SOP Number	ADM-02-08
Title	Preparation and Review of Standard Operating Procedures
Revisions Made	• Definitions: Control Copy Number" 0": The version of the SOP with original signatures from which all other control copies are made. • 10. Cautions: Difference between copy 0 and original version -00 of the SOP explained. • 12. Procedure and Analysis: Added language about Test Methods under Development. Each SOP is written in the standard laboratory format (see sections 12.2 through 12.4); however, some SOPs are designated as *Test Methods Under Development* and follow a basic outline format and may not contain all the sections or criteria specified in 12.2-12.4. • 12.2 Title page Additional approval signature blocks (e.g., Safety, Health, and Environmental Manager) may be added as necessary. • 12.4 SOP Contents **14. Forms and Data Sheets**: This section lists the forms and data sheets referenced in the SOP in addition to appendices and attachments. Forms, data sheets, and attachments (supplemental information) are not page numbered and are stored separately from the SOP to facilitate changes without the need to re-issue the SOP. Appendices (details pertinent to the conduct of the SOP but not included in the body of the SOP) should be page numbered parts of the SOP. • **12**.6 Revising Existing SOPs and Forms Forms are separate from the SOP. If a form is revised independently of the SOP, archive the previous copy in a designated folder (by the year it was revised) and save with the date that it was retired in the file name. • 15, References: https://www.epa.gov/quality/guidance-preparing-standard-operating-procedures-epa-qag-6-march-2001

SOP Number	ADM-02-08
Title	Preparation and Review of Standard Operating Procedures
Scope	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:	Kiran Verma	10/27/22
	Print Name: Kiran Verma	
SOP Reviewer	Lisa Smith	10/27/22
	Print Name: Lisa S. Smith	
Quality Assurance Unit	Michele Cottrill	10/27/22
	Print Name: Michele Cottrill	
Branch Chief	Rebecca Pines	10/27/22
	Print Name: Rebecca Pines	

Date SOP issued:	10/27/22
Controlled copy number:	0
Date SOP withdrawn:	

TABLE OF CONTENTS

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. Control Copy Number "0": the version of the SOP with original signatures from which all other control copies are made. 5. Abbreviations/definitions are also provided in the text.
2. **Health and Safety**	None
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**	1. The QAU maintains an index of the SOPs and revision dates in the electronic MLB Master List, see section 14 (Forms and Data Sheets). 2. Appropriate quality control measures are integrated into each SOP. 3. Revise SOPs at least every three years.
7. **Interferences**	Promptly issue new or revised SOPs following approval by the Branch Chief.
8. **Non-conforming Data**	Procedures to handle non-conformances are consistent with SOP ADM-07, Non-conformance Reports.
9. **Data Management**	1. Archive SOPs consistent with SOP ADM-03, Records and Archives. 2. Archive control copy number "0" (copy zero) of the SOPs in the archive room D217 and electronically. 3. Do not confuse control copy number zero with the original version of the SOP which is numbered -00 as a suffix to the SOP number, e.g., ADM-01-00. The suffix -00 denotes the first version of the SOP, the next version being-01.
10. **Cautions**	1. Do not photocopy the SOPs. If a temporary copy is used (for training

	purposes, etc.), mark it "Verified Copy" and destroy it after use. 2. Make changes to the SOPs through the official revision process (see 12.6). Handwritten changes are not permitted.
11. **Special Apparatus and Materials**	None
12. **Procedure and Analysis**	Summary. Each SOP is written in the standard laboratory format (see sections 12.2 through 12.4); however, some SOPs are designated as *Test Methods Under Development* and follow a basic outline format and may not contain all the sections or criteria specified in 12.2-12.4. The following procedure describes the organization and format of all SOPs including their review, approval, distribution, and storage.
12.1 SOP Identification	a. The QAU tracks all SOPs in the MLB Master List (see section 14). b. SOPs are organized into groups according to subject area. The following acronyms 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 Test Methods Under Development c. The QAU assigns each SOP a unique number in the MLB Master List. The acronyms (e.g., ADM, MB, EQ) identify the category of the SOP. The middle two-digit number (00-99) is the SOP number in that group. The last two-digit number (00-99) is the revision number for that SOP. The revision marked "00" for each SOP is the original version of the SOP. The next revision takes the next sequential number (e.g., 01, 02, 03, etc.). An example of the identification format is presented below: ADM-01-01 (Group ID - SOP No. - Revision No.)
12.2 Title Page	a. Every SOP has a title page (page 1) which identifies the SOP as an OPP Microbiology Laboratory SOP and contains the SOP

	number, title, scope, and application. b. The title page also contains approval signature blocks for the following: SOP Developer, SOP Reviewer, Quality Assurance Unit and Branch Chief. Additional approval signature blocks (e.g., Safety, Health, and Environmental Manager) may be added as necessary. c. At the bottom of Title page are blocks for Date SOP Issued, Controlled Copy Number, and Date SOP Withdrawn. d. 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.
12.3 Page Identification	a. Number all pages of the SOP. b. The header on the top right corner of each page, including the title page (page 1), contains the following information: SOP No. (X)XX-XX-XX Date Revised XX-XX-XX Page XX of XX
12.4 SOP Content	SOPs contain the following sections using format listed below: a. The **Table of Contents** is the second page of the SOP. It lists the sections of the SOP with 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. Specify any required holding times. 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 known or potential 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 or potential interferences, the format shall read: Interferences: None i. **8. Non-conforming Data**: When a non-conformance (e.g., deviation, omission) is identified, it must be documented. An effort should be made to prevent recurrence of the non-conformance. Include the following statement: "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 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: "Archive data consistent with SOP ADM-03, Records and Archives." k. **10. Cautions**: This section identifies any known activities that may result in equipment damage or sample degradation, 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 no special apparatus or materials are specified, the format shall read:

Special Apparatus and Materials: None

m. **12. Procedure and Analysis**: Provides a step-by-step description of the operation.

i. If relevant to the topic of the SOP, add a statement at the end of the section on "Resource Management." For example:

"12.X Resource Management.

12.X.Y 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 in addition to appendices and attachments. Forms, data sheets, and attachments (supplemental information) are not page numbered and are stored separately from the SOP to facilitate changes without the need to re-issue the SOP. Appendices (details pertinent to the conduct of the SOP but not included in the body of the SOP) should be page numbered parts of the SOP. If no forms, data sheets, appendices, or attachments 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. 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 Development, Review, and Distribution	a. The analyst most familiar with the method or procedure serves as the lead author and develops the draft SOP. Once the draft SOP is available, the lead author submits the SOP for review by a technical reviewer (SOP Reviewer), and the QAU. Each reviewer is responsible for ensuring that the procedures are adequate and accurate based on their area of expertise. b. After review and comment by the SOP reviewer and the QAU, route the SOP to the Branch Chief for review. The lead author of the SOP incorporates all comments and issues a final copy for signatures/approval. The QAU issues the SOP following approval by the Branch Chief or designee (see section 12.2). c. Archive control copy number "0" in the archive room D217 and/or electronically. d. The QAU issues and distributes up to six copies of each SOP. Copy 1: Team Lead, Copy 2: Branch Chief, Copy 3: Conference room D wing, Copy 4: D wing, Copy 5: Lab copy, and Copy 6: QAU.
12.6	Revising Existing SOPs and Forms	a. Review and revise SOPs 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 the three-year cycle if a modification or change to the procedure is required. c. Revise the SOP as necessary, including the SOP identification number, creating a new version (section 12.1). d. Submit the revised SOP for review, approval, and issuance as per section 12.5. e. Forms are separate from the SOP. If a form is revised independently of the SOP, electronically archive the previous copy in a designated folder (by the year it was revised) and save with the date that it was retired in the file name.
12.7	Withdrawal and Re-instatement of SOPs	a. SOPs that are no longer in use (e.g., SOP for operation of equipment that has been removed from the laboratory and archived) are withdrawn by the QAU. Any SOP withdrawal must be approved by the Branch Chief or designee (see section 12.2). b. To officially withdraw an SOP version, the QAU should remove

	all controlled copies from circulation and revise the MLB Master List to reflect that the SOP is "obsolete". c. Move the electronic version of the withdrawn SOP to the archive folder of SOPs on the G drive. d. Archive the withdrawn SOP's electronic and/or controlled copy "0". Withdrawn SOPs can 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-02-08_F1.docx SOP Review Summary/Cover Sheet for QA SOPs — ADM-02-08_F2.docx MLB Master List — ADM-02-08_F3.xlsx
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. https://www.epa.gov/quality/guidance-preparing-standard-operating-procedures-epa-qag-6-march-2001