UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4

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

NOV 10 2015

Ms. Elizabeth Dieck
Director of Environmental Quality Control
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Dear Ms. Dieck:

The staff of the U.S. Environmental Protection Agency, Region 4, Office of Quality Assurance (OQA) completed a drinking water assessment of the South Carolina Department of Health and Environmental Control (DHEC), Bureau of Environmental Health Services (BEHS), Analytical and Radiological Environmental Services Division (ARESD) located at the Environmental Quality Control (EQC) Laboratory in Columbia, South Carolina. The on-site assessment was performed on August 25-28, 2015 to assess the capability of the laboratory to analyze drinking water samples for maintaining Primacy under the Safe Drinking Water Act. The OQA also reviewed the South Carolina, DHEC, BEHS, Office of Environmental Laboratory Certification, which provides certification of laboratories for microbiological and chemical testing of drinking water. Enclosed is the report from the assessment of the chemistry and microbiology laboratories and the certification program.

Based on the results of the assessment, the South Carolina ARESD at the EQC Laboratory will maintain the status of ***Certified*** for the analysis of regulated drinking water organic, inorganic and microbiological contaminants. The laboratory may analyze samples for the regulated chemical and microbiological contaminants using the analyte/method combinations listed in Tables 2 and 3 of the assessment report. There were a few 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 ARESD. 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 OQA 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 chemical and microbiological contaminants. It should also be noted that the OQA staff may perform a follow-up evaluation to determine the effectiveness of the corrective actions.

Based on the administrative review of the South Carolina, DHEC, BEHS, Drinking Water Certification Program, it was determined to be ***Effective*** in certifying laboratories for drinking water analysis.

The OQA would like to thank the staff for their professionalism and courteousness throughout the assessment. If there is any assistance the OQA can provide with the corrective action plans, please contact Ray Terhune, Acting OQA Chief, at (706) 355-8557.

Sincerely,

[redacted]

Michael V. Peyton
Director

Enclosures (1)

cc w/ encl: Renee Shealy, SC DHEC BEHS Chief
Sandra Flemming, SC DHEC BEHS Assistant Chief
Micheal Mattocks, SC DHEC BEHS ARESD Chief
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 Department of Health and Environmental Control, Bureau of Environmental Health Services, Analytical and Radiological Environmental Services Division and Office of Environmental Laboratory Certification

Submitted to:

Ms. Elizabeth Dieck
Director of Environmental Affairs
Environmental Quality Control
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

Submitted by:

U.S. Environmental Protection Agency, Region 4
Science and Ecosystem Support Division
Office of Quality Assurance
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, Office of Quality Assurance (OQA) performed an on-site evaluation of chemistry and microbiology drinking water parameters at the South Carolina Department of Health and Environmental Control (DHEC), Bureau of Environmental Health Services (BEHS), Analytical and Radiological Environmental Services Division (ARESD) located at the Environmental Quality Control (EQC) Laboratory in Columbia, South Carolina. The EPA Region 4 also performed an evaluation of the South Carolina DHEC, BEHS, Office of Environmental Laboratory Certification, which provides certification of laboratories for microbiological and chemical testing of drinking water by application reviews, performance evaluations, and on-site inspections.

Currently, the 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. To maintain primacy, a State must comply with 40 CFR §142.10, which includes 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) and 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. The State elects to maintain the capability of performing compliance testing of drinking water for chemistry and microbiological parameters, in addition to certifying private laboratories to provide support. This report focuses on the on-site evaluation performed at the EQC laboratory in Columbia, SC for chemistry and microbiology drinking water parameters.

In response to an EPA request for pre-visit information, members of the laboratory provided a list of analytical methods to be assessed for primary drinking water contaminants. These methods are listed in Table 1.

Table 1 Summary of Drinking Water Methods For which Certification is Requested	
Regulated Substance Group	**Methods**
Metals	EPA 200.7, 200.8,200.9, SM 3112B
Volatile Organic Compounds	EPA 504.1, EPA 524.2
Semi-volatile Organic Compounds	EPA 508, EPA 515.3, EPA 525.2, EPA 531.1, EPA 547, EPA 548, EPA 549.2, EPA 550.1, EPA 551.1, EPA 552.2
Inorganic Chemistry	EPA 300.1, SM 4500 CN-E, QuikChem 10-107-04-1-C, QuikChem 10-109-12-2-A
Total Coliforms	SM 9223B: Enzyme Substrate Test, SM 9221D: P-A Broth
Escherichia coli	SM 9223B: Enzyme Substrate Test, SM 9221F: EC-MUG
Heterotrophic Bacteria	SM 9221E: SimPlate Method

SM- Standard Methods for the Examination of Water and Waste Water

During the period of August 25-28, 2015, the EPA Region 4 performed an on-site evaluation for drinking water primary contaminants. The on-site evaluation consisted of discussions with laboratory staff/analysts, an inspection of the facilities and equipment, record reviews, a review of operating procedures and a review of quality assurance activities. Assessors representing EPA during the on-site evaluation included:

Ms. Jeannie Williamson, Acting OQA Section Chief
Mr. Ray Terhune, Chemist
Dr. John Thomason, Chemist
Ms. Viola Reynolds, Microbiologist

The on-site evaluation began with an opening conference on August 25 that included a round of introductions of the auditors and representative staff from the SC DHEC. An explanation of the goals and objectives of the evaluation was made by EPA staff. On August 28, an exit conference was held between the EPA auditors and representative staff of the SC DHEC. The purpose of the exit 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 laboratory that will need to be addressed for the continuance of certification.

The key managerial staff from the laboratory and laboratory certification program participating in the assessment opening were:

Ms. Sandra Flemming - SC DHEC BEHS Assistant Chief
Mr. Micheal Mattocks - SC DHEC BEHS ARESD Director
Ms. Carol Smith - SC DHEC BEHS Office of Environmental Laboratory Certification Director
Mr. Roger Brewer - SC DHEC BEHS ARESD Inorganic Chemistry Manager
Mr. David Dale - SC DHEC BEHS ARESD Organic Chemistry Manager
Ms. Karen Suber - SC DHEC BEHS ARESD Environmental Microbiology Team Leader

2.0 LABORATORY GENERAL OBSERVATIONS AND DEFINITIONS- CHEMISTRY

2.1 OBSERVATIONS

The laboratory was staffed with qualified analysts and supervisory personnel. The laboratory was housed in excellent facilities with adequate workspace. The laboratory had ample equipment to perform day-to-day operations. Laboratory instrumentation appeared to be in excellent operating condition. All analytical instrumentation necessary for performing certified drinking water analyses were available for inspection. The laboratory-wide water purification system for providing ASTM Type I water to each of the laboratories was functioning properly at the time of the laboratory evaluation. It was observed that Standard Operating Procedures (SOPs) were kept current and up-to-date with approved drinking water methods. Except where noted below under findings, laboratory analysts were following the revised and updated SOPs.

2.2 DEFINITIONS

Findings, for the EPA Region 4 States 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 Part 136.3 holding times, 40 CFR Parts 142.10-142.19 primacy enforcement requirements and requirements from the Manual for the Certification of Laboratories Analyzing Drinking Water, EPA-815-R-05-004, January 2005 (Certification Manual).
- The laboratory's QA/QC manual, QA/QC procedures, SOPs and documented practices.

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

2.3 FINDINGS, CORRECTIVE ACTIONS AND RECOMMENDATIONS - CHEMISTRY

Except as noted below, the equipment, procedures and personnel used by the laboratory conforms 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.

3.0 GENERAL LABORATORY QUALITY, TRAINING AND DOCUMENTATION

3.1 **Recommendation:** Due to the varying timeframes used for the certification of equipment such as thermometers, pipettes, balances and autoclaves, it is recommended that the certification expiration date be recorded on the equipment.

3.2 **Recommendation:** The laboratory should consider entering PT samples and other QC samples such as MDL samples into the LIMS. This will create consistency across the laboratory with sample login and QC data management.

3.3 **Recommendation:** The laboratory should consider purchasing disposable sample containers for VOA, SVOA and pesticide analyses. There is possible risk of contamination when reusing sample containers. However, if this is not economically feasible, the laboratory should designate groups of bottles cleaned together with a unique lot number and analyze one bottle to demonstrate lack of contamination.

4.0 SAMPLE RECEIVING, REPORTING AND STORAGE

4.1 **Finding:** The ID of the certified thermometer used in the sample receipt area was not documented in the receipt log book.

Corrective Action: In accordance with Chapter IV, Sect. 8.1 of the Certification Manual, compliance monitoring data should be made defensible by keeping thorough and accurate records. Begin recording the unique identifier of the thermometer on sample receipt forms so that a link can be made to the thermometer calibration.

4.2 **Recommendation:** The laboratory indicated that samples were dropped off at a loading dock. It is recommended that samples be secured in a locked area when they are dropped off.

5.0 ORGANIC CHEMISTRY

General Organic Chemistry

The findings described under the General Organic Chemistry category are those that span over multiple methods.

5.1 **Finding:** Residual Chlorine checks were not performed for organic analysis to verify that the preservative added to the sample was sufficient to neutralize any chlorine that may have been present

Corrective Action: The Drinking Water Certification Manual, Chapter IV, Section 6.3, requires that laboratories verify that samples' preservation was sufficient to neutralize residual chlorine. This should be performed for all associated methods, by a chlorine test strip, and documented in the sample preparation logbook or bench sheet.

Method Specific Organic Chemistry

The findings described under the method specific organic chemistry category are those that relate specifically to a particular method and each finding is referenced by a citation for requirements found in the method, Code of Federal Regulations, and/or Certification Manual.

EPA Method 515.3, Chlorinated Herbicides

5.2 **Finding:** The laboratory was raising the pH of the sample extract to greater than 12 as required in the method but this was not documented.

Corrective Action: All steps in a method or procedure must be documented during the process by the analyst which performs the step(s). See Chapter IV, Section 8.4 of the DW Cert Manual.

EPA Method 524.2, Volatile Organics

5.3 **Finding:** The laboratory was using a sample surrogate (4-BFB) which is also used to verify the tuning criteria for the Gas Chromatograph / Mass Spectrometer, to verify that the instrument was acceptable for further analysis.

Corrective Action: The method requires that the tune criteria check be performed with a blank standard which is spiked with the tune check criteria solution (4-BFB). A sample is inappropriate as there may be positive or negative interferences which would affect the results of the tune criteria verification. See Section 10.3.1 of EPA Method 524.2.

EPA Method 525.2 Semi-volatile Organics

5.4 **Finding:** The acceptable limits designated in the laboratory SOP for the Laboratory Fortified Blank (LFB) and Laboratory Fortified Matrix (LFM) were 37 – 68 % recovery and 32 – 74 % recovery respectively. These are outside of the acceptable limits required by the method (70 – 130 % recovery).

Corrective Action: The method requires that control charts be generated that establish an acceptable range for each analyte of interest. However, these limits cannot exceed the maximum allowable limits set in the method. See Chapter IV, Section 7.2.8 of the DW Cert Manual.

EPA Method 549.2, Diquat and Paraquat

5.5 **Finding:** The pH meter used to determine appropriate pH measurements during the sample preparation was calibrated before each use but this was not documented.

Corrective Action: All steps in a method or procedure must be documented during the process by the analyst which performs the step(s). See Chapter IV, Section 8.4 of the DW Cert Manual.

5.6 **Finding:** The laboratory was using different reagent concentrations than those specified in the method.

Corrective Action: The laboratory should begin using the reagent concentrations specified in EPA Method 531.1. The SOP should be updated to include the concentrations listed in the Method.

5.7 **Finding:** The laboratory was not analyzing the laboratory performance check sample as described in EPA Method 531.1, Sect. 9.8.

Corrective Action: The laboratory performance check sample analysis should be included in the analytical procedure for this method. The SOP should be updated to include the requirement.

EPA Method 551.1, Trihalomethanes (THMs)

5.8 **Finding:** Section 6.11 of the laboratory SOP describes the Laboratory Performance Check Solution (LPC). It notes that four compounds (not listed) are used to determine the performance of the instrument. However, the SOP has a photocopy of the LPC table that is in the method and it lists seven compounds that must be analyzed for various performance acceptance criteria before the analysis of samples can begin. Data packages verify that only four compounds, Lindane, Hexachlorocyclopentadiene, Bromodichloromethane and Trichloroethylene are checked. The remaining three, Bromacil, Alachlor and Endrin are not evaluated.

Corrective Action: The method requires that all seven compounds must pass various acceptance criteria for the instrument to be properly calibrated. See section 7.5 and table 7 of the method.

5.9 **Finding:** Sample extracts were stored in the same freezer as calibration standards.

Corrective Action: Chapter IV, Section 2 of the DW Lab Cert Manual requires that "The analytical and sample storage areas should be isolated from all potential sources of contamination." Sample extracts should be relocated to an area free of potential contamination.

5.10 **Recommendation:** The laboratory should consider purchasing disposable sample containers for VOA, SVOA and pesticide analyses. The risk of contamination is possible when reusing sample containers. However, if this is not economically feasible, the laboratory should designate groups of bottles cleaned together with a unique lot number and analyze one bottle to demonstrate lack of contamination.

6.0 METALS AND INORGANIC CHEMISTRY

General Inorganic Chemistry

The findings described under the general chemistry category span over multiple methods.

6.1 **Finding:** The metals and general chemistry analysts are capturing most of the information on preparation logs needed to trace standards back to the manufacturer and on run logs that allow for the reconstruction of the data. However, there were some gaps in documentation and traceability that prohibit the unambiguous reconstruction of data and analytical conditions. Examples include:

a. The preparation of the matrix spike was not documented for nearly all areas of inorganic chemistry. The spike ID, volume, and final volume needs to be documented.
b. Hot blocks and thermometers used for metals analysis did not have unique IDs for analyst to definitively determine calibration status.
c. For metals analysis by EPA Method 200.7, the working QCS prepared on 07/15/15 was made from High Purity standards, but AccuStandard was hardcoded (typed) into the preparation logbook. Auto-pipettes used for dilution did not contain a unique ID for analyst to definitively determine calibration status. The unique ID of ICP (B) was missing from analytical run logs.
d. For metals analysis by EPA Method 200.8, the preparation of working QC solutions was not documented.
e. For metals analysis by EPA Method 200.9, the balance ID was not documented for the preparation of palladium/magnesium nitrate matrix modifier. The exact weight shown on the balance was not recorded, only the nominal weight required, which was hardcoded (typed) into the preparation logbook.
f. For mercury analysis by SM 3112B, the preparation of reagents, QC standards, and the matrix spike was not documented. The balance ID was not documented in preparation logbooks. The addition of reagents for sample pretreatment was not documented for each sample batch. The heating of samples for 2 hrs at 90-95 °C was not documented for each sample batch. The certified thermometer ID used for monitoring temperature was not recorded.
g. For disinfection by product analysis by EPA Method 300.1, the preparation of the working Quality Control Solution (QCS) was not documented.
h. For cyanide analysis by SM 4500 CN E, the distillation logbook did not document the temperature and heating time.
i. For fluoride analysis by Lachat QuikChem 10-109-12-2-A, the balance ID was not documented on the preparation log, and only a nominal weight was being recorded, instead of all places on the balance.

Corrective Action: In accordance with Chapter IV, Sect. 8.1 of the Certification Manual, compliance monitoring data should be made defensible by keeping thorough and accurate records. Also, in accordance with Chapter IV, Sect. 8.5 of the Certification Manual, adequate information should be available to allow the auditor to reconstruct the final results for compliance samples and PT samples. A procedure should be developed to ensure that samples, reagents, calibration standards, and QC standards are unambiguously traceable from data system printouts, run logs, sample preparation logs, and standard preparation logs back to the original sample containers or chemical lot numbers. Sample preparation logs should document all measurements and required procedures performed in the utilized method such as interference checks, heating at a certain temperature, and weighing.

6.2 **Finding:** Residual Chlorine checks were not performed for inorganic analysis by EPA Method 200.7 and 200.8, and SM 3112B to verify that the preservative added to the sample was sufficient to neutralize any chlorine that may have been present

Corrective Action: The Drinking Water Certification Manual, Chapter IV, Section 6.4, requires that laboratories verify that sample preservation was sufficient to neutralize residual chlorine. This should be performed for all associated methods, by a chlorine test strip, and documented in the sample preparation logbook or bench sheet.

Method Specific Inorganic Chemistry

The findings described under the method specific inorganic chemistry category are those that relate specifically to a particular method and each finding is referenced by a citation for requirements found in the method, Code of Federal Regulations, and/or Certification Manual.

SM 3112B, Mercury

6.3 **Finding:** The laboratory not analyzing a minimum reporting level (MRL) check standard every time the instrument was calibrated.

Corrective Action: In accordance with Standard Methods 3020 B Sect. 2e governing method QC requirements, begin analyzing a QC standard at the minimum reporting level after every new calibration.

7.0 ARESD LABORATORY'S QUALITY ASSURANCE MANUAL FINDINGS

7.1 There were no findings associated with the laboratory's quality assurance manual during this audit period.

8.0 PERFORMANCE EVALUATION STUDIES - CHEMISTRY

The laboratory had acceptable performance on the FY 2015 Water Supply (WS) Proficiency Testing (PT) Study by scoring acceptable in 146 of 147 analyses, which represents overall acceptable results for 99.3 percent of the individual analysis. The one missed analyte was scored acceptable in a later PT study, raising the performance results to 100 percent.

9.0 CONCLUSIONS - CHEMISTRY

During the period of August 25-28, 2015 the EPA, Region 4, Office of Quality Assurance performed an on-site evaluation of the South Carolina, DHEC, BEHS, ARESD, EQC laboratory located in Columbia, SC for organic and inorganic chemistry drinking water parameters. The on-site evaluation consisted of discussions with laboratory staff/analysts, an inspection of the facilities and equipment, a records review, a review of operating procedures and quality assurance activities and a review of the PT results. As outlined in this report there were findings and corrective actions for the 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.

Based on the on-site laboratory evaluation and the presence of an acceptable Quality System, which includes an acceptable Quality Assurance Plan, the laboratory will maintain the status of ***Certified*** for inorganic and organic methods, and may analyze drinking water samples by the methods listed in Table 2 for SDWA compliance purposes.

For the Findings presented in this report, the laboratory must submit a corrective action plan to this office within ninety days of receipt of this report. If the laboratory fails to complete all of the corrective

actions, the EPA may elect to downgrade the laboratory to a "Provisionally Certified" status. In addition, the EPA, Region 4 may perform a follow-up evaluation of the laboratory to determine the effectiveness of the corrective actions for maintaining certification.

[redacted]

Ray Terhune, Acting Section Chief, Office of Quality Assurance

[redacted]

John Thomason, Ph D, SDWA Certification Officer

[redacted]

Jeannie Williamson, Analytical Services Branch, QA Officer

Table 2 Laboratory Certification Status (Based on Annual Proficiency Testing and Current On-Site Audit Inspection)	
DW Method	**Certification Status**
EPA 504.1 EDB/EDCP	Certified
EPA 508A PCBs as DCB (by contract)	Certified
EPA 508 PCB Aroclor Screen, Toxaphene	Certified
EPA 515.3 Herbicides (2,4-D, 2,4,5-TP (silvex), dalapon, dinoseb, pentachlorophenol, picloram).	Certified
EPA 524.2 Volatile Organics	Certified
EPA 525.2 Adipate/Phthalates and Pesticides (alachlor, atrazine, chlordane, endrin, heptachlor, heptachlor epoxide, hexachlorobenzene, hexachlorocyclopentadiene, lindane, methoxychlor, simzine).	Certified
EPA 531.1 Carbamates (aldicarb sulfone, aldicarb sulfoxide, carbofuran, oxamyl).	Certified
EPA 547 Glyphosate	Certified
EPA 548.1 Endothall	Certified
EPA 549.2 Diquat/Paraquat	Certified
EPA 550.1 Benzo(a)pyrene	Certified
EPA 551.1 THMs	Certified
EPA 552.2 HAAs	Certified
EPA 200.7 Ba, Be, Ca, Cu, Cr,	Certified
EPA 200.8 As, Ba, Be, Cd, Cr, Cu, Pb, Sb, Se, Tl	Certified
EPA 200.9 As, Cd, Pb, Sb, Se, Tl	Certified
SM 3112 B Mercury	Certified
EPA 300.1 Bromate, Chlorite	Certified
SM 4500 CN E Cyanide	Certified
Lachat QuikChem 10-107-04-1-C Nitrate/Nitrite, Nitrite as N	Certified
Lachet QuikChem 10-109-12-2-A Fluoride	Certified

10.0 LABORATORY GENERAL OBSERVATIONS AND DEFINITIONS-MICROBIOLOGY

10.1 OBSERVATIONS

An on-site evaluation of the South Carolina, DHEC, BEHS, ARESD, Environmental Microbiology Laboratory - Central Laboratory in Columbia, SC was conducted on August 25-26, 2015, by Viola Reynolds of the US EPA Region 4 Science and Ecosystem Support Division, Office of Quality Assurance, located in Athens, Georgia. The laboratory was spacious and had equipment in good operating condition. The supervisor and analyst were extremely knowledgeable and qualified.

This on-site evaluation was conducted as part of the requirement for continuing certification of the State of South Carolina under the Safe Drinking Water Act. It consisted of discussions with laboratory staff, inspections of the facility and equipment, a review of Standard Operating Procedures (SOPs), and a review of the laboratory's quality system. The purpose was to assess compliance with individual drinking water analytical methods and EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition, January 2005.

10.2 DEFINITIONS

Findings, for the EPA Region 4 States 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 Part 136.3 holding times, 40 CFR Parts 142.10-142.19 primacy enforcement requirements and requirements from the Manual for the Certification of Laboratories Analyzing Drinking Water, EPA-815-R-05-004, January 2005 (Certification Manual).
- The laboratory's QA/QC manual, QA/QC procedures, SOPs and documented practices.

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

10.3 FINDINGS, CORRECTIVE ACTIONS AND RECOMMENDATIONS–MICROBIOLOGY

Except as noted below, the equipment, procedures and personnel used by the laboratory conforms 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.

11.0 FINDINGS AND RECOMMENDATIONS – MICROBIOLOGY

11.1 Finding: There was no record of contents or analyst's initials each time the autoclave was used.

Corrective Action: The following information should be recorded each time the autoclave is used: date, contents, sterilization time and temperature, total time in the autoclave, and analyst's initials. Refer to Chapter 5, Section 3.5.3 of the Certification Manual.

11.2 Finding: All drinking water samples were not shaken 25 times before analysis.

Corrective Action: All water samples should be shaken vigorously at least 25 times before analyzing. The laboratory should add this procedure to their SOP. Refer to Chapter 5, Section 5.1.3 of the Certification Manual.

11.3 Finding: The instrument services laboratory had questionable readings when using the UV light meter. There were no standard procedures on how to accurately take readings each time, therefore the laboratory needs to create a SOP for the UV light meter.

Corrective Action: The laboratory should have a Standard Operating Procedure available, pertaining to its own calibration of equipment or supplies. Refer to Chapter 5, Section 7.1 of the Certification Manual.

11.4 Finding: During the review of the pre-audit data packages, it was noted for:

- EM15-PT 6C – The wrong expiration date for SimPlate Multi-dose was recorded.
- EM15-PT 6F – The wrong 48 hour incubation date for SimPlate was recorded.

Corrective Action: The laboratory should peer review data to ensure that all data reported by the laboratory meets the required quality assurance and regulatory criteria. Refer to Chapter 5, Section 1.1 of the Certification Manual.

Note: This finding was corrected at the time of the audit.

11.5 Recommendation: The laboratory should start recording/documenting the pre-warming incubation times for Colilert-18 samples.

11.6 Recommendation: The laboratory should follow the manufacturer's recommendation concerning the subculture of commercial stock cultures.

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

11.8 Recommendation: When analyzing annual Proficiency Testing (PT) samples, EPA auditors recommend occasionally alternating between Colilert and Colilert-18 samples since the laboratory is certified for both.

11.9 Recommendation: The laboratory should modify the Calibration of Thermometers SOP to include:

a. Allowing time for equilibration before comparing the NIST thermometer to the laboratory thermometer.
b. Checking several degree increments instead of just one (i.e. at, below and above the temperature at which the thermometer will be used) when verifying thermometers to obtain a more accurate correction factor.

11.10 Commendation: The Microbiology Laboratory performed more QC than what was required in several different areas, such as calibrating the balance quarterly instead of annually, calibrating the NIST reference thermometer annually instead of every five years, and spore ampules used weekly instead of monthly to confirm the sterilization of the autoclave.

12.0 PERFORMANCE EVALUATION STUDIES – MICROBIOLOGY

The South Carolina Environmental Microbiology Laboratory – Central Laboratory in Columbia, SC, 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.

13.0 CONCLUSIONS – MICROBIOLOGY

Based on the on-site evaluation and the presence of an acceptable Quality System, which includes an acceptable Quality Assurance Plan, the South Carolina, DHEC, BEHS, ARESD, Environmental Microbiology Laboratory - Central Laboratory will maintain the status of ***Certified*** for the analysis of the regulated microbiological contaminants listed in table 3 and may analyze drinking water samples by the methods listed for compliance purposes.

Tabie 3
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, and Colisure	Certified
Total Coliforms	SM 9221D: P-A Broth >> BGLBB	Certified
Escherichia coli	SM9223B: Enzyme Substrate Test Colilert, Colilert-18, and Colisure	Certified
Escherichia coli	SM9221F: EC-MUG	Certified
Heterotrophic Bacteria	SM9215B: SimPlate Method	Certified

As outlined in this report there were findings and corrective actions for the 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.

Failure to complete a corrective action plan to the findings in this report may downgrade this laboratory to a provisionally certified status. A corrective action plan should be received by this office within ninety days of receipt of this report. In addition, the EPA, Region 4 may perform a follow-up evaluation of the laboratory to determine the effectiveness of the corrective actions for maintaining certification.

[redacted]

Viola Reynolds, Microbiology SDWA Certification Officer

14.0 EVALUATION OF THE SOUTH CAROLINA DRINKING WATER LABORATORY CERTIFICATION PROGRAM

INTRODUCTION

In accordance with the National Primary Drinking Water Regulation 40CFR § 142.17, the U.S. Environmental Protection Agency, Region 4 (EPA) performed an administrative review of the SC DHEC, Office of Environmental Laboratory Certification's, Drinking Water Laboratory Certification Program. The administrative review was conducted at the Environmental Laboratory Certification office located in Columbia, South Carolina on August 27, 2015. The purpose of this review was to assess the adequacy of the Drinking Water Laboratory Certification Program with respect to scope, staffing, policy, procedures and effectiveness. Representing the EPA during the assessment included:

Ms. Jeannie Williamson, Acting Office of Quality Assurance Section Chief
Mr. Ray Terhune, Chemist
Ms. Viola Reynolds, Microbiologist
Dr. John Thomason, Chemist

The administrative review began with an opening conference that included a round of introductions of the auditors and Office of Environmental Laboratory Certification staff. An explanation of the goals and objectives of the evaluation was made. On the same day, a post assessment conference was held for the auditors to summarize any findings from the administrative review, discuss the schedule for the findings report, and to answer questions. This section of the report summarizes the administrative review of the Certification Program of the Office of Environmental Laboratory Certification. The staff from the Office of Environmental Laboratory Certification participating in the opening and closing conferences included:

Ms. Carol Smith, Office of Environmental Laboratory Certification Director
Mr. Alfred Baquiran, Laboratory Certification Officer
Mr. Jamie Berry, Laboratory Certification Officer
Ms. Nydia Burdick, Laboratory Certification Officer
Ms. Susan Butts, Laboratory Certification Officer
Mr. Bennie Cockerel, Laboratory Certification Officer
Mr. Paul Miller, Laboratory Certification Officer

OBSERVATIONS

14.1 SCOPE

The SC DHEC, Office of Environmental Laboratory Certification, Laboratory Certification Program applies to all analytical laboratories performing compliance monitoring of regulated chemical and microbiological analytes for public water supply systems meeting the requirement as defined in 40 CFR §§ 141 and 142. All analyses of water supply systems' monitoring samples are performed by the SC DHEC, Office of Environmental Laboratory Certification certified laboratories or the State principal drinking water laboratory.

14.2 POLICY

South Carolina Regulation 61-81 gives the Office of Environmental Laboratory Certification authority to issue certification to laboratories analyzing regulatory compliance samples for reporting to the S. C. Department of Health and Environmental Control. This Regulation implements Code Section 44-55-10 et seq., known as the South Carolina Safe Drinking Water Act; Code Section 48-1-10 et seq., known as the South Carolina Pollution Control Act; and Act #436 of 1978, known as the South Carolina Hazardous Waste Management Act. The purpose of the regulation is to provide the mechanism to assure the validity and quality of the data being generated, for compliance with State regulations.

14.3 PROCEDURES

The certification procedures for SC's certification program are outlined in South Carolina Regulation 61-81, to include: the authority, scope, purpose, parameters requiring certification, certification criteria, certification, loss of certification, appeals, reciprocity, and more. In summary, the certification procedures include application to the certifying authority, on-site laboratory inspections, and participation in Proficiency Test Studies. Successful completion of Proficiency Test (PT) samples for each parameter is required by the State Program prior to an on-site laboratory inspection. Certification may be issued after an on-site inspection if analytical capability and proficiency have been established. All certified laboratories must participate in PT Studies at least once per year and must successfully analyze one PT sample for each certified parameter on an annual basis to retain certification. Certified laboratories must use EPA approved methods for each analyte. Laboratory on-site evaluations are performed on a three-year cycle.

The Office of Environmental Laboratory Certification uses a database for tracking all aspects of laboratory certification from application to issuance of certification. The database also includes functions for storing electronic correspondences and for tracking certification expiration dates. This is a great system for providing up to date information regarding all aspects of certification. The Office of Environmental Laboratory Certification should be commended for instituting and maintaining such an effective tracking system.

Table 4
Summary of Tennessee Certified Drinking Water Laboratories

Laboratory Type	In-State by On-Site Inspection	Out-of-State by On-Site Inspection	Total Number of Certified Laboratories
Chemistry	136	11	147
Microbiology	119	6	125
Cryptosporidium	0	0	0
Radiochemistry	1	4	5

14.4 FINDINGS and RECOMMENDATIONS – CERTIFICATION PROGRAM

The EPA Region 4 uses a Drinking Water Certification Program Assessment Checklist for evaluating a certification program's adherence to the Certification Manual. Based on the elements of the Office of Environmental Laboratory Certification's certification program that were evaluated, there were no findings noted during the administrative review of the SC DHEC, Office of Environmental Laboratory

Certification, Drinking Water Laboratory Certification Program. The Office of Environmental Laboratory Certification should be commended for this achievement. The EPA assessors had one recommendation to strengthen the Certification Program.

14.5 Recommendation: It is recommended that the Certification Program retain the auditors' checklists, which contain the original observations, and that they be available for review. This is noted in Chapter III, Sect. 15 of the Certification Manual.

14.6 EFFECTIVENESS

The EPA Region 4 Quality Assurance assessors reviewed approximately twelve (12) laboratory certification audit files for municipal, commercial, large and small laboratories. This included the review of corrective action reports, certification certificates, laboratory PT Studies, certification officers' personnel training files, and inspection reports to confirm the effectiveness of the program.

Based on the information gathered from the above information, the SC DHEC Office of Environmental Laboratory Certification Laboratory Certification Program is ***Effective*** in assuring that all laboratories submitting monitoring data for public water supplies meet the criteria established by the EPA in the Manual for the Certification of Laboratories Analyzing Drinking Water, or equivalent criteria. A response to the one recommendation provided in Sect. 14.5 of this report should be developed by the South Carolina Office of Laboratory Certification within ninety days of receipt of this report.

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Ray Terhune, Acting Section Chief, Office of Quality Assurance

[redacted]

John Thomason, Ph D, SDWA Certification Officer

[redacted]

Viola Reynolds, SDWA Certification Officer

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Jeannie Williamson, Analytical Services Branch, QA Officer

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15.0 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.