64802.20 On-Site Assessment

(a)

An on-site assessment, either announced or unannounced, shall be conducted by an Assessment Agency to verify the information submitted with a laboratory's application and to verify a laboratory is in compliance with: (1) Quality system requirements, in accordance with Section 64802.05; (2) Analytical methods used for each Field of Accreditation for which the laboratory seeks to obtain or maintain accreditation; (3) Laboratory instrumentation, equipment, and facility requirements, in accordance with Section 64812.05; and (4) All applicable ELAP statutes and regulations.

(1)

Quality system requirements, in accordance with Section 64802.05;

(2)

Analytical methods used for each Field of Accreditation for which the laboratory seeks to obtain or maintain accreditation;

(3)

Laboratory instrumentation, equipment, and facility requirements, in accordance with Section 64812.05; and

(4)

All applicable ELAP statutes and regulations.

(b)

An on-site assessment shall be conducted: (1) For initial accreditation, no more than twelve (12) months prior to applying for accreditation; (2) For renewal accreditation, once within the two (2) years prior to the expiration date of accreditation; (3) For amendment accreditation, in accordance with Section 64808.15; and (4) For enforcement purposes, when ELAP decides to conduct an assessment in accordance with Health and Safety Code section 100865.

(1)

For initial accreditation, no more than twelve (12) months prior to applying for accreditation;

(2)

For renewal accreditation, once within the two (2) years prior to the expiration date of accreditation;

(3)

For amendment accreditation, in accordance with Section 64808.15; and

(4)

For enforcement purposes, when ELAP decides to conduct an assessment in accordance with Health and Safety Code section 100865.

(c)

An on-site assessment shall be conducted by ELAP or a third-party Assessment Agency contracted by ELAP to perform on-site assessments. (1) A laboratory requesting assessment to Field(s) of Accreditation that utilizes Sophisticated Technology shall use a third-party Assessment Agency; (2) A third-party Assessment Agency shall be one of the following: (A) A National Environmental Laboratory Accreditation Program (NELAP)-recognized accreditation body; (B) A NELAP-recognized non-government accreditation body; or (C) An agency that is recognized by the Department of Defense or Department of Energy as an

accrediting body. (3) ELAP will publish a list of approved third-party Assessment Agencies on the ELAP website.

(1)

A laboratory requesting assessment to Field(s) of Accreditation that utilizes Sophisticated Technology shall use a third-party Assessment Agency;

(2)

A third-party Assessment Agency shall be one of the following: (A) A National Environmental Laboratory Accreditation Program (NELAP)-recognized accreditation body; (B) A NELAP-recognized non-government accreditation body; or (C) An agency that is recognized by the Department of Defense or Department of Energy as an accrediting body.

(A)

A National Environmental Laboratory Accreditation Program (NELAP)-recognized accreditation body;

(B)

A NELAP-recognized non-government accreditation body; or

(C)

An agency that is recognized by the Department of Defense or Department of Energy as an accrediting body.

(3)

ELAP will publish a list of approved third-party Assessment Agencies on the ELAP website.

(d)

The laboratory is responsible for requesting an on-site assessment through ELAP or a third-party Assessment Agency.

(e)

When a scheduled on-site assessment is performed by ELAP, a laboratory shall pay an assessment fee in accordance with Section 64802.25.

(f)

When an on-site assessment is performed by a third-party Assessment Agency contracted by ELAP to perform on-site assessments, a laboratory shall pay the third-party Assessment Agency its market rate for onsite assessments.

(g)

Within thirty (30) days of the on-site assessment, a laboratory shall receive an on-site assessment report. If there are findings in the on-site assessment report, a laboratory shall: (1) Within thirty (30) days of receipt of the on-site assessment report, submit a Corrective Action Plan that contains a Root Cause Analysis of the finding(s), the corrective actions that will take place, and the date the finding(s) will be corrected. (2) Subsection (g)(1), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to submit, within thirty (30) days of receipt of the on-site assessment report, a Corrective Action Plan that contains a Root Cause Analysis of the finding(s), the corrective actions that will take place, and the date the finding(s) will be corrected in accordance with 2016 TNI Standard - Revision 2.1, Volume 1, Module 2, Section 4.11, 4.12, and 4.13, herein incorporated by reference.

(1)

Within thirty (30) days of receipt of the on-site assessment report, submit a Corrective Action Plan that contains a Root Cause Analysis of the finding(s), the corrective actions that will take place, and the date the finding(s) will be corrected.

(2)

Subsection (g)(1), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to submit, within thirty (30)

days of receipt of the on-site assessment report, a Corrective Action Plan that contains a Root Cause Analysis of the finding(s), the corrective actions that will take place, and the date the finding(s) will be corrected in accordance with 2016 TNI Standard - Revision 2.1, Volume 1, Module 2, Section 4.11, 4.12, and 4.13, herein incorporated by reference.

(h)

If a laboratory is notified that a Corrective Action Plan does not address the finding(s) identified, then the laboratory shall have an additional thirty (30) days from the receipt of the notification to submit a revised Corrective Action Plan. If the revised Corrective Action Plan does not demonstrate the required corrections have been made, then ELAP will take action to deny, suspend or revoke accreditation for the Field(s) of Accreditation affected by the failure to take corrective action.

(i)

If a subsequent on-site assessment, either announced or unannounced, reveals that a laboratory failed to take the corrective action(s) specified in a Corrective Action Plan, ELAP will take action to deny, suspend, or revoke accreditation for the Field(s) of Accreditation affected by failure to take corrective action.

(j)

If a scheduled on-site assessment is not conducted within six (6) months from the scheduled assessment date and the delay is not a result of the Assessment Agency error or procedure, ELAP may take action to deny, suspend or revoke accreditation.

(k)

If a laboratory has submitted a complete renewal or amendment application package in accordance with Section 64808.05 or 64808.15, respectively, and

additional time is needed by the Assessment Agency to complete an on-site assessment, then the laboratory shall be issued an interim certificate of accreditation. (1) A laboratory that holds an interim certificate of accreditation is accredited for Field(s) of Accreditation listed on the laboratory scope of accreditation. (2) An interim certificate is non-renewable and shall be valid until one of the following occurs: (A) An on-site assessment has been completed and a certificate of accreditation issued; (B) The laboratory fails to meet the requirements for accreditation in accordance with Article 2; or (C) The expiration date on the interim certificate of accreditation is reached.

(1)

A laboratory that holds an interim certificate of accreditation is accredited for Field(s) of Accreditation listed on the laboratory scope of accreditation.

(2)

An interim certificate is non-renewable and shall be valid until one of the following occurs: (A) An on-site assessment has been completed and a certificate of accreditation issued; (B) The laboratory fails to meet the requirements for accreditation in accordance with Article 2; or (C) The expiration date on the interim certificate of accreditation is reached.

(A)

An on-site assessment has been completed and a certificate of accreditation issued;

(B)

The laboratory fails to meet the requirements for accreditation in accordance with Article 2; or

(C)

The expiration date on the interim certificate of accreditation is reached.