conformance is identified (deviation, omissions), it must be documented. An effort will be made to prevent recurrence of the non-conformance. At a minimum, the following statement is included:

“Any deviations from the standard protocol must be

documented in the paperwork and corrective action applied if warranted.”

- 10.1.5.15 15.0: REFERENCES: This section lists any document used as a source for writing the SOP such as standard methods, QA Manual, publications, and instrument manuals. References shall be listed alphabetically. Ensure that the latest version of a standard or manual is referenced, unless it is not appropriate to do so. Citing a reference is not a substitute for a description of a procedure. Include a description of the procedure in the SOP to allow for consistent performance of the method. When no references were used, the format shall read:

REFERENCES: None

- 10.1.5.16 16.0: FORMS AND DATA SHEETS: This section lists the forms and data sheets referenced in the SOP. If no forms or data sheets are referenced, the format shall read:

FORMS AND DATA SHEETS: None

- 10.1.6 Submit SOP for review by a technical reviewer, the Team Leader, and the QA Officer. Each reviewer is responsible for ensuring that the procedures are adequate and accurate based on his/her area of expertise.

- 10.1.7 After review and comment by the Team Leader and the QA Officer, the SOP is routed to the Branch Chief for approval. The QA Officer will issue the SOP following approval by the Branch Chief (see section 12).

10.2 Revising Existing SOPs.

- 10.2.1 SOPs are reviewed and revised at least every three years to ensure that policies and procedures continue to be relevant and accurate.

- 10.2.2 An SOP may be revised prior to the end of the three-year cycle if a major modification is required. The Team Leader is responsible, in consultation with the QA Officer, for determining whether the SOP changes are major or minor. Minor changes may be made through the addendum process (see section 10.3).

- 10.2.3 Revise the SOP as necessary, including the SOP identification number (see section 10.1.2). Incorporate addenda prepared during the three-year cycle.
 - 10.2.4 Submit the revised SOP for review and approval as per sections 10.1.6 and 10.1.7.
 - 10.2.5 The QA Officer will issue the SOP following approval by the Branch Chief and remove all controlled copies of the previous version from circulation (see section 12).
- 10.3 Making Minor Modifications to SOPs.
- 10.3.1 Minor modifications to SOPs are made through the addendum process.
 - 10.3.2 Handwritten changes to SOPs are not permitted.
 - 10.3.3 Any member of the laboratory may request a modification to an SOP. The changes should be discussed with the Team Leader prior to preparing the addendum.
 - 10.3.4 Complete the SOP Addendum Form (see 16.0).
 - 10.3.5 Each addendum is sequentially numbered using the following format: A – Year – addendum number. For example, the first addendum prepared in 2008 is numbered A-2008-01.
 - 10.3.6 Submit the SOP Addendum Form to the Team Leader and QA Officer for review and approval by the Branch Chief or designee. The QA Officer will issue the addendum once the review and approval process is completed.
 - 10.3.7 Following issuance of an SOP addendum, the QA Officer is responsible for retaining controlled copy number 0 of the addendum as an archived copy.
- 10.4 Withdrawing SOPs.
- 10.4.1 SOPs that are no longer in use should be withdrawn by the QA Officer (e.g., SOP for operation of equipment that has been removed from the laboratory) and archived. Management must

approve SOP withdrawal.

10.4.2 The QA Officer documents the withdrawal of the SOP on the SOP title page on controlled copy '0' (see section 12.4). The withdrawn controlled copy '0' is archived. All other controlled copies are destroyed.

10.4.3 Withdrawn SOPs may be reinstated at a later date, if necessary.

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Documentation used for initiating, revising, issuing, and withdrawal of an SOP will be recorded on the SOP title page. SOPs will be written and stored using the Agency's standard word processing software.

12.2 The QA Officer is responsible for issuing controlled copies of approved SOPs to each laboratory and to appropriate personnel. The date of issuance is recorded on the SOP title page. (see 16.1). There are seven controlled copies (0-6). The original signed SOP is designated as controlled copy 0. The remaining controlled copies are assigned as follows:

Copy 1 – Team Leader
Copy 2 – Branch Chief
Copy 3 – C Wing Office Area
Copy 4 – D Wing Office Area
Copy 5 – Laboratory
Copy 6 – QA Officer

12.3 For each newly developed or revised SOP, controlled copy 0 will be scanned and converted to a pdf file to prevent unauthorized changes to the SOP. The hard copy 0 will be archived. The QA Officer is responsible for maintaining archives of controlled copy 0 and the pdf files. The electronic files will be backed up monthly by a staff member designated by the Branch Chief.

12.4 When an SOP is revised or withdrawn, the QA Officer is responsible for collecting the previous version of all controlled copies of the SOP. The QA Officer signs and dates the SOP Title Page of controlled copy 0 in the "Withdrawn By;" field, thus designating the SOP as withdrawn. The withdrawn controlled copy 0 is retained as an archived copy. All other controlled copies will be destroyed.

12.5 The QAU maintains archived SOPs in a secured file cabinet located in D217. Only authorized personnel have access to the secured files. Archived files are subject to OPP=s official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 An index of the SOPs is attached to the OPP Quality Assurance Management Plan which is sent to the OPP QA Manager.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 If a number of addenda have accumulated, the SOPs may be revised earlier than 3 years. If an SOP has not been revised within the 3 year timeframe, the QAU will notify the Team Leader, and the SOP will be given immediate attention. If it is determined that the lab fails to routinely update the SOPs on the established schedule, the Branch Chief, Team Leader, and QAU will meet to discuss the issue and will develop appropriate procedures/schedules to foster conformance.

15.0 REFERENCES:

15.1 Guidance for Preparing Standard Operating Procedures (SOPs), EPA QA/G-6. EPA/600/B-07/001. US EPA Office of Environmental Information. April 2007.

16.0 FORMS AND DATA SHEETS:

16.1 SOP Review Summary/Cover Sheet for SOPs except QA SOPs

16.2 SOP Review Summary/Cover Sheet for QA SOPs

16.3 SOP Addendum Form

EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Name of SOP Here

SOP Number:

Date Revised: MM-DD-YY

Initiated By: _____ Date: ___/___/___

Print Name: _____

Technical Review: _____ Date: ___/___/___

Print Name: _____

Technical Staff

QA Review: _____ Date: ___/___/___

Print Name: _____

QA Officer

Approved By: _____ Date: ___/___/___

Print Name: _____

Branch Chief

Effective Date: ___/___/___

Controlled Copy No.: _____

Withdrawn By: _____ Date: ___/___/___

EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
[Quality Assurance Operations]

SOP QA-01-00

Date Revised: MM-DD-YY

Initiated By: _____ Date: ___/___/___

Print Name: _____
Quality Assurance Officer

Approved By: _____ Date: ___/___/___

Print Name: _____
Branch Chief

Effective Date: ___/___/___

Controlled Copy No.: _____

Withdrawn By: _____ Date: ___/___/___

Standard Operating Procedure (SOP) Addendum Form
OPP Microbiology Laboratory

Addendum A-2008-XX

SOP Name :	
SOP Number:	
Addendum Number:	
Changes made by (name/date):	
Description of Change(s)/ Addition(s):	
Justification(s) for the Change(s):	
Reviewed By: Team Leader	
Reviewed By: QA Officer	
Approved By: Branch Chief	

Date Issued: _____

Controlled Copy Number: _____

Addendum A-2008-XX