DRINKING WATER BUREAU

Drinking Water Laboratory Certification Program Guidance Manual

Revision 5.0 Effective: June 5, 2023

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.

Approvals

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Revision History Table

Revision #	Revision Date	Revised By	Reason for Revision
5.0	June 2023	Bethany Anderson	Return document to original pre 2021 format. Remove the MDL submission requirement. Specify individual SOPs that are to be submitted to the DWLCP. Add DWLCP certificate signatory authority for DWB Chief.
4.0	11/1/2021	Diane Van Hoy	Annual Revision
3.0	1/1/2020	Bethany Anderson	Annual Revision

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Acronyms
A2LA: American Association for Laboratory Accreditation
CA: Certification Authority
CFR: Code of Federal Regulations
CM: Certification Manager
CO: Certification Officer
COC: Chain-of-Custody
DL: Detection Limit
DOH: Department of Health
DWB: Drinking Water Bureau
DWLCP: Drinking Water Lab Certification Program
EPA: Environmental Protection Agency
HM: Heavy Metals
ISO\IEC: Internal Organization for Standardization/International Electrotechnical Commission
MCL: Maximum Contaminant Level
MPA: Microscopic Particulate Analysis
NELAC: National Environmental Laboratory Accreditation Conference
NELAP: National Environmental Laboratory Accreditation Program
NPDWR: National Primary Drinking Water Regulations
NM: New Mexico
NMAC: New Mexico Administrative Code
NMED: New Mexico Environment Department
OSHA: Occupational Safety and Health Administration
PAA: Primary Accrediting Authority
PT: Proficiency Test
QA: Quality Assurance
QAP: Quality Assurance Plan
QC: Quality Control
RAD: Radiological
SDWA: Safe Drinking Water Act
SDWIS: Safe Drinking Water Information System

SLD: Scientific Laboratory Division
SOC: Synthetic Organic Compound
SOP: Standard Operating Procedure
SUVA: Specific Ultraviolet Absorption
TOC: Total Organic Carbon
TNI: The NELAC Institute
VOC: Volatile Organic Compound
WCF: Water Conservation Fund

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 NMAC 20.7.10, and federal regulations 40 CFR 141-143.

The specific program goals ensure that all laboratories certified to test drinking water in New Mexico (NM) adhere to quality assurance procedures and meet all Environmental Protection Agency (EPA) standards throughout the 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.

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 and National Primary Drinking Water Regulations (NPDWR). This includes the designation by the State of a laboratory certification officer, or officers, certified by EPA to perform onsite audits.

As a condition of primary enforcement responsibility, 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).

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 for compliance with SDWA. DWB also 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.

1.3 ORGANIZATION

Certification Authority (CA): The DWB Water Conservation Fund (WCF) Manager currently acts as the CA and is responsible for oversight of the DWLCP in its entirety. This includes final certification document review. After reviewing the certification letter and the scope of accreditation the CA creates and signs the Drinking Water Laboratory Certification Program (DWLCP) certificate. The DWLCP certificate is then submitted to the Drinking Water Bureau Chief for their review and signature of approval. The CA also addresses laboratory issues, downgrades, and due process appeals. This position is not required to be certified by EPA.

Certification Manager (CM): The DWB Quality Assurance Coordinator currently acts as the CM and is responsible for administrative support to the CA. This includes application processing and record keeping for all laboratory certifications. This position is not required to be certified by EPA.

Certified Officers (CO): DWB has a third-party contract with EPA certified COs 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, DWB only certifies microbiological laboratories in New Mexico through this process. Asbestos, Chemical, and Microscopic Particulate Analysis (MPA) labs are certified through reciprocity.

1.4 DRINKING WATER LABORATORIES

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

1.5 LABORATORY CATAGORIES AND CERTIFICATION TYPES

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

Laboratory Categories:

- Chemical and Asbestos Labs: Test for analytes including asbestos, heavy metals, Synthetic Organic Compounds (SOCs), Volatile Organic Compounds (VOCs), radiologicals, disinfection byproducts, etc. For a full list see Appendix A. Certification for asbestos and chemical labs is currently only issued based on reciprocity.

- Microbiological Labs: Test for the presence and/or quantity of total coliforms and E. *coli*. Microbiological labs typically have the NM DWLCP as their Primary Accrediting Authority (PAA); however, they may also be certified through reciprocity.

- Microscopic Particulate Analysis Labs: Test for the presence and/or quantity of cryptosporidium and giardia. Certificates for MPA labs are currently issued through reciprocity.

Certification Types:

- 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 deficiencies but demonstrates its ability to consistently produce valid data within the acceptance limits specified in the NPDWR and within the policy required by the 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.

- 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 certification with DWLCP, a laboratory must make the request in writing for those parameters and methods for which it seeks to be certified using the application form included as Appendix A**.** The request must be signed by a laboratory official, such as the Laboratory Director or Quality Assurance Officer, and sent with all applicable supporting documents by email to NMENV-DWBlabcert@state.nm.us.

The certification process begins when a laboratory official makes a formal request via the DWLCP application to be certified. This application may be one of the following:

- New: Request for the first-time certification for regulated chemical analytes or microbiological contaminants;
- Amendment: Request for certification to analyze additional, or newly regulated contaminant groups;

- Renewal: Request to re-certify a current certification before it expires;
- Reciprocity: Can be used in combination with one of the other three types. Reciprocity certifications require the laboratory to be certified by either EPA, American Association for Laboratory Accreditation (A2LA), or The NELAC Institute (TNI).

An email notification of receipt will be provided within five (5) days for all applications submitted. If any additional information is needed to process the application during the initial review the applicant will be notified within fifteen (15) days. As the CM performs a more in-depth review of the supporting documentation, they may request further documents or clarification.

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.

Certification renewal applications, along with all supporting documentation, should be submitted ***at least*** ninety (90) days prior to certification expiration to allow enough time for the review and approval process. This also allows for the CM to complete their initial review of all documents within fifteen (15) days.

The certification renewal process shall be completed no later than two (2) weeks following the expiration date of the laboratory's primary certification. This is to allow time for the lab's PAA to provide them with their new certification.

New Mexico microbiological laboratories not requesting a reciprocity certification 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.

2.1 APPLICATION REQUIREMENTS

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

2.1.1 Completed certification application which consists of the following:

- Date the application is submitted;

- Type of application;
- Legal Name, ID#, lab type, and contact information for the lab owner;
- Lab's primary/secondary accrediting authority;
- Date of lab's last onsite audit by the primary/secondary accrediting authority;
- Signatures of the Laboratory Director and QA Officer attesting that all personnel have the appropriate education/training;

  NOTE: The QA Officer should not be the Laboratory Director and should be separate from the analytical group they are responsible for overseeing. However, the exception is for smaller laboratories that do not have sufficient personnel to separate these duties.

- List of technical personnel including the test methods they perform;
- List of approved analytical methods and analytes the lab wishes to be certified for;
- Analytical methods must appear on the PAA scope of accreditation for the lab's primary/secondary certification;
- Major instrument list-May make a reference to QAP or attach a separate document, must include all major equipment used for method(s) requested;
- Signatures acknowledging the requirements for PT studies;
- Signatures that the lab has not made any false statements;
- Date that the lab demonstrated capability to upload data to SDWIS;

  NOTE: This is done through a practice upload of test data. Analytical data does not have to be real results. This demonstration only needs to be performed once and it must be performed successfully for each analyte for which certification is requested. (Not applicable to MPA laboratories.) For instructions on how to sign up for DWB's SDWIS application known as LabToState see Appendix I.

- Copy of the lab's current primary/secondary certification and scope of accreditation;
- Current resumes for the lab director, supervisors, and QA Officer listed in the application.

2.1.2 Audit documentation

- For chemical/MPA labs this includes the audit report, any corrective action reports requested by the auditor, and an audit closure letter or some form of proof that the auditor is satisfied with the corrective action report and has officially closed the audit. In some cases, this may be the new PAA certificate, certification letter, and scope of accreditation.

- For NM microbiological labs this includes the SLD audit report, or proof that an

audit has been scheduled. SLD will send the audit report directly to NMED if the audit report is not ready at the time of application. If any deficiencies are found during the audit the lab must submit a separate corrective action report for each deficiency within thirty (30) days of receiving the audit report. If the corrective action report does not address the findings or is not received within the thirty-day limit it may constitute grounds for downgrading, revoking, or denying certification status by the DWLCP. The CM assists the labs with the CAR.

2.1.3 The laboratory's current Quality Assurance Plan (QAP): All certified laboratories are required to have a documented QAP to ensure that routinely generated analytical data are scientifically valid, legally defensible, and are of known and acceptable precision and accuracy.

2.1.4 Applicable Standard Operating Procedures (SOPs) which will include the following:

- SOPs for each of the requested analytical methods;
- Sample Receipt and Login SOP (May be included in QAP);
- Subcontracting SOP (Only if requesting to subcontract, may be included in QAP);
- Document/Records Control SOP (May be included in QAP);
- Data Validation SOP (May be included in QAP);
- Also include a list of SOPs, either in the QAP, or as a separate document.

The QAP and SOPs must have some form of approval signature, date, and revision number. Electronic signatures and tracking procedures are acceptable.

Per EPA requirements the QAP and all analytical method SOPs must be reviewed **annually** and should include a review/revision history table. If no revisions are made during the annual review process a master document list or form documenting the annual review took place is sufficient. If the laboratory provides documentation that an annual review took place, and no revisions were made, it is not necessary to change the date or revision number on the SOPs.

The EPA annual review criteria are **only** for the QAP and the SOPs as listed above in this section. DWLCP staff understand that your PAA may have less stringent requirements and will only be reviewing the documents relevant to your DWLCP reciprocity certification.

2.1.5 Last two sets of PT test results for all analytes/methods for which certification is being requested. Laboratories adding new analytes or analyses must submit at least two successful sets of PT sample results for analytes and methods for which certification is being requested.

2.1.6 A blank copy of the laboratory's Chain-of-Custody (COC) form(s). Laboratories must agree to accept a NM issued COC or obtain approval of their COC by 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.

2.1.7 Subcontract laboratory request forms (Appendix E) for labs requesting to subcontract NM compliance samples. You may only subcontract to labs that are certified by DWLCP.

2.2 APPLICATION FEES FOR CERTIFICATION

At this time, there are no fees required for the application review and DWLCP certification. However, accreditation/auditing services with which the laboratory chooses to do business and required PT studies will levy additional fees on the laboratory.

2.3 NEW MEXICO ONSITE AUDIT REQUEST

Microbiological laboratories in New Mexico using the DWLCP as their primary accrediting body must indicate on their applications that the onsite audit has been completed or scheduled with the SLD CO.

2.4 ELECTRONIC REPORTING REQUIREMENTS

DWLCP requires that analytical data be electronically uploaded to SDWIS, the current database of record. This ensures that compliance data may be shared quickly and accurately; internally, and externally. DWLCP requires that all laboratories certified in NM demonstrate this ability by creating and uploading a test data set to SDWIS 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 may only be performed by the laboratory personnel listed in the DWLCP application, or as notified by lab for personnel changes.

2.6 DWLCP CERTIFICATION

Laboratories approved for certification in New Mexico will receive a certificate signed by the CA and the Drinking Water Bureau Chief. It is provided as a signed and dated, (effective date and expiration date) official document containing the NMED logo. For chemical laboratories the certification also includes a scope of accreditation documenting the 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, DWLCP must be notified so the scope may be reviewed and revised as appropriate. Upon approval, a new scope of accreditation will be issued detailing the parameters of the revised certification.

2.7 USE OF DWLCP CERTIFICATION

A certified laboratory must 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 New Mexico microbiological laboratories if successful PT study results are reported annually.

2.9 MAINTAINING CERTIFICATION

In order to maintain certification, all chemical and microbiological laboratories must submit their current QAP, SOPs, and PT study results to the DWLCP CM **annually** at NMENV-DWBlabcert@state.nm.us. Chemical laboratories shall submit these documents along with their annual certification renewal application.

NM microbiological labs shall submit the QAP, SOPs, and PT study results annually based on the month the lab's DWLCP certification expires. For clarification, this includes the years when the lab does not apply for certification renewal.

Laboratories under contract with DWLCP must also submit quarterly QA reports to the CM 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. See Appendix E for a template.

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 for each analyte and method for which they are requesting 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 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. The methods listed on the laboratory's scope of accreditation 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 may be asked 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 CM at NMENV-DWBlabcert@state.nm.us. The list below is from the NELAP website https://nelac-institute.org/content/NEPTP/ptproviders.php

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 PAA's requirements and ensure those results are provided to DWLCP. Laboratories failing their PTs must correct them in accordance with their accrediting authority's requirements to avoid being downgraded or revoked by DWLCP.

NOTE: DWLCP only reviews the failed PT corrective actions for the microbiological labs in NM.

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 seven 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 seven 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 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 as described in this guidance manual, may be grounds for downgrading, revoking, or denying certification 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 these methods will produce results which meet the specified Detection Limit (DL) for each analyte.

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 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 subcontract 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 if requested by DWLCP. Laboratories are not permitted to subcontract out samples unless they have completed the *DWLCP Subcontract Laboratory Request Form* and received approval from the CM or CA.

NOTE: NM microbiological laboratories certified by DWLCP may **NOT** subcontract any samples to a secondary laboratory.

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 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 DWLCP.

2.9.4 Contact log

NM microbiological laboratories 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 DWLCP.

2.9.5 Notification of the CM of major changes

Certified laboratories must notify the CM, in writing, within thirty (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 lab director, QA officer, 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 or CA should discuss the situation with the laboratory 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 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 DWLCP.

2.9.6 Onsite Audits

The CM should be satisfied that a laboratory is maintaining the required standard of quality for certification. This is based on the results of the laboratory's onsite audits.

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, A2LA, or a qualified TNI approved third party assessor. All costs associated with an onsite audit are the responsibility of the laboratory applying for certification.

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

New Mexico Microbiological Laboratory Onsite Audit Requirements

Following the completion of the onsite audit, the SLD CO 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 CM to any deficiencies, in writing, specifying what immediate corrective actions are being taken and what proposed corrective actions will occur. The CM will consider the adequacy of the response. If the response and accompanying documentation appropriately address the findings, the CM will provide notification to the laboratory.

If the response does not address the deficiencies, or lacks the appropriate documentation, or no response is received within the thirty (30) day limit, the CM will work with the laboratory to resolve the issues.

A failed audit may be grounds for downgrading, revoking, or denying certification status by 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. An onsite audit is required 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.

2.11 CERTIFICATION DENIAL

Denial means refusal to accredit a laboratory applying for an initial certification or certification renewal. Reasons to deny a certification request include:

- Failure to submit an accurate and complete application;
- Failure to submit the appropriate supporting documentation;
- Failure to successfully analyze and report PT samples annually;
- Failure to pass required onsite audit(s);
- Misrepresentation of any fact pertinent to receiving or maintaining certification.

NOTE: 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 may 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;
- 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 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, QA Officer, or owner 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 notification, 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 CA 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 their satisfaction within thirty (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 fourteen (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 (14) days by email.

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 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 all report.

2.12.3 Criteria for revoking certification

A laboratory shall be downgraded from certified to provisionally 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 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 will notify the laboratory, by email 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 by email. 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, by email, 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 CA 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 and several technical requirements specific for testing and calibration laboratories. Numerous organizations can issue third-party laboratory accreditation according to ISO 17025.

The NELAC Institute (TNI), formerly known as the National Environmental Laboratory Accreditation Program (NELAP), 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 studies. 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 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	Adhere to required QC procedures according to the Laboratory's QA Plan

		apprenticeship with experienced analyst (data must be reviewed and validated by qualified analyst or supervisor until training requirements are met)	
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 requirements and training on a case-by-case basis. If such a waiver is granted, the CA will prepare a written and signed justification. Laboratories must keep a copy of the waiver available for review.

For New Mexico microbiological laboratories the SLD CO 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. This shall be submitted as a resume.

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 the OSHA Laboratory Standard (29 CFR 1910.1450).

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 QA requirements for use, storage, and disposal.

3.4 GENERAL LABORATORY PRACTICES

While safety criteria are not covered by the DWLCP, all laboratories should follow a documented Health and Safety Plan or Chemical Hygiene Plan in their common practices, and ensure personnel are trained on these practices. Safety Data Sheets should be available for all hazardous materials maintained on laboratory premises.

3.5 ANALYTICAL METHODS

All laboratories must use methods specified by EPA SDWA, 40 CFR 141.21-141.30, 141.40-42, or the most current EPA approved method(s).

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.

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. 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 two (2) 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 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 are 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.

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 Quality Assurance Plan (QAP) 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 Officer to maintain the plan and ensure laboratory personnel are provided a current version. Quality Assurance Plans describing all quality control procedures must be submitted with the certification application. Any specific quality control information such as quality control sample results, traceability of calibration, reference standards, calibration, support equipment, instrument calibration, and related general requirements must be assessed during onsite audits.

The laboratory QAP should be a separately prepared text. However, documentation for many of the listed QAP items may be made by reference to 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 QAP must be reviewed at least annually (EPA Order 5360. I A2).

The following items should be addressed in each QAP:

- Laboratory organization and responsibility;
- Process used to identify clients' Data Quality Objectives;
- Process for reviewing and maintaining Standard Operating Procedures;
- General document control procedures;
- Laboratory sample receipt and handling procedures;
- Instrument calibration procedures;
- Analytical procedures;
- Data reduction, validation, reporting, and verification;
- Types of quality control (QC) checks and the frequency of their use;
- Lists of internal and external system and data quality audits;
- Preventative maintenance procedures and schedules;
- Corrective action contingencies.

NOTE: Laboratories certified by the DWLCP through reciprocity are also expected to meet the requirements of their primary accrediting body.

NOTE: New Mexico microbiological labs the DWLCP has created a QAP template. To

request this template, send an email to NMENV-DWBlabcert@state.nm.us. If a section of the template is not applicable to the laboratory it may be removed, or a brief explanation may be provided to explain why it is not applicable.

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.

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.