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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 4

GENERAL REQUIREMENTS FOR AN ACCREDITATION BODY OF ENVIRONMENTAL PROFICIENCY TESTING PROVIDERS

TNI Standard

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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 Expert 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 and replaces preceding documents in whole or in part. It may be used by any organization that wishes to implement a program for the accreditation of TNI Proficiency Testing Providers.

Standard Revision History

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VOLUME 4

General Requirements

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 (CABs) that are either seeking accreditation or are currently accredited in accordance with TNI Standard Volume 3 (EL-V3).

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 (PTPAB)
Conformity Assessment Body (CAB)	Proficiency Testing Provider (PTP)
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, *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 (PTPEC) to serve as a PTPAB for ISO/IEC 17043 accredited PTPs seeking to obtain or maintain accreditation in conformance with TNI Standard EL-V3.

All references to external standards are to the current version unless a year is included.

NOTE: The PTPEC 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 PTPABs, 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 PTPAB to obtain and maintain TNI recognition, building upon the foundational requirements established by ISO/IEC 17011. The PTPAB's recognition status serves as evidence of its conformance with ISO/IEC 17011.

2.0 Normative References

The following documents are referenced in this standard in a manner that makes some or all of the document's content inclusive requirements of this volume. Unless otherwise specified, the most recent edition of the reference document applies.

TNI Standard EL-V3 – General Requirements for Environmental Proficiency Testing Providers

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

3.0 Terms and Definitions

The terms relevant for this volume are defined below.

Comprehensive Assessment: a thorough and systematic evaluation conducted by a PTPAB every two years to examine all aspects of a PTP's organizational structure, processes, capabilities, and competence. The purpose of this assessment is to determine the PTP's competency and conformance with the requirements of TNI Standard EL-V3.

Field of Proficiency Testing (FoPT): 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 (PTPEC).

Proficiency Testing (PT): A means to evaluate a laboratory's performance, under controlled conditions, relative to a given set of criteria, through analysis of unknown samples provided by an external source.

Proficiency Testing Program (PT 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.

Proficiency Testing Program Executive Committee (PTPEC): A volunteer committee within TNI that establishes and maintains the TNI PT program.

Proficiency Testing Provider (PTP): A conformity assessment body seeking initial or renewed accreditation by a TNI- recognized Proficiency Testing Provider Accreditor to operate a TNI PT program.

Proficiency Testing Provider Accreditation Body (PTPAB): An accreditation body that is recognized by the TNI PTPEC to accredit and monitor the performance of Proficiency Testing Providers.

Proficiency Testing Sample (PT 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.

Study (or PT Study): This term refers to a scheduled PT Study or a supplemental PT Study.

- a) **Scheduled Proficiency Testing Study (Scheduled PT Study):** A single complete sequence of circulation and scoring of proficiency testing samples to all participants in a proficiency testing program where the study must have the same pre-defined opening and closing dates for all participants.
- b) **Supplemental Proficiency Testing Study (Supplemental PT Study):** A PT sample that may be from a lot previously released by a PT Provider that meets the requirements for supplemental PT samples given in EL-V3 of this Standard, but that does not have a pre-determined opening and closing date.

Surveillance Assessment: a risk-based evaluation conducted by a PTPAB between comprehensive assessments to monitor the PTP's continued conformance with TNI Standard EL-V3.

4.0 Qualification Requirements

- 4.1** A PTPAB seeking or holding recognition as a PTPAB must meet the following qualifications:
- a) demonstrate to the PTPEC that it has technical expertise, administrative capacity, and financial resources necessary to implement and operate a PTP accreditation program in conformance with this standard,
 - b) establish and maintain an accreditation program for PTPs that verifies initial and on-going conformance with TNI EL-V3,
 - c) be recognized by at least one member of the international cooperation of accreditation bodies for conformance to ISO/IEC 17011, and
 - d) be a signatory of the International Laboratory Accreditation Cooperation (ILAC) of the Asia Pacific Accreditation Cooperation (APAC) for accreditation to ISO/IEC 17025 and ISO/IEC 17043.

5.0 Process Requirements

5.1 Initial Accreditation

- 5.1.1** The PTPAB must establish and implement an initial accreditation process that verifies the PTP:
- a) holds ISO/IEC 17043 accreditation,
 - b) does not have any conflicting interests with TNI-accredited laboratories, and
 - c) has the technical expertise, administrative capacity, and financial resources necessary to implement and operate a PT program in conformance with TNI EL-V3.

- 5.1.2** The PTPAB's initial accreditation process must:

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

5.2 Accreditation Renewal

- 5.2.1** The PTPAB must establish and implement a process for PT program accreditation renewal not to exceed 2 years from the date of issue unless an extension is justified and granted. This process must define the criteria for accreditation 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.

5.3 Scope of Accreditation Expansion or Reduction

The PTPAB 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

The PTPAB 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. Additionally, the process must outline the criteria for reinstating accreditation once the PTP has demonstrated renewed conformance.

5.5 Assessments

The PTPAB 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, and
- d) includes a requirement to conduct at least one surveillance assessment between comprehensive assessments.

5.5.1 Comprehensive Assessment

After the successful initial accreditation, the PTPAB must conduct a comprehensive assessment of the PTP every two (2) years.

5.5.2 Surveillance Assessment

The PTPAB must establish and implement a risk-based process for surveillance assessments that minimally includes:

- a) a review of any changes to the management systems, including key personnel, since the last comprehensive assessment to determine if these changes impact conformance with EL-V3,
- 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 PTPAB 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 PTPAB 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 PTPAB.

5.7 Information Requests

5.7.1 The PTPAB must conduct a presentation at the PTPEC meeting during TNI forums and provide presented information to the PTPEC when requested. The contents of the presentation must minimally include:

- a) a complete list of PTPs accredited to the PT program and 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 PTPAB concerning the PT program or the PTPs under their accreditation.

5.7.2 The PTPAB must have a procedure and implement a process to warn, suspend, or revoke PTP accreditation status when notified by the PTPEC that the PTP failed to meet requirements in EL-V3 5.10.4.

6.0 Procedure Requirements

6.1 PT Study Evaluation

6.1.1 The PTPAB must establish and maintain a procedure to evaluate each scheduled PT study administered by its accredited PTP for conformance with TNI EL-V3 and the applicable TNI FoPT tables to verify the following:

- a) study report conforms with the PTP's scope of accreditation,
- b) study reports were released in the timeframes specified in EL-V3,
- c) defined TNI analyte codes were used,
- d) assigned duration of the study conforms with EL-V3,
- e) assigned values appear to be randomly selected and are within the specified concentration ranges,
- f) required minimum number of analytes were included,
- g) any adjustments to initial assigned values are recorded,
- h) assigned value is within the appropriate FoPT defined range, and acceptance limits are appropriate per analyte, and
- i) homogeneity and stability testing were conducted, where required.

6.1.2 The PT study evaluation procedure must include:

- a) maintenance of records, including any communications between the PTPAB and the PTP, for each study evaluation for the duration specified by the PTPEC, and
- b) issuance of any nonconformities found during the study evaluation to the PTP and verification corrective actions are implemented by the PTP.