



US Environmental Protection Agency Office of Pesticide Programs

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

**Standard Operating Procedure for
OPP Microbiology Laboratory Personnel Training**

SOP Number: ADM-04-06

Date Revised: 03-18-21

SOP Number	ADM-04-06
Title	OPP Microbiology Laboratory Personnel Training
Revisions Made	<ul style="list-style-type: none">• Addition of New Employee Training Forms• After completion of the 24-hour laboratory safety training, new employees are provided with an introduction to basic laboratory processes. This information is documented on the New Employee Laboratory Training Form (see section 14). (Section 12.1)• In the absence of a group training, individuals should review the revised SOP and the summary of changes made to the previous version. (Section 12.2)• Minor editorial changes.

SOP Number	ADM-04-06
Title	OPP Microbiology Laboratory Personnel Training
Scope	This SOP describes the Microbiology Laboratory Branch (MLB) requirements for training for individuals working in the laboratory.
Application	The training requirements described in this SOP are applicable to all positions in the Microbiology Laboratory Branch.

	Approval	Date
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1. Definitions	<p>Additional abbreviations/definitions are provided in the text.</p> <ol style="list-style-type: none"> 1. EPA Good Laboratory Practices (GLP) = 40 CFR Part 160 2. Quality Assurance Unit (QAU) = Comprised of the Quality Assurance Officer (QAO), who serves as the quality manager for the laboratory and the alternate QAO. 3. Trainee = A staff member being trained on technical methods, equipment, and quality assurance practices as well as other required training. 4. Qualified Technical Trainer = Including SOP Lead Authors and Method Developers, a staff member qualified and competent to train others in microbiological methods and operation, maintenance, and calibration of equipment. 5. Quality Assurance Trainer = MLB staff member qualified, competent, and authorized by the Branch Chief in quality assurance practices and requirements of GLP and ISO-17025 international standards. The QAU provides training on GLP and ISO-17025 standards. 6. External Trainer = Equipment vendors (e.g., Vitek, confocal microscope) from an external organization may serve as trainers.
2. Health and Safety	<p>See details listed in specific SOPs.</p>
3. Personnel Qualifications and Training	<ol style="list-style-type: none"> 1. <u>Branch Chief or designee</u> has the overall responsibility to ensure that personnel are adequately trained for their assigned tasks, using current SOPs and other appropriate training materials (see ref. 15.3). 2. <u>Qualified Technical Trainers</u> provide training for SOPs, new techniques and quality assurance practices on an ongoing basis. Trainers must verify the competency of trainees and update the MLB training spreadsheet within 3-5 business days of training completion. A trainer must have the following: <ol style="list-style-type: none"> a. A complete and thorough understanding of the current SOP, hands-on experience with and a working knowledge of the procedure. b. The trainers are identified in the training spreadsheet by SOP. 3. <u>Trainees</u> must familiarize themselves with the relevant SOP(s) and associated procedures prior to receiving hands-on training in the laboratory. Document this step in the training spreadsheet.
4. Calibration	<p>Not applicable.</p>

5. Sample Handling and Storage	Not applicable.
6. Quality Control	<ol style="list-style-type: none"> 1. On a bi-annual basis, the QAU will verify and update the assigned list of qualified trainers. 2. The QAU will verify staff training periodically (e.g., quarterly) by reviewing the training spreadsheet and saving the (Pdf) file. 3. The QAU will review the status of the employee’s training prior to sign-off on study protocols. 4. Training using a draft SOP is permissible; inform the QAU of this action and note in the training spreadsheet.
7. Interferences	<ol style="list-style-type: none"> 1. Training using outdated (‘Obsolete’) SOPs will not be permitted.
8. Non-conforming Data	<ol style="list-style-type: none"> 1. Management of non-conformances will be consistent with SOP ADM-07, Non-Conformance Reports.
9. Data Management	<ol style="list-style-type: none"> 1. Training records are maintained and archived consistent with SOP ADM-03, Maintaining, Tracking and Archiving of Records. 2. Training is documented in the MLB training spreadsheet located on the shared drive. The MLB training spreadsheet is archived quarterly by the QAU. 3. Position descriptions, vendor training certificates, and group training records for all personnel are maintained in the current Personnel Training Record Book stored in the D corridor near room D206. 4. Training records for employees no longer working in MLB, are retired to an archived training binder in the file room (D217).
10. Cautions	Not applicable.
11. Special Apparatus and Materials	Not applicable.
12. Procedure and Analysis	
12.1 New Employee Training	<ol style="list-style-type: none"> a. New employees must complete the initial 24-hour laboratory safety training and provide the printout from the training modules to the ESC safety manager and the Branch Chief. b. New employees are provided with a comprehensive introduction to the EPA and the Microbiology Laboratory Branch, overview of administrative procedures, introduction to testing and laboratory equipment, a tour of the Environmental Science Center (ESC),

	<p>training on MB-01 (biosafety), and an overview of the Quality Assurance Unit, Good Laboratory Practice Standards, and ISO 17025 standard during the first several weeks of their employment. This information is documented on the New Employee: General Training Form (see section 14). Additionally, the lab biosafety officer, QA trainer and the trainee complete appropriate sections of the MLB Training spreadsheet.</p> <ul style="list-style-type: none"> c. The Branch Chief places a copy of the position description for the new employee in the training notebook. d. The employee reads the basic SOPs assigned and updates the training spreadsheet once the SOPs are read. e. After completion of the 24-hour laboratory safety training, new employees are provided with an introduction to basic laboratory processes. This information is documented on the New Employee: Laboratory Training Form (see section 14).
<p>12.2 Continuing Training for Employees</p>	<ul style="list-style-type: none"> a. Individuals participate in the 8-hour ESC annual safety refresher training. b. As SOPs are updated, group training sessions are held to review the changes to each SOP. The overview of the changes to the SOP are covered by the lead author or technical reviewer for the SOP. The employees update their records on the training spreadsheet within 5 business days of SOP overview completion. The training materials are archived in the training notebook. In the absence of a group training, individuals should review the revised SOP and the summary of changes made to the previous version. c. Based on assigned projects, individuals receive specialized technical training. d. Individuals attend training provided by vendors as necessary to perform their duties. The training is noted by the individual on the training spreadsheet. Certificates issued by the vendor are maintained in the training notebook.
<p>12.3 Technical, Method or Equipment Training</p>	<ul style="list-style-type: none"> a. Technical training for laboratory procedures encompass the following steps: <ul style="list-style-type: none"> i. The trainee reviews the SOP and applicable forms and documents that they are familiar with the SOP on the MLB training spreadsheet within 5 business days after completion. ii. The trainee observes in-lab demonstration of the procedure by a qualified technical trainer.

	<ul style="list-style-type: none"> iii. The trainee performs the procedure under the observation of a qualified technical trainer. Multiple observations may be necessary and finally, the trainee performs the procedure independently. iv. Trainee successfully completes the procedure and updates the “Completion of Training” field on the MLB Training Spreadsheet within 5 business days after completion. v. The trainee may be required to participate in proficiency testing as determined by management. See section 12.5.
<p>12.4 Quality Assurance Unit Training Requirements</p>	<ul style="list-style-type: none"> a. <u>Review of Agency Quality Documents</u>: The QAU must review the following required documents located at the EPA Quality website, as assigned by the OPP QA Director. EPA Quality website: https://www.epa.gov/quality/policies-and-procedures-about-quality-assurance-epa-organizations <ul style="list-style-type: none"> i. Overview of the EPA Quality System ii. Introduction to EPA Quality System Requirements iii. Introduction to Data Quality Assessment iv. EPA Quality Policy CIO 2106 b. <u>Review of Guidance Documents</u>: The QAU must review the following guidance documents available at the EPA Quality website, https://www.epa.gov/quality, as needed <ul style="list-style-type: none"> i. Quality Assurance Project Plans (QAPPs) ii. Quality Management Plans (QMP) iii. Standard Operating Procedures (SOPs). c. <u>Internal Auditor Training</u>: QAU should complete this training available through the EPA quality website upon serving as a member of the QAU. Continued ongoing training of the QAU through A2LA or other similar organizations is encouraged by management. The training for these modules will be tracked for individuals serving in the QAU on the training spreadsheet. EPA Quality training website: http://intranet.epa.gov/quality/training.html
<p>12.5 Proficiency Testing (PT)</p>	<ul style="list-style-type: none"> a. <u>Proficiency testing (PT)</u>: The laboratory uses internal PT program to determine the effectiveness of technical training of personnel. The QAU, in consultation with the branch chief, arranges targeted PT exercises per year to cover important technical aspects based on the

	<p>scope of accreditation for the ISO-17025 standard.</p> <ul style="list-style-type: none"> i. PT may be required prior to performance of certain tasks. ii. The results from the PT exercises are used to assess employees' additional training needs. iii. The successful completion of PT is noted in the MLB Training spreadsheet by individuals within 5 business days after completion (e.g., results are evaluated by the QAU). iv. If PT results are unsatisfactory, additional training will be conducted by a qualified trainer. 						
<p>12.6 Other Agency Training Requirements</p>	<ul style="list-style-type: none"> a. <u>Mandatory Agency training</u>: On an annual basis, several mandatory training sessions are required by the Agency for all employees (e.g. ethics, information security, environmental justice, confidential business, email records etc.). <ul style="list-style-type: none"> i. Training sessions are listed on the FedTalent portal for each employee and must be completed by all employees within the required time frames. ii. Upon completion of Agency required training, file the certificates in the current Personnel Training Record Book under employee's name. 						
<p>13. Data Analysis/ Calculations</p>	<p>None</p>						
<p>14. Forms and Data Sheets</p>	<p>1. Test Sheets. Test sheets are stored separately from the SOP under the following file names:</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 70%;">New Employee: General Training Form</td> <td>ADM-04-06_F1.docx</td> </tr> <tr> <td>New Employee: Laboratory Training Form</td> <td>ADM-04-06_F2.docx</td> </tr> <tr> <td>MLB Training Spreadsheet</td> <td>ADM-04-06_F3.xlsx</td> </tr> </table>	New Employee: General Training Form	ADM-04-06_F1.docx	New Employee: Laboratory Training Form	ADM-04-06_F2.docx	MLB Training Spreadsheet	ADM-04-06_F3.xlsx
New Employee: General Training Form	ADM-04-06_F1.docx						
New Employee: Laboratory Training Form	ADM-04-06_F2.docx						
MLB Training Spreadsheet	ADM-04-06_F3.xlsx						
<p>15. References</p>	<ul style="list-style-type: none"> 1. US EPA Good Laboratory Practice Standards, Title 40 Code of Federal Regulations (CFR) Part 160. 2. ISO/IEC: 17025 (2017): General Requirements for the Competence of Testing and Calibration Laboratories. 3. Quality Management Plan (QMP) for the Office of Pesticide Programs. and Appendix B-2 (QMP for Microbiology Laboratory Branch; 2020), US Environmental Protection Agency, Environmental Science Center, Fort Meade, MD. 						