

## **64802.15 Proficiency Testing**

### **(a)**

The Proficiency Testing requirements in this section shall not negate or supersede the Proficiency Testing requirements of other state or federal regulatory programs.

### **(b)**

When participating in a Proficiency Testing study, a laboratory shall: (1) Comply with 2016 TNI Standard - Revision 2.1, Volume 1, Module 1, herein incorporated by reference, for each Field of Accreditation for which the laboratory is requesting accreditation, with the following exceptions: (A) Volume 1, Module 1, Section 5.0 - Proficiency Testing Study Frequency Requirements for Accreditation; and (B) Volume 1, Module 1, Section 8.0 - Proficiency Testing Requirements for Reinstatement of Accreditation after Suspension or Revocation; or (2) Comply with the following Proficiency Testing requirements: (A) Analyze Proficiency Testing samples in accordance with the laboratory's routine standard operating procedure using the same quality control, acceptance criteria, and staff as used for the analysis of routine environmental samples; (B) Analyze Proficiency Testing samples of the same matrix as the Field(s) of Accreditation for which the laboratory holds or seeks accreditation; (C) On or before the closing date of the study, direct the Proficiency Testing provider to report the Proficiency Testing study results directly to ELAP; (D) Report in such a way that results of the Proficiency Testing study

corresponds to the Field of Accreditation offered by ELAP; and (E) Retain all records necessary to facilitate reconstruction of the preparation, processing, and reporting of analytical results for Proficiency Testing samples for a minimum of five (5) years and provide them to ELAP upon request; and (3) Not engage in the following activities: (A) Send Proficiency Testing study samples, in which the laboratory is participating, to another laboratory for the analysis of a Field of Accreditation for which it seeks accreditation or is accredited; (B) Knowingly receive or analyze any Proficiency Testing samples from another laboratory for which the results are to be used for accreditation; (C) Communicate with any individual at another laboratory concerning the analysis of Proficiency Testing samples of an ongoing study; (D) Attempt to obtain the assigned value of any portion of a Proficiency Testing study from the Proficiency Testing provider; and (E) Request the Proficiency Testing provider to alter any portion of the laboratory's Proficiency Testing report after it was issued as final.

**(1)**

Comply with 2016 TNI Standard - Revision 2.1, Volume 1, Module 1, herein incorporated by reference, for each Field of Accreditation for which the laboratory is requesting accreditation, with the following exceptions: (A) Volume 1, Module 1, Section 5.0 - Proficiency Testing Study Frequency Requirements for Accreditation; and (B) Volume 1, Module 1, Section 8.0 - Proficiency Testing Requirements for Reinstatement of Accreditation after Suspension or Revocation; or

**(A)**

Volume 1, Module 1, Section 5.0 - Proficiency Testing Study Frequency Requirements for Accreditation; and

**(B)**

Volume 1, Module 1, Section 8.0 - Proficiency Testing Requirements for Reinstatement of

Accreditation after Suspension or Revocation; or

**(2)**

Comply with the following Proficiency Testing requirements: (A) Analyze Proficiency Testing samples in accordance with the laboratory's routine standard operating procedure using the same quality control, acceptance criteria, and staff as used for the analysis of routine environmental samples; (B) Analyze Proficiency Testing samples of the same matrix as the Field(s) of Accreditation for which the laboratory holds or seeks accreditation; (C) On or before the closing date of the study, direct the Proficiency Testing provider to report the Proficiency Testing study results directly to ELAP; (D) Report in such a way that results of the Proficiency Testing study corresponds to the Field of Accreditation offered by ELAP; and (E) Retain all records necessary to facilitate reconstruction of the preparation, processing, and reporting of analytical results for Proficiency Testing samples for a minimum of five (5) years and provide them to ELAP upon request; and

**(A)**

Analyze Proficiency Testing samples in accordance with the laboratory's routine standard operating procedure using the same quality control, acceptance criteria, and staff as used for the analysis of routine environmental samples;

**(B)**

Analyze Proficiency Testing samples of the same matrix as the Field(s) of Accreditation for which the laboratory holds or seeks accreditation;

**(C)**

On or before the closing date of the study, direct the Proficiency Testing provider to report the Proficiency Testing study results directly to ELAP;

**(D)**

Report in such a way that results of the Proficiency Testing study corresponds to the Field of

Accreditation offered by ELAP; and

**(E)**

Retain all records necessary to facilitate reconstruction of the preparation, processing, and reporting of analytical results for Proficiency Testing samples for a minimum of five (5) years and provide them to ELAP upon request; and

**(3)**

Not engage in the following activities: (A) Send Proficiency Testing study samples, in which the laboratory is participating, to another laboratory for the analysis of a Field of Accreditation for which it seeks accreditation or is accredited; (B) Knowingly receive or analyze any Proficiency Testing samples from another laboratory for which the results are to be used for accreditation; (C) Communicate with any individual at another laboratory concerning the analysis of Proficiency Testing samples of an ongoing study; (D) Attempt to obtain the assigned value of any portion of a Proficiency Testing study from the Proficiency Testing provider; and (E) Request the Proficiency Testing provider to alter any portion of the laboratory's Proficiency Testing report after it was issued as final.

**(A)**

Send Proficiency Testing study samples, in which the laboratory is participating, to another laboratory for the analysis of a Field of Accreditation for which it seeks accreditation or is accredited;

**(B)**

Knowingly receive or analyze any Proficiency Testing samples from another laboratory for which the results are to be used for accreditation;

**(C)**

Communicate with any individual at another laboratory concerning the analysis of Proficiency Testing samples of an ongoing study;

**(D)**

Attempt to obtain the assigned value of any portion of a Proficiency Testing study from the Proficiency Testing provider; and

**(E)**

Request the Proficiency Testing provider to alter any portion of the laboratory's Proficiency Testing report after it was issued as final.

**(c)**

Subdivisions (b)(2) and (b)(3), above, will become invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (b)(1), above.

**(d)**

If there are no available Proficiency Testing samples for a Field(s) of Accreditation, ELAP may require verification of quality control data as an alternative demonstration of capability.

**(e)**

To obtain initial accreditation, within twelve (12) months prior to ELAP's receipt of the laboratory's initial application package, a laboratory shall achieve Acceptable Scores in a Proficiency Testing study for each Field of Accreditation requested in the application.

**(f)**

To maintain accreditation, a laboratory shall achieve Acceptable Scores in a Proficiency Testing study at least once per year for each Field of Accreditation for which the laboratory holds accreditation. Acceptable Scores in Proficiency Testing studies shall be achieved: (1) Within twelve (12) months from the accreditation date in year one of the accreditation period; and (2) At least ninety (90) days prior to the expiration date of accreditation in year two of the accreditation period.

**(1)**

Within twelve (12) months from the accreditation date in year one of the accreditation period; and

**(2)**

At least ninety (90) days prior to the expiration date of accreditation in year two of the accreditation period.

**(g)**

To add or reinstate a Field of Accreditation, a laboratory shall achieve Acceptable Scores in a Proficiency Testing study for each Field of Accreditation for which the laboratory is requesting to add and submit an amendment application in accordance with Section 64808.15.

**(h)**

If on the first attempt, a laboratory does not achieve an acceptable score for a Field of Accreditation, then within forty-five (45) days of receipt of the "Not Acceptable" score from the Proficiency Testing provider, the laboratory shall: (1) Notify ELAP of the "Not Acceptable" score; (2) Document the root cause of the failure; (3) Take corrective action; (4) Achieve an acceptable score in a subsequent Proficiency Testing study for that Field of Accreditation; (5) Notify ELAP of the "Acceptable" score; and (6) Upon request from ELAP, provide documentation of the root cause investigation and corrective action.

**(1)**

Notify ELAP of the "Not Acceptable" score;

**(2)**

Document the root cause of the failure;

**(3)**

Take corrective action;

**(4)**

Achieve an acceptable score in a subsequent Proficiency Testing study for that Field of Accreditation;

**(5)**

Notify ELAP of the "Acceptable" score; and

**(6)**

Upon request from ELAP, provide documentation of the root cause investigation and corrective action.

**(i)**

If a Proficiency Testing study for a Field of Accreditation is not available within forty-five (45) days of receipt of a "Not Acceptable" result, the laboratory shall:

(1) Submit a plan to ELAP that states when the next Proficiency Testing study will be completed, and; (2) Achieve Acceptable Scores for the Field of Accreditation when the subsequent Proficiency Testing study becomes available and submit to ELAP.

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**(2)**

Achieve Acceptable Scores for the Field of Accreditation when the subsequent Proficiency Testing study becomes available and submit to ELAP.

**(j)**

If on the second attempt, a laboratory does not achieve an acceptable score for a Field of Accreditation a laboratory shall: (1) Notify ELAP of the "Not Acceptable" result within three (3) days; (2) Be suspended for that Field of Accreditation; (3) Cease reporting of results for Regulatory Purposes for that corresponding Field of

Accreditation; (4) Notify affected Clients of second "Not Acceptable" Proficiency Testing result by registered mail, email with return receipt, or electronic signature document; (5) Within thirty (30) days: investigate and document the root cause of the failure and take corrective action; (6) Upon request from ELAP, provide documentation of the root cause investigation and corrective action.

**(1)**

Notify ELAP of the "Not Acceptable" result within three (3) days;

**(2)**

Be suspended for that Field of Accreditation;

**(3)**

Cease reporting of results for Regulatory Purposes for that corresponding Field of Accreditation;

**(4)**

Notify affected Clients of second "Not Acceptable" Proficiency Testing result by registered mail, email with return receipt, or electronic signature document;

**(5)**

Within thirty (30) days: investigate and document the root cause of the failure and take corrective action;

**(6)**

Upon request from ELAP, provide documentation of the root cause investigation and corrective action.

**(k)**

To be reinstated after Suspension of a Field(s) of Accreditation, the laboratory shall: (1) Achieve Acceptable Scores in a Proficiency Testing study for the corresponding Field(s) of Accreditation; and (2) Submit an amendment application package, in accordance with Section 64808.15.

**(1)**

Achieve Acceptable Scores in a Proficiency Testing study for the corresponding Field(s) of Accreditation; and

**(2)**

Submit an amendment application package, in accordance with Section 64808.15.

**(l)**

For toxicity bioassay analyses, each laboratory shall: (1) Achieve Acceptable Scores in a Proficiency Testing study, where available, for each Field of Accreditation for which the laboratory is requesting accreditation, in accordance with (b), above; (2) Perform reference toxicant tests, at a minimum, annually for each method, organism, and endpoint; and (3) Plot and maintain control charts of reference toxicant test results for each method, organism, and endpoint.

**(1)**

Achieve Acceptable Scores in a Proficiency Testing study, where available, for each Field of Accreditation for which the laboratory is requesting accreditation, in accordance with (b), above;

**(2)**

Perform reference toxicant tests, at a minimum, annually for each method, organism, and endpoint; and

**(3)**

Plot and maintain control charts of reference toxicant test results for each method, organism, and endpoint.

**(m)**

For pesticide residue in food, each laboratory shall obtain Proficiency Testing samples from a Proficiency Testing provider that meets TNI standards.

**(n)**

If a laboratory has a financial interest, familial relationship, or contractual agreement for consultation with the provider of a Proficiency Testing study, the results from that study shall not be used to meet the Proficiency Testing study requirements for accreditation.