# FLORIDA DEPARTMENT OF Environmental Protection

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

**Ron DeSantis**
Governor

**Jeanette Nuñez**
Lt. Governor

**Noah Valenstein**
Secretary


VIA EMAIL
*Read receipt requested*

May 3, 2019

Kelly Bortle
Advanced Environmental Laboratories, Inc., Gainesville
4965 SW 41st Blvd
Gainesville, FL 32608
Email: kbortle@aellab.com

**Re: Final Audit Report for Microbiology Lab Records and Systems Audit**

Dear Mr. Bortle:

Thank you for responding to the preliminary audit report for the Microbiology Lab Records and Systems 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 also be posted on the department's website at http://www.dep.state.fl.us/labs/cgi-bin/reports/search.asp. As noted in the report, the department concludes that the laboratory procedures and laboratory documentation used by AEL have not met one or more critical Quality Control (QC) criteria required by the approved methods, NELAC 2003 standards, Chapter 62-160, Florida Administrative Code (F.A.C.), and/or requirements outlined in purchase order B1696A. The critical findings are the lack of colony verification and outside of range or missing temperatures on incubator logs. DEP auditors found other QC deficiencies as well, as outlined in the report.

DEP will verify the implementation of corrective actions with future requests for QC documentation. Due to findings deemed critical by DEP auditors, data analyzed during the date range evaluated under this audit and data affected by the problems identified in the audit may be considered by DEP as estimated values for certain uses of the data.

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 Nia Wellendorf at (850) 245-8190 or Kristen Sapp at (850) 245-8686.

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

Attachments:
Final Audit Report

Copies furnished to:

Kenneth Hayman, DEP Office of General Counsel
Cheryl Swanson, DEP Biology Program
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 May 6, 2019, 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 Phillepo 5/6/19
Clerk Date

# *Final Audit Report*
# *AEL-Gainesville*
# *DOH ID 82001*
# *Microbiology Lab Records & Quality System Audit*
# *Conducted October 2018*

**Division of Environmental Assessment and Restoration**
**Florida Department of Environmental Protection**
**May 3, 2019**

## Introduction

This laboratory quality system and records audit of the Advanced Environmental Laboratory-Gainesville location (AEL-Gainesville) was conducted by the Florida Department of Environmental Protection (DEP or department) Aquatic Ecology and Quality Assurance Section (AEQAS) and Biology Program. The audit was conducted in accordance with Rules 62-160.650 and 62-160.670, Florida Administrative Code (F.A.C.), to verify that AEL-Gainesville is complying with the quality assurance (QA) requirements of DEP purchase order B1696A 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

On October 2-3, 2018, DEP staff Jessica Patronis, Kristen Sapp, and Jennifer Mihalic met with AEL Quality Control (QC) officer Kelly Bortle and several lab personnel to conduct a quality system review at the AEL-Gainesville lab. DEP staff reviewed analytical and quality control records for nine samples analyzed for *Escherichia coli* (E. coli) under contract during the last year (Table 1). Records reviewed included custody chains, laboratory check in logs, analytical runs, laboratory reports, and QA and quality control (QC) documentation. The systems audit included verification of laboratory procedures through review of laboratory analytical and QC records for the microbiological tests, the laboratory Quality Manual and Standard Operating Procedures (SOPs), interviews with laboratory staff, and direct observation, with review of information from January 2017 to September 2018. The DEP purchase order No. B1696A, the 2003 National Environmental Laboratory Accreditation Conference (NELAC) standards, Chapter 62-160, F.A.C., and the relevant methods (Table 1) provided the criteria for the audit and all findings.

## Preliminary Audit Report and Implementation of Corrective Actions

A preliminary audit report of findings and deficiencies was sent to Kelly Bortle of AEL on January 11, 2019. Procedures or documentation that did not comply with audit criteria are identified in Tables 2 and 3, along with the department's suggested or required corrective actions. Mr. Bortle replied on February 19, 2019 with proposed corrective actions and implementation dates for the noted deficiencies, which have been included in Tables 2 and 3. Documentation and clarification were requested by the auditors on March 11, 2019, and Mr. Bortle provided additional documentation on March 13, 2019. The auditors reviewed and accepted the proposed corrective actions. The auditors' responses are found in the last column of Tables 2 and 3.

## Audit Conclusions

Based on the findings from this audit, DEP has determined that the laboratory has not met one or more critical QC criteria required by the approved methods, NELAC 2003 standards, and/or DEP contract requirements. The critical findings for the AEL Gainesville Laboratory include:

(1) Lack of colony verification, and
(2) Outside of range or missing temperatures on incubator logs.

DEP auditors determined other QC deficiencies as well, as outlined in the findings tables. The laboratory's implementation of corrective actions described in this report will lead to an improved quality system. DEP will verify the implementation of corrective actions with future requests for QC documentation. Due to findings deemed critical by DEP auditors, data analyzed during the date range evaluated under this audit and data affected by the problems identified in the audit may be considered by DEP as estimated values for certain uses of the data.

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 lab records audit of AEL- Gainesville conducted on October 2-3, 2018, by DEP.

| Lab ID | Collection Date | Analyte | Method |
|---|---|---|---|
| G1705499002 | 07/06/2017 | *E. coli* | EPA 1603 |
| G1705665005 | 7/11/2017 | *E. coli* | EPA 1603 |
| G1707137004 | 08/22/2017 | *E. coli* | EPA 1603 |
| G1707306001 | 08/29/2017 | *E. coli* | EPA 1603 |
| G1708503002 | 10/05/2017 | *E. coli* | EPA 1603 |
| G1708988004 | 10/18/2017 | *E. coli* | EPA 1603 |
| G1709861002 | 11/15/2017 | *E. coli* | EPA 1603 |
| G1710721003 | 12/18/2017 | *E. coli* | EPA 1603 |
| G1710750001 | 12/19/2017 | *E. coli* | EPA 1603 |

**Table 2.** Audit Findings for the *E. coli* analysis lab records audit of AEL-Gainesville conducted on October 2-3, 2018, by DEP.

| Finding # | Requirement Reference | Finding | Sample(s) Affected (lab ID) | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|---|
| 1. | NELAC 2003 standard (5.4.12.2.5.3.b and 5.5.10.2.g); Guidance document, page 1 and Table 3* | Date and time analyzed is reported incorrectly on the electronic data delivery (EDD) files. Analysis time should be the time removed from the incubator, but appears to be the time placed in the incubator. | G1705499002 G1705665005 | **Required:** Report analysis time on the EDD as the time samples are removed from incubator and sample results are read, as required by the contract. | EDD files since August 2017 have the date/ time out of incubator as date/time analyzed. | 8/22/17 | Acceptable |
| 2. | Guidance document, page 2* NELAC 2003 5.4.12.2.1 | Chain of custody (COC) has the lab ID written in the top right corner without indicating what the number represents, making it difficult to establish an audit trail. Lab ID was not clearly linked to the field ID. | ALL | **Recommended:** Create a field on the COC to house the lab ID to clearly link field and lab ID for each sample on the field sheet. | Field created. The project number label shall be placed on the chain so that it does not cover the Gainesville address or lab ID. | 2/12/19 | Acceptable |
| 3. | NELAC 2003 5.4.12.1.5 b), 5.4.12.2.5.3 g) and 5.5.8.2.d) | The bench sheet does not clearly indicate which incubator/water bath is used for first or second incubation. | ALL | **Required:** Document on the bench sheet which equipment is used for each phase of analysis. | The bench sheet was edited to include a field for entry. Placed in use in lab in 2018 and incubator ID is now being documented. | 02/7/2019 | Acceptable |
| 4. | NELAC 2003 5.4.12.2.5.3 b) and g); 5.5.8.2.d) | Date and time for initial incubation was written in margins on the bench sheet and not clearly linked to what actions occurred at those times. This lack of linkage led to no time recorded for some samples. | G1707306001, G1708988004 | **Required:** For each incubation phase, document on the bench sheet the corresponding times and incubator IDs for each time a sample is put into and taken out of incubation. | Documentation is now being clearly written on the bench sheet for the incubator times and IDs for when sample is put into and taken out of incubation. | 11/15/2017 | Acceptable |

| Finding # | Requirement Reference | Finding | Sample(s) Affected (lab ID) | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|---|
| 5. | Guidance document, page 1*; EPA 1603 (9/2014), section 11.5 | Five out of 9 samples did not have any dilutions with colony counts within the ideal range. | G1707137004, G1707306001, G1708503002, G1708988004, G1709861002 | **Required:** Ensure that appropriate dilutions are utilized to have colony counts within the ideal range. | Dilutions levels are now chosen to ensure that colony counts are within the ideal range. | 2/12/19 | Acceptable. Refer to Guidance document (Table 2). |
| 6. | EPA 1603, section 13, and Appendix B | Calculated result does not match reported result. Interview with the QA manager indicated that results on bench sheets are calculated by fecal method, but the results reported to DEP are correctly calculated for the EPA 1603 method. | ALL | **Required:** Instruct and teach analysts to use the appropriate calculation for the method employed by the laboratory. Ensure reported results match the calculated result on the bench sheet. | Analyst training conducted for method EPA 1603 calculations. Reported result now match the calculated results listed on the bench sheet. | 2/12/2019 | Acceptable |
| 7. | EPA 1603 sections 9.7 & 12; Guidance Document, page 5* | Verification procedures for positive colonies were not conducted during the date range covered by the audited samples. | ALL | **Required:** Initiate verification procedures for positive colonies as required by the method and contract. The laboratory should verify 10 typical (positive) colonies and 10 atypical (negative) colonies per month, or 1 typical colony and 1 atypical colony from 10% of all positive samples, whichever is greater. | Typical and atypical colonies are now being verified monthly per method and contract procedures. | 2/12/19 | Acceptable |

| Finding # | Requirement Reference | Finding | Sample(s) Affected (lab ID) | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|---|
| 8. | EPA 1603 section 9.8 & 9.11 | Daily checks are not performed for filter and media sterility. | ALL | **Required:** Conduct daily sterility checks of the filters and media used for sample analysis. | Pre and post blanks were being run ever batch and every ten samples indicting sterility for media and filter on each day of use. A check is also now performed without filtering any fluid for check of media and filter alone. | 02/12/2019 | Acceptable. |
| 9. | EPA 1603 section 9.2 & 9.4 | No record of ongoing precision and recovery (OPR) samples were found in the audited records. | ALL | **Required:** The laboratory should analyze one OPR sample after every 20 field samples or one per week that samples are analyzed, whichever occurs more frequently. | The lab shall now perform an OPR every 20 samples or once per week, (whichever occurs more frequently) using a spike of known value. | 2/12/2019 | Acceptable |
| 10. | EPA 1603 section 9.12; NELAC 2003 D.3.2 | No counting variability tests were available for the month of December 2017. | G1710721003, G1710750001 | **Required:** Explain the reason for the missing counting variability and provide a corrective action for when counting variability is not conducted. | Count comparisons were accidently missed as analysts cycled through end of year vacation time, missed scheduling. Supervisor shall now review QC checks monthly prior to end of month to ensure it will get done. | 2/12/19 | Acceptable |

| Finding # | Requirement Reference | Finding | Sample(s) Affected (lab ID) | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|---|
| 11. | NELAC 2003, 5.5.8.3.1a)1) and b) | Temperature check not recorded in the appropriate field on COC. | G1705499002 | **Required:** Ensure that staff complete the temperature prompt on COC when receiving samples. | Login staff shall now ensure temperature is listed on COC. Project Manager will also review COC for temperature documentation. | 8/2018 | Acceptable |
| 12. | NELAC 2003, 5.4.12.1.5 f); 5.4.12.2.3 | Batch information is unclear due to strike through on the bench sheet that was confirmed by the QA manager to be an accident and does not apply to the sample data. | G1705665005 | **Required:** Ensure that errors in documentation are annotated as necessary for clarifications or corrections. | Training has been conducted explaining how corrections are to be made and how they are to be annotated. | 1/9/2019 | Acceptable |
| 13. | NELAC 2003, 5.4.12.1.2, 5.4.12.1.5 e), and 5.5.8.2 | Handwriting on media sterility logs and media positive/negative control logs is often difficult to read, resulting in an inability to link log data to sample bench sheets. | G1707137004, G1707306001 | **Required:** Ensure that records are legible and linked to the associated documents. | Training has been conducting to ensure that ALL handwritten records are legible. Supervisor shall review records. | 1/9/2019 | Acceptable |
| 14. | Guidance document, pages 4 and 7*; NELAC 2003, 5.5.10.3.1 | Sample was not reported with a qualifier despite result falling outside the acceptable range. | G1707306001 | **Required:** Resubmit sample result with the "B" qualifier code. | Report amended. | 2/19/2019 | Acceptable |

| Finding # | Requirement Reference | Finding | Sample(s) Affected (lab ID) | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|---|
| 15. | EPA 1603 section 6.23, 10.1 and 11.8; NELAC 2003, D.3.8 b) 6); | Recorded temperature is outside the acceptable range (Incubators G4S and G4R) during recorded incubation times for the first incubation phase. | G1708503002, G1708988004 | **Required:** Ensure that the incubator is maintaining the appropriate temperature for the designated incubation phase. Per the method, the first incubation phase temperature is 35.0 +/- 0.5°C. Develop corrective actions for out of control test conditions. | Incubator was replaced. Analysts were re-trained to rigorously follow rules for immediate QA notification of any temperatures out of range. Failure to notify will now result in disciplinary action. Immediate repair to any out of range incubators. Sample results to be qualified when warranted. | August 2018 | Acceptable. Document corrective actions for incubator failures in incubator records. |
| 16. | per Guidance document, page 7* | Filtration end times are not recorded for each sample batch or sequence, per the cited reference requirements. Filtration end times and start times are the same. | ALL | **Required:** Record accurate filtration times for each sample. | Filtration start times are now recorded on bench sheets. Filtration end times are the same as start time into incubator, also recorded on bench sheets. Filtration start and stop times are not to exceed 30 minutes. | 2/7/2019 | Acceptable |

| Finding # | Requirement Reference | Finding | Sample(s) Affected (lab ID) | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|---|
| 17. | EPA 1603 section 10.1; NELAC 2003 D.3.8b)6) i) | Did not record incubator/water bath temperature twice daily, at least four hours apart. | G1708988004 | **Required:** Record the temperature of the incubator/water bath twice daily at least four hours apart. | Analysts now record the temperature of the incubator/water bath twice daily at least four hours apart. | 11/15/2017 | Acceptable |
| 18. | NELAC 2003 D.3.1 a); EPA 1603 section 9.11 | Media not checked for sterility prior to use. | G1708988004 | **Required:** Check media sterility prior to use with samples. | The media is now being checked for sterility, along with positive and negative controls prior to use with samples. The lab is informed when samples are scheduled to arrive at least one day in advance. | 2/12/19 | Acceptable |
| 19. | NELAC 2003 D.3.1 a) 5). | Buffered dilution solution not checked for sterility prior to use. | G1708988004, G1709861002, G1710721003 G1710750001 | **Required:** Check dilution solution sterility prior to use with samples. | The dilution buffer water is now being checked for sterility prior to use with samples. | 2/12/19 | Acceptable |

*Guidance for Microbiological Data Reported to DEP, attached to purchase order

**Table 3.** Audit findings for the systems audit of AEL – Gainesville, conducted by DEP, October 2-3, 2018.

| Finding # | Reference | Finding | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|
| 1. | SM9020B | The laboratory is not performing bench surface contamination monitoring procedures. | **Recommended:** Monitor bench surface contamination weekly or more frequently if the laboratory has a heavy sample load. | The lab has strict cleaning procedures that include wiping down the bench surface with bleach before and after each batch of samples. | Daily | Acceptable. Conduct surface wipe tests if prescribed in the SM 9020 version used by the lab. |
| 2. | SM9020B | In October 2017, air density positive control plates had no growth. There was a note stating that the plates were frozen. Air quality monitoring was not re-analyzed for the month. | **Required:** Monitor air at least monthly, with air density plates. Make sure plates are properly thawed before use. | HPC Plates used for air monitoring are now always fresh or properly thawed prior to use. | July 2018 | Previous DEP required corrective action was incorrect. Media should not be frozen. |
| 3. | NELAC D.3.6 d), NELAC 5.5.6.4; SM9020B. | The date opened for media containers is not documented in a log book. | **Required:** Maintain logs to document the opened date for each container of media. Bottles of media should be used within 6 months of opening. | The date opened is now also recorded in consumables log book instead of just on the bottles. | 2/12/19 | Acceptable |
| 4. | NELAC D.3.8 b) 2) iii); Table 9020:III, SM9020B | The lab is not maintaining a record of autoclave operations. Additionally, there is no record of media or buffered dilution solution sterilization. | **Required:** Create a log and record autoclave operations including date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time and analysts initials. Maintain a record of | The autoclave log is now in use documenting the following: date, contents, maximum temperature reached, pressure, time in, time out, and analyst's initials. Media | 2/7/2019 | Acceptable |

| Finding # | Reference | Finding | Required or Recommended Corrective Action | Laboratory Response | Implement ation Date | DEP Response |
|---|---|---|---|---|---|---|
| | | | media and rinse water sterilization. | and rinse water sterilization recorded. | | |
| 5. | NELAC D.3.8 b) 2) ii); | The laboratory is using a steam indicator tape instead of a proper indicator for buffered water for each autoclave cycle to determine sterilization. | **Required:** Use appropriate indicator material to show efficacy of autoclave for buffered water. | Tape is to be replaced. Autoclave tape will be used. Presently on order. | 2/15/19 | Acceptable |
| 6. | NELAC D.3.8 b) 2); SM9020B | The lab did not conduct corrective actions after the autoclave biological (*Geobacillus stearothermophilus*) check for effectiveness of sterilization failed. | **Required:** Establish and carry out corrective action procedures when autoclave sterilization checks fail. Ensure that failures and corrective actions are recorded. | Analysts were re-trained to rigorously follow rules for immediate QA notification of any Autoclave QC failures. Failure to notify will now result in disciplinary action. Failures are to be recorded on log and on Nonconformity Forms with root cause analysis and corrective action taken. | August 2018 | Acceptable |
| 7. | NELAC D.3.8b)2)v) | Autoclave timer check is missing for October 2017. The last timer check was recorded July 2017. | **Required:** Check the autoclave timing device quarterly against a stopwatch and document the actual time elapsed. | The autoclave timer is now checked quarterly for accuracy using a NSIT certified stopwatch. | 03/11/2019 | Acceptable |
| 8. | NELAC 5.5.5.3; | There is no record of water bath, incubator, or UV lamp bulb maintenance. Laboratory staff affirmed in an interview | **Required:** Record all water bath, incubator and UV lamp bulb | Maintenance log books have been created to record cleaning events as well as any maintenance done. Incubators are now cleaned | | Acceptable |

| Finding # | Reference | Finding | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|
| | SM9020B l. | that water bath maintenance was occurring. The laboratory analyst stated that incubator cleaning occurs when media is spilled, but not monthly. Laboratory staff affirmed that UV lamp bulbs are not being cleaned monthly with ethanol. | maintenance activities including dates cleaned. | monthly. Water baths are cleaned more frequently than monthly. UV sterilizer bulbs are being cleaned monthly. | 2/15/19 | |
| 9. | NELAC 5.5.5.2.1 d); SM9020B | The thermometer is not checked annually (preferably semi-annually) for accuracy. | **Required:** Check accuracy of thermometers annually (preferably semi-annually) against a NIST certified (or NIST traceable) thermometer. | All thermometers are checked annually for accuracy against a NIST certified thermometer. | Last checked 3/20/2018 and 1/22/2019. | Acceptable |
| 10. | NELAC 5.5.9.2 a)8); NELAC D.3.8 b)6); SM9020B | The temperature in the incubator room is not maintained at 16 – 27ºC or 60 - 80ºF. The auditor observed that there is a noticeable temp/humidity difference between the incubator room and the rest of the lab. There is no thermometer or thermostat that shows the temperature in the incubator room. There is a dehumidifier in the room, and the door to the rest of the lab | **Required:** Maintain air temperature in the incubator area between 16 – 27ºC or 60 - 80ºF. | Room temperature shall now be monitored to be within 16-27° C. New thermometer calibrated on 2/14/19 and installed. | 2/15/19 | Acceptable |

| Finding # | Reference | Finding | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|
| | | remains open. Laboratory staff stated that they are working on the problem. | | | | |
| 11. | SM9020B 3.c.; DEP SOPs FT 1000, FT 1100 | Analysts are reusing aliquots of pH buffers for pH meter calibration. | **Required:** Analysts should discard the aliquots of buffer solution after each use. | The lab is now disposing the pH buffers after each calibration check. | 1/15/2019 | Acceptable. Must dispose of aliquot after calibration and calibration verification. |
| 12. | NELAC D.3.8 b) 7) i); SM9020B | Per interview with a laboratory analyst, membrane filtration funnels are not washed; only autoclaved. The auditor observed that the funnels were old and appeared cloudy. | **Required:** Wash and rinse filtration assemblies thoroughly after use, wrap in nontoxic paper or foil, and sterilize. Discard filtration units if inside surfaces are scratched. | The lab is now washing and rinsing filtration assemblies thoroughly after use, wrapping in aluminum foil, and then sterilizing. Funnels are check for scratches each day of use and will be disposed of if scratches seen. | 1/15/2019 | Acceptable |
| 13. | NELAC D.3.1 | Sterility checks of lab sterilized items are not performed. | **Recommended:** Check sterility of at least one item per sterilization batch using a non-selective media. | An extra item is now being placed in the autoclave with each cycle of the autoclave so that it can be tested for sterility. | 2/15/19 | Acceptable |
| 14. | NELAC 5.4.12; SM9020B | The data entry process does not include a verification step. | **Required:** Perform and document verification of data entry to minimize transcription errors. | Supervisory or peer review is now being performed for all data entry. Reviewer signs off on data reviewed. | 2/15/19 | Acceptable. Ensure verification of data entry is documented. |

| Finding # | Reference | Finding | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|
| 15. | SM 9020B | Laboratory water HPC and TOC checks are missing for the months of September 2017 and October 2017. | **Required:** Perform monthly laboratory water heterotrophic plate count and total organic carbon checks. Explain why checks are missing for the dates indicated. | During a transition of analysts in the department, the monthly checks for HPC and TOC were missed. As corrective action the lab now logs in the checks as a sample with the lab manager reviewing and approving each month. | Aug, 2018 | Acceptable |
| 16. | EPA 1603 section 9; Guidance Document page 5 and 6. | Laboratory is not performing verification of positive colonies. | **Required:** Perform verification procedures as outlined in the method for the audited analytes. | Typical and atypical colonies are now being verified monthly per method and contract procedures. | 2/12/2019 | Acceptable |
| 17. | EPA 1603 9.6.1.1 | The laboratory uses *P. aeruginosa* as a negative culture control. | **Required:** Use appropriate negative control organism, *E. faecalis*, for quality control analysis to ensure that the modified mTEC agar is performing properly. | The labs has switched to *E. faecalis* for the negative control culture. | 2/15/19 | Acceptable |
| 18. | EPA1603 9.6, 9.11, 11.0 | Lab analysts streak pure cultures on modified mTEC agar for media QC. | **Required:** Prepare and analyze media QC per the method. | Standards of known quantity will be used for QC samples and will be prepared per method requirements. | 2/15/19 | Acceptable |

| Finding # | Reference | Finding | Required or Recommended Corrective Action | Laboratory Response | Implementation Date | DEP Response |
|---|---|---|---|---|---|---|
| 19. | SM9020B | Media record DCN:MI-D203 instructs analysts to pour media into plates. | **Recommended:** Use an appropriate measuring device to accurately dispense media. | Sterile pipettes are now being used to dispense media. | 03/11/2019 | Acceptable |
| 20. | N/A | Analysts pour sample volumes greater than 10 ml but less than 50 ml. | **Recommended:** Use appropriate measuring devices to accurately dispense volumes less than 50 ml. | A class A graduated cylinder is used to measure sample volumes below 50mls and above 10mls. Pipettes are used for volume of 10mls and below. | 02/12/2019 | Acceptable |
| 21. | EPA 1603 section 6, 10 and 11; NELAC 2003 D.3.8 b) 6) and 5.5.5.2.1; | Incubator logs indicate temperatures are out of range several times throughout a monthly log, and corrective actions are not always indicated. Incubators: G4R, G4H, and G4I. | **Required:** Verify that all incubators are operating correctly and holding the appropriate temperature. Institute guidelines for when corrective actions should be taken and when/how to qualify samples when incubator is out of temperature range. | The failing incubators were replaced. Analysts were re-trained to rigorously follow rules for immediate QA notification of any incubator failure. Failure to notify will now result in disciplinary action. Failures are recorded on the temperature log and on Nonconformity Forms with root cause analysis and corrective action taken. For incubators where temperatures are out of range (after samples and incubator reach thermal equilibrium) the data will be qualified, and notification of the failure given to FDEP's immediate contact person. | August 2018 | Acceptable |

References

APHA-AWWA-WEF. Standard Methods for the Examination of Water and Wastewater, Part 9000, Microbiological Examination, Section 9020, Quality Assurance. Approved by Standard Methods Committee, 1997.

Florida Department of Environmental Protection (DEP). Request for Proposals Contractual Services, Microbiological Overflow Services, Solicitation Number 2017004C, Agency Release Date July 29th, 2016.

Florida Department of Environmental Protection (DEP). Guidance for Microbiological Data Reported to DEP (attached to purchase order), Version 060117.

National Environmental Laboratory Accreditation Conference (NELAC). 2003 NELAC Standard, EPA/600/R-04/003, Volume 1, Module 5, Quality Systems, Approved June 5th, 2003.

United States Environmental Protection Agency (EPA). EPA Publication EPA-821-R-14-010, September 2014, EPA Method 1603, *Escherichia coli* (E. coli) in Water by Membrane Filtration Using Modified Membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC).