Applying for Accreditation

ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM

Introduction

Environmental laboratories conduct analyses of our air, water, soil and other materials. Clients of environmental laboratories include municipalities, consultants, public health officials and commercial entities. Analyses performed by laboratories are often used to determine compliance status with federal, state and local regulations. These analyses have a direct effect upon human health and the environment. Therefore, laboratories must employ standardized procedures and methodologies to ensure that environmental data are reliable and accurate.

The Minnesota Department of Health Environmental Laboratory Accreditation Program (MNELAP) was established in 1989 to help ensure laboratories submit reliable and consistent data to Minnesota's various environmental programs. MNELAP offers accreditations designed to accommodate the needs of many state and federal environmental programs including testing required by the Underground Storage Tank Program, Clean Water Act, Clean Air Act, Resource Conservation and Recovery Act and the Safe Drinking Water Act.

Minnesota Statutes 144.97 and 144.98 direct the commissioner of health to establish rules for accreditation of environmental laboratories and charge fees for these services. Specifically, Minnesota Statutes 144.98 authorizes the commissioner of health to accredit laboratories that test environmental samples. The commissioner may adopt rules accrediting laboratories including standards for certificate approval, analytical methods and quality assurance methods.

Reliable technical and scientific analyses are essential for making sound decisions necessary for the protection of the environment and public health. With this in mind, MNELAP develops procedures and requirements to ensure accredited laboratories produce accurate and precise test results and oversees onsite assessments and performs assessment to monitor and enforce requirements per Minnesota Statutes 144.99. Accreditation requires the laboratory's quality systems, staff, facilities, equipment, test methods, records and reports to be evaluated using objective and measurable criteria. The 2009 Minnesota Statutes requires the commissioner to accredit laboratories against a national standard as adopted by the National Environmental Laboratory Accreditation Program (NELAP) of The NELAC Institute. Effective July 1, 2009, laboratories accredited by the department must comply with the 2003 NELAC standard or the 2009/2016 TNI Standard, the current adopted standards for NELAP. The standard is substantially equivalent to the Minnesota Rules, Chapter 4740 as adopted in October 2006.

The Accreditation Process

Accreditation of environmental laboratories typically includes four steps: application, on-site assessment, award of accreditation, and proof of ongoing proficiency. The major procedural requirements for each step are as follows:

1. **Application.** A laboratory submits an application, fees and documentation to MNELAP for review. Applications types include: initial requests for accreditation, renewal of current accreditation, requests to transfer accreditation to a new owner or new location, or requests to add fields of testing to a current accreditation. In addition, requests for reinstatement of accreditation after suspension requires the laboratory to submit an application. Accreditations may be for primary (MNELAP is the assessing body) or secondary (another NELAP AB is the assessing body and MNELAP is a reviewer) evaluation. In either case, an application and payment of fees to MNELAP are required. If the lab is seeking initial accreditation for a new lab or expanding the scope of fields of testing, an onsite assessment might be necessary prior to application. Please contact the MNELAP.
2. **On-Site Assessment.** MNELAP staff or an MNELAP approved Third Party assessor or assessment organization conducts an on-site inspection of the facility to ensure compliance with the application materials.
3. **Award of Accreditation.** An accreditation is awarded to laboratories that successfully complete the application process. The certification is officially documented with issuance of a certificate and a scope of accreditation. The accreditation consists of two parts:
    a. Base Accreditation acknowledges (on a certificate from the commissioner) that the laboratory has the policies, procedures and equipment necessary to produce reliable data, and
    b. Fields of Testing Accreditation is a list of all analyte-method-matrix-test category (fields of testing) combinations (on the scope of certification) for which the laboratory meets the minimum requirements specified in rule.
4. **Ongoing Proficiency.** Laboratories accredited by the department must continue to demonstrate the capability to produce reliable environmental data. Laboratories must implement a quality system that identifies potential areas of noncompliance. In identifying areas of risk and proposing quality controls to mitigate these risks, the laboratory's implementation of the quality system is performance-based. Should errors occur too frequently or remain undetected, the laboratory is expected to modify its processes to ensure that actions are preventive rather than solely corrective in nature. Part of the quality system must include the analysis of proficiency testing samples. Laboratories obtain and analyze standardized samples that have qualitative and quantitative values known only to the provider. The proficiency testing provider publishes the identity and concentration of the sample after a specified date thereby allowing all parties to review the accuracy of their processes. Laboratories are subject to these and other ongoing requirements to ensure that their operations are consistent with the certification rules. Failure to maintain compliance with the rules for accreditation may require enforcement action by the department. The department's enforcement actions for laboratory accreditation are guided by the principles in the Health Enforcement Consolidation Act (MN Statutes 144.99). A laboratory may appeal the department's administrative decision according to the conditions in Minnesota Rules, Chapter 4740, part 4740.2050, subpart 17.

Step 1. Application

(Minnesota Rules, Chapter 4740, part 4740.2050)

Required laboratory information

The MNELAP application process is an annual cycle. A laboratory requesting accreditation must supply demographic information (i.e. the laboratory identification, the physical address and mailing address, ownership, personnel and contact information, hours of operation, and driving directions to the facility). Because the department delivers most communications via electronic mailing, the application also requires an electronic mailing address for the primary contact person. Electronic delivery reduces paper consumption and improves timeliness of delivery.

Personnel

Designated personnel must meet the criteria in the Minnesota Rules, 4740.2050 and in 2009/2016 TNI Standard, Volume 1 Module 2. The laboratory may use the Technical Director Qualifications worksheet (ELAP-F-14) to determine if the personnel meet the minimum criteria established by the 2009/2016 TNI Standard as implemented by the MNELAP.

The laboratory must designate a quality manager (however titled) who is responsible for the data quality provisions in 2009/2016 TNI Standard, Volume 1 Module 2. The laboratory must identify the owner, the managing agent, the laboratory director and a primary contact person. The designated personnel must meet the definitions in Minnesota Rules 4740.2010 and perform the applicable responsibilities in Minnesota Rules, Chapter 4740 and the 2009/2016 TNI Standard. The laboratory may designate one person who serves all of these functions.

The national standard requires approval of the application materials by the quality manager and the laboratory director prior to the submitting the application to MNELAP for review.

Fees

With the laboratory information, the application requires payment of fees according to the amount and schedule in Minnesota Statutes 144.98. The department posts links to the laws and regulations on the MNELAP webpage. In addition, MNELAP posts an invoice worksheet to assist applicants in calculating estimated fees for the test categories of interest to their laboratory. The fee calculation sheet is provided for your information only. Your actual fee will be calculated and invoiced by MNELAP. All application fees are non-refundable and must be paid before the department initiates a technical review of the application.

The fees submitted with an initial application are prorated based on the quarter in which the application is submitted. Applications arriving in January to March pay the full annual fee; applications arriving in April to June pay 75% of the annual fee total; applications arriving in July to September pay 50% of the annual fee total. Applications arriving in October to December will pay 125% of the annual fee total in order to cover the prorated amount for the final quarter (25%) and the full annual renewal for the following year. Renewal applications are during the month of October each year. Late fees are assessed for renewal applications received on or after November 1st. All certificates expire on December 31st of each year.

Electronic payments made by credit cards will incur a processing fee that will be clearly displayed at the time of payment. Electronic payments made by ACH/debit do not incur a fee.

Documents

Applicants must submit an electronic copy (.pdf only) of required documents to the department at the time the laboratory applies. The electronic documents will be uploaded by the applicant into an electronic system and the files must be less than 15MB in size. The department will accept other modes of delivery with prior notification. Please contact the MNELAP at 651-201-5200 (TTY: 651-201-5897) if you require alternate arrangements for application.

Minnesota Rules, Chapter 4740, part 4740.2050 lists the required documents for application. The documents include: a quality manual, a laboratory procedures manual, and a list of the detection and reporting limits for each field of testing requested. The documents must meet the minimum requirements in 2009/2016 TNI Standard, Volume 1 Module 2. Templates for the manuals are on the program's website under the Tools and Resources link.

Initial applicants to the program must submit two successfully completed proficiency testing sample results with the application form. Initial applications must include two passing proficiency tests with no more than three studies attempted within18 months of the application date. The acceptable results must be from analyses performed at least fifteen calendar days apart from the closing date of one study to the shipment date of the second study. The analysis date of the most recent PT analysis is to be within 6 months prior to the date that the laboratory applies for the applicable accreditation.

Expected review timeline

The department does not review applications until the laboratory delivers all information, fees and documents. The estimated time to review a completed application and documentation is between 60 and 90 days. The review time depends on the requested scope of tests and the organization, clarity, and completeness of the materials submitted with the application. Timely responses to an MNELAP assessor's requests for additional information will significantly reduce the turnaround times.

Within 90 days, the technical review will be completed and the MNELAP will issue a report of deficiencies, if any. The laboratory must correct the errors and omissions in the application packet within 15 days of receiving the notice of deficiencies. The response time is brief because laboratories must ensure compliance with Minnesota laws and regulations prior to initiating the application process. Therefore, the laboratory is expected to supply documentation unintentionally omitted rather than develop new documents for compliance. If the application packet must be returned a second time for incompleteness or inadequacy, the laboratory will be required to begin the process over and pay a new application fee.

Restricted access to the application form

The online application form is designed to restrict access to authorized persons only. Authorization to use the system is automated through the initial log-in screens on the MNELAP webpage. MNELAP will verify all requests for access with the managing agent of the laboratory

prior to authorizing new users. The laboratory is responsible for notifying MNELAP if user approvals should be removed from the system due to changes in authority or employment with the laboratory.

In addition to personnel restrictions, the system restricts access to the application form based on allowable timelines in the national standards. Laboratories that have had an application denied must wait for six months before re-applying for accreditation.

Step 2. On-Site Assessment

(2009/2016 TNI Standard and Minnesota Rules, Chapter 4740, part 4740.2050, subpart 6)

The routine on-site assessment is scheduled in advance at least once every two years (+/- six months) and at a date mutually agreeable to MNELAP and the laboratory. Unannounced on-site assessments may be performed for cause, such as complaints or misrepresentation of accreditation. In order to maintain accreditation, the laboratory must allow the assessors access during any normal business hours unless there are extenuating circumstances that are accepted and documented by the MNELAP.

Assessors will review a laboratory's conformance with the 2003 NELAC Standard (primarily Chapter 5) or the 2009/2016 TNI Standard and the Minnesota Rules using a checklist containing the NELAP-required review items. Assessors may use method-specific or project-specific checklists to evaluate technical compliance. The laboratory must allow MNELAP to access all relevant areas of the laboratory or premises for the onsite inspection and witnessing of laboratory activities.

Opening conference

Upon arrival, the lead assessor will introduce him/herself and any team members. The assessors will meet with the facility's administrator or laboratory director (however named) and management staff. The purpose of the assessment and assessment process will be briefly explained. Plans for an exit interview shall be made known. During the Opening conference the assessors will:

- Review the agenda, the purpose of the assessment, the declaration of any perceived conflicts of interest, and the overall schedule of activities for the assessment;
- Identify the standards that will be used by the assessors in judging the compliance status of the laboratory operation;
- Verify information on the application;
- Indicate which tests will be examined;
- Examine the roles and responsibilities of key managers and staff in the laboratory;
- Identify any records and operating procedures to be examined during the assessment;
- Address Confidential Business Information (CBI) concerns;
- Review special requirements that the laboratory may have (e.g., requirements related to health and safety or security);
- Allow the laboratory director (however named) to ask any questions necessary to understand the assessment process and events that will follow the assessment;

- Provide the responsible laboratory official with an assessment appraisal form to be submitted to MNELAP;
- Identify tentative time for the closing conference; and
- Request a laboratory tour.

Impartiality documentation and analytical records and data review

The laboratory shall provide access to documents that provide insight into the level of independence and impartiality of the lab and it related bodies. If applicable, the laboratory must supply documentation and information necessary to prove that activities of related bodies do not impact the confidentiality and impartiality of the laboratorians or the related data (e.g organizational charts, conflict of interest procedures, or etc.).

The analytical records and data review includes all laboratory documents, tracking a particular sample from laboratory receipt to the final laboratory reporting of the sample testing results. The analytical records and data review will vary widely depending on the field of testing that is being assessed. Analytical records can vary from simple hand-written transcriptions by an analyst of observations in microbiology and wet chemistry analyses to more complex computer hardcopy of chemical absorption, chromatograms, or mass spectra. In general, however, all data will be evaluated by an assessor from its rawest form to determine method compliance and scientific defensibility.

The minimum set of records for review includes:

- Standard Operating Procedures and method protocols for each parameter for which accreditation is sought;
- Maintenance and calibration records for specific equipment separate for those included in measurement records;
- Records for the preparation and calibration of stock solutions and standard reagents
- Documentation of the origins, purities, assays, and expiration dates of primary standards, analytical reagents and standard reference materials;
- Records associated with method specific quality control requirements;
- Records associated with the Method Detection Limit (MDL) or Limit of Detection (LOD) and Initial Demonstration of Capability (IDC) study associated with each method for which the laboratory seeks accreditation, to be examined in detail with the historical calibration data
- Records associated with the methods used to estimate precision and accuracy in general for specific analyses;
- Sample receipt and sample handling documentation;
- Records of any internal audits conducted or corrective actions taken by the laboratory; and
- The documentation of the laboratory's annual management review.

Staff interviews qualifications

Information on all laboratory personnel and their qualifications (education and laboratory experience) should be on file in the laboratory and made available to assessors for review. The assessors will verify through interviews with key staff personnel that the staff have the appropriate qualifications and are performing the duties as reported and are truly knowledgeable of the procedures for which they are responsible. Staff members should be:

- qualified and competent to perform specific analyses.
- familiar with the laboratory quality manual and follow its guidelines.
- understand the laboratory SOP's and have them immediately available.
- Following method and program specific QA\QC.

Equipment and Testing Supplies

The assessor will observe and confirm that appropriate equipment, reagents, and media are available to perform tests reported. The laboratory equipment must be in good working order and must be maintained on a regular basis with maintenance and repairs well-documented. All reagents and media must be within expiration date, labeled properly and stored according to manufacturer's instructions. The procedure manuals must be readily available to laboratory staff for all instruments including operation and troubleshooting instructions.

Assessment Team Debriefing

At the conclusion of the assessment, the assessment team will meet in private to discuss and organize findings. The assessment team will develop a closing conference outline, listing findings and order of presentation.

Closing Conference

Upon completion of the assessment, the assessment team conducts a closing conference to relay the observations to the laboratory representatives. Before adjourning, the lead assessor will review information the laboratory claims as trade secret, discuss any disputed items (if applicable) review the schedule for completing the assessment report, and inform the laboratory director of procedures for responding to the assessment findings, which include:

- Submitting a plan of corrective action, if needed.
- Requesting a review of the assessment in accordance with the provisions of the TNI Standards and Minnesota Laws and Rules.

The closing session will reflect the fact that the purpose of the assessment is to judge the extent to which the laboratory is in compliance with the TNI Standards and Minnesota laws and Rules, not to pass judgment on the overall quality of the operation.

Assessment Report

Within 30 calendar days of the date of the assessment, MNELAP will deliver an assessment report to the laboratory. The report will contain findings with relevant citations to the requirements in the NELAC/TNI standard and a description of the observations of the assessors which support the finding.

Corrective Action

After being notified of findings, the laboratory shall have 30 calendar days from the date of receipt of the finalized assessment report to provide a corrective action plan. The corrective action plan shall include the action that the laboratory will implement to correct each deficiency and the time period required to accomplish the corrective action.

MNELAP will respond to the action noted in the corrective action plan within 30 calendar days of receipt. If the corrective action plan (or a portion) is deemed unacceptable to remediate a finding, the laboratory shall have an additional 30 calendar days to submit a revised corrective action plan.

The laboratory will be subject to MN Statutes 144.99 for enforcement for all or any portion of its scope of accreditation for any or all of a field of testing, or a method, or analyte within a field of testing. If the laboratory fails to implement the corrective actions as stated in their corrective action plan, accreditation for fields of testing, specific methods, or analytes within those fields of testing shall be denied or revoked. No laboratory will have their accreditation denied, suspended, or revoked without due process (i.e. adequate notice, a hearing and a neutral judge to hear the appeal).

Proprietary data, Trade Secret Information, and classified national security information will be excluded from all public records. All other information included and documented in an assessment report and the corrective action plan are considered public information.

Follow-up Assessment

Follow-up assessments may be necessary after enforcement actions are planned or taken or when a major change occurs at a laboratory in personnel, equipment, or in a laboratory's location that might alter or impair analytical capability and quality. Any follow-up assessment that might warrant enforcement action shall be completed and reported within 30 days after the follow-up assessment.

Determination of the need for a follow-up assessment will be decided on a case-by-case basis through discussion by the assessment team assigned to the laboratory. The final decision to perform a follow-up assessment will be made by the MNELAP program coordinator based on assessment team's recommendation.

Step 3: Award of Accreditation

If there is an emergency or immediate public health need and a laboratory completes all of the requirements for accreditation except the onsite assessment because MNELAP is unable to schedule the assessment, MNELAP may issue an interim accreditation. Interim accreditation allows the laboratory to perform analyses and report results with the same status as an accredited laboratory until the onsite assessment requirements have been completed. Interim accreditation status shall not exceed twelve months. The interim accreditation status is a matter of public record and shall be entered into the national database. MNELAP shall grant accreditation to laboratories that meet the base requirements (application, fees, and documentation) and the testing requirements for at least one field of testing. Documentation of a laboratory's accreditation is issued electronically via two documents: the certificate and the scope of accreditation. The two documents presented together constitute representation of accreditation status from the department.

A laboratory must make available its current certificate and corresponding scope of accreditation upon the request of the client, certification authority, or regulatory agency. The

laboratory must not supply a copy of its certificate without the accompanying copy of its scope of accreditation.

Although MNELAP supplies a convenience copy of the certificate to the laboratory, the official record of accreditation resides with the MNELAP. MNELAP removes expired or withdrawn official certificates from the program's webpage on the expiration date or the effective date of withdrawal, whichever is sooner. After expiration or withdrawal from the program, all convenience copies retained by the laboratory must be removed from display or advertisement. An accredited laboratory must not misrepresent its accreditation on any document.

If the laboratory maintains compliance with laws and rules regarding accreditation, the MDH-issued accreditation is valid through December 31st of each year.

If a laboratory's scope of accreditation changes, MNELAP shall supply the laboratory with a new certificate and scope of accreditation.

The MNELAP does not distribute the TNI logo to accredited laboratories, and as a result MNELAP does not control the distribution and tracking of the logo to Minnesota accredited laboratories. However, the TNI logo is available on the TNI website and is available for use by any interested party. The accredited laboratory must use the accreditation symbol for its intended use. The laboratory shall not use the logo in such a way to mislead the reader regarding the status of their accreditation or to imply that non-accredited activities are covered by the accreditation logo. An accredited laboratory is allowed to use the TNI accreditation logo on reports or certificates issued within the scope of accreditation for which the laboratory conducts analyses on a defined laboratory premises. The laboratory must clearly and unambiguously identify accredited and non-accredited reported results. Accreditation cannot be used to imply that a product, process, system or person is approved by the Minnesota Department of Health, MNELAP or other NELAP- recognized accreditation bodies.

The accreditation body will take all necessary actions (e.g. enforcement or legal action) to ensure that any incorrect references to accreditation status, unauthorized or misleading use of the logo (e.g. advertisements, websites, publicity materials or etc.) is discontinued. The Accreditation Program protects the integrity of the accreditation it issues through the use of the department's Enforcement Manual and the Administrative Penalty Order Plan as required in Minnesota Statute 144.99.

Step 4: Ongoing Proficiency

In addition to passing a review of the application and a biennial on-site assessment, the laboratory must participate in a Proficiency Testing (PT) program. The requirements are found in the 2009/2016 TNI Standard and are summarized below:

To be accredited and to maintain accreditation, a laboratory shall participate in two single-blind, single-concentration PT studies, where available, per year for each field of proficiency testing for which the laboratory seeks accreditation. For all fields of testing, including those for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a total quality management system that meets all applicable requirements of Volume 1 Module 2 of the 2009 TNI Standards.

PT samples may be obtained from any NELAP-designated PTPA-approved provider for the analyte of interest if the laboratory:

- adheres to its pre-defined testing schedule;
- purchases a sample meeting the design, testing and verification requirements for approved studies; and
- analyzes the sample within one month of the six-month schedule (i.e. greater than five months and less than seven months between studies) as required in TNI Standard.

The laboratory must authorize the PT provider to release all results used for accreditation and/or remediation of failed studies to MNELAP.

The samples shall be analyzed and the results returned to the PT provider no later than 45 calendar days from the opening date. The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff and methods as used for routine analysis of that analyte. The PT samples must be prepared according to the PT provider's instructions.

The laboratories must pass two out of the last three PT studies for every matrix-technology/method-analyte for which they are requesting accreditation. These PT studies are to be done approximately each six months apart. Failure to meet the semi-annual schedule is regarded as a failed study. Supplemental studies for failed analytes or initial applications, including requests to add fields of testing to an existing scope, may be no closer than 15 calendar days from the closing date to the shipment date of the last study.

MNELAP recommends a spring/fall schedule; however, the actual schedule is left to the decision of the laboratory and must be maintained. MNELAP will not remind laboratories to run PT samples. Failure to participate in a biannual PT study is considered grounds for suspension or revocation.

A laboratory may withdraw from a PT study for an analyte(s) or for the entire study if the laboratory notifies both the PT provider and the MNELAP program coordinator before the closing date of the PT study.

The Primary AB shall accept results from non-Proficiency Test Provider Accreditor accredited Proficiency Test Providers when the field of testing (FOPT) is not available from any accredited PTP.

Restrictions on exchanging information

Laboratories shall comply with the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released:

- A laboratory shall not send any PT sample, or portion of sample, to another laboratory for any analysis for which it seeks accreditation, or is accredited.
- A laboratory shall not knowingly receive any PT sample of portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation or is accredited.

- Laboratory management or staff shall not communicate with any individual at another laboratory (including intra-company communication) concerning the PT sample.
- Laboratory management or staff shall not attempt to obtain the assigned value of any PT sample from their PT provider prior to the end of the study.

Failed studies

Whenever the laboratory fails a study, it shall determine the cause for failure and take necessary corrective action. You must document the action taken in your own records and provide the records documenting the investigation and action taken at the request of the MNELAP program coordinator or the on-site assessment team.

If you fail a second study out of the most recent three, MNELAP will take action within 60 calendar days to determine the accreditation status of the unacceptable analyte(s) for that matrix and technology/method. When a laboratory completes a PT study to re-establish its acceptable performance, the laboratory must notify the PT Provider at the time the study is ordered that the study is for corrective action.

Records

The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for five years or longer if required by applicable regulatory program. These records must be made available to assessors during the on-site assessment.

Notification Requirements

The laboratory shall notify the MNELAP program coordinator, in writing, of any changes in key accreditation criteria within 30 calendar days of the change. This written notification includes but is not limited to changes in the following:

- laboratory ownership, legal status or organizational status;
- location/address;
- key personnel;
- major instrumentation;
- scope of accreditation;
- main policies and other such matters that may affect the ability of the lab to fulfill requirements for accreditation.

A laboratory that wishes to withdraw accreditation, in total or in part, must make the request in writing (preferably, through the application form) and must submit the request to the MNELAP program coordinator. All such updates are public record and any or all of the information may be placed in the national database.

Where there is a change in ownership, all records and analyses performed pertaining to accreditation must be kept for a minimum of five years and are subject to inspection by MNELAP per the requirements in the standard.

A technical director absent for more than 15 consecutive calendar days must designate qualified person to temporarily perform the technical director duties. If the absence exceeds thirty-five (35) consecutive calendar days, the laboratory must send written notification to MNELAP.

Traceability of Measurements

The laboratory must maintain quality policies or procedures regarding the laboratory's process for ensuring the traceability of measurements. Accredited laboratories may demonstrate traceability of measurement through establishing policies and procedures for:

- the purchase and use of standards, reagents, and consumable materials (e.g. ensure vendor meets standard requirements of traceability, maintenance of reference material documentation, uniquely identify purchased and prepared standards or media, and maintain records of initial use and verification of reference material, standard, regents, media, and consumable lab items); and
- the documentation and calibration of support and analytical equipment (e.g. weight records, thermometer calibrations, pipette calibrations, unique identification of equipment and maintenance.

The laboratory should ensure traceability of measurements by reviewing analytical results produced within the laboratory to ensure the laboratory retained the necessary documentation and records associated with the analytical results to ensure historical reconstruction and legal defensibility of the data (e.g. unique sample identification, records retained for consumable material verifications, unique sample identification, equipment calibrations, documentation of unique standard identification and associated certifications of analysis records, and analytical equipment used for the unique sample identifier). The measurement of traceability must be proven through the laboratory's documentation of the sample from the time of receipt to the final reporting of the data.

Records Retention

All laboratory records associated with accreditation parameters shall be maintained for a minimum of five years, unless otherwise designated for a longer period in another regulation or authority.

Use of This Guide

The contents of this handbook are intended to guide new applicants through the steps in the MNELAP application process and provide background regarding the program. New applicants or currently accredited laboratories are responsible for ensuring compliance with program requirements as stated in the 2009 Minnesota Statutes, 144.97 and 144.98; the 2006 Minnesota Rules, Chapter 4740; and the applicable national standard implemented by the National Environmental Laboratory Accreditation Program (NELAP) of The NELAC Institute.

Applications and other information can be found online at Minnesota Department of Health Environmental Laboratory Accreditation Program (MNELAP) (https://www.health.state.mn.us/accreditation) or available through the MNELAP offices:

Minnesota Department of Health
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651-201-5324
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