

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

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Title: Laboratory Practices and Equipment Preventative Maintenance		
Revision: 1	Replaces: 09/01/01	Effective: 02/01/02

1. Purpose:

To provide standard procedures for Quality Assurance (QA) of microbiology laboratories participating in 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.

The objective of this SOP is to outline measures and procedures that will help in the verification of the accuracy and precision of data obtained in the MDP. The QA measures are designed to ensure that data obtained from the analyses used in the MDP are suitable for use in decision making in assessing the quality of fruits and vegetables. The principal objective of a laboratory quality assurance program is to ensure the correctness of data. The systems, measures, and procedures required for an effective program will most likely prevent cross contamination of samples being examined as well as protect personnel from infecting themselves and the working environment.

3. Outline of Procedures:

- 5.1 Laboratory Management
 - 5.2 Standard Operating Procedures Manual (SOPM)
 - 5.3 Laboratory Operations
 - 5.4 Criteria for Acceptance of Samples
 - 5.5 Equipment Maintenance
 - 5.6 Laboratory Personnel
 - 5.7 Laboratory Facilities
 - 5.8 Results Reporting Recordkeeping
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4. References:

1. Biosafety in Microbiological and Biomedical Laboratories 3rd Edition May 1993, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, U.S. Government Printing Office, Washington, D.C.
2. Compendium of Methods For The Microbiological Examination of Foods, 3rd Edition, 1992, Chapter 1, American Public Health Association, Washington, D.C.
3. Statistical Method from the Viewpoint of Quality Control, by Walter A. Shewhart, W. Edwards Deming, Dover Publications, Inc., 1986, New York.
4. Quality Control In Microbiology, by J. Michael Miller, Reprinted August 1990, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Public Health Practice Program Office, Atlanta, GA.

5. Specific Procedures:

5.1 Laboratory Management

Responsibility for the design and implementation of the laboratory quality assurance program lies with the management of the laboratory. In accepting this responsibility, management must evaluate the risks associated with laboratory error and the cost and benefits of reducing error through systematic quality assurance. The following steps describe a general approach to be followed in establishing a laboratory quality assurance program.

- a. The laboratory must develop objectives and policies that specify the accuracy of laboratory work required, including the selection of appropriate methods and sample handling requirements.
 - b. The laboratory must acquire and/or properly train personnel to perform laboratory tasks with the required level of proficiency.
 - c. The laboratory must have or be willing to provide the necessary facilities and equipment for the performing of laboratory tasks. The laboratory must be kept reasonably secure to prevent unauthorized personnel from entering the premises.
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- d. The laboratory must develop procedures and measures for monitoring, documenting, and record keeping that verifies the accuracy, precision, and reproducibility as well as the consistency of the laboratory work.
- e. The laboratory must establish/implement measures and procedures for initiating corrective and abatement actions when unacceptable performance is discovered.
- f. The universal biohazard symbol on orange or red background shall be used as a warning sign on all laboratory access doors where infectious agents are present. The warning sign should indicate the name of the infectious microbial culture(s) present, the person(s) responsible for handling and maintaining the cultures, the name and phone number of the Biological Safety Manager, and any restrictions on access to the room.

5.2 Standard Operating Procedures Manual (SOPM) or Laboratory Quality Manual (LQM)

This manual, which must be backed by the laboratory management, is needed as a resource for the bench technologist. It will also serve as a powerful communications tool for laboratory staff and others involved in the MDP.

- a. The SOPM/LQM should include the following⁴:
 - 1. A flow diagram which shows the administrative structure of the laboratory participating in the MDP.
 - 2. A list of fire and safety precautions, including instructions for emergency electrical problems.
 - 3. The requirements for sample receipt. This shall include criteria for the laboratory to accept or reject samples, and what actions are taken when a sample is rejected.

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4. SOPs that prescribe how the sample is processed through the laboratory. It shall also include instructions on record keeping and reporting results.
 5. Instructions on the referring of samples and cultures to reference laboratories.
 6. Instructions on special tests such as serological procedures, stains, biochemical tests, rapid test methods, and media and reagent preparation.
 7. The SOP for each method used in the MDP.
- b. Good Laboratory Practice Requires that⁴:
1. The SOPM/LQM shall be reviewed annually; this action must be signed, dated, and initialed by a technical supervisor or laboratory director in the laboratory.
 2. The SOPM/LQM must be kept in the workbench area where procedures are actually performed.
 3. The SOPM/LQM must contain only procedures currently in use in the laboratory.
 4. All changes made in the SOPM/LQM must be documented by recording in the manual the description of the change, and the date that the change was approved, and the initials of the person who made the change.
 5. All changes in the SOPM/LQM must have the written approval of the technical supervisor or the laboratory director.
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5.3 Laboratory Operations

The laboratory must develop operating procedures to help meet quality assurance objectives. Specific standard operating procedures must be put in place to ensure that approved sample preparation and analytical methods are followed. Standard operating procedures must be developed that sufficiently describe the analytical methods used in the MDP.

- a. Standard operating procedures must be sufficiently described to prevent minor modifications having a pronounced influence on the outcome of each analysis.
- b. The standard operating procedures must be sufficiently described to prevent deviations that could arise from misinterpretation of a method and to provide an accurate record of each stage of the procedures.
- c. Each laboratory will develop a quality assurance checklist to perform internal reviews of their QA/QC programs. Written reports will be done to document reviews and corrective actions taken to resolve QA/QC issues. An internal QA review shall be performed quarterly and documentation of corrective actions shall be available for MDP laboratory reviewers.
- d. The laboratory must have a written policy of contingency plans to handle or address occurrences that are beyond their control such as power outages, earthquakes, or other natural disasters.
- e. The Quality Assurance (QA) Officer or his/her designee will be held responsible for making sure that requirements of this SOP are complied with. Laboratories that do not have QA Officers or that have limited staff, shall designate someone to be responsible for making sure that the requirements of this SOP are complied with.

5.4 Criteria for Acceptance of Samples

- a. Samples must arrive at the laboratory with a Sample Information Form (SIF) which has the required information as prescribed in MDP SOP No: SAMP
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PROC'S-2, 3, and 4. If there is no SIF accompanying the samples the laboratory must request one, if it is not provided, the samples are not to be analyzed.

- b. The laboratory must examine the sample shipping container and the samples within to insure that sample integrity has been maintained. That is, the samples are not spoiled, smashed, or otherwise unacceptable for use in testing.
- c. Samples are to be shipped to arrive at the laboratory on the day after collection.
- d. The temperature of the samples is to be taken upon arrival. The laboratory should note the time at which the sample-shipping container was officially packaged and sealed for shipment to the laboratory.
- e. After receipt, MDP samples must be properly handled within the laboratory to maintain their condition upon arrival until analysis is completed. This requires that samples be refrigerated at a temperature range of 2-7⁰C.
- f. Sample analysis must begin as soon as possible after arrival at the laboratory. If analysis cannot begin immediately after arrival, samples must be stored to maintain their original condition until analyzed. Sample storage must not exceed 24 hours.
- g. When analysis is performed, the laboratory must document each step of all analyses by using appropriate laboratory work sheets and workbooks.
- h. Documentation of method quality assurance must be as prescribed in each MDP analytical SOP.

5.5 Equipment Maintenance

All laboratory equipment shall be subjected to a preventative maintenance program. Records of preventative maintenance actions shall, as a matter of policy, be maintained for the entire time the equipment is in use.

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a. Autoclaves

1. The manufacturer or an authorized service representative shall perform semi-annually or annually preventative maintenance inspections. Results of these inspections are to be documented and filed.
 2. Operating parameters (temperature and pressure) of each autoclave are to be checked and documented daily.
 3. Replace autoclave temperature/pressure charts daily and file in QA files.
 4. Document the sterilization of media, reagents, and apparatuses. Be sure to record time, temperature and cycle for items sterilized.
 5. At least weekly, document the cleanliness of the autoclave steam chamber.
 6. It is recommended that a chart be prepared that lists the time, temperature, and pressure requirements for all items routinely sterilized. This chart or list shall be posted in an area near the autoclaves.
 7. All items shall be properly labeled prior to sterilization.
 8. At monthly intervals, the Q/A Officer (or his/her designee) of the laboratory shall review and insure that autoclave records are properly documented.
 9. The laboratory shall use autoclave tape with each run, and perform spore tests at least monthly, or institute other means to measure/monitor the internal temperature of the autoclave. These checks must be documented.
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b. Analytical Balances

1. Electronic balances are to be calibrated and checked semi-annually or annually by the manufacturer or an authorized service representative under a preventative maintenance service contract.
2. At least weekly the laboratory will check each balance for condition and accuracy. A set of NIST or NIST traceable weights will be used to check each balance.
3. Balances used for microbiological purposes must be accurate to ± 0.1 grams with a 200 gram load.

c. pH meters

1. pH electrodes are to be partially submerged in distilled water or other appropriate storage solution when not in use.
2. The pH meter is to be calibrated including slope determination each day of use with two standard pH buffers that bracket the pH value of the media, reagent, or solution to be checked.
3. pH electrodes shall be observed for condition prior to each use.

d. Automatic Pipettors

1. The unit must be calibrated quarterly. Follow manufacturer's recommendations when performing calibrations.
2. Calibrations are to be documented.

e. Thermometers

1. Thermometers are to be calibrated annually against an NIST certified or NIST traceable thermometer at or near the temperature at which the test thermometer will be used.
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2. The quality assurance officer or his/her designee will be responsible for insuring the calibrations and records to document these checks.

f. Microscope

1. The microscope shall be checked and cleaned once a year under a yearly preventative maintenance service contract.
2. When not in use, the microscope should be properly stored. In addition, for each employee using the microscope, the laboratory shall have documentation that each employee has been properly trained in its use and operation.

g. Water Stills

1. At least semi-annually all glass water stills and deionized water systems will be cleaned.
2. The quality of water produced by such stills will be monitored monthly by the laboratory using a conductivity meter. The specific conductance of the water shall be greater than 1.0-megaohm/cm resistivity.
3. The water produced by the still shall have a pH value of 5.5 to 7.5.

h. Refrigerators/Freezers

1. Electric circuits used for refrigerators and freezers are to be properly rated for the equipment used on that power supply and properly grounded.
 2. The laboratory will check all refrigerators (1-8⁰C) and freezer (0 to -20⁰C) daily for proper internal temperature. For refrigerators used for sample receipt the temperature range is set at 2-7⁰C.
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3. The internal temperature of refrigerators/freezers will be monitored by use of at least one thermometer partially immersed in a tightly closed vial containing mineral oil, glycerin, or other suitable substance. The thermometer shall be immersed such that it does not touch the bottom of the vial. Place the vial and thermometer in a location where airflow will not be impeded. The exception to the above is thermometers clearly designed for use in freezers. Refrigerated units with built in dials and recording charts should have manual thermometers placed in them to monitor the accuracy of temperatures on dials and recording charts.
 4. Each refrigerator and freezer will be set and maintained at a specific temperature.
 5. The exterior of each refrigerator and freezer is to be labeled with the specific function and temperature for which it is used.
 6. The universal biohazard-warning symbol shall be affixed to the exterior surface of the freezer or refrigerator when it contains infectious microbial cultures. The National Response Center's 24-hour telephone number (1-800-424-8802) shall be posted on the storage equipment to use in case of an emergency situation.
- i. Rotary Shaker
1. The rotary shaker shall have a stroke of 1-inch (2.5cm).
 2. The calibration of the rotary shaker shall be checked quarterly using a tachometer to measure revolutions per minute (RPM). (See manufacturer's specification for your unit or follow the following instructions.) There are three ways to set the rotary shaker to operate at 160 revolutions per minute.
 3. If your rotary shaker is a new unit with a digital read-out set the unit to 160 rpm.
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4. If your unit does not have a digital read-out, then it must be calibrated using a tachometer. There are two approaches to calibrating using a tachometer.
 5. To calibrate the rotary shaker using a digital contact tachometer:
 - a. This type of tachometer may be purchased from most scientific supply warehouses. They usually come with two convex tips, one concave tip, and one linear speed wheel, instructions manual and a carrying case. To use this type unit to calibrate the rotary shaker, use the unit with the linear speed wheel to measure surface speed of the shaker (ft/min or m/min measurements). The tachometer will automatically suppress insignificant zeros to provide precise rpm readings.
 6. To calibrate the rotary shaker using an optical tachometer:
 - a. This type of tachometer may be purchased from the same suppliers as mentioned in (5. a.) above. The tachometer comes with reflective tape, instruction manual and a carrying case. The optical tachometer is used to take non-contact speed measurements of rotating objects. To use this type unit to calibrate the rotary shaker one would place the reflective tape on a piece of paper attached to the rotary shaker or simply attach the reflective tape to the shaker itself. Then direct the beam of light of the tachometer directly at the reflective tape attached to the rotary shaker. Note the reading of the Tachometer in rpm. Adjust the setting of the shaker until desired 160 rpm is obtained.
 7. Tachometers shall be purchased with a certificate of calibration to NIST standards.
 8. The accuracy of the units are ± 1 rpm at $23\pm 5^{\circ}\text{C}$ for a contact tachometer with a range of 0.5 to 19, 999 rpm, and ± 1 rpm at $23\pm 5^{\circ}\text{C}$
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for an optical tachometer with a range of 5 to 99,999 rpm in two ranges.

9. The rotary shaker shall be kept clean, properly lubricated, and in good working order.
10. Quality assurance checks of the rotary shaker shall be documented in the laboratory's QA logbook.

j. Hot Air Ovens

1. Hot air ovens used for dry heat sterilization shall be set at 170⁰C and be equipped with a thermometer.
2. This oven will be checked for proper temperature when in use and documented in the QA logbook. The oven will be checked quarterly using a biological indicator to document effective sterilization.
3. Items to be heat sterilized will be heated an appropriate length of time (approximately 3 hours) and aseptically stored. If shorter times are used, the laboratory must have documented results demonstrating the effectiveness of the designated shorter time. The shorter times documentation must be done with the use of a biological indicator.
4. It is recommended that an independent temperature controller be used to prevent overheating.

k. Incubators

1. Incubators or incubator rooms must be properly constructed and controlled, and must be of sufficient size to prevent crowding of the interior.
 2. Incubator rooms, if used must be well insulated, equipped with proper heating units, and have forced-air circulation.
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3. Incubators shall be loaded such that there is at least 2.54 centimeters space between adjacent stacks of plates, tubes, and other items placed in them.
 4. Incubators shall be kept in rooms where the temperature is within the range of 16⁰ to 27⁰C.
 5. The temperature within the incubator must not vary by more than \pm 1⁰C.
 6. The temperature within the incubator shall be measured by no fewer than two thermometers. One on the upper and one on a lower shelf of each incubator. The bulb of the thermometer shall be submerged in sterile distilled water using a 20 X 150 mm stoppered test tube or other suitable unit.
 7. The temperature of each incubator shall be taken and documented twice daily. Preferably early morning after the incubators have been closed over night, and again just prior to the end of the workday.
 8. If automatic devices of predetermined accuracy are used to control and record temperatures within the incubators and /or incubator rooms, their accuracy must be checked weekly by comparing their readings with those from accurate thermometers and the results documented. When standard thermometers are used, minimum and maximum registering thermometers may be placed in each incubator to indicate undetected gross temperature deviations.
 9. Do not depend on readings from the special minimum and maximum registering thermometers in # 8 above for daily records of temperatures. As stated these units are placed in the incubator to detect gross temperature deviations. As necessary, adjust thermostats to maintain proper temperature.
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1. Water Baths

1. Each water bath will be set and maintained at a specific temperature.
2. The exterior of each water bath will be labeled with the specific function and temperature for which it will be used. Water baths will be examined weekly or if needed, more frequently for cleanliness.
3. Each water bath will be filled with distilled or deionized water to which an appropriate amount and concentration of a non-corrosive sanitizer has been added.
4. Each water bath will contain a thermometer calibrated by use of a NIST certified or NIST traceable thermometer.
5. The temperature and condition of each water bath shall be checked and documented each day of use.
6. The water level of each water bath must be above the level of the media immersed in the bath.

m. Laboratory Glassware and Plasticware

1. Reusable glassware shall be made of high-quality, low alkali borosilicate glass.
 2. Etched or chipped glassware shall be discarded.
 3. Reusable glassware shall be properly cleaned, prepared (wrapped or packaged), and if required heat-treated prior to reuse.
 4. Procedures must be established and in place to sterilize and wash microbiologically contaminated reusable glass or plasticware.
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5. Microbiologically contaminated reusable labware must be sterilized by autoclaving or by other suitable means of sterilizing prior to being washed.
 6. Reusable glassware and plasticware shall be washed manually or mechanically with hot water containing a suitable detergent.
 7. Stubborn residues on glassware may be removed by using a suitable soaking and cleaning solution before washing.
 8. Screw caps, test tube caps, and other reusable closures shall also be washed in a detergent solution and rinsed thoroughly.
 9. All reusable plasticware and glassware shall be checked for residues of detergents yearly or when the detergent is changed.
 10. Glassware and plasticware shall be checked routinely for alkaline or acidic residues by applying a few drops of bromthymol blue pH indicator just after washing and rinsing and prior to autoclaving. The bromthymol blue pH indicator displays color changes from yellow to blue-green to blue in a pH range of 6.5 to 7.3. Since most cleaning solutions are either acidic or alkaline, this test assures proper rinsing. These checks must be documented.
 11. Disposable glassware and plasticware may be sterilized by ethylene oxide gas. Items treated in this manner may have toxic residues remaining. All items treated with ethylene oxide shall be checked (new lots) periodically for toxic residues and/or the laboratory shall request certification from the supplier of items treated in this manner that no toxic residues of ethylene oxide are present in or on the labware.
 12. Opened sleeves of Petri dishes and opened bags of pipettes will be closed and stored in designated areas of the laboratory where their sterility can be maintained.
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n. Disposal of Waste

1. When small volume cultures alone are sterilized, all cultures will be sterilized by autoclaving 15 minutes at 121⁰C prior to disposal. If cultures are sterilized along with other waste the waste shall be sterilized one hour at 121⁰C prior to disposal.
 2. Large volumes of pre-enrichment cultures will be sterilized by autoclaving one hour at 121⁰C prior to disposal, or by autoclaving for a specific time, temperature, and pressure to effectuate kill of cultures as determined by documented laboratory evaluation. For waste items held longer than 24 hours, (in cases where the autoclave is not working or excessive amounts of waste have accumulated) they shall be treated with an appropriate disinfectant.
 3. All microscope slides will be placed in an autoclavable bag or container immediately after use. This bag or container is to be sterilized by autoclaving for one hour at 121⁰C prior to disposal. It is recommended that regular microscope slides not be saved. Save only specialty glass slides such as those used for direct microscopic clump count, hanging drop slides, or other specialty slides.
 4. All used disposable pipettes, Petri dishes, disposable loops, disposable needles, etc., used in testing MDP samples will be placed in autoclavable bags, or containers with disinfectants immediately after use. These materials will then be sterilized for 60 minutes at 121⁰C prior to disposal.
 5. All cultures and items to be sterilized prior to disposal are to be held in a designated area and sterilized on a daily basis. In cases where autoclavable bags or containers are not completely full and ready to be sterilized, these bags should be securely closed for overnight storage. Autoclavable bags with small amounts of waste may be re-opened and re-used until filled, then sterilized.
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6. Autoclaves will have periodic spore tests run during disposal of waste to check their performance. These quality assurance checks will be documented monthly in the laboratory's quality assurance logbook. QA checks shall be done to check the performance of the disinfectant used to destroy cultures or disinfect waste products.
- o. Laboratory Sanitation
1. Work surfaces in the laboratory will be sanitized prior to and after use with an appropriate sanitizer. An appropriate sanitizer is, one that is approved by the U.S. Environmental Protection Agency for this purpose.
 2. Water baths will be examined weekly for cleanliness or more frequently if needed.
 3. The interior and exterior of incubators will be cleaned at least quarterly or more often if necessary with an appropriate disinfectant.
 4. Compounds that may enhance the growth of certain organisms on workbenches and other surfaces such as some phenolic compounds will not be used in the laboratory.
 5. Swab tests or other appropriate tests of work surfaces, balances, shakers, refrigerators, freezers, storage areas for gloves, forceps, and other equipment used in sample preparation area will be conducted weekly to determine effectiveness of sanitation and cleaning.
 6. Settling air plates will be used on a monthly basis to check air quality in the laboratory.
- p. Inter-Laboratory Quality Assurance Samples
1. The frequency on these samples sent to all laboratories participating in the MDP will be determined by the MDP Program Director.
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2. The laboratory quality assurance officer or laboratory supervisor will be responsible for follow-up on these samples.
3. If results from these samples document internal quality assurance/quality control problems in MDP participating laboratory, further follow-up may be necessary.

5.6 Laboratory Personnel

Quality results require proficient personnel. The personnel selected must have the education and experience necessary to perform their jobs and execute the requirements of the laboratory's quality assurance program.

- a. The laboratory must have performance criteria in place for each employee participating in MDP.
- b. There shall be an on-going documented training and education program in place in each laboratory.
- c. Each laboratory analyst participating in the MDP shall be trained to perform the required duties. This training shall be documented.
- d. The laboratory will have measures in place for routine evaluation of the analyst's performance.

5.7 Laboratory Facilities

A laboratory should be designed and constructed such that the most important part of the facility is the safety of the workers that use it. The food microbiology laboratory should be properly equipped to carry out the stated objectives of the MDP program.

- a. The laboratory shall be well ventilated. Normally, an ambient temperature of 21⁰ to 25⁰C and a relative humidity of 45 percent (%) to 50% is recommended.
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- b. Laboratory lighting shall be maintained at an average intensity of 50 to 100 foot-candles. Natural sunlight shall be discouraged as much as possible, especially direct sunlight. Direct sunlight is known to have adverse effects on media, reagents, and some types of specimens.
 - c. Laboratory space and bench areas shall, for most routine work, be six linear feet as the recommended minimum work area for each analyst. The ideal bench top height is 36 to 38 inches with a depth of 28 to 30 inches.
 - d. Bench tops must be made of impervious material.
 - e. Storage space for equipment, materials, and samples shall be sufficient for needed media, reagents, glassware, and plasticware.
 - f. To ensure the safety of personnel, all facilities shall be designed according to established federal, state, and local building and safety codes.
 - g. Each laboratory shall be equipped with fire extinguishers, alarms, sprinkler systems, eyewash stations, and safety showers.
 - h. The laboratory shall have available to each employee and/or visitor a pair of approved safety glasses.
 - i. There shall be in place a documented on-going comprehensive safety education program, which includes the actual operation of safety equipment in place in the laboratory.
 - j. There shall be available Material Safety Data Sheets for each chemical compound, reagent and media used in the laboratory.
 - k. The MDP laboratory shall have in place a routine cleaning and disinfection schedule for the entire laboratory. This program shall be documented and monitored for its effectiveness.
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5.8 Results Reporting and Recordkeeping

All results for USDA/AMS Microbiological Data Program (MDP) samples, along with any associated sample set quality assurance (QA) data, shall be reported to the USDA/AMS Monitoring Programs Office in 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.

- a. 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. Samples may be discarded after the sample wash has been successfully performed.
 - b. 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.
 - c. Each laboratory participating in the MDP must develop their own worksheets for capturing data and results. The records must be in the form of worksheets that become a part of the entire record for each sample, or a notebook that can be referred to in the sample record or in correspondence.
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- d. The analytical records must be reviewed periodically for completeness and accuracy before the results are reported through the RDE system. Specific data and information required by the RDE system must be reported to the MDP Program Director as prescribed in instructions for the RDE system.
 - e. The in-house review of results prior to reporting must be a three step process. The results and supporting data must first be reviewed by another analyst in the laboratory other than the one that actually prepared the data for reporting. The laboratory supervisor and laboratory director or their designee must perform the second and third review.
 - f. Records must be kept of all quality assurance and quality control testing.
 - g. Records are to be kept on analytical worksheets or on separate logbooks that are entered as a part of the analytical routine in the laboratory.
 - h. The analyst responsible for each QA check should be indicated, and the steps taken to bring into control any procedures or functions out of compliance or tolerance are to be recorded.
 - i. The system in place for storage and retrieval of analytical data of MDP samples and quality assurance must provide ready retrieval of all the data generated in the laboratory upon request if necessary. The length of time that data and other records can be kept may vary. Therefore it is very important that the MDP Program Director or the S&T Deputy Administrator be notified before any and all records are removed or destroyed as specified in SOP MDP-DATA-01.
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Isaac G. Sterling

February 14, 2002

Prepared by: Isaac G. Sterling, Microbiologist Date
Technical Services Branch, Microbiologist
USDA, AMS, Science and Technology
P.O. Box 96456, Room 3521-S
Washington, D.C. 20090-6456
(202) 720-5898

Anita J. Okrend

February 14, 2002

Approved by: Anita J. Okrend Date
Technical Services Branch, Chief
USDA, AMS, Science and Technology
P.O. Box 96456, Room 3521-S
Washington, D.C. 20090-6456
(202) 690-0621

Martha Lamont

2/20/02

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

Diana Haynes

2/20/02

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

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Revision 1

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Monitoring Programs Office

- Changed maximum laboratory holding time prior to analysis from 72 hours to 24 hours in subsection 5.4.f
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