DRINKING WATER BUREAU

Drinking Water Laboratory
Certification Program Guidance Manual

Revision 3.0
Effective January 1, 2020

NEW MEXICO ENVIRONMENT DEPARTMENT
DRINKING WATER BUREAU

Drinking Water Laboratory Certification Guidance Manual

This program guidance document details the Drinking Water Laboratory Certification Program (DWLCP) process, organization, and requirements for drinking water laboratory certification in New Mexico. The program is designed to meet the United States Environmental Protection Agency (EPA) primacy conditions (40 CFR 142), the EPA Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, 5th Ed. (815-R-05 -004, January 2005) and all subsequent supplements; including Supplement 1 (EPA 815-F-08-006, June 2008) and Supplement 2 (EPA 815-F-12-006, November 2012), and the National Environmental Laboratory Accreditation Program (NELAP) requirements as described in The NELAC Institute (TNI) Standard. Italicized portions of the texts are direct quotes from the EPA Manual.

Approvals

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DWLCP Guidance Manual: Table of Contents

PART ONE: INTRODUCTION

1.1 DWLCP OBJECTIVE

The mission of the New Mexico Environment Department (NMED) Drinking Water Laboratory Certification Program (DWLCP) is to ensure that comparable, consistent, and legally defensible drinking water quality compliance data are reported from public water systems in New Mexico as required by the Safe Drinking Water Act (SDWA), New Mexico Drinking Water Regulations 20.7.10 NMAC, and federal regulations 40 CFR 141-143.

The specific program goals ensure that all laboratories certified to test drinking water in New Mexico adhere to quality assurance procedures and meet all Environmental Protection Agency (EPA) standards throughout the analysis process, from sample collection through the reporting of data into the NM/EPA database of record at the time of upload, currently Safe Drinking Water Information System (SDWIS). It is necessary for all public water system compliance data to be reported to SDWIS properly for the NMED Drinking Water Bureau (DWB) to assess and share data as required, and ultimately to protect public health in New Mexico (NM).

1.2 AUTHORITY

The regulations governing primacy at 40 CFR 142.10(b)(3)(i) require 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 certification officer, or officers, certified by EPA, as the official(s) responsible for the State's certification program.

As a condition of primary enforcement responsibility (primacy), 40 CFR 142.10(b)(4) requires that a state have laboratory facilities available (the Principal State Laboratory) certified by EPA. In addition, 40 CFR 141.28 requires 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 laboratory certification in NM. The program is 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, 5th Ed. (815-R-05-004, January 2005) and all subsequent supplements; including Supplement 1 (EPA 815-F-08-006, June 2008) and Supplement 2 (EPA 815-F-12-006, November 2012), and the National Environmental Laboratory Accreditation Program (NELAP) requirements as described in The NELAC Institute (TNI) Standard.

The Department of Health Scientific Laboratory Division (SLD) is the Principal State Laboratory for drinking water in New Mexico and is certified by EPA to perform drinking water analyses. The DWLCP only certifies laboratories for analyzing samples under methods that are allowed for compliance with the SDWA per EPA. Only NM certified laboratories are eligible to bid for DWB contracts to analyze drinking samples for determining compliance with the SDWA and NM Drinking Water Regulations. Requests for other analyses or methods not identified or authorized for compliance under the EPA SDWA, 40 CFR 141-143 will not be considered.

The DWB authorizes the SLD team of EPA certified laboratory auditors to perform laboratory onsite audits for laboratories requesting certification from the DWLCP on a fee-for-service basis. The SLD audit report is submitted to DWB for inclusion in the certification evaluation.

DWB will also accept reciprocity certification applications from The NELAC Institute (TNI), or EPA accredited drinking water laboratories.

1.3 ORGANIZATION

The DWLCP meets the EPA requirements to maintain primacy by utilizing the expertise of the NM Principal State Laboratory, SLD, as DWB does not employ any full-time chemists or microbiologists.

Certification Authority (CA): DWB Water Conservation Fund (WCF) Manager is responsible for final review and certificate approvals, addressing problems, downgrades, and due process appeals. This position is not certified by EPA.

Certification Manager (CM): DWB Quality Assurance Coordinator is responsible for correspondence, application processing, and record keeping for all laboratory certifications. This position is not certified by EPA.

DWB has a third-party contract with EPA Certified Officers (CO) at SLD; they review laboratory files, perform onsite audits (also referred to as assessments or evaluations), and recommend laboratories to DWB for certification based upon their findings, and are available in the following areas:

- Microbiological Certification Officer
- Organics Certification Officer
- Inorganics Certification Officer

Currently, the DWB only certifies microbiological laboratories through this process. Organics and Inorganics are certified through reciprocity.

1.4 DRINKING WATER LABORATORIES

For certification purposes, any laboratory which analyzes drinking water compliance samples is considered a drinking water laboratory.

1.5 CERTIFICATION TYPES

The following are the different certification types. All levels of certification are authorized to perform drinking water analyses except for those deemed Not Certified.

Certified: Laboratory that meets the requirements of the current revision of the DWLCP Guidance Manual and all applicable regulatory requirements.

Provisionally Certified: Laboratory that has discrepancies 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 as long as they notify their clients of this downgrade in writing and indicate this status on any analytical reports. Provisional certification may not be given if the CA believes that the laboratory cannot perform an analysis within the acceptance limits specified in the regulations.

Interim Certification: May be granted in certain circumstances when it is impossible or unnecessary to perform an onsite 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 COs should perform an onsite audit as soon as possible. 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.

Not Certified: Laboratory that possesses major deficiencies and, in the opinion of the CA, cannot consistently produce valid data.

PART TWO: 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 using the application form included as **Appendix A.** The application includes all the required information to process a drinking water certification request. The request must be signed by a responsible laboratory

official and sent with all applicable supporting documents by email to NMENV-DWBlabcert@state.nm.us.

The certification process begins when the responsible laboratory official, such as laboratory director or manager, makes a formal request via application to the CM to be certified. This application may be one of the following:

- A request for the first-time certification for regulated chemical analytes or microbiological contaminants,
- A request for certification to analyze additional, or newly regulated contaminant groups,
- 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 re-certify a current certification before it expires, or
- A request to re-certify after certification has expired.

A notification of receipt will be provided for all applications submitted. If any additional information is needed to process the application the applicant will be notified within 45 days.

Microbiological laboratories should ensure that all required onsite audits are completed or scheduled with SLD CO at the time of application submission. The onsite audit should be conducted prior to the certification expiration, if currently certified.

The DWLCP only certifies laboratories for analytes and/or groups of analytes and methods that are identified as acceptable for meeting compliance under SDWA, 40 CFR 141, and NM Drinking Water Regulations 20.7.10 NMAC. The DWLCP requires that laboratories seek certification for groups of analytes as outlined under the SDWA (see 40 CFR §141-National Primary Drinking Water Regulations, Subpart C-Monitoring and Analytical Requirements & 40 CFR §143-National Secondary Drinking Water Regulations). Laboratories must be certified for all the parameters of a specific group covered under the rule. ***No partial certifications will be issued*** (See table in Appendix A). Conversely, if a laboratory loses certification for a particular analyte, the whole group is removed from certification.

2.1 APPLICATION REQUIREMENTS

Laboratories requesting drinking water certification are required to submit the complete application packet found in **Appendix A**, to the DWLCP at NMENV-DWBlabcert@state.nm.us. This includes:

- laboratory information,
- certifications,
- personnel description(s) verified with laboratory supervisor signatures,
- instrumentation list(s), selection of requested analytes and methods,
- request for SLD on-site audits (microbiological only at this time),

- the laboratory's Quality Assurance Manual/Quality Assurance Plan (QAM/QAP),
- applicable Standard Operating Procedures (SOPs),
- information regarding the SDWIS test upload,
- last 2 sets of PT test sample results for all analytes/methods for which certification is being requested,
- copy of the laboratory's Chain of Custody (COC),
- annual Method Detection Limit (MDL) studies and the associated Minimum Reporting Levels (MRL) for each method and analyte for which they are seeking certification, and
- the signed certification of information and records access form.

Laboratories must agree to accept a NM issued COC or obtain approval of their COC by the DWLCP. COCs must contain the necessary information required by SDWA regulations to successfully upload information into DWB's database of record at the time of upload.

Laboratories adding new analytes or analyses must be able to submit at least two successful sets of PT sample results for analytes and methods for which certification is being requested.

Certification renewal applications, along with all supporting documentation, should be submitted ***at least*** 90 days prior to certification expiration to allow enough time for the auditing and approval process.

2.2 APPLICATION FEES FOR CERTIFICATION

At this time, there are no fees required for the application review and certification. However, the SLD onsite audits and required PT are at the expense of the laboratory. Accreditation services and/or secondary accrediting/certification authorities with which the laboratory chooses to do business may levy additional fees on the laboratory.

2.3 NEW MEXICO ONSITE AUDIT REQUEST

A successful onsite audit is required for certification approval. In the application packet, Microbiological laboratories must indicate that the onsite audit has been completed or scheduled with the SLD CO.

2.4 RECIPROCITY CERTIFICATION

Laboratories already accredited by EPA or TNI should indicate on the application that they are requesting a reciprocity certification. When requesting reciprocity certification laboratories must submit a copy of their current EPA/TNI certificate, including the scope of accreditation, most recent onsite audit report, the laboratory's corrective action response, and audit closure letter. This is in addition to the other supporting documents listed in section *2.1 Application Requirements*.

Reciprocity certifications are only established for the duration of the EPA, or TNI accreditation period stated on the primary certification.

2.5 ELECTRONIC REPORTING REQUIREMENTS

In NM, it is required that analytical data be electronically uploaded to the DWB's SDWIS, or current database of record. This ensures that compliance data may be shared quickly and accurately; internally, and externally. The DWLCP requires that all laboratories certified in NM demonstrate this ability by creating and uploading a test data set to SDWIS, or current database of record, for each analyte which certification is requested prior to certification approval. Laboratories are required to maintain this data upload capability with the current database of record at time of upload. Failure to maintain electronic data upload capabilities may be grounds for revocation of certification. NOTE: Uploading of data can only be performed by the laboratory personnel listed in the DWLCP application, or as notified by lab for personnel changes.

2.6 CERTIFICATE

Laboratories approved for certification in New Mexico will receive a certificate signed by the CA and it shall be considered an official document. It will be transmitted as a signed and dated (effective date and expiration date) document containing the NMED logo. The certificate shall include specific fields of testing, analytes, and methods for which the laboratory is certified.

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 wishes to change its scope of accreditation, the DWLCP must be notified so the scope may be reviewed and revised as appropriate. Upon approval, a new certificate will be issued detailing the parameters of the revised certification.

2.7 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.

Laboratories subcontracting out samples to secondary laboratories for analyses must ensure secondary laboratories are certified by DWLCP to perform those methods. This includes providing the DWLCP laboratory certification number on any records of results or electronic upload of results performed by the subcontracted laboratory.

2.8 PERIOD OF CERTIFICATION

For a chemical laboratory that is approved for certification the period of certification is up to

one year, but no longer than the duration of the accreditation period of their primary certification.

The certification period may be up to three (3) years for microbiological laboratories if successful PT study results are reported annually. The lab must also submit their QAM/QAP and SOPs annually.

Failure to meet the requirements to maintain certification shall constitute grounds for downgrading or revocation of certification as described in section 2.12 of this document.

2.9 MAINTAINING CERTIFICATION

In order to maintain certification, all chemical and microbiological laboratories must submit their current QAM/QAP, SOPs, and PT results to the DWLCP CM **annually** at NMENV-DWBlabcert@state.nm.us. Chemical laboratories may submit these documents along with their annual certification renewal application, their annual Method Detection Limit (MDL) studies, and the associated Minimum Reporting Levels (MRL) for each method and analyte for which they seek to maintain certification.

Laboratories under contract with DWLCP must also submit quarterly QA reports to the CA at NMENV-DWBlabcert@state.nm.us to maintain their certification. These reports should be submitted within fifteen (15) days of the quarter ending.

Microbiological laboratory QA reports should include the following data: total number of sample results reported, total number of samples rejected (with reason for rejection noted on the report), total number of lab errors (sample analyzed but results could not be reported), total number of routine total coliform and E. coli positives reported, and percent of results reported within 10 days of analysis.

Chemical laboratory QA reports should include, at a minimum, the following data: total number of sample results reported, total number of samples rejected (with reason for rejection noted on the report), total number of lab errors (sample analyzed but results could not be reported), percent of results reported within 10 days of analysis, percent of results reported within 30 days of analysis, percent of results reported within 60 days of analysis, and percent of results reported within 90 days of analysis.

2.9.1 Proficiency Testing (PT) Studies

Proficiency Testing is the means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an accredited proficiency test provider.

Certified laboratories must, at their own expense, analyze PT samples (both chemical and microbiological) for each analyte and method for which they desire certification. PT studies

must be analyzed at the frequency required by the laboratory's accrediting authority; but in no case less frequent than annually. **Failure to meet these schedules, whether annual or semiannual, is regarded as a failed study**.

If a laboratory wishes to be certified for a contaminant by more than one method, it must analyze the PT samples by each method for which it wishes to be certified (40 CFR 141.23(k)(3)(ii), 14I.24(h)(l 7)(i)(A) and 141.89(a)(l)(i)). The methods listed on the laboratory's certificate must be the methods by which the PT samples were analyzed.

When analyzing a PT sample, a laboratory must use the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples.

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

DWLCP permits laboratories to participate in any accredited PT study and have the results sent to the Certification Manager (CM) at **NMENV-DWBlabcert@state.nm.us.** The following is a listing of TNI approved organizations which are accredited to provide PT samples:

Absolute Standards, Inc.	800-368-1131
Advanced Analytical Solutions, LLC	304-422-4274
Environmental Resource Associates, Inc.	303-431-8454
MilliporeSigma	307-742-5452
NYS DOH Wadsworth Center	518-474-7161
NSI Solutions, Inc.	800-234-7837
Phenova	303-940-0033

To maintain certification, laboratories must continue to complete their PT studies in accordance with their accrediting authority's requirements and ensure those results are provided to the DWLCP. Laboratories failing their PTs should strive to correct them in accordance with their accrediting authority's requirements to avoid being downgraded or revoked by DWLCP.

New Mexico Microbiological Laboratory PT Requirements

The following types of PT studies are required for New Mexico microbiological laboratories with primary certification through the DWB's DWLCP:

- Initial - A laboratory seeking to obtain accreditation must successfully complete two PT studies for each requested analyte/method. These two studies must have occurred within 18 months of the laboratory's application date and must be a minimum of 7 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing.
- Continuing - Once a laboratory has been certified, it must continue to successfully

complete a minimum of one PT study for each analyte/method annually (within the calendar year).

- Supplemental - A laboratory participates in supplemental PT studies when the lab desires to add new fields of testing to their scope or when the lab fails an initial or continuing PT study and wishes to re-establish its history of successful performance. Analysis date of supplemental PT studies must be a minimum of 7 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing.

Microbiological PT Studies will be evaluated as follows:

- Qualitative Analyses - Participating laboratory results shall be considered "Acceptable" or "Unacceptable" when compared to the known presence or absence of total coliform or fecal coliform (E. coli) bacteria. **Passing shall be considered as nine out of ten samples having acceptable results, and no false negatives reported.**
- Quantitative Analyses - Quantitative result data sets shall be evaluated by analytical method using standard statistical analysis with outlier rejection. Most Probable Number data should be transformed to logs prior to statistical analysis. Acceptable results are those that are within the interval defined by the mean plus the or minus two standard deviations or with the 99% confidence limits as set by the mean, standard deviation, and set size *(n)* for their respective data for all other analytes.

If a microbiological laboratory fails a PT study they must notify the DWLCP immediately, determine the cause of the failure, and submit a corrective action response to the CM within 30 days of the PT failure. The laboratory must also order a supplemental PT study to verify they are still able to successfully analyze samples for compliance. **If a microbiological laboratory fails two consecutive studies, they must pass two consecutive studies to remain in compliance and must meet the requirements of the initial accreditation.**

Failure to analyze the PT sample within the acceptance limits specified in the regulations, or within policy described by their CA may be grounds for downgrading, revoking, or denying certification status by the DWLCP.

2.9.2 Analytical Methodology

Laboratories must use the methods specified in the drinking water regulations under 40 CFR Part 141. Laboratories must ensure that methods used will produce results which meet the Detection Limit (DL) for each analyte as specified under section 2.54.

Failure to use the correct methods or meet the DL may be grounds for downgrading, revoking, or denying certification status by the DWLCP.

2.9.3 Reporting and Notification

Laboratories must provide a copy of all sample results to the submitter/client within ten (10)

working days from the completion of the analyses. Electronic reports of analytical results and data elements must be provided in a format that will upload effectively into the DWB SDWIS database, or current database of record in accordance with the terms and conditions specified by DWB. In the event that the DWB database is upgraded or changed to meet requirements set forth by DWB or EPA, the laboratory will be provided training by DWB to modify the data elements as needed to complete an updated method of data transfer.

Results obtained from a subcontracted-laboratory must indicate their NM laboratory ID# number (as listed in SDWIS) on the report. Primary laboratories must provide Chain of Custody (COC) from subcontracted laboratory as required by DWLCP. Laboratories are not permitted to subcontract out samples unless they have completed the *DWLCP Subcontracted Laboratory Request Form* and received approval from the CM or CA.

Immediate notification, within 12-24 hours, to the submitter/client is required for the following circumstances:

- Any Total Coliform (TC) or *E. coli* positive result (12 hours)
- Any organic sample result that is identified at the DL as specified under 40 CFR 141.24(f)(11) or (h)(18) or greater (24 hours),
- any inorganic sample result that is identified at ½ of the MCL as specified under 40 CFR 141.23(a)(4)(i) or greater (24 hours), or
- any Radiological sample result that is identified at ½ of the MCL or greater as specified under 40 CFR 141.66 (24 Hours),
- Any sample that is rejected by the laboratory for not meeting the submission criteria for which analysis is being requested (i.e. leaking, frozen, temperature exceedance, hold time exceedance, etc.) must be reported to the water system and the DWB, or EPA (or the EPA designate) (24 hours), or
- 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 (24 hours).

Failure to properly report or notify sample results may be grounds for downgrading or revoking certification status by the DWLCP.

2.9.4 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).

Failure to maintain a contact log may be grounds for downgrading or revoking certification status by the DWLCP.

2.9.5 Notification of the CM of major changes

Certified laboratories must notify the CM, 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 CM should discuss the situation with the laboratory supervisor and establish a schedule for the laboratory to address major changes. If the CM determines that the laboratory can no longer produce valid data, the CM should follow the procedure for revocation of certification.

Failure to notify the CM of a major change that impacts or has the potential to significantly impact data quality may be grounds for downgrading or revoking certification status by the DWLCP.

2.9.6 Onsite Audits

The CM should be satisfied that a laboratory is maintaining the required standard of quality for certification. Normally, this should be based on a recommendation from an onsite audit. However, if the laboratory undergoes a major change, or repeatedly fails a PT sample or other unknown test sample, the CM should consider conducting an onsite audit before the period has expired.

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

The regulations governing certification (40 CFR141.28) 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). An onsite audit is not required for these analytes. Approved methodologies must be used, and successful annual PT results will only be required upon request as a Quality Control (QC) check for these analytes.

Subsequent audits may be initiated by the CA, CM, CO, or the laboratory. If initiated by the CA, CM 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.

Following the completion of the onsite audit, the auditor will provide a report to the laboratory identifying any findings or documenting a successful onsite audit. The laboratory will have thirty (30) days to respond to the SLD CO to any findings, in writing, specifying what immediate

corrective actions are being taken and what proposed corrective actions will occur. The SLD CO will consider the adequacy of the response. If the response and accompanying documentation appropriately address the findings, the SLD CO will provide notification to the laboratory and CM of the successful onsite audit.

If the response does not address the findings, or lacks the appropriate documentation, or no response is received within the thirty (30) day time limit, then the laboratory and CM will be notified by the SLD CO of the audit failure.

A failed audit may be grounds for downgrading, revoking, or denying certification status by the DWLCP.

2.10 CHANGE OF LABORATORY OWNERSHIP OR LOCATION

Certification may be transferred when the legal status, ownership, or location of a certified laboratory changes without affecting its staff, equipment, or organization. Any change in ownership and/ or location of a certified laboratory must be reported in writing to DWLCP within thirty (30) days of the change. The CM may require an onsite audit to verify impacts of such changes on laboratory performance.

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

- 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

- 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.

- 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.

- 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.

2.11 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 include:

- Failure to submit an accurate and complete 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 (or as required by accrediting authority);
- Failure to successfully upload data to SDWIS or current database of record;
- Failure to maintain capabilities or credentials necessary to provide data uploads as required by regulatory changes;
- Failure to respond to an onsite 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 onsite audit(s);
- Misrepresentation of any fact pertinent to receiving or maintaining certification;
- Denial of entry during normal business hours for an onsite audit as required.

If the laboratory is not successful in addressing 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, as applicable, incurred as part of the initial application.

DWLCP reserves the right 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 laboratories to meet the SDWA compliance analysis demand for any particular analyte.

2.12 CRITERIA AND PROCEDURES TO DOWNGRADE/ REVOKE CERTIFICATION STATUS

The following sections provide information on the criteria and procedures for downgrading or revoking certification status.

2.12.1 Criteria for downgrading certification

A laboratory should be downgraded to "provisionally certified" status for an analyte group for any of the following reasons:

- Failure to analyze a PT sample at least annually (or at an increased frequency as required by their accrediting body) 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 for any analyte within the group; (note: Failure to meet required frequency is regarded as a failed PT study).
- Failure of a certified laboratory to notify the CM within 30 days of major changes (e.g.,

in personnel, equipment, or laboratory ownership/location);

- Failure to maintain the required standard of quality, based upon a[n] EPA (or other DWLCP approved) onsite evaluation.
- Failure to report or notify submitter/client (SDWIS database and hard copy) in a timely manner and in accordance with the requirements specified in Section 2.9.3, *Sample Reporting and Notification*, thereby preventing or delaying determination of compliance with Federal or State regulations and potentially endangering public health.
- Failure to respond to the CO and CM within thirty (30) days of receiving an onsite audit report with findings/deviations.
- Failure to analyze samples to the required DL as specified in 40 CFR 141 for each analyte for which the laboratory is certified.
- Failure to implement the procedures and requirements of this Guidance Manual, as well as all requirements included in the Appendices.

2.12.2 Procedures for downgrading certification:

If a laboratory is subject to downgrading on the basis of the above criteria, the CA must notify the Laboratory Director, Quality Assurance Officer, 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 official should review the problems cited and, within fourteen (14) 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 of its certification status within fourteen (14) days of receipt of its response. The CM should follow up to ensure that corrective actions have been implemented.

If a laboratory fails to analyze a PT sample/study within the acceptance limits, the CA should not downgrade certification if the laboratory identifies and corrects the problem to the CM's satisfaction within 30 days of being notified of the failure. If, after a review of the submitted information, the CM determines that the laboratory need not be downgraded, then within 14 days of this decision, the CM should notify the laboratory that it is required to analyze another PT, if applicable. 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 (l4) 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 as described in Appendix A. During any phase of this procedure, a laboratory may request that the EPA or State provide technical assistance to help identify and resolve any problems.

After the CM 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 thirty (30) days. 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 CA, 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.

2.12.3 Criteria for revoking certification

A laboratory shall be downgraded from certified, provisionally certified, or interim certified status to "not certified" for a particular analyte or group of analytes 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;
- Failure by a provisionally certified laboratory to successfully analyze a PT study for a particular analyte within the acceptance limits specified;
- Failure by a provisionally certified laboratory to correct/address deviations/findings identified during the onsite evaluations;
- Persistent failure by a provisionally certified laboratory to report or notify the client/submitter according to the requirements specified in Section 2.9.3 *Sample Reporting and Notification*.
- Refusal to participate in an onsite evaluation.

2.12.4 Procedures for revocation and denial of certification:

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 fourteen (14) 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 fourteen (14) 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 fourteen (14) days of the reevaluation.

2.12.5 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 findings/deficiencies which produced provisionally certified status or revocation, have been corrected. This may include an onsite evaluation, successful PT study or any other measure the CM deems appropriate.

PART THREE: CERTIFICATION EVALUATION

Laboratories performing analysis of drinking water under the SDWA are required to operate a formal Quality Control program. Laboratories should also have a formal Quality Management system documented and fully implemented. Programs that operate in accordance with International Organization for Standardization (ISO) 9001, particularly ISO/IEC 17025 (*General Requirements for the Competence of Testing and Calibration Laboratories*), are encouraged. ISO/IEC 17025 includes both quality management requirements (based on ISO 9001) and several technical requirements specific for testing and calibration laboratories. ISO documents can be purchased from ISO (www.iso.org) or through other organizations, such as the American National Standards Institute (ANSI) (www.ansi.org). In the Unites States of America (USA), ANSI is the ISO member body and ANSI-ASQ National Accreditation Board (ANAB) is the accreditation body for management systems. Numerous organizations can issue third-party laboratory accreditation according to ISO 17025.

The NELAC Institute (TNI) (www.nelac-institute.org), formerly known as the National Environmental Laboratory Accreditation Conference (NELAC), implements an accreditation program with a Quality Management approach that is based on ISO/IEC 17025; the TNI program has also integrated SWDA-based requirements from the drinking water program into its standards.

The Certification approval is dependent on an evaluation of information gathered through the application packet, the onsite 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*, 5th Ed. (81 5-R-05-004, January 2005). The SLD Microbiology Onsite Audit Manual will also provide detailed expectations of the onsite audit portion of the certification review for microbiological labs in New Mexico.

The following sections describe the criteria used to evaluate a drinking water laboratory certification application.

3.1 PERSONNEL

3.1.1 Education and Experience

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.
The following table summarizes the required education and experience requirements for Chemistry laboratory personnel:

CHEMICAL LABORATORY PERSONNEL REQUIREMENTS			
Personnel	**Education**	**Experience**	**Responsibilities**
Laboratory Supervisor	Bachelor's degree in Chemistry or equivalent	Minimum one year analyzing drinking water samples; working knowledge of quality assurance principles	Ensure all laboratory personnel have demonstrated ability to satisfactorily perform the analyses to which they are assigned and that all data meet QA and regulatory requirements
Laboratory Analyst	Bachelor's degree in Chemistry or equivalent	Minimum one year analyzing drinking water samples; specialized training for analytical equipment or apprenticeship with experienced analyst (data must be reviewed and validated by qualified analyst or supervisor until training requirements are met)	Adhere to required QC procedures according to the Laboratory's QA Plan
Technician	High school diploma or equivalent	Completion of method training program under experienced analysts and six months of analyzing drinking water samples	Adhere to required QC procedures according to the Laboratory's QA Plan

The following table summarizes the required education and experience requirements for Microbiology laboratory personnel:

MICROBIOLOGICAL LABORATORY PERSONNEL REQUIREMENTS			
Personnel	**Education**	**Experience**	**Responsibilities**
Laboratory Supervisor/ Consultant (Consultant must be accepted by CA)	Bachelor's degree in microbiology, biology, or equivalent; if not microbiology, then at least one college-level microbiology laboratory course that covered environmental microbiology;	Minimum two weeks training at federal or state agency or academic institution in microbiological analysis of drinking water or 80 hours of on-the-job training in water microbiology at a certified laboratory or other training acceptable to the CA	Ensure all laboratory personnel have demonstrated ability to satisfactorily perform the analyses to which they are assigned and that all data meet QA and regulatory requirements
Laboratory Analyst	High school diploma or equivalent	Minimum three months bench experience in water, milk, or food microbiology and training acceptable to CA in microbiological analysis of drinking water and minimum 30 days on-the-job training in drinking water microbiology under an experienced analyst	Demonstrate acceptable results on unknown samples

3.1.2 Waiver of Academic Training

The CA may waive the need for the above specified academic training, on a case-by-case basis, for highly experienced analysts. The CA may also waive the need for the above specified training, on a case-by case basis, for supervisors of laboratories associated with drinking water systems that only analyze samples from that system. If such a waiver for supervisor training is granted, the CA will prepare a written and signed justification for such a waiver and have it available for inspection. Laboratories must also keep a copy of the waiver.

For New Mexico microbiological laboratories the EPA certified laboratory SLD auditor will evaluate the academic training and experience of the laboratory staff during the onsite audit. If a waiver is deemed appropriate the audit report serves as the written waiver.

3.1.3 Personnel Records

Personnel records that include academic background, specialized training courses completed, and types of analyses conducted must be maintained for all laboratory personnel.

3.2 LABORATORY FACILITIES

Facilities must meet all requirements so that the integrity and security of samples collected are maintained. Facilities should be clean, climate controlled, well-lit and adhere to all applicable Occupational Safety and Health Administration (OSHA) standards.

3.3 LABORATORY EQUIPMENT, INSTRUMENTATION AND SUPPLIES

The laboratory must have all equipment, instrumentation and supplies needed to perform the approved methods for which certification has been requested. All equipment must be available, maintained, and calibrated as required. Chemicals, reagents, and glassware preparation must meet all requirements for use, storage, and disposal.

3.4 GENERAL LABORATORY PRACTICES

Safety criteria are not covered by the DWLCP, all laboratories should follow a documented Health and Safety Plan in their common practices, and ensure personnel are trained on these practices. Each laboratory should follow personal protection guidelines as appropriate. Safety Data Sheets should be available for all hazardous materials maintained on laboratory premises.

3.5 ANALYTICAL METHODS

All laboratories should use methods specified by EPA SDWA, 40 CFR 141.21-141.30, 141.40-42, methods specified by NMED, or the most current EPA approved method(s). Official methods may include EPA approved alternate analytical techniques as approved by the CA.

3.6 CHAIN-OF-CUSTODY (COC)

Certified laboratories must use an adequate COC procedure which would allow for the legal documentation and defensibility of a sample. The procedure used should be documented.

Samples must be submitted with sample collector's signature and Utility Operator Certification Identification Number (if applicable, required for compliance samples), using a request form that meets all the reporting information requirements and is approved or issued by the CA, and which includes full COC documentation.

Laboratories should ensure all samples have sufficient information to process the sample and upload the results into SDWIS or the current database of record before analysis. The laboratory must attempt to obtain complete sample information from the sample collector to process and

upload the sample. If the laboratory is unable to contact the sample collector, the sample will be rejected. The submitting sample collector must be notified of the rejected sample within 24 hours of rejection.

3.7 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 laboratory and must meet method and regulatory requirements. The laboratory must document a sample rejection procedure and adhere to sample collection and transport requirements. Sample request form documentation must meet requirements to preserve the legal defensibility of all compliance data reported and must be approved by the CA. All accepted samples must have a complete COC and be delivered in a sealed cooler(s) or individual sample container(s); however, samples can be accepted without custody seals, provided that this is noted on the COC.

Sample temperatures should be noted upon receipt. Samples that arrive at the laboratory within 24 hours of sample collection may not yet have reached the appropriate temperature by the time they arrive at the laboratory due to the proximity of a public water system to the laboratory. These samples should be considered acceptable ONLY if packed on ice or with frozen gel/ice packs immediately after sample collection and hence, delivered while the samples were in the process of reaching an appropriate equilibrium temperature.

NOTE FOR MICROBIOLOGICAL SAMPLES*: The time from sample collection to placement of the sample in the incubator (i.e. the 'holding time') for total coliforms and fecal coliforms in surface water sources, and heterotrophic bacteria in drinking water, must not exceed eight hours for samples being analyzed in compliance with the Surface Water Treatment Rule (40 CFR 141.74(a)(1)). Per 40 CFR 141.704, for surface water E. coli samples being analyzed in compliance with the Long Term 2 (LT2) rule, the holding time for the sample must not exceed 30 hours, unless an exception is granted by the State. The State may approve, on a case-by-case basis, the holding of an LT2 E. coli sample for up to 48 hours if the State determines that analyzing the sample within 30 hours is not feasible.*

3.8 RECORDS AND DATA REPORTING

Legally defensible data is 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 SDWIS or the current database of record successfully to analyze drinking water samples in NM. All laboratory records associated with certification parameters shall be maintained for five years. For more information regarding data reporting, see *Section 2.5 Electronic Reporting Requirements* and *Section 2.9.3 Sample Reporting and Notification*.

3.9 NONCOMPLIANT LABORATORY RESULTS

All laboratories are required to report noncompliant sample results to the client/submitter within 24 hours.

3.10 QUALITY ASSURANCE/QUALITY CONTROL

All certified laboratories are required to document a QA Manual/Plan to ensure that routinely generated analytical data are scientifically valid and defensible and are of known and acceptable precision and accuracy. It is the responsibility of the laboratory's QA Manager to maintain the plan and ensure laboratory personnel are provided a current version. QA Manuals/Plans describing all QC procedures must be submitted with the certification application. Any specific QC information such as 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 onsite audit.

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. I A2).

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

The following items should be addressed in each QA Manual/Plan:

1. Laboratory organization and responsibility
    a. include a chart or table showing the laboratory organization and lines of responsibility, including QA Officers;
    b. list the key individuals who are responsible for ensuring the production of valid measurements and the routine assessment of measurement systems for precision and accuracy (e.g., who is responsible for internal audits and reviews of the implementation of the plan and its requirements);
    c. reference the job descriptions of the personnel and describe training to keep personnel updated on regulations and methodology, and document that laboratory personnel have demonstrated proficiency for the methods they perform.
2. Process used to identify clients' Data Quality Objectives
3. SOPs with dates of last revision
    a. maintain SOPs that accurately reflect all phases of current laboratory activities

b. keep a list of SOPs;
c. ensure that current copies of SOPs are in the laboratory and in the QA Officer's files;
d. ensure that SOPs are reviewed annually and revised as changes are made;
e. ensure that SOPs have signature pages and revisions dated.

4. Field sampling procedures
    a. describe the process used to identify sample collectors, sampling procedures and locations, required preservation, proper containers, correct sample container cleaning procedures, sample holding times from collection to analysis, and sample shipping and storage conditions;
    b. ensure that appropriate forms are legibly filled out in indelible ink or hard copies of electronic data are available. See Chapters IV, V, and VI for specific items to be included;
    c. describe how samples are checked when they arrive for proper containers and temperature and how samples are checked for proper preservation (e.g., pH, chlorine residual) before analysis;
    d. ensure that sampling protocol is written and available to samplers.
5. Laboratory sample receipt and handling procedures
    a. bound laboratory notebooks, if used, should be filled out in ink; entries dated and signed (A secure, password protected, electronic data base is acceptable);
    b. store unprocessed and processed samples at the proper temperature, isolated from laboratory contaminants;
    c. standards and highly contaminated samples and, sometimes, each other; holding times may not be exceeded;
    d. maintain integrity of all samples, (e.g., by tracking samples from receipt by laboratory through analysis to disposal);
    e. require Chain-of-Custody procedures for samples likely to be the basis for an enforcement action;
    f. specify criteria for rejection of samples which do not meet shipping, holding time and/or preservation;
    g. requirements and procedures for notification of sample originators.
6. Instrument calibration procedures (may reference SOP)
    a. specify type of calibration used for each method and frequency of use;
    b. describe calibration standards' source, age, storage, labeling;
    c. perform data comparability checks;
    d. use control charts and for radiochemistry, report counting errors with their confidence levels.
7. Analytical procedures (may reference SOP)
    a. cite complete method manual;
    b. describe quality control procedures required by the methods that need to be followed.

8. Data reduction, validation, reporting, and verification (may reference SOP)
    a. describe data reduction process: method of conversion of raw data to mg/L, picocuries/L, coliforms/100 mL, etc.;
    b. describe data validation process;
    c. describe reporting procedures, include procedures and format;
    d. describe data verification process;
    e. for radiochemistry, describe reporting of counting uncertainties and confidence levels;
    f. describe procedure for data corrections.
9. Types of quality control (QC) checks and the frequency of their use (may reference SOP)
    a. Parameters for chemistry and radiochemistry should include or reference:
        i. instrument performance check standards;
        ii. frequency and acceptability of method detection limit (MDL) calculations;
        iii. frequency and acceptability of demonstration of low level capability;
        iv. calibration, internal and surrogate standards;
        v. laboratory reagent blank, field reagent blank and trip blank;
        vi. field and laboratory matrix replicates;
        vii. quality control and proficiency testing samples;
        viii. laboratory fortified blank and laboratory fortified sample matrix replicates;
        ix. initial demonstration of method capability;
        x. use of control charts;
        xi. qualitative identification/confirmation of contaminants.
    b. Parameters for microbiology should include or reference:
        i. positive and negative culture controls;
        ii. confirmation/verification of presumptive total coliform positive samples;
        iii. sterility controls;
        iv. proficiency testing and quality control samples.
10. Lists of internal and external system and data quality audits and inter laboratory comparisons (may reference SOP)
11. Preventative maintenance procedures and schedules
    a. describe location of instrument manuals and schedules and documentation of routine equipment maintenance;
    b. describe availability of instrument spare parts in the laboratory;
    c. list any maintenance contracts in place.
12. Corrective action contingencies
    a. describe response to obtaining unacceptable results from analysis of PT samples and from internal QC checks;
    b. name persons responsible for the various corrective actions;
    c. describe how corrective actions taken are documented.
13. Record Keeping Procedures
    a. describe procedures and documentation of those procedures;
    b. list length of storage, media type (electronic or hard copy);

c. describe security policy of electronic databases;
d. all electronic data should have software support, so it may be regenerated.

If an item is not relevant, the QA Manual/Plan should state this and provide a brief explanation. A laboratory QA Manual/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.

3.11 LABORATORY ETHICS AND FRAUD DETECTION/DETERRENCE

Laboratories are encouraged to have an ethics policy and implement a fraud detection and deterrence policy/program, including use of the following, as appropriate:

- Use data validation and verification techniques; and
- Use analyst notation and sign-off on manual integration changes to data.

Four key areas of concern include:

- Inappropriate procedure: A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable.
- Laboratory fraud: The deliberate falsification during reporting of analytical and quality assurance results that failed method and contractual requirements to make them appear to have passed requirements.
- Data quality: The degree of acceptability or utility of data for a particular purpose – in this case, reporting public drinking water sample information.
- Laboratory integrity: The laboratory's meeting general standards of objectivity, data quality, and ethical behavior, thus reporting accurate, complete, and valid information.

It is unlawful to knowingly provide false information related to a public water systems and material to the protection of public health. Doing so could result in misdemeanor charges.

If a laboratory employee suspects that fraudulent behavior is occurring, they should report it to the DWLCP CA. COs should familiarize themselves with their State and/or Regional reporting procedures and follow them upon becoming aware of suspected fraudulent behavior. EPA's Office of Enforcement and Compliance Assurance (OECA) may also be used as a resource (www.epa.gov/compliance/complaints/index.html) for questions and concerns related to suspected fraud.

Laboratories are particularly encouraged to become familiar with the following prohibited practices:

- Fabrication, falsification, or misrepresentation of data;
- Improper clock setting (time traveling) or improper date/time recording;
- Unwarranted manipulation of samples, software, or analytical conditions;

- Misrepresenting or misreporting QC samples;
- Improper calibrations;
- Concealing a known analytical or sample problem;
- Concealing a known improper or unethical behavior or action; and
- Failing to report the occurrence of a prohibited practice or known improper or unethical act.