FLORIDA DEPARTMENT OF Environmental Protection

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2600 Blair Stone Road
Tallahassee, FL 32399-2400

Ron DeSantis
Governor

Jeanette Nuñez
Lt. Governor

Shawn Hamilton
Secretary

VIA EMAIL
Read receipt requested

December 13, 2021

Rico Bartolo
Advanced Environmental Laboratories, Inc., Gainesville
4965 SW 41st Blvd
Gainesville, FL 32608
Email: RBartolo@aellab.com

Re: Final Audit Report for Nutrients Lab Records Audit

Dear Mr. Bartolo:

Thank you for responding to the preliminary audit report for the Nutrients Lab Records Audit of the Advanced Environmental Laboratory-Gainesville laboratory (AEL). The Florida Department of Environmental Protection (department or DEP) has reviewed your response and accepted the proposed corrective actions.

Attached is the final audit report detailing the audit procedure, audit findings, and the department's audit conclusions. This final audit report will be posted on the department's website at https://floridadep.gov/dear/florida-dep-laboratory/content/fdep-biological-and-audit-report-search. As noted in the report, the department concludes that the laboratory procedures and laboratory documentation used by AEL have met quality control (QC) criteria required by the AEL-Gainesville Quality Manual and laboratory SOPs, Cannon Creek Mobile Home Park Wastewater Treatment Facility (Permit Number FLA011412-008-DW4P) and Super 8 Motel Complex Wastewater Treatment Facility – Lake City (Permit Number FLA011403-007-DW3P), Chapter 62-160, Florida Administrative Code (F.A.C.), Chapter 62-620, F.A.C., The NELAC Institute (TNI) 2016 standards and the relevant methods. The laboratory's implementation of corrective actions described in the final audit report will lead to an improved quality system. None of the findings in the audit were deemed critical to data usability for National Pollution Discharge Elimination System (NPDES) permit compliance. However, there is insufficient evidence to conclude whether unusually high total nitrogen (TN) results for two samples, G2002590002 for total Kjeldahl nitrogen (TKN) and G1911059002 for nitrate + nitrite (NOx) were caused by sampling error, laboratory error, or were representative of the sample source at the time the samples were taken.

NOTE: The audit evaluated the indicated data for the use(s) described in the final audit report. The usability of the audited data for other purposes or the usability of data produced by the audited organization for other analytes or other date ranges must be determined separately according to applicable requirements in Rule 62-160.670, F.A.C.

Under Chapter 120 of the Florida Statutes, AEL, and any other person whose substantial interests are affected by the department's agency action, may challenge the attached final audit report, including the corrective actions and the data usability analysis. The process to challenge any portion of this agency action is described below in the Notice of Rights section.

If you have any questions or concerns about this final audit report, please feel free to contact Sarah Noble at (850) 245-8533 or Jessica Patronis at (850) 245-8980.

Notice of Rights

This action is final and effective on the date mailed (via e-mail) unless a sufficient petition for an administrative hearing is timely filed under Sections 120.569 and 120.57 of the Florida Statutes as provided below. If a sufficient petition for an administrative hearing is timely filed, this agency action becomes only proposed agency action, subject to the result of the administrative review process. Therefore, on the filing of a timely and sufficient petition, this action will not be final and effective until further order of the department. Because an administrative hearing may result in the reversal or substantial modification of this action, the petitioner is advised not to proceed until the deadlines noted below for filing a petition for an administrative hearing or request for an extension of time have expired. Mediation is not available.

A person whose substantial interests are affected by the department's action may petition for an administrative proceeding (hearing) under Sections 120.569 and 120.57 of the Florida Statutes. The petition must contain the information set forth below and must be filed (received by the clerk) in the Office of General Counsel of the Department at 3900 Commonwealth Boulevard, Mail Station 35, Tallahassee, Florida 32399-3000. The petitioner shall also mail a copy of the petition to AEL at the address indicated above at the time of filing.

Under Rule 62-110.106(4), F.A.C., a person whose substantial interests are affected by the department's action may also request an extension of time to file a petition for an administrative hearing. The department may, for good cause shown, grant the request for an extension of time. Requests for extension of time must be filed with the Office of General Counsel of the Department at 3900 Commonwealth Boulevard, Mail Station 35, Tallahassee, Florida 32399-3000, before the applicable deadline. A timely request for extension of time shall toll the running of the time period for filing a petition until the request is acted upon. If a request is filed late, the department may still grant it upon a motion by the requesting party showing that the failure to file a request for an extension of time before the deadline was the result of excusable neglect.

If a timely and sufficient petition for an administrative hearing is filed, other persons whose substantial interests will be affected by the outcome of the administrative process have the right to petition to intervene in the proceeding. Intervention will be permitted only at the discretion of the presiding officer upon the filing of a motion in compliance with Rule 28-106.205, F.A.C.

In accordance with Rules 28-106.111(2) and 62-110.106(3)(a), F.A.C., petitions for an administrative hearing by the petitioner must be filed within 21 days of receipt of this written notice. Petitions filed by any persons who were not entitled to written notice under Section 120.60(3) of the Florida Statutes must be filed within 21 days of publication of the notice, if published, or within 21 days of receipt of the written notice, whichever occurs first. Under Section 120.60(3) of the Florida Statutes, however, any person who has asked the department for notice of agency action may file a petition within 21 days of receipt of such notice, regardless of the date of publication. The failure of any person to file a petition for an administrative hearing within the appropriate time period shall constitute a waiver of that person's right to request an administrative determination (hearing) under Sections 120.569 and 120.57 of the Florida Statutes.

A petition that disputes the material facts on which the department's action is based must contain the following information: (a) The name and address of each agency affected and each agency's file or identification number, if known; (b) The name, address, and telephone number of the petitioner; the name, address, and telephone number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding; and an explanation of how the petitioner's substantial interests are or will be affected by the agency determination; (c) A statement of when and how the petitioner received notice of the agency decision; (d) A statement of all disputed issues of material fact. If there are none, the petition must so indicate; (e) A concise statement of the ultimate facts alleged, including the specific facts that the petitioner contends warrant reversal or modification of the agency's proposed action; (f) A statement of the specific rules or statutes that the petitioner contends require reversal or modification of the agency's proposed action, including an explanation of how the alleged facts relate to the specific rules or statutes; and (g) A statement of the relief sought by the petitioner, stating precisely the action that the petitioner wishes the agency to take with respect to the agency's proposed action.

A petition that does not dispute the material facts on which the department's action is based shall state that no such facts are in dispute and otherwise shall contain the same information as set forth above, as required by Rule 28-106.301, F.A.C. Under paragraphs 120.569(2)(c) and (d) of the Florida Statutes, a petition for administrative hearing must be dismissed by the agency if the petition does not substantially comply with the above requirements or is untimely filed.

This determination constitutes an order of the department. Subject to the provisions of paragraph 120.68(7)(a) of the Florida Statutes, which may require a remand for an administrative hearing, the applicant has the right to seek judicial review of the order under Section 120.68 of the Florida Statutes, by the filing of a notice of appeal under Rule 9.110 of the Florida Rules of Appellate Procedure with the Clerk of the Department in the Office of General Counsel, 3900 Commonwealth Boulevard, Mail Station 35, Tallahassee, Florida, 32399-3000; and by filing a copy of the notice of appeal accompanied by the applicable filing fees with the appropriate district court of appeal. The notice of appeal must be filed within 30 days from the date when the final order is filed with the Clerk of the Department.

Executed in Tallahassee, Florida.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL PROTECTION



David Whiting, Deputy Director
Division of Environmental Assessment and Restoration
2600 Blair Stone Road
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Attachments:
Final Audit Report

Copies furnished to:

Kenneth Hayman, FDEP Office of General Counsel
Tamara Blyden, FDEP Division of Water Resource Management
Thomas Kallemeyn, FDEP Northeast District Office
File

CERTIFICATE OF SERVICE

The undersigned duly designated deputy clerk hereby certifies that this determination, including all copies, was e-mailed before the close of business on December 13, 2021, to the above listed persons.

FILING AND ACKNOWLEDGMENT

FILED, on this date, pursuant to 120.52(7)
Florida Statutes, with the designated Department Clerk,
receipt of which is hereby acknowledged.

Ashley Phillips 12/13/2021

Clerk Date

Final Audit Report
Advanced Environmental Laboratory, Inc. – Gainesville
DOH ID E82001
Nutrient Lab Records Audit
Conducted May 2021

Division of Environmental Assessment and Restoration
Florida Department of Environmental Protection
December 10, 2021

Introduction

The Florida Department of Environmental Protection's (DEP or department) Division of Water Resource Management requested a records audit of Advanced Environmental Laboratories, Inc. – Gainesville (AEL-Gainesville or AEL). The Aquatic Ecology and Quality Assurance section (AEQAS) conducted the audit in accordance with Rules 62-160.650 and 62-160.670, Florida Administrative Code (F.A.C.). The purpose of this audit was to verify that AEL-Gainesville is complying with the quality assurance (QA) requirements of the QA Rule, Chapter 62-160, F.A.C., and correctly implementing approved analytical methods, including acceptable quality control, and maintaining adequate laboratory documentation.

This final audit report lists the procedural and documentary deficiencies, as determined by the department auditors, responses from the audited party, and the department's response to the corrective actions proposed by the laboratory.

Audit Description

AEQAS staff requested analytical and quality control records for nutrient samples representing the laboratory's analyses for total nitrogen (including nitrate-nitrite and TKN components) and total phosphorus for data submitted to DEP from August 2019 – May 2020 (Table 1). Records were requested from AEL-Gainesville on April 12, 2021 and received on May 17, 2021. AEQAS auditors reviewed records pertaining to the selected samples, which included the laboratory's certification information, Quality Manual and relevant SOPs, MDL studies, sample chain of custody documents, check-in logs, analytical runs, lab quality assurance and quality control documentation, laboratory reports, and discharge monitoring reports (DMRs). Due to Covid-19 restrictions, a laboratory visit and systems audit were not conducted. Instead, AEL-Gainesville sent digital records and AEQAS conducted a records-only audit of the selected samples remotely. AEQAS audited total nitrogen (TN) and components (total Kjeldahl nitrogen [TKN] and nitrate+nitrite [NOx]) and/or total phosphorus (TP) of 17 sample IDs, consisting of 11 TN and component analyses (11 TKN and 11 NOx) and 12 total phosphorus (TP) analyses, for a total of 45 analyses. The AEQAS auditing team met over video conference with staff from AEL-Gainesville for an audit overview and introductory meeting on May 24, 2021, and further correspondence was conducted via email. The AEL-Gainesville Quality Manual and laboratory SOPs, Cannon Creek Mobile Home Park Wastewater Treatment Facility (Permit Number FLA011412-008-DW4P) and Super 8 Motel Complex Wastewater Treatment Facility – Lake City (Permit Number FLA011403-007-DW3P), Chapter 62-160, F.A.C., Chapter 62-620, F.A.C., The NELAC Institute (TNI) 2016 standards and the relevant methods (Table 1) provided the criteria for the audit and all findings. Personnel involved in the audit were Jessica Patronis, Sarah Noble, Kristen Sapp, Kara Sprague, and Chandler Hammond from AEQAS. AEL's corporate Quality Assurance officer, Stephen Cantin, was the main contact for AEL-Gainesville.

Preliminary Audit Report and Implementation of Corrective Actions

A preliminary audit report of findings and deficiencies was sent to Stephen Cantin of AEL on August 13, 2021. Procedures or documentation that did not comply with audit criteria are identified in Table 2, along with the department's recommended or required corrective actions. Mr. Cantin replied on September 27, 2021 with proposed corrective actions and implementation

dates for the noted deficiencies, which have been included in Table 2. Mr. Cantin informed the auditors at that time that he would be passing correspondence for this audit to Rico Bartolo, Corporate Technical Director of AEL, going forward. Additional documentation and clarification were requested by the auditors on October 19, 2021, and AEQAS auditors met with AEL staff on November 1, 2021, via video conference to discuss the additional request and any further questions regarding findings and corrective actions for the audit. Vivian Abare, AEL Quality Assurance Officer, provided additional documentation on November 9, 2021. Review of the additional documentation led to finding 19. The additional finding and a draft of the final report were reviewed by AEL and their response was received on December 10, 2021. The auditors reviewed all information and accepted the implementation dates and proposed corrective actions. The auditors' responses are found in the last column of Table 2.

Audit Conclusions

Based on the findings from this audit, DEP has determined that the corrective actions for the laboratory meet the department's minimum quality assurance standards. The laboratory's implementation of corrective actions described in this report will lead to an improved quality system. None of the findings in the audit were deemed critical to data usability for National Pollution Discharge Elimination System (NPDES) permit compliance. However, there is insufficient evidence to conclude whether unusually high TN results for two samples, G2002590002 for TKN and G1911059002 for NOx were caused by sampling error, laboratory error, or were representative of the sample source at the time the samples were taken.

NOTE: The audit evaluated the indicated data for the use(s) described in this report. The usability of the audited data for other purposes or the usability of data produced by the audited organization for other analytes or other date ranges must be determined separately according to applicable requirements in Rule 62-160.670, F.A.C.

Table 1. List of audited samples for the laboratory nutrient records audit of AEL-Gainesville conducted by DEP, May 2021.

Sample ID	Collection Date, Time	Analyte(s)[1]	Method(s)[2]
G1906358002	08/07/19, 10:40	TP	EPA 365.4
G1907379002	09/04/19, 13:05	TN, TKN, NOx, TP	EPA 351.2, EPA 353.2, SM 4500-NO3-F, EPA 365.4
G1908832002	10/09/19, 08:35	TN, TKN, NOx	EPA 351.2, EPA 353.2, SM 4500-NO3-F
G1908833002	10/09/19, 09:00	TN, TKN, NOx	EPA 351.2, EPA 353.2, SM 4500-NO3-F
G1909637002	11/06/19, 10:00	TP	EPA 365.4
G1909639002	11/06/19, 11:55	TP	EPA 365.4
G1911058002	12/18/19, 10:25	TN, TKN, NOx	EPA 351.2, EPA 353.2, SM 4500-NO3-F
G1911059002	12/18/19, 10:40	TN, TKN, NOx, TP	EPA 365.4
G2000988002	01/29/20, 11:50	TN, TKN, NOx	EPA 351.2, EPA 353.2, SM 4500-NO3-F
G2000987002	01/29/20, 12:15	TN, TKN, NOx, TP	EPA 351.2, EPA 353.2, SM 4500-NO3-F, EPA 365.4
G2001916002	02/26/20, 10:05	TN, TKN, NOx	EPA 351.2, EPA 353.2, SM 4500-NO3-F
G2001915002	02/26/20, 10:40	TP	EPA 365.4
G2002591002	03/11/20, 10:05	TP	EPA 365.4
G2002590002	03/11/20, 10:30	TN, TKN, NOx, TP	EPA 351.2, EPA 353.2, SM 4500-NO3-F, EPA 365.4
G2004202002	04/29/20, 10:25	TN, TKN, NOx, TP	EPA 351.2, EPA 353.2, SM 4500-NO3-F, EPA 365.4
G2005107002	05/27/20, 12:35	TN, TKN, NOx, TP	EPA 351.2, EPA 353.2, SM 4500-NO3-F, EPA 365.4
G2005108002	05/27/20, 13:00	TP	EPA 365.4

[1] Analytes: Total Nitrogen (TN) Calculated, Total Kjeldahl Nitrogen (TKN), Nitrate + Nitrite (NOx), and Total Phosphorus (TP).

[2] Methods: EPA Method 351.2, Revision 2.0: Determination of Total Kjeldahl Nitrogen by Semi-Automated Colorimetry (1993); EPA Method 353.2, Revision 2.0: Determination of Nitrate-Nitrite Nitrogen by Automated Colorimetry (1993); Standard Methods 22nd Edition, Nitrogen (Nitrate) 4500-NO3-F. Automated Cadmium Reduction Method (2016); Method 365.4: Phosphorus, Total (Colorimetric, Automated, Block Digester AA II) (1974).

Table 2. Audit findings for the laboratory nutrient records audit of AEL-Gainesville conducted by DEP, May 2021.

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
1.	All analytes	2016 TNI V1M2 5.8.6 a), 5.8.7.1 and 5.8.7.2; Rule 62-160.340 (1)(a) and (2)(b)3, F.A.C.; AEL QM (Rev. 10.3) Section 6.1.1.4 and 6.4	Acid preservation and type of acid used is not indicated on the Chain of Custody (COC).	All samples	**Required:** Document and check all preservation of samples upon receipt. Qualify results of any improperly preserved samples.	The lab is now documenting and checking all preservation of TP-TKN-NOX samples upon receipt per AEL login SOP, the QM and TNI guidance. The lab will qualify results of any improperly preserved samples noted at receipt. **Implementation date:** 9/15/2021	Acceptable
2.	NOx and TP	2016 TNI V1M4 1.7.4 (a); Rule 62-160.340 (2)(b)3, F.A.C.	Positive verification check on receipt of samples for temperature ≤6 degrees Celsius was not recorded on the COC.	G1908833002, G1908832002, G1909637002, G1909639002, G2004202002	**Required:** Check and record sample temperature (≤6 degrees Celsius) upon receipt. Document the temperature check on the COC.	The login personnel was retrained to check and record sample temperature (≤6 degrees Celsius) upon receipt and to document the temperature check on the COC per AEL login SOP, the QM and TNI guidance. **Implementation date:** 9/15/2021	Acceptable
3.	TKN, NOx and TP	2016 TNI V1M4 1.7.4 (b); Rule 62-160.340 (2)(b)3, F.A.C.	There was no positive verification check of sample for pH <2 SU on the COC.	G1908833002, G1908832002, G1909637002, G1909639002, G2001915002, G2001916002, G2004202002	**Required:** Check and document acid preservation for all appropriate samples and include the information on the COC.	AEL records the pH check values of received preserved samples in a lab logbook separate from the COC. The lab is now documenting and checking all preservation of TP-TKN-NOX samples upon receipt per AEL login SOP, the QM and TNI guidance.	Acceptable. This finding was discussed at a meeting with AEL on 11/1/21. AEL provided the following response and corrective action via email on 11/16/21, 'These

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
					Add the acceptance criteria to the COC.	**Implementation date:** 9/15/2021	records are unavailable for the requested samples as the pH was not being recorded in Sample Receiving or at the bench level. Going forward we will be recording sample pH at the bench level prior to analysis." Adding the preservation acceptance criteria to the sample receipt documentation as required by Rule 62-160.340, F.A.C., was also discussed and implemented at the meeting.
4.	TKN (TN) and TP	2016 TNI V1M2 Section 5.5.13.1 d)	Data logger for digestion block is not checked against a NIST thermometer.	All TKN and TP samples	**Required:** Calibrate and/or verify the data logger at least annually. Document all calibrations/verifications and any other maintenance.	The lab verified and recorded the data loggers for the digestion blocks and will continue to do so annually. **Implementation date:** 6/28/2021	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
5.	TKN (TN), TP	2016 TNI V1M4 1.7.3.3 a); AEL SOP WC-041, AEL SOP WC-044 Rev 11 Section 18.9and AEL QM (Rev 10.3) Section 12.0; Rule 62-160.340 (3), F.A.C.; Rule 62-160.700 Table 1, F.A.C.	Percent recovery calculation for a 1 mg/L spike, per AEL SOPs, by DEP does not match the documented percent recovery on the analytical run and this discrepancy may have affected qualifications. Calculations cannot be confirmed based on the records provided for percent recovery of the associated matrix spikes of the following samples: For sample ID G1911058002 (TKN), DEP calculated 387% and AEL reported 192%. For sample ID G2000988002 (TKN), DEP calculated 165% and AEL reported 82%.	G1911058002, G2000988002, G2004202002, G2000987002, G2001915002, G1909637002	**Required**: Explain the discrepancy between the calculations. Correct any errors in calculations and issue an amended lab report for affected results. When matrix spike percent recovery is out of the expected range, the associated sample shall be qualified with a "J" and accompanied by a detailed explanation to justify the reason for designating the value as estimated.	G1911058002 (TKN) is based on a prep factor of 2 at a spike of 1ppm. The calculation was still slightly off. MS/MSD values calculated based on prep of 2X recovered at 194 and 157% respectively. Analyst error. The LIMS calculated the recoveries correctly. No change in qualifier or amendment needed on final report as MS/MSD not included in report to client. G2000988002 (TKN) is based on a prep factor of 2 at a spike of 1ppm. The calculation is accurate as documented on the raw data. No change in qualifier or amendment needed on final report as MS/MSD not included in report to client. G2004202002 (TKN), spiked sample J2005957002 is calculated correctly as reflected on the raw data, [(1.286-0.459)/1]*100=83%. G2000987002 (TP) is based on a prep factor of 2 at a spike of 1ppm. The calculation is accurate as documented on the raw data. G2001915002 (TP) - 118% is correct. Analyst calc error. The LIMS reported the	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
			For sample ID G2004202002 (TKN), spiked sample J2005957002, DEP calculated 81.7% and AEL reported 83%. For sample ID G2000987002 (TP), DEP calculated 204% and AEL reported 102%. The associated sample (G2000988002) was not qualified with a "J." For sample ID G2001915002 (TP), spiked sample G2001916002, DEP calculated 118% and AEL reported 99%. For sample ID G1909637002 (TP), the matrix spike percent recovery (122%) was not within the expected range (90-			calculation correctly. No change to the client report as they didn't request the spike QC on their final report. G1909637002 (TP) - G1909619001 was a re-run from another batch. G1909637002 is associated to G1909804001. G1909804001 passed MS/MSD criteria. No change to report required. G1909619001 was originally qualified on its report for TP as required. The analyst was retrained to take care when making manual calculations to verify passing QC. **Implementation date:** 9/16/2021	

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
			110%) and the associated sample (G1909619001) was not qualified with a "J."				
6.	TKN, NOx (TN) and TP	2016 TNI V1M4 Section 1.7.3.3 (a)	Relative percent difference results were not provided for matrix spikes and the matrix spike duplicates.	All samples	**Required:** Provide and maintain records for the calculations of relative percent difference of matrix spike recoveries.	The LIMS calculates the %RPD for MS/MSD pairs and those values are reviewed at the first two levels of review. The lab did not provide those results at initial request to FDEP as the "Records for Review" section provided to the lab was not clear that all calculations were required to be provided. Going forward the lab will begin calculating the RPD values on the raw data or providing the LIMS QC batch reports for assessors requiring the RPD verifications when requested. The data requested was provided to FDEP. **Implementation date:** 9/16/2021-training; FDEP response-9/27/2021	Acceptable
7.	TN (Calculation)	Rule 62-160.340 (1)(a) and (b), F.A.C.	Procedures for incorporating qualified values in the TN calculation are not documented in AEL SOP WC-068 Rev 04. Per	G1907379002, G1908832002, G2000988002, G2000987002	**Required:** Revise AEL SOP WC-068 to include procedures documenting how the laboratory incorporates qualified	The policy that resulted in the reported calculations for the affected projects was the previous policy in place prior to mid- February 2020. Those values were reported correctly based on the	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
			email correspondence with Mr. Cantin on 6/10/2021, if either the TKN or NOx value is non-detect the greater of either the non-detected parameter MDL or the detected parameter is reported as the final value. The following sample IDs were not calculated per AEL guidance: For sample ID, G1907379002, DEP calculated 10 mg/L, AEL reported 11 mg/L. For sample ID G1908832002, DEP calculated 7.2 mg/L, AEL reported 8 mg/L. For sample ID, G2000988002, DEP calculated 5.0		values in the TN calculation. Document procedures for calculating TN when one or both component results are less than the MDL. Correct any errors in calculations and issue an amended lab report for affected results.	previous policy. The affected projects are not associated to the current AEL policy and are not required to be amended. The SOP WC-068 was updated to include procedures for qualified values in the TN calculation. **Implementation date:** 9/24/2021	

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
			mg/L, AEL reported 5.4 mg/L. For sample ID, G2000987002, DEP calculated 17 mg/L, AEL reported 18 mg/L.				
8.	TN (TKN, NOx)	Rule 62-160.340 (1)(a) and (b), F.A.C.	TN calculation consisted of TKN and/or NOx results with a J4 qualifier. There is no documentation for incorporating qualified values in the TN calculation.	G1908833002, G1911058002, G2000988002, G2001916002	**Required:** Revise AEL SOP WC-068 to include procedures documenting how the laboratory incorporates qualified values in the TN calculation. Explain how qualifiers and information pertaining to the quality of the component result is incorporated in the final TN result.	The lab staff has been retrained to qualify the TN values when the individual components are qualified for a QC issue. The SOP WC-068 has been updated to reflect the new procedures. **Implementation date:** 9/24/2021	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
9.	TKN, NOx, TP	AEL SOP Admin-011, Revision 05, Section 3.1.2, 3.3.1, 3.3.2, and 3.4; SM4500-NO3 F. Section 6	For TP sample IDs G2000987002 and G2004202002, AEL did not follow AEL-SOP Admin-011 (Rev 5) rounding rules for ICV (secondary source) check. FDEP calculated 96.5% and 94.5%, respectively, and AEL-Gainesville reported 96% and 94%, respectively, on the analytical run. For sample ID G1911058002 (TKN), AEL did not follow AEL-SOP Admin-011 (Rev 5) rounding rules for CCV (primary source) check. FDEP calculated 94.4%, AEL-Gainesville reported 95% on the analytical run	G1911058002, G1907379002, G2000987002, G2004202002	**Required:** Round up to the next number if the last digit is 5 or greater to follow the AEL lab SOP rounding rules. Correct any rounding errors, qualify results not meeting acceptance criteria and issue an amended lab report for affected sample results. Retrain analysts on rounding rules and/or correct in Horizon. For sample ID G1907379002, qualify affected results and issue an amended lab report.	The analysts have been retrained on the rounding rules protocol and trained on the reduction efficiency upper control criteria. The Nitrate SOP is being updated to include the upper range criteria of the reduction efficiency. The lab will correct any rounding errors, qualify results not meeting acceptance criteria and issue an amended lab report for the affected sample result in G1907379002. **Implementation date:** 9/20/2021-retraining; 9/24/2021-Amended report & SOP edit.	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
			For sample ID G1907379002 (NOx), column efficiency was 110.576%. According to AEL-SOP Admin-011 (Rev 5), this value would round to 111%, which is greater than the column reduction efficiency acceptance criteria (90-110%).				
10.	NOx	2016 TNI 1.5.2.4 (b); Rule 62-160.340 (2)(f), F.A.C.	DEP calculated the percent recoveries for the ICVs, CCVs, PQLs and all were within range of the expected value, but the calculation is not documented in the sample records submitted to DEP.	All NOx samples	**Required:** Calculate and record all percent recoveries.	The analysts were trained to calculate, review and record all batch QC % recoveries on the raw data going forward. **Implementation date:** 9/16/2021	Acceptable

Finding #	Analyte	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
11.	NOx	2016 TNI V1M2 4.13.3 (f); Rule 62-160.340 (2)(f)3, F.A.C.	Spike concentrations for matrix spikes and matrix spike duplicates were not described in AEL SOP WC-012 Rev. 13, nor were they provided on the bench sheets or analytical runs.	All NOx samples	**Required:** Add the spike concentrations to AEL SOP WC-012 Rev. 13. If spiking concentrations vary from the AEL SOP, document the spike concentration on the bench sheet or analytical run. Retrain analysts on the updated protocol.	The SOP WC-012 was updated to reflect the known concentrations of all spikes. **Implementation date:** 9/24/2021	Acceptable
12.	TP, TKN	2016 TNI V1M2 4.13.3.f) xiii.	Samples that were re-run with a dilution in a different analytical run, reported the analysis time as the initial analysis time and not the re-run analysis time.	G1906358002, G1907379002, G1909637002, G2004202002, G1907379002, G2004202002	**Recommended:** Report the analysis time for the reported result.	The analysts were retrained to update the analytical date and time as required when LIMS batch results are updated due to re-runs and dilutions. **Implementation date:** 9/20/2021	Acceptable
13.	TP and TKN	2016 TNI V1M4 1.5.2.1.	The reported MDLs in use for TKN and TP samples do not follow current TNI requirements and are lower than those calculated using the updated MDL procedure.	All TKN and TP samples	**Required:** Use MDLs calculated using the current TNI requirements as the basis for reported MDLs.	AEL was between updating MDLs from the 2009/2013 TNI requirements to the 2016 TNI requirements during the projects in question. The 2016 TNI TP MDL started 6/7/2020 in the LIMS is accurate based on the study completed in 2019, but the TKN MDL started during that time period is not. The MDL in the LIMS for TKN has been updated to reflect the most recent 2019 MDL and	Acceptable

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						verification study completed for 2020. **Implementation date:** 9/20/2021	
14.	TP	AEL SOP WC-044 Rev 11 Section 12.5.1	Per AEL SOP WC-004, CCV value is 0.5 mg/L; however, in one analytical run, the CCV value was reassigned to 0.426 mg/L with no documentation as to why this change occurred.	G1906358002	**Required:** Explain why the CCV value was reassigned. Follow AEL SOP WC-044 and document when and why changes occur.	Analyst error. The analyst was trained to never use a recovered value in the curve as a "true" value to assess if an analyzed continuing calibration standard passed criteria. **Implementation date:** 9/20/2021	Acceptable
15.	TP	2016 TNI V1M4 1.7.2.3.; AEL SOP WC-044 Rev 11 Section 12.8	The sample was re-analyzed with no MS/MSD in the batch. The MS/MSD from the initial analysis were not quantitatively bracketed within the calibration range.	G2004202002	**Required:** Qualify data that are not quantitatively bracketed by the calibration range or verifications.	The MS/MSD that was prepared with sample G2004202002 in the prep batch did not require a re-run as the parent sample value recovered initially within range of the curve. The raw values of the MS/MSD QC is allowed to recover outside the curve range as long as the spike standard is set within the middle of the curve range and the parent sample falls within the bracketed curve. The MS/MSD is not reanalyzed with dilutions or re-runs of the associated prep samples unless further	Auditor error. Acceptable

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						dilution of the prepared batch QC is necessary. The parent sample of the MS/MSD digestates from the initial analysis, J2005957002, was quantitatively bracketed within the calibration range. **Implementation date:** N/A	
16.	TN	Rule 62-160.340 (6) and (7), F.A.C.	The lab reported result for TN was 360 mg/L. The DMR result for TN was 340 mg/L.	G1911059002	**Required:** Explain the discrepancy between the lab report and the DMR.	The lab does not recall reporting a DMR for TNs for this client and shows nothing on file but the final report. The client is likely transferring the data from AELs final report to the DMR format. If the DMR shows otherwise please pass it along to AEL for corrective action. **Implementation date:** N/A	Acceptable. The facility will be notified of the discrepancy.
17.	TN (TKN and NOx)	Rule 62-160.340 (1)(a), F.A.C.	TN results are unusually high due to a high component result. Documentation justifying high dilution was not provided for the following samples: Sample ID G2002590002 (TKN) required a 10x and then a 50x dilution and the	G2002590002, G1911059002	**Required:** Provide the raw data (absorption records) and any analytical run records, documentation or prior knowledge leading to the 50x dilution and use of M qualifier on the analytical run. Include any additional QC	The TKN sample, G2002590002, was reviewed and found to have been reported correctly. The analysis at a 50X resulted in a value in the upper range of the curve and confirmed from the original analysis. The peak markers were moved manually due to a slight pause between the QC sets to switch out the buffer. The pause was noted on the raw data. Replacing the reagents	Acceptable. This finding was discussed in a meeting with AEL on 11/1/2021. There was no evidence of laboratory error found in the available records. It was confirmed for sample G1911059002

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			sample analytical run showed an M indicating the Peak Marker was moved manually. Sample ID G1911059002 (NOx) required a 50x dilution.		measures taken to verify the results. Qualify results and issue an amended lab report if indicated by investigation of records.	in the middle of a run is an uncommon occurrence. The absorption records are now provided. The NOx was reported at a 5X, not a 50. The diluted value did recover within the calibration range but on the lower end. The dilution was not a bad one, but was not necessary and could have been re-run without a dilution to recover a value in the middle to upper end of the calibration. The analysts have been retrained to monitor reagent levels before the beginning of a sequence, make it fresh if needed and to avoid switching out reagents between QC sets to avoid the M qualifiers where possible. The analysts have been retrained to re-run samples at a lower dilution to recover a value within the middle to top range of a curve whenever a result falls within the bottom half of a curve. **Implementation date:** 9/24/2021	that the NOx sample was run at a 50X dilution. The lab was unable to recover raw data and absorption records due to computer back up failure. The laboratory had no known historical or sample condition documentation leading to the decision to initially dilute either of the samples. The DMR records for this facility over the audited time period do not show repeatedly high TN results where a single component (TKN or NOx) was consistently affected.

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18.	All analytes	2016 TNI V1M2 4.13.3 (f) and Rule 62-160.340 (1)(a), F.A.C.	Absorption records were not provided for the audit. Auditors were unable to verify raw instrument results using the records provided.	All samples	**Required:** Provide raw instrument output.	The absorption records are not typically requested by assessment groups during an external audit and the "Records for Review" requested by FDEP was not clear enough for the lab to have known to provide those records. The records have now been provided to FDEP for TKN & TP. The records for the affected NOx data could not be recovered and provided as the original PC hard drive in use during that timeline for the instrument went down and could not be recovered. There was a backup company procedure put into place but it was not completed routinely enough. The lab will now backup the local PCs monthly to prevent a re-occurrence. **Implementation date:** 9/25/2021	Acceptable.
19.	All analytes	2016 TNI V1M4 1.7.1.1 (k) and Rule 62-160.340 (2)(c) 2 and (2)(e) 2, F.A.C.	The acceptance criteria for the relative error of the calibration standards used for instrument initial calibration was not implemented or documented in the laboratory SOP in	All samples	**Required:** Establish and document in the laboratory SOP calibration criteria for the relative error of the calibration standards and the procedure for deriving the criterion. Evaluate initial	The following SOPs were updated to include specific acceptable acceptance criteria for the Relative Error (%RE) calculation for the mid-point and the low point for calibrations evaluated using correlation coefficient or coefficient of determination:	Acceptable

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			accordance with the 2016 TNI standard.		calibration results using these criteria and if the calibration is not acceptable, perform corrective actions and re-analyze all associated samples. If re-analysis is not possible, qualify data associated with an unacceptable initial calibration.	- WC-012 13 2021-12-09 NOX 353.2 4500NO3-F - WC-041 15 2021-12-09 TKN 351.2 - WC-044 11 2021-12-09 TP 365.4 **Implementation date:** The initial implementation date of the relative error calculation was 12.31.2020. Modifications were made and implemented on 12.09.2021.	