FLORIDA DEPARTMENT OF Environmental Protection

Bob Martinez Center
2600 Blair Stone Road
Tallahassee, FL 32399-2400

Ron DeSantis
Governor

Jeanette Nuñez
Lt. Governor

Shawn Hamilton
Secretary

VIA EMAIL
Read receipt requested

January 9, 2023

Thomas Widera
Pace Analytical Services, LLC
8 East Tower Circle
Ormond Beach, FL 32174
Email: Thomas.Widera@pacelabs.com

Re: Final Audit Report for Chlorophyll Laboratory Records Audit

Dear Mr. Widera:

Thank you for responding to the preliminary audit report for the Chlorophyll Laboratory Records Audit of Pace Analytical Services LLC – Ormond Beach, FL (Pace). 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 Pace have not met one or more quality control (QC) criteria required by the Pace Quality Manual and laboratory SOPs, Chapter 62-160, Florida Administrative Code (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. Several findings in the audit were deemed critical for data usability for the Impaired Waters Rule, 62-303, F.A.C., and other DEP uses. Critical deficiencies involve abnormal absorption readings that were not appropriately addressed during sample analysis and resulted in inaccurate chlorophyll *a* – corrected results. Caution should be taken for use of chlorophyll data, especially where negative chlorophyll *a* – corrected results are observed, for the time period of February 27, 2018 through November 16, 2021 and results shall be considered estimated values. Data produced after November 16, 2021 are considered usable pursuant to the implementation of corrective actions. Details about the findings as they relate to data usability are described in the final audit report.

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, Pace, 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 Jessica Patronis at 850-245-8980 or Sarah Noble at 850-245-8533.

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 Pace 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
Tallahassee, FL 32399
Tel No.: (850) 245-8191

Attachments:
Final Audit Report

Copies furnished to:

Kenneth Hayman, FDEP Office of General Counsel
Kevin O'Donnell, Program Administrator, Water Quality Evaluation &TMDL Program
Jessica Mostyn, Environmental Administrator, Watershed Assessment Section
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 January 9, 2023, 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 1/9/2023
Clerk Date

Final Audit Report
Pace Analytical Services, LLC – Ormond Beach, FL
DOH ID E83079
Chlorophyll Lab Records Audit
Conducted June 2022

Florida Department of Environmental Protection
Division of Environmental Assessment and Restoration
January 9, 2023

Introduction

The Florida Department of Environmental Protection's (DEP or department) Division of Environmental Assessment and Restoration (DEAR) requested a records audit of Pace Analytical Services LLC – Ormond Beach, FL (Pace) to inform its various uses of chlorophyll *a* data. DEP's DEAR data users found several unusual results for chlorophyll *a* corrected for phaeophytin (chlorophyll *a* – corrected), where the values were low or non-detect in samples collected from lakes with historical high concentrations. 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 Pace is complying with the quality assurance (QA) requirements of the QA Rule, Chapter 62-160, F.A.C., 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 samples representing the laboratory's chlorophyll determinations by spectrophotometry using Standard Methods, 10200 H. Chlorophyll determinations under this method included chlorophyll *a* – corrected, pheophytin *a*, and chlorophyll *a*, *b* and *c*. AEQAS audited 30 samples submitted to DEP's Watershed Information Network (WIN) database from February 2018 – April 2021 (Table 1). Records were requested from Pace on April 18, 2022 and received on June 10, 2022. AEQAS auditors reviewed records pertaining to the selected samples, which included the laboratory's certification information, Quality Manual and relevant SOPs, detection limit studies, sample chain of custody documents, check in logs, analytical runs, instrument test reports, lab quality assurance and quality control documentation, and laboratory reports. The AEQAS auditing team met over video conference with Pace's Quality Manager, Thomas Widera, and the former Quality Manager, Tina Buttermore, for an audit overview and introductory meeting on June 10, 2022. Further correspondence was conducted via email. The Pace Quality Manuals and laboratory SOPs, Chapter 62-160, F.A.C., The NELAC Institute (TNI) 2016 standards and Standard Methods 10200 H provided the criteria for the audit and all findings. Personnel involved in the audit were Jessica Patronis, Sarah Noble, Kristen Sapp, and Jennifer Piacente from AEQAS. Quality Manager, Thomas Widera, was the main contact for Pace.

Preliminary Audit Report and Implementation of Corrective Actions

A preliminary audit report of findings and deficiencies was sent to Thomas Widera of Pace on September 8, 2022. 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. Widera replied on October 10, 2022, with proposed corrective actions and implementation

dates for the noted deficiencies, which have been included in Table 2. AEQAS auditors met with Pace staff on December 2, 2022, via video conference to address clarifications and remaining questions regarding findings and corrective actions for the audit. A draft of the final report was reviewed by Pace and their response was received on December 21, 2022. 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.

Findings 2, 3, and 4 involve errors in the loading of data to WIN. To resolve these findings, auditors corresponded with the following Pace customers; Leon County (Johnny Richardson), Seminole County (Michelle Shelton), and Hillsborough County (Troy Green). Pace identified and reviewed a wider range of data affected by finding 2 from January 2014 – December 2021, applied qualifiers to affected results and issued revised lab reports.

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. Several findings in the audit were deemed critical for data usability for the Impaired Waters Rule, 62-303, F.A.C., and other DEAR uses. The deficiencies involve abnormal absorption readings that were not appropriately addressed during sample analysis and resulted in inaccurate chlorophyll *a* – corrected results. Pace determined that deficiencies were primarily related to poorly clarified extracts due to the use of cellulose filters. Prior to the DEP audit, Pace conducted an internal audit and reached the same conclusions and replaced cellulose filters with glass fiber on November 16, 2021. Pace intends to review data generated during the affected period as time allows, and reissue lab reports with "J" qualified results in cases where they could determine the data were affected by established quality control failures associated with findings 12, 14, 15, 18 and 20. Other factors that could have affected sample results included inappropriate path length of the cuvette, insufficient cleaning of cuvettes and inaccuracies in analyst performance with the acidification step. However, since the issues did not directly relate to established quality control failures, associated data were not qualified as a result of the audit. Caution should be taken for use of chlorophyll data, especially where negative chlorophyll *a* – corrected results are observed, for the time period of February 27, 2018 through November 16, 2021 and results shall be considered estimated values. Data produced after November 16, 2021 are considered usable pursuant to the implementation of corrective actions. Pace will continue to evaluate existing data that may have been impacted by the audit findings.

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 chlorophyll records audit of Pace conducted by DEP, June 2022.

Sample ID	Collection Date, Time	Analyte[1]	Method[2]
35376789002	2/27/2018, 11:40	Chlorophylls	SM 10200 H.
35395445002	5/31/2018, 11:00	Chlorophylls	SM 10200 H.
35416028001	9/6/2018, 10:05	Chlorophylls	SM 10200 H.
35427392002	10/30/2018, 12:05	Chlorophylls	SM 10200 H.
35437182003	12/13/2018, 11:40	Chlorophylls	SM 10200 H.
35475160003	6/13/2019, 12:40	Chlorophylls	SM 10200 H.
35500830002	9/26/2019, 10:45	Chlorophylls	SM 10200 H.
35506847002	10/22/2019, 12:10	Chlorophylls	SM 10200 H.
35510645004	11/7/2019, 13:30	Chlorophylls	SM 10200 H.
35518228001	12/11/2019, 10:30	Chlorophylls	SM 10200 H.
35524890001	1/16/2020, 10:25	Chlorophylls	SM 10200 H.
35537602005	3/16/2020, 10:57	Chlorophylls	SM 10200 H.
35537603002	3/16/2020, 14:21	Chlorophylls	SM 10200 H.
35537912005	3/17/2020, 9:14	Chlorophylls	SM 10200 H.
35556523001	6/15/2020, 12:10	Chlorophylls	SM 10200 H.
35556970005	6/16/2020, 13:00	Chlorophylls	SM 10200 H.
35575656001	9/3/2020, 10:30	Chlorophylls	SM 10200 H.
35577762002	9/15/2020, 10:46	Chlorophylls	SM 10200 H.
35592638005	11/17/2020, 12:20	Chlorophylls	SM 10200 H.
35597152002	12/8/2020, 12:34	Chlorophylls	SM 10200 H.
35601414001	12/29/2020 11:50	Chlorophylls	SM 10200 H.
35603945003	1/12/2021 9:55	Chlorophylls	SM 10200 H.
35610543004	2/9/2021 11:45	Chlorophylls	SM 10200 H.
35612239001	2/16/2021 8:55	Chlorophylls	SM 10200 H.
35612990001	2/18/2021 10:56	Chlorophylls	SM 10200 H.
35619336003	3/16/2021 10:51	Chlorophylls	SM 10200 H.
35619336002	3/16/2021 11:51	Chlorophylls	SM 10200 H.
35619745004	3/17/2021 13:30	Chlorophylls	SM 10200 H.
35623385003	4/5/2021 9:40	Chlorophylls	SM 10200 H.
35625573001	4/13/2021 12:40	Chlorophylls	SM 10200 H.

[1] Analytes: Chlorophyll determinations for chlorophyll *a* corrected for pheophytin, pheophytin *a*, and chlorophyll *a.*

[2] Method: Standard Methods for the Examination of Water and Wastewater, Online Edition, 10200 H. Chlorophyll, Spectrophotometric Determination of Chlorophyll (2001).

Table 2. Audit findings for the laboratory records audit of Pace conducted by DEP, June 2022.

Finding #	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
1.	Rule 62-160.400 (1) F.A.C.; Rule 62-160.700 Table 1 F.A.C.; 2016 TNI V1M2 4.13.3. a)	Times recorded for filtering, extraction, and analysis times between the prep log and analysis run log and between the analysis run log and the lab report are not always consistent across documentation. For sample ID 35437182003, the receipt time on the chain of custody was different from the lab report. For Sample IDs: 35395445002, 35524890001, and 35575656001, using the filtered date/time from the analysis run would have resulted in the sample out of 48-hour hold from collection to time of filtration.	35376789002, 35395445002, 35416028001, 35427392002, 35437182003, 35475160003, 35510645004, 35518228001, 35524890001, 35537912005, 35556523001, 35556970005, 35575656001, 35577762002, 35592638005, 35601414001, 35603945003, 35610543004	**Required:** Ensure times for various steps in sample processing and analysis are transcribed correctly across documentation. For Sample IDs: 35395445002, 35524890001, and 35575656001, determine correct filtration time. If the holding time was not met, issue an amended lab report with appropriately qualified results.	Sample 35395445002 was filtered on 6/1/18 at 17:34, not 6/9/18 at 10:15. Sample 35524890001 was filtered on 1/17/20 @ 13:15 not 1/23/20 at 7:35, and 35575656001 was filtered 9/5/20 at 9:27 and not 9/15/20 @6:52. All samples were filtered within holding time. It appears as there was inadequate review of the data prior to release. The department has recently hired a data validator to review data. The recent data files reviewed are consistent. **Implementation Date:** 4/25/22	Acceptable. Per email and meeting on 12/2/2022, the correct filtration time is recorded on the prep log and the lab report. Pace will add a data validation check to ensure filtration times are accurate across all documentation. Pace hired the data validation employee on 4/25/22.
2.	Rule 62-160.340 (2) (c) 5. and (3) F.A.C.; 2016 TNI V1M2 5.10.1 and 5.10.3.1 a)	Laboratory report indicates chlorophyll *a* – uncorrected result. Organization ID 21FLLEON, responsible for uploading results to WIN, loaded the result as chlorophyll *a* - corrected.	35395445002, 35416028001, 35427392002, 35475160003, 35500830002, 35506847002, 35556970005, 35575656001	**Required:** Ensure appropriate analytical result is uploaded to WIN. Correct the analyte name in WIN to chlorophyll *a* for affected results.	Pace labs is actively working to provide Leon County (Organization Code 21FLLEON) with an updated chlorophyll *a* – corrected data file that will include properly reported chlorophyll *a* – corrected data for the entire period of record. This updated data file will be provided to Leon County by November 30, 2022. Leon County plans to submit the updated data to FDEP/WIN. As discussed in a meeting on 12/2/2022, Pace identified data that were affected by this finding, including results not captured by this audit from October 2014 through December 2020. Pace completed the evaluation of affected data on 12/2/2022. **Implementation Date:** 12/2/2022	Acceptable.
3.		The laboratory report indicates that samples were analyzed by Pace Analytical Services LLC – Ormond Beach, FL, DOH ID E83079. The entity for Organization ID, 21FLSEM, responsible for uploading results	35592638005, 35597152002 35601414001, 35603945003, 35610543004, 35619745004,	**Required:** Ensure the laboratory DOH ID for the lab location that analyzed the samples is uploaded to WIN. Correct the laboratory DOH ID in WIN for affected samples.	Per phone conversation and email, Organization ID 21FLSEM corrected lab IDs in WIN on 11/17/2022 for results analyzed at the Ormond Beach Pace location. Per email, the lab ID for sample ID 35597152002 was corrected by	Acceptable.

Finding #	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
		to WIN loaded the results under DOH ID E84973. The laboratory report indicated Sample ID 35597152002 was subcontracted to Benchmark lab, DOH ID E84167. The entity for Organization ID, 21FLHESD, responsible for uploading results to WIN loaded the results under DOH ID E83079.	35623385003, 35625573001		Organization ID 21FLHESD for all chlorophyll components as of 10/19/2022. Samples from 15 additional sites collected on 12/08/2020 and 12/09/2020 were also contracted to Benchmark and loaded under the incorrect lab ID number. 21FLHESD has also corrected those lab IDs in WIN. **Implementation Date:** 11/17/2022 and 10/19/2022	
4.	Rule 62-160.340 (7), F.A.C.; Rule 62-160.700 Table 1, F.A.C.	The lab appropriately applied a J qualifier code and comment to the affected pheophytin *a* sample result, but the entity for Organization ID 21FLLEON, responsible for uploading results to WIN, did not include the comment.	35416028001	**Required:** Retain original data qualifiers including required comment from the original lab report when uploading results to the data repository. Add the comment for this result qualifier to the WIN database.	Per email, "Leon County has updated the affected 2021 calendar year data to reflect the required comments. We are currently working to add the required comments to the 2020 calendar year data." Per phone discussion with Leon County, corrections to J qualifier code comments will be made for the entire period of record. **Implementation Date:** 2021 data corrections affecting 35 results were sent to FDEP on 11/4/2022 and applied to WIN.	Acceptable.
5.	2016 TNI V1M2 4.13.3. a) and f), 2016 V1M4 1.7.2.2.1 and 1.7.2.2.3; Pace SOP S-FL-I-012-rev.05 and ENV-SOP-ORB1-0008 Rev 02, Section 10.7	The laboratory's calculation for LCS percent recovery uses only the chlorophyll *a* result. Audit calculation of percent recovery using chlorophyll *a* + chlorophyll *b*, as the Pace SOP implies, leads to many results outside control limits. The Pace SOP is not clear about whether the results for chlorophyll *a* and chlorophyll *b* should be added together in the % recovery calculation. Pace SOPs S-FL-I-012-rev.05 and ENV-SOP-ORB1-0008 Rev 02, Section 10.7 both refer to the "final concentration of 10 mg/m3 of chlorophyll A + B" for the chlorophyll *a* working standard for the LCS.	All Sample IDs Out-of-control: 35395445002, 35416028001, 35427392002, 35437182003, 35475160003, 35575656001, 35577762002, 35610543004, 35510645004, 35518228001, 35537912005, 35619336003, 35619336002, 35619745004	**Recommended:** Add formula for calculation of % recovery of the LCS specific to chlorophyll in the lab SOP or describe how this calculation should be performed. **Required:** Determine if % recovery calculations were done correctly for sample results obtained during the audited period. Qualify any sample results associated with out-of-control LCS results.	The LCS is prepared so that the chlorophyll a concentration is 10 mg/m3. The SOP needs to be clarified to indicate this. All calculations were performed correctly. There were no out of control LCS values. **Implementation Date:** 11/30/2022	Acceptable.

Finding #	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
6.	EPA 446.0, 7.3	The commercial standard referenced in the SOP and used for the audited samples is Absolute Standards Inc. part number 71592, Chlorophyll A/B Standard with Isomer A/B ratio [1:3]. The type of standard is not discussed in Standard Methods, but EPA 446.0 requires the use of a standard free of chlorophyll *b*.	All	**Recommended:** Use a chlorophyll *a* standard substantially free of chlorophyll *b*.	We don't use Method 446.0, so that requirement does not apply. Standards for this test are difficult to obtain. This standard is stable. We will investigate trying to find a standard free of chlorophyll b. **Implementation Date:** 11/30/2022	Acceptable.
7.	2016 TNI V1M2 4.13.3 a) and f)	Pace SOP does not include procedure for preparation and analysis of sample duplicates.	All	**Required:** Include procedure for preparation and analysis of sample duplicates in section 9 of the Pace Chlorophyll *a* SOP.	Requirement will be added to step 9.3.11. **Implementation Date:** 11/30/2022	Acceptable. Section 9.3.11 refers to Pace SOP ENV-SOP-ORB-0143, V02.
8.	Rule 62-160.340 (2) (d) 1., F.A.C.; 2016 TNI V1M2 4.13.3 a); DEP SOP Table FS 1000-5	Freezing of filters and refrigeration of extracts were not documented for individual samples. Auditors were unable to unequivocally link Equipment ID to individual samples to verify that the temperature was stable during storage. Freezer listed in the temperature log was <-10 degrees Celsius. Sample Filters are required to be frozen at -20 degrees C.	All	**Required:** Indicate on the prep log that the filter was frozen/extract was refrigerated and link sample documentation to equipment ID. Store frozen sample filters at -20 degrees C in accordance with DEP SOPs.	Electronic logbook will be updated to include column for determining freezing/steeping and recording the equipment ID. We follow SM 10200H not 446.0. 10200H does not specify a temperature. The freezer currently in use has temps -15-19ºC consistently. We will attempt to adjust to -20ºC with the current equipment. **Implementation Date:** 11/30/2022	Acceptable. Per 12/2/2022 meeting, the freezer was adjusted to and is maintaining the DEP required negative 20ºC temperature.
9.	TNI V1M2 5.6.4.2 c) and e); Pace SOP ENV-SOP-ORB1-0008, Rev2 section 12.1.4	Aqueous magnesium carbonate solution (for use in the filtration step) was created after the filtration time of the sample, but before the extraction step. For sample ID 35537912005, both the aqueous magnesium carbonate solution and the filter were created/dated between the filtration time of the sample and the sample extraction.	35518228001, 35537912005	**Required:** Determine the discrepancy between reagent/filter creation in relation to appropriate steps in the analytical method process. Accurately document dates and times for Standard Log Created date/time and filtration/extraction. Retrain staff on proper documentation procedures.	An internal audit on 10/29/21 found this error type. CAPA audit ticket 33062 was opened for this. The team was trained on the necessity for point of use documentation. Effectiveness checks were performed on 4/13/22 and 6/3/22 and were considered acceptable. A third check is due 10/15/22. Retraining will be performed to reinsure this process is followed. **Implementation Date:** 11/30/2022	Acceptable.

Finding #	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
10.	Rule 62-160.340 (1) (a), (c) F.A.C.; 2016 TNI V1M2 5.6.4.2 c) and 5.8.5 d); Pace ENV-SOP-FL-0017, 6.3.3	It is unclear from the documentation which solution is meant to be entered in the prep log field "Carbonate Solution." In some cases, the ID number linked to the WET 90% Acetone Magnesium Carbonate Standard and in other cases it linked to the aqueous Magnesium Carbonate Solution. Standard Logs were not received for solutions that no ID number was recorded on the Prep Log. IDs for both solutions were not documented on the prep log.	All	**Required:** Clearly document ID numbers for both the aqueous Magnesium Carbonate Solution for the filtration step and the 90% Acetone Magnesium Carbonate for extraction. Revise log documentation to include ID numbers for both solutions. Retain standard log preparation documentation for all standards and reagents.	Both solutions exist in the Standards Log. Separate solutions are being made but documentation is lacking for the magnesium carbonate solution. Staff will be trained to create separate Standard IDs for both solutions. Effectiveness checks will be performed at 30, 60, 90 days to ensure it is being done consistently. **Implementation Date:** 11/30/2022	Acceptable.
11.	Rule 62-160.340 (1) (a), (c) and (2), F.A.C.; 2016 TNI V1M4 4.13.3 b), Pace QM (Rev 4) 4.13.1.2	Analysis run records and freezer logs were not retained for some audited samples.	Analysis run: 35506847002, 35537602005, 35537603002, 35577762002 Freezer log: 35524890001, 35537602005, 35537603002, 35537912005	**Required:** Retain records for a minimum of 5 years, including all information needed to reconstruct analysis.	Retaining records for a minimum of 5 years is standard practice. Some paper files have been difficult to retrieve. Pace has gone to an electronic data storage, whereas run logs are scanned into a paperless drive for record retention. This issue should not recur. **Implementation Date:** 6/2022	Acceptable.
12.	SM 10200 H, section 2. b.; 2016 TNI 5.9.3 a) viii and c)	Absorbance values for 665 after acidification increased compared to the 664 absorbance values before acidification. This resulted in the absorption ratio of 664b:665a being below the range specified in Standard Methods that mixtures of chlorophyll *a* and pheophytin should have an absorption ratio between 1.0 and 1.7. Additionally, the absorbance at 750 nm (for turbidity) increased after acidification. Having absorption ratios outside the range indicates problems with analyst accuracy performing the acidification step.	35395445002, 35416028001, 35427392002, 35437182003, 35556523001, 35575656001, 35592638005, 35610543004 750 nm increased after acidification: 35395445002, 35416028001, 35427392002, 35437182003, 35537912005, 35556523001, 35575656001,	**Required:** Implement a process for second-level review of absorbance readings from analytical runs and resulting calculations for chlorophyll. Add this process to the laboratory SOP. Monitor 664b:665a ratio. Determine the cause of out-of-range absorption ratios and absorbance increases at 750 nm after acidification. Retrain analysts on proper method procedures. Qualify erroneous data with a J and associated comment and reissue affected lab reports.	Each test method contains a cover sheet of items to review. The Chlorophyll cover sheet will be updated to ensure these items are being reviewed. The raised turbidity ratios are due in large part from the use of cellulose filters which precipitate following acidification. Glass fiber filters are now being used. Erroneous data will be corrected. **Implementation Date:** Filter change on 11/16/2021; Data corrections and SOP changes on 11/30/2022.	Acceptable. Per 12/2/22 meeting, Pace agreed to "J" qualify erroneous data associated with this finding. Review of absorbance readings and 664b:665a ratio checks will be added to the Pace data validation checklist and this process updated in the Pace SOP.

Finding #	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
			35592638005, 35610543004			
13.	SM 10200 H, section 2. b.; 2016 TNI 5.9.3 a) viii and c)	The absorbance 664 before acidification is less than the appropriate range of 0.1 and 1.0 AU as specified in Standard Methods. The method states absorbances below this range indicate a dilute extract and the sample should have a cuvette with a longer path than the 1 cm used.	35376789002, 35395445002, 35416028001, 35427392002, 35437182003, 35475160003, 35500830002, 35510645004, 35518228001, 35524890001, 35537912005, 35575656001, 35592638005, 35601414001, 35603945003, 35610543004, 35623385003, 35625573001	**Required:** Evaluate absorbance readings to determine the appropriate path length for the sample cuvette. Add this procedure to the lab SOP.	We currently only have 1 cm cuvettes. 4 and 10 mL cuvettes will be purchased and the SOP will be updated. **Implementation Date:** 11/30/2022	Acceptable. Per 12/2/22 meeting, Pace will add a process to the SOP describing what events will trigger the use of a longer path length cuvette for analysis.
14.	SM 10200 H 1. b. 4) and 2. c.; 2016 TNI 5.9.3 a) viii and c)	Absorption at 750 nm before acidification is greater than or equal to 0.005 AU, indicating a poorly clarified extract solution which should have been re-centrifuged (or filtered) according to EPA 446.0. This is not discussed in detail in SM10200H.	35376789002, 35416028001, 35437182003, 35475160003, 35500830002, 35524890001, 35575656001, 35601414001, 35603945003	**Recommended:** Determine and explain the cause of poorly clarified extracts. Develop a procedure for evaluating 750 nm readings for extract clarity during analysis and a process for treating sample extracts that are not sufficiently clarified. Document the procedures in the lab SOP. Qualify erroneous data with a J and associated comment.	We do not use 446.0. This is not a requirement of SM 10200H.	Acceptable. Per 12/2/22 meeting, Pace agreed to "J" qualify erroneous data associated with this finding and will add a procedure such as what is in EPA 446.0 to evaluate 750 nm absorbances for turbidity and treating sample extracts that are not sufficiently clarified.
15.	SM 10200 H 2. B.; 2016 TNI 5.9.3 a) viii and c)	Chlorophyll *a* – corrected result is a negative value. The absorption value after acidification (665a) is greater than before acidification (664b), resulting in a negative result in the calculation.	35395445002, 35416028001, 35427392002, 35437182003, 35556523001, 35575656001, 35592638005, 35610543004	**Required:** Determine and explain the abnormal absorption readings upon acidification of the sample. Determine potential problem with acidification step and retrain analysts. Implement a procedure for evaluating analysis run absorption readings, corrective action for analyst performance errors, and a process for handing affected data.	The high readings after acidification were mainly due to the cellulose filters. Cellulose is not soluble in HCl, so the filter was precipitating out. When the sample was being mixed the precipitate was rising up the cuvette. Switching to Glass Fiber filters has fixed this. Current data is reflecting that this problem has been corrected.	Acceptable. Per 12/2/22 meeting, Pace agreed to "J" qualify erroneous data associated with this finding and observed analyst technique with acid addition and mixing and analysts are consistently and

Finding #	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
		The negative chlorophyll *a* – corrected results are associated with high pheophytin *a* results in most cases, suggesting a problem with the acidification step. The sum of chlorophyll *a* – corrected and pheophytin *a* should agree with the chlorophyll *a* - uncorrected result.		Document the procedures in the lab SOP. Qualify erroneous data with a J and a comment.	**Implementation Date:** Filter change on 11/16/2021	appropriately performing these procedures. Pace will add a procedure such as what is in EPA 446.0 to evaluate 750 nm absorbances for turbidity and treating sample extracts that are not sufficiently clarified.
16.	2016 TNI V1M2 5.5.5 g), h) and 5.5.7	Absorbance readings for blanks are unusual and blank results are routinely around 0.1 or above. This may indicate a problem with instrument drift or problems with the cuvette. This issue is not discussed in Standard Methods.	35376789002, 35395445002, 35416028001, 35427392002, 35437182003, 35475160003, 35500830002, 35510645004, 35518228001, 35524890001, 35537912005, 35556523001, 35575656001, 35592638005, 35601414001, 35603945003, 35610543004, 35612239001, 35612990003, 35619336003, 35619336002, 35619745004, 35623385003, 35625573001	**Required:** Determine whether the instrument was malfunctioning or if there was a problem with the cuvettes used. Document the problem, implement a corrective action, and retain maintenance records.	An internal audit was performed on 9/9/22 for a different method using the same spec and cuvettes. It was determined that the cuvettes were extremely dirty. It is suspected this may causing many of the analytical issues. The analyst was shown by QA how to check and clean. This requirement will be added to the SOP. **Implementation Date:** Analyst trained on proper cuvette cleaning on 9/9/2022. SOP changes on 11/30/2022.	Acceptable.
17.	Rule 62-160.340 (2) (d) 1., F.A.C.; 2016 TNI V1M2 4.13.3. a)	Sample ID is not clearly linked between COC and lab report.	35612239001, 35612990001, 35619336003, 35619336002, 35619745004, 35623385003, 35625573001	**Required:** Describe in the Pace Quality Manual how sample IDs are assigned.	Pace Sample Management SOP, ENV-SOP-ORB1-0120, Section 6.2 Sample Login describes the link between the COC and Pace Sample ID.	Acceptable.

Finding #	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
18.	Pace Chlorophyll A, B, C and Pheophytin SOP (all versions)	Extraction and analysis did not occur on the same date. This is the protocol as described by Pace staff on 6/10/2022. The maximum steeping time for samples is not discussed in the procedural section of the laboratory's SOPs. Pace ENV-SOP-ORB1-0140 6.0 General Requirements Table, footnote 3 states, "Once extracted, samples can be steeped in the cooler a maximum of 24 hours before centrifugation and analysis." One sample was steeped over the 24-hour maximum steeping time.	35556523001	**Recommended:** Establish a maximum steeping time and add this information to the Pace SOP section 9.4.1.8 and 9.4.2.5. For reference, EPA 446.0 requires a maximum steeping time of 24 hours. **Required:** Steep samples for no longer than 24 hours.	The maximum steep time of 24 hours will be added to the appropriate steps in the SOP **Implementation Date:** 11/30/2022	Acceptable. Per email and 12/2/22 meeting, Pace will "J" qualify the result for sample 35556523001 and issue and amended report.
19.	SM 10200 H 2. B.; 2016 TNI 5.9.3 c)	DEP audit and Pace result calculations for chlorophyll *a* – corrected (DEP 1.92, Pace 1.85), uncorrected chlorophyll *a* (DEP 16.46, Pace 14.47), and pheophytin *a* (DEP 23.45, Pace 19.93) do not match.	35623385003	**Required:** Account for the discrepancy between DEP's calculated result and Pace's results. Issue corrected reports if Pace's results are found to be different than what was provided on the original lab report.	The discrepancy is due to how the turbidity 750 nm is used. If the turbidity is less than 0, it is set to 0 for the calculation. There are no discrepancies. Revised reports not needed. The spreadsheet used to calculate results was developed many years ago. I am trying to ascertain the reasoning for the calculation. If the reason is valid it will be documented. If the reason is not valid, the spreadsheet will need to be corrected for future batches. **Implementation Date:** 11/30/2022	Acceptable. Per email and 12/2/22 meeting, setting negative 750nm absorbances to zero is an internal policy decision. Pace will continue this practice as no internal or external reference was available to determine whether it is an appropriate practice.
20.	2016 TNI V1M4 1.7.1.2 f); Pace ENV-SOP-ORB1-0008 Rev. 2 and 3, 9.2.4 and Appendix B	CCV at the end of the sample run failed the acceptance criteria. There is no documentation of reattempt of CCV analysis on the Prep Log Report or corrective action for the failure.	35556970005	**Required:** Document corrective actions when QC failures occur. Determine the cause of the CCV failure and whether results from the associated sample run should be qualified as estimated values.	The data in the prep log report is manually entered. This data is old and the validity of the result could not be determined. Based on the results of the other wavelengths and the CCV prior, it is suspected that the technician inadvertently hit the number 3 button instead of the period button as they are one on top of another and the result should have been .181 and not 3181. If this is the case, the CCV would have been passing. Required corrective actions are documented in Appendix B of the SOP. It appears that the prep log was reviewed without the reviewer catching the error.	Acceptable. Per email and 12/2/22 meeting, since the validity of the result could not be determined, Pace will provide an amended report with the result "J" qualified for sample ID 35556970005.
21.	2016 TNI V1M4 Section 1.7.3.3 b)	RPD not calculated. The chlorophyll *a* – corrected sample value was below the MDL (1.3 U) but the duplicate result was	35603945003	**Recommended:** Investigate the cause of the discrepancy between sample and duplicate results. Document course of action for when duplicate results are	Many of the data discrepancies witnessed are due to the cuvettes. Separate cuvettes were being used and many of them were not properly cleaned. The process has changed	Acceptable.

Finding #	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
		detected (7.6). The sample and duplicate results were exceptionally different from one another.		unexpected and an RPD or other statistical treatment cannot be applied.	to using the same cuvette for the whole analytical run and they are being cleaned routinely. Recent evaluation of data is showing the RPD of duplicates has improved dramatically. We currently have data qualifiers if the duplicate RPD cannot be calculated, it is qualified as may be statistically unreliable. **Implementation Date:** Process was changed for cuvette use and cleaning on 9/9/2022.	
22.	2016 TNI V1M2 5.10.1 and TNI V1M4 1.7.2.1 a)	Method Blank for pheophytin *a* was not reported correctly on lab report. Analysis run blank result for pheophytin *a* was 5.8, lab reported 2.2 U on lab report Quality Control Data section.	35510645004	**Required:** Report the blank result when the value is above the MDL.	This appears to have been missed in review. The department now has a data validator to catch these errors. The analysis cover sheet will be updated to include this review. **Implementation Date:** Data validator staff hired on 4/25/2022. Cover sheet updated on 11/30/2022.	Acceptable.
23.	SM10200 H 1., Pace Chlorophyll A, B, C and Pheophytin SOP (all versions)	Pace Laboratory SOP versions relative to the audited sample analysis dates state that glass fiber filters are used, but the Prep Log Reports and certificates of analysis for the filters indicate that cellulose filters were used. In a meeting with Pace, they stated that the lab has discontinued use of cellulose filters and currently use glass fiber filters.	All	**Required:** Use glass fiber filters for sample filtration. Update the current lab SOP and prep log report field to indicate use of glass fiber filters rather than cellulose.	The lab is currently using glass fiber filters. SOP will be updated to remove cellulose filters. The prep log will be updated. **Implementation Date:** Filter change on 11/16/2021. SOP and prep log changes on 11/30/2022.	Acceptable.
24.	SM 10200 H b. 4)	Pace Lab SOP versions relative to the audited sample period do not specify in the clarification step that sample tubes are centrifuged at a speed of 500 g or 3000 rpm as required by Standard Methods.	All	**Required:** Update the current lab SOP to indicate centrifuge speed required by Standard Methods.	SOP will be updated. Our centrifuge is currently not capable of attaining that RPM value. We will determine the possibility of purchasing a centrifuge that meets that requirement. This is pending budgetary issues. It may be necessary to filter extracts. **Implementation Date:** 11/30/2022	Acceptable.

Finding #	Requirement Reference	Finding	Sample(s) Affected	Recommended or Required Corrective Action	Laboratory Response	AEQAS Response
25.	Rule 62-160.340 (2) (f) 2. A., F.A.C.; EPA MDL procedure, EPA 821-R-16-006, Rev. 2, 12/2016; Pace ENV-SOP-FL-007, 6.7	MDL studies are missing or not conducted covering the timeframe of 9/2019 through 12/2019. MDL studies were conducted on 8/2018 and 1/2020.	35500830002, 35506847002, 35510645004, 35518228001	**Required:** Perform MDL studies at least every 13 months.	Ongoing MDL spikes/studies have consistently been performed since July 2020.	Acceptable.
26.	Rule 62-160.340 (2) (f) 2. A., F.A.C.; 2016 TNI V1M4 1.5.2.1.1 f)	Pace SOP does not describe how the MDL is determined for each chlorophyll pigment. MDLs are the same for chlorophyll *a* and pheophytin *a* on lab reports. The SOP does not describe the process for applying a new MDL to results once an MDL study is performed or when an existing MDL is verified.	All	**Recommended:** Describe in the laboratory SOP how MDLs are determined for each chlorophyll pigment and implementation of new MDLs to results.	The MDL spike is currently performed only for chlorophyll a, and applied to all fractions. Section 11.3.1.1 references the SOP for the MDL process.	Acceptable. Section 11.3.1.1 refers to the Pace Chlorophyll SOP ENV-SOP-ORB1-0143, V02.

References:

Department of Environmental Protection, 2008. Quality Assurance (QA Rules). Chapter 62-160, Florida Administrative Code (F.A.C.).

The NELAC Institute (TNI). 2016 TNI Standard, EL-V1-ISO-2016-Rev2.0, Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis, Module 4, Management Requirements.

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