

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

SOP No.: PDP-QC-05		Page 1 of 4
Title: Approval Process for Method Modification		
Revision: 5	Replaces: 07/01/04	Effective: 07/01/06

1. Purpose:

To ensure a uniform procedure for modifying methodology used for the USDA/AMS Pesticide Data Program (PDP). In addition to ensure that PDP project management is aware of any changes in methodology.

2. Scope:

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

3. Outline of Procedures:

- 5.1 Validation of Modification
- 5.2 Local Approval
- 5.3 Program Administrative Director Notification

4. References:

- USDA/AMS PDP Quality Assurance – Technical Meeting, May 18-20, 2004
 - USDA/AMS PDP Quality Assurance Meeting, May 18-20, 1999
 - Good Laboratory Practice Standards, 40CFR160.81, 160.31, 160.33, 160.35, 160.63, 160.120, and 160.85.
 - Demonstration of Method Performance, USDA/AMS PDP-SOP "QC-07".
 - Performance Evaluation of Technical Personnel, USDA/AMS PDP SOP "QC-03".
 - Preparation of Standard Operating Procedures, USDA/AMS SOP "PDP-ADMIN-07".
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5. Specific Procedures:

This SOP represents minimum PDP requirements and is presented as a general guideline. Each laboratory shall have written procedures that provide specific details concerning how the procedure has been implemented in that laboratory.

5.1 Validation of Modification

5.1.a Any request for a significant modification (i.e., extraction or clean-up procedure, etc.) of an approved analytical method shall be submitted in writing to the Monitoring Programs Office (MPO).

5.1.b Any modifications of an approved analytical method shall be reviewed by QAU and approved by the Technical Program Manager.

5.1.c Proceed with method evaluation requirements as stated in PDP-QC-07.

5.2 Local Approval

5.2.a The request for analytical method modification shall be reviewed by QAU and approved by the Technical Program Manager.

5.2.b The written modification plus validation documentation shall be reviewed by QAU and approved by the Technical Program Manager.

5.3 Program Administrative Director Notification

5.3.a The written modification of the analytical method plus validation documentation and local approvals (as required by sections 5.1 and 5.2 above) shall be approved by the Administrative Manager and sent to the USDA/AMS Program Administrative Director through the USDA/AMS Technical Director, USDA/AMS PDP, 8609 Sudley Road, Manassas, VA 20110 (FAX (703) 369-0678).

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Revision 5 April 2006 Monitoring Programs Office

- Updated format to conform with other SOPs
- Added introductory paragraph to subsection 5
- Specified significant modifications to approved analytical methods by submitted to MPO in subsection 5.1.a and 5.3.a

Revision 4

- Updated reference in subsection 4
 - Updated MPO address in subsection 5.3.a
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