3745-4-05 Appendix B Guidelines for laboratory quality assurance plans.

All laboratories that perform analysis under a level 2 study plan shall implement a quality assurance program and shall document all elements of the program in a quality assurance manual (QAM) or quality assurance plan (QAP). The elements covered in the QAM or QAP should, at a minimum, include the items listed in this appendix.

(1) Title page with authorization signatures and dates.

(2) Table of contents.

(3) Statement of quality assurance policy.

(4) Laboratory organization and responsibility, including:

(a) Organizational tables;

(b) Position descriptions for all personnel; and

(c) Training, education, and experience of laboratory personnel.

(5) Data quality objectives for accuracy, precision, and reporting limits for each test, target analyte, and sample matrix.

(6) Analytical methods variances.

(7) Laboratory equipment and instrument lists.

(8) Sample receipt and chain-of-custody procedures. This section should include procedures for:

(a) Receiving samples;

(b) Sample login;

(c) Sample security;

(d) Sample storage;

(e) Sample tracking; and

(f) Sample disposal.

(9) Laboratory standard operating procedures (SOPs) with dates of last revision. This section should include procedures for:

(a) Glassware preparation;

(b) Sample preparation;

(c) Sample cleanup;

(d) Sample analysis; and

(e) A description of quality control procedures that are required and followed for each method.

(10) Calibration procedures. This section should describe:

(a) The type of calibration used for each method;

(b) The criteria for acceptance or verification; and

(c) The frequency of calibration.

(11) Preventive maintenance and documentation. This section should describe:

(a) The location of instrument manuals; and

(b) The schedules for performance of routine equipment maintenance;

(12) Internal quality control checks, frequency, and criteria for acceptability. This section may reference laboratory SOPs, and should include the frequency and acceptability of method detection limit (MDL) calculations.

(13) Data reduction, review, and reporting. This section could include discussion of the process used to do data assessment, evaluation of data completeness, comparability, and trends.

(14) Standard corrective action procedures for quality control failures.

(15) External and internal audits, accreditations, and certifications. This section should list all laboratory accreditations and or certifications, and participation in inter and intra laboratory studies.

(16) Document retention and control. In this section, the lab should discuss its document retention schedule, storage, and retrieval procedures, including procedures for review and approval of revised lab documents (i.e., QAP and SOPs).

(17) Procedures for procurement and process control. This section should describe the laboratory's policy and procedures for the selection and purchasing of equipment and supplies it uses that affect the quality of the environmental tests and calibrations.