

BACKGROUND

Accreditation of laboratories is based on a single set of standards developed by The NELAC Institute (TNI). Members represent federal agencies, state programs and the private sector. This single standard is a uniform standard for all laboratories.

The standard developed by TNI incorporates current state program requirements and the International Standards Organization (ISO) standard ISO/IEC 17025:2005, "General Requirements for the Competence of Calibration and Testing Laboratories." The standard includes all quality assurance (QA) policies and quality control (QC) procedures that must be presented in either a QA Manual or laboratory procedures to help ensure and document the quality of the data produced.

Laboratories seeking accreditation under NELAP must assure implementation of all QA policies and the essential applicable QC procedures specified in Volume 1 of the TNI standard. The QA policies are applicable to environmental laboratories regardless of the size and complexity.

This course has been revised and materials updated to meet the requirements of the 2016 TNI Environmental Laboratory Standard for basic assessor training.

The status of the implementation will be reviewed in the class.

The TNI standards may be downloaded from the web at www.nelac-institute.org. Click on "Standards", "Standards Home" to find the 2016 TNI Standards. The standard is purchased from TNI with the full version of the 2016 TNI standard including the ISO/IEC 17025:2005 and ISO/IEC 17011:2004 language.

The TNI Checklist: (2016 TNI Version in Excel), 2016 TNI EL Standard Volume 1 and Volume 2 are used throughout this course. Download the checklist here: <https://nelac-institute.org/content/NELAP/qscheck2016-access.php>

AGENDA

Day 1 – September 28, 2020 (11 am to 4 pm eastern)

Chapter 1: Introduction to Standards

- Preliminary Examination
- Questions about TNI Standard Development
- Questions on Assessment Process (TNI Volume 2 Module 1-3)
- Conformance to Standard, Methods, Procedures (Any questions)

Any Questions on the following:

Chapter 2: Assessor Performance

- Qualifications
- Ethics
- Skills and Handling Difficult Situations

Chapter 3: Assessment Process (V2M3)

- Planning, Conducting, Reporting
- Completing
- Checklist
- Writing deficiencies (findings)

Chapter 4: Proficiency Testing (PT) (V1M1)

- Reviewing PT data
- Understanding reporting limits
- Review how to use PT data for an assessment

EXERCISES

Complete Exercise 2 from 2:30 to 3:15 pm eastern (Return to large group from 3:15 until 4:00pm eastern) Exercise 2 in breakout room, 45 minutes

Exercise 3 on your own)

Day 2 – September 29, 2020 (11 am to 4 pm eastern)

Review Day 1 exercises

Any Questions on the following:

Chapter 5: Management System Elements (V1M2 Section 4)

- Organization, Administration
- Improvement, Preventive Action
- Corrective Action, Internal Audits, Management Review
- Documentation and Data Integrity
- Records, Paper and Electronic

EXERCISES

**Complete Exercise 4 and 5 in breakout groups assigned
(Exercise 4 and 5 Breakout interviews – Total 3 hours
(1 to 4 pm eastern)**

**Assessors prepare – 45 minutes
(Lab personnel prepare work together in separate room)
(15 minute break during exercise)**

Labs go to breakout room for assessor group 2:00 pm eastern

**Assessors interview lab person - 45 minutes two methods **

Labs return to breakout room

Write finding (at least one per group per exercise) 45 minutes

Day 3 – September 30, 2020 (11 am to 4 pm eastern)

Review Day 2 exercises

Any Questions on the following:

Chapter 6: Technical Elements (V1M2 Section 5) (V1M3-M7)

- Personnel
- Method Selection
- Quality Control
- Traceability-Methods, Sample, Data, Standards, Process
- Proficiency Testing (V1M1, V2M1)

EXERCISES

Complete Exercise 6 and 7

Work on your own – 1.5 hours

Day 4 – October 1, 2020 (11 am to 1 pm eastern)

Review Day 3 exercises

Any Questions on the following:

Chapter 7: Laboratory Assessment (V1M1-M7)

- Documentation and Data Review
- Conformance Evaluation
- Effectiveness of Management System

Prepare for the final exam for tomorrow

Day 5 –October 2, 2020 (11 am to 3 pm eastern)

Any Questions:

Chapter 8: Conclusion

- Questions and Final Comments
- Scoring
- Final Examination
- Review of Final Examination

END CLASS

Students are requested to read the TNI standards Volume 1 and 2
the Student book and slides before class.
Bring your questions to class

NOTES

Students should prepare for the final exam each evening.

Pretest score is 25% of your final grade.

*Students should read TNI Environmental Laboratory Standard Volume 1 and 2.
Students are expected to be thoroughly familiar with the TNI standards before
arrival at the course.*

Final Exam score is 75% of your final grade.

*You must obtain a 70% score to “successfully complete” the course. (NELAP
assessors: You are required to have successfully completed a basic assessor-
training course.)*

All students receive a certificate of course attendance if not successful in completing
the examination.

Students with test scores of greater than 70% receive a certificate of course completion.

This course is not approved by NELAP. It is up to the accreditation body to approve a basic assessor-training course in order to qualify its assessors

State accreditation body assessors have attended this class. Accreditation bodies have accepted this course for meeting the basic assessor training requirements of its assessors.

This course was prepared in accordance with the TNI standard.