UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4

Science and Ecosystem Support Division
980 College Station Road
Athens, Georgia 30605-2720

JUN 2 2016

Ms. Myra Reece
Director of Environmental Affairs
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Dear Ms. Reece:

The staff of the U.S. Environmental Protection Agency, Region 4, Quality Assurance Section (QAS) completed a drinking water assessment of the South Carolina Department of Health and Environmental Control (DHEC), Bureau of Environmental Health Services (BEHS), Low Country Region Area, Beaufort Environmental Microbiology Laboratory located in Burton, SC. The on-site assessment was performed on April 13-14, 2016 to assess the capability of the laboratory to analyze drinking water samples for maintaining Primacy under the Safe Drinking Water Act. Enclosed is the report from the assessment microbiology laboratory.

Based on the results of the assessment, the South Carolina Beaufort Environmental Microbiology Laboratory will maintain the status of ***Certified*** for the analysis of regulated drinking water microbiological contaminants. The laboratory may analyze samples for the regulated microbiological contaminants using the analyte/method combinations listed in Tables 1 of the assessment report. There were findings noted in the report that require corrective actions to maintain the laboratory's certified status. A corrective action plan for all findings must be developed by the South Carolina BEHS, Beaufort Environmental Microbiology Laboratory. When responding to a particular finding in the report, please reference the corresponding paragraph number. Once a corrective action plan has been developed and implemented to address the noted findings, the laboratory's status will remain as certified. These plans must be submitted to the QAS for review and approval within ninety days of receipt of this report. Failure to correct the findings listed in this report may result in a downgrade of the laboratory to a provisionally certified status for the microbiological contaminants. It should also be noted that the QAS staff may perform a follow-up evaluation to determine the effectiveness of the corrective actions.

The QAS would like to thank the staff for their professionalism and courteousness throughout the assessment. If there is any assistance the QAS can provide with the corrective action plans, please contact Viola Reynolds, Certification Officer, at (706) 355-8569.

Sincerely,

[redacted]

Antonio Quinones
Acting Director

Enclosures (1)

cc w/ encl: Renee Shealy, SC DHEC BEHS Chief
Jennifer Hughes, SC DHEC BEHS Assistant Chief
Russell Berry, SC DHEC BEHS Low Country Area Beaufort/Orangeburg Director
Penny Cornett, SC DHEC BEHS Low Country Area Beaufort Laboratory Manager
Becky Allenbach, EPA Reg. 4 WMD
Shawneille Campbell-Dunbar, EPA Reg. 4 WMD

Report of the On-Site Evaluation for Drinking Water Certification South Carolina DHEC Bureau of Environmental Health Services Low Country Region Area Beaufort/Orangeburg Beaufort Environmental Microbiology Laboratory

Submitted to:

Ms. Myra Reece
Director of Environmental Affairs
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

Submitted by:

Quality Assurance Section
U.S. Environmental Protection Agency
Region 4
Science and Ecosystem Support Division
980 College Station Road
Athens, Georgia 30605

1.0 INTRODUCTION

In accordance with National Primary Drinking Water Regulations, the U.S. Environmental Protection Agency, Region 4, Science and Ecosystem Support Division, Quality Assurance Section (QAS) performed an on-site evaluation of the South Carolina Department of Health and Environmental Control (DHEC), Bureau of Environmental Health Services, Beaufort Environmental Microbiology Laboratory located in Burton, SC for microbiological drinking water parameters.

Currently, SC DHEC has primary enforcement responsibility (Primacy) for public water systems based upon submissions made to 40 CFR §142.11, and submissions under 40 CFR §142.12. For maintaining primacy, a State must comply with 40 CFR §142.10, which include the following provisions:

> The establishment and maintenance of a State program for the certification of laboratories conducting analytical measurements of drinking water contaminants pursuant to the requirements of the State primary drinking water regulations including the designation by the State of a laboratory officer, or officers, certified by the Administrator, as the official(s) responsible for the State's certification program. The requirements of this paragraph may be waived by the Administrator for any State where all analytical measurements required by the State's primary drinking water regulations are conducted at laboratories operated by the State and certified by the Agency. (40 CFR §142.10(b)(3)(i)), (EPA 815-R-05-004);
>
> Assurance of the availability to the State of laboratory facilities certified by the Administrator and capable of performing analytical measurements of all contaminants specified in the State primary drinking water regulations ... (40 CFR §142.10(b)(4)), (EPA 815-R-05-004).

Therefore, the State is required by law to maintain certified resources for compliance testing of the regulated drinking water parameters as specified in the National Primary Drinking Water Program. South Carolina elects to maintain the capability of performing compliance testing of drinking water for chemistry and microbiological parameters, in addition to certifying other laboratories to provide support.

On April 13-14, 2016, the EPA assessment team performed an on-site evaluation of the SC DHEC Beaufort Environmental Microbiology Laboratory for microbiological drinking water parameters. The on-site evaluation consisted of discussions with laboratory staff and analysts, an inspection of the facilities and equipment, record reviews, a review of operating procedures and a review of quality assurance activities. Assessors representing the EPA during the on-site evaluation were:

Ms. Viola Reynolds, Microbiology Certification Officer
Ms. Sandra Aker, Chemistry Certification Officer

The on-site evaluation began with an opening conference on April 13, 2016, that included a round of introductions of the auditors and representative staff from the SC DHEC Beaufort Environmental Microbiology Laboratory. An explanation of the goals and objectives of the evaluation was made by EPA staff. On April 14, 2016, a post assessment conference was held between the EPA auditors and representative staff of the SC DHEC Beaufort Environmental Microbiology Laboratory. The purpose of the post assessment conference was for the auditors to summarize the general findings from the on-site evaluation, discuss the schedule for the findings report and answer questions. This report presents the findings and recommendations from the on-site evaluation of the SC DHEC Beaufort Environmental Microbiology Laboratory that will need to be addressed for the continuance of certification.

The key managerial staff from the SC DHEC, Bureau of Environmental Health Services, Beaufort Laboratory participating in the assessment opening/closing conference included:

Ms. Penny Cornett – SC DHEC BEHS Beaufort Microbiology Laboratory Supervisor
Mr. Russell Berry – SC DHEC BEHS Low Country Area Beaufort/Orangeburg Director

2.0 GENERAL LABORATORY DISCUSSION AND OBSERVATIONS

The SC DHEC Beaufort Environmental Microbiology Laboratory was housed in adequate facilities with ample workspace. Laboratory instrumentation appeared to be in excellent operating condition. All analytical instrumentation necessary for performing certified drinking water analyses were available for inspection. The techniques and methods used were appropriate and consistent with the drinking water requirements. Sample information was observed in the LIMS system which was used by the staff for entering, storing, and retrieving sample information and analytical data.

Upon further examination, it was noted that the SC DHEC Beaufort Environmental Microbiology Laboratory was inadequately staffed. Currently, Ms. Cornett, the Environmental Microbiology Laboratory Supervisor, serves as the primary analyst for the lab. A vacancy announcement has been posted for the primary analyst position.

3.0 FINDINGS AND CORRECTIVE ACTIONS

Findings for USEPA Region 4 State Safe Drinking Water Act (SDWA) laboratory assessments are defined as factual, objective statements which provide evidence of non-conformance with any of the following and which may adversely affect the quality of the data. Findings are supported with the citations to applicable regulations and/or examples of the data from actual case files including but not limited to the following:

- The Agency's mandatory methods for supporting the SDWA program.
- Official Agency mandates and policies i.e. title 40 of the Code of Federal Regulations (40 CFR) Part 141, 40 CFR holding times, Part 136.3, and requirements from the Certification Manual, combined with Supplement 1 to the Certification Manual, EPA 815-F08-006.
- The laboratory's QA/QC manual, QA/QC procedures, standard operating procedures (SOPs) and documented practices.

Recommendations are those corrective measures that would enhance laboratory operations, but are not mandatory. However, the EPA strongly encourages implementation of the recommendations to better conform to standard laboratory practices currently employed within the environmental industry.

Except as noted below, the equipment, procedures and personnel used by the SC DHEC Beaufort Environmental Microbiology Laboratory conform to the provisions contained in the current 40 CFR, §§136, 141 and 142; and the Drinking Water Certification Manual. The following discussions present the findings, corrective actions and recommendations based on the on-site evaluation and review of the documents submitted by the laboratory.

FINDINGS

3.1 **Finding:** The SC DHEC Beaufort Environmental Microbiology Laboratory did not have a primary laboratory analyst. The current laboratory supervisor is functioning as analyst, QA Officer, Office Manager, and Engineer.

Corrective Action: The Laboratory Supervisor and QA Officer duties should be separate from the daily lab operations. Refer to Chapter 3, Section 10.3 of the Certification Manual.

3.2 **Finding:** No training records were kept on file to document the Initial Demonstration of Capability (IDC) or Continuing Demonstration of Capability (CDC) of the backup laboratory analyst, Nia Frazier.

Corrective Action: The laboratory supervisor has the responsibility to ensure that all laboratory personnel have demonstrated the ability to satisfactorily perform the analyses to which they are assigned. Analysts must demonstrate acceptable results on unknown samples before analyzing compliance samples. Refer to Chapter 5, Sections 1.1 and 1.2 of the Certification Manual.

3.3 **Finding:** Several samples lacked traceability documentation due to missing lot numbers of sample bottles in QC logbook. Auditors could not trace the quality control of sample bottles due to the missing lot numbers.

Corrective Action: Laboratory supervisor should be able to demonstrate that all data reported by the laboratory meets the required quality assurance and regulatory criteria. All compliance data maintained by the laboratory should be legally defensible by being complete and accurate. Refer to Chapter 5, Sections 1.1 and 8.1 of the Certification Manual.

3.4 **Finding:** Several thermometer bulbs located in the incubator and refrigerator were not completely immersed in liquid.

Corrective Action: Thermometer bulbs should be immersed in liquid as directed by the manufacturer. Refer to Chapter 5, Sections 3.4.1 and 3.9.1 of the Certification Manual.

Note: The finding was corrected during the audit.

3.5 **Finding:** The laboratory had no results for the annual Silica test, therefore the lab could not verify the use of satisfactorily tested reagent water.

Corrective Action: Reagent grade water from deionization units used to prepare media and dilution/rinse water should be tested annually either by the Bacteriological Quality of Reagent Water Test or the Silica Test. Refer to Chapter 5, Sections 4.3.1 and 4.3.2 of the Certification Manual.

Note: The finding has been corrected since the audit.

3.6 **Finding:** The glassware inhibitory residue test was last performed in February, 2013 on the Contrex detergent, however results were not passing.

Corrective Action: The glassware inhibitory residue test should be performed before the initial use of a washing compound and whenever a different formulation or washing procedure is used. Refer to Chapter 5, Section 4.5.3 of the Certification Manual.
Note: The finding has been corrected since the audit.

3.7 **Finding:** Chemistry, SM 4500-Cl G. The SC DHEC uses the Hach pocket colorimeter meter for both lab and field analyses for total residual chlorine. If the field results are being reported for public water system's residual disinfectant concentrations, the SOP should include the required method QC. Section 14.7.10 of the field SOP for total residual chlorine does not include a calibration verification standard (CVS) at the end of the run and the analysis of a quality control sample (QCS).

Corrective Action: Per the Manual for the Certification of Laboratories Analyzing Drinking Water Manual, Chapter IV, Sect. 5.2 (Analyses approved by the state), the SC DHEC should update the field SOP to include the following QC requirements to assure the validity of data for these measurements:

1) CVS: Analyze a CVS at the end of the run, and vary the concentration of the CVS over the range of the sample values as noted in Sect. 8.3 of the SC DHEC lab SOP for SM 4500-Cl- G. SM 4020 2.b (2011) gives the acceptance range of the CVS of +/- 10 %, and states to verify calibration by periodically analyzing a calibration standard during a run – typically, after each batch of ten samples and at the end of the run.

2) QCS: A QCS should be analyzed at least annually and each time a new ICV is done. See SM 4020 2.C and also Sect. 8.5 of the SC DHEC SOP for total residual chlorine by SM 4500-Cl-G (QCS sample).

3.8 **Finding:** Chemistry, SM 4500-Cl G. The QCS for total residual chlorine analyzed on 09/22/2015 as part of the IDC for a new analyst was recovered outside of the +/- 10% method defined acceptance limits. The analyst was using the provider's acceptance criteria.

Corrective Action: The QCS analyzed as an IDC sample should be from an external source. The results of the QCS samples must be within +/-10 % of the vendors certified value to meet method requirements. See Sect. 8.5 of the SC DHEC SOP for total residual chlorine by SM 4500-Cl- G.

3.9 **Finding:** Chemistry, SM 4500-Cl G. The analyst diluted samples above 2.2 mg/L for total residual chlorine as required by the method. However, dilutions were not calculated and reported properly. See sample #A07018 (50/50 dilution) analyzed on 05/19/2015; reported as 1.22 mg/L.

Corrective Action: The recorded result should include the dilution factor (result x 2, in this case) per Sect. 14.7.7 of the residual chlorine field SOP.

RECOMMENDATIONS

3.10 **Recommendation:** The name of laboratory should be added to all laboratory logbooks for proper identification. **Note:** This action was performed at the time of the audit.

3.11 **Recommendation:** The laboratory should add the time, date, initials and the name of the person spoken to, when documenting public notification of positive and invalid samples.

3.12 **Recommendation:** The laboratory should take the actual pH reading of any commercial reagent or media if the manufacturer's certificates of analysis (COA) lists a range instead of a specific pH for that lot number.

3.13 **Recommendation:** When analyzing annual Proficiency Testing (PT) samples, the laboratory should alternate between Colilert and Colilert-18 samples since the laboratory is certified for both. Also, the lab should document the analyst's name and reagent used on the PT result form.

3.14 **Recommendation:** The laboratory should modify the autoclave sterilization record log sheet to include the name/brand of spore ampules used as the bioindicator.

3.15 **Recommendation:** The laboratory should store sterile water for no longer than three months, instead of one year as listed in SOP.

3.16 **Recommendation:** During annual calibration of thermometers, it is recommended to check several degree increments instead of just one (i.e. at, below and above the temperature at which the thermometer will be used) to obtain a more accurate correction factor.

3.17 **Recommendation:** The total residual chlorine calibration check standards log book could be expanded to include the full range of calibration standards. The 0.05 mg/L and 2.0 mg/L standards are written in each time.

COMMENDATION

3.18 **Commendation:** Ms. Cornett currently documents the pre-warming incubation times for Colilert-18 samples. She also records the actual temperature read when performing final analysis results.

4.0 PERFORMANCE EVALUATION STUDIES

The SC DHEC Beaufort Environmental Microbiology Laboratory reported acceptable results for the total coliforms and E. coli Proficiency Testing (PT) samples analyzed in FY 2015. A 100 percent rating for acceptable data was achieved for the methods in this study.

Table 1 presents the microbiological parameters and methods that were evaluated according to the *Manual for Certification of Laboratories Analyzing Drinking Water*, Fifth Edition, January 2005.

Table 1
Summary of Microbiological Parameters, Methods, and Certification Status
(Based on Annual Proficiency Testing and Current On-Site Audit Inspection)

Parameter	Drinking Water Method	Certification Status
Total Coliforms	SM9223B: Enzyme Substrate Test Colilert, Colilert-18, Colisure	Certified
Escherichia coli	SM9223B: Enzyme Substrate Test Colilert, Colilert-18, Colisure	Certified
Heterotrophic Bacteria	SM9215B: Pour Plate Method	Certified
Heterotrophic Bacteria	SimPlate	Certified

5.0 MICROBIOLOGY CONCLUSIONS

Based on the on-site evaluation and the presence of an acceptable Quality System, the South Carolina Department of Health and Environmental Control, Bureau of Environmental Health Services, Beaufort Environmental Microbiology Laboratory will remain ***Certified*** for the analysis of the regulated microbiological drinking water contaminants listed above in Table 1.

As outlined in this report there were findings and corrective actions for the SC DHEC Beaufort Environmental Microbiology Laboratory to implement for compliance with the published drinking water methods. Drinking water methods are prescriptive, and the laboratory must follow the methods in their entirety to maintain certification. In addition, this report provides recommendations. Recommendations are those corrective measures that would enhance laboratory operations, but are not mandatory. The EPA encourages implementation of the recommendations to better conform to standard laboratory practices currently employed within the environmental industry.

A corrective action plan for all findings must be developed by the SC DHEC, Bureau of Environmental Health Services, Beaufort Environmental Microbiology Laboratory. Failure to complete a corrective action plan to the findings in this report may downgrade this laboratory to a "Not Certified" status. A corrective action plan should be received by this office within ninety (90) days of receipt of this letter.

[redacted]

Viola Reynolds, Microbiology SDWA Certification Officer

[redacted]

Sandra Aker, Chemistry SDWA Certification Officer

6.0 REFERENCES

Manual for the Certification of Laboratories Analyzing Drinking Water, EPA-815-R-05-004, January 2005.

Title 40 of the Code of Federal Regulations (40 CFR) Part 136.

Title 40 of the Code of Federal Regulations (40 CFR) Part 141.

Title 40 of the Code of Federal Regulations (40 CFR) Part 142.

Standard Methods for the Examination of Water and Wastewater.