



ENVIRONMENTAL LABORATORY SECTOR

VOLUME 4

GENERAL REQUIREMENTS FOR AN ACCREDITATION BODY OF ENVIRONMENTAL PROFICIENCY TESTING PROVIDERS

TNI Standard

**This Document Presented for Review and Comment
Only**

**P.O. Box 2439
Weatherford, TX 76086
817-598-1624
www.nelac-institute.org**

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PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) Proficiency Testing Committee. The TNI Board of Directors wishes to thank these committee members for their efforts in preparing this Standard as well as those TNI members who offered comments during the voting process.

This Standard supersedes TNI Standard EL-V4-2016-Rev.2.0.

This Standard must be used by any organization seeking recognition for the accreditation of proficiency testing providers in conformance with TNI Standard EL-V3.

Standard Revision History

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VOLUME 4
General Requirements for An Accreditor of Environmental Proficiency
Testing Providers

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VOLUME 4

General Requirements for An Accreditor of Environmental Proficiency Testing Providers

1.0 Introduction, Scope and Applicability

1.1 Introduction

This volume of the TNI Standard defines the requirements for an accreditation body to achieve TNI recognition as an accreditor of conformity assessment bodies that are either seeking accreditation or are currently accredited in accordance with TNI EL-V3-2024 Rev 3.0.

Users of this standard should apply the following substitutions, acknowledging that minor contextual variations may be necessary when referring to accreditation bodies that are not yet recognized by TNI.

For this term:	Substitute this Term:
Accreditation Body (AB)	Proficiency Testing Provider Accreditation Body (PTP AB)
Conformity Assessment Body (CAB)	Proficiency Testing Provider (PTP)
Proficiency Testing (PT) Program	TNI PT Program

1.2 Scope and Applicability

This standard applies to any accreditation body recognized under a cooperative Mutual Recognition Agreement (MRA) or Multilateral Recognition Arrangement (MLA) for conformance with ISO/IEC 17011:2017, Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies, that is seeking or has obtained recognition from the TNI Proficiency Testing Program Executive Committee (PTP EC) to serve as a PTP AB for ISO/IEC 17043:2023 accredited PTPs seeking to obtain or maintain accreditation in conformance with TNI Standard EL-V3.

NOTE: The PTP EC is a TNI executive committee responsible for establishing and maintaining the PT program, including the required fields of proficiency testing (FoPT). It oversees initial and on-going TNI recognition of PTP ABs, monitors their activities for conformance, and evaluates the overall suitability and performance of the PT program.

NOTE: The requirements outlined in this standard are supplementary to those specified in ISO/IEC 17011 and do not duplicate them. Instead, they provide additional criteria necessary for the PTP AB to obtain and maintain TNI recognition, building upon the foundational requirements established by ISO/IEC 17011:2017. The PTP AB's recognition status serves as evidence of its conformance with ISO/IEC 17011:2017.

2.0 Normative References

The following documents are referenced in this standard in a manner that makes some or all the document's content inclusive requirements of this volume.

TNI Volume 3 – General Requirements for Environmental Proficiency Testing Providers, 2024

ISO/IEC 17011 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies, 2017.

3.0 Terms and Definitions

The terms relevant for this volume are defined below.

- 3.1 Comprehensive Assessment:** A thorough and systematic activity conducted by a PTP AB to examine all aspects of a PTP's organizational structure, processes, procedures, capabilities, and competence.
- 3.2 Field of Proficiency Testing:** Matrix, technology/method, analyte combinations for which the composition, spike concentration ranges and acceptance criteria have been established by the Proficiency Testing Program Executive Committee.
- 3.3 Proficiency Testing:** Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043:2023).
- 3.4 Proficiency Testing Program:** The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of results, and the collective demographics and results summary of all participating laboratories.
- 3.5 Proficiency Testing Program Executive Committee:** The committee responsible for the administration and maintenance of the TNI PT Program.
- 3.6 Proficiency Testing Provider:** An organization accredited by a TNI-recognized Proficiency Testing Provider Accreditation Body to operate a TNI-compliant PT program.
- 3.7 Proficiency Testing Provider Accreditation Body:** An accreditation body that is recognized by the TNI PTP EC to accredit and monitor the performance of Proficiency Testing Providers.
- 3.8 Proficiency Testing Sample:** A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.
- 3.9 Proficiency Testing Study:** This term refers to a scheduled PT Study or a supplemental PT Study.
- 3.10 Surveillance Assessment:** a risk-based activity conducted by a PTP AB between comprehensive assessments to monitor the PTP's continued conformance with TNI EL-V3-2024 Rev 3.0.

4.0 Qualification Requirements

A PTP AB seeking or holding recognition as a PTP AB must meet the following qualifications:

- a) demonstrate to the PTP EC that it has the technical expertise, administrative capacity and financial resources necessary to implement and operate a PTP accreditation program in conformance with this TNI standard,
- b) establish and maintain an accreditation program for PTPs that verifies initial and on-going conformance with TNI EL-V3-2024 Rev 3.0,
- c) be recognized by at least one member of an international cooperation of accreditation bodies for conformance to ISO/IEC 17011:2017, and
- d) have ISO/IEC 17025:2017 and ISO/IEC 17043:2023 included in their Scope of Recognition.

5.0 Process Requirements

- 5.1 Initial Accreditation** – The PTP AB must establish and implement an initial accreditation process that:
- a) verifies the PTP does not have any conflicting interests with TNI-accredited laboratories,

- b) includes a comprehensive assessment to verify the PTP's conformance with TNI EL-V3-2024 Rev 3.0,
- c) verifies nonconformities identified during the comprehensive assessment are resolved before granting the PTP accreditation, and
- d) verifies the scope of accreditation issued clearly identifies the items accredited under the PTP's PT program.

5.2 Accreditation Renewal

- 5.2.1 The PTP AB must establish and implement a process for PTP accreditation renewal not to exceed two years and 6 months from the date of issue, unless an extension is justified and granted. This process must define the criteria for accreditation extension. Records must be retained for explaining the rationale for granting or denying the extension.
- 5.2.2 The accreditation renewal process must include a comprehensive assessment to verify the PTP's on-going conformance with TNI EL-V3-2024 Rev 3.0.

5.3 Scope of Accreditation Expansion or Reduction – The PTP AB must establish and implement a process to review requests from the PTP to expand or reduce their PT program scope of accreditation.

5.4 Accreditation Suspension, Revocation, and Reinstatement

- 5.4.1 The PTP AB must establish and implement a process to suspend or revoke the PTP's accreditation if assessment or monitoring activities determine the PTP is no longer in conformance with TNI EL-V3-2024 Rev 3.0. The process must define the actions that justify suspension or revocation of the PTP's accreditation.
- 5.4.2 The process must outline the criteria for reinstating accreditation once the PTP has demonstrated renewed conformance.

5.5 Assessments

- 5.5.1 The PTP AB must establish and implement a process for conducting PTP assessments that:
 - a) requires clear disclosure of the assessment's purpose to the PTP prior to the assessment,
 - b) requires the development of standardized assessment materials, and mandates availability of the materials to the PTP upon request prior to the assessment,
 - c) verifies nonconformities identified during the assessment are effectively addressed and resolved by the PTP,
 - d) includes a requirement to conduct at least one surveillance assessment between comprehensive assessments, and
 - e) determines the PTP's competency and conformance with the requirements of TNI EL-V3-2024 Rev 3.0.
- 5.5.2 **Comprehensive Assessment** – After the successful initial accreditation, the PTP AB must conduct a comprehensive assessment of the PTP every two years (not to exceed two years and six months).
- 5.5.3 **Surveillance Assessment** – The PTP AB must establish and implement a risk-based process for surveillance assessments that includes:
 - a) a review of changes in the PTP's organizational structure, key personnel, and management systems since the last comprehensive assessment to determine if these changes impact conformance with TNI EL-V3-2024 Rev 3.0,
 - b) confirmation that the PTP conducted internal audits and management reviews as required and whether risks related to the PT program were identified and addressed,

- c) an evaluation of the number, type and status of complaints received against the PTP related to the PT program and the effectiveness of the PTP's response to these complaints, and
- d) the type and frequency of surveillance assessments and decision-making criteria.

5.6 Data Management

- 5.6.1 The PTP AB must establish and implement a data management system that stores and exports summary data and results of all verification, homogeneity, and stability determinations for each scheduled PT study.
- 5.6.2 The PTP AB must establish and implement a process for obtaining this data from the PTP including instructions for how the PTP is to submit this data to the PTP AB.

5.7 Information Requests

- 5.7.1 Annually, the PTP AB must conduct a presentation at the PTP EC meeting during the TNI forum and provide presented information to the PTP EC when requested. The contents of the presentation must include:
 - a) a complete list of PTPs accredited to the PT program, their accreditation status, and any withdrawals,
 - b) PT study failure rates and potential or observed biases, specifically highlighting those that have historical failure rates of >10% for at least 2 consecutive years, and
 - c) the number, nature, and status of complaints received by the PTP AB concerning the PT Program or the PTPs under their accreditation.
- 5.7.2 The PTP AB must have a procedure and implement a process to warn, suspend, or revoke PTP accreditation status when notified by the PTP EC that the PTP failed to meet requirements in TNI EL-V3-2024 Rev 3.0 5.10.4.

6.0 Procedure Requirements

- 6.1 The PTP AB must have procedures to evaluate each scheduled PT study administered by its accredited PTP for conformance with TNI EL-V3-2024 Rev 3.0 and the applicable TNI FoPT tables to verify the following:
 - a) report conforms with the PTP's scope of accreditation;
 - b) reports were released in the timeframes specified in TNI EL-V3-2024 Rev 3.0;
 - c) defined TNI analyte codes were used;
 - d) assigned duration conforms with TNI EL-V3-2024 Rev 3.0;
 - e) required minimum number of analytes were included;
 - f) assigned value is within the appropriate FoPT defined range, and acceptance limits are appropriate per analyte; and
 - g) verification, homogeneity, and stability testing were conducted, where required.
- 6.2 The PT study evaluation procedures must include:
 - a) maintenance of records, including any communications between the PTP AB and the PTP regarding the study evaluation and
 - b) issuance of any nonconformities found during the study evaluation to the PTP and verification that corrective actions are implemented by the PTP.