NEW MEXICO
DEPARTMENT OF
HEALTH

Scientific Laboratory Division

Title:	New Mexico Department of Health Scientific Laboratory Division Drinking Water Testing - Chemical Parameters Laboratory Certification On-site Audit Manual
Version:	1.0
Organizational Unit:	Quality, Safety, Security, and Emergency Preparedness
Author:	Timothy Chapman

New Mexico Department of Health
Scientific Laboratory Division
Drinking Water Testing - Chemical Parameters
Laboratory Certification On-site Audit Manual

Introduction

This is the New Mexico Department of Health Scientific Laboratory Division's (SLD) Laboratory Certification On-site Audit Manual for regulated chemical contaminants in drinking water. Laboratories seeking certification through the New Mexico Environment Department's Drinking Water Bureau (DWB) are required to follow the requirements in the Drinking Water Bureau's Program Guidance Manual.

The bulk of this manual is taken from various chapters of the Environmental Protection Agency's (EPA) ***Manual for the Certification of Laboratories Analyzing Drinking Water:*** *Criteria and Procedures Quality Assurance* (EPA 815-R-05-004 January 2005). This document can be found at http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm

Entities responsible for the certification program

The Drinking Water Bureau of the New Mexico Environment Department is the entity granted primacy by EPA for ensuring public water supply systems are in compliance with the requirements of the Safe Drinking Water Act within New Mexico. As the primacy agency, the DWB has authorized the SLD to audit laboratories performing chemical analyses on drinking water samples for compliance monitoring, when required to do so. SLD staff scientists perform the role of chemical drinking water laboratory certification officers (CO). In short, EPA-certified SLD personnel are the laboratory auditors who assess a laboratory's ability to perform drinking water testing, and then issue an audit report to the DWB for review. The DWB will then make a determination, based on the audit report, on whether to grant certification to a laboratory. The DWB is the final certifying authority.

The certification authority (CA) is the person who has signature authority for all certification decisions. For the DWB Laboratory Certification Program, the CA is normally the DWB Program Manager.

On-site laboratory audit team

The SLD, in conjunction with the DWB, will establish one or more teams of COs and auditors to audit laboratories. It is the responsibility of these teams to perform the on-site laboratory audits, review the laboratory performance evaluation (PE) data, and make recommendations to the CA concerning the certification status of the laboratories.

Team members will be SLD laboratory professionals with experience in the analysis of drinking water, hold at least a bachelor's degree (or equivalent education/experience) in the discipline for which they certify, and have recent laboratory experience in the review of the analytical methods they will audit. The team members will all have successfully completed the EPA laboratory certification course.

Team members must also have experience in laboratory evaluation and quality assurance, be familiar with the drinking water regulations and data reduction and reporting techniques, be technically conversant with the analytical techniques being evaluated, and be able to communicate effectively - both orally and in writing.

Plans for the certification of laboratories

The CA should develop plans for certifying drinking water laboratories under her/his authority. Written plans will include the following:

- Documentation of the certification authority, the laboratory certification officers, and their education/experience.
- Schedules of the laboratories to be audited.
- Specific types of analyses to be examined.
- Protocols to be followed.
- Strategies for assessing laboratory performance (e.g., PEs, data audits, etc.)
- Plans for providing technical assistance to laboratories which need upgrading.

The certification process

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

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

The response to a formal application for any of the above requests should be given within 30 days. At this time a mutually agreeable date and time should be set for the on-site laboratory audit.

Subsequent audits may be initiated by the CA (or CO) or the laboratory. If initiated by the CA (or CO), the audit may be announced or unannounced. Reasonable access by the certification team must be granted during regular work days and hours.

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

Pre-evaluation procedures

The audit team leader will send a pre-audit package to the laboratory at least six weeks prior to the on-site evaluation. When the audit team leader receives the completed laboratory's pre-audit package, he/she will distribute the package to all auditors. The team leader ensures that any major problems noted in the pre-audit package are addressed during the on-site evaluation. The pre-audit package contains:

- The last on-site audit report.

- The most recent PE/proficiency test (PT) sample results, along with a copy of the instrument data package for that method.
- Checklists.
- Certification parameters/methods to be audited.
- Laboratory standard operating procedures (SOPs).
- Current method detection limits (MDLs) and an initial demonstration of capability (IDC).
- Internal audits, blinds and quality control (QC) corrective actions

Review of the analytical SOPs

Each SOP will be compared closely with the EPA-approved method from which it was derived, and the following questions will be answered:

- Does the SOP include all the required procedural steps given in the EPA-approved method?
- Does the SOP include all the mandatory quality control criteria?
- Does the SOP contain enough lab-specific detail so that a trained technician, newly employed by the lab, could follow this SOP without assistance?
- What are your overall recommendations for the SOP?
- Are the current method detection limit and the initial demonstration of capability data included in, or submitted with, the SOP?

If a CO or auditor finds that one or more SOP is severely deficient, the CO will inform the CA immediately, before completing the review, so that the CA can contact the laboratory and request a revised or improved SOP.

Review of the laboratory's QA plan

The CO and CA will review the laboratory quality assurance (QA) plan before the on-site evaluation to determine if it meets the quality control criteria given in Chapter IV of the EPA's laboratory certification manual.

Conducting the on-site evaluation

The on-site evaluation will confirm issues that were identified during the review of the SOPs, the laboratory QA plan, the PT study records and other correspondence. It will include reviews of analytical procedures, QA and QC practices, and sample handling practices. The typical on-site evaluation takes four to five consecutive days and includes the following stages, listed in chronological order:

- An initial briefing and laboratory tour.
- Interviews with the analysts, supervisors and managers.
- A review of laboratory documentation.
- A SLD CO team caucus.
- An exit briefing.

Initial briefing and laboratory tour

The team will meet briefly with the laboratory director or manager and the supervisory staff to restate the purpose of the evaluation, to finalize the schedule of events, and to answer any questions. Non-supervisory staff are included in the meeting upon the request of the laboratory director. If any team members are unfamiliar with the facility, or if significant renovations have been made since the previous evaluation, the team is given a brief tour.

Duties of each team member

The organic and inorganic COs evaluate the laboratory's performance of the drinking water methods within their respective areas of expertise. The CA along with the COs will evaluate the laboratory's QA activities. The team will evaluate the laboratory's sample handling practices starting with sample check-in, chain of custody procedures, and the qualifications of those who collect drinking water compliance samples and other program-related issues.

Because it is important that the evaluation be as thorough as possible, each team member is responsible for bringing the following documents to the evaluation:

- A checklist for the on-site evaluation of state drinking water laboratories.
- SOPs reviewed prior to the on-site evaluation.
- Appropriate EPA-approved methods.
- The SLD certification manual.
- Other documents which may be helpful, such as past PT study data, past evaluation reports, etc.

Types of certification

After a review of the PE sample results and an on-site visit, the certification authority will provide a written report within 45 days and classify the laboratory for each contaminant or group of contaminants according to the following rating scheme:

- ***Certified*** - a laboratory that meets the minimum requirements of the laboratory certification manual and all applicable regulatory requirements.
- ***Provisionally Certified*** - a laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within the acceptance limits specified in the National Primary Drinking Water Regulations, and within the policy required by their certification authority. A provisionally certified laboratory may analyze drinking water samples for compliance purposes, if the said clients are notified of its downgrade status in writing, on any report. Provisional certification may not be given if the evaluation team believes that the laboratory cannot perform an analysis within the acceptance limits specified in the regulations.
- ***Not Certified*** - a laboratory that possesses major deficiencies and, in the opinion of the certification authority, cannot consistently produce valid data.
- ***Interim Certification*** - interim certification may be granted in certain circumstances when it is impossible or unnecessary to perform an on-site audit. Interim certification status may be granted only when the CA judges that the laboratory has the appropriate instrumentation, is using the approved methods, has adequately trained personnel to perform the analyses, and has satisfactorily analyzed PE samples, if available, for the contaminants in question. The COs should perform an on-

site audit as soon as possible but in no case later than three years. An example of a situation where this type of certification is warranted might be a laboratory that has requested certification for the analysis 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.

Drinking water laboratories

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

Other considerations for laboratory certification

Laboratory Personnel
The laboratory should have sufficient supervisory and other personnel, with the necessary education, training, technical knowledge and experience for their assigned functions.

Laboratory director/manager or technical director
The laboratory director/manager should be a qualified professional with the technical education and experience and managerial capability commensurate with the size/type of the laboratory. The laboratory director/manager is ultimately responsible for ensuring that all laboratory personnel have demonstrated proficiency for their assigned functions, and that all data reported by the laboratory meet the required QA criteria and regulatory requirements.

Quality assurance officer/manager
The QA officer/manager should be independent from the laboratory management if possible, and have direct access to the highest level of management. The QA officer/manager should have a bachelor's degree in science, training in quality assurance principles commensurate with the size and sophistication of the laboratory, and at least one year of experience in a quality assurance/control environment. The QA officer/manager should have at least a working knowledge of the statistics involved in the quality control of laboratory analyses, and a basic understanding of the methods which the laboratory employs.

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

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

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

1. Laboratory organization and responsibility

- Include a chart or table showing the laboratory organization and lines of responsibility, including the QA manager.
- 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).
- Reference the job descriptions of the personnel, describe training to keep personnel updated on regulations and methodology, and document that laboratory personnel have demonstrated proficiency for the methods they perform.

2. Processes used to identify clients' data quality objectives.

SOPs with dates of last revision

- The laboratory should maintain SOPs that accurately reflect all phases of current laboratory activities.
- Keep a list of SOPs.
- Ensure that current copies of SOPs are in the laboratory and in the QA Manager's files.
- Ensure that SOPs are reviewed annually, and revised as changes are made.
- Ensure that SOPs have signature pages, and that the revisions are dated.

Field sampling procedures

- Describe the processes used to identify the sample collectors, the sampling procedures and locations, the required preservation, the proper containers, the correct sample container cleaning procedures, the sample holding times from collection to analysis, and the sample shipping and storage conditions.
- Ensure that the appropriate forms are legibly filled out in indelible ink, or hard copies of electronic data are available.
- Describe how the samples are checked when they arrive for being in the proper containers, and at the correct temperature.
- Ensure that a sampling protocol is written and available to the samplers.

Laboratory sample handling procedures

- Use laboratory note books, filled out in ink; entries dated and signed (A secure, password protected, electronic data base is acceptable).
- Store unprocessed and processed samples at the proper temperature, isolated from laboratory contaminants, standards and highly contaminated samples and, sometimes, each other; holding times may not be exceeded
- Maintain integrity of all samples, (e.g., by tracking samples from receipt by laboratory through analysis to disposal).
- Specify criteria for rejection of samples which do not meet shipping, holding time and/or preservation requirements and procedures for notification of sample originators.
- Require Chain-of Custody procedures for samples likely to be the basis for enforcement action (i.e. repeat samples).

Analytical procedures (may reference the SOP)

- Cite complete method manual.
- Describe quality control procedures required by the methods that must be followed.

Data reduction, validation, reporting and verification (may reference the SOP)

- Describe data reduction process.
- Describe data validation process.
- Describe reporting procedures, include procedures and format.
- Describe data verification process.
- Describe procedure for data corrections.

Types of QC checks and the frequency of their use.

Parameters for chemicals should include or reference:

- Traceability of standards or solvents used.
- Performance evaluation and quality control samples appropriate for the method.

List schedules of internal and external system and data quality audits and inter laboratory comparisons *(may reference SOP).*

3. Preventive maintenance procedures and schedules

- Describe the location of instrument manuals and schedules, and the documentation of routine equipment maintenance.
- Describe the availability of instrument spare parts in the laboratory.
- List any maintenance contracts in place.

4. Corrective action contingencies

- Describe the response to obtaining unacceptable results from the analysis of PE samples, and from internal QC checks.
- Name the persons responsible for the various corrective actions.
- Describe how any corrective actions taken are documented.

5. Record keeping procedures

- Describe the procedures, and the documentation of these procedures.
- List the length of storage, and the media type (electronic or hard copy).
- Describe the security policy of electronic databases.
- All electronic data should have software support so it may be regenerated.

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

Chain-of-custody procedures

Certified laboratories, when requested to process a sample for possible legal action against a supplier, should use an adequate chain-of-custody procedure. The procedure used should be documented.

Requirements for maintaining certification status

Performance Evaluation Samples

All certified drinking water laboratories **must** satisfactorily analyze PE samples to maintain certification. If the laboratory does not analyze the PE sample within the acceptance limits of time – within twelve months of the previous PE sample - then the certifying authority must follow the procedure discussed in the section entitled, "Criteria and Procedures for Downgrading/Revoking Certification Status."

If a laboratory wishes to be certified for a contaminant by more than one method, it must analyze the PE samples by each method for which it wishes to be certified. The methods listed on the laboratory's certification certificate must be the methods by which the PE samples were analyzed.

The laboratory should be able to provide documentation to the certification authority that the laboratory staff who analyze any PE sample are laboratory employees who routinely analyze drinking water compliance samples.

Methodology

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

Sample Reporting

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

Results that require immediate notification:

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

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 contact, 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).

Notification of the CA of major changes

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

On-site evaluation

The CA should be satisfied that a laboratory is maintaining the required standard of quality for certification. If the laboratory undergoes a major change, or if it fails a PE sample or other unknown test sample, the CA should consider conducting an evaluation at any time during the three-year certification period.

Response to on-site evaluation

The laboratory will have thirty (30) days to respond to the SLD CO, in writing, specifying what immediate corrective actions are being taken *and* what proposed corrective actions will occur. The SLD CO and the CA will consider the adequacy of the response. If the response and accompanying documentation correct the deviations, the laboratory will receive notification of its certification status. If the response does not address the deviations, or lacks the appropriate documentation, the laboratory will be notified of its downgraded status. If no response is received within the thirty (30) day time limit, the SLD CO will initiate the process to revoke the laboratory's certification. This section does not negate the three-month time frame specified in ***Procedures for downgrading to provisionally certified status*** below, it requires the laboratory to inform the CO of the plan and time frame required to correct deviations cited.

Criteria and Procedures for Downgrading/Revoking Certification Status

Criteria for downgrading certification status

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

- Failure to analyze a PE sample at least annually within the acceptance limits specified in the regulations.
- Failure of a certified laboratory to notify the CA within 30 days of major changes (e.g., in personnel, equipment, or laboratory location).
- Failure to satisfy the CA that the laboratory is maintaining the required standard of quality, based upon an on-site evaluation.
- Failure to respond to the CO within thirty (30) days of receiving an on-site report with deviations.
- Failure to report compliance data to the public water system or the DWB or the EPA (or EPA designate) in a timely manner, thereby preventing compliance with Federal or State regulations and endangering public health. Data, which may cause the system to exceed an MCL, should be reported as soon as possible.

Procedures for downgrading to "provisionally certified" status

If a laboratory is subject to downgrading on the basis of the above-indicated criteria, the CA must notify the laboratory director or owner (by registered or certified mail) of its intent to downgrade within fourteen (14) days from becoming aware of the situation warranting downgrading. The laboratory director/manager should review the problems cited and, within thirty (30) days of receipt of the letter, send a written response to the CA specifying what immediate corrective actions are being taken, and any proposed actions that need the concurrence of the CA. The CA should consider the adequacy of the response and notify the laboratory in writing (by registered or certified mail) of its certification status within fourteen (14) days of receipt of its response. The CA should follow up to ensure that corrective actions have been taken.

If a laboratory fails to analyze a PE or other unknown sample within the acceptance limits, the CA should not downgrade certification if the laboratory identifies and corrects the problem to the CA's satisfaction within 30 days of being notified of the failure. If, after a review of the submitted information, the CA determines that the laboratory need not be downgraded, then within 30 days of this decision, the CA should notify the laboratory that it is required to analyze another PE. If the laboratory analyzes this second unknown sample within the acceptance limits established by the State, the laboratory should not be downgraded. If the laboratory fails to analyze this second unknown sample within the established limits, the CA should downgrade the laboratory to provisionally certified status and notify the laboratory within fourteen (14) days (by registered or certified mail). Laboratories should be downgraded only for the method failed.

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

Once the CA notifies a laboratory, in writing, that it has been downgraded to provisionally certified status for procedural, administrative, equipment, or personnel deficiency, the laboratory should correct its problem within three months. If the laboratory was downgraded to provisionally certified status because of a failure to analyze a PE sample within the acceptance limits specified, the laboratory should correct its problems and satisfactorily analyze another PE sample within one month of receipt of the second PE 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.

Criteria for revoking certification status

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

- Reporting PE data from another laboratory as its own;
- Falsification of data or other deceptive practices;
- Failure to use the analytical methodology specified in the regulations;
- For provisionally certified laboratories, failure to successfully analyze a PE sample or any other unknown test sample for a particular contaminant within the acceptance limits specified;
- For provisionally certified laboratories, failure to satisfy the CA that the laboratory has corrected deviations identified during the on-site evaluations;

- For provisionally certified laboratories, persistent failure to report compliance data to the public water system or the State Drinking Water Program in a timely manner thereby preventing compliance with Federal and/or State regulations and endangering public health.
- Refusal to participate in an on-site evaluation conducted by SLD.

Procedures for revocation

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

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

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

Reinstatement of certification

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