

**United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Pesticide Data Program**

SOP No.: PDP-ADMIN-06B		Page 1 of 8
Title: Laboratory Quality Assurance Units (QAUs)		
Revision: 7	Replaces: 07/01/03	Effective: 10/01/04

1. Purpose:

To establish requirements for uniform quality assurance units (QAUs) within the laboratories participating in the USDA/AMS Pesticide Data Program (PDP).

2. Scope:

This standard operating procedure (SOP) shall be followed by all analytical laboratories conducting residue studies for PDP, including support laboratories conducting stability or other types of studies that may impact the program.

3. Outline of Procedure:

- 5.1 Description
- 5.2 Files and Records
- 5.3 Reports
- 5.4 Data Review and Transmission
- 5.5 Audits
- 5.6 Proficiency Testing (PT) Program
- 5.7 Deviation(s) from Plan and SOPs
- 5.8 QA SOPs
- 5.9 USDA and EPA Access to Records

4. References:

- PDP QA/Technical Meeting, May 7-9, 2003
 - QA Committee Meeting, May 19-21, 1998
 - QA Committee Meeting, July 9-11, 1996
 - USDA/AMS, EPA/OPP, EPA/OCM Meeting, Minutes, May 21, 1992
 - Jon McNeal, Branch Chief, USDA/AMS Technical Services, Communication to William Franks, Jr., May 8, 1991
 - U.S. EPA, Quality Assurance Unit, 40 CFR part 160.35, August 17, 1989
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5. Specific Procedures:

5.1 Description

- a. Each laboratory shall have a QAU which shall be responsible for monitoring PDP residue studies to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the plans and SOPs issued by USDA/AMS and by the laboratory, as well as all applicable Good Laboratory Practices (GLP) and ISO17025 regulations.
- b. The QAU shall be entirely separate from and independent of personnel engaged in the technical direction and conduct of the residue studies. The QAU shall report to non-technically involved laboratory management such as the Laboratory Director or the Administrative Manager. The Technical Program Manager is considered to be involved in the technical direction and conduct of the residue studies, and therefore, may not direct the QAU.
- c. The QAU may consist of one or more personnel of suitable qualifications.
- d. For those participants where there are two or more field facilities under a common administration there only needs to be a single QAU.
- e. The QAU shall conduct audits and maintain records appropriate to PDP residue studies.

5.2 Files and Records

- a. The QAU shall maintain a copy of the PDP annual, semi-annual, or quarterly plan including the schedule of samples, chemicals, and commodities to be tested.
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- b. The QAU shall assure that project status reports (e.g., progress on validation studies or annual SOP review) are prepared. The QAU shall maintain a copy of the report.
- c. A schedule of audits and audit report submissions shall be maintained. This shall include the dates audits were made, the dates findings were reported to management, the Administrative Manager, the Technical Program Manager, and the USDA/AMS Technical Director, and the response(s) including any corrective actions taken.
- d. The QAU shall maintain copies of all SOPs pertaining to PDP residue studies in which the laboratory is involved and for which the unit is responsible. The documents shall include as a minimum requirement: all USDA/AMS SOPs, all internal laboratory SOPs, analytical methods utilized for sample analysis, and any other documents required (in writing) to be maintained by USDA/AMS.
- e. The QAU may also maintain whatever documentation is deemed necessary to show compliance with USDA/AMS requirements (e.g., control charts).
- f. The QA documents shall be maintained in a secure manner with reasonable environmental protection from deterioration. The duration shall be in compliance with data archiving requirements of USDA/AMS and the individual laboratory records policy, whichever is more stringent. Refer to PDP-DATA-04.

5.3 Reports

The QAU shall prepare and submit to Manassas semi-annual updates based on calendar year summarizing QA issues. Updates shall be submitted within 30 days after the completion of the reporting period and should include the status of the following:

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- a. Progress on Validation of New Commodities and Analytes as Required by PDP (refer to PDP-QC-07 and PDP-QC-13, program plans, and current/proposed shipping charts)
- b. Problematic Recovery Trends and Corrective Action(s) Taken (refer to subsection 5.4.b of this SOP and PDP-QC-08)
- c. SOPs, New and Revised, titles and status specified (refer to subsections 5.8 and 5.9)
- d. Internal Audit Summary, including dates, areas audited, and unresolved issues.
- e. Internal PT Sample Results, where applicable
- f. PDP PT Samples, specification of any corrective actions taken based upon program PT results (refer to PDP-QC-03, subsection 5.3.b.3)
- g. Changes to Methodology (refer to PDP-QC-05)
- h. Staff Changes (refer to PDP-ADMIN-02, subsection 5.6.b.3)
- i. Miscellaneous QA Issues

5.4. Data Review and Transmission

- a. The QAU shall review all data packages as one of the final steps prior to submission to USDA/AMS. The QAU review shall be documented. See SOPs PDP-DATA-01 through PDP-DATA-06 for guidelines. Each laboratory shall, in an internal SOP, establish the proper procedures for data review which shall include the stipulation that after the QAU review of a data package, data may not be changed by any lab personnel unless as a response to comments/concerns/recommendations by the QAU.
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- b. The QAU shall notify the Technical Program Manager of any recurring data errors or problems, and recommend corrective action as necessary.

5.5 Audits

- a. The QAU shall audit the operations of each laboratory for which it has responsibility at intervals adequate to ensure the integrity of PDP residue studies. Each segment or phase of the PDP's laboratory operations shall be audited once per year.
- b. Written and properly signed records of each audit shall be maintained.
- c. The audit report shall be distributed to the Administrative Manager and Technical Program Manager.
- d. The audit reports shall be made available for inspection to authorized employees or duly designated representatives of USDA/AMS.

5.6 Proficiency Testing (PT) Program

The QAU shall review the USDA PT reports and submit comments on their laboratory's performance to the Administrative Manager, the Technical Program Manager, and the USDA/AMS PDP Technical Director. The comments shall include recommendations as necessary to improve performance.

5.7 Deviation(s) from Plan and SOPs

The QAU shall assure that any deviations from approved plans or SOPs were properly authorized and documented.

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5.8 QA SOPs

The responsibilities and procedures applicable to the QAU, the records maintained by the QAU, and the method of indexing such records shall be in writing and shall be maintained.

5.9 USDA and EPA Access to Records

An authorized employee or duly designated representative of USDA/AMS shall have access to the written procedures established per SOP PDP-ADMIN-07 and may request laboratory management to certify that laboratory SOPs are being implemented, performed, documented, and followed up in accordance with section 5.5 of that SOP.

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Gail Parker

9-22-04

Reviewed By: Gail Parker

Date

Presiding Member of PDP QA Committee

Florida Department of Agriculture and Consumer Services

Chemical Residue Laboratory

3125 Conner Boulevard, Building 3

Tallahassee, FL 32399-1650

(850) 410-3057

Diana Haynes

9-23-04

Approved By: Diana Haynes

Date

Technical Director, Monitoring Programs Office

8609 Sudley Road, Suite 206

Manassas, VA 20110

(703) 330-2300

Martha Lamont

9-23-04

Approved By: Martha Lamont

Date

Program Administrative Director, Monitoring Programs Office

8609 Sudley Road, Suite 206

Manassas, VA 20110

(703) 330-2300

