



The Florida Department of Health (FL DOH) Environmental Laboratory Certification Program (ELCP) Procedure

PJLA offers third-party accreditation services to Conformity Assessment Bodies (e.g., Testing and/or Calibration Laboratories, Reference Material Producers, Field Sampling and Measurement Organizations, Inspection Bodies). This procedure outlines PJLA's process to meet the requirements of the Florida Department of Health (FL-DOH) Environmental Laboratory Certification Program (ELCP) as an assessment firm. FL DOH ELCP assessments alone do not fall under PJLA's international recognition (ILAC, APLAC). However, laboratory's wishing to obtain other PJLA offered programs (e.g., ISO/IEC 17025, DoD ELAP, DOECAP-AP EPA NLLAP, TNI NEFAP, TNI EL) may do so in which PJLA's full accreditation system documents will apply.



The Florida Department of Health (FL DOH) Environmental Laboratory Certification Program (ELCP) Procedure

1.0 SCOPE/PURPOSE

The FL DOH ELCP includes the use of assessors or assessment bodies to assess to the following standards: TNI EL Volume 1 Management and Technical Requirements for Laboratories Performing Environmental Analysis, the United States Environmental Protection Agency's (EPA) Manual for the Certification of Laboratory's Analyzing Drinking Water, Fifth Edition, and Florida Administrative Code (FAC) 64 E-1 Certification of Environmental Testing Laboratories. This procedure outlines PJLA's process for supporting the FL DOH ELCP requirements as a contracted Non-Governmental Accreditation Body (TNI NGAB).

2.0 REFERENCES

- 2.1 Management and Technical Requirements for Laboratories Performing Environmental Analysis (TNI-EL-V1-2016)
- 2.2 General Requirements for Accreditation Bodies Accrediting Environmental Laboratories (TNI EL-V2-2016)
- 2.3 General Requirements for Environmental Proficiency Testing providers (TNI EL-V3-2016-Rev 2.0)
- 2.4 United States Environmental Protection Agency's (EPA) Manual for the Certification of Laboratory's Analyzing Drinking Water, Fifth Edition
- 2.5 International Standard ISO/IEC 17011 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies, November 2017

3.0 ROLES AND RESPONSIBILITIES

- 3.1 Review applications within required timeframes
- 3.2 Select qualified assessors and provide documentation as specified
- 3.3 Schedule assessments
- 3.4 Conduct assessments
- 3.5 Prepare on-site assessment reports in formats as instructed
- 3.6 Conduct post-assessment activities
- 3.7 Submit materials gathered and used during assessments
- 3.8 Provide reports within specified timelines
- 3.9 Ensure no conflict of interests exist between assessors and laboratories
- 3.10 Update the FL DOH as required on assessor training, qualifications and new assessors to be utilized for the FL DOH environmental certification program

4.0 MANUAL/ORGANIZATION

PJLA maintains a quality management system in accordance with ISO/IEC 17011:2017 as well as TNI accreditation program criteria as outlined in TNI EL-V2-2016 PJLA is a recognized International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory for testing, which provides evidence of compliance to the ISO/IEC 17011:2017



The Florida Department of Health (FL DOH) Environmental Laboratory Certification Program (ELCP) Procedure

standard. Additionally, PJLA is recognized by The NELAC Institute (TNI) as a TNI NGAB which attests our adherence to TNI EL-V2-2016

5.0 TRAINING AND QUALIFICATION

Training, qualification, and on-going continuing education programs are maintained for assessors based on the requirements outlined in ISO/IEC 17011:2017 TNI EL-V2-2016 the EPA Manual for the Certification of Laboratory's Analyzing Drinking Water, Fifth Edition Criteria and as outlined in PJLA procedures SOP-2 Personnel Procedure and SOP-1-TNI EL TNI Environmental Laboratory Program- Accreditation Procedure.

FL DOH ELCP assessor training course material elements include:

- Basic theoretical and operating principles of the analytical technology;
- Instrumentation, apparatus, and software required;
- Critical steps and processes of the analytical technology that must be executed to ensure quality data;
- Relevant quality control indicators and expected acceptance criteria;
- Major sources of error and how to control them;
- Inappropriate procedures and practices for the analytical technology and ways to detect improper practices;
- Key information required to document completely the reported results;
- Essential elements for assessing data generated;
- Evaluation exercises of raw data to reported results;
- A final examination; and; and
- A certificate of satisfactory completion.

Training and competency records, including examination results and the certificate of satisfactory completion of the training materials used to qualify the assessor, shall be provided to FL DOH for assessors utilized to conduct FL DOH ELCP assessments. The National Environmental Laboratory Accreditation Program (NELAP) assessor technologies table shall be used to indicate the specific matrices and technologies for which each assessor is individually qualified to conduct assessments for.

Approval to utilize an assessor for new technologies shall be obtained from the FL DOH prior to assigning the assessor to conduct a FL DOE ELCP assessment. An updated NELAP assessor technologies table shall be provided along with examination results and the certificate of satisfactory completion of the training materials used to qualify the assessor for each additional technology.

6.0 ASSESSMENT PROCESS

6.1 Application Process

Upon receipt by the FL DOH, all applications which include the laboratory's scope of accreditation and pending analytes and test methods shall be reviewed to determine



The Florida Department of Health (FL DOH) Environmental Laboratory Certification Program (ELCP) Procedure

assessment needs, the number of assessors required, the appropriate amount of assessment time (on-site and off-site for pre/post assessment documentation review).

The FL DOH shall be contacted to verify the eligibility of the application for inclusion in the assessment. Assessments for any additional accreditation activities (e.g., ISO/IEC 17025, DoD/DOE QSM) provided to the laboratory shall not compromise the assessment team composition or the number of workdays required to assess the laboratory's FL DOH certified fields of accreditation.

All cost estimates are provided directly to the laboratory for consideration within a reasonable or agreed upon timeframe. Any changes of scope after the receipt of the application shall be considered including the adjustment of assessment time or the assessment team. The FL DOH shall be notified of any changes to the laboratory's scope prior to the commencement of the assessment.

6.2 Assessment Scheduling and Team

Once PJLA receives notification from the laboratory that PJLA was selected to conduct their FL DOH ELCP assessment.

- The assessment shall be scheduled within 15 calendar days of the notification.
- The FL DOH shall be notified that the laboratory is notified of an assessment being scheduled.

The FL DOH shall be notified of all assessments scheduled including the details of the assessment team, allocated assessment time and specific dates.

An assessment shall take place no later than 60 days following the scheduling confirmation. Any deviations from this timeline shall be provided to the FL DOH for consideration. All travel costs related to the on-site assessment will be in accordance with Section 112.061, Florida Statutes and Florida Administrative Code Rule 691-42.

Assessment teams are selected based on the scope of accreditation and will consist of at least one qualified lead assessor. The assessment team may also include additional qualified assessors, technical specialists, and observers if authorized by the laboratory to ensure the assessment team has sufficient personnel, knowledge, skills, training, qualifications, personal attributes, and sufficient organizational authority.

- One assessor may be assigned that can accommodate both lead and technical assessor roles.
- Observers may include members of the FL DOH.

All assessment team members shall sign a conflict-of-interest statement prior to attending the assessment, which will be forwarded to the FL DOH. These conflict-of-interest statements will include matters such as, but not limited to:

- a statement that no consultancy has been provided or will be provided to the laboratory; and



The Florida Department of Health (FL DOH) Environmental Laboratory Certification Program (ELCP) Procedure

- they do not directly work or contract with a laboratory certified by the FL DOH through the ELCP.

If any assessor status changes in the regards to conflict of interest, the FL DOH shall be notified within one (1) business day of this concern. All assessment activities assigned to the assessor will be suspended until written guidance is provided by the FL DOH regarding how to proceed.

6.3 On-site Assessment

For each on-site assessment, the lead assessor shall prepare and issue an assessment plan to the laboratory. Assessors shall make every effort to stay on schedule according to the assessment plan. All assessments are conducted in accordance to the applicable standards (e.g., ISO/IEC 17011, TNI EL-V2) and FL DOH ELCP requirements. Assessments include the assessment of the standards in their entirety including the assessment of all Fields of Accreditation (Matrix, Method, Analyte combinations) for which the laboratory holds accreditation. If all fields of accreditation are not assessed during the on-site assessment, the FL DOH shall be notified of the reasoning.

6.4 Assessment Reporting

The assessment team shall prepare and issue an assessment report in compliance with applicable requirements (e.g., ISO/IEC 17011, TNI EL-V2) and FL DOH ELCP requirements. The assessment report shall be provided to the laboratory and the FL DOH within 30 calendar days from the last day of the assessment.

The assessment report shall document all nonconformities discovered during the assessment and link, by reference, each of the nonconformities directly to the applicable standard (e.g., TNI EL-V1) and include:

- Indication of whether all fields of accreditation for which the laboratory is certified or seeking recertification were assessed during an assessment.
- Report Header - The laboratory name, physical address and mailing address, Florida certification number, names of the assessment team, assessment dates, and categories assessed.
- Introduction - A statement that the on-site assessment was performed to determine the laboratory's compliance with chapter 64E-1 FAC.
- Deficiencies - Refers to the accompanying form referenced in rule 64E-1.104(5), FAC, currently DH 1137, if any deficiencies that require a Plan of Correction are noted during the on-site assessment. Each deficiency must contain an appropriate citation to the NELAC and/or TNI Standard that was violated.
- Technical Directors/Managers - Lists the names and titles of the Laboratory Director, Technical Director(s), QA Officer, supervisors, etc.
- Comments - Includes in narrative format any of the following that are applicable:
 - a) Information that substantiates, supplements, or augments deficiencies noted on the form referenced in rule 64E-1.104(5), FAC, currently DH 1137.
 - b) The identifier and effective date of the laboratory Quality Manual reviewed (if applicable) during the assessment.



The Florida Department of Health (FL DOH) Environmental Laboratory Certification Program (ELCP) Procedure

- c) A list of all laboratory personnel interviewed or who participated in the assessment.
 - d) Fields of Accreditation that are recommended for certification with regard to any application addressed during the assessment.
 - e) Fields of Accreditation that require initial calibrations, IDOCs, MDLs, or other laboratory data not available during the on-site assessment, if any, that must be submitted to obtain or maintain certification. A reasonable time deadline for compliance should also be specified.
 - f) In the event the laboratory disagrees with the deficiencies of the assessor(s), and the Lead Assessor adheres to the original deficiencies; the deficiencies with which the laboratory takes exception shall be documented and included in the report.
 - g) Other comments and technical recommendations that will improve laboratory performance and data quality within the constraints of allowed consultancy and respective of any conflict of interest.
 - h) Obsolete certifications for which the laboratory management may have requested relinquishment, including the effective date.
- Conclusions – Includes recommendations regarding the laboratory's compliance with the provisions of chapter 64E-1, FAC.

Nonconformities shall be documented with appropriate standards and FAC citations using the form specified in FAC 64 E-1.104(5).

6.5 Post Assessment Activities

Laboratories shall be required to submit a corrective action plan for the nonconformities identified during the assessment, including proposed completion dates, on the form specified in FAC 64E-1.104 within 30 calendar days from the receipt of the assessment report. The lead assessor shall review the corrective action plan within 14 days of receipt. PJLA shall provide the itemized report of recommendation for approval along with the final certification recommendations within 30 calendar days of receipt of the laboratory's corrective action plan or within one day of receiving payment from the laboratory, whichever comes later. If any rejections are made upon review of the corrective action plan, the rationale for the rejection will be provided.

Documentation (e.g., checklists, correspondence, quality manuals, laboratory data, conflict of interest forms, confidential business information forms) gathered prior to and during on-site assessments shall be provided to the FL DOH within seven (7) business days of a request from the FL DOH. Checklists gathered and used for all *Cryptosporidium* and *Giardia* assessments shall be provided to the FL DOH within 30 days following the completion of the assessment report.

7.0 RECORD RETENTION (RECORDS/COMPLAINTS)

Assessment records for the FL DOH ELCP shall be retained for at least (6) years from the termination of the agreement between PJLA and FL DOH.



The Florida Department of Health (FL DOH) Environmental Laboratory Certification Program (ELCP) Procedure

All laboratory assessment records, financial records, supporting documents, statistical records, and any other documents pertinent to the agreement between PJLA and FL DOH shall be retained for a period of six (6) years after termination of the contract. If an assessment has been initiated and assessment findings have not been resolved at the end of six (6) years, the records shall be retained until resolution of the assessment findings or any litigation which may be based on the terms of the agreement between PJLA and FL DOH.

8.0 PARTICIPATION & MAINTENANCE WITH THE FL DOH ELCP

By July 1 of each calendar year, any updates to assessor qualification records and a signed attestation from each assessor confirming they have not been investigated by any state or federal inspector within the past year shall be provided to FL DOH.

PJLA will participate in meetings with the FL DOH as scheduled and announced, to help in the evaluation, maintenance, and improvement of the FL DOH ELCP and undergo periodic evaluations as specified by the FL DOH. PJLA and its assessors will be available to support FL DOH external and internal audits or any disputes that may arise from assessments.

9.0 CONFLICT OF INTEREST/CONFIDENTIALITY

The appropriate conflict of interest and confidentiality agreements shall be maintained for all assessors and staff utilized for the FL DOH ELCP. If at any time staff members of PJLA should impose any detrimental success to the FL DOH ELCP, then those staff members (employees or subcontracted employees) will be replaced with another member of equal and superior qualification.