



## **The NELAC Institute (TNI) Position Statement SMALL LABORATORY QUALITY SYSTEMS**

Every environmental laboratory, regardless of its size, should operate with an effective quality system. The TNI Standard, which is based on the ISO/IEC (International Organization for Standardization) 17011 and 17025 Standards, sets forth the principles and practices of a laboratory quality system applicable to both large and small laboratories. Implementation of the TNI Laboratory Standard benefits small laboratories by increasing confidence in their data, improving the quality of their overall analytical processes, and improving defensibility of their data.

### **BACKGROUND**

The TNI Standard is a consensus-based laboratory standard, developed by a group of environmental laboratory community stakeholders. This Standard describes a well-documented quality system for the management of environmental analytical laboratories and is currently the Standard followed in 14 states. In addition, nearly every other state has adopted sections of the TNI Standard into their laboratory regulations, grants reciprocity, or recognizes the standards in other ways. The 2009 TNI Standard was recognized by the American National Standards Institute (ANSI) in 2012 as an American National Standard for the environmental laboratory sector. As a result, the 4 volumes of the TNI Standard are designated as accepted practice and are made available to any accredited or non-accredited laboratory.

Small laboratories with a limited number of employees and where an employee often fills the roles of both the analyst and Quality Control Officer/Technical Manager often do not seek implementation of a comprehensive quality system, such as that described by the TNI Standard, unless required to do so by their State regulations. TNI Standard implementation has been made easier, though, by several new TNI resources:

- Quality Manual Template;
- Standard Operating Procedure (SOP) Templates;
- Small Laboratory Guidance Manual;
- Small Laboratory Advocate Group (SLAG) – provides a forum for small laboratories to discuss and exchange ideas and as a result to create tools that assist labs in understanding and implementing the TNI Standard;
- Training Courses and Webinars; and
- Annual Mentor Sessions and Technical Assistance at TNI Forums.

Laboratories performing Safe Drinking Water Act analyses are required to be certified. EPA's *Manual for the Certification of Laboratories Analyzing Drinking Water* is the guidance document for drinking water testing certification, but does not include as comprehensive a quality system as the TNI Standard. However, EPA recognizes and accepts accreditation to the TNI Standard as equivalent to their certification.

## **BENEFITS OF A QUALITY SYSTEM**

The TNI Standard is a recognized national standard for laboratory testing that is achievable and attainable by any small laboratory. A good quality system does not have to be expensive or require the time of a large number of employees. In the long run, having such a system will reduce errors that can jeopardize compliance and often require expensive retesting. The result of adopting the principles and practices in the TNI Standard is improved data quality with increased confidence in the safeguarding of public health and the environment.

Over 2,000 laboratories have implemented the TNI Standard, many of them small laboratories with one or two analysts. Proved benefits to these laboratories from use of the TNI Standard include:

- Improved data usability;
- Easier analyst training using a well-documented standard;
- Uniformity of laboratory documentation and processes;
- Improved analytical processes through established documentation and review processes;
- Easier problem identification due to more complete documentation procedures;
- Improved data defensibility and customer confidence; and
- Improved customer confidence in safeguarding the public health and the environment.

## **BENEFITS OF ACCREDITATION**

Once a laboratory implements a quality system, it is then a fairly easy step to become accredited to the TNI Standard. Taking this next step will provide the following benefits to laboratories:

- Formally recognized testing competence from an authoritative independent body;
- National recognition for data produced of a known and documented quality;
- External assessment of the health of the lab's implemented quality system and its continued compliance with requirements; and
- For commercial laboratories, a marketing advantage.

## **RECOMMENDATIONS**

Specific Actions to be taken by TNI:

- Continue support for the Small Laboratory Advocate
- Continue to create tools to facilitate documentation and implementation of quality systems in small laboratories
- Create a document based on the Small Laboratory Handbook that emphasizes quality systems, but without references to the TNI Standard or TNI laboratory accreditation.

**ACKNOWLEDGEMENTS**

2012 Small Laboratory Advocacy Group

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Elizabeth Turner, REM, Laboratory Manager, North Texas Municipal Water District and TNI Small Laboratory Advocate, 2013

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TNI ELV1, Management and Technical Requirements for Laboratories Performing Environmental Analysis, September 8, 2009

TNI Quality Manual Template, February 23, 2011

TNI Guidance for Small Labs, August 1, 2011

EPA Manual for the Certification of Laboratories Analyzing Drinking Water, 5th Edition

ISO 17025 Standard: General Requirements for the Competence of Testing and Calibration Laboratories

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| <b>Position Statement Number:</b>            | <b>1204</b> | <b>REVISION NO:</b>                  | <b>0</b> |
| <b>Advocacy Committee Approval Date:</b>     | 4-2-13      | <b>Policy Committee Review Date:</b> | 6-21-13  |
| <b>TNI Board of Directors Endorsed Date:</b> | 11-13-13    | <b>Effective Date:</b>               | 11-13-13 |