



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

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

**Standard Operating Procedure for  
Quality Assurance Unit and its Functions**

**SOP Number: QA-01-04**

**Date Revised: 01-26-09**

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

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Initiated By: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

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Approved By: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

Print Name: \_\_\_\_\_  
Branch Chief

Effective Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

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1.0 SCOPE AND APPLICATION:

- 1.1 The purpose of this SOP is to describe the functions of the Quality Assurance Unit (QAU) for the Office of Pesticide Programs (OPP), Microbiology Laboratory Branch (MLB). The Quality Assurance Officer (QAO) and alternate QAO function as the QAU. The QAU shall function independently of personnel engaged in the direction and conduct of the laboratory procedures and studies.
- 1.2 The QAU ensures that all work conducted at the laboratory complies with the EPA Good Laboratory Practice Standards (GLPs), and adheres to guidance stipulated in the MLB Quality Management Plan, and the overall OPP Quality Management Plan.

2.0 DEFINITIONS:

- 2.1 Branch Chief = The Branch Chief for MLB has overall responsibility for management of the work, personnel, resources and administrative and programmatic functions for the Branch.
- 2.2 OPP DQA = The OPP DQA is the Office of Pesticide Programs' Director of Quality Assurance located at Potomac Yard 1. When the need arises, the QAU will consult with the DQA.
- 2.3 Senior Science Advisor = The Senior Science Advisor directs and administers laboratory programs related to homeland security including oversight on contract deliverables and may act for the Branch Chief during absence from the office.
- 2.4 Team Leader = The Team Leader provides oversight for the resource management and technical direction for the antimicrobial testing, method validations and general laboratory quality control procedures and may act for the Branch Chief during absence from the office.
- 2.5 GLP = Good Laboratory Practices (EPA GLPs are codified in 40 CFR Part 160).

3.0 HEALTH AND SAFETY: Not applicable

4.0 CAUTIONS: None

5.0 INTERFERENCES: None

6.0 PERSONNEL QUALIFICATIONS:

6.1 The QAO and alternate shall complete the Agency's basic quality assurance course "Introduction to EPA Quality Systems." Continuing education is recommended by participating in the EPA Annual National Conference on Managing Environmental Quality Systems, and by attending additional workshops or courses offered by Quality Staff of the EPA Office of Environmental Information or other organizations that may offer such training.

7.0 SPECIAL APPARATUS AND MATERIALS: None

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE: Not applicable

10.0 PROCEDURE AND ANALYSIS:

This section describes the various documents prepared and/or maintained by the Quality Assurance Unit (QAU) and associated activities.

10.1 Conformance to GLPs: The QAU ensures compliance of laboratory work with GLPs. Specific responsibilities of the QAU are included in Section 160.35 (Quality Assurance Unit) of 40 CFR, "Good Laboratory Practice Standards."

10.1.1 Master Schedule: The QAU maintains a copy of the Master Schedule of all studies conducted at the laboratory, indexed by test substance, and containing the test system, nature of study, date study was initiated, current status, identity of the sponsor, and name of the study director. The schedules of testing activities are developed by the Branch Chief in conjunction with the laboratory Team Leader and Senior Science Advisor. These schedules are used to develop auditing schedules. The QAU updates the Master Schedule regularly (see SOP QA-04) and archives quarterly printouts.

10.1.2 Training Records: The Laboratory maintains a current summary of training and experience for each individual involved in the supervision or conduct of a study. These files contain, but are not necessarily limited to, the following: curriculum vitae, job descriptions, training certifications, and courses and seminars taken.

- 10.1.3 Internal Audits: The QAU schedules and conducts internal audits for the MLB to ensure integrity of data and maintains written and properly signed records of each inspection.
  - 10.1.3.1 The QAU, in conjunction with the Branch Chief develops the audit schedule. The list reflects all audits of laboratory operations and methods to be performed during the year, using the Master Schedule, project plans, and other factors as a guide.
- 10.1.4 External Audits: The Branch Chief is responsible for the coordination of technical audits performed by external parties.
- 10.1.5 Audit of Records: Laboratory records and books are periodically audited. The Branch Chief is kept informed of the audit schedule.
- 10.1.6 Technical Systems Audit: The annual technical audit of general laboratory operations includes a review of the systems in place for quality assurance, sample handling, preparation, analyses and data reduction. The audits are based on current versions of SOPs followed in the Laboratory. Apparatus and supplies are reviewed for conformance to SOP specifications. A sampling of calculations is verified and documentation is examined for accuracy and completeness.
- 10.1.7 In- Progress Audits: The QAO has responsibility for study-in-progress audits at the Laboratory. The QAO may designate that certain audits be performed by other qualified QA/QC trained individuals, such as a contractor.
  - 10.1.7.1 At the initiation of an announced audit, appropriate personnel (Study Director, Team Leader or others) are contacted and the audit purpose is reviewed. The lead analyst provides any necessary assistance, such as making personnel available, locating records, etc. Unannounced audits may also be conducted.
  - 10.1.7.2 SOPs are used as the audit standard against which operations and procedures will be evaluated. A checklist may also be used as guidance during the audit of general laboratory operations. The QAO may probe related areas in depth, as necessary, to satisfy the objective of the audit.

- 10.1.7.3 During the audit, if applicable, previous corrective action plans are verified. Any problems which are likely to affect study integrity found during the course of an inspection are brought to the attention of the Study Director and management immediately.
  - 10.1.7.4 At the completion of the audit, all observations and findings are reported to the Branch Chief, Team Leader, Senior Science Advisor, Study Director and the analyst(s). The analysts are responsible for resolving the findings and initiating corrective action(s) within the suggested timeframe (see 10.1.8.10).
  - 10.1.7.5 The QAU determines that no deviations from approved protocols or SOP were made without proper authorization and documentation.
  - 10.1.7.6 The QAU reviews the final study report to ensure that each report accurately describes the methods and SOPs, and that the reported results accurately reflect the raw data.
- 10.1.8 Audit Reporting: The QAU periodically submits to management and Study Director written status reports on each study, noting any problems and the corrective actions taken. Audit reports are formatted and processed as described below.
- 10.1.8.1 Audit Identification - An audit report is identified with the following information;
    - Audit Title
    - Audit Number
    - Audit Date, and
    - Performed by.
- The audit number consists of the year and the sequential number of the audit performed that year. Research project audits have a prefix R, followed by the year and the sequential number of the audit performed that year. For example, the first ATP audit performed in the lab in Fiscal Year 2009 would be coded 2009-01 and first research audit of year 2009 would be coded R-2009-01

- 10.1.8.2 Objective - Short paragraph(s) that outlines the objectives of the audit.
- 10.1.8.3 Scope - A brief description of when the audit was performed, what phase of the study was inspected, what areas were reviewed and the names of key persons contacted.
- 10.1.8.4 Findings/Observations - Each finding or observation is listed. When used, a completed checklist may be included. The QAO determines that no deviations from approved protocols and SOPs were made without proper authorization and documentation.
- 10.1.8.5 Previous Audits Status - A short summary detailing the status of corrective action of previous audits.
- 10.1.8.6 Conclusions/Recommendations - covers an overall summary of the audit with recommendations for a time-frame for the corrective actions.
- 10.1.8.7 Checklists - Checklists that are used during the audit are to be completed and attached to the report.
- 10.1.8.8 Audit reports may be sent through electronic mail. Copies of audit reports are directed to the MLB Branch Chief, Team Leader, Senior Science Advisor and the analysts.
- 10.1.8.9 Audit reports shall be issued within 15 working days of the conclusion of the audit.
- 10.1.8.10 Responses to audits and schedules for completion of audit findings are due 30 days following the issuance of an audit report. Corrective actions must be completed within 60 days of issuance of the audit report. The Study Director/Team Leader is responsible for addressing each finding or observation. A reason for the noncompliance, as well as a plan for corrective action is required. If the QAO finds the plan of corrective action deficient, the QAO will discuss the situation with the Team Leader, Senior Science Advisor and/or the Branch Chief. If any unresolved issues remain, the QAO will raise them to the BEAD Associate

Director, who may discuss the issue with OPP Senior management and/or the OPP Quality Assurance Manager.

- 10.2 Quality Management Plan (QMP): The laboratory QMP is revised annually by the QAU. The QMP establishes the overarching principles of the laboratory quality system. All Agency organizational units governed by EPA Order shall document their quality system in a QMP. The QMP is a policy statement describing how an EPA organization shall comply with the requirements of the EPA Order.
- 10.3 Quality Assurance Annual Report and Workplan (QAARWP): Annually, the QAU prepares a QAARWP and provides a copy to the Office of Environmental Information (OEI) using a template provided by OEI.
- 10.4 Quality Assurance Project Plan(s) (QAPP): EPA policy requires that all work performed by or on behalf of the EPA including the collection of environmental data shall be implemented in accordance with an Agency approved QAPP. The QAPP defines and documents how specific data collection activities shall be planned, implemented, and assessed during life cycle of a particular project. The Microbiology Laboratory Branch currently maintains five separate QAPPs which cover the quality requirements associated with unique programs. The QAPPs are revised periodically to capture the latest changes in a specific program. The QAPPs are reviewed by QAU and approved by the Branch Chief.
- 10.5 Standard Operating Procedures: A standard operating procedure (SOP) is a document which provides step-by-step description of how a specific operation, method or procedure is performed. The laboratory has SOPs for administrative, chain of custody, quality control, equipment calibration and maintenance, microbiological methods for several programs including antimicrobial testing, biofilm, virology and plant incorporated protectant and homeland security programs. All major revisions of SOPs follow SOP ADM-02, Preparation of SOPs, which describes the procedure, organization, and format of SOPs as well as their revision, review, approval, and archiving process. The QAU retrieves outdated SOPs and issues the new versions for all official folders and archives official (Copy O) copies of all SOPs according to EPA's records retention schedule.
- 10.6 Study Protocols: The laboratory develops study protocols for antimicrobial product testing as well as for unique laboratory studies associated with homeland security and other research programs. The original signed copies of all Study Protocols and pdf copies of the original are maintained by the QAU.

- 10.7 Final Reports: The QAU reviews the final study reports to assure that the reported results accurately reflect raw data for the study. The QAU issues Quality Assurance Statement (QA statement) for each Antimicrobial Testing Program (ATP) report, which specifies the audit dates and the dates when the audit findings were reported to the management and the study director. The Study Director prepares and signs a statement that the study was either conducted in compliance with GLP or that certain deviations were made.
- 10.8 The QAO or alternate participate in the monthly meetings with the National Program Office and OPP Director of Quality Assurance.
- 11.0 DATA ANALYSIS/CALCULATIONS: None
- 12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:
- 12.1 Results of reviews of data and reports, findings from audits, and any other documentation of quality assurance activities, including quality assurance records required by GLPs, will be maintained according to SOP ADM-03, Records and Archives, and filed in the QAU's files located in Room D217, at the Environmental Science Center. These documents are subject to Agency's official records retention schedule.
- 13.0 QUALITY CONTROL/QUALITY ASSURANCE:
- 13.1 The OPP Microbiology Laboratory quality assurance issues are discussed and resolved with the Team Leader, Senior Science Advisor and Branch Chief, and if needed, with senior Divisional Management and the OPP QAM.
- 14.0 NONCONFORMANCE AND CORRECTIVE ACTION:
- 14.1 If the quality related issues cannot be resolved between the QAU and Branch Chief, the QAU can appeal directly to the Divisional Associate Director or OPP Director of Quality Assurance for resolution.
- 14.2 Based on audit findings, if needed, a reply from analysts/Study Director is expected within 30 working days of the audit report, and a schedule for completion of corrective actions must be prepared that would have all corrective actions scheduled for completion within 60 working days from the date of the audit report.

15.0 REFERENCES:

15.1 EPA Good Laboratory Practice Standards, 40 CFR Part 160.

15.2 Office of Pesticide Programs, Quality Management Plan (2008-09)

16.0 FORMS AND DATA SHEETS: None