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#### 1. **Purpose:**

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

#### 2. Scope:

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. **Outline of Procedure:**

- Facilities
- <u>5.</u> <u>5.1</u> 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**
- <u>6.</u> Personnel and Organization
- <u>6.1</u> **Personnel Requirements**
- <u>6.2</u> USDA/AMS Responsibilities
- <u>6.3</u> 6.4 MPD Director
- **Responsibilities of Participants**
- 6.5 State/Facility Administrative Manager
- 6.6 State Sampling Manager
- **6.7** State/Facility Technical Program Manager (TPM)
- 6.8 State/Facility Quality Assurance Unit (QAU)
- Purchases, Inventory, and Salvage Procedures
- <u>7.</u> <u>7.1</u> Purchases
- 7.2 Equipment Inventory

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- Permission to Salvage, Dispose of Equipment, or Trade In <u>7.3</u>
- 7.4 Forms Instructions
- PDP Quality Assurance Program <u>8.</u>
- **8.**1 Overview
- 8.2 Files and Records
- <u>8.3</u> **SOPs**
- 8.4 Method Validation
- 8.5 Proficiency Testing (PT) Program
- 8.6 Technical Advisory Group (TAG)
- 8.7 **Records Archival**
- **Standard Operating Procedures**
- Description of an SOP
- <u>9.</u> <u>9.1</u> <u>9.2</u> Components of an SOP
- 9.3 USDA/AMS/MPD SOPs
- 9.4 State/Facility Internal SOPs
- 9.5 **SOP** Deviations
- Example: File Index for Electronic Records Transfer Attachment 1.
- Attachment 2. Form GSA-49, Requisition/Procurement Request for Equipment Supplies or Services
- **Example: Equipment Inventory** Attachment 3.
- Attachment 4. Form AD-112, Report of Unserviceable, Lost, Stolen, Damaged or **Destroyed Property**
- Form AD-107, Report of Transfer or Other Disposition or Construction Attachment 5. of Property

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Note: References consulted in the preparation of this SOP document.

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#### 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 their specific needs, 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 are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain data integrity; and
- 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

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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)/MPD, 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/MPD shall communicate any serious deficiencies identified during the facility inspection in a memo format within 10 days. Additionally, USDA/AMS/MPD 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/MPD 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
- Annual State Meeting minutes
- Interim and final reports
- Data interpretations

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#### • 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., standards preparation, instrument, freezer, temperature, etc.)
- Chromatograms generated during standards checking
- Sample worksheets (e.g., homogenization, extraction, etc.)
- 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
- Raw Sample Information Form data sheets, etc.

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#### 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 shall be transferred electronically to USDA/AMS/MPD for future archival to the U.S. National Archives and Records Administration (NARA) 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/MPD shall be contacted if a laboratory wishes to transfer records within a timeframe shorter than 2 years.

**5.4.3.3** The laboratory shall retain the 5-year items in 5.4.2.2 above unless arrangements are made with USDA/AMS/MPD to transfer these items separately.

#### 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** Archived electronic records at the laboratory shall be secured to protect the files, including access control, permissions to prevent accidental deletion, and back-ups.

**5.5.1.3** Each electronic data package retained shall be filed by calendar year and month.

#### **5.5.2** Transferring Electronic Records to USDA/AMS/MPD

Effective July 1, 2024, only electronic records will be allowed for archival to NARA. Paper records can no longer be transferred to a Federal Records Center (FRC). Laboratories shall transfer electronic records to USDA/AMS/MPD for future archival to NARA, which will be done after a viable transfer mechanism has been implemented by NARA.

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**5.5.2.1** All electronic records for transfer shall be saved in Adobe Acrobat PDF format as mandated by NARA. The same records that were previously transferred on paper within accordion folders and binders in a box shall now be transferred in PDF files within electronic folders.

**5.5.2.2** PDP Sample data packages representing a single calendar year shall be transferred separately from other calendar years. Within each calendar year, the data packages shall be filed by month and commodity. The electronic folders holding the sample data packet records in PDF files for transfer shall use the following naming convention to ensure consistency across all laboratories: *Lab-Year-Month*-DataSet-*Name/Number/Description*. Either the 2-letter commodity code(s) or the commodity name(s) may be included in the filename. Example: OH1-2022-09-DataSet-GR-1 and OH1-2022-09-DataSet-GR-2 for the two folders holding records for the two grape data sets for the Ohio laboratory in September 2022.

**5.5.2.3** Each electronic folder holding sample data packet records shall be compressed into a ZIP file for transfer. The ZIP file can hold an individual electronic folder for a sample data set, multiple folders for sample sets of the same commodity within the same month, or multiple folders for sample sets of multiple commodities within the same month. The ZIP file shall not hold records for multiple months. The ZIP filename shall follow the same naming convention as the electronic folders described in Section 5.5.2.2 above, with the ending *Name/Number/Description* describing the included folder(s). Either the 2-letter commodity code(s) or the commodity name(s) may be included in the filename. Examples: OH1-2022-09-Dataset-GR-1.ZIP holding the electronic folder for the single grape sample set; OH1-2022-09-Dataset-Grapes.ZIP holding the two electronic folders for the two grape sample sets and two pear sample sets for September 2022.

**5.5.2.4** PDP method validation sets may be transferred concurrently with sample data packets from the same calendar year or they may be transferred separately at a later date. The electronic folders holding the method validation set records in PDF files for transfer shall use the following naming convention to ensure consistency across all laboratories: *Lab-Year-Month*-MethodVal-*Name/Number/Description*. Example: TX1-2023-12-MethodVal-AV for the folder holding records for the avocado method validation completed by the Texas laboratory in December 2023. Each electronic

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folder holding method validation set records shall be compressed into their own ZIP file with the same filename as the electronic folder for transfer, like TX1-2023-12-MethodVal-AV.ZIP.

**5.5.2.5** PDP 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. The electronic folders holding the proficiency testing sample set records in PDF files for transfer shall use the following naming convention to ensure consistency across all laboratories: *Lab-Year-Month-*PT-*Name/Number/Description*. Example: FL1-2023-11-PT-256 for the folder holding records for the PT #256 set completed by the Florida laboratory in November 2023. Each electronic folder holding proficiency testing set records shall be compressed into their own ZIP file with the same filename as the electronic folder for transfer, like FL1-2023-11-PT-256.ZIP.

**5.5.2.6** A file index in PDF format shall be prepared by the laboratory listing all ZIP files that are being transferred at the same time. This is similar to the box list for the paper record archival. An Excel template file provided by USDA/AMS/MPD shall be used to prepare the file index in a spreadsheet showing a column for the ZIP file name sorted in ascending order within each record type and a second column showing a description of the content in the ZIP file. See Attachment 1 for an example file index list. The completed spreadsheet file shall be converted to PDF format for transfer with the ZIP files. The PDF file holding the file index list shall use the following naming convention to ensure consistency across all laboratories: *Lab-Year-Month-Day*-Index.PDF. Example: MI1-2024-10-22-Index.PDF for the file index completed by the Michigan laboratory on October 22, 2024. USDA/AMS/MPD will use this file index to verify that all expected ZIP files have been transferred.

**5.5.2.7** The ZIP files holding electronic folders and the file index (PDF) shall be uploaded to the USDA CloudVault site in a State-specific folder that can be accessed with a private link (web address) provided by USDA/AMS/MPD.

**5.5.2.8** The laboratory shall notify the USDA/AMS/MPD NARA liaison when the upload to CloudVault is completed.

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**5.5.2.9** The laboratory shall retain the electronic records that were transferred until USDA/AMS/MPD provides confirmation that the transfer was successful, i.e. that all ZIP files listed on the uploaded file index PDF were received.

**5.5.2.10** The archived records will be retained by NARA and will be available for retrieval during the specified storage time through the USDA/AMS/MPD NARA liaison.

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

#### 6.1 **Personnel Requirements**

#### **6.1.1** 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:

- 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. 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, curriculum vitae, employment applications, job descriptions, etc.).

6.1.3 Technical Personnel Performance Evaluation

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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 SOP.
- 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 SOP.

#### 6.2 USDA/AMS Responsibilities

**6.2.1** USDA/AMS has named the MPD Director as the PDP Program Administrative Manager and the PDP Technical Program Manager in charge of administrative and technical affairs. See the appropriate section of this SOP.

#### **6.2.2** USDA/AMS management shall:

- Replace the MPD 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 MPD Director

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

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The MPD Director also has overall responsibility for the sampling and technical conduct of the PDP studies. The MPD Director, through their own efforts or through the work assignments of PDP staff, shall ensure:

**6.3.1** The Deputy Administrator for USDA/AMS, Science and Technology, is kept informed on PDP financial and administrative affairs.

**6.3.2** Annual budgets for the administration of PDP at the national level are prepared and submitted.

**6.3.3** Work agreements are negotiated in cooperation with the States and/or other Federal agencies.

**6.3.4** The States' and/or Federal facilities' use of Federal funds is monitored through appropriate documentation.

**6.3.5** MPD serves as liaison to EPA, U.S. Food and Drug Administration (FDA), and other USDA agencies participating in PDP.

**6.3.6** The quality assurance of sampling, technical, and database operations are monitored to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with USDA/AMS/MPD program plans and SOPs.

**6.3.7** PDP data are reported in an annual program summary. This includes the interpretation, analysis, documentation, and reporting of results.

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

**6.3.9** All sampling information and experimental data are accurately recorded and verified.

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**6.3.10** 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.

**6.3.11** 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.

**6.3.12** 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; and
- The USDA/AMS MPD Director

For laboratory reviews, the review report is distributed to:

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

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

#### 6.4 **Responsibilities of Participants**

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**6.4.1** Each participant State/facility 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.

6.4.2 The participant management shall:

**6.4.2.1** 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.

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

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

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

**6.4.2.5** 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 an 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.

**6.4.2.6** 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 MPD Director and laboratory liaison and that corrective actions are taken and documented.

**6.4.2.7** Ensure an accurate and timely inventory of supplies and equipment purchased or utilized for PDP is maintained. See section 7.2 and Attachment 3.

**6.4.2.8** 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/MPD.

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**6.4.2.9** 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/MPD within 30 days of any staff changes that may affect sample collection and/or data delivery.

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

#### 6.5 State/Facility Administrative Manager

Each participating agency 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:

**6.5.1** Prepare and maintain annual budgets for PDP cooperative agreement 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 MPD Director when requesting funding to cover program operations.

**6.5.2** In cooperation with USDA/AMS/MPD, prepare and negotiate work agreements for PDP.

**6.5.3** Maintain appropriate accounting records to document the State/facility use of Federal cooperative agreement funding.

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

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#### 6.6 State 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:

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

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

**6.6.3** 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.

**6.6.4** Internal reviews of the procedures utilized by the sample collectors are performed at intervals adequate to ensure the integrity of PDP samples. Sample collector evaluations shall be conducted once a year or more frequently as necessary (see PDP-SAMP SOP section 9.2).

6.6.5 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; and
- Observations, findings and problems, recommendations and suggested corrective actions.

**6.6.6** 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

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problems have been reported by either the MPD Director or the applicable analytical laboratory(ies).

**6.6.7** 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.).

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

### 6.7 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 assigned to the laboratory, as well as for the interpretation, analysis, documentation, and reporting of results. The TPM shall ensure that:

**6.7.1** The PDP program plan and all USDA/AMS/MPD SOPs, including any changes, are followed. Any problems regarding compliance with the program plan or SOPs shall be communicated immediately to the MPD Director or designee and MPD laboratory liaison chemist.

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

**6.7.3** 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.

**6.7.4** 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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6.7.5 When requested, project status reports (e.g., progress on validation studies) are prepared.

**6.7.6** All required data is accurately transmitted electronically to USDA/AMS/MPD via Remote Data Entry (RDE).

**6.7.7** 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.

### 6.8 State/Facility Quality Assurance Unit (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.

#### 6.8.1 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.

#### 6.8.2 Data Review and Transmission

The QAU shall review all data packages as one of the final steps prior to submission to USDA/AMS/MPD. The QAU review shall be documented. See PDP DATA SOP 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.

#### **6.8.3** Internal Audits

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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 facilities, equipment, personnel, methods, practices, records, and controls in conformance with the plans and SOPs issued by USDA/AMS/MPD 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.

### 6.8.4 Proficiency Testing (PT)

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

#### 6.8.5 Reports

The QAU shall prepare and submit to USDA/AMS/MPD 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 SOP).

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

7.1 Purchases

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All purchases must be made within the confines of the current year's Cooperative Agreement 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 MPD 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/MPD authorization. The laboratory shall contact the assigned laboratory liaison to discuss purchase plans. If the laboratory liaison is unavailable, the MPD Director may be contacted instead. Upon concurrence of the purchase, the laboratory will then obtain formal cost estimates and complete a GSA-49 Requisition/Procurement Request (*see Attachment 2*). The GSA-49, along with estimates, will be emailed to the assigned laboratory liaison. The laboratory liaison will obtain the MPD Director's signature on the GSA-49 and it will be returned to the laboratory. Upon receipt of the 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

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equipment requiring approval, the laboratory shall send an email notification to USDA/AMS/MPD stating 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 form SF 270 Request for Advance or Reimbursement 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/MPD 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/MPD authorization. The laboratory shall contact the assigned laboratory liaison to discuss purchase plans. If the laboratory liaison is unavailable, the MPD Director may be contacted instead. Upon concurrence of the purchase, the laboratory will then obtain formal cost estimates and complete a GSA-49 Requisition/Procurement Request (*see Attachment 2*). The GSA-49, along with estimates, will be emailed to the assigned laboratory liaison. The laboratory liaison will obtain the MPD Director's signature on the GSA-49 and it will be returned to the laboratory. Upon receipt of the signed GSA-49, the laboratory may then proceed

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with the necessary steps to complete the purchase. *Purchases are not authorized to occur until the signed GSA-49 is in hand.* 

**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 MPD Director if an expense could be questionable.

**7.1.3.2** Non-equipment/supply expenditures require USDA/AMS/MPD authorization regardless of cost. The laboratory shall contact the assigned laboratory liaison to discuss purchase plans. If the laboratory liaison is unavailable, the MPD Director may be contacted instead. Upon concurrence of the purchase, the laboratory will then obtain formal cost estimates and complete a GSA-49 Requisition/Procurement Request (*see Attachment 2*). The GSA-49, along with estimates, will be emailed to the assigned laboratory liaison. The laboratory liaison will obtain the MPD Director's signature on the GSA-49 and it will be returned to the laboratory. Upon receipt of the 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 employee's day-to-day routine duties does not require USDA/AMS/MPD 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 laboratory liaison and/or MPD Director when attending or presenting at a meeting, seminar, or training.

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#### 7.1.4 Memberships

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

#### 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 AMS-PDP SharePoint site (*see requirements in Attachment 3*).

#### 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 4*), by dating and completing Section 1, numbers 1-4, and email to the assigned laboratory liaison. The AD-112 will be submitted to the MPD Director requesting permission to salvage or dispose of the equipment. If approved, USDA/AMS/MPD 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/MPD. If the MPD Director authorizes the donation of the property, the laboratory must complete Form AD-107, Report of Transfer or Other Disposition or Construction of Property (*see Attachment 5*), by dating and completing Sections 1, 3 through 5 (if applicable), 4A (with the laboratory name as the organizational unit) and 6 and submit it to the MPD 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 MPD Director (see *Attachment 5*).

**7.3.4** The laboratory must inform the laboratory liaison and MPD 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 AMS-PDP SharePoint site in the PDP Administrative/Forms for Authorization folder.

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

#### 8.1 Overview

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

**8.1.2** The MPD Director shall appoint an individual to serve as the PDP QA Coordinator. The QA coordinator 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 MPD 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 AMS-PDP SharePoint site) 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 MPD Director shall ensure that copies of the following documents are maintained in the centralized files:

- PDP Semi-Annual Program Plans that specify the commodities 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 AMS-PDP SharePoint site.

**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(s) is (are) responsible for maintaining all program sampling SOPs. This includes: scheduling issuance of SOPs, developing/revising SOPs in consultation with the MPD Director, distributing SOPs, updating the program SharePoint/website with active SOPs, and maintaining all current and historical program

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SOPs (electronic and hardcopy files) related to sampling according to established PDP procedures.

**8.3.2** The PDP QA Coordinator is responsible for maintaining all program administrative and laboratory SOPs. This includes: scheduling issuance of SOPs, developing/revising SOPs in consultation with the MPD Director, distributing SOPs, updating the AMS-PDP SharePoint/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 MPD Director is responsible for ensuring that internal MPD SOPs are prepared/revised. The QA coordinator is responsible for: distributing SOPs, updating the program centralized files 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/MPD in accordance with PDP-QC SOP.

**8.4.1** The MPD 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 laboratory liaisons to ensure that consistent policies are applied, then make 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, etc.) 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/MPD within 90 days of receipt of the data package.
- Promptly communicate to the MPD Director delays in study reports submission, or issuance of USDA/AMS/MPD Letters of Concurrence/requests for further data.

**8.4.2.** Letters of Intent

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- Letters of Intent submitted by laboratories shall be reviewed and verified against electronically submitted data (upon availability) by the assigned laboratory liaison.
- 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 laboratory liaison 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 laboratory liaisons to ensure that consistent policies are applied, to make recommendations based on findings, and ensure all required studies are performed by applicable laboratories.

**8.4.3.3** The MPD 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/MPD.

**8.5.2** The MPD 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 AMS-PDP SharePoint site.

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

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#### 8.6 Technical Advisory Group (TAG) and Sampling Advisory Group (SAG)

**8.6.1** The assigned PDP staff member(s), in consultation with the MPD Director, shall serve as liaison to the PDP Technical Advisory Group (TAG) and Sampling Advisory Group (SAG). The TAG shall be composed of at least three selected members of participant QAOs and/or TPMs and shall address program QA issues/concerns. The SAG shall be comprised of at least three selected members of participant Sampling Managers and shall address program sampling issues/concerns.

**8.6.2** Each TAG/SAG 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 MPD 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 ensure 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).

9.2.2 Program and participants' SOPs shall be uniquely identified and shall include at

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least a title, revision number, and effective date.

**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/MPD SOPs

**9.3.1** USDA/AMS/MPD 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 MPD Procedures

**9.3.2** All USDA/AMS/MPD 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/MPD 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 PDP administrative SOP, as well as USDA/AMS MPD formal internal SOPs, shall be approved and signed by the USDA/AMS MPD Director. Each USDA/AMS PDP sampling SOP shall be prepared and signed by the author/revisionist, approved and signed by the MPD Director, and reviewed and signed by the Presiding Member of the Sampling Advisory Group. Each USDA/AMS PDP laboratory SOP shall be prepared and signed by the author/revisionist, approved and signed by the Chairperson/Presiding Member of the PDP Technical Advisory Group.

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

**9.3.6** An index of USDA/AMS MPD 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 MPD Director and MPD Archives; participating facilities' Administrative Managers, Sampling Managers, TPMs, and QAOs; and all other applicable personnel.

**9.3.8** Active USDA/AMS PDP SOPs and SOP index are posted to the AMS-PDP SharePoint site and PDP website. Each sampling and laboratory participant shall maintain access to a current copy in their facility.

#### 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 PDP SOPs. Following changes to the USDA/AMS PDP SOPs, each participant shall update their internal SOPs (if necessary for compliance) no later than three months after the USDA/AMS PDP 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/MPD 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 State internal 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 the MPD Director and laboratory liaison. The request shall be in writing but may be informal (e.g., email) and may originate from the TPM, QAO, Sampling Manager, and/or Administrative Manager. Requests from laboratory participants shall include the QAU 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(s). 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/MPD to evaluate the request.

**9.5.5** The MPD 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 MPD Director shall ensure that precise and technically accurate documentation of such deviations is maintained. All deviations shall indicate the duration of the deviation for the purposes of review/renewal. In lieu of a formal deviation letter, approval via email is acceptable for one-time deviation requests (e.g., apple samples stored on the counter overnight instead of in a refrigerator) submitted via email by the laboratory (see 9.5.2 above).

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**9.5.6** USDA/AMS/MPD 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 AMS-PDP SharePoint site.

**9.5.7** The participant shall maintain records of USDA/AMS/MPD 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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Revision: 12	Replaces: 09/01/2023	Effective: 07/01/2024

Original signed by Brenda Foos

6/26/2024

Approved By: Brenda Foos Monitoring Programs Division Director 1400 Independence Ave., SW Washington, DC 20250 (202) 572-8167 Date

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### Revision 12July 2024Monitoring Programs Division

- Various grammatical and editorial corrections
- Updated the AOAC International reference to reflect the current version available
- Updated the link for reference USDA, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, 7 CFR, part 3016 as there is a more recent version
- Removed Taylor, J.K., Quality Assurance of Chemical Measurements, 1989 reference as it is no longer available
- Revised sections 5.4.3 and 5.5 to remove guidance for paper/box archival to FRCs and add guidance for electronic records transfer to NARA via USDA/AMS/MPD
- Added a new Attachment 1 for an example file index list for electronic records transfers
- Removed 4 attachments for paper/box archival procedures, then renumbered Attachments 6 thru 9 to become Attachments 2 thru 5

Revision 11	September 2023	Monitoring Programs Division	
Various grammatic	cal and editorial corrections		
• Added clarifying l	anguage of electronic records to	o section 5.5.2	
• Referenced Attach	ment 1 in section 5.5.2.4		
• Removed MPD fro	om the fourth bullet in section 6	5.2.2	
• Changed "contract	Changed "contracts" to "agreements" in section 6.3.3 and section 6.5		
• Removed "CDC"	from section 6.3.5		
• Clarified sample c	Clarified sample collector evaluation frequency in section 6.6.4		
• Changed "contract	ed" to "assigned" in section 6.7	7	
• Changed "USDA/	AMS" to AMS-PDP" in section	n 7.2.2	
• Removed "manage	ement" from section 8.1.1		
• Added language p	ertaining to SAG in section 8.6		

- Added "formal" in regards to internal SOPs in section 9.3.4
- Added a duration requirement to deviation letters to section 9.5.5

#### Revision 10June 2022Monitoring Programs Division

- Various grammatical and editorial corrections
- Changed filament tape to clear packing tape in section 5.5.2.11
- Removed section 6.2.2 since technical program reports are no longer sent by mail
- Renumbered section 6.2.3 as section 6.2.2 due to text removal

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- Removed the reference to chemicals in the PDP Semi-Annual Program Plan in section 8.2.1
- Revision 9June 2021Monitoring Programs Division
- Updated section 4 with weblinks, and organized references alphabetically and by order of appearance in CFR
- Updated section 6.1.1 Employee Qualifications with correct numbering
- Changed room number from 0601 to 2911 and removed fax number in section 6.2.2
- Changed USDA/AMS Extranet to AMS-PDP SharePoint site throughout the document
- Added folder locations for files listed in section 7.4.2
- Changed QA Records Room to AMS-PDP SharePoint site in section 8.1.4
- Changed Extranet/website to centralized files in section 8.3.3

Revision 8	June 2020	Monitoring Programs Division
• Updated the title for atta	achment 7 in section 3	
• Updated section 4 with	weblinks and added a note	indicating references were consulted in the
preparation of this SOP		
Changed PDP reference	e to MPD for clarification in	section 8.3.3

- Updated heading for section 9.3 from USDA/AMS SOPs to USDA/AMS/MPD SOPs
- Changed USDA/AMS reference to USDA/AMS/MPD throughout the document where applicable
- Added PDP for clarification in sections 9.3.4 and 9.4
- Added MPD for clarification in section 9.3.6
- Added posting PDP SOPs to the Extranet and PDP website, and updates to access current SOPs at PDP facilities in section 9.3.8
- Updated deviation notification from USDA/AMS to MPD Director and Laboratory liaison

### Revision 7July 2019Monitoring Programs Division

- Changed PDP Program Administrative Director and PDP Technical Director titles to MPD Director throughout the document
- Changed liaison chemist to laboratory liaison throughout the document
- Renumbered sections 6.3.1 through 6.9.5
- Updated sections 6.3.1 through 6.4.2.6 by combining PDP Program Administrative Director and PDP Technical Director duties

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- Updated section 6.3.12 by removing sampling and laboratory review report distribution to AMS Compliance and Analysis Programs
- Changed laboratory to State/facility in section 6.4.1
- Added laboratory liaison to section 6.4.2.6
- Added clarification to sections 7.1.1.2, 7.1.2.2 and 7.1.3.2 regarding MPD contact for laboratory purchase plans
- Added liaison reference to section 7.1.3.4
- Changed PDP QAO to PDP QA Coordinator in sections 8.1.2, 8.3.2, 8.3.3 and 8.6.1
- Updated section 8.4.1
- Clarified section 8.4.3.2 by removing duplicate entries referenced in section 8.4.1

Re	evision 6	May 2017	Monitoring Programs Division
•	Undated section 3	by changing Attachment A	removing Attachments 5 and 6 and renumbering

- Updated section 3 by changing Attachment 4, removing Attachments 5 and 6 and renumbering Attachments 7 through 11
- Updated section 5.5.2.4 to include box listing
- Updated section 5.5.2.5
- Renumbered Attachments 7,8,9,10 and 11 to 5,6,7,8 and 9 throughout the document

#### Revision 5 May 2016

Monitoring Programs Division

- Clarified archival procedures for method validation and proficiency testing packages in section 5.5.2.3
- Clarified requirements for completing AD112 in section 7.3.1
- Added option for email approval of deviation requests in section 9.5.5

**Revision 4** 

April 2015 Monitoring Programs Division

- Reformatted sections 5.4.1, 5.4.2.2, and 5.4.2.3
- Updated MPD address in section 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

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## Revision 3October 2013Monitoring 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

### Revision 2October 2011Monitoring Programs Division

- 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."
- 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

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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)

Revision 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.

ZIP File Name	Description of Content in ZIP File
NY1-2022-01-DataSet-BU-MU-TO.ZIP	Folders holding data packets for January Butter/Mushroom/Tomato sets.
NY1-2022-02-DataSet-BU-MU-TO.ZIP	Folders holding data packets for February Butter/Mushroom/Tomato sets.
NY1-2022-03-DataSet-BU-MU-TO.ZIP	Folders holding data packets for March Butter/Mushroom/Tomato sets.
NY1-2022-04-DataSet-BU-MU-TO.ZIP	Folders holding data packets for April Butter/Mushroom/Tomato sets.
NY1-2022-05-DataSet-BU-MU-TO.ZIP	Folders holding data packets for May Butter/Mushroom/Tomato sets.
NY1-2022-06-DataSet-BU-MU-TO.ZIP	Folders holding data packets for June Butter/Mushroom/Tomato sets.
NY1-2022-07-DataSet-BU-MU-TO.ZIP	Folders holding data packets for July Butter/Mushroom/Tomato sets.
NY1-2022-08-DataSet-BU-MU-TO.ZIP	Folders holding data packets for August Butter/Mushroom/Tomato sets.
NY1-2022-09-DataSet-BU-MU-TO.ZIP	Folders holding data packets for September Butter/Mushroom/Tomato sets.
NY1-2022-10-DataSet-IP-MU-TO.ZIP	Folders holding data packets for October Infant Pear/Mushroom/Tomato sets.
NY1-2022-11-DataSet-IP-MU-TO.ZIP	Folders holding data packets for November Infant Pear/Mushroom/Tomato sets.
NY1-2022-12-DataSet-IP-MU-TO.ZIP	Folders holding data packets for December Infant Pear/Mushroom/Tomato sets.
NY1-2022-08-MethodVal-MU.ZIP	Folder holding all mushroom method validation documentation.
NY1-2022-11-MethodVal-TO.ZIP	Folder holding all tomato method validation documentation.
NY1-2022-05-PT-251.ZIP	Folder holding results for PT # 251 (FAPAS May-2022)
NY1-2022-07-PT-252.ZIP	Folder holding results for PT # 252 (CDFA July-2022)
NY1-2022-07-PT-253.ZIP	Folder holding results for PT # 253 (CDFA November-2022)

		ION/PROCURE				IT		PAGE	OF	GES
2. REQUISITION/PR REQUEST NO.		3. ACT NUMBER	<u>1020 motra</u>			4. DATE	PREPARED	5. JOB/P	ROJECT NUMBER	
6. TO (Stockroom	/Contracting office, Na	me and Location)		7. FROM (Requis	sitioning offi	ice, Name,	Symbol, Locatio	n and Telep	hone Number)	
8. FOR INFORMAT	ION CALL Name and	Telephone Number)		9. RECEIVING OF	FFICE <i>(Nam</i>	ne, Symbol	and Telephone N	Number		
	10. ACCOUNTIN	)N	11. SHIP TO (Ad	ldress, ZIP	Code and T	elephone				
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FUNC CODE	C/E CODE	PROJ/PROS. NO.	CC-A							
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# Equipment Inventory Example

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	•	% 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.)

-	U.S. DEPARTMENT OF AGRICU	ILTURE	PROPERTY REPORT NO. DATE				
REPORT OF	UNSERVICEABLE	E, LOST, STOLEN					
	D OR DESTROYE						
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Unserviceab							
Obsolete		ized for parts					
Damaged		d					
j	Others						
		3. PROPERTY ITEMS (See at		1			
QUANTITY		OTHER DETAILS, INCLUDING AND ACQUISITION DATE	G ACQUISITION COST		SPOSAL INSTRUCTIONS or destroyed, give detail.		
(Or property no.)		and estimated cost of repair)	ACQUISITION COST		d to proper authorities?)		
(A)		(B)	(C)		(D)		
4. NAME IN PRINT AND SI	GNATURE OF CUSTODIAN	DATE	5. NAME IN PRINT AND SIGN		DATE		
			ACCOUNTABLE PROPERT	Y OFFICER			
		ROPERTY MANAGEMENT OF					
1 After due consideration a		ATION FOR LOST, STOLEN, D tances in this case, it is determine		PROPERTY			
_							
a. The loss, the	eft, damage, or destructior	n did not result from employe	ee negligence and any invo	lved employees are he	ereby relieved of liability.		
b. There appea	rs to be gross negligence	involved; therefore, the cas	e is returned to agency officient	cials for appropriate a	ction under the Debt		
Collection A	ct.						
🔄 c. There appea	rs to be negligence involv	ed; therefore, the case is re	turned to agency personne	l officials for considera	tion of disciplinary action.		
2 NAME IN PRINT AND SI	GNATURE OF PROPERTY	MANAGEMENT OFFICER			3. DATE		
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		ed for cannibalization, abandon					
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a. Property h	as no commercial value.		e. Property is unecor	nomical to repair/not n	eeded by another user and		
b. Health, sat	fety, or security considera	tions require immediate	may be cannibaliz	ed for parts. (Canniba	alization is a form of use		
	ent or destruction.				hall apply. Remainder of		
C. Costs of ca	are and handling exceed e	expected small lot sales	property must be	disposed of through us	sual procedures.)		
proceeds.							
_ '	or directive requires aba	ndonment or destruction					
					3. DATE		
					S. DATE		
				MENT OF DESTRUCT			
		ON FOR COMPLETION OF CA ction action for the items auth					
	JNTABLE PROPERTY OFFIC				2. DATE		
3. SIGNATURE OF WITNE	SS				4. DATE		
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United States Department of Agriculture				Report No.		
REPORT OF TRANSFER OR OTHER DISPOSITION OR CONSTRUCTION OF PROPERTY						
				Date		
1. Type of Transaction ( <i>Report Each Type Separately</i> )			2. Authorization Reference			
				3. Proc	eeds Received	
🔄 Transfer 🔄 Sale 🔄 Trade In 🔄 Donation						
	on Temporary Loan Record				\$	
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 TH		D TH	-		E Data	
D. Title		D. Title		E. Date		
6. Property Items		Derei	4			
Quantity (Or Property No.)	Item Description (Give Full Details Including Serial Number, If Any, and Condition Code)				Inventory Value	
					Valao	

Quantity (Or Property No.)	(Give Full Deta	2)	Inventory Value				
(Or Property No.)	(Give Full Det	ails Including Serial I	Number, If Any, and Condition Code		Value		
	C	utification of Drana	rty and Figure 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:			erty and Fiscal Officers         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 accounting records.         Amount (\$)       Schedule No.				
Signature		Date	Signature		Date		