Documentation Required for Third-Party Assessment Agencies Performing CA ELAP Assessments

This document is intended to outline the expectations for completed on-site assessment packets and what should be provided to the laboratory upon completion of the on-site assessment. The laboratory is expected to submit the full package to ELAP as part of their application without modifying the contents.

If significant issues are observed onsite, significant problems are apparent with a laboratory's Corrective Action Plan, or in any situation where the assessor feels immediate action by ELAP is warranted, please contact elapCA@waterboards.ca.gov immediately. ELAP will provide further direction after discussion with the auditor.

Formatting and Acceptable Packets

All required elements should be collected into a single PDF document, preferably as a PDF portfolio. PDFs (except for scanned documents) created by the Assessment Agency must be word-searchable. Scanned documents must be clearly readable. All elements should be in the order provided below.

If a packet, or part of a packet, ever needs to be revised after issuance by the Assessment Agency, the packet must:

A. identify that it (or the part of it) was revised,
B. date of the revision(s),
C. state what revision(s) occurred, and
D. state why the revision(s) occurred.

ELAP recommends revisions be in a different color and font for additions, and strikethrough used for removed text. Packets must be uniquely identifiable should multiple revisions be issued.

Required Elements

Each packet must contain the following elements, regardless of the type of assessment, identified in the order listed below. Each sub-list under the required elements does not necessarily need to be in the order listed, unless numbered.

1. Close-Out Letter & Summary

This short document should identify the closure of the Assessment Agency's responsibilities, and identify that the laboratory did or did not successfully complete the on-site assessment. It should also clearly state that completion of the assessment does not grant the laboratory ELAP accreditation, rather that the assessment is occurring in preparation for a future application and ELAP is the authority granting accreditation.

This Close-Out Letter should contain the following elements at a minimum:

A. The name of the Assessment Agency
B. The name and location of the Laboratory
C. Dates the assessment occurred and identification if part occurred remotely
   NOTE1: Remote assessment approval must be requested from ELAP and granted prior to conducting the assessment
D. The purpose of the assessment (for application to CA ELAP, renewal, or amendment)
E. Identification that the laboratory acceptably responded (or did not) to all findings
F. A statement that ELAP will make the final determination to grant, deny, or partially deny accreditation
G. Name and signature with date of the primary assessor's conclusion/summary or other post-assessment review and conclusion
H. Name and contact information for the TPA representative

2. Laboratory Third-Party Assessor (TPA) Commitment and Qualification Statement and Conflict of Interest Form

This form must be included for all assessments performed after January 1, 2024. This form is a self-certification on behalf of the assessor and agency that the assessor has met qualifications outlined in the TNI Standard to perform the assessment for which they are assigned, as well as that they have no conflicts of interest. All past and current relationships must be disclosed on this form.

3. Finalized List of Methods or Fields of Accreditation

ELAP needs conclusive evidence of each method reviewed by the assessors while onsite. ELAP and US EPA require Assessment Agencies to review all drinking water methods and requirements with the Safe Drinking Water Act for any Fields of Accreditation (FOAs) in a drinking water matrix. For non-drinking water matrixes, where methods share identical technologies (ex. EPA 6020 and EPA 200.8), each method must be assessed while onsite; however, one may be assessed as a focus, and the remainder may be assessed as a survey. For all methods, a selection of data packages must be reviewed, with a review of Proficiency Testing or Demonstration of Capability data at a minimum if no other compliance data is available.

At a minimum, the information in the packet must be method- and matrix-specific and contain the assessor's initials for each FOA reviewed as part of the assessment. ELAP needs conclusive evidence of the individual FOAs reviewed during the assessment, and ELAP recommends using any of these documents:

A. ELAP's published Field of Accreditation Tables, with each FOA selected by the laboratory and initialed by the assessor for each FOA assessed.

B. A list of methods and associated matrixes, initialed by the assessor for each FOA assessed.
C. The laboratory's prior scope of accreditation, with each individual FOA initialed by the assessor for each FOA assessed.

NOTE2: Using the prior scope of accreditation may result in a denial if the old scope identifies methods ELAP no longer offers for accreditation.

For assessments which combine both methods new to the laboratory and existing methodologies, ELAP suggests combining these into one list if the assessment occurs on the same dates, or adding an attachment that clearly identifies the new FOAs that were assessed in addition to existing/renewal FOAs.

4. On-Site Assessment Report (OSAR)

The OSAR should contain all aspects of the assessor's review of the laboratory and their practices. Each assessment is different, with each necessitating different levels of review and detail. The following list is the minimum that ELAP expects in each OSAR; however, additional information or items should be included as necessary.

A. Opening Documentation, with date of the start of on-site duration
B. Closing Documentation, with date of the end of the on-site duration
C. Date of submission to the laboratory, with subsequent dates if additional follow-up other than the "formal" Corrective Action Plan responses (see section 5 below) is needed
D. Observations relevant to the laboratory assessment, such as a narrative description of the laboratory's facilities, general review, and notes made in checklists (section 5)
E. Table listing Standard Operating Procedures or other documents selected for review, correlating reviewed materials to the method(s) assessed
F. Table listing the Review of Data Packages, PT studies, or other records, correlating reviewed materials to the method(s) assessed
G. Documentation identifying that review of the laboratory's prior on-site assessment occurred, and that the laboratory successfully implemented corrections to all prior findings
H. List of Findings and Deficiencies, including a citation to the analytical method, TNI standard, or regulatory requirement. Each should include at least one observational example of the finding or deficiency.

5. Corrective Action Plan(s) and Assessor Responses

The laboratory's corrective action plan (CAP) must be submitted to the Assessment Agency no later than 30 calendar days after the laboratory's receipt of the OSAR. For documentation purposes, the laboratory's responses to the issued findings should be preserved as written by the laboratory. The Assessment Agency may choose the

formatting and response protocols for the laboratory, so long as documentation correlates responses to each finding and the general order in this section is followed.

1. Finding
   A. Description of observation(s) of finding or deficiency
   B. Citation to the analytical method, TNI standard, or regulatory requirement
2. Laboratory's Corrective Action Plan
   A. Narrative description of the laboratory's proposed CAP, including:
      a. Root Cause Analysis
      b. The corrective actions that will take place
      c. The date the finding will be corrected
   B. Date of submission from the laboratory
   C. Optional/As Needed: objective evidence submitted by the laboratory
3. Assessment Agency's Response to the CAP
   A. Acceptance of the laboratory's CAP or request for revision with additional narrative as to the reasoning for the denial
   B. Date of submission to the laboratory
4. If Needed – Laboratory's Revised CAP
   A. Narrative corrections of outstanding issues with initial CAP
   B. Date of submission from the laboratory
   C. Optional/As Needed: objective evidence submitted by the laboratory
5. Assessment Agency's Response to the Revised CAP
   A. Acceptance of the laboratory's CAP or request for revision with additional narrative as to the reasoning for the denial (e.g. CAP timeframe exceeds 6 months)
   B. Date of submission to the laboratory

6. Checklists Utilized for the Assessment

The checklists should be formatted to be readable when opened, either by ensuring that readable ink is used if filled in by hand or that formatting is clear to see assessor's observations associated with each item in the checklist. Checklists used include:

A. ELAP-issued regulations checklist
   NOTE3: A regulatory checklist is required for every assessment, even those conducted for amendment only
B. For specific methods where ELAP has provided the Assessment Agency with advance notice, any ELAP-issued method-specific checklists relevant to the assessment
C. TNI Module based checklists