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

SOP No: MDP-DATA-01		Page 1 of 14
Title: Data Entry, Record Keeping and Results Reporting		
Revision: 11	Replaces: 10/01/2010	Effective: 9/1/2011

1. Purpose:

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

2. Scope:

This Standard Operating Procedure (SOP) shall be followed by laboratories conducting microbiological studies for MDP, including support laboratories conducting non-routine activities that may impact the program. The procedures and measures required under this SOP must be documented and records must be kept in laboratory logbooks.

3. Outline of Procedures:

4. References:

- Remote Data Entry (RDE) procedures are found in the RDE system's "On-line Help" function and are provided in a User Guide that was distributed to all laboratories.
- SOP MDP-SHIP-03, Procedures for Packaging, Shipping, and Archiving Microbiological Cultures
- SOP MPO-ADMIN, Administrative Procedures for the Microbiological Data Program and Pesticide Data Program

5. Procedures:

5.1 **Remote Data Entry (RDE) System** - 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 Division (MP), Manassas, Virginia, following established Remote Data Entry (RDE) procedures.

5.1.1 **System Administration**

5.1.1.1 Each laboratory shall designate an individual or individuals to administer applicable aspects of the RDE system. MP shall create or modify the RDE account for the designated individual to grant laboratory system administrator privileges.

5.1.1.2 The laboratory system administrator shall create RDE user accounts for laboratory personnel using the Maintain User option on the RDE System Admin menu. Each user account shall be assigned one or more roles, which serve as defined permissions to access the different RDE options, based on position requirements.

5.1.1.3 The laboratory system administrator shall disable the RDE user account when an individual terminates employment with the organization. A user account will be automatically disabled if there is no log-in activity for 90 days.

5.1.1.4 The laboratory system administrator may reset passwords and unlock accounts as needed using the Maintain User option in the RDE System.

5.1.2 **System Access**

5.1.2.1 The RDE system requires a Web browser and an assigned user account and password to gain access.

5.1.2.2 Laboratory users shall access the secured RDE site by preceding the Web address with “https” for encrypted data communication between the central server and the user’s workstation.

5.1.3 **Data Entry**

5.1.3.1 The laboratory shall create analytical sets, referred to as Groups in RDE, so that samples related to specific QA results are included under one unique Group identification number.

5.1.3.2 Sample identity information shall be entered into RDE if a paper Sample Information Form (SIF) was submitted. A sample shall be attached to a Group in RDE if an electronic SIF was submitted.

5.1.3.3 Analytical data results shall be entered for each sample through the RDE system in the prescribed format.

5.1.3.4 Data may be entered and maintained on a Laboratory Information Management System (LIMS), but shall be imported into the RDE System for sign-off and transmission to MP.

5.1.3.5 Refer to the latest RDE System documentation for further information. The system documentation is the User's Manual provided by the contractor and any documentation supplied by MP. System documentation is available on the Extranet.

5.1.4 **Data Review Requirements**

5.1.4.1 The data shall go through a multi-level review and sign-off process prior to submission to MP. The RDE system provides for up to three reviewer sign-offs for each analytical set.

5.1.4.2 Analyst - this first-level sign-off is optional.

5.1.4.3 The Technical Program Manager or designee shall review the data for accuracy and completeness. This sign-off is required by the RDE system before the analytical set is allowed to be transmitted

5.1.4.4 Laboratory Quality Assurance Officer (QAO) or designee shall review the data for integrity of the overall quality system and adherence to MDP criteria. The Quality Assurance Unit (QAU) shall have access to the data and supporting documentation. The QAO sign-off is required.

5.1.4.5 Following QAU review of a data package, data may not be changed by any laboratory personnel unless approved by the QAU. Corrections taken shall be documented.

5.1.5 **Data Transmission**

5.1.5.1 Data shall be electronically transmitted to MP using the Transmit option in the RDE System. Analytical data on any other media shall not be submitted without prior authorization from MP. Data may be entered and maintained on a

Laboratory Information Management System (LIMS), but shall be signed off and transmitted through the Web-based RDE system.

5.1.5.2 Participating laboratories shall submit electronic results of routine testing to MP via RDE within 60 calendar days of sample receipt according to established procedures as detailed in this SOP. If the 60 day reporting requirement will not be met, the laboratory shall send the MP Director or Deputy Director, monthly updates detailing the reason for the delay and a projected schedule for data delivery.

5.2 **Pathogen Detection Results Reporting**

5.2.1 **Preliminary POSITIVE findings** are defined in the method SOP for each target organism listed below:

a. *Salmonella*

b. Non-O157 Shiga-toxin carrying *Escherichia coli* (STEC)

c. *E. coli* O157:H7

For this SOP, PRELIMINARY positive findings for the above listed target organisms are defined as a positive PCR result, e.g., BAX® PCR for *Salmonella*, BAX® real-time PCR for *E. coli* O157:H7, FDA's real-time or quantitative PCR methods for STEC. The preliminary positive results report from real-time PCR for non-O157 STECs should also include results from real-time BAX® PCR for *E. coli* O157:H7. MDP laboratories must continue to keep MP informed of subsequent testing, isolation status or confirmation.

Laboratories shall report preliminary positive findings (see 5.2.6 table) for all target pathogens to the MP laboratory liaison(s) with a courtesy copy provided to the Deputy Director, using Results Notification Form, MDP DATA-01- Atch 1. Preliminary positive reports should be submitted to MP as soon as possible (MP prefers receiving report not later than close of next business day).

5.2.2. **Final NEGATIVE results** should be reported as soon as possible. In the event that a preliminary positive advanced to cultural (Example: PCR pool positive followed by a PCR individual positive, then cultural), but the target organism was not isolated, test results (see 5.2.6 table) should accompany the final negative report form. If other than target organisms are isolated and identified, e.g., *Enterobactor sakazakii*, this information shall be annotated in the comment section of the report form.

This type of negative results reporting is important in gaining understanding of the limitations in procedures and technology. The final reports and/or support documentation shall be reviewed by the QAO or designee. The dates, identities/names of analyst(s) and reviewer must be annotated on all final report forms prior to transmission to MP.

5.2.3 **Final POSITIVE results:**

5.2.3.1 **For *Salmonella*:** Send the Final Positive report using the Results Notification Form, MDP-DATA-01- Atch 1 and include the required test results (see 5.2.6 table). Reporting to MP shall be done within 24 hours of completing VITEK® and poly O/H testing.

5.2.3.2 **For *E. coli* O157:H7:** Send the Final Positive report using the Results Notification Form, MDP-DATA-01-Atch 1, and include the required test results (see 5.2.6 table). Reporting to MP shall be done within 24 hours of completing the VITEK® test.

5.2.3.3 Once a *Salmonella* or *E. coli* O157:H7 organism is isolated, confirmed and reported to MP, the laboratories shall insure Pulsed-field Gel Electrophoresis (PFGE) and/or serotyping is initiated within five business days of isolation **OR** ship **(3)** slants of the isolate to the MDP repository so PFGE and/or serotyping, can be initiated within five business days of isolation.

Clearly annotate on Isolate Shipment form (Refer to MDP SHIP-03 SOP) that accompanies slants to MDP repository, whether PFGE and serotyping have been completed or if it still needs to be done.

5.2.3.4 **For non-O157 STECs:** Send the Final Positive report using the Results Notification Form, MDP-DATA-01-Atch 1 and include required test results (see 5.2.6 table). Reporting to MP shall be done within 24 hours of completing the confirmatory SmartCycler® real-time PCR test on the positive isolate(s) already tested by cultural and VITEK®.

5.2.3.5 When a non-O157 STEC organism is isolated and reported to MDP, the laboratory shall ship **(3)** slants of the isolate to the MDP repository within five business days of isolation so PFGE, serotyping, virulence characterization, archival and antimicrobial susceptibility testing, can be initiated as soon as possible.

Note: *Prior to shipping isolates to the MDP Repository, provide notification via email to: achen@agri.ohio.gov and jbalogh@agri.ohio.gov. Attach the Results Notification Form, MDP-DATA-01 Attachment 1, the Isolate Information Form, MDP-DATA-01 Attachment 4 (Form 001) and the Isolate Shipment Form, MDP-SHIP-03 Atch 4 to the notification email.)*

5.2.4. Pulsed-Field Gel Electrophoresis (PFGE) - The isolates of target pathogens listed in section 5.2.1 shall be subjected to molecular fingerprinting by PFGE within five business days after isolation and this data will be uploaded to Centers for Diseases Control and Prevention's (CDC) PulseNet database within three days after completion of PFGE (refer to SOP MDP-SHIP-03, section 4.6).

5.2.4.1 To correctly populate PFGE entries to the PulseNet database, **the originating laboratory** will insure that the fully completed Microbiological Data Program Isolate Information Form (MDP DATA-01 Form 001) accompanies the isolate to the PFGE laboratory.

5.2.4.2. PFGE-uploading laboratories must update the isolate's data in PulseNet once they receive any additional isolate information such as serotyping and/or virulence factors. In this regard, MDP prefers that the laboratories that perform *Salmonella* PFGE and upload to PulseNet should also perform the serotyping. This will minimize delay in updating the data record in PulseNet.

5.2.4.3 All PFGE and serotyping results shall be communicated to MP as soon as results are available.

5.2.5. **After-hours notification -** For immediate after-hours telephonic results notifications (weekends, holidays, etc.), refer to Attachment 2 of this SOP, "MP Contact Information".

5.2.6 **Required Results Table** - The required test results to accompany reports to MP are shown in the table below.

Organism	**Tests Results Required for Preliminary Positive Report**	**Tests Results Required for Final Positive Report**	**Tests Results Required for Final Negative Report (refer to section 5.2.2)**
Salmonella	BAX® PCR (melting curves, +/- display page and detailed BAX® printout)	Cultural worksheets, IMS (when required), poly O/H serology, VIDAS®, VITEK® (≥ 95% confidence interval)	Cultural worksheets, VIDAS®; target pathogen not isolated or isolation of non-target organism
E. coli O157:H7	FDA Real-time PCR (rtPCR) and BAX® O157 rtPCR	Cultural worksheets, IMS (when required), O157: H7 serology, VITEK® (≥ 95% confidence interval)	Cultural worksheets; target pathogen not isolated or isolation of non-target organism
Non-O157 STEC	FDA rtPCR and BAX® O157 rtPCR	Cultural worksheets, IMS (when required), VITEK® (≥ 95% confidence interval), FDA rtPCR results of isolate	Cultural worksheets; target pathogen not isolated or isolation of non-target organism

5.3 **Recordkeeping** - This is a general guideline representing minimum requirements. Each laboratory shall develop written procedures providing specific details about how recordkeeping has been implemented.

5.3.1 Data Package Contents -Each data package retained by the program participant (e.g., State or Federal laboratory) shall consist of laboratory records (i.e., worksheets and/or completed forms), USDA records of collection and analytical results reports, and all raw and/or derived sample data for a given set or group of samples analyzed. If raw data/observations are collected in a bound notebook, the notebook need not be included in the raw data package; however, it must be maintained by the laboratory as supporting documentation.

5.3.2 Supporting documentation (e.g., refrigerator/freezer logs, training records) do not need to be included in the data package, but must be maintained separately by the laboratory.

5.3.3 Data packages shall be maintained for at least two years following electronic transmission (via RDE) and before applying for disposition to Federal Records Centers as described in ADMIN SOP. Special consideration shall be granted for early disposition on a case-by-case basis. Supporting documentation generated by MDP participants shall be maintained by the laboratory and may be transferred to a Federal Records Center as described in ADMIN SOP after a period of at least two years.

5.3.4 Records shall be maintained documenting the custody of samples from collection to final disposition. These records shall show the storage conditions and personnel handling the samples.

5.3.5 Records shall be kept regarding sample preparation and analyses, including sample description, storage condition, description of analytical methods, raw data, observations, calculations, and conclusions. The analyst(s) responsible for each segment of a procedure shall be legibly identified in the record.

5.3.6 Records regarding shipment of cultures to other laboratories shall be documented as described in SOP MDP-SHIP-03.

5.3.7 USDA/AMS MP will provide the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) with appropriate information semi-annually.

5.3.8 Data will be compiled on an annual basis and a summary report released by MP. Standard USDA/AMS practices to ensure protection of confidential business information will be used when publishing data.

5.4 **Additional Reporting Requirements:**

5.4.1 Laboratories shall report all final positive results to MP **first.** MP will review final positive results and then report to the FDA's Office of Food Safety, Produce Safety Staff and Laboratory Operations Branch. If a collected sample and the testing laboratory are from the same state, as soon as MP receives FDA's acceptance and confirmation of the positive results, MP will inform the testing laboratory and also provide a Sample and Isolated Pathogen Information form. That testing laboratory will then have the option to report the positive detection results to its own State agencies or let FDA handle any further investigations/actions. MP will ensure rapid feedback to the testing laboratory's Administrative, Quality, and Technical Program Managers regarding these reporting actions.

5.4.2 If a laboratory reports positive results to its State agencies, it is required to furnish MP with information on the agency/department/office notified and the person of contact information (name, email, phone, etc.) for that agency.

5.4.3 For positive detections on trans-state shipped samples, MP will inform appropriate agencies of the State where the samples were collected. MP may also share positive detection isolate information with the testing laboratory and Centers for Disease Control and Prevention (CDC).

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Revision 11 May 2011 Monitoring Programs Division

- Added words "…data entry, record-keeping and…" to Section 1
- Updated Outline of Procedures, Section 3
- Updated References, Section 4
- Added words "routine" and "or Deputy Director", Section 5.1.5.2
- Added words "a. *Salmonella;* b. Non-O157 Shiga-toxin carrying *Escherichia coli* (STEC); c. *E. coli* O157:H7" after first sentence of Section 5.2.1. Added new paragraph: "For this SOP, PRELIMINARY positive findings for the above listed target organisms are defined as a positive PCR result, e.g., BAX® PCR for *Salmonella*, BAX® real-time PCR for *E. coli* O157:H7, FDA's real-time or quantitative PCR methods for STEC. The preliminary positive results report from real-time PCR for non-O157 STECs should also include results from real-time BAX® PCR for *E. coli* O157:H7. MDP laboratories must continue to keep MP informed of subsequent testing, isolation status or confirmation."
- To 2nd paragraph, Section 5.2.1, added bold-type words: "Laboratories shall report preliminary positive findings **(see 5.2.6 table)** for all target pathogens to the MP laboratory liaison(s) with a **courtesy** copy **provided** to the Deputy Director, using Results Notification Form, MDP DATA-01- Atch 1. **Preliminary** positive reports should be submitted to MP as soon as possible (MP prefers receiving report not later than close of next business day).
- After first sentence, replaced remaining old Section 5.2.2 with new paragraph
- Redefined and expanded Section 5.2.3 to separate target organisms and their reporting requirements by adding: "5.2.3.1, 5.2.3.2, 5.2.3.3, 5.2.3.4, 5.2.3.5"
- Added new Section 5.2.4
- Added new Section 5.2.6
- Redefined and expanded additional participant reporting requirements in old Section 5.4 by adding: "5.4.1, 5.4.2, 5.4.3"
- Revised Attachment 1, Results Notification Form: added "CT" to commodity codes; added stx1/stx2 in results designations

Revision 10 September 2010 Monitoring Programs Office

- Updated References, Section 4
- Revised Section 5.4 to read "**Additional Reporting Requirements –** Laboratories will first report final positive results to MP. MP will be responsible for reporting final positive results to other Federal and/or State agencies/departments. MP will ensure rapid feedback to the testing laboratory's Administrative, Quality, and Technical Program Managers regarding these reporting actions."
- Updated Attachment 02, Contact Information
- Revised Attachment 03, PFGE Quick Reference Guide, Paragraph 2
- Updated Form 001

Revision 09 June 2010 Monitoring Programs Office

- Throughout document, removed the word "ETEC" and replaced the words "mPCR" with Real-time BAX® O157:H7
- Throughout document, removed "OH" and/or "Ohio" replaced with "MDP repository"
- Added sentence "A user account will be automatically disabled if there is no log-in activity for 90 days.", Section 5.1.1.3
- Removed Sections 5.1.2.3 and 5.1.2.4
- Added words "Ct values" to Section 5.2.1 and 5.2.2
- Added word "archival" to Section 5.2.4
- Replaced the word "secondary" with "additional", section 5.2.6
- Updated Attachment 1, Results Notification Form
- Updated Attachment 2, MP Contact Info

Revision 08 December 2009 Monitoring Programs Office

- Added Section 3, Outline of Procedures
- Alphabetized and removed numbering from Section 4, References
- Replaced "is not" with "will not be", Section 5.1.5.2
- Changed order of paragraphs in Section 5.2
- Removed "/presumptive" and replaced "within 24 hours of positive results or before close of next business day" with "as soon as possible (MP prefers receiving report not later than by close of next business day).", Section 5.2.1
- Added new Sections 5.2.2 through 5.2.7

- Replaced the word "confirmed" with the word "final" throughout the SOP, in association with reporting of results
- Added "MDP DATA-01 Form 001" to SOP

Revision 07 September 2009 Monitoring Programs Office

- Updated References, Section 3
- Revised Sections 4.1 through 4.4
- Updated Attachment 1, Fillable, Positive Results Notification Form
- Added Attachment 2, MP Contact Info
- Added Attachment 3, PulseNet Quick Reference Guide

Revision 06 December 2008 Monitoring Programs Office

- Removed warning letter in subsec. 5.5.2

Revision 05 May 2008 Monitoring Programs Office

- Revised subsec. 5.6.1.1 to reflect reporting of target pathogens
- Revised subsec. 5.6 to remove Preliminary/Final Results Notification Form (data elements to be emailed to MP)
- Archived USDA/AMS MDP Preliminary/Final Results Notification Form

Revision 04 February 2008 Monitoring Programs Office

- Revised data reporting requirement in subsection 5.5.2

Revision 03 May 2006 Monitoring Programs Office

- Updated RDE procedures
- Revised data review requirements
- Revised data reporting to include use of LIMS
- Added CDC as data recipient
- Updated recordkeeping requirements

Revision 02 November 2004 Monitoring Programs Office

- Revised to include notification of preliminary and final positive results to MP, using Attachment 01
- Added data review requirements and RDE review documentation procedures
- Revised to accommodate review process done in LIMS rather than RDE.
- Revised to update references to related SOPs
- Revised to extend data submission frequency to thirty days