

Mobile Laboratory Quality Assurance/Quality Control Plans

Guidance Document 25

This fact sheet lists the general standards that must be present in the quality assurance/quality control plan for all mobile laboratories submitting data to the Minnesota Department of Agriculture's (MDA) Pesticide and Fertilizer Management Division.

The MDA project manager/project team must determine the scope of the project and the data quality objectives for the project prior to deciding to use a mobile laboratory on a specific site. The level of Quality Assurance documentation (e.g. standard operating procedures, quality control plan) must, at a minimum, be complete enough to give the project staff data of a quality that meets the data quality objectives (DQO) for the site. For some screening analyses somewhat less stringent quality assurance may be acceptable, whereas for some very involved analyses even more stringent quality assurance may be required. The QA/QC plan submitted will be reviewed by MDA QA/QC staff to determine adequacy for the project. Generally, the QA/QC plan should contain the following sections:

All information provided to the MDA will be public information unless clearly marked as a trade secret under Minn. Statutes, Section 13.37, Subd. 1(b).

1. Introduction to Mobile Laboratory

This section should give a general introduction to the laboratory and the different kinds of analyses performed on the premises.

- Mission statement of the mobile laboratory;
- Quality assurance policy of the mobile laboratory;
- Size of the laboratory;
 - Dimensions and layout
 - Equipment list (major items)
- Definition of terms; and,
- Lab certifications.

2. Laboratory Organization and Responsibilities

This section should introduce the reader to the different key personnel in the Laboratory.

- Organization chart (this includes the company as well as the mobile lab);
- Description of lines of communication;
- Work units in laboratory; and,
- Brief description of key positions.

3. Sample Custody

This section should completely describe the procedure from the receipt of the samples until the samples are disposed of (cradle to grave). (Note: Standard Operating Procedures (SOPs) may be referenced where applicable.)

- Sample receipt policies;
- Sample log-in;
- Example laboratory chain of custody (COC);
- Condition of sample upon receipt;
- Sample storage, preservation and contamination controls;
- Tracking of samples;
- Evidence files (for legal samples); and,
- Sample disposal.

4. Calibration Procedures and Frequencies

This section shall describe the procedures used by the lab to calibrate instrumentation and equipment, including balances, in the lab. SOPs may be referred to (where appropriate). All applicable analyses to the site must be discussed.

- Frequency of Calibration of All Instruments;
 - 3 to 5 points for the calibration curves. This does not include the method blank.
 - Type of curve(s)
- Criteria for acceptance of calibration;
- Updating and verification of calibrations;
 - Continuing calibration verification standards
 - Continuing calibration blanks (frequency, required for continued analysis)
 - Frequency of updates of curves
- Records of calibration for instruments; and,
- Standards
 - Expiration dates
 - Testing for purity and validation
 - Records of receipt and tracking
 - Disposal of unused standards

5. Internal Quality Control Checks

The mobile laboratory shall describe in detail all Quality Assurance/Quality Control (QA/QC) practices that are used in the laboratory. It is recommended that a flow chart showing from sample receipt to report generation, be included to give a visual picture of the path taken by a sample and the QA/QC association with the sample. The items listed below describe some of the parameters associated with the Internal Quality in a laboratory. This list is not intended to be conclusive as to all the QA/QC a laboratory performs.

The limits associated with specific parameters and how they are developed must be described by the laboratory. Control Charting and any other method of tracking the limits must also be included.

- 10% matrix spikes and matrix spike duplicates and/or duplicates with a minimum of once per sample set;
- Lab control samples;
- Surrogates and internal standards, (where appropriate);
- Blanks (equipment, field, reagent, instrument and refrigerator);
- 10% method blanks;
- Zero and span gases, mass spectrometer (MS) tuning if an MS is used onsite;
- Proficiency testing of analysts and method;
- Sample preservation and holding times;
- Reagent storage and purity; and,

- Glassware cleaning.

6. Data Reduction, Validation and Reporting

The laboratory will describe, in detail, the in-house data reduction and validation procedures. It is strongly recommended that someone besides the analyst review all raw data and final reports that are generated in the analytical process. Any SOPs associated with these procedures should be referenced. The review process taken by an analyst/field chemist to report data must include:

- Procedures for re-running a sample;
- A description of the different flags and procedures for flagging data;
- Use of spikes and duplicates in assessing data;
- Use of blanks in assessing data;
- Use of laboratory control samples in assessing data;
- Use of surrogates in assessing data;
- Data reporting format;
- Assessing if data meets reporting limits for project;
- Questionable sample condition;
- Holding times; and,
- Practical quantitation limits.

7. Performance and System Audits

The laboratory should have a policy of internal audits to verify the QA/QC plan is being followed. The audit should include an examination of the sample receipt documentation, sample log-in, sample storage, chain of custody procedures, sample preparation and analysis, instrument operating records, etc. External audits performed on the mobile laboratory should be discussed as to who performs them, who has performed them, what will be and has been audited, and the results of these audits. Blind QC samples should be submitted to the lab to verify system performance.

8. Preventative Maintenance

The laboratory will describe routine preventative maintenance program used to minimize equipment failure and breakdown. Trained staff should be on the premises to repair equipment and/or a contract be in place with a vendor to do so in a timely manner. All maintenance performed on the equipment shall be recorded in individual books that are kept with the instrument. The lab shall submit a table of its instrumentation and all preventive maintenance regularly performed.

9. Routine Procedures to Assess Data Quality and Determine Reporting Limits

The procedures that are used by the laboratory to assess data shall be annotated.

- Precision;
- Accuracy;
- Representativeness;
- Completeness;
- Reporting Limits; and, (these must be explained on how they were derived)
 - Instrument Detection Limits (IDLs)
 - Method Detection Limits (MDLs)
 - Practical Quantitation Limits (PQLs) or Reporting Limits (RLs)
- A method detection level study will be run onsite prior to samples being run.

10. Corrective Action

Corrective action may be required for instruments or in the analytical process. The laboratory must list common problems associated with corrective action and corresponding actions taken by the analysts to correct the situation. If the corrective action of the analyst cannot correct the problem, there must be a procedure in place for informing management and the

QA/QC Officer. The procedures that management will take must be listed. All corrective action taken must be documented on appropriate forms and in the maintenance book for the specific instrument (when applicable).

11. Quality Assurance Reports to Management

On long term projects, the laboratory will normally submit quality assurance reports to the Contractor's Project Manager (and to the state liaison, upon request). The report should include:

- Any changes or modifications to the QA/QC Plan;
- Any changes to any of the standard operating procedures;
- Any significant QA/QC problems and recommended solutions;
- Results of corrective action;
- Any limits that shall be imposed on data;
- Samples received in questionable condition;
- Holding times that have been missed;
- Management changes that affect work done for the State of Minnesota; and,
- Any other issues that will affect the project.

12. File Handling and Storage

This section shall describe the procedures used by the laboratory to file data for immediate and long-term storage. Discussion of longevity of files and data, Laboratory Information Management System (LIMS) backups, and any other applicable items can be included.

Appendices

- **Analytical Standard Operating Procedures**

Use the standard operating procedures (SOPs) format recommended by the USEPA. Include all steps done to perform the analytical method. Do not make a reference or submit a copy of an Instrument Manual, SW-846, or Standard Methods in lieu of an SOP. The SOPs are to show, in detail, how the mobile laboratory is actually performing the methods.

- **Resumes**

Items minimally required include education, experience, current area of assignment, and responsibilities of personnel.