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

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Title: Sample Information Forms and Chain of Custody		
Revision: 3	Replaces: 4/24/06	Effective: 4/29/09

1. Purpose:

To establish proper use of Sample Information Forms (SIFs) and Chain of Custody procedures for implementation by all States/facilities collecting samples for the USDA/AMS Microbiological Data Program (MDP).

2. Scope:

This Standard Operating Procedure (SOP) shall be followed by all individuals collecting and shipping samples for MDP.

3. Outline of Procedure:

5.1 MDP General Requirements
5.2 Paper Sample Information Forms
5.3 Electronic Sample Information Forms
5.4 Chain of Custody

4. References:

- Sample Advisory Committee Meeting, December 2-4, 2008
- Sampling Advisory Committee and Sampling Manager communications (email and telephone), January, February, and April 2008
- PDP/MDP Technical Meeting, Richmond, VA, March 27-31, 2006
- Sampling Managers' conference Call, March 13, 2006
- PDP/MDP Federal/State Meeting, Denver, CO, September 27-29, 2005
- Email communication from Ken Stoub, Group Seven Environmental Services, May 20, 2005
- Meeting with Monitoring Programs Office (MPO) database personnel, Roger Fry and Milton Bonilla, to discuss electronic sample information form requirements, March 30, 2005

- MDP/PDP Remote Data Entry (RDE) e-SIF Software Information Sheet, August 23, 2004
- User Guide for PDP/MDP Remote Data Entry (RDE) System, July 23, 2004
- MDP Federal/State Meeting, Fairfax, VA, July 22-24, 2004
- MDP Public Meeting, Washington, DC, April 15, 2002
- MDP Public Meeting, Washington, DC, January 10, 2002
- MDP Public Meeting, Washington, DC, April 15, 2002
- MDP Public Meeting, Washington, DC, January 10, 2002
- Program Plan, July-December 2002
- Program Plan, January-June, 2002
- Program Plan, April-September 2001
- MDP SAMP APPE-1: A blank MDP Sample Information Form (version effective May 1, 2002) with accompanying instructions.
- MDP Federal/State Meeting, Tallahassee, Florida, January 10-11, 2001
- Workplan for MDP Pilot Study, August 25, 1999

5. Specific Procedures:

5.1 MDP General Requirements

5.1.1 The sample collector shall ensure that *one* SIF is completed for each sample box/carton collected at a particular site. If sub-samples from each box/carton have different lot numbers, a separate SIF must be completed for each different lot number. A SIF must be completed even if an assigned sample was not collected.

5.1.2 In addition to sample identification information, the MDP SIF shall include: (1) available facts regarding State of origin, brand name, grower, packer, distributor, and product code/lot number, and (2) available details pertaining to agricultural practices employed during or after production, such as organically grown or chemically treated with sanitizers.

5.1.3 Product variety information shall always be included on the SIF, when available.

5.1.4 When proxy sites are used for sample collection [special circumstances only—refer to MDP SAMP PROC-01, Section 5.1.4], the sample collector shall include a "P" in the Source ID box of the form, the proxy site's name (or store number) and address.

5.1.5 Collectors shall ensure that SIFs are fully and correctly completed and that the correct number of SIFs is submitted. SIFs allow MPO to track the number and type of samples collected, the number of missing samples, and the reason(s) why the sample was not collected/analyzed. States should make every effort to collect the assigned number of samples each month.

5.1.6 *It is important that sample collectors complete all appropriate fields of the SIF*. Free-form fields such as Variety, Packer Name, Grower Name, Distributor Name, Lot Number/Other ID, and Post Harvest Fungicide Labeling **must not be left blank**. If the requested information cannot be found on the commodity container/box/carton, the sample collector shall enter "unk" or, preferably, "NA" or "na" in the field provided for that information. Fields left blank yield no valuable information.

5.1.7 It is strongly recommended that when routine tracking information is not available, the collector record any other available identification information that could be used to track the sample in the Comments Field of the SIF

5.1.8 Paper versions of the SIF are acceptable only in instances where problems occur with the use of the electronic version (power outages, computer shut-downs, etc.). When paper SIFs are used, copies must be sent, faxed, or emailed to the appropriate laboratory within a timeframe to coincide with sample arrival [refer to Section 5.3.7].

5.1.9 MPO occasionally requests that special information (specific ingredients, expiration date, generic varieties, etc.) be recorded and collected for certain commodities. Sample collectors are required to include this information on their SIFs. The MPO Sampling Manager prepares and distributes quarterly Quick Reference Sheets for sample collectors that list these special requests and explain where the information should be recorded on the SIF. Also included on the Quick Reference Sheet is a list of current unacceptable commodities---commodity types that should not be collected.

5.1.10 If, due to illness, natural disaster, weather conditions, etc., a State is unable to collect the scheduled sample(s), a new collection date shall be rescheduled for a different week/day of that month with the approval of the receiving laboratory. When the items are collected on the rescheduled date, the new collection date shall be entered on the SIF.

5.1.11 If re-scheduling must occur during the following month [refer to MDP SAMP PROC-02, Section 5.2.5 for special exceptions], the new collection date shall be entered on the SIF, along with a brief explanation of the delay.

5.1.12 If the sample collector has no samples to ship, he/she shall notify the State Sampling Manager, complete the SIF with the required information, and email or fax the SIF to the appropriate laboratory.

5.1.13 Once the sample collector has mailed, faxed, or e-mailed the SIF, no changes shall be made to the document without approval from the State Sampling Manager.

5.2 Paper Sample Information Forms (SIFs)

5.2.1 Although not encouraged, it is acceptable for sample collectors to hand-write sample information on a paper SIF form for later recording on the electronic SIF. If this practice is performed, the sample collector must: (1) record all necessary sample information on the paper SIF BEFORE leaving the site, (2) sign and date the paper SIF and, (3) keep all paper SIFs on file for a minimum of two years because they are considered “raw data.” It is required that handwritten sample information be recorded on a current paper SIF form to ensure that all pertinent sample information is included.

5.2.2 After two years, State Sampling Managers may transfer paper SIF forms to a Federal Records Center (FRC) by completing form SF-135 for Supporting Data Packages (refer to template in Attachment 1, example in Attachment 2, and FRC addresses in Attachment 3 in MDP SAMP PROC-02) and follow directions in MDP DATA-08. MPO should be contacted for any questions concerning the disposition or transfer of records or if a State wishes to transfer records within a timeframe shorter than two years.

5.2.3 It is required that all hand-written sample information be recorded on a paper SIF form. Sample collectors shall ensure that all applicable portions of the form are PRINTED neatly and legibly. Mistakes on the SIF shall be marked through with a single line and dated and initialed at the time of the correction.

5.2.4 The SIF must be signed and dated by the sample collector at the time of collection. If someone else collects the sample in place of the originally assigned collector, that individual must sign the form. Forms should never be pre-signed prior to sample collection.

5.2.5 SIFs for uncollected samples shall be packed in a separate sealed plastic bag in the same box with any other samples collected by the sample collector and mailed to the designated laboratory(ies).

5.2.6 Sample collectors shall refer to the MDP SIF instruction sheets for further explanation on filling out the form. Instructions may be found on MPO's Extranet site or MDP's website at: www.ams.usda.gov/mdp.

5.2.7 Paper SIFs shall be faxed to MPO as soon as possible after completion.

5.3 Electronic Sample Information Forms (e-SIFs)

5.3.1 Sample information is entered on a windows-based laptop/desktop or a handheld computer.

5.3.2 Proper training for all sample collectors on the use of the e-SIF system is strongly recommended.

5.3.3 Sample information shall be entered into the e-SIF system as specified in the "User Guide for PDP/MDP Remote Data Entry (RDE) System" referred to in Section 4 of the guide. If someone else collects the sample in place of the originally assigned collector, that individual must enter his/her name in the "Other Alternate Collector" Field of the e-SIF.

5.3.4 If sample information is pre-entered into the sample collector's e-SIF device, special care must be taken to review all entered data AFTER sample collection is completed. As an example, an unplanned change in collection site may necessitate site code changes/additions. Re-checking is important to ensure that accurate comparisons can be made between the sample once it is received at the laboratory and its corresponding e-SIF.

5.3.5 Multiple samples may be exported from the e-SIF system into a text file that shall be transmitted to MPO.

5.3.6 All e-SIF text files shall be e-mailed to a designated USDA account (amsmpo.data@usda.gov).

5.3.7 It is strongly recommended that e-SIF files be emailed on the same day as sample collection; however, e-SIF files **must be e-mailed no later than 8:00 a.m., Eastern Time, on the day following sample collection when samples are shipped to arrive at laboratory by 10:00 a.m. on the day following sample collection. If samples are shipped to arrive in the afternoon on the day following sample collection (usually with non-perishable commodities), e-SIFs must be emailed no later than 11:30 a.m., Eastern Time, on the day following sample collection**.

5.3.8 New RDE program information shall be updated on State's field computers (handheld or laptop computers) when supplied by MPO.

5.4 Chain of Custody

5.4.1 Chain of custody requirements ensure the chronological possession of the samples as they pass from sample collector to the carrier to the laboratory.

5.4.2 Paper SIFs serve as written documentation of the sample collector's possession of the sample and shall include the commodity collected, the site code, the date the samples were collected, the signature of the individual collecting and packaging the samples, and the date and time of transfer to the carrier.

5.4.3 When electronic SIFs are used, written documentation (a paper SIF placed inside the sample shipping container) is unnecessary if all sample collection information entered into the electronic SIF is received by the laboratory.

5.4.4 Two duplicate legible and permanently marked sample labels shall be placed in a clear packing envelope affixed to the outside of each sample bag. Notations shall include: (1) unique sample identification information [refer to SAMP PROC-02, Section 5.4.2.11], (2) date, (3) collector name, and (4) alternate or proxy site information (if applicable). The tamper-proofing mechanism shall be initialed and dated by the sample collector who has bagged the sample. This information, coupled with a Quarterly Sampling Schedule that each laboratory maintains on file, will suffice to complete chain of custody requirements and will allow initiation of sample processing and analysis in the event of a delayed e-SIF.

5.4.5 The sample collector shall ensure that all chain of custody requirements are fulfilled.

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Revision 3

- Added new reference in Section 4.
- Added reference e-SIF requirements (# required per box versus site sampled).
- Added statement that there should be no blank fields on SIFs (NA shall be recorded when information is not available).
- Removed reference to the acceptability of the use of paper SIF now that all States are using electronic SIFs.
- Removed statement that the inclusion of tracking information (State of origin, grower, packer, distributor, etc.) on SIFs was prohibited. The collection of tracking information for MDP is now required.
- Added reference to proxy sites.
- Added statement that there should be no blank fields on SIFs (NA shall be recorded when information is not available).
- Reference added for Quick Reference Guides.
- All sample information is required to be recorded before leaving the sampling site.
- Added requirement that handwritten sample information be recorded only on a paper SIF form and be kept as raw data for a minimum of two years.
- Clarified disposition and transfer of records.
- Stated that SIF forms and instructions are now on MPO's Extranet site.
- E-SIF arrival times (at MPO) changed to accommodate different sample shipping times.
- Clarifications made for reference to shipping labels.
- Enhanced clarifications by word changes in many sections.
- Made formatting changes.