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

SOP Number: ADM-02-05

Date Revised: 04-10-13

SOP Number	ADM-02-05
Title	Preparation and Review of Standard Operating Procedures
Scope	The purpose of this procedure is to provide guidance for the development, revision, and oversight of Standard Operating Procedures (SOPs) used by the Microbiology Laboratory Branch
Application	MLB follows the guidance document EPA QA/G-6 (see section 15) for the update and revision of all SOPs.

	Approval Date
SOP Developer:	_____ Print Name: _____
SOP Reviewer	_____ Print Name: _____
Quality Assurance Unit	_____ Print Name: _____
Branch Chief	_____ Print Name: _____

Date SOP issued:	
Controlled copy number:	
Date SOP withdrawn:	

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1. **Definitions**	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. MLB: Microbiology Laboratory Branch 3. QAU: Quality Assurance Unit of MLB 4. Abbreviations/definitions are also provided in the text.
2. **Health and Safety**	Not Applicable.
3. **Personnel Qualifications and Training**	Refer to SOP ADM-04, OPP Microbiology Laboratory Training.
4. **Instrument Calibration**	Not applicable
5. **Sample Handling and Storage**	Not applicable
6. **Quality Control**	An index of the SOPs is included in the MLB Quality Management Plan. The MLB Quality Management Plan is an appendix to the OPP Quality Management Plan.
7. **Interferences**	1. New SOPs should be issued promptly following approval by the Branch Chief.
8. **Non-conforming Data**	Not applicable
9. **Data Management**	Not applicable
10. **Cautions**	1. Official SOPs are issued and tracked by the QAU. The QAU maintains a log of all official copies. 2. Photocopying of SOPs is discouraged. If a temporary copy is used (for training purposes etc.), it must be appropriately marked as a "Copy" and destroyed after use. 3. Changes to the SOPs are made through the official revision process (see 12.6). Handwritten changes are not permitted. 4. The SOPs and addenda are prepared using the Agency's acceptable

	software in use at the time of their preparation.
11. **Special Apparatus and Materials**	None
12. **Procedure and Analysis**	1. Summary. Each SOP is written in the standard laboratory format (see sections 12.2 through 12.4). The following procedure describes the organization and format of SOPs, including their review, approval, distribution, and storage. 2. The control copy number "0" is the official original version (with original signatures) of the SOP. Control copy number "0" is archived. Six copies of each SOP are issued and distributed to 6 binders. 3. Copy 1: Team Leader, Copy 2: Branch Chief, Copy 3: C wing, Copy 4: D wing, Copy 5: Lab copy and Copy 6: QA Officer. 4. When a new version of the SOP is issued, only control copy number '0' is retained and marked with 'Date SOP withdrawn". The other six copies are withdrawn from circulation and destroyed.
12.1 SOP Identification	a. SOPs are organized into groups according to subject area. Each SOP is assigned a unique number. An example of the identification format is presented below: ADM-01-01 (Group ID - SOP No. - Revision No.) b. The following group letters are used to identify SOP categories: ADM: Administrative COC: Chain-of-Custody EQ: Equipment Calibration and Maintenance MB: Microbiological Test methods QA: Quality Assurance QC: Quality Control VTP: Virology c. The first two to three alphabetical characters identify the grouping. The middle two digit number is the assigned SOP number in that group. The last two-digit number is the revision number for that SOP. The revision marked "00" for each SOP is the original version of the SOP.

12.2 Title Page	a. Every SOP shall have a title page (Page 1) which identifies the SOP as an OPP Microbiology Laboratory SOP. The title page contains the SOP number, title of the SOP, scope and application fields. The title page also contains approval signature blocks for the following: SOP Developer, SOP Reviewer, Quality Assurance Unit and Branch Chief. At the bottom of Title page are blocks for: Date SOP issued, Controlled Copy number, and Date SOP withdrawn. b. The QA-series of SOPs may have fewer signature blocks. However, all SOPs must contain the signatures of the Quality Assurance unit and the Branch Chief. c. The title page for all SOPs includes the dates of review/approval and signatures of the developer, technical reviewer (if applicable), Quality Assurance Unit and the Branch Chief (or designee).
12.3 Page Identification	a. All pages of the SOP are numbered. b. The header on the top right corner of each page, including the title page (Page 1), shall contain the following information: SOP No.: (X)XX-XX-XX Date Revised: XX-XX-XX Page: XX of XX
12.4 SOP Content	All SOPs shall contain following sections and format as listed below: a. **Table of Contents** is the second page of the SOP. It lists contents of the SOP and the corresponding page number. b. **1. 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 c. **2. Health and Safety:** This section highlights any unique health or safety issues pertaining to the specific SOP. When there are no health and safety practices to define, the format shall read: Health and Safety: None d. **3. Personnel Qualifications and Training:** 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:

	"Refer to SOP ADM-04, OPP Microbiology Laboratory Training." e. **4. Instrument 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 Calibration: Not applicable f. **5. 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 g. **6. Quality Control:** This section describes the procedures used to meet GLP and ISO/IEC 17025 requirements. 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 section 14)." h. **7. 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: Interferences: None i. **8. Non-conforming Data:** When a non-conformance is identified (e.g. deviation, omission), it must be documented. An effort will be made to prevent recurrence of the non-conformance. At a minimum, the following statement may be included: "Management of non-conforming data will be specified in the study protocol; procedures will be consistent with SOP ADM-07, Non-conformance reports." j. **9. Data Management:** This section describes the procedures that are used to meet Agency, OPP, and GLP data management/records management requirements. Insert standard text, modified as necessary, to fit the specific SOP. "Data will be archived consistent with SOP ADM-03, Records and Archives". k. **10. 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

l. **11. 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

m. **12. Procedure and Analysis:** Provides a step-by-step description of the operation. Method SOPs include a statement indicating that the staff must demonstrate (e.g., through documented training) that they can perform a method before using it in the laboratory. If the procedure changes, confirmation of the ability to perform the method must be repeated. If relevant to the topic of the SOP, a statement can be added at the end of the section on "Resource Management". For example:
"12.X Resource Management.
12.X Water Conservation. Laboratory Personnel should be mindful of water consumption, and whenever possible, employ practices that minimize water use."

n. **13. Data Analysis/Calculations:** Provides instructions for use of equations and formulae, including spreadsheets necessary to produce the results of the method. If there are no analyses or calculations, the format shall read:

Data Analysis/Calculations: None

o. **14. 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

p. **15. 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. 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 are used, the format shall read:

	References: None
12.5 SOP Review	a. Submit the SOP for review by a technical reviewer (if applicable), and the QA Officer. Each reviewer is responsible for ensuring that the procedures are adequate and accurate based on his/her area of expertise. b. After review and comment by the Technical reviewer and the QA Officer, the SOP is routed to the Branch Chief for approval. The QA Officer issues the SOP following approval by the Branch Chief or designee (see section 12.2).
12.6 Revising Existing SOPs.	a. SOPs are reviewed and revised at least every three years to ensure that policies and procedures continue to be relevant and accurate. b. An SOP may be revised prior to the end of three year cycle if a modification or change to procedure is required c. Revise the SOP as necessary, including the SOP identification number. Create a new version (section 12.1b). d. Submit the revised SOP for review and approval as per section 12.2. e. The QA Unit issues the SOP following approval by the Branch Chief and all controlled copies of the previous version are removed from circulation.
12.7 Withdrawal and Re-instatement of SOPs	a. SOPs that are no longer in use are withdrawn by the QA Unit (e.g., SOP for operation of equipment that has been removed from the laboratory and archived). However, any SOP withdrawal must be approved by management. b. The QA Unit documents the withdrawal of the SOP on the SOP title page on controlled copy "0" (see section 12.2). The withdrawn SOP's controlled copy "0" is archived. All other controlled copies (6) are destroyed. c. Withdrawn SOPs may be reinstated at a later date, if necessary, and re-issued with appropriate revision.
13. **Data Analysis/ Calculations**	None
14. **Forms and Data Sheets**	Test Sheets. Test sheets are stored separately from the SOP under the following file names: SOP Review Summary/Cover Sheet for SOPs except QA SOPs — ADM-02-05_F1.docx

	SOP Review Summary/Cover Sheet for QA SOPs ADM-02-05_F2.docx
15. **References**	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.