

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

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Revision: Original	Replaces: N/A	Effective: 08/15/03

**1. Purpose:**

To standardize the organization, operations, and personnel for those participating in the collection of samples and performance of analytical determinations for the USDA/AMS Microbiological Data Program (MDP).

**2. Scope:**

This standard operating procedure (SOP) shall be followed by all laboratories conducting microbiological studies for MDP, including support laboratories conducting non-routine activities that may impact the program.

**3. Outline of Procedure:**

- 5.1 Personnel Requirements
- 5.2 USDA/AMS MDP Responsibilities
- 5.3 Program Administrative Director
- 5.4 Technical Director
- 5.5 Quality Assurance Unit (QAU)
- 5.6 Responsibilities of MDP Participants
- 5.7 Administrative Manager
- 5.8 Sampling Manager
- 5.9 Technical Program Manager (TPM)
- 5.10 Quality Assurance Unit (QAU)

**4. References:**

- U.S. EPA, Inspection of a testing facility, 40 CFR part 160.15, July 1, 1999
  - U.S. EPA, Personnel, 40 CFR part 160.29, July 1, 1999
  - U.S. EPA, Testing facility management, 40 CFR part 160.31, July 1, 1999
  - U.S. EPA, Study director, 40 CFR part 160.33, July 1, 1999
  - U.S. EPA, Quality assurance unit, 40 CFR part 160.35, July 1, 1999
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**5. Specific Procedures:**

**5.1 Personnel Requirements**

- 5.1.1 Each individual engaged in the conduct of or responsible for the supervision of the sample collection process or an MDP study shall have the education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.
- 5.1.2 Each participant shall maintain a current summary of training and experience and a job description for each individual engaged in the conduct of or responsible for the supervision of the sample collection process or an MDP study.
- 5.1.3 Personnel engaged in an MDP study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent contamination of samples and reference materials. Individuals shall take personal sanitation precautions necessary to avoid contamination of themselves, the samples, or reference materials.

**5.2 USDA/AMS MDP Responsibilities**

- 5.2.1 USDA/AMS/Science and Technology (S&T) has named the Monitoring Programs Office (MPO) Director as the MDP Program Administrative Director in charge of Financial and Administrative Affairs. Refer to section 5.3 of this SOP.
- 5.2.2 The MPO Deputy Director has been designated as the MDP Technical Director. Technical program reports shall be made to the MDP Technical Director at USDA/AMS/S&T MPO, 8609 Sudley Road, Suite 206, Manassas, VA 20110 [telephone (703) 330-2300 or fax (703) 369-0678]. Refer to section 5.4 of this SOP.
- 5.2.3 USDA/AMS management shall:
  - 5.2.3.1 Replace the Program Administrative Director or the Technical Director promptly if it becomes necessary to do so during the conduct of the MDP studies.

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5.2.3.2 Assure that there is a USDA/AMS QAU as described in MDP-ADMIN-06.

5.2.3.3 Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

5.2.3.4 Assure that personnel clearly understand the functions they are to perform.

5.3 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 MDP. 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:

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

5.3.2 Inform the Deputy Administrator, Science and Technology as necessary on financial and administrative affairs.

5.3.3 Prepare and submit annual budgets for the administration of MDP at the national level.

5.3.4 In cooperation with the States and/or other Federal agencies, and after consultation with the Technical Director on the Statement of Work, negotiate work contracts.

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

5.3.6 Serve as liaison to EPA, FDA, and other USDA agencies participating in MDP.

5.4 Technical Director

USDA/AMS shall identify a scientist of appropriate education, training, and experience, or combination thereof, as the Technical Director for MDP. The Technical Director is the major point of program control and has the responsibility for the sampling and technical conduct of the MDP study and monitoring of quality assurance. This includes the

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interpretation, analysis, documentation, and reporting of results in an annual program summary. The Technical Director shall:

- 5.4.1 Appoint and supervise an individual to be responsible for and fulfill the duties of Quality Assurance Officer (QAO).
- 5.4.2 Inform the S&T Deputy Director and the Program Administrative Director as necessary on MDP sampling, laboratory, and database issues.
- 5.4.3 Serve as an additional liaison to EPA, FDA, and other USDA agencies participating in MDP.
- 5.4.4 Consult with the Administrative Director on the Statement of Work during contract negotiations.
- 5.4.5 Assure that:
  - 5.4.5.1 The program plan and MDP SOPs, including any changes, are approved and followed.
  - 5.4.5.2 All sampling information and experimental data, including observations of unanticipated occurrences or responses, are accurately recorded and verified.
  - 5.4.5.3 Unforeseen circumstances that may affect the quality and integrity of MDP samples and/or technical studies are documented as they occur, and corrective actions as necessary are taken and documented.
  - 5.4.5.4 MDP sampling procedures and test systems are as specified in the program plan and SOPs. This shall be accomplished through reviews and frequent communications with participants.
  - 5.4.5.5 Reviews of participant sampling and laboratory facilities are performed at intervals adequate to ensure the integrity of MDP 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:
    - 5.4.5.5.1 time elapsed since the last review, and/or
    - 5.4.5.5.2 designated need because of problems associated with the collection or analysis of samples performed by that

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participant. Participant Administrative Managers shall be notified and final arrangements shall be made several weeks in advance of the review if at all possible.

5.4.5.6 For sampling reviews, the review report is distributed to the participant's Administrative Manager and Sampling Manager and the USDA/AMS Administrative Director and QAO. For laboratory reviews, the review report is distributed to the participant's Administrative Manager, Technical Program Manager, and QAO and the USDA/AMS Administrative Director and QAO.

5.4.5.7 The review reports are made available for inspection by authorized employees or duly designated representatives of USDA/AMS.

5.4.5.8 All raw data, documentation, protocols, SOPs, and final reports are transferred to the archives during or at the close of MDP.

5.5 Quality Assurance Unit (QAU)

USDA/AMS shall have a QAU that shall be responsible for the overall monitoring of the MDP study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with USDA/AMS program plans and SOPs.

The QAU shall be entirely separate from and independent of participant personnel engaged in the technical direction and/or conduct of the study. The QAU shall report to the USDA/AMS Technical Director. Refer to USDA/AMS SOP MDP-ADMIN-06 for detailed duties.

5.6 Responsibilities of Participants

5.6.1 Each participant shall designate an Administrative Manager, a Sampling Manager, and a Technical Program Manager for MDP. Refer to sections 5.7, 5.8, and 5.9 of this SOP.

5.6.2 The participant management shall:

5.6.2.1 Replace the Administrative Manager, Sampling Manager, or the Technical Program Manager promptly if it becomes necessary to do so during the conduct of the MDP study.



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5.6.2.2 Assure that there is a QAU as described in MDP-ADMIN-06.

5.6.2.3 Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

5.6.2.4 Assure that personnel clearly understand the functions they are to perform.

5.6.2.5 Assure that any deviations from the MDP standard operating procedures (SOPs), program policies, and approved analytical methodologies as reported by the QAU are communicated to the USDA/AMS Technical Director and QAU and corrective actions are taken and documented.

5.7 Administrative Manager

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

5.7.1 Appoint and supervise a qualified individual to be responsible for and fulfill the duties of Sampling Manager.

5.7.2 Appoint and supervise a qualified individual to be responsible for and fulfill the duties of Technical Program Manager.

5.7.3 Appoint and supervise a qualified individual(s) to be responsible and fulfill the duties of QAO.

5.7.4 Maintain an accurate and timely inventory of supplies and equipment purchased or utilized for MDP.

5.7.5. Prepare and maintain annual budgets for MDP contract administration.

5.7.6. In cooperation with USDA/AMS prepare and negotiate work contracts for MDP.

5.7.7. Maintain appropriate accounting records to document State use of federal contract funding.

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5.7.8. Maintain appropriate performance records to document state performance and productivity on MDP studies (e.g., records of samples analyzed).

5.8 Sampling Manager

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

- 5.8.1. The MDP program plan and USDA/AMS SOPs, including any changes, are followed. Any problems regarding compliance with the program plan or SOPs shall be communicated immediately to the USDA/AMS Technical Director or designee.
  - 5.8.2. Participant internal SOPs are prepared documenting specific procedures utilized by the facility in collecting and shipping MDP samples. These SOPs are intended to serve as an attachment/appendix to USDA/AMS SOPs.
  - 5.8.3. The participant sampling plan and internal SOPs, including any changes, are followed.
  - 5.8.4. All required sampling information is accurately recorded and verified.
  - 5.8.5. Unforeseen circumstances that may affect the quality and integrity of MDP samples are documented as they occur, and corrective actions are taken and documented as necessary.
  - 5.8.6. Internal reviews of the procedures utilized by the sample collectors are performed at intervals adequate to ensure the integrity of MDP 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.
  - 5.8.7. 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
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sampling problems have been reported by either the USDA/AMS Technical Director or the applicable analytical laboratory.

5.8.8. Written and properly signed records of each review are maintained. Each review report shall show:

5.8.8.1 date of the review,

5.8.8.2 person(s) performing the review,

5.8.8.3 observations, findings, and problems, recommendations and suggested corrective actions.

5.8.9. The review reports are made available for inspection by authorized employees or duly designated representatives of USDA/AMS. Access to review reports should be limited to those individuals participating in MDP; however, storage under lock and key is not required.

5.9 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 MDP. The TPM has overall responsibility for the technical conduct of the MDP study contracted to the laboratory, as well as for the interpretation, analysis, documentation, and reporting of results. The TPM shall assure that:

5.9.1 The MDP 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 USDA/AMS Technical Director or designee.

5.9.2 The laboratory plan, internal SOPs, and analytical methodologies, including any changes, are followed.

5.9.3 All experimental data, including observations of unanticipated responses, are accurately recorded and verified.

5.9.4 Unforeseen circumstances that may affect the quality and integrity of the MDP study are documented as they occur, and corrective action as necessary is taken and documented.

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- 5.9.5 All MDP test systems are as specified in the plan, SOPs, or analytical methods, including any approved changes.
- 5.9.10 When requested, project status reports (e.g., progress on validation studies) are prepared.
- 5.9.11 All required data is accurately transmitted electronically to USDA/AMS via remote data entry (RDE).
- 5.9.12 All raw data, documentation, plans, SOPs, and final reports are transferred to the archives during or at the close of the MDP study.

5.10 Quality Assurance Unit (QAU)

Each MDP participating laboratory shall have a QAU which shall be responsible for monitoring the MDP study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the plans and SOPs issued by USDA/AMS and by the laboratory.

The QAU shall be entirely separate from and independent of the personnel engaged in the technical direction and/or conduct of the study. 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 studies and therefore may not direct the QAU. Refer to USDA/AMS SOP MDP-ADMIN-06 for detailed duties.

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