

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

SOP No.: PDP-ADMIN-07		Page 1 of 7
Title: Standard Operating Procedures (SOPs)		
Revision: 7	Replaces: 04/01/07	Effective: 04/01/08

1. Purpose:

To provide uniform and standardized guidelines to all participants in the USDA/AMS Pesticide Data Program (PDP). These guidelines detail the components of a standard operating procedure (SOP) and the structure of the SOP system for PDP residue studies.

2. Scope:

This SOP shall be followed by USDA/AMS and all facilities involved in the collection of samples and performance of analytical determinations for PDP, including those laboratories which are conducting residue studies for PDP and support laboratories conducting stability or other types of studies which may impact the program.

3. Outline of Procedure:

- 5.1 Description of an SOP
- 5.2 Components of an SOP
- 5.3 USDA/AMS-PDP SOPs
- 5.4 State/Facility Internal SOPs

4. References:

- USDA/AMS PDP Quality Assurance/Technical Meeting, February 26-28, 2008, Crystal City, VA
 - USDA/AMS-PDP GLP Meeting, Minutes, April 27-29, 1992
 - Jon McNeal, Branch Chief, USDA/AMS-Technical Services, Communication to William Franks, Jr., May 8, 1991
 - Garfield, Quality Assurance Principles for Analytical Laboratories, Pg. 9, 1991
 - U.S. EPA SOP No. GLP-S-01, Preparation of Standard Operation Procedures, October 1, 1990
 - U.S. EPA, Standard Operating Procedures, 40 CFR part 160.81, August 17, 1989
 - Taylor, Quality Assurance of Chemical Measurements, pp. 85, 90, 113, 114, 173, 210, 223, 236, 261, and 262, 1989
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5. Specific Procedures:

5.1 Description of an SOP

5.1.a SOPs are written instructions on how to perform tasks and give instructions for procedures. The task or procedure is to be performed in an optimized and consistent manner as described by the document. The term “SOP” may be interpreted as any type of internal document (e.g., policy, work instructions, etc.).

5.1.b The SOPs are intended to assure consistency of data, quality, and procedures throughout the PDP residue studies.

5.1.c In addition, SOPs are utilized for audit or review purposes.

5.2 Components of an SOP

5.2.a This SOP serves as an example of the basic components to be included in the preparation of an SOP. There shall be a Purpose, Scope, Outline of Procedures, References (if any), the Specific Procedure(s), and signatures with dates. Sampling facilities shall be permitted to restructure the format of their internal SOPs if desired.

5.2.b The Specific Procedure(s) shall be written in precise and explicit terminology. Outline form is acceptable.

5.2.c USDA/AMS-PDP and participating laboratory SOPs shall be identified with an introduction (or header) box giving the SOP number, title, revision number, replacement identification, and effective date. Sampling SOPs need only be identified with a title, revision number, and effective date.

5.2.d Each laboratory shall have internal SOPs describing the formatting of their SOPs.

5.2.e The SOP is intended to provide consistency in the conduct of routine operations and to serve as a guide for the conduct of audits. It is not intended to replace experience and basic training but may be used as a training tool.

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5.2.f The SOP shall address each specific area of the topic it is intended to address. The SOP shall specifically identify the raw data to be generated as well as all other information required to prepare the end product of the topic of the SOP.

5.3 USDA/AMS-PDP SOPs

5.3.a USDA/AMS shall provide SOPs giving the requirements for common aspects of the program, and specific requirements as needed. These include SOPs in the areas of:

- 5.3.a.1** Administrative Procedures;
- 5.3.a.2** Sampling Procedures;
- 5.3.a.3** Laboratory Procedures
 - 5.3.a.3.a** Standards;
 - 5.3.a.3.b** Laboratory Operations;
 - 5.3.a.3.c** Data Handling;
 - 5.3.a.3.d** Instrumentation;
 - 5.3.a.3.e** Quality Control; and
- 5.3.a.4** Internal USDA/AMS Procedures

5.3.b All USDA/AMS SOPs shall be considered directive in principle, unless the SOP explicitly states that the SOP or a section of the SOP is suggestive in nature.

5.3.c USDA/AMS shall have immediately available manuals and SOPs relative to the laboratory or field procedures being performed. Published literature may be used as a supplement to SOPs.

5.3.d Each USDA/AMS administrative SOP, as well as USDA/AMS internal SOPs, shall be approved and signed by the USDA/AMS Program Administrative Director and the Technical Director. Each USDA/AMS sampling SOP shall be: prepared and signed by the author/revisionist; approved and signed by the Program Administrative Director and Technical Director; and reviewed and signed by the Presiding Member of the Sampling Advisory Group. Each USDA/AMS laboratory SOP, with the exception of the administrative series, shall be: prepared and signed by the author/revisionist; approved and signed by the Program Administrative Director and Technical Director; and reviewed and signed by the Presiding Member of the PDP Technical Advisory Group. Each internal laboratory SOP shall be: prepared and signed by the author/revisionist and approved and signed by the Program Administrative Director and Technical Director.

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5.3.e All USDA/AMS SOPs shall be revised as needed.

5.3.f An index of PDP SOPs shall be maintained and distributed along with any SOP revisions.

5.3.g Distribution of the SOPs, original and subsequent revisions, shall include the USDA/AMS Program Administrative Director, Technical Director, and Archives; participating facilities' Administrative Managers, Sampling and Technical Program Managers, and Quality Assurance Officers (QAOs); and all other applicable personnel.

5.3.h Each PDP sampling and laboratory participant shall maintain a copy of current USDA/AMS PDP SOPs and SOP index.

5.4 State/Facility Internal SOPs

Each participating State/Agency performing sample collection or laboratory analyses for PDP (hereafter "participant") shall prepare internal SOPs giving specific details of procedures utilized to comply with the USDA/AMS SOPs.

5.4.a The participant shall have SOPs in writing setting forth specific procedures and methods that management is satisfied are adequate to assure the quality and integrity of PDP sample data and/or analytical results data.

5.4.b Each participant shall have immediately available manuals and SOPs relative to the procedures being performed. Published literature may be used as a supplement to SOPs.

5.4.c Authorized employees or duly designated representatives of USDA/AMS shall have access to internal SOPs during laboratory and sampling reviews.

5.4.d Each internal SOP shall be approved and signed by at least two of the following senior managers: the QAO, the laboratory Administrative Manger or Technical Program Manager, the Sampling Manager, or Sampling Administrative Manager. The signature block for each approval shall contain the handwritten signature, the printed name, title, and date. Address and telephone number shall be included if the individual is not based at the laboratory.

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5.4.e Any deviation from a USDA/AMS SOP shall be authorized in writing by the USDA/AMS Technical Director. Participants shall maintain USDA/AMS authorization records and document deviations in their sampling and laboratory records.

5.4.f SOPs shall be revised as needed. Revisions shall be signed as stated in 5.4.d

5.4.g SOPs or additional information may be requested by USDA/AMS.

5.4.h Each participant shall maintain copies of current and historical internal SOPs as well as records of the dates they are (or were) in effect.

5.4.i Distribution of the internal SOPs, original and subsequent revisions, shall include each affected participant employee



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4/1/08

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Revision 7

January 2008

Monitoring Programs Office

- Changed title to ‘Standard Operating Procedures’
- Noted that SOPs may be interpreted as any type of internal documents in Section 5.1.a
- Specified each laboratory shall document SOP formatting requirements as part of an internal SOP in Section 5.2.d
- Deleted Section 5.2.e and renumbered remaining 5.2 sections
- Specified that MPO is responsible for reviewing and updating USDA/AMS SOPs as necessary in Section 5.3.e
- Specified that each sampling and laboratory participant maintain copies of current PDP SOPs in Section 5.3.h
- Combined Section 5.4, State/Facility Sampling Internal SOPs, and Section 5.5 State/Facility Laboratory Internal SOPs and renamed section as “State/Facility Internal SOPs”

Revision 6

- Modified format to conform with other SOPs
- Added procedures for internal and financial SOPs to subsection 5.3.d

Revision 5

- Modified format to conform with other SOPs
 - Updated subsections 5.3, 5.4, and 5.5 to conform with current Monitoring Programs Office organization
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