Internal Audits and Quality System Management Review

1.0 INTERNAL AUDITS

An internal audit of the laboratory is conducted by the QA officer every fall, typically during the last quarter of the calendar year. Records for a set of randomly selected events in chemistry and biology are requested from groups in the laboratory. The audit includes the examination of sample custody forms, raw laboratory data, training records, and laboratory records and interviews with laboratory staff. In addition to home-grown checklists, checklists published by the Florida Department of Health Environmental Laboratory Certification Program and by TNI are used for the audit.

Elements of the review, including reviews of laboratory SOPs, are conducted throughout the year on an annual basis as SOPs became due for reauthorization. The laboratory QA Manual is revised once a year, typically in late fall. A review and edits to the QA manual are conducted by lab supervisors and the QA officer in the months of September – November. The edits are finalized and a final review is conducted in late November. A final version is then published by posting an electronic version on the laboratory website in late December. The new version of the QA manual becomes the official version of the manual beginning January 1 of the following year.

Deficiencies identified during an internal audit need to be addressed by the lab within thirty days of distribution of the report to lab managers. Corrective actions require a more formal approach, that includes establishing the cause of the failure (root cause analysis), the corrective action taken and a verification of the implementation of the corrective action.

2.0 MANAGEMENT REVIEW

A management review of the laboratory is conducted at the end of the calendar year. The management review is typically finalized in January or early February for the preceding calendar year. The review of the laboratory's quality system is a key component for maintaining data integrity, quality and efficiency. The Quality System Management review summarizes Quality Assurance (QA) activities conducted by lab employees to meet the goals of improving laboratory operations and data quality and increasing customer satisfaction. The purpose of the review is to document lab activities that advance these goals based on customer feedback, performance testing, audits, and corrective actions. The elements of this review conform to the requirements of the 2016 TNI standard, V1M2, section 4.15**.** The laboratory's quality system management review consists of seven (7) elements:

1) All laboratory supervisors review the laboratory's Quality Manual on an annual basis. Laboratory supervisors may submit proposed changes to the manual. Upon approval of the

revised manual by senior technical directors and the Quality Assurance Officer (QAO), a new revision is published. The revised quality manual is signed by technical directors and published for dissemination online via the Internet.

2) All laboratory supervisors review standard operating procedures (SOPs) for which they are responsible at least once a year. The updated SOPs are authorized by the QAO. Once authorized, the SOP becomes the official copy in the lab's Laboratory Information Management System (LIMS). It is due for its next review and reauthorization after one year (365 days). The SOP may be updated and reauthorized sooner, if changes such as the addition of analytes are made to the method. The QAO emails a list of SOPs coming up for review to laboratory supervisors once every month. The authorization of revised or existing SOPs is performed according to SOP LB-001.

3) The QAO performs a system audit once annually. The audit consists of a physical system and data audit. The protocol for conducting the audit is documented in the laboratory's Quality Manual. Any valid deficiencies noted as a consequence of internal or external audits are corrected by incorporated new or revised protocols into the laboratory's quality system. Incorporation of new or revised protocols into the laboratory's quality system may be accomplished through changes to SOPs or by revisions to the Quality Manual.

4) Performance reports are generated monthly, semi-annually and annually to track workload performance, efficiency and spending. The reports are maintained by the laboratory and disseminated to laboratory supervisors.

5) Regular staff meetings are held to discuss quality issues, workload and staffing issues and other items of importance to the laboratory. Necessary changes to the quality system as a consequence of performance on proficiency samples, round robins, split samples or audits are discussed for incorporation and implementation. Corrective and preventive actions taken during the calendar year and recommendations for improvement are also documented in the management review.

6) Feedback, including complaints from clients are primarily obtained using an annual online customer satisfaction survey conducted every spring. Detailed customer feedback from the survey is reviewed by the laboratory's senior management and used to improve laboratory operations. Improvements and corrective actions are implemented on a continuous basis throughout the year. Complaints received via email or phone are also documented. Other key performance indicators such as the sample workload and turn-around-times for sample results are also included in the review. When non-conformances occur, corrective actions to fix them are documented in non-conformance reports that are included in laboratory reports sent to customers.

7) Other performance metrics for the laboratory include various types of training taken by lab employees, training provided by lab staff to other DEP employees and talks or presentations

made by lab staff at conferences during the calendar year. A summary of new instrumentation and capabilities acquired by the lab, and plans for the future are also included in the report.

8) The QAO prepares an annual report summarizing the completion of items 1 through 7 to include the completion date and responsible personnel for each of the activities. This report will include a summary of assessments by external bodies, the results of inter-laboratory comparisons or proficiency tests, QC activities, staffing issues or any relevant client feedback or complaints.