

**New Mexico Environment Department Drinking Water Bureau**



**Drinking Water Laboratory Certification Program Guidance Manual**

**July 2011**

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The mission of the New Mexico Environment Department Drinking Water Laboratory Certification Program (DWLCP) is to ensure that comparable, consistent and legally defensible compliance drinking water quality data are reported from public water systems in New Mexico as required by the Safe Drinking Water Act (SDWA), state regulations NMAC 20.7.10 and federal regulations 40 CFR 141.

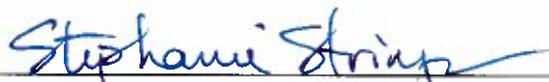
This program guidance document details the DWLCP process, organization, and requirements for drinking water lab certification in New Mexico. The program details are designed to meet the EPA primacy conditions (40 CFR 142) and follow the EPA *Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, 5<sup>th</sup> Ed.* (815-R-05-004, January 2005).



Danielle Shurn, DWLCP Laboratory Certification Authority



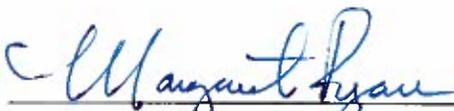
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Stephanie Stringer, DWB Quality Assurance Officer



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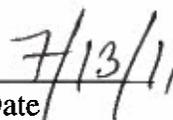
Margaret Ryan, Drinking Water Bureau Chief



Date



Raj Solomon, Operations and Infrastructure Division Director



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## PART 1: INTRODUCTION

### 1.0 DWLCP OBJECTIVE

The mission of the New Mexico Environment Department Drinking Water Laboratory Certification Program (DWLCP) is to ensure that comparable, consistent and legally defensible compliance drinking water quality data are reported from public water systems in New Mexico as required by the Safe Drinking Water Act (SDWA). The specific program goals ensure that all labs certified to test drinking water in New Mexico are adhering to quality assurance procedures and are meeting all Environmental Protection Agency (EPA) standards throughout the analysis process, from sample collection through reporting compliance data to the Safe Drinking Water Information System (SDWIS). It is necessary for all public water system compliance data to be reported to SDWIS properly in order for the New Mexico Environment Department Drinking Water Bureau (DWB) to assess and share data as required, and ultimately to protect public health in New Mexico (NM).

### 1.1 AUTHORITY

*The regulations governing primacy at 40 CFR 142.10(b)(4) require, as a condition of primary enforcement responsibility (primacy), that a state have laboratory facilities available (the Principle State Laboratory) certified by the regional administrator. In addition, the regulations governing certification (40 CFR 141.28) require that all testing for compliance purposes be performed by certified laboratories except that turbidity, free chlorine residual, temperature, pH, alkalinity, calcium, conductivity, orthophosphate, Total Organic Carbon (TOC), Specific UV Absorption (SUVA), daily chlorite, and silica may be performed by anyone acceptable to the state. (EPA 815-R-05-004, January 2005)*

This program guidance document details the DWLCP process, organization, and requirements for drinking water lab certification in New Mexico. The program details are designed to meet the EPA primacy conditions and follow the EPA *Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, 5<sup>th</sup> Ed.* (815-R-05-004, January 2005).

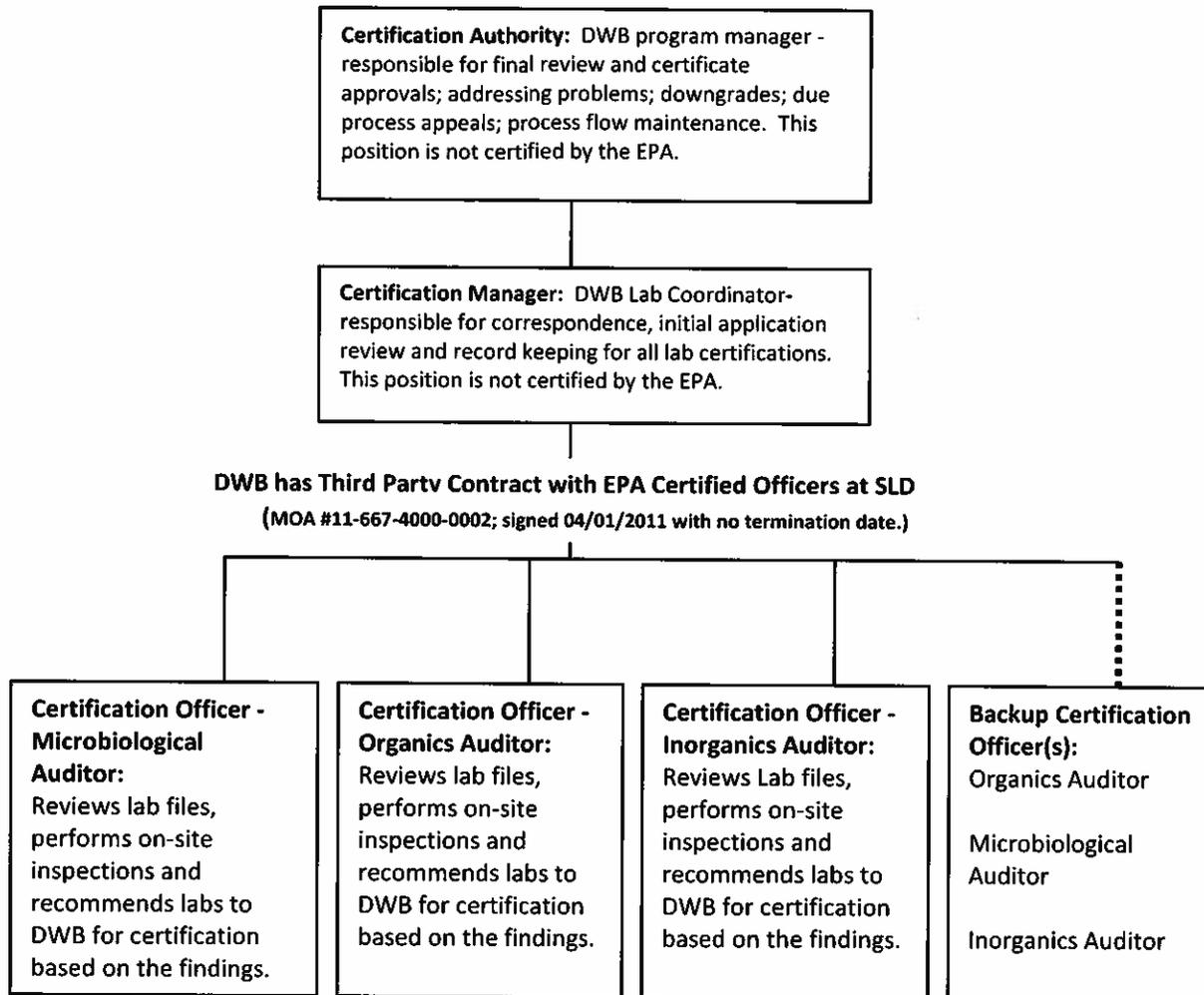
The Department of Health Scientific Laboratory Division (SLD) is the Principal State Laboratory for drinking water in New Mexico and is certified by the EPA (the administrator) to perform all SDWA compliance drinking water analyses except for dioxin and asbestos. DWB issues a request for bid contract to all other NM certified laboratories in order to meet the compliance monitoring demands of the public water systems in NM for dioxin, asbestos, and all other SDWA compliance testing. NM certified laboratories are not required to bid for DWB contract services.

The DWB authorizes the SLD team of currently EPA certified laboratory auditors to perform laboratory on-site audits for chemical and microbiological laboratories requesting

certification from the DWLCP with DWB approved standard operating procedures (SOP), on a fee-for-service basis. The SLD audit report will be submitted to DWB for inclusion in the certification evaluation. DWB will also accept reciprocity certification applications from The NELAC Institute (TNI), The American Association for Laboratory Accreditation (A2LA), or EPA accredited drinking water laboratories.

### 1.2 ORGANIZATION

The DWLCP is designed to meet the EPA requirements to maintain primacy, utilizing the expertise of the NM Principal State Laboratory, as DWB does not employ any full time chemists or microbiologists:



### 1.3 DRINKING WATER LABORATORIES

For the purpose of certification, any laboratory which analyzes drinking water compliance samples is considered a drinking water laboratory.

## 1.4 CERTIFICATION TYPES

After a review of the proficiency testing (PT) sample results and an on-site visit, the Certification Authority (CA) will provide a written report within 45 days and classify the laboratory for each contaminant or group of contaminants according to the following rating scheme:

- **Certified**: a laboratory that meets the minimum requirements of the laboratory certification manual and all applicable regulatory requirements.
- **Provisionally Certified**: a laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within the acceptance limits specified in the National Primary Drinking Water Regulations (NPDWR) and within the policy required by their CA. A provisionally certified laboratory may analyze drinking water samples for compliance purposes, if the said clients are notified of its downgrade status in writing, on any report. Provisional certification may not be given if the evaluation team believes that the laboratory cannot perform an analysis within the acceptance limits specified in the regulations.
- **Not Certified**: a laboratory that possesses major deficiencies and, in the opinion of the CA, cannot consistently produce valid data.
- **Interim Certification**: interim certification may be granted in certain circumstances when it is impossible or unnecessary to perform an on-site audit. Interim certification status may be granted only when the CA judges that the laboratory has the appropriate instrumentation, is using the approved methods, has adequately trained personnel to perform the analyses, and has satisfactorily analyzed PT samples, if available, for the contaminants in question. The Certification Officers (CO) should perform an on-site audit as soon as possible, but in no case later than three years. An example of a situation where this type of certification is warranted might be a laboratory that has requested certification for the analyses of additional analytes that involve the use of a method for which it already has certification, or a very similar method. The CA should review the laboratory's quality control data before granting this type of certification.

## PART 2: CERTIFICATION PROCESS

### 2.0 CERTIFICATION APPLICATION

In seeking NM drinking water certification, a laboratory must indicate its request in writing for those parameters and methods for which it seeks to be certified. An application form is included as Appendix A and includes all of the required information to process a drinking water certification request. The request must be signed by a responsible laboratory official and sent to:

NMED-DWB Drinking Water Laboratory Certification Program

525 Camino de Los Marquez, Suite 4

Santa Fe, New Mexico 87505

Or electronic applications may be sent to:

[NMENV-DWBlabcert@state.nm.us](mailto:NMENV-DWBlabcert@state.nm.us)

**\*\*Electronic applications are preferred.\*\***

The certification process begins when the laboratory director or manager makes a formal request to the CA to be certified. This application may be one of the following:

- A request for the first-time certification for regulated chemical analytes.
- A request for certification to analyze additional or newly regulated contaminants.
- A request to re-apply for certification after the correction of deficiencies that resulted in a downgrading or revocation of certification status.
- A request to recertify after current certification has expired.

The response to a formal application for any of the above requests should be given within 30 days. This response will not be a decision on certification, but notice of any additional information required for the certification review. At this time a mutually agreeable date and time should be set between the laboratory and CO for the on-site laboratory audit(s).

Drinking water laboratories should verify that they plan to analyze drinking water samples when they request certification. If a laboratory has not been analyzing drinking water samples, and does not plan to, the State may choose to not approve their certification.

### **2.01 Application Requirements**

Laboratories requesting drinking water certification will be required to submit a complete application packet found in Appendix A, which includes: laboratory information, a personnel description verified with laboratory supervisor signatures, a list of instrumentation, selection of analytes and methods to be reviewed, a request for SLD on-site audits, the laboratory's Quality Assurance (QA) Plan and Standard Operating Procedures (SOPs), information on the SDWIS test upload requirement, PT test sample results from the past 2 years for analytes and methods to be certified, and the signed certification of information and records access form. New laboratories or laboratories adding new analyses (performing for less than one year) must be able to submit at least one successful set of PT sample results for analytes and methods to be certified. It is recommended that certification renewal applications are submitted at least 90 days prior to certification expiration to allow enough time for the auditing and approval process.

### **2.02 Application Fees for Certification**

Where required and applicable, the level and timing of application fee payments shall be established by NMED. At this time there are no fees required for the application review, however the on-site audit and proficiency testing are required at the expense of the

laboratory for each analyte requested for NM drinking water laboratory certification. Accreditation services and/or secondary accrediting/certification authorities with which the laboratory chooses to do business may levy additional fees on the laboratory.

### **2.03 NM On-site Audit Request**

A successful on-site audit is required for certification approval. In the application packet laboratories may request a fee-for-service on-site audit performed by SLD to satisfy the audit requirement of NM drinking water certification.

### **2.04 Reciprocity Certification**

Laboratories already accredited by EPA, A2LA, or TNI should indicate on the application that they are requesting a reciprocity certification. When requesting reciprocity certification, laboratories should submit a copy of their most recent on-site audit report, applicable scope of work, and accreditation information along with the application packet.

## **2.1 SDWIS REPORTING REQUIREMENTS**

The end point of the drinking water laboratory's reporting in NM is currently SDWIS. Demonstrating the ability to upload to SDWIS is required in NM prior to certification approval so that compliance data may be shared quickly and accurately, internally and externally. The DWLCP requires that all laboratories certified in NM demonstrate the ability to create and upload a test data set to SDWIS for each analyte for which certification is requested prior to certification approval.

## **2.2 CERTIFICATE OF CERTIFICATION**

The certificate shall be signed by the CA and shall be considered an official document. It will be transmitted as a sealed and dated (effective date and expiration date) document containing the NMED insignia. The certificate shall include specific fields of testing, analytes, and methods that the laboratory or sub facility is certified for.

The certificate shall explain that continued certification status depends on successful ongoing participation in the program. The certificate must be returned to NMED upon revocation of certification. However, this does not require the return of a certificate that has passed the expiration date. If a certified laboratory changes its scope of certification, a new certificate shall be issued which details the parameters of the revised certification.

## **2.3 USE OF DWLCP CERTIFICATION**

A certified laboratory shall not misrepresent its certified fields of testing, methods, analytes, or its status on any document. This includes laboratory reports, catalogs, advertising, business solicitations, proposals, quotations, or other materials. Such misrepresentation may result in certification suspension or revocation.

## 2.4 PERIOD OF CERTIFICATION

For a laboratory that is approved for certification, the period for certification within fields of testing for methods or analytes shall be up to three (3) years if successful PT samples results are reported annually. Failure to meet the requirements to maintain certification shall constitute grounds for suspension or revocation of certification as described in section 2.8. Upon certification expiration a renewal application packet should be filled out, submitted, and another on-site audit performed. Renewal applications should be submitted at least 90 days prior to certification expiration. Reciprocity certifications are only established for the duration of the EPA, A2LA, or TNI accreditation.

## 2.5 MAINTAINING CERTIFICATION

(Italicized sections taken from Chapter 3 Section 13: Requirements for Maintaining Certification; EPA 815-R-05-004, Jan. 2005)

### 2.51 Proficiency Testing (PT) Samples

*At least annually drinking water laboratories certified for chemical contaminants must satisfactorily analyze a PT sample to maintain certification (40CFR 141.23(k)(3)(i)(A) and 141.89(a)(1)(i)). PT samples should be analyzed in the same manner as routine samples. Laboratories must acquire the PT sample from a supplier acceptable to the appropriate certification authority.*

Certified laboratories must, at their own expense, analyze PT samples annually for each method that they desire certification. DWLCP permits laboratories to participate in any accredited PT study and have the results sent to the CA. Information on currently acceptable PT study providers can be found on the EPA's website.

<http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm#testing>

*If the certified laboratory does not analyze the PT sample within the acceptance limits specified in the regulations, or within policy described by their certification authority, the certification authority should follow the procedure discussed in the section entitled, "Criteria and Procedures for Downgrading/Revoking Certification Status."*

*If a laboratory wishes to be certified for a contaminant by more than one method, it must (40CFR 141.23(k)(3)(ii), 141.24(h)(17)(i)(A) and 141.89(a)(1)(i)) analyze the PT samples by each method for which it wishes to be certified. The methods listed on the laboratory's certificate must be the methods by which the PT samples were analyzed.*

*The laboratory should be able to provide documentation to the certification authority that the person(s) analyzing any PT sample is a laboratory employee who routinely analyzes drinking water compliance samples.*

## 2.52 Methodology

*Laboratories must use the methods specified in the drinking water regulations at 40 CFR Part 141.*

## 2.53 Sample Reporting

Laboratories must provide a copy of all compliance sample results to the submitter of the sample and the appropriate NMED/DWB or EPA (or EPA designate) office within ten (10) working days from the completion of the analyses.

## 2.54 Results that require immediate notification:

- Any sample that exceeds the maximum contaminant level (MCL).
- Any sample that is rejected by the laboratory for not meeting the submission criteria (*i.e.* leaking, frozen, > 10 °C, or > 30 hours from collection) must be reported to the water system and the DWB or EPA (or the EPA designate) within twenty-four hours of the rejection.
- Any sample that will be reported by the laboratory as “laboratory accident” must be reported to the water system and the DWB or EPA (or the EPA designate) within twenty-four hours of the accident.

## 2.55 Contact log

A laboratory must keep a written record of contacts made to report positive results, invalid results, or samples rejected by the laboratory. The record must contain information identifying the sample collector, who was contacted (name and affiliation), when the contact was made (date and time), and how the contact was made (in person, by phone, or by e-mail).

## 2.56 Notification of the certifying authority (CA) of major changes

*Certified laboratories should [must] notify the CA, in writing, within 30 days of major changes in personnel, equipment, or laboratory location. A major change in personnel is defined as the loss or replacement of the laboratory supervisor, or a situation in which a trained and experienced analyst is no longer available to analyze a particular parameter for which certification has been granted. The CA should discuss the situation with the laboratory supervisor and establish a schedule for the laboratory to address major changes. If the CA determines that the laboratory can no longer produce valid data, the CA should follow the procedure for revocation of certification.*

Failure to notify the CA of a major change that impacts compliance data quality will result in the CA initiating procedures described in Section 2.8 CRITERIA AND PROCEDURES TO DOWNGRADE/ REVOKE CERTIFICATION STATUS.

## 2.57 On-site evaluation

*The CA should be satisfied that a laboratory is maintaining the required standard of quality for certification. Normally, this should be based on a recommendation from a triennial on-site evaluation. However, if the laboratory undergoes a major change, or repeatedly fails a PT sample or other unknown test sample, the CA should consider conducting an evaluation before the usual three year period has expired.*

On-site audits are a requirement of the certification process and are performed on a fee-for-service basis by an SLD CO (for microbiology and chemistry only), EPA, or a qualified TNI or A2LA approved third party assessor. All costs associated with an on-site audit are the responsibility of the laboratory applying for certification.

Beginning July 1, 2011 SLD will make available DWLCP approved SOPs for the chemical and microbiological laboratory audit processes and a fee schedule for auditing the analytical methods for NM drinking water laboratory certification. SLD will not offer on-site audits for radiological analyses. All on-site audit findings will be reported to the lab and DWLCP within 45 days of the SLD CO audit.

*In addition, the regulations governing certification (40 CFR 141.28) require that all testing for compliance purposes be performed by certified laboratories except that turbidity, free chlorine residual, temperature, pH, alkalinity, calcium, conductivity, orthophosphate, TOC, SUVA, daily chlorite, and silica may be performed by anyone acceptable to the state. (EPA 815-R-05-004, January 2005)*

For the analytes listed above as exceptions to certification requirements, an on-site audit will not be required. Approved methodologies must be used and successful annual PT results will only be required as a Quality Control (QC) check for these analytes.

Subsequent audits may be initiated by the CA, CO, or the laboratory. If initiated by the CA or CO, the audit may be announced or unannounced and will be paid for by the DWLCP. Reasonable access to the facilities, equipment, and records must be granted to the audit team during regular work days and hours.

## 2.58 Response to on-site evaluation

The laboratory will have thirty (30) days to respond to the SLD CO, in writing, specifying what immediate corrective actions are being taken *and* what proposed corrective actions will occur. The SLD CO and the CA will consider the adequacy of the response. If the response and accompanying documentation correct the deviations, the laboratory and DWLCP will receive notification of the successful on-site audit. If the response does not address the deviations, or lacks the appropriate documentation, the laboratory will be notified by the SLD CO of its audit failure and subsequently from the CA of denial/downgrade of certification. If no response is received within the thirty (30) day time limit, the SLD CO will send notification to the laboratory and the CA of the audit failure. This section does not negate the three-month time frame specified in Section 2.8 below,

it requires the laboratory to inform the CO and the CA of the plan and time frame required to correct deviations cited.

## **2.6 CHANGE OF LABORATORY OWNERSHIP OR LOCATION**

Certification may be transferred when the legal status or ownership of a certified laboratory changes without affecting its staff, equipment, and organization. The CA may charge a transfer fee and may conduct an on-site audit to verify impacts of such changes on laboratory performance.

Any change in ownership and/or location of a certified laboratory must be reported in detail in writing to NMED within thirty (30) days of the change. Change in ownership and/or location may require an on-site audit.

For a change in ownership, the following conditions must be in effect:

1. The previous (transferring) owner must agree in writing before the transfer of ownership takes place, to be accountable and liable for any analyses, data and reports generated up to the time of legal transfer of ownership; and
2. The buyer (transferee) must agree in writing to be accountable and liable for any analyses, data and reports generated after the legal transfer of ownership occurs.
3. All records and analyses performed pertaining to certification must be kept for a minimum of 5 years and are subject to inspection by the accrediting authorities during this period without prior notification to the laboratory. This stipulation is applicable regardless of change in ownership, accountability or liability.
4. If ownership is transferred, the transferee may not be responsible for payment of fees to the accrediting authorities during the remainder of the yearly period, provided that the previous owner has fully paid the required fees, if any.

## **2.7 CERTIFICATION DENIAL**

Denial shall mean to refuse to accredit a laboratory applying for initial certification or resubmission of initial application. Reasons to deny an initial application shall include:

- Failure to submit a completed application;
- Failure of laboratory staff to meet the personnel qualifications (education, training, and experience requirements) as required;
- Failure to successfully analyze and report PT samples annually;
- Failure to successfully upload data to the SDWIS database;
- Failure to respond to an on-site audit report with a corrective action report within the required thirty (30) calendar days after receipt of the audit report;
- Failure to implement the corrective actions detailed in the corrective action report within the time frame as specified by DWLCP;
- Failure to pay required fees, if any;
- Failure to pass required on-site audit(s);
- Misrepresentation of any fact pertinent to receiving or maintaining certification;

- Denial of entry during normal business hours for an on-site audit as required.
- DWLCP reserves the ability to deny a certification application if the laboratory does not have the intention or ability to analyze compliance samples for public water systems in NM, or if the DWLCP already has enough certified labs to meet the SDWA compliance analysis demand for any particular analyte.

If the laboratory is not successful in correcting the deficiencies as required by the standards and has been denied certification, the laboratory must wait six months before reapplying for certification. Upon reapplication, the laboratory will again be responsible for all or part of the fees if any, as applicable, incurred as part of the initial application.

## **2.8 CRITERIA AND PROCEDURES TO DOWNGRADE/ REVOKE CERTIFICATION STATUS**

(Italicized sections taken from Chapter 3 Section 14: Criteria and Procedures for Downgrading/Revoking Certification Status; EPA 815-R-05-004, Jan. 2005)

### **2.81 Criteria for downgrading certification status**

*A laboratory should be downgraded to "provisionally certified" status for a contaminant or group of contaminants for any of the following reasons:*

- *Failure to analyze a PT sample at least annually within the acceptance limits specified in the regulations, or, if there are no requirements specified in the regulations, within policy described by their certifying authority;*
- *Failure of a certified laboratory to notify the CA within 30 days of major changes (e.g., in personnel, equipment, or laboratory location);*
- *Failure to satisfy the CA that the laboratory is maintaining the required standard of quality, based upon a[n] EPA on-site evaluation.*
- *Failure to report compliance data to the public water system or the State drinking water program [SDWIS database and hard copy] in a timely manner [within 10 days after completion of analysis], thereby preventing compliance with Federal or State regulations and endangering public health. Data, which may cause the system to exceed an MCL, should be reported as soon as possible [within 24 hours].*
- Failure to respond to the CO and CA within thirty (30) days of receiving an on-site audit report with deviations.

### **2.82 Procedures for downgrading to "provisionally certified" status**

*If a laboratory is subject to downgrading on the basis of the above indicated criteria, the CA must notify the laboratory director or owner (by registered or certified mail) of its intent to downgrade within fourteen (14) days from becoming aware of the situation warranting downgrading. The laboratory director/manager should review the problems cited and,*

*within thirty (30) days of receipt of the letter, send a written response to the CA specifying what immediate corrective actions are being taken, and any proposed actions that need the concurrence of the CA. The CA should consider the adequacy of the response and notify the laboratory in writing (by registered or certified mail) of its certification status within fourteen (14) days of receipt of its response. The CA should follow up to ensure that corrective actions have been taken.*

*If a laboratory fails to analyze a PT or other unknown sample within the acceptance limits, the CA should not downgrade certification if the laboratory identifies and corrects the problem to the CA's satisfaction within 30 days of being notified of the failure. If, after a review of the submitted information, the CA determines that the laboratory need not be downgraded, then within 30 days of this decision, the CA should notify the laboratory that it is required to analyze another PT. If the laboratory analyzes this second unknown sample within the acceptance limits established by the State, the laboratory should not be downgraded. If the laboratory fails to analyze this second unknown sample within the established limits, the CA should downgrade the laboratory to provisionally certified status and notify the laboratory within fourteen (14) days (by registered or certified mail). Laboratories should be downgraded only for the analyte failed, except where the EPA/State certifies a group of related analytes based on a limited number of analytes in the group.*

*During any phase of this procedure, a laboratory may request that the SLD provide technical assistance to help identify and resolve any problems.*

*After the CA notifies a laboratory, in writing, that it has been downgraded to "provisionally certified" status for procedural, administrative, equipment, or personnel deficiency, the laboratory should correct its problem within three months. If the laboratory was downgraded to "provisionally certified" status because of a failure to analyze a PT sample (or other unknown test sample) within the acceptance limits specified in the regulations, or within policy required by their certifying authority, the laboratory should correct its problems and satisfactorily analyze another PT sample (or other unknown sample) within one month of receipt of the second PT sample. A provisionally certified laboratory may continue to analyze samples for compliance purposes, but should notify its clients of its downgraded status, and provide that information, in writing, on any report.*

### **2.83 Criteria for revoking certification status**

*A laboratory shall be downgraded from certified, provisionally certified, or interim certified status to "not certified" for a particular contaminant analysis for the following reasons:*

- Reporting PT data from another laboratory as its own;*
- Falsification of data or other deceptive practices;*
- Failure to use the analytical methodology specified in the regulations;*

- *For provisionally certified laboratories, failure to successfully analyze a PT sample or any other unknown test sample for a particular contaminant within the acceptance limits specified;*
- *For provisionally certified laboratories, failure to satisfy the CA that the laboratory has corrected deviations identified during the on-site evaluations;*
- *For provisionally certified laboratories, persistent failure to report compliance data to the public water system or the State Drinking Water Program in a timely manner thereby preventing compliance with Federal and/or State regulations and endangering public health. Data which may cause a system to exceed the MCL should be reported as soon as possible [within 24 hours].*
- *Refusal to participate in an on-site evaluation conducted by the CA or CO.*

#### **2.84 Procedures for revocation and denial**

*The CA should notify the laboratory, in writing (by registered or certified mail) of the intent to revoke [or deny] certification. If the laboratory wishes to challenge this decision, a notice of appeal should be submitted in writing to the CA within thirty (30) days of receipt of the notice of intent to revoke [or deny] certification. If no notice of appeal is filed, certification shall be revoked [or denied].*

*The notice of appeal should be supported with an explanation of the reasons for the challenge and must be signed by a responsible official from the laboratory such as the president/owner for a commercial laboratory, or the laboratory supervisor in the case of a municipal laboratory or the laboratory director for a State or Regional laboratory.*

*Within thirty (30) days of receipt of the appeal, the CA should make a decision and notify the laboratory in writing (by registered or certified mail). Denial of the appeal shall result in the immediate revocation [or denial] of the laboratory's certification. Once the certification is revoked [or denied], a laboratory may not analyze drinking water samples for compliance until its certification has been reinstated.*

*If the appeal is determined to be valid, the CA should take the appropriate measures to re-evaluate the facility and notify the laboratory, in writing (by registered or certified mail), of its decision within thirty (30) days of the reevaluation.*

#### **2.85 Upgrading or Reinstatement of Certification**

*Through a written request, a laboratory may seek upgrading or reinstatement of certification, when and if the laboratory can demonstrate to the CA's satisfaction that the deficiencies which produced provisionally certified status or revocation, has been corrected. This may include an on-site evaluation, successful analysis of unknown samples or any other measure the CA deems appropriate.*

## PART 3: CERTIFICATION EVALUATION

### 3.0 CERTIFICATION CRITERIA

The Certification approval is dependent on an evaluation of information gathered through the application packet, the on-site audit, and reported PT samples. The evaluation is based on the elements described specifically in Chapter IV: Critical Elements of Chemistry and Chapter V: Critical Elements for Microbiology in the EPA *Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, 5<sup>th</sup> Ed.* (815-R-05-004, January 2005). The SLD Chemistry and Microbiology On-site Audit Manuals will also provide detailed expectations of the on-site audit portion of the certification review.

#### 3.01 Criteria Summary

A summary of the elements evaluated for all types of certification are:

1. **Personnel**: Laboratory manager, supervisors, staff, and QA officer must meet the necessary education, training, technical knowledge and experience for their assigned functions. All personnel shall be responsible for complying with all QA/QC requirements that pertain to their organizational/technical function.
2. **Laboratory Facilities**: Facilities must meet all requirements so that the integrity and security of samples collected are maintained.
3. **Laboratory Equipment and Instrumentation**: All required equipment must be available, maintained, and calibrated as required.
4. **General Laboratory Practices**: Chemicals, reagents, and glassware preparation must meet all requirements. All labs should follow a documented Safety and Quality Assurance Plan in their general practices.
5. **Analytical Methods**: All laboratories should use methods specified by EPA Safe Drinking Water Act of 1974, amendments of 1986 and 1996, 40 CFR 141.21 – 141.30, 141.40 – 42, methods specified by NMED, or the most current EPA approved method(s). Official methods will include EPA approved alternate analytical techniques.
6. **Sample Collection, Preservation, and Handling**: Sample collection, preservation, and hold time requirements must be made available to sample collectors for all certified methods analyzed by the lab. The lab must document a sample rejection procedure and adhere to sample collection and transport requirements listed. Sample request form documentation must meet requirements to preserve the legal defensibility of all compliance data reported. **It is expected that all accepted samples have a complete chain of custody and either the cooler or individual sample container are sealed.**
7. **Quality Control**: QA Plans describing all QC procedures should be submitted with the certification application. Any specific QC information such as method detection limit (MDL) studies, initial demonstration of capabilities, QC sample results, traceability of calibration, reference standards, calibration, support equipment, instrument

calibration, and related general requirements shall be assessed during the on-site audit.

8. **Records and Data Reporting:** Legally defensible data are required from all laboratories. Sampling and analytical records must be maintained as required. All laboratories will be required to demonstrate the ability to submit compliance data electronically to the SDWIS database successfully in order to analyze compliance data in NM. All laboratory records associated with certification parameters shall be maintained for five years.
9. **Action in Response to Noncompliant Laboratory Results:** All labs are required to report noncompliant sample results to DWB per the analytical services contract requirements.

### 3.1 Laboratory Quality Assurance Plan Evaluation

(Italicized sections taken from Chapter 3 Section 11: Laboratory Quality Assurance Plan; EPA 815-R-05-004, Jan. 2005)

The CO and CA will review the laboratory QA Plan before the on-site audit to determine if it meets the QC criteria given the EPA *Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, 5<sup>th</sup> Ed.* (815-R-05-004, January 2005).

*All laboratories analyzing drinking water compliance samples must adhere to any required QC procedures specified in the methods. This is to ensure that routinely generated analytical data are scientifically valid and defensible, and are of known and acceptable precision and accuracy. To accomplish these goals, each laboratory should [must] (EPA Order 5360.1 A2) prepare a written description of its QA activities (a QA plan). It is the responsibility of the QA manager to keep the QA plan up to date. All laboratory personnel need to be familiar with the contents of the QA plan. This plan should be submitted to the auditors for review prior to the on-site visit, or should be reviewed as part of the on-site visit.*

*The laboratory QA plan should be a separately prepared text. However, documentation for many of the listed QA plan items may be made by reference to appropriate sections of this manual, the laboratory's standard operating procedures (SOPs), or other literature (e.g., promulgated methods, Standard Methods for the Examination of Water and Wastewater, etc.) The QA Plan should be updated at least annually (EPA Order 5360.1 A2).*

*At a minimum, the following items should be addressed in each QA plan:*

1. *Laboratory organization and responsibility...*
2. *Process used to identify clients' Data Quality Objectives...*
3. *SOPs with dates of last revision...*
4. *Field sampling procedures...*
5. *Laboratory sample receipt and handling procedures...*

6. *Instrument calibration procedures (may reference SOP)...*
7. *Analytical procedures (may reference SOP)...*
8. *Data reduction, validation, reporting, and verification (may reference SOP)...*
9. *Types of quality control (QC) checks and the frequency of their use (may reference SOP)...*
10. *Lists of internal and external system and data quality audits and inter laboratory comparisons (may reference SOP)...*
11. *Preventative maintenance procedures and schedules...*
12. *Corrective action contingencies...*
13. *Record Keeping Procedures...*

*If a particular item is not relevant, the QA PLAN should state this and provide a brief explanation. A laboratory QA plan should be responsive to the above items while remaining brief and easy to follow. Minimizing paperwork, while improving dependability and quality of data, are the intended goals.*