64802.05 Quality Systems

To ensure analytical data produced by the laboratory are of known and documented quality, and sufficient to evaluate the usability of the data for State Regulatory Agency needs, a laboratory shall:

(a)

Comply with quality system requirements in accordance with 2016 TNI Standard - Revision 2.1, Volume 1: (1) Module 2, herein incorporated by reference, with the following exceptions:(A) Module 2, Section 4.1.7.2(f) - Technical Manager Qualifications; and (B) Module 2, Section 5.2.6 - Technical Manager Requirements; (2) Modules 3 through 7, herein incorporated by reference, where appropriate based on laboratory operations; or

(1)

Module 2, herein incorporated by reference, with the following exceptions:(A) Module 2, Section 4.1.7.2(f) - Technical Manager Qualifications; and (B) Module 2, Section 5.2.6 - Technical Manager Requirements;

(A)

Module 2, Section 4.1.7.2(f) - Technical Manager Qualifications; and

(B)

Module 2, Section 5.2.6 - Technical Manager Requirements;

(2)

Modules 3 through 7, herein incorporated by reference, where appropriate based on

laboratory operations; or

(b)

Develop and implement a quality assurance program. As evidence of such a program, the laboratory shall: (1) Develop and maintain a Quality Manual. The Quality Manual shall address the quality assurance and quality control practices to be employed by the laboratory and shall include at a minimum: (A) The quality assurance and quality control requirements specified in the test methods for which the laboratory seeks to obtain or maintain accreditation for; and (B) Documents, or references to documents, that contain the following elements: (i) Laboratory organization and job descriptions; (ii) Ethics and integrity clause; (iii) Quality assurance objectives for measurement data; (iv) Sampling procedures (when the laboratory performs the sampling); (v) Procedures for sample acceptance/rejection, custody, handling, and disposal of samples; (vi) Calibration procedures and frequency; (vii) Analytical procedures; (viii) Acquisition, reduction, validation and reporting of data; (ix) Internal quality control checks; (x) Performance and system audits; (xi) Preventive maintenance; (xii) Assessment of precision and accuracy; (xiii) Corrective action; and (xiv) Quality assurance reports; (2) The Technical Manager or designee shall review and amend, if necessary, the quality assurance program and Quality Manual at least annually and when the following occurs: (A) Changes to laboratory equipment or instrumentation; (B) Changes to laboratory structure or physical arrangements; or (C) Changes in the laboratory organization; (3) Perform annual quality assurance audits documenting compliance with subdivision (b)(1), above, including corrective actions for any noted findings. Audit reports shall be provided to ELAP upon request; and (4) Maintain records of the implementation of the quality assurance program. Records of the implementation of the quality assurance

program shall be provided to ELAP upon request.

(1)

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(B)

Documents, or references to documents, that contain the following elements: (i) Laboratory organization and job descriptions; (ii) Ethics and integrity clause; (iii) Quality assurance objectives for measurement data; (iv) Sampling procedures (when the laboratory performs the sampling); (v) Procedures for sample acceptance/rejection, custody, handling, and disposal of samples; (vi) Calibration procedures and frequency; (vii) Analytical procedures; (viii) Acquisition, reduction, validation and reporting of data; (ix) Internal quality control checks; (x) Performance and system audits; (xi) Preventive maintenance; (xii) Assessment

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Laboratory organization and job descriptions;

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Ethics and integrity clause;

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Quality assurance objectives for measurement data;

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Sampling procedures (when the laboratory performs the sampling);

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Procedures for sample acceptance/rejection, custody, handling, and disposal of samples;

(vi)

Calibration procedures and frequency;

(vii)

Analytical procedures;

(viii)

Acquisition, reduction, validation and reporting of data;

(ix)

Internal quality control checks;

(x)

Performance and system audits;

(xi)

Preventive maintenance;

(xii)

Assessment of precision and accuracy;

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Corrective action; and

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Quality assurance reports;

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The Technical Manager or designee shall review and amend, if necessary, the quality assurance program and Quality Manual at least annually and when the following occurs: (A) Changes to laboratory equipment or instrumentation; (B) Changes to laboratory structure or physical arrangements; or (C) Changes in the laboratory organization;

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Changes in the laboratory organization;

(3)

Perform annual quality assurance audits documenting compliance with subdivision (b)(1), above, including corrective actions for any noted findings. Audit reports shall be provided to ELAP upon request; and

(4)

Maintain records of the implementation of the quality assurance program. Records of the implementation of the quality assurance program shall be provided to ELAP upon request.

(c)

Subdivision (b), 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 (a), above.