

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

SOP No: MDP-DATA-01		Page 1 of 6
Title: Microbiological Record Keeping and Results Reporting		
Revision: 01	Replaces: 09/01/01	Effective: 04/15/03

1. Purpose:

To provide standard procedures to ensure that all data and results retained in and reported by laboratories participating in the Microbiological Data Program (MDP) meet minimum reporting requirements.

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. All of the procedures and measures required under this SOP must be documented and records must be kept in laboratory logbooks.

3. Outline of Procedure:

- 5.1 Recordkeeping
- 5.2 Results Reporting

4. References:

- Compendium Of Methods for the Microbiological Examination of Foods, Third Edition, 1992, American Public Health Association, Washington, D.C.
- Standard Methods for The Examination Of Dairy Products, 16 Th. Edition, 1992, American Public Health Association, Washington, D.C.
- Quality Control in Microbiology, Department of Health and Human Services, Public Health Service, by J. Michael Miller, May 1993



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5. Specific Procedures:

5.1 Recordkeeping

All results for USDA/AMS MDP samples, along with any associated sample set quality assurance (QA) data, shall be reported to the USDA/AMS Monitoring Programs Office (MPO), Manassas, Virginia, following established Remote Data Entry (RDE) procedures.

In those cases where a State has an action protocol in place to respond to the isolation of a pathogen, the State shall follow its established reporting procedures. In those cases where a State requests results for a sample, or group of samples, collected in that State and analyzed by another MDP laboratory, those results may be released to the collection State.

USDA/AMS MDP will provide the U.S. Food and Drug Administration (FDA) with appropriate information at quarterly intervals. Data will be compiled on an annual basis and a summary report released by the MDP Program Director, the Science and Technology Deputy Administrator, or their designees. Standard USDA/AMS practices to ensure protection of confidential business information will be used when publishing data.

5.1.1 The laboratory must develop a system that provides storage and ready retrieval of all the data/results generated in the laboratory related to the analysis of MDP samples.

5.1.2 The type of system may be manual or automated incorporating the use of worksheets, logbooks, computers, and other equipment and materials as needed. When computers are used, data must be properly backed up on computer hard drives or floppy disk. Proper safe guards must be in place to provide computer security of data.

5.1.3 The data/records generated by participants in the MDP are to be kept for the duration of the program. Older documents can be stored in a Federal Storage Facility.

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5.1.4 Records must be kept documenting the care and disposition of samples during their time in the laboratory. These records must show the storage condition, personnel with custody, and the final disposition of samples when they are no longer needed.

5.1.5 Records must be kept regarding sample analyses, including sample description, storage condition, sample retention, description of analytical method, all raw data, and observations, calculations, and conclusions. The analyst(s) responsible for each segment of a procedure should be identified in the record.

5.2 Results Reporting

5.2.1 The analytical records must be reviewed for completeness and accuracy before the results are reported using the RDE system. Specific data and information required to be entered into the RDE system must be reported to the MDP Program Director as prescribed in instructions for the RDE system.

5.2.2 The laboratory must have a fax machine, computer, and software needed to submit data in accordance with RDE system instructions.

5.2.3 Prior to reporting data and results, the supporting data must first be reviewed by another analyst in the laboratory other than the one that actually performed the analysis.

5.2.4 The analyst that performed the analysis or a designated deputy may then enter results and other data into their own Laboratory Information Management System (LIMS) or directly into the RDE system in preparation for submission to MPO, Manassas, Virginia. The person entering the data must enter his/her initials in the appropriate place in the RDE database as sample data review and reporting will be a three-step process.

5.2.5 The data entered into the Laboratory Information Management System (LIMS), or directly into the RDE system, must be reviewed by the laboratory

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supervisor, laboratory director, or their designee. The reviewer must sign-off the set in the RDE system in order to capture his/her User ID in the appropriate place in the RDE database.

- 5.2.6 The laboratory quality assurance officer, or his/her designee, must perform a final review of the data to check for accuracy of data transcription and authorize transmittal of data. The reviewer must sign-off the set in the RDE system in order to capture his/her User ID in the appropriate place in the RDE database.
 - 5.2.7 The information may then be transmitted to MPO, Manassas, Virginia.
 - 5.2.8 Data submission frequency is at the laboratory's convenience but shall not be delayed more than two weeks following completion of analysis.
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Grace Hall

04/09/03

Approved by: Grace Hall, Chairperson, MDP Technical Advisory Committee
Florida Department of Agricultural and Consumer Services
Food Laboratory, Bldg. 9
3125 Conner Blvd.
Tallahassee, Florida 32399-1650
(850) 488-4407

Anita Okrend

04/15/03

Approved by: Anita Okrend
Technical Services Branch Chief, MDP
14th and Independence Av., Room 3521
Washington, D.C. 20090-6456
(202) 690-0621

Date

Martha Lamont

04/15/03

Approved By: Martha Lamont
Director, Monitoring Programs Office
8609 Sudley Road, Suite 206
Manassas, VA 20110
(703) 330-2300

Date

Diana Haynes

04/15/03

Reviewed By: Diana Haynes
Quality Assurance Officer, Monitoring Programs Office
8609 Sudley Road, Suite 206
Manassas, VA 20110
(703) 330-2300

Date

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Revision 1

November 2002

Monitoring Programs Office

- General update
 - Renumbered subsections for consistency with other SOPs
 - Modified review process to require initial technical review by Technical Program Manager (or designee) followed by QA review
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