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-04-04

Date Revised: 2-10-15

SOP Number	ADM-04-04
Title	OPP Microbiology Laboratory Personnel Training
Scope	This SOP describes the Microbiology Laboratory Branch (MLB) requirements for education, experience, and training of each employee in order to ensure that testing and other laboratory procedures are performed by qualified individuals.
Application	The training and authorization requirements described in this SOP are applicable to all positions in the Microbiology Laboratory.

	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Date SOP withdrawn:	

TABLE OF CONTENTS

1. Definitions	Additional abbreviations/definitions are provided in the text. 1. A2LA= American Association for Laboratory Accreditation 2. MLB= Microbiology Laboratory Branch 3. EPA Good Laboratory Practices (GLP)= 40 CFR Part 160 4. Quality Assurance Unit (QAU) = Comprised of the Quality Assurance Officer (QAO), who serves as the quality manager for the laboratory and the alternate QAO. 5. Trainee= A staff member being trained for technical methods, equipment use and calibration, and quality assurance practices and other required training. 6. Technical Trainer= A staff member who is considered qualified, competent and authorized by the Branch Chief and able to train others in microbiological methods and operation, maintenance and calibration of equipment. 7. Quality Assurance Trainer= MLB staff member who is considered qualified, competent and authorized by the Branch Chief in quality assurance practices and requirements of GLP and ISO-17025 international standards. 8. Special Trainer= Equipment vendors (e.g., Vitek, Confocal microscope) from an external organization may serve as trainers. Additionally, GLP and A2LA trainers may serve as trainers for GLP and ISO-17025 standards. 9. SOP Lead Author/Method Developer= MLB staff member who can serve in training capacity for other staff.
2. Health and Safety	None.
3. Personnel Qualifications and Training	1. Branch Chief assigns trainers for specific activities. 2. Update Trainer Qualification Forms for Technical or Quality Assurance activities (see section 14), as a staff member is authorized to be a trainer. 3. Equipment vendors may serve as trainers for specific equipment (e.g., Vitek, Leica) 4. Standard operating procedure/method developer may serve as a trainer for other staff members. As other staff members gain expertise in specific laboratory practices, they may serve as qualified trainers.
4. Calibration	Not applicable.

5. Sample Handling and Storage	Not applicable.
6. Quality Control	For quality control purposes, document the required information on the appropriate form(s) (see section 14).
7. Interferences	1. All training must be conducted by qualified trainers. 2. Qualified Trainers must be approved and authorized by Branch Chief to conduct training on a particular technical procedure, equipment, or quality assurance practice. 3. The trainer must ensure that the most current version of the SOP along with the appropriate forms are used when training.
8. Non-conforming Data	1. Management of non-conformances will be consistent with SOP ADM-07, Non-Conformance Reports.
9. Data Management	1. Training records are maintained and archived consistent with SOP ADM-03, Maintaining, Tracking and Archiving of Records. a. Training records for all current personnel are stored in a labeled binder in the D corridor near room D206. b. Training records, for employees no longer in MLB, are retired to an archived training binder in secure file cabinets in file room D217.
10. Cautions	None.
11. Special Apparatus and Materials	None.
12. Procedure and Analysis	1. Position descriptions are filed in the current Personnel Training Records Book. 2. All staff must undergo Good Laboratory Practices (see ref. 15.1) and ISO-17025 (General requirements for the competence of testing and calibration laboratories) training (see 15.5). 3. An employee should not perform any procedure or method until all applicable training has been completed and competency demonstrated. 4. Laboratory based training is required for all testing procedures, operation, calibration and maintenance of equipment, test related quality control activities, sample-log-in and chain-of-custody procedures. 5. Upon completion of training, file documentation for each employee in the Personnel Training Records Book.
12.1 Use of PT to	a. The laboratory uses internal Proficiency Testing (PT) to determine

	determine Effectiveness of Training	the effectiveness of technical training for personnel. PT may be required prior to performance of certain tasks. b. The laboratory QAU arranges PT exercises throughout the year to cover important technical areas. c. The successful completion of PT is noted in the Personnel Training Records Book. d. If PT provides non-conforming data, additional training is recommended for analysts and is conducted by a qualified trainer.
12.2	Qualifications of trainers	a. To train another employee on a technical procedure, equipment use and calibration, and MLB quality assurance requirements, a trainer must have the following: i. A complete and thorough understanding of the SOP and hands-on, working knowledge of the procedure and must be an approved trainer for the method. ii. A current sign-off as a Qualified Trainer in the Personnel Training Record Book (see 14.3) for the technical method or quality assurance requirements (see 14.4). iii. Branch Chief evaluates and approves individuals as Trainers for test procedures or QA activities based on their current/relevant experience. b. Company representatives (vendors e.g., Vitek) may serve as trainers for the use and operation of specialized equipment. c. In the process of developing new methods and SOPs, the lead author automatically serves as the trainer for other staff members.
12.3	Training Responsibilities	a. The Branch Chief has overall responsibility to ensure that the personnel in the Laboratory are adequately trained for their assigned tasks. The Branch Chief or his/her designee manages training requirements for employees to perform assays and other procedures using the laboratory's current SOPs and other appropriate training materials (see ref. 15.2). b. Upon hire, and as needed, the Branch Chief or his/her designee identifies and documents the training needs of each employee (see 14.1 for New Employee Training Checklist). c. Training for revised SOPs, new techniques and quality assurance is arranged on an ongoing basis by qualified trainers. d. Trainers must verify the competency of individuals they train and document this competency by initialing the trainee's Personnel

	Training Record Form (14.2), which is kept in the Personnel Training Record Book. e. Trainees must ensure that they understand the information being communicated to them. They are encouraged to ask questions about specific procedures. f. Signatures of the trainee in the "Training Complete" box on the Personnel Training Record Form (see 14.2) means the employee fully understands the procedure and can perform it independently without supervision. g. The trainer who signs the Personnel Training Record Form (see 14.2) of a trainee for a particular SOP/ procedure is responsible for verifying the competency of that person to perform the procedure. A trainee should request a sign off on an SOP when he/she is fully confident of the ability to perform the procedure without supervision.
12.4 Health and Safety	a. Analysts must complete an initial 24 hour laboratory safety training provided by the Safety Health and Environmental Manager (SHEM) and subsequently an 8 hour refresher course, every year thereafter, is required. b. If specific personal protective equipment, such as a respirator, is required, the analyst must be certified each year per SHEM requirements.
12.5 Training Requirements for New Employees	a. New employees receive a comprehensive introduction to the EPA and the Microbiology Laboratory Branch during the first several weeks of their employment. b. Qualified Trainers provide bio-safety, MLB quality assurance, GLP and ISO-17025 training to new employees. c. Complete the New Employee Training Checklist (see 14.1). The lab bio-safety officer, QA trainer, Branch Chief and trainee initial the New Employee Training Form and file it in the Personnel Training Record Book.
12.6 Training Requirements for Quality Assurance Officer	a. Review of Agency Quality Documents. The QAU must review the following documents found at the EPA Quality website: http://www.epa.gov/quality/internal.html. 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. Training and review of guidance documents available at the EPA Quality website: http://www.epa.gov/quality/train.html i. Quality Assurance Project Plans (QAPPs) ii. Quality Management Plans (QMP) iii. Standard Operating Procedures (SOPs). c. Quality Assurance Annual Reports and Workplan (QAARWP) Training. The QAU must be familiar with preparation of QAARWP, following Agency Guidelines for QAARWP reports. d. Internal Auditor: Training is available through the EPA quality website, http://www.epa.gov/quality/train.html, A2LA or other similar organization. The QAU must be authorized by the Branch Chief to serve as an auditor after successful completion of auditor training. e. GLP and ISO-17025 Training: MLB Quality Assurance Unit personnel must have GLP and ISO-17025 training (arranged internally or externally) in order to comply with the GLP and ISO-17025 standards. f. QAO and alternate QAO must be signed off as qualified trainers for QA activities, to train other laboratory personnel. g. QAO and alternate QAO must be proficient in the review of antimicrobial product efficacy reports (ATP), summary memoranda and review of data associated with microbiological research projects. h. Document QA Training for QAO (and alternate) in the Trainer Qualification Form/QA (see 14.4), and file in the Personnel Training Record Book including certificates (if available), related to training.
12.7 Technical Method or Equipment Training	a. Technical training for laboratory procedures encompasses the following steps: i. The trainee reads the SOP and other applicable documents. ii. The trainee observes demonstration of the procedure by a qualified trainer. iii. The trainee performs the procedure under observation by a qualified trainer as many times as necessary to become proficient.

	iv. Trainee successfully completes the procedure and signs the "Completion of Training" box on the Personnel Training Record Form (see 14.2). v. If necessary, the trainee may be required to perform a proficiency test as determined by laboratory management.
12.8 Assessment of Ongoing Training Needs	a. Observation of Procedure: Internal auditing is used to observe employees during testing and conduct of a procedure. b. Proficiency testing: Analysts participate in multiple proficiency testing exercises per year, the results from PT are used to assess employee needs for additional training. c. Familiarity with current versions of SOPs: Analysts are required to be familiar with current versions of SOPs. In addition, SOP revisions are discussed in a formal setting to ensure that each analyst is aware of new practices and procedures. i. When new or newly revised SOPs are issued, copies are issued and made available to all employees. ii. Each employee is required to participate in the SOP training for revised SOPs. A copy of the presentation, along with names of attendees, is maintained as documentation of training in the Personnel Training Record Book under yearly Group Training Records.
12.9 Verification of Competency and Authorization	a. The trainee and the trainer sign the Personnel Training Record Form (see 14.2) and forward it to the QAU and Branch Chief. Signatures of Branch Chief on the training form serve as authorization for the trainee to independently perform procedures.
12.10 Other Agency Requirements	a. Several on-line core training sessions are recommended by the agency for each employee on an annual basis, (e.g. ethics, information security, environmental justice, confidential business, email records etc.) b. These are listed on the e-skillport for each employee. c. Purchase card holder undertakes refresher training annually. d. The employee must take the required training within the specified time period, as directed. e. Upon completion of training, file the certificates in current Personnel Training Record Book under employee's name.
12.11 Documentation of Training and	a. When new protocols are launched, training records are reviewed by the QAU to ensure the analysts have valid training records for the

Records	methods listed in the protocol. b. All training records are filed in the current employees' Personnel Training Record Book. c. An electronic, quarterly Analyst Training List (see 14.5) is maintained by the QAU for each employee, which is updated each quarter during the fiscal year.
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: New employee training checklist — ADM-04-04_F1.docx Personnel Training Record Form — ADM-04-04_F2.docx Trainer Qualification Form: Technical — ADM-04-04_F3.docx Trainer Qualification Form: Quality Assurance — ADM-04-04_F4.docx Analyst Training List (Updated quarterly): — ADM-04-04_F5.docx
15. References	1. US EPA Good Laboratory Practice Standards, Title 40 Code of Federal Regulations (CFR) Part 160. 2. Quality Management Plan (QMP) for the Office of Pesticide Programs. (2015) and Appendix B-3 (QMP for Microbiology Laboratory Branch), US Environmental Protection Agency, Environmental Science Center, Fort Meade, MD. 3. Centers for Disease Control and Prevention and National Institutes of Health, 2007. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services. U.S. Government Printing Office, Washington, D.C. 4. U.S. Office of Personnel Management. Operating Manual for Qualification Standards for General Schedule Positions. OPM Publication No. HX 118. http://www.opm.gov/qualifications/index.asp. 5. ISO/IEC: 17025 (2005): General Requirements for the Competence of Testing and Calibration Laboratories.