GUAM ENVIRONMENTAL PROTECTION AGENCY

LABORATORY CERTIFICATION PROGRAM

Prepared by: _____ 2/2/16
Rodolfo B. Paulino, Chemist II — Date

Peer Reviewed by: _____ 2/2/16
Edelisa S. Yanit, Chemist II — Date

Reviewed by: _____ 2/3/16
Jesse T. Cruz, EMAS Division Administrator — Date

Approved by: _____ 02/11/16
Eric M. Palacios, Administrator
Guam Environmental Protection Agency — Date

CONTENTS

1.0 Introduction

This program describes the process in which a drinking water laboratory is certified by the Guam Environmental Protection Agency (GEPA). The GEPA laboratory certification program was established in accordance with the provisions of 40 CFR 142.10 which states that the State in order to obtain and maintain primacy must establish and maintain a program for the certification of laboratories conducting analytical measurements of drinking water contaminants. The basis for the certification process is found in the US EPA Manual for the Certification of Laboratories Analyzing Drinking Water 5th edition (MCLADW).

As a reference, this program utilizes guidelines found in the MCLADW 5th edition and Environmental Laboratory Accreditation Programs (ELAP) or National ELAP (NELAP) used in the United States. In addition, assessing the quality systems of drinking water laboratories, this program also uses guidelines in the guidebook "Complying with ISO 17025-A practical guidebook".

At the Guam Environmental Protection Agency, the division that is tasked in enforcing this program is the Analytical Services section of the Environmental Monitoring and Analytical Services Division (EMAS).

2.0 GEPA Laboratory Certification Team Organization

2.1 Certification Authority (CA)

This is the person who has signature authority to grant certification upon the recommendation of the GEPA laboratory certification team. This is the Administrator of the Guam Environmental Protection Agency.

2.2 Certification Program Manager (CPM)

This is the person who reports to the CA and is the supervisor of the certification program that includes the Certification Officers. This is the EMAS Division Administrator.

2.3 Certification Officers (CO)

These are the persons who have undergone the certification training course given by the USEPA and are qualified by experience and training in conducting on-site audits and evaluation (actual or documentary) of a laboratory's performance. They make the reports and recommendations for certification. These are the Chemists within the Analytical Services Section of the EMAS Division.

3.0 Types of Certification

3.1 Certified

A laboratory that meets the regulatory performance criteria as described in this program and all other applicable regulatory requirements.

3.2 Provisionally Certified

A laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within the acceptable limits of the National Primary Drinking Water Regulations (NPDWR) shall be granted a provisional status. A provisionally certified laboratory may analyze drinking water for compliance purposes, if the clients are notified of its downgraded status in writing,

3.3 Not Certified

A laboratory that possesses deficiencies and cannot consistently produce valid data will not be certified.

3.4 Interim Certification

An interim certification may be granted initially in certain circumstances when an on-site audit could not be immediately scheduled or is not necessitated. The interim certification is only granted if the certifying authority through the certification team determines that the laboratory has documentary evidence that shows that it has the proper instrumentation, is using approved methods, and has trained personnel to carry out the analysis. It should also show that it can provide reliable data by the successful testing of proficiency test (PT) samples from an acceptable PT provider. In an interim certification, the CO should perform an on-site audit as soon as possible and not later than 18 months. An example of this certification would be for a laboratory that has requested certification of additional analytes or parameters not yet covered by a test method for which it already has certification in other parameters. The CO based on its previous documentation should review quality control data for the additional parameters before granting this type of certification.

4.0 Methods of Certification

4.1 On-site Laboratory Audit

An on-site audit is conducted upon request by the laboratory and involves the site visit by a team of GEPA certifying officers (CO). A check list is used to ensure that the laboratory meets regulatory requirements for certification based upon the criteria contained in the

MCLADW 5th edition. Any cost associated with conducting this audit will be the responsibility of the applicant.

4.2 Third Party Auditors

In certain instances where agency's certification team lacks expertise in a certain analyte or method (e.g., asbestos), third party auditors may be employed.

Third party auditors must be qualified by having successfully completed the appropriate EPA laboratory certification officer training course and have periodically audited the course at least every three years after their initially completion. They also must have the knowledge of the area being audited. Third party auditors must be accompanied by at least one of the agency's certification officers in an onsite visit.

Although third party auditors may be used to assist agency's certification officers, they may not make final certification decisions. These decisions rest with the Certification Authority (CA) upon recommendation by the agency's Certification Officer (CO).

4.3 Certification through Reciprocity

Through recognition of other state's certification programs, laboratories may be certified by reciprocity. Laboratories that are certified in the United States with NELAP or ELAP accrediting bodies may apply for certification through reciprocity. With the review of the laboratory's most current certification by the state, quality documents such as the Quality Manual, and acceptable PT results, the applying laboratory may be granted certification through reciprocity.

5.0 Certification Process

5.1 Letter of Request

The certification process begins when the laboratory manager or the head of a laboratory organization makes a formal request in writing. The request may include the following:

- A request for first time certification. The request must specify the type of certification process and parameters/methods to be certified.
- For laboratories previously certified, may also request additional parameters/methods to be certified.
- For laboratories that do not have full certification (i.e. provisional or interim) requests may include corrective actions and a request for granting of full certification in their letter.
- For laboratories whose certification have been revoked, a letter to reapply for certification after the corrections actions have been completed may be submitted.

5.2 Review of Documentation

Laboratory document review is mandatory for all laboratories seeking certification by Guam EPA, regardless of certification type, level or location, and is carried out by the COs. The types of documents to review are:

- Quality Assurance (QA) Manual and other QA documents such as SOPs, key laboratory personnel and qualifications
- Proficiency Testing (PT) results

The normal review time frame for documents is one to two weeks.

5.3 On-Site Audit

An on-site audit is required for laboratories requesting certification that fall within Guam's jurisdiction. These laboratories can either be located in the island of Guam, nearby islands or in foreign countries. These laboratories will incur all expenses, i.e. travel and accommodations, for any of the on-site audits conducted by Guam EPA.

On-site audits will include the following steps:

- Scheduling of on-site audit
- Preparation of Audit team (Certifying officers, or third party audit team)
- Actual on-site audit.
- Review with laboratory management of any findings and recommended corrective action. If possible an agreement is made as to the time frame of completing these corrective actions.

For on-site audits, the typical time frame is one to five days, depending on the number of methods and analytes the laboratory requested to be certified.

5.4 Grant/Denial of Certification

The grant or denial of certification depends on the result of the on-site audit and/or documentary review (for certification through reciprocity). This is accomplished by the following steps:

- The team of COs, determines through documentary review and/or onsite audit what type of certification is granted.
- A certification letter and audit/review report is drafted by the lead CO recommending the type of certification granted or denied. The results, findings, and recommended corrective actions are also included in the report.

- This letter and report is then reviewed by the CPM who will make any comment. The CPM will either return it back to the CO for revisions or submit to the CA for approval.
- The CA will approve or disapprove the letter and report. Should there be a disapproval, a reason would be included so the necessary revisions or actions are made.
- The CA will notify the laboratory regarding the certification or denial of certification.

5.5 Certification Period

The certification period for laboratories that have completed the on-site audit and have been awarded full certification is three years from the date when the certification was issued. To maintain certification status, laboratories must comply with the requirements listed in section 5.6 below.

Laboratories certified through reciprocity have a yearly expiration date from the date when the certification was issued. Renewal letters must be submitted 30 days before their expiration date.

Interim certifications must be resolved within the time frame specified in the interim certification letter but no longer than 18 months (please refer to section 3.4).

5.6 Maintaining Certification Status

To maintain certification, laboratories must submit proficiency testing (PT) results from nationally approved providers at least annually for chemical and microbiological parameters. In addition they must report to GEPA within 30 days any major changes in the organization, key personnel and Quality Manual in their laboratories.

5.7 Appeals

Managers of Drinking Water laboratories may appeal final certification actions within 30 days of receipt of the notification from the CA, Guam EPA Administrator. The appeal should be supported by an explanation of the reasons to challenge. It should be signed by a responsible official from the laboratory.

Upon receipt of the appeal, the CA with the certification team (CPM and COs) should determine whether the appeal is valid or not. Within 30 days of receipt of the appeal, the CA must inform the laboratory of its decision in writing.

If the appeal is accepted, the CA must take appropriate measures to re-evaluate the facility by the certifying team. After re-evaluation, the CA must inform the laboratory in writing of

the revised final certification actions. This must be accomplished within 30 days after the decision to accept appeal has been made.

If the appeal is not accepted, the CA must inform the laboratory of its final decision and the laboratory must complete the corrective actions stated in the audit/review report before certification can be reconsidered.

6.0 Requirements for Participation in GEPA's Laboratory Certification Program

6.1 Quality Assurance Manual

When an initial request for certification is submitted, it would facilitate the process if a Quality Assurance Manual or a similarly named document is submitted. A quality assurance manual is a document that identifies the laboratory's policies, organization, objectives, responsibilities, SOPs, and recordkeeping procedures. It is designed to give confidence to users of the laboratory's data by indicating specific methods or procedures by which the laboratory achieves its quality objectives. This is to ensure that routinely generated analytical data are scientifically valid and defensible, and are of known and acceptable precision and accuracy. For an example format see Appendix A.

6.2 Proficiency Testing

Proficiency Testing (PT) is the process by which a laboratory analyzes unknown samples from acceptable PT providers. A PT provider must be recognized by the American Association for Laboratory Accreditation (A2LA). A successful test is when the results of a particular analysis are within the established limits as determined by the PT provider's statistical study.

For initial and continuing certification one set of successful PT results per parameter must be submitted annually directly to Guam EPA.

6.3 Certification Evaluation

The final requirement for certification is an on-site assessment by certification officers. For a certification process not requiring an on-site visit such as certification through reciprocity see section 4.3 for details.

The criteria for certification is based on the guideline requirements found in the 5th edition of the Manual for the Certification of Laboratories Analyzing Drinking Water (MCLADW) by US EPA. To implement this, a checklist per promulgated method in the MCLADW (Chemistry or Microbiology) is used. These checklists are developed by the certifying team and is based on the MCLADW and Standard or EPA methods.

Findings are determined as non-compliances detected during the audit. This will be discussed with the laboratory management and corrective actions are agreed upon. Critical elements of certification must be met. This will determine the resulting certification of the laboratory.

For a satisfactory result to be granted during evaluations, the CA upon a recommendation by a team of COs and review by the CPM should be satisfied that a laboratory is maintaining the required standard of quality. However, if a laboratory does not meet critical elements for certification or does not have the capability to meet them, a denial for certification will be granted.

During the certification period, the CO should consider a re-evaluation before the certification period has expired if it was found that the laboratory has not maintained certification as required in section 5.6.

6.4 Critical Elements for Certification

6.4.1 Chemistry

Critical elements for chemistry certification are listed in the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water 5th edition. The elements are listed below:

- Qualified Personnel
- Proper Laboratory Facilities
- Appropriate Equipment and Instrumentation for the approved methods.
- Good Laboratory Practices
- Approved or Standard Analytical Methods
- Proper Sample Collection, Handling and Preservation
- Quality Assurance/Quality Control (QA/QC)
- Good Records and Data Reporting
- Prompt Action in Response to Non-Compliant Laboratory Result

6.4.2 Microbiology

Critical elements for microbiology certification are listed in the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water 5th edition. The elements are listed below:

- Qualified Personnel
- Proper Laboratory Facilities
- Appropriate Equipment and Supplies
- Good Laboratory Practices
- Approved or Standard Analytical Methodology

- Proper Sample Collection, Handling and Preservation
- Quality Assurance/Quality Control (QA/QC)
- Good Records and Data Reporting
- Prompt Action in Response to Non-Compliant Laboratory Result

6.5 Recommended Practices

To assist in the certification process the following may be used as a guideline for the successful certification by a requesting laboratory:

6.5.1 Personnel

Lab Director should have the following:

- Academic Training: Minimum Bachelor's degree in Chemistry or a biology science
- Experience: Minimum of two years' experience in an environmental lab.

Supervisors should have:

- At least a bachelor's degree with a major in Chemistry (or Microbiology, Radiochemistry as applicable for specialty labs) or equivalent
- At least one year of experience in the analysis of drinking water, and
- At least a working knowledge of quality assurance principles

Lab Analysts should have:

- At least a bachelor's degree in Chemistry or equivalent
- At least one year experience in the analysis of drinking water and
- Specialized training on applicable instrumentation or a year apprenticeship or use of such instrumentation.
- Additionally lab analysts must demonstrate acceptable results for blanks, precision, acceptable bias, and ability to meet method detection limits and satisfactory PT samples before assuming independent testing.

Lab Technicians should have:

- At least a High School diploma
- Complete a method training program under an experienced analyst, and
- Six months experience in the analysis of drinking water samples

Sampling Personnel

- Should be trained in proper sampling techniques and abilities checked by an experienced sampling or lab personnel.

6.5.2 Facilities

The GEPA recommends the following:

The facilities of a requesting laboratory should have the capability or is sufficient enough to allow the efficient generation of reliable, defensible, accurate data. Laboratory facilities should be clean, have temperature and humidity adequately controlled in instrument areas, and have adequate lighting at the bench top. The laboratory should have provisions for proper storage and disposal of chemical wastes. Exhaust hoods with a verified air flow of 75-125 cubic feet per minute should be available for preparation, extraction, and analysis where applicable.

For Chemistry determinations, a minimum of 150 square feet of lab space and at least 15 linear feet of usable bench space per analyst is recommended. Work bench should be convenient to sink, water gas, vacuum, and electrical sources. Electrical sources should be free of surges and unanticipated outages. Inorganic and organic facilities should be separate rooms. Facilities used for analysis of volatile organics should be at an overpressure relative to other lab areas. The analytical and sample storage area should be isolated from all potential sources of contamination. Standards requiring refrigeration (e.g. volatile organics should be stored separately from samples.

For Microbiology determinations, a minimum of 150 square feet of lab space and five linear feet of usable bench space per analyst is recommended. Lab facilities should include sufficient bench-top area for processing samples; storage space for media, glassware, and portable equipment; floor space for stationary equipment (e.g., incubators, water baths, refrigerators); and associated areas for cleaning glassware and sterilizing materials.
For further details, laboratories are also recommended to follow the USEPA Manual for the Certification of Laboratories Analyzing Drinking Water 5th edition.

6.6 Special Requirements of Certifying Team

Certification Officers (COs) must attend and pass the Laboratory Certification Course given by the USEPA. They must have a working proficiency for the laboratory methods that they assess for. This is provided by training workshops given by instrument providers, USEPA, or the American Chemical Society. It is also recommended that they also attend Quality Assurance workshops/conferences given by the USEPA certified trainers.

The Certification Program Manager (CPM) should also audit the Laboratory Certification Course given by the USEPA and have a working knowledge of the certification process which would be able to assist him/her in supervision of the certification team.

The Certification Authority (CA) must be able to act on the recommendation of the certification team.

6.7 Guidance for Users of Data from Certified Laboratories

GEPA laboratory certification program requires that certified laboratories include quality control tests in their normal sample analytical test runs. This assures users of such data that the analytical test conducted by such laboratories are within control limits and data is reliable and defensible in legal proceedings.

7.0 References

- Complying with ISO 17025, A practical guidebook for meeting laboratory accreditation schemes based on ISO 17025: 2005 or equivalent national standards, United Nations Industrial Development Organization.
- USEPA Manual for the Certification of Laboratories Analyzing Drinking Water 5th edition.
- Washington State Dept. of Ecology, Procedural Manual for the Environmental Laboratory Accreditation Program, Publication No, 02-03-055, Nov. 2002.

***PLEASE NOTE THAT THIS DOCUMENT IS THE SECOND VERSION OF LCP WHICH IS HEREBY RE-NUMBERED AS QA-01-02**

APPENDIX A

AN EXAMPLE OF A QUALITY ASSURANCE MANUAL FORMAT

QA Manual Format

1. Title Page and Table of Contents

This is not required for short manuals

2. Glossary

Because some QA/QC terms are not universally recognized, it is highly recommended that a glossary be included of terms used in the manual and the laboratory's quality system.

3. Organization and Responsibilities

This section identifies management that sets QA policy, analysts/staff that implement the policy, and a QA officer/ coordinator if one exists (especially for larger organizations). Large laboratory should include an organizational chart.

This section should also set the responsibilities of key personnel of the organizations quality system.

4. Quality Policy

The organization's philosophy or overall policy with regards to quality should be stated here. Quality objectives for data generation and operations in general should also be included here.

5. Sample Management

This section includes (1) aspects of sampling which relate to or are responsibility of the lab, (2) specifies procedures for requesting sample analyses (needed by users or clients of the lab) and receipt, logging, storage, and handling of samples, (3) includes procedures for chain of custody and (40 criteria of acceptance or rejection of samples submitted to the lab.

6. Methods

The laboratory's analytical methods should be included in this section. References to written SOPs or external standard methods may be listed here. All modifications or amendments to methods should be indicated in the list here.

7. Calibration and Quality Control Procedures

This section includes procedures for calibration, standardization, and QC for each method or technique used in the lab. Guidelines should be given for when and how the following QC samples should be analyzed, and how result for each type is to be interpreted:

- Blanks (Lab blank, Calibration Blank (CB/CCB), Laboratory Fortified Blank (LFB)
- Check standards (Calibration Verification Standards (CV/CCV), LFB, laboratory control standards (LCS))
- Duplicate samples
- Spiked samples (Laboratory Fortified Matrix (LFMs))
- Certified reference materials (Quality Control Standard (QCS) and LFB – second source standards)

8. Monitoring Performance

SOPs should be written to describe the construction and use of control charts to see how the laboratory performs with regard to meeting repeated analysis of check standards, PT samples, etc. This will greatly assist the certification process.

9. Data Management

Data Management includes the following:

- Data recording: how data is recorded/stored
- Data reduction: Computations, etc.
- Data Validation: data checked by peer, supervisor, etc.
- Data entry: How data is entered in the system for final reporting
- Data reporting: How the final report is generated

10. Assessments

This section includes procedures how the quality system is assessed. This may be by internal or external audits, PT sample testing, or other means to check that the quality system is working properly. For Laboratory Certification this is mainly through PT check requirements mentioned in section 6.2

11. Reports

Reports describe the requirements and frequency of reports on QA/QC to management is done. For reference, drinking water labs should follow Appendix B USEPA Manual for the Certification of Laboratories Analyzing Drinking Water 5th edition.