

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

SOP No.: PDP-ADMIN-06B		Page 1 of 6
Title: Laboratory Quality Assurance Units (QAUs)		
Revision: 10	Replaces: 07/01/07	Effective: 04/01/08

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 Reports
- 5.3 Data Review and Transmission
- 5.4 Audits
- 5.5 Deviation(s) from Plan and SOPs
- 5.6 QA SOPs
- 5.7 Proficiency Testing

4. References:

- USDA/AMS PDP Quality Assurance/Technical Meeting, February 26-28, 2008, Crystal City, VA
 - USDA/AMS PDP Quality Assurance/Technical Meeting, March 20-22, 2007, Crystal City, VA
 - USDA/AMS Combined Microbiological Data Program/PDP Technical-Quality Assurance Meeting, March 27-31, 2006, Richmond, VA
 - 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
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- 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

5. Specific Procedures:

5.1 Description

5.1.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.

5.1.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.

5.1.c The QAU may consist of one or more personnel of suitable qualifications.

5.1.d For those participants where there are two or more field facilities under a common administration there only needs to be a single QAU.

5.1.e The QAU shall conduct internal audits.

5.2 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:

5.2.a Progress on Validation of New Commodities and Analytes as Required by PDP (refer to PDP-QC-07 and PDP-QC-13, commodity-specific memos, program plans, and current/proposed shipping charts)

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5.2.b Summary of Corrective Action(s) Taken

5.2.c SOPs, New and Revised, titles and status specified

5.2.d Internal Audit Summary, including dates, areas audited, corrective actions, and unresolved issues.

5.2.e Internal PT Sample Results, where applicable

5.2.f Summary of PDP PT Samples

5.2.g Changes to Methodology (refer to PDP-QC-05)

5.2.h Staff Changes (refer to PDP-ADMIN-02, subsection 5.5.b.3)

5.2.i Quarterly two times the limit of quantitation spike results for all reported compounds (refer to PDP-QC-01, subsection 5.4)

5.2.j Reports on any current PDP projects not already covered above

5.2.k Miscellaneous QA Issues

5.3 Data Review and Transmission

5.3.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-07 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.

5.3.b The QAU shall notify the Technical Program Manager of review findings.

5.4 Audits

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5.4.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 every two years.

5.4.b Records of each audit shall be maintained. The records shall include the dates the audits were performed, the audit findings, and any corrective actions initiated.

5.4.c The audit report shall be distributed to the Administrative Manager and Technical Program Manager.

5.4.d The audit reports shall be made available for inspection to authorized employees or duly designated representatives of USDA/AMS.

5.5 Deviation(s) from Plan and SOPs

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

5.6 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.

5.7 Proficiency Testing (PT)

The QAO shall notify MPO (PDP Technical Director and assigned liaison chemist) of any corrective actions initiated (refer to SOP PDP-QC-04).

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4/1/08

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Revision 10

January 2008

Monitoring Programs Office

- Removed GLP and ISO references from Section 5.1.a
- Moved MPO files and records requirements to SOP PDP-ADMIN-06A
- Added commodity-specific memos to Section 5.2.a
- Added corrective actions to Section 5.2.d
- Removed reference to SOP PDP-ADMIN-03 from Section 5.2.f
- Added new Section 5.2.j and renamed remaining 5.2 sections
- Changed internal audit schedule from annual to biennial in Section 5.4.a
- Updated requirements for maintaining audit records in Section 5.4.b
- Specified MPO notification of unacceptable PT results and moved all other PT program requirements to SOP PDP-QC-04
- Moved USDA and EPA access to records requirements to SOP PDP-ADMIN-07

Revision 9

- Removed 21 CFR Part 11 requirement from section 5.2.f
- Changed semi-annual spike requirement to quarterly in section 5.3.i
- Changed data SOP reference in section 5.4.a

Revision 8

- Updated format to conform with other SOPs
- Added reference to 2006 Combined MDP/PDP Technical-Quality Assurance Meeting to subsection 4
- Replaced term “ISO regulations” with “ISO standards” in subsection 5.1.a
- Specified only current USDA/AMS SOPs be maintained by the QAU in subsection 5.2.d
- Specified QA documents may be retained in either hardcopy or electronic formats in subsection 5.2.f and if electronic formats are retained, the requirements in 21 CFR Part 11 must be met
- Deleted reference to SOP PDP-DATA-04 in subsection 5.2.f
- Changed reference to SOP PDP-QC-03 to SOP PDP-ADMIN-03 in subsection 5.3.f
- Corrected cross reference in subsection 5.3.h
- Added requirement that semi-annual 2x LOQ spike results be included in the Semi-Annual QA Report to subsection 5.3.i and renumbered remaining 5.3 subsections
- Included EPA access to written procedures in subsection 5.9

Revision 7

- Updated format to conform with other SOPs
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