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1. <u>Purpose:</u>

To standardize administrative procedures for sampling and testing activities of the US Department of Agriculture (USDA) Pesticide Data Program (PDP).

2. <u>Scope:</u>

This standard operating procedure (SOP) shall be followed by the USDA Monitoring Programs Division (MPD) and all facilities involved in the collection of samples and performance of analytical determinations for PDP, including support laboratories conducting non-routine activities that may impact the program. This SOP does not supersede any requirements specified in the Cooperative Agreement between USDA and the participant.

3. <u>Outline of Procedure:</u>

- 5. <u>Facilities</u>
- 5.1 Facilities for Handling Test, Control, and Reference Substances
- 5.2 Specimen and Data Storage Facilities
- 5.3 Inspection of Facilities
- 5.4 Data and Records Retention Periods
- 5.5 Records Archival Procedure
- 6. <u>Personnel and Organization</u>
- 6.1 Personnel Requirements
- 6.2 USDA/AMS Responsibilities
- 6.3 PDP Program Administrative Director
- 6.4 PDP Technical Director
- 6.5 Responsibilities of Participants
- 6.6 State/Facility Administrative Manager
- 6.7 State/Facility Sampling Manager
- 6.8 State/Facility Technical Program Manager (TPM)
- 6.9 State/Facility Quality Assurance Unit (QAU)
- 7. Purchases, Inventory, and Salvage Procedures
- 7.1 Purchases
- 7.2 Equipment Inventory

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- 7.3 Permission to Salvage, Dispose of Equipment, or Trade In
- 7.4 Forms Instructions
- 8. <u>PDP Quality Assurance Program</u>
- 8.1 Overview
- 8.2 Files and Records
- 8.3 SOPs
- 8.4 Method Validation
- 8.5 Proficiency Testing (PT) Program
- 8.6 Technical Advisory Group (TAG)
- 8.7 Records Archival
- 9. <u>Standard Operating Procedures</u>
- 9.1 Description of an SOP
- 9.2 Components of an SOP
- 9.3 USDA/AMS SOPs
- 9.4 State/Facility Internal SOPs
- 9.5 SOP Deviations
- Attachment 1. PDP Designated Federal Records Centers
- Attachment 2. Standard Form SF-135 Template
- Attachment 3. Example SF-135 for Routine Data Packages
- Attachment 4. Example SF-135 for Method Validation Data Packages
- Attachment 5. Example SF-135 for Supporting Documentation
- Attachment 6. Example SF-135 for Sampling Documentation
- Attachment 7. Instructions for Assembly and Packaging of Record Boxes
- Attachment 8. Form GSA-49, Requisition/Procurement Request for Equipment Supplies or Services
- Attachment 9. Equipment Inventory
- Attachment 10. Form AD-112, Report of Unserviceable, Lost, Stolen, Damaged or Destroyed Property
- Attachment 11. Form AD-107, Report of Transfer or Other Disposition or Construction of Property

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4. <u>References:</u>

- U.S. Environmental Protection Agency (EPA), *Inspection of a Testing Facility*, 40 CFR part 160.15
- U.S. EPA, *Personnel*, 40 CFR part 160.29
- U.S. EPA, Testing Facility Management, 40 CFR part 160.31
- U.S. EPA, Study Director, 40 CFR part 160.33
- U.S. EPA, Quality Assurance Unit, 40 CFR part 160.35
- U.S. EPA, Facilities for Handling Test, Control, and Reference Substances, 40 CFR part 160.47
- U.S. EPA, Laboratory Operation Areas, U.S. EPA, 40 CFR part 160.49
- U.S. EPA, Specimen and Data Storage Facilities, 40 CFR part 160.51
- U.S. EPA, Equipment Design, 40 CFR, part 160.61
- U.S. EPA, Standard Operating Procedures, 40 CFR part 160.81
- USDA, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, 7 CFR, part 3016
- USDA, Equipment Management Requirements, 7 CFR, part 3015.169
- U.S. EPA, Determining Compliance of Audited Studies with GLP Standards Requirements, SOP GLP-02
- U.S. EPA, Preparation of Standard Operation Procedures, SOP GLP-S-01
- Garfield, F.M., Klesta, E., Hirsch, J., Quality Assurance Principles for Analytical Laboratories, pg. 9, 1991
- Taylor, J.K., *Quality Assurance of Chemical Measurements*, pp. 85, 90, 113, 114, 173, 210, 223, 236, 261, and 262, 1989
- US Department of Health and Human Services, Center for Disease Control and Prevention (CDC), and National Institute of Health (NIH), *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed., US GPO, 2007
- U.S. EPA, *Good Laboratory Practices for Commodity Laboratory Analyses*, 7 CFR Subchapter E, Subpart C, Section 90.3.
- U.S. EPA, Storage and retrieval of records and data, 40 CFR 160.190
- U.S. National Archives and Records Administration (NARA, *Unscheduled Records FAQS*, <u>http://www.archives.gov/frc/unscheduled-records-faqs.html</u>
- U.S. National Archives and Records Administration (NARA, *Records Transmittal and Receipt, SF-135, instructions*, <u>http://www.archives.gov/frc/forms/sf-135-intro.html</u>

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• AOAC International, Guidelines for Laboratories performing Microbiological and Chemical Analyses of Food and Pharmaceuticals, An Aid to Interpretation of ISO/IEC 17025:2005 (Rev March 2010), Section: General requirements for the competence of testing and calibration laboratories.

5. <u>Facilities</u>

5.1 Facilities for Handling Test, Control, and Reference Substances

Adequate space shall be provided for conducting sampling and analytical laboratory work performed for PDP. Space shall be as needed to prevent contamination or mix-ups of samples, reference materials, and other work in place in the facility.

5.2 Specimen and Data Storage Facilities

5.2.1 Adequate space shall be provided for the storage and retrieval of all samples, for raw data including archived data and for the analysis of samples to ensure integrity and prevent the possibility of contamination and cross-contamination. Access to this space shall be limited to authorized personnel.

5.2.2 Each participating laboratory shall maintain a site-specific record system to suit its particular circumstances, which assures orderly storage and expedient retrieval of data and other records.

5.2.3 Physical and environmental conditions of storage shall minimize deterioration of the documents in accordance with the requirements for the time period of their retention and the nature of the documents.

5.2.4 Where computers or automated equipment are used for the storage or retrieval of data, the laboratory shall ensure that:

• Computer software is documented, adequate for use and is run periodically to verify correct operation. Computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain data integrity; and

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• Appropriate procedures are established and implemented for protecting the integrity of data (such procedures shall include but not be limited to integrity of data entry or capture and data storage) and for the maintenance of security of data including the prevention of unauthorized access or amendment of electronic records.

5.3 Inspection of Facilities

5.3.1 A sampling or laboratory facility shall permit an authorized employee or duly designated representative of USDA/Agricultural Marketing Services (AMS), at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the areas of records to copy) all records and samples required to be maintained regarding PDP operations.

5.3.2 USDA/AMS shall communicate any serious deficiencies identified during the facility inspection in a memo format within 10 days. Additionally, USDA/AMS shall provide a draft, written report for the sampling or laboratory facility's comments. A final report incorporating any comments received shall be issued within 60 days of the last day of the review.

5.3.3 When the review results in adverse findings, the sampling or laboratory facility shall provide a written response to the USDA/AMS report, outlining plans to correct any adverse findings within 60 days of receipt of the report.

5.4 Data and Records Retention Periods

5.4.1 Monitoring Programs Division (10 years)

- General information relating to USDA/AMS PDP correspondence,
- SOPs,
- protocols,
- semi-annual program plans,
- annual and/or semi-annual Federal/State meeting minutes and/or presentations,
- sampling plans,
- sampling site information,
- semi-annual State Meeting minutes,
- interim and final reports,

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- data interpretations, and
- other significant program-unique information.

5.4.2 States and Laboratories

5.4.2.1 25 years

- PDP sample data packages
- PDP method validation data packages
- PDP proficiency testing data packages

5.4.2.2 5 years

Supporting data generated by PDP Federal/State laboratories including, but not limited to:

- historical internal SOPs and work instruction documents,
- logbooks (e.g. standard preparation, instrument, freezer, temperature, etc.),
- chromatograms generated during standards checking,
- sample worksheets (e.g., homogenization, extraction, etc.) not specific to individual sample sets,
- correspondences and other documents relating to interpretation and evaluation of data,
- corrective actions,
- deviation letters,
- method development studies other than official PDP method validation packages,
- control charts, etc.

5.4.2.3 2 years

Supporting data and records for PDP sampling including, but not limited to:

- historical internal SOPs,
- sampling plans,
- site information,
- commodity payment records,
- surplus commodity disposition records,

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• raw Sample Information Form data sheets, etc.

5.4.3 Data Transfer

5.4.3.1 The minimum on-site retention for items in 5.4.2 above is 2 years after which they may be transferred to a designated federal records center (FRC) per section 5.5 below or, if longer retention is not stipulated, destroyed according to applicable internal records destruction procedures.

5.4.3.2 USDA/AMS shall be contacted if a laboratory wishes to transfer records within a timeframe shorter than 2 years.

5.5 Records Archival Procedure

5.5.1 Data Archival at the Participating Laboratory

5.5.1.1 An individual(s) shall be identified as the archivist for the laboratory.

5.5.1.2 Access to archived records shall be monitored and controlled. Use of manual or electronic logs is recommended.

5.5.1.3 Physical and environmental conditions of storage shall minimize deterioration of the documents in accordance with the requirements for the time period of retention and the nature of the documents. Locked file cabinets, temperature-controlled and/or secured records storage facilities, etc. are acceptable.

5.5.1.4 Each data package retained shall be filed by calendar year and month.

5.5.2 Transferring Records to the Federal Records Centers

5.5.2.1 Dispose of all extra copies of records, non-record material (e.g., buckslips, post-it notes, etc.), and metal items (e.g., paperclips, binder clips, etc.) in accordance with individual laboratory security policies. The use of accordion folders is suggested. Binders with non-metal parts (e.g., plastic combs/spirals, 3-ring "Tuffy" mechanisms, etc.) are also acceptable.

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5.5.2.2 Sample data packages representing a single calendar year must be transferred separately from other calendar years (i.e., utilizing a different transfer number). Within each calendar year, the data packages shall be filed by month and commodity. Supporting documentation must be archived separately by time span and subject (e.g., 2007-2009 Temperature Logs, 2006-2009 Administrative Documents, etc.) at the discretion of the laboratory.

5.5.2.3 PDP method validation sets and proficiency testing sample sets may be transferred concurrently with sample data packets from the same calendar year or they may be transferred separately at a later date.

5.5.2.4 All transfers must be requested electronically using the SF-135 fillable form (*Attachment 2*, Standard Form SF-135, Fillable Template) through the USDA/ AMS NARA liaison.

5.5.2.5 Examples of the required information on the SF-135 form for various records are provided. Records Transmittal and Receipt (refer to *Attachment 2* for form template, *Attachment 3* as an example for routine data, *Attachment 4* as an example for method validation data, *Attachment 5* as an example for supporting documentation and *Attachment 6* as an example for sampling documentation). **Note:** An Adobe Acrobat fillable form SF-135 is available on the internet at Federal Records Centers — Records Retrieval Services, Records Transmittal and Receipt, SF-135 (http://www.archives.gov/frc/forms/sf-135-intro.html).

5.5.2.6 Use only FRC boxes when transferring records. Boxes may be obtained by contacting USDA/AMS. Refer to *Attachment* 7 for illustrated box assembly and packing instructions.

5.5.2.7 When packing records, do not force files into the boxes. Leave approximately one inch of space in each box to permit easy withdrawal of folders. Pack folders upright, with letter size folders facing the front of the container. Do not place folders one on top of another.

5.5.2.8 Number the cartons sequentially (e.g., 1/10, 2/10, 3/10, etc.) with permanent black marker in the upper right front corner. The box numbers shall correspond to the completed SF-135.

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5.5.2.9 USDA/AMS will submit the SF-135 to the FRC for approval and assignment of the transfer number. Once the transfer number is received by USDA/AMS, a hard copy of the SF-135 will be generated and sent back to the transferring laboratory. Upon receipt of the approved SF-135, the transfer number shall be placed in the upper left front of the carton. All transfers must be forwarded to the FRC within 90 days of the assignment of a transfer number. If the FRC does not receive the records during the allotted time period, the transfer number becomes null and void. Include the date of disposal on the approved SF-135 on the outside of each box.

5.5.2.10 Place the approved SF-135 and box listing inside the first box of the transfer.

5.5.2.11 Close all boxes and seal with filament tape. Ensure that the filament tape does not cover the transfer number or the carton number.

5.5.2.12 Ship all boxes to the appropriate designated FRC using the most economical and secure carrier (e.g., Certified US Mail 3rd Class or equivalent). All expenses incurred in transferring records must be charged to the laboratory's PDP allocated funds. The records will be retained by the FRC and will be available for retrieval during the specified storage time through the USDA/AMS NARA liaison.

6. <u>Personnel and Organization</u>

6.1 **Personnel Requirements**

Employee Qualifications

Each individual responsible for the supervision of or engaged in the conduct of the sample collection process or laboratory analyses for PDP shall have the education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

Note: the term "each individual" includes temporary and part-time workers as well as aides and others who participate in PDP-related activities.

6.1.2 Employee Records shall be kept current and shall include:

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- Information to support that the individual meets at least the minimum standards for the position which they hold.
- Information pertaining to training, competency, and authorization to perform activities. The records for laboratory personnel shall reflect whether an analyst's proficiency is individual or as part of a team.
- Publications and articles authored as well as participation in professional societies should be included in the records.

Note: Each participating State/facility stipulates the specific information required (e.g., resumes, CV, employment applications, job descriptions, etc.).

6.1.3 Technical Personnel Performance Evaluation

Each laboratory shall document the procedures for individual performance evaluation in an internal SOP. Suggestions for performance evaluation include:

- Proficiency test (PT) results
- Control charting of process controls and fortification spikes. Acceptance criteria for recoveries and coefficient of variation are outlined in PDP-QC.
- Internal blind check samples prepared by the QAU and fortified with PDP pesticides varying between 1xLOQ and 10xLOQ. Acceptance criteria for recoveries and coefficient of variation are outlined in PDP-QC.

6.2 USDA/AMS Responsibilities

6.2.1 USDA/AMS has named the MPD Director as the PDP Program Administrative Director in charge of Financial and Administrative Affairs. See the appropriate section of this SOP.

6.2.2 The MPD Deputy Director has been designated as the PDP Technical Director. Technical program reports shall be made to the Technical Director at USDA/AMS, S&T, MPD, 1400 Independence Avenue, SW, Room 0601, Washington, DC 20250, (telephone (202) 572-8177 or FAX (202) 619-1724) (*see the appropriate section of this SOP*).

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6.2.3 USDA/AMS management shall:

- Replace the Program Administrative Director or the Technical Director promptly if it becomes necessary to do so during the conduct of the PDP studies.
- Ensure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.
- Ensure that personnel clearly understand the functions they are to perform.
- Ensure any PDP-related records (e.g., sampling, laboratory, equipment, financial, etc.) are available for inspection by authorized employees or duly designated representatives of USDA/AMS.

6.3 PDP Program Administrative Director

USDA/AMS shall identify a scientist or other professional of appropriate education, training, and experience, or combination thereof, as the Program Administrative Director for PDP. The Program Administrative Director has the overall administrative responsibility for program expansion, budgeting, cooperative agreements, memoranda of understanding, and major disbursement of funds. The Program Administrative Director shall:

6.3.1 Appoint and supervise a qualified individual to be responsible for and fulfill the duties of Technical Director.

6.3.2 Inform the Deputy Administrator for USDA/AMS, Science and Technology, on financial and administrative affairs, as necessary.

6.3.3 Prepare and submit annual budgets for the administration of PDP at the national level.

6.3.4 Negotiate work contracts in cooperation with the States and/or other Federal agencies, after consultation with the Technical Director on the Statement of Work.

6.3.5 Monitor through appropriate documentation the States' and/or Federal facilities' use of Federal funds.

6.3.6 Serve as liaison to CDC, EPA, U.S. Food and Drug Administration (FDA), and other USDA agencies participating in PDP.

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6.4 PDP Technical Director

USDA/AMS shall identify a scientist of appropriate education, training, and experience, or combination thereof, as the Technical Director for PDP. The Technical Director shall:

6.4.1 Serve as the major point of program control with responsibility for the sampling and technical conduct of the PDP studies.

6.4.2 Be responsible for overall monitoring of quality assurance of sampling, technical, and database operations to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with USDA/AMS program plans and SOPs.

6.4.3 Ensure that data are reported in an annual program summary. This includes the interpretation, analysis, documentation, and reporting of results.

6.4.4 Inform the Deputy Administrator for USDA/AMS, Science and Technology, and the Program Administrative Director on PDP sampling, laboratory, and database issues, as necessary.

6.4.5 Serve as an additional liaison to CDC, EPA, FDA, and other USDA agencies participating in PDP.

6.4.6 Consult with the Program Administrative Director on the Statement of Work during contract negotiations.

6.4.7 Ensure that:

6.4.7.1 The program plans and PDP SOPs, including any changes, are approved and followed.

6.4.7.2 All sampling information and experimental data are accurately recorded and verified.

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6.4.7.3 Unforeseen circumstances that may affect the quality and integrity of PDP samples and/or studies are documented as they occur, and corrective actions are taken and documented, as necessary.

6.4.7.4 PDP sampling procedures and test systems are as specified in the program plans and SOPs. This shall be accomplished through conference calls, reviews, and frequent communications with participants.

6.4.7.5 Reviews of participant sampling and laboratory facilities are performed at intervals adequate to ensure the integrity of PDP samples and analytical results and written records of each review are maintained. The frequency of reviews for a particular participant shall be based on two factors:

- Time elapsed since the last review, and/or
- Designated need due to problems associated with the collection or analysis of samples performed by that participant. Participant Administrative Managers shall be notified and final arrangements shall be made at least two weeks in advance of the review, if at all possible.

For sampling reviews, the review report is distributed to:

- The participant's Administrative Manager, supervisor of the Sampling Manager, and Sampling Manager;
- The USDA/AMS Administrative Director and Technical Director; and
- AMS Compliance and Analysis Programs.

For laboratory reviews, the review report is distributed to:

- The participant's Administrative Manager, Technical Program Manager (TPM), and Quality Assurance Officer (QAO);
- The USDA/AMS Administrative Director and Technical Director; and
- AMS Compliance and Analysis Programs.

6.4.7.6 All raw data and supporting laboratory records are stored, retained, and transferred to the archives during or at the close of PDP.

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6.5 **Responsibilities of Participants**

6.5.1 Each participant laboratory shall designate an Administrative Manager. Each sample collection participant shall designate a Sampling Manager. Each laboratory participant shall designate a TPM and a QAO. See the appropriate sections of this SOP.

6.5.2 The participant management shall:

6.5.2.1 Replace the Administrative Manager, Sampling Manager, QAO, or the TPM promptly if it becomes necessary to do so during the conduct of the PDP testing.

6.5.2.2 Ensure that there is a Quality Assurance Unit (QAU) as described in this SOP.

6.5.2.3 Ensure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

6.5.2.4 Ensure that personnel clearly understand the functions they are to perform.

6.5.2.5 Ensure that laboratory activities are conducted in compliance with applicable Federal, State, and local safety and waste disposal codes/requirements. Laboratories shall also comply with applicable Chemical Hygiene Plan (CHP), biosafety manual, Injury and Illness Prevention Programs, Employee Right-To-Know Programs, etc., and have Material Safety Data Sheets (MSDS) and/or Safety Data Sheets (SDS) available to all applicable personnel.

6.5.2.6 Ensure that any unauthorized deviations from the PDP SOPs, program policies, and approved analytical methodologies as reported by the QAU are communicated to the USDA/AMS Technical Director and that corrective actions are taken and documented.

6.5.2.7 Ensure an accurate and timely inventory of supplies and equipment purchased or utilized for PDP is maintained. See section 7.2 and Attachment 9.

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6.5.2.8 Ensure any PDP-related records (e.g., sampling, laboratory, equipment, financial, personnel, etc.) are available for inspection per section 5.3 by authorized employees or duly designated representatives of USDA/AMS.

6.5.2.9 Provide the name and position for all administrative, sampling, and technical personnel associated with PDP-related activities annually, at the beginning of the Federal fiscal year (October 1). An update shall be submitted to USDA/AMS within 30 days of any staff changes that may affect sample collection and/or data delivery.

6.5.2.10 Inform USDA/AMS of any critical personnel vacancies, staffing issues, expected increases in rent (due to laboratory or office renovation/relocation, etc.), sampling issues, and technical issues.

6.6 State/Facility Administrative Manager

Each participating laboratory shall identify a scientist or other professional of appropriate education, training, and experience, or combination thereof, as the Administrative Manager for PDP. The Administrative Manager has overall administrative responsibility for their organization's participation in PDP. This would include but not be limited to PDP activities such as: sampling operations, laboratory management, budgeting, contracting, purchasing, inventory maintenance, and receipt of QA reports and associated corrective actions. The State/facility Administrative Manager shall:

6.6.1 Prepare and maintain annual budgets for PDP contract administration. For States/Facilities where budget functions are managed by person(s) other than the assigned Administrative Manager, a description of how laboratory costs are calculated (number of FTEs including salary and benefits, supplies, rent, utilities, etc.) shall be provided to the PDP Program Administrative Manager when requesting funding to cover program operations.

6.6.2 In cooperation with USDA/AMS prepare and negotiate work contracts for PDP.

6.6.3 Maintain appropriate accounting records to document the State/facility use of federal contract funding.

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6.6.4 Maintain appropriate performance records to document State/facility performance and productivity on PDP studies (e.g., records of samples analyzed).

6.7 State/Facility Sampling Manager

Each sample collection participant shall identify a professional of appropriate education, training, and experience, or combination thereof, as the Sampling Manager for PDP. The Sampling Manager is responsible for the conduct of the participant's sampling procedures. The Sampling Manager shall ensure that:

6.7.1 The PDP program plan and USDA/AMS Sampling SOPs, including any changes, are followed. Any problems regarding compliance with the program plan or Sampling SOPs shall be communicated immediately to the PDP Technical Director or designee.

6.7.2 The participant sampling plan and internal sampling SOPs, including any changes, are followed. Participant internal sampling SOPs document specific procedures utilized by the facility in collecting and shipping PDP samples. These SOPs are intended to augment the USDA/AMS SOPs, by providing state-specific instructions.

6.7.3 All required sampling information is accurately recorded and verified, including unforeseen circumstances that may affect the quality and integrity of PDP samples and when corrective actions were taken and documented, as necessary.

6.7.4 Internal reviews of the procedures utilized by the sample collectors are performed at intervals adequate to ensure the integrity of PDP samples. The timeframe for performing internal reviews shall vary among participants based on the number of collectors to be reviewed. Each collector should be reviewed once before repeating the process. An exception would be if a number of problems are determined to be the result of a particular collector's negligence or failure to comply with the program SOPs.

6.7.5 Records of each review are maintained. Each review report shall show:

- The date of the review,
- The name(s) and title(s) of the person(s) performing the review
- Observations, findings and problems, recommendations and suggested corrective actions.

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6.7.6 Group/individual training sessions are held periodically for the sample collectors. This is especially important if there are major program changes, or a number of sampling problems have been reported by either the PDP Technical Director or the applicable analytical laboratory(ies).

6.7.7 Any other documents required in the PDP Sampling SOPs shall be kept on file and updated as necessary (e.g., master site lists, FTE information, volume weighting information for collection sites, donation receipts, etc.).

6.7.8 All PDP supporting records for sampling activities are stored, retained, and transferred to the archives as specified in Sections 5.4 and 5.5.

6.8 State/Facility Technical Program Manager (TPM)

Each participating laboratory shall identify a scientist or other professional of appropriate education, training, and experience, or combination thereof, as the TPM for PDP. The TPM has overall responsibility for the technical conduct of the PDP testing contracted to the laboratory, as well as for the interpretation, analysis, documentation, and reporting of results. The TPM shall ensure that:

6.8.1 The PDP plan and all USDA/AMS SOPs, including any changes, are followed. Any problems regarding compliance with the program plan or SOPs shall be communicated immediately to the PDP Technical Director or designee.

6.8.2 The laboratory plan, internal SOPs, and analytical methodologies, including any approved changes and/or deviations, are followed.

6.8.3 All experimental data are accurately recorded and verified, including unforeseen circumstances that may affect the quality and integrity of the PDP testing, and corrective actions, if any, are documented.

6.8.4 All PDP test systems are as specified in the plan, SOPs, or analytical methods, including any approved changes and/or deviations.

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6.8.5 When requested, project status reports (e.g., progress on validation studies) are prepared.

6.8.6 All required data is accurately transmitted electronically to USDA/AMS via remote data entry (RDE).

6.8.7 All PDP raw data and supporting laboratory records are stored, retained, and transferred to the archives as specified in Sections 5.4 and 5.5.

6.9 State/Facility QAU

Each PDP participating laboratory shall have a QAU consisting of one or more personnel of suitable qualifications. For those participants where there are two or more field facilities under a common administration there only needs to be a single QAU. Each PDP participating laboratory shall appoint an individual within the QAU to serve as the QAO.

6.9.1 QAU Independence

The QAU shall be entirely separate from and independent of the personnel engaged in the technical direction and/or conduct of sample analyses. The QAU shall report to non-technically involved laboratory management such as the laboratory director or the Administrative Manager. The TPM is considered to be involved in the technical direction and conduct of the residue studies and therefore may not direct the QAU.

6.9.2 Data Review and Transmission

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 PDP DATA SOPs for guidelines. After the QAU review of a data package, data may not be changed by any laboratory personnel unless as a response to comments/concerns/recommendations by the QAU.

6.9.3 Internal Audits

The QAU shall perform audits of the laboratory operations at intervals adequate to ensure the integrity of PDP sample analyses and to evaluate the compliance of laboratory

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facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the plans and SOPs issued by USDA/AMS and by the laboratory. Each segment or phase of PDP laboratory operations shall be audited at least every two years. Audit records shall include the dates the audits were performed, the audit findings, and reference to any corrective actions initiated.

6.9.4 Proficiency Testing (PT)

The QAU shall notify the PDP Technical Director and assigned liaison chemist of any corrective actions initiated in response to a PT result, and the resolution of each corrective action.

6.9.5 Reports

The QAU shall prepare and submit to USDA/AMS semi-annual updates based on calendar year (i.e., January through June and July through December) 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:

- Progress on Method Validations
- Corrective Action Summary
- Laboratory SOPs, New and Revised, titles and status specified
- Internal Audit Summary, including dates, areas audited, corrective actions, and unresolved issues
- Internal PT Sample Results, where applicable
- PT Sample Summary
- Changes to Methodology
- Miscellaneous QA Issues
- Status of two times the Limit of Quantitation (2x LOQ) quarterly spike results for all reported compounds (refer to PDP-QC).

7. <u>Purchase, Inventory, and Salvage Procedures</u>

7.1 Purchases

All purchases must be made within the confines of the current year's Cooperative Agreement

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terms. Details regarding purchase and reimbursement may be found in the agreement.

The requirements below are for routine planned purchases. In emergency cases that may impact production, the PDP Technical Director and/or Program Administrative Director should be contacted immediately.

7.1.1 Equipment Purchases

7.1.1.1 Equipment used in the generation, measurement, or assessment of data for PDP and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to PDP protocols and SOPs. Equipment shall be suitably located for operation, inspection, cleaning, and maintenance. Equipment is defined as nonexpendable, tangible personal property with a unit cost of \$5,000 or more.

7.1.1.2 Equipment purchases costing \$5,000 or more using USDA funds, including split-funded purchases, require USDA/AMS authorization. The laboratory shall contact the assigned laboratory liaison and/or the Technical Director to discuss purchase plans. Upon concurrence of the purchase, the laboratory will then obtain formal cost estimates and complete a GSA-49 Requisition/Procurement Request (attachment 8). The GSA-49, along with estimates, will be emailed to the assigned laboratory liaison and Technical Director. The liaison and/or Technical Director will obtain the Program Administrative Director's signature on the GSA-49 and it will be returned to the laboratory. Upon receipt of signed GSA-49, the laboratory may then proceed with the necessary steps to complete the purchase. *Purchases are not authorized to occur until the signed GSA-49 is in hand.*

7.1.1.3 Equipment purchases costing less than \$5,000 and <u>required</u> to conform to PDP SOPs, do not require prior authorization if they meet the "prudent person" rule. For an expense/cost/need to be reasonable, the total cost may not be more than a "prudent person" would spend under the circumstances prevailing at the time the decision was made to incur the cost. If this rule cannot be met or the decision could be questionable, refer to the steps above for obtaining prior approval.

7.1.1.4 Upon receipt, installation, and training (if included in the purchase) of equipment requiring approval, the laboratory send an email notification to

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USDA/AMS that the equipment is installed and operational and enter the equipment into the PDP Equipment Inventory Database (see Section 7.2). After all of these steps have occurred, the equipment purchase may then be reimbursed via SF 270 but not before.

7.1.1.5 The equipment shall vest with the State Agency upon acquisition. The equipment shall be tagged as State inventory; however, documentation shall be maintained citing the equipment as purchased with Federal funds. USDA/AMS retains the right to transfer said equipment for use by another State Agency or Federal facility performing PDP analyses during the course of the residue studies; however, the equipment remains tagged as the property of the originating State Agency or facility. Upon termination of the program, equipment will become the property of the originating State Agency.

7.1.2 Supply Purchases

7.1.2.1 Supplies are generally defined as an item with an acquisition cost of \$5,000 or less and a useful life expectancy of less than one year. Supplies are generally consumed during the project performance. Supply items must be direct costs to the project and meet the "prudent person" rule. For an expense/cost/need to be reasonable, the total cost may not be more than a "prudent person" would spend under the circumstances prevailing at the time the decision was made to incur the cost. If this rule cannot be met or the decision could be questionable, refer to the steps below for obtaining prior approval.

7.1.2.2 Supplies costing more than \$5,000 per item or \$10,000 for multiples of the same item in one purchase require USDA/AMS authorization. The laboratory shall contact the assigned laboratory liaison and/or the Technical Director to discuss purchase plans. Upon concurrence of the purchase, the laboratory will then obtain formal cost estimates and complete a GSA-49 Requisition/Procurement Request (attachment 8). The GSA-49, along with estimates, will be emailed to the assigned laboratory liaison and Technical Director. The liaison and/or Technical Director will obtain the Program Administrative Director's signature on the GSA-49 and it will be returned to the laboratory. Upon receipt of signed GSA-49, the laboratory may then proceed with the necessary steps to complete the purchase. *Purchases are not authorized to occur until the signed GSA-49 is in hand.*

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7.1.2.3 Supply purchases costing less than \$5,000 and <u>required</u> to conform to PDP SOPs, do not require prior authorization if they meet the "prudent person" rule as defined in 7.1.2.1 above. If this rule cannot be met or the decision could be questionable, refer to the steps above for obtaining prior approval.

7.1.3 Non-Equipment or Supply Expenses

7.1.3.1 Examples include maintenance agreements for laboratory equipment, repairs, renovations, vehicles, employee development, all training, conferences, meetings, seminars, accreditation fees/charges, consultants, etc. This list is not all inclusive. Contact your laboratory liaison and/or Technical Director if an expense could be questionable.

7.1.3.2 Non-equipment/supply expenditures require USDA/AMS authorization regardless of cost The laboratory shall contact the assigned laboratory liaison and/or the Technical Director to discuss purchase plans. Upon concurrence of the purchase, the laboratory will then obtain formal cost estimates and complete a GSA-49 Requisition/Procurement Request (attachment 8). The GSA-49, along with estimates, will be emailed to the assigned laboratory liaison and Technical Director. The liaison and/or Technical Director will obtain the Program Administrative Director's signature on the GSA-49 and it will be returned to the laboratory. Upon receipt of signed GSA-49, the laboratory may then proceed with the necessary steps to complete the purchase. *Expenditures are not authorized to occur until the signed GSA-49 is in hand.*

7.1.3.3 Travel that is part of the employees day-to-day routine duties does not require USDA/AMS authorization (e.g., travel to and between collection sites by Samplers).

7.1.3.4 A synopsis of topics covered, benefits, received, etc. shall be provided to the assigned liaison and/or Technical Director when attending or presenting at a meeting, seminar, or training.

7.1.4 Memberships

Individual memberships may not be expensed to PDP, as these are considered personal in nature

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7.2 Equipment Inventory

7.2.1 The laboratory shall maintain up-to-date property records for any piece of equipment (defined in 7.1.1.2) purchased with PDP funds, including split-funded purchases.

7.2.2 A physical inventory of property shall be taken and the results reconciled with the PDP Equipment Inventory database at least once per year. After reconciling the individual State spreadsheet in the PDP database, include the date and name of the person that performed the reconciliation at the top of the spreadsheet. The PDP Equipment Inventory Database is located on the USDA/AMS Extranet (*see requirements in Attachment 9*).

7.3 Permission to Salvage, Dispose of Equipment, or Trade In

7.3.1 For equipment purchased by PDP or using PDP Cooperative Agreement funds and that is no longer in working condition or is technically outdated, the laboratory must complete form AD-112, Report of Unserviceable, Lost, Stolen, Damaged or Destroyed Property (*see Attachment 10*), by dating and completing Sections 1-4, and email to the assigned laboratory liaison and Technical Director. The AD-112 will be submitted to the Program Administrative Director requesting permission to salvage, or dispose of the equipment. If approved, USDA/AMS will return the signed AD-112 authorizing disposal. The laboratory shall use their internal equipment salvage/disposal procedures to dispose of the property.

7.3.2 For equipment purchased by PDP or using PDP Cooperative Agreement funds and that is in working condition, but no longer being used, the laboratory will notify USDA/AMS, which will offer it to other potential government programs or Federal facilities. If no government agency accepts the equipment, the Program Administrative Director will authorize the donation of the property and the laboratory must complete Form AD-107, Report of Transfer or Other Disposition or Construction of Property (*see Attachment 11*), by dating and completing Sections 1, 3-5 (if applicable), 4.a (with the laboratory name as the organizational unit) and 6 and submit it to the Program Administrative Director. Expenses related to the Transfer of said property will be incurred by the recipient.

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7.3.3 For equipment purchased by PDP or using PDP Cooperative Agreement funds that is being traded in, the laboratory must complete Form AD-107, Report of Transfer or Other Disposition or Construction of Property, and submit it to the Program Administrative Director (see *Attachment 11*).

7.3.4 The laboratory must inform the laboratory liaison and Technical Director, in writing, of any changes regarding the disposition of equipment and the inventory list must be updated within 30 days.

7.4 Forms Instructions

7.4.1 The PDP Cooperative Agreement Number should be used for the GSA-49 Box 12, Contract # field.

7.4.2 Required fields are highlighted on the fillable versions of GSA-49, AD-107, and AD-112 that are posted on the USDA/AMS Extranet.

8. <u>PDP Quality Assurance Program</u>

8.1 Overview

8.1.1 The Program Administrative Director and Technical Director shall ensure that a quality assurance (QA) program is in place to monitor overall QA for sampling, technical, and database functions. The Technical Director shall have overall responsibility for assuring management that facilities, equipment, personnel, methods, practices, records, and controls of the program are in conformance with the plans and SOPs issued by USDA/AMS.

8.1.2 The Program Administrative Director and Technical Director shall appoint an individual to serve as the PDP QAO. The QAO shall be responsible for selected SOPs as detailed below and shall serve as the focal point for selected documents, reports, and correspondence pertaining to program quality control (QC) and/or QA issues.

8.1.3 Additional, specific QA functions shall be assigned by the Program Administrative Director and Technical Director to appropriate sampling, technical, and database staff.

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8.1.4 Appropriate PDP records shall be maintained by assigned staff. Documents shall be maintained in a secure manner with reasonable environmental protection from deterioration for the life of the program. Electronic and hardcopy records shall be centrally maintained (i.e., on the shared drive and/or in the QA Records Room) according to established PDP procedures. Maintenance shall be in an organized and systematic manner which allows accessibility by authorized staff.

8.2 Files and Records

8.2.1 The Technical Director shall ensure that copies of the following documents are maintained in the centralized files:

- PDP Semi-Annual Program Plans that specify the commodities and organisms/chemicals to be tested, as well as quarterly shipping charts that provide a schedule of samples to be collected and/or tested by each participant.
- A current PDP Master Schedule of administrative, sampling, and laboratory reviews and report submissions. The Master Schedule shall include the dates reviews were made and the dates findings were reported to appropriate individuals. The Master Schedule shall be posted to the Extranet.

8.2.2 The following documents shall be maintained in the centralized files by the assigned sampling and/or laboratory liaison(s):

- Administrative, sampling, and laboratory review reports.
- Authorizations for deviations from PDP SOPs.
- Semi-annual laboratory QA reports.

8.3 SOPs

8.3.1 The PDP Sampling Manager is responsible for maintaining all program sampling SOPs. This includes: scheduling issuance of SOPs, developing/revising SOPs in consultation with the Technical Director, distributing SOPs, updating the program Extranet/website with active SOPs, and maintaining all current and historical program SOPs (electronic and hardcopy files) related to sampling according to established PDP procedures.

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8.3.2 The PDP QAO is responsible for maintaining all program administrative and laboratory SOPs. This includes: scheduling issuance of SOPs, developing/revising SOPs in consultation with the Technical Director, distributing SOPs, updating the program Extranet/website with active SOPs, and maintaining all current and historical program SOPs (electronic and hardcopy files) related to administrative and testing activities according to established PDP procedures.

8.3.3 The Technical Director is responsible for ensuring that internal PDP SOPs are prepared/revised. The QAO is responsible for: distributing SOPs, updating the program Extranet/website with active SOPs, and maintaining all current and historical program SOPs (electronic and hardcopy files) related to internal PDP activities according to established PDP procedures.

8.4 Method Validation

All laboratories perform method validation studies and submit method validation reports and records to USDA/AMS in accordance with PDP-QC SOP.

8.4.1 The Program Administrative Director and Technical Director shall appoint an individual to serve as the PDP Method Validation Coordinator. The Method Validation Coordinator shall:

- Perform a final review of all validation study reports prepared by liaison chemists to ensure that consistent policies are applied, makes recommendations based on findings.
- Track and file all method validation documentation (i.e., Letters of Intent, Method Validation Data Packages, associated PDP reviews, Letters of Concurrence, requests for additional data, etc) to ensure that all required studies are performed by all applicable laboratories.
- Promptly communicate to the Technical Director delays in study reports submission.

8.4.2. Letters of Intent

• Letters of Intent submitted by laboratories shall be reviewed and verified against electronically submitted data (upon availability) by the assigned liaison chemist.

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• Letters of Intent shall be tracked and maintained in centralized files by the Method Validation Coordinator.

8.4.3. Method Validation Data Packages

8.4.3.1 The assigned liaison chemist shall review the data package according to established internal PDP procedures and draft a Letter of Concurrence, including any recommendations or requirements for additional data. Refer to PDP internal procedure, PDP-INTN-QC-01.

8.4.3.2 The Method Validation Coordinator shall perform a final review of all validation study reports prepared by liaison chemists to ensure that consistent policies are applied, make recommendations based on findings, and:

- Track and file all validation study reports to ensure that all required studies are performed by all applicable laboratories and that Letters of Concurrence/requests for further data are issued by USDA/AMS within 90 days of receipt of the data package.
- Promptly communicate to the Technical Director delays in study reports submission or issuance of ASDA/AMS Letters of Concurrence/requests for further data.
- Prepare draft Letters of Concurrence for the Technical Director.

8.4.3.3 The Technical Director is responsible for final authorization of the Letter of Concurrence issued to the submitting laboratory.

8.5 **Proficiency Testing (PT) Program**

8.5.1 All PDP laboratories analyzing routine PDP samples are required to participate in PT programs as coordinated by USDA/AMS.

8.5.2 The Technical Director is responsible for management of the PT programs and shall assure that PT samples are delivered on schedule and reports are prepared. The PT schedule and the reports will be posted to the Extranet.

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8.5.3 The assigned liaison chemist shall be responsible for monitoring that laboratory's performance on PT rounds and shall communicate any concerns/corrective actions to the Technical Director. The Technical Director shall be responsible for overall monitoring of the proficiency of laboratories.

8.6 Technical Advisory Group (TAG)

8.6.1 The PDP QAO, in consultation with the Technical Director, shall serve as liaison to the PDP Technical Advisory Group (TAG). The TAG shall be comprised of at least three selected members of participant QAOs and/or TPMs and shall address program QA issues/concerns.

8.6.2 Each TAG member shall serve a three-year term, with the final year served as the Presiding Member. The Presiding Member shall have sign-off responsibility for PDP program SOPs, with the exception of administrative SOPs, developed or revised during their term.

8.7 Records Archival

The Program Administrative Director and Technical Director shall appoint an individual to serve as the National Archives and Records Administration (NARA) contact for records disposition. The NARA contact shall be responsible for coordinating and tracking data submissions to NARA.

9. <u>Standard Operating Procedures (SOPs)</u>

9.1 Description of an SOP

SOPs are written instructions on how to perform tasks and procedures. SOPs are intended to assure consistency of data, quality, and procedures throughout the PDP studies and to be utilized for audit or review purposes. **Note**: The term "SOP" may be interpreted as any type of participant internal document (e.g., policy, work instructions, etc.).

9.2 Components of an SOP

9.2.1 This SOP serves as a guideline of the basic components to be included in the preparation of an SOP. They may contain a Purpose, Scope, Outline of Procedures, References (if any), and Specific Procedure(s).

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9.2.2 Program and participants' SOPs shall include a title, revision number, effective date and approval signatures (signatures may be handwritten or electronic).

9.2.3 The Specific Procedure(s) shall be written in precise and explicit terminology. The SOP shall be detailed enough to cover every aspect of the procedure and 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.

9.3 USDA/AMS SOPs

9.3.1 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:

- Administrative Procedures
- Sampling Procedures
- Laboratory Procedures
- Internal MP Procedures

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

9.3.3 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.

9.3.4 Each USDA/AMS administrative SOP, as well as USDA/AMS internal MP 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 Chairperson/Presiding Member of the PDP Technical Advisory Group.

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9.3.5 All USDA/AMS SOPs shall be revised as needed.

9.3.6 An index of USDA/AMS SOPs shall be maintained and distributed along with any SOP revisions.

9.3.7 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 Managers, TPMs, and QAOs; and all other applicable personnel.

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

9.4 State/Facility Internal SOPs

9.4.1 Each participant shall prepare internal SOPs in writing, giving specific details of procedures and methods utilized to comply with the USDA/AMS SOPs. Following changes to the USDA/AMS SOPs, each participant shall update their internal SOPs (if necessary for compliance) no later than three months after the USDA/AMS SOPs' effective date. The internal SOPs shall ensure the quality and integrity of data.

9.4.2 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.

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

9.4.4 Each internal SOP shall be approved by at least two of the following senior managers: the QAO, the laboratory Administrative Manager or TPM, the Sampling Manager, or Sampling Administrative Manager, and the approval shall be recorded. The approval may be recorded by use of signature blocks in the SOP itself, or separately. Alternatively, electronic document management systems may also be utilized to record approvals. Each participant shall maintain copies of current and historical internal SOPs as well as records of the dates they are (or were) in effect.

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9.4.5 SOPs shall be revised as needed.

9.4.6 Distribution of the internal SOPs, original and subsequent revisions, shall be available to each affected participant employee.

9.5 SOP Deviations

9.5.1 An SOP Deviation is the mechanism to allow participants to make pre-approved changes to written PDP requirements (SOPs, program plans, etc). Changes that are not pre-approved are dealt with via the participant's corrective action process.

9.5.2 An SOP Deviation request is submitted from the participant to USDA/AMS. The request shall be in writing but may be informal (e.g. e-mail) and may originate from the TPM, QAO, Sampling Manager, and/or Administrative Manager. Requests from laboratory participants shall include the QAU in order to ensure that any deviations do not compromise data quality.

9.5.3 The SOP Deviation request shall cite the particular SOP (including revision and subsection numbers) or other requirement. A description of need and/or rationale shall be included. The narrative should make clear the scope of the request (e.g. a particular sample, project, timeframe, etc., or a permanent change that would be in effect until affected by an SOP revision).

9.5.4 Additional information may be requested from the participant by USDA/AMS in order to evaluate the request.

9.5.5 The PDP Technical Director shall sign and approve all letters of deviation and shall ensure that any authorization for deviations from approved program plans or program SOPs does not compromise integrity of data. The PDP Technical Director shall ensure that precise and technically accurate documentation of such deviations is maintained.

9.5.6 USDA/AMS may issue program-wide deviations (e.g. addressed to all Sampling Managers, all TPMs, etc) if applicable. Program-wide SOP Deviations will be posted in the SOP section of the USDA/AMS Extranet.

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9.5.7 The participant shall maintain records of USDA/AMS authorizations for deviation from PDP SOPs/plans and ensure that they are communicated to appropriate personnel.

9.5.8 When a revised PDP SOP is issued, participants are not required to submit a new SOP Deviation request provided the revision to the SOP does not impact operations (e.g. revision number and subsection number changes).

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Diana Haynes 04/01/2015

Approved By: Diana Haynes Date PDP Acting Technical Director, Monitoring Programs Division 1400 Independence Ave. SW, Washington, DC 20250

Diana Haynes

04/01/2015

Approved By: Diana Haynes Date PDP Program Administrative Director, Monitoring Programs Division 1400 Independence Ave. SW, Washington, DC 20250

ORIGINAL SIGNATURE PAGE MAINTAINED BY USDA, AMS, SCIENCE & TECHNOLOGY, MONITORING PROGRAMS DIVISION ELECTRONICALLY REPRODUCED SIGNATURE

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| Re | evision 4 | April 2015 | Monitoring Programs Division |
|----|--|------------|------------------------------|
| • | • Reformatted sections 5.4.1, 5.4.2.2, and 5.4.2.3 | | |
| • | Updated MDP address in secti | on 6.2.2 | |

- Added reference to Safety Data Sheet to section 6.5.2.5
- Added requirement for trip synopsis to section 7.1.3.4
- Reformatted section 7.3
- Added section 7.4 Forms Instructions
- Updated internal SOP approval documentation in section 9.4.4

| Revision 3 | October 2013 | Monitoring Programs Division |
|------------|--------------|------------------------------|
| | 0010001 2013 | Monitoring Programs Division |

- Removed references to MDP throughout document
- Changed MP references to USDA/AMS or PDP (as appropriate) throughout the document
- Modified Section 2, Scope to indicate SOP does not supersede Cooperative Agreement
- Specified laboratory shall notify USDA/AMS of corrective action resolution in section 6.9.4
- Updated Section 7
- Added language to section 9.4.1 to allow States 90 days to modify internal SOPs after USDA/AMS SOPs issued

| Re | evision 2 | October 2011 | Monitoring Programs Division |
|----|-------------------------------|-------------------------------|--------------------------------------|
| • | Updated the entire SOP, inclu | uding SOP number, with the ne | w program's name Monitoring Programs |

- Updated the entire SOP, including SOP number, with the new program's name Monitoring Programs Division or MP instead of MPO
- Section 5.4.1.1: added annual and/or semi-annual Federal/State meeting minutes and/or presentations to list of records to be maintained by MP for 10 years
- Removed section 5.4.1.2 regarding MP retention of electronic databases and data summaries
- Section 5.4.2.1: removed statement regarding 2 year retention at laboratory of records requiring a total of 25 years retention (2 year requirement is addressed in Section 5.4.3.1)
- Moved Section 5.5.2.1 ("Each data package retained shall be filed by calendar year and month.") to become new Section 5.5.1.4
- Renumbered sections in 5.5.2
- Section 6.4.7.5: removed QAO from sampling review report distribution list
- Section 6.7.6: removed requirement for signature of reviewer (first bullet) and removed word "printed" from second bullet ("The printed name(s) and title(s) of the person(s) performing the review")
- Moved Section 6.7.6 to become Section 6.7.5 and renumbered old Section 6.7.5 as 6.7.6
- Section 6.7.8 reworded as: "All MDP/PDP supporting records for sampling activities are stored, retained, and transferred to the archives as specified in Sections 5.4 and 5.5."

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- Section 6.8.7 reworded as: "All MDP/PDP raw data and supporting laboratory records are stored, retained, and transferred to the archives as specified in Sections 5.4 and 5.5."
- Section 6.9: added requirement for laboratory to appoint and individual within the QAU as the QAO
- Moved Section 6.9.6 requirement for QAU to ensure that deviations are properly authorized and documented to new Section 9.5, "SOP Deviations"
- Section 7.3: revised inventory requirements for clarification (laboratory shall immediately notify MP via email of equipment installation and shall add the equipment to the MDP/PDP Equipment Inventory Database within 30 days of installation) and to provide the reason for immediate MP notification of equipment installation (allows MP to process payment and reconciled affected reimbursement request)
- Section 8.3: changed title from "SOPs and Deviations from SOPs" to "SOPs"
- Moved Section 8.3.4 requirement for Technical Director approval and documentation of deviations to new Section 9.5
- Moved Section 9.4.5 requirement for participant maintenance and communication of deviations as well as stipulation that MP may require supporting documentation to new Section 9.5; renumbered remaining Sections
- Added new Section 9.5, "SOP Deviations"
- Section 9.4.1 added provision for updating internal SOPs: "Due to the time interval between issuance dates and effective dates for USDA/AMS SOPs, each participant may update their internal SOPs in order to comply at any time during the time interval."
- Updated Attachment 1 with the e-mail addresses
- Updated Attachment 9 by replacing "Room Location" with "Location" and added footnote that the specific location within the laboratory is required to be documented (examples provided are room number, GC section)
- Updated Attachment 9 by adding new, required field for funding source (percentage of MDP/PDP funds used for purchase)

| Re | vision 1 | October 2010 | Monitoring Programs Office |
|----|----------------------------|--------------|----------------------------|
| • | Updated References section | | |

- Updated and reorganized section 5.4 (Data and Records Retention Periods)
- Updated and added new requirements for records' transfers to FRC in section 5.5.2
- Updated sections 6.5.2.9 regarding Responsibilities of Participants on updating MPO
- Updated requirements for laboratory review repots in section 6.7.6
- Updated sections 7.2 and 7.3 regarding Purchases and Equipment Inventory requirements
- Updated section 8.6.1 regarding MDP TAG
- Removed section 9.2.4 regarding the internal SOP formatting.

USDA/AMS Pesticide Data Program Designated Federal Records Centers

| Laboratory+ | Region | Send to: | | | | | | | |
|--|-----------------------|----------|---|----------------------------------|--|--|--|--|--|
| | _ | Name | Address | MP to E-Mail | | | | | |
| California Department of Food and Agriculture | Pacific Region | FRC | 1000 Commodore Drive | | | | | | |
| | | | San Bruno, CA 94066-2350 | SanBruno.transfer@nara.gov | | | | | |
| Florida Department of Agriculture | Southeast Region | FRC | 4712 Southpark Blvd. | | | | | | |
| and Consumer Services | | | Ellenwood, GA 30294 | atlanta.transfer@nara.gov | | | | | |
| Maryland Department of Agriculture | Washington National | FRC | 4205 Suitland Road | | | | | | |
| | Records Center | | Suitland, MD 20746-8001 | suitland.transfer@nara.gov | | | | | |
| Michigan Department of Agriculture | Great Lakes Region | FRC | 7358 South Pulaski Road | | | | | | |
| | | | Chicago, IL 60629-5898 | chicago.transfer@nara.gov | | | | | |
| New York Department of Agriculture and Markets | Northeast Region | FRC | National Archives-Central Plains Region | | | | | | |
| | | | 200 Space Center Drive | | | | | | |
| | | | Lee's Summit, MO 64064-1182 | KansasCityCave.transfer@nara.gov | | | | | |
| Ohio Department of Agriculture | Great Lakes Region | FRC | Federal Records Center – Dayton | | | | | | |
| | | | 3150 Springboro Road | | | | | | |
| | | | Dayton, OH 45439-1883 | kingsridge.transfer@nara.gov | | | | | |
| Texas Department of Agriculture | Southwest Region | FRC | 1400 John Burgess Drive | | | | | | |
| | | | Fort Worth, TX 76140 | FtWorth.transfer@nara.gov | | | | | |
| Washington State Department of Agriculture | Pacific Alaska Region | FRC | 6125 Sand Point Way NE | | | | | | |
| | | | Seattle, WA 98115-7999 | seattle.transfer@nara.gov | | | | | |
| USDA, AMS, S&T, National Science Laboratory | Southeast Region | FRC | 4712 Southpark Blvd. | | | | | | |
| | | | Ellenwood, GA 30294 | atlanta.transfer@nara.gov | | | | | |
| USDA, GIPSA, TSD, Pesticide Residue Laboratory | Central Plains Region | FRC | 17501 West 98th Street, Room 47-48 | | | | | | |
| | | | Lenexa, KS 66219 | lenexa.transfer@nara.gov | | | | | |

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United States Department of Agriculture Microbiological and Pesticide Data Programs Instructions for Assembly and Packaging of Record Boxes

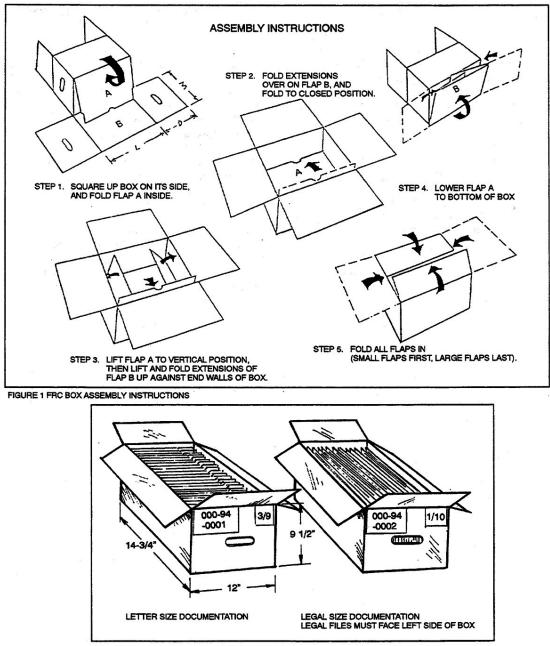


FIGURE 2 FILE PLACEMENT IN BOX AND LOCATION OF BOX IDENTIFICATION

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USDA/AMS Pesticide Data Program Equipment Inventory

Equipment Inventory

USDA, AMS, S&T, Monitoring Programs Division

| Lab or State | Item Description | Manufacturer | Model | Serial Number | Location* | Unique Internal Lab ID | Acquisition Cost | Approval Date | Purchase Date | Purchase Ref | Surplus** | % of MDP/PDP Funds Used for Purchase | Remarks*** |
|-----------------|------------------|--------------|-----------------|------------------|-----------|------------------------------|------------------|------------------|------------------|--------------|-----------|---|------------|
| WA1 | LC/MS/MS | Micromass | Quattro Premier | VAA 045 | Rm 225 | Waters #1 | \$300,000.00 | 1/1/2004 | 6/1/2004 | 041846 | FALSE | 65% USDA | |

*Specific location within the laboratory (e.g., room number, GC section, etc.)

**Enter "True" if the equipment is designated as surplus, and "False" if the equipment is still active.

***Enter any additional comments concerning the item (e.g., more detailed description, asset number, etc.)

| REPORT OF | U.S. DEPARTMENT OF AGRI | CULTURE LE, LOST, STOLEN | | PROPERTY REPORT NC |). | DATE |
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| | | SECTION I - ACCOUNTABLE PR | ROPER | RTY OFFICER'S REPORT | Г | |
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| Unserviceable | Lost or Stolen | | | | | |
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| Damaged | Destroyed | | | | | |
| | Others | | | | | |
| | | 3. PROPERTY ITEMS (See at | tachm | ent for additional entries) | | |
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| b. There appears | to be gross negligence involv | of result from employee negligence ed; therefore, the case returned to prefore, the case is returned to age | ageno | y officials for appropriate | action under the Debt (| Collection Act. |
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| | / listed above is hereby author explained in section I-3(D): | ized for cannibalization, abandonn | nent, c | r destruction in accordance | ce with FPMR 101-45.9 | based on any of the following |
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| | , or security considerations re or destruction. | quire immediate | | user and may be canni a form of use and prop Remainder of property | erty management regu | lations shall apply. |
| c. Costs of care | and handling exceed expecte | d small lot sales proceeds. | | usual procedures.) | | lough |
| d. Regulation or | directive requires abandonme | ent or destruction. | | | | |
| 2. SIGNATURE OF PROP | PERTY MANAGEMENT OFF | CER | | | | 3. DATE |
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| | OUNTABLE PROPERTY OFF | | | | | 2. DATE |
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| | | v action has been taken to adjust tl st collection from involved employe | | ounting records and, whe | re required by a | 4. DATE |

| United States Department of Agriculture | | Report No. | | |
|--|--|----------------------|--|--|
| Report of Transfer or Other Disposition or | | | | |
| 1. Type of Transaction (Report each type separately) | 2. Authorization Reference | | | |
| □ Transfer □ Sale □ Trade In □ Donation | | 3. Proceeds Received | | |
| \Box Construction \Box Rehab \Box As-Is | | \$ | | |
| 4. Reporting Agency | 5. Receiving Agency (Or Name of Purchaser or Donee): | | | |
| A. Organizational Unit | A. Organizational Unit (Or Address of Purchaser) | | | |
| B. Location | B. Location | | | |
| C. Signature | C. Signature | | | |
| D. Title | D. Title | E. Date | | |
| 6. Property Items | | | | |

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| Certifications of Property and Fiscal Officers | | | | | | |
| 7. Property Officer: This transaction is completed and the necessary entries have been made to adjust the property records proceeds, if any, are to be deposited to: | | 8. Fiscal Officer A. □ The sum indicated below has been received in payment for the property disposed of. | | | | |
| | | B. The necessary entries have been made to adjust the a | | | | |
| | | | Amount (\$) | Schedule I | No. | |
| Signature | | Date | Signature | 1 | Date | |