**THE INSTITUTE REVIEW**
First Quarter 2013

# Assessors Reveal the Top 10 Common Onsite Assessment Findings

*By Stephanie Drier, Minnesota DOH, J. Steven Gibson, TCEQ, and Carl Kircher, Florida DOH*

Two out of three accredited laboratories do not demonstrate compliance with the requirements contained in the management standards for quality systems (i.e. management system). The laboratory must review the lab's management system, documentation, and records to ensure continual improvements as similarly done with the technical aspects of a laboratory. Below, the references to the 2003 NELAC and 2009 TNI Standard citations create a list of common findings made during onsite laboratory assessments:

**1. Control of Records (NELAC 5.4.12; TNI V1M2 4.13)**

The laboratory must establish and maintain procedures to control quality and technical system records. Records are information that are created or received by the laboratory. Most findings for the control of records did not affect the data generated; however, the laboratory's record is the objective evidence that the activity occurred and as a result provides the client with data of a known and documented quality. Common citations for control of records are:

- traceability of observations and derived data must be perform and recorded in accordance with NELAC 5.4.12.2.1 and TNI V1M2 4.13.2.1. As an example, the laboratory must record the originally observed incubator and the derived temperature data after thermometer correction factor was applied;
- standard and reagent origin, receipt, preparation and use with analytical run logs, bench sheets, and notebooks must be maintained by the laboratory (NELAC 5.4.12.2.5.3. i and TNI V1M2 4.13.3.xi); and
- equipment used in analytical testing is incorrectly identified or not identified in the analytical records. The laboratory must track the equipment used to produce the data and allow for historical reconstruction of the lab activities used to produce the analytical data (NELAC 5.4.12.1.5 b and TNI V1M2 4.13.3.f.

**2. Equipment (NELAC 5.5.5; TNI V1M2 5.5)**

The laboratory must maintain support equipment in working order and must calibrate or verify the equipment annually for the entire range for which the equipment is used. The lab must also ensure to calibrate support equipment used to weigh media and soil samples, infrared temperature measuring devices, and non-class A volumetric glassware at the required frequencies. Here are two additional areas of concern for equipment and support equipment:

- all support equipment shall be calibrated or verified annually bracketing the range of use (NELAC 5.5.5.2.1.b; TNI V1M2 5.5.13.1.b.); and
- initial calibrations must be verified with a second source material or independently prepared lot from the same manufacturer (NELAC 5.5.5.2.2.1.d and TNI V1M4 1.7.1.1d).

**3. Quality System/Management System (NELAC 5.4.2; TNI V1M2 4.2)**

The quality and management system requirements are defined in the Standards, and TNI offers quality system manual templates (http://www.nelac-institute.org). However, the laboratory must review and incorporate the requirements and revise the templates to reflect the actual laboratory practice. Specifically, laboratories do not define in detail the data integrity policies and procedures (NELAC 5.4.2.6; TNI V1M2 4.2.8.1), internal audits, and management review procedures. The laboratory must define within the management procedures the frequency of data integrity training for current and newly hired laboratorians, the covered topics, and training documentation. In addition, the laboratory's management system must use internal audits (see below) and management reviews (see below) to assess and improve the implemented system to ensure compliance with the requirements, such as the periodic in-depth data integrity monitoring and other laboratory policies, procedures, and processes.

## Assessors Reveal the Top 10 Common Onsite Assessment Findings cont.

**4. Handling of Samples (NELAC 5.5.8; TNI V1M2 5.8)**

The procedure for handling samples must clearly describe the process used to uniquely label all sample containers to ensure sample bottles cannot be confused physically or when referred to in records or other documents (NELAC 5.5.8.2 a; TNI V1M2 5.8.5 a).

**5. Personnel (NELAC 5.5.2; TNI V1M2 5.2)**

The laboratory's personnel records do not include or meet standard requirements as commonly observed in the following ways:

- initial data integrity training and the annual refresher training shall have a signature attendance sheet or other form of documentation that demonstrates all staff has participated and understand their obligations related to data integrity ( NELAC 5.5.2.7; TNI VIM2 5.2.7); and
- technical manager designations must meet requirements for both bench and academic credentials (NELAC 4.1.1.1; TNI V1M2 5.2.6.1).

**6. Management Reviews (NELAC 5.4.14; TNI V1M2 4.15)**

- The annual review of the quality system must ensure effectiveness of the system for the size and scope of the laboratory. The laboratory management review must also assess any evidence of inappropriate actions or vulnerabilities related to data integrity (NELAC 5.4.14.1 and TNI 4.15.1);
- The laboratory must have a predetermined schedule or maintain a procedure for the management review process (NELAC 5.4.14.2 and TNI V1M2 4.15.2); and
- Several accredited labs conduct internal management reviews; however, the scope of the management review and required actions resulting from the review are not documented (NELAC 5.4.14.2; TNI V1M2 4.15.2).

**7. Standard Operating Procedures (NELAC 5.5.4.1.1 and 5.5.4.1.2; TNI V1M2 4.2.8.5)**

The laboratory must provide sufficient detail within the procedures to allow someone similarly qualified, other than the analyst, to perform the test procedures and must contain information for all the laboratory activities as listed (e.g. waste management and pollution prevention) by topic in the requirements per NELAC 5.5.4.1.2 b; TNI V1M2 4.2.8.5.f.

**8. Document Control (NELAC 5.4.3; TNI V1M2 4.3)**

The laboratory must establish and maintain procedures for approval, issuance, and change to all documents that form part of the laboratory's quality system. The laboratory must also ensure the adopted document control procedures address the following items:

- retained obsolete documents marking process (NELAC 5.4.3.2.2 d; TNI 4.3.2.2d); and
- control of internally generated and external source documents (e.g. regulations, standards, software specification, instruction manuals and etc.) per NELAC 5.4.3.1; TNI V1M2 4.3.1.

**9. Internal Audits (NELAC 5.4.13; TNI V1M2 4.14)**

The laboratory's internal audit procedure must address all elements of the lab's quality system and testing activities. The quality manager must:

- conduct internal audits of its all its activities to verify that its operations continue to comply with the requirements of the quality system and the standard requirements;

## Assessors Reveal the Top 10 Common Onsite Assessment Findings cont.

- ensure that the internal audit is annually planned and conducted to adequately review all technical and **management** systems within the laboratory (NELAC 5.4.13.1; TNI V1M2 4.14.1).

**10. Review of Requests, Tenders, and Contracts (NELAC 5.4.4.; TNI V1M2 4.4)**

The contract review procedure must include the process the lab will follow to ensure that client requirements, including the method to be used, are defined, the laboratory has the resources to perform the work, and the appropriate test method is selected to meet the clients' needs.

The laboratory's contract review procedure must include a plan for subcontracting samples in case of unforeseen circumstances. The lab must maintain a register of all subcontractors that it uses and a record of their certificates/scopes of accreditation (NELAC 5.4.5.4; TNI V1M2 4.5.4).

Please review the common findings and observations to determine if your laboratory is in compliance with the standard requirements and use the listed items to evaluate and improve the health of your lab's management system.

*Note: The information was compiled based on common assessment finding presentation and materials presented by the Minnesota Department of Health Environmental Laboratory Accreditation Program, the Florida Department of Health Environmental Laboratory Accreditation Program, Texas Commission on Environmental Quality, and the New York Department of Health. Finding information based on observations and findings cited from 2010 through early 2013.*