



Lab Quality Manual

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1.0 Scope

The lab at North American Testing (NAT) is committed to a policy of providing exemplary service with respect to providing accurate testing and analysis of wastewater samples. The NAT lab does not engage in the design or development of new testing methods. The lab conforms to ISO/IEC Standard 17025.

2.0 References

1. ISO/IEC Standard 17025 General requirements for the competence of testing and calibration laboratories.
2. ISO Standard 19011 Guidelines for quality and/or environmental management systems auditing.
3. Standard Methods for the Examination of Water and Wastewater (21st edition).
4. NSF/ANSI Standard 40 Residential Wastewater Treatment Systems.
5. NSF/ANSI Standard 46 Evaluation of Components and Devices Used in Wastewater Treatment Systems.
6. NSF/ANSI Standard 245 Wastewater Treatment Systems - Nitrogen Reduction.

3.0 Terms and Definitions

For the purposes of this document, the relevant terms and definitions given in ISO/IEC 17000 apply.

4.0 Management Requirements

4.1 Organization

- 4.1.1 NAT is a legal entity registered as a Limited Liability Company to do business in the state of Ohio.
- 4.1.2 NAT shall carry out its testing and calibration activities according to the requirements of ISO/IEC Standard 17025 to satisfy the needs of the customer.
- 4.1.3 This management system covers work carried out by NAT employees at the NAT permanent facilities, at sites away from its permanent facilities or in associated temporary or mobile facilities.
- 4.1.4 In addition to the services described in section 1.0, NAT also provides product certification services. This function is managed by the NAT Program Manager (See QF4.2.2).
- 4.1.5 The NAT lab:
 - a) has the personnel with the authority and resources to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests, and to initiate actions to prevent or minimize such departures (See QF4.2.5);
 - b) ensures its personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work (See QF5.2.2.1);
 - c) has policies and procedures to ensure the protection of its clients confidential information and proprietary rights (See LQSP4.1.5.2);
 - d) has policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity (See LQSP4.1.5.2 and QF5.2.2.1);
 - e) defines the organization and management structure of the laboratory (See QF4.2.2);

- f) specifies the responsibility, authority and interrelationships of all personnel (See LQSP4.1.5.2);
- g) provides adequate supervision of staff (See LQSP4.1.5.2);
- h) has technical management (Lab General Manager) who has overall responsibility for the technical operations and the provisions of the resources (Program Manager) needed to ensure the required quality of laboratory operations (See QF4.2.5);
- i) has a Quality Manager to ensure that the quality system is implemented and followed at all times (See QF4.2.2);
- j) has deputies for key positions as feasible;
- k) ensures its personnel are aware of the relevance of their activities and how they contribute to the achievement of the objectives of the management system (See LQSP4.1.5.2 and QF4.5.1.1).

4.1.6 See LQSP4.1.5.2

4.2 Management System

4.2.1 The NAT lab has implemented and maintains a management system appropriate to the scope of its activities. This manual serves as the basis for the management system. The Program Manager is responsible for ensuring all employees read, understand and follow the policies and procedures of the management system.

4.2.2 The NAT lab is committed to a policy of providing exemplary service with respect to providing accurate testing and analysis of wastewater samples for its clients. The management system ensures an exemplary level of service as all personnel are required to read, understand and implement the management system policies and procedures as they perform their work.

4.2.3 The Lab Quality Manual and associated quality procedures are evidence of management's commitment to the development, implementation and improvement of the management system.

4.2.4 The Program Manager is responsible for ensuring all NAT staff members are aware of the importance of meeting customer requirements. All staff is required to read and understand the NAT Quality Manual and the NAT Lab Quality Manual as documented in QF4.5.1.1. A signed copy of this document is kept in the employee's personnel file. A Management Review is performed at least annually and the results of this review are communicated to the staff by the Program Manager in the next regularly scheduled staff communication meeting following the Management Review (See LQSP4.1.5.2).

4.2.5 The NAT lab has Quality System Procedures to ensure consistent and accurate work is performed by NAT staff. These procedures are kept in a separate manual titled "Lab Quality System Procedures." The Program Manager is responsible for the maintenance of the procedures manual.

4.2.6 The roles and responsibilities of technical and quality management are outlined in NAT job descriptions (see QF4.5.3.3). The Quality Assurance Officer ensures the NAT lab conforms to ISO/IEC Standard 17025.

4.2.7 The Program Manager ensures integrity of the management system as outlined in section 4.15 of this manual.

4.3 Document Control

4.3.1 NAT has a Document Control Procedure (See QSP4.8.2.1). The document master list is LQF4.3.1.

4.4 Review of Requests, Tenders and Contracts

4.4.1 NAT has a procedure for the review of requests, tenders and contracts (See LQSP4.4.1).

4.5 Subcontracting Tests and Calibrations

- 4.5.1 If NAT subcontracts testing, this work will be placed with a competent subcontractor that complies with the appropriate International Standard (See QSP4.4.1 and LQF4.5.1.1).
- 4.5.2 NAT will advise clients in writing if a subcontractor is used during the certification of their product(s) (See QF4.4.3).
- 4.5.3 NAT is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory agency specifies which subcontractor is to be used.
- 4.5.4 NAT maintains a list of all subcontractors and a record of their compliance with appropriate International Standards (See LQF4.5.1.1).

4.6 Purchasing Services and Supplies

- 4.6.1 NAT has a procedure for the selection and purchasing of services and supplies it uses that affect the quality of the tests and calibration of equipment (See LQSP4.6.1).
- 4.6.2 Purchased materials are not used until they are verified as complying with specifications defined in the methods for the applicable tests. The Quality Assurance Officer is responsible for this function and recording his/her actions (See LQSP4.6.1 and LQF4.6.2.1).
- 4.6.3 NAT has a purchasing document (See LQSP4.6.1 and LQF4.6.3.1).
- 4.6.4 NAT evaluates suppliers of critical consumables and services that affect the quality of testing, and maintains records of approved suppliers (See LQF4.6.4.1).

4.7 Service To The Client

- 4.7.1 NAT affords clients cooperation to clarify the client's request and to monitor NAT's performance in relation to the work performed, provided that the laboratory ensures confidentiality of other clients. Clients are welcome to visit NAT as long as a minimum of 48 hours notice is provided. The Program Manager shall maintain a minimum of weekly communication with clients when the time frame of applicable tests merit it.
- 4.7.2 NAT shall utilize LQF4.7.2 to generate feedback from its customers. This questionnaire shall be distributed to the customer upon project completion.

4.8 Complaints

NAT has a procedure for the resolution of complaints received from clients or other parties. Records are maintained of all complaints, investigations and corrective actions taken by the laboratory (See LQSP4.8.1 and LQF4.8.1).

4.9 Control of Non-Conformances

- 4.9.1 NAT has a procedure for the handling of non-conformances (See LQSP4.9.1.1).
- 4.9.2 Where an evaluation of the non-conformance indicates the non-conformance could recur or there is doubt about the lab's compliance with its own policies and procedures, the Corrective Actions Procedure should be promptly followed (See LQSP4.9.1.1).

4.10 Improvement

NAT strives to improve the effectiveness of its management system through the use of its quality system, audit results, customer feedback, management reviews, corrective actions and preventive actions.

4.11 Corrective Action

NAT has a policy for implementing corrective action when non-conforming work or departures from the procedures and policies in the management system or technical operations have been identified (See LQSP4.9.1.1 and LQF4.11.2.1 and LQF4.11.3.1).

4.12 Preventive Action

4.12.1 All NAT Lab personnel shall meet on the first working day of each month to discuss needed improvements and potential sources of non-conformances, either technical or concerning the quality system. If needed improvements and/or sources of non-conformance are identified, preventive action shall be initiated by the Quality Assurance Officer following the Preventive Actions Procedure (See LQSP4.12.1.1).

4.12.2 The Preventive Actions Procedure includes controls to ensure the preventive actions are effective (See LQSP4.12.1.1).

4.13 Record Control

4.13.1 General

NAT has a procedure for the control of general records including identification, collection, indexing, access, filing, storage, maintenance and disposal of records. These records include reports from internal audits, management reviews and corrective and preventive actions. All records shall be legible and stored in a safe manner (See QSP4.9.1.1).

4.13.2 Technical

NAT has a procedure for the execution and retention of technical records to facilitate identification of factors affecting uncertainty of test results and to enable the test to be repeated as close as possible to the original (See QSP4.9.1.1).

4.14 Internal Audits

4.14.1 NAT has a procedure for conducting Internal Audits. Internal Audits shall be conducted annually and arranged by the Quality Assurance Officer (See QSP4.7.1.1).

4.15 Management Reviews

4.15.1 NAT has a procedure for conducting Management Reviews. Management Reviews shall be conducted in a timely manner after each Internal Audit (See QSP4.7.2.1).

5.0 Technical Requirements

5.1 General

5.1.1 Many factors determine the correctness and reliability of the tests and calibrations performed by the lab. The lab takes account of these factors in developing test methods and procedures, in the training and qualification of personnel and in the selection and calibration of the equipment it uses. NAT has procedures to address these factors.

5.2 Personnel

- 5.2.1** The Lab General Manager will ensure the competence of all employees who operate specific equipment, perform tests and /or calibration, evaluate results and sign test reports. The personnel assigned to these tasks must meet the requirements set forth in the appropriate job description (See QF4.5.3.3). Lab personnel shall complete an Initial Demonstration of Capability following successful training for all lab analysis prior to initial data reporting.
- 5.2.2** New employees or employees assigned to a new task will be trained by a qualified employee for a period of time to be determined by the Lab General Manager. NAT has a procedure for training of new employees (See QSP5.1.1.1).
- 5.2.3** NAT shall only use employees who are employed by, or under contract to, NAT.
- 5.2.4** NAT maintains Job Descriptions for all positions (See QF4.5.3.3).
- 5.2.5** NAT authorizes only certain personnel to perform certain tasks. These tasks are described in the Job Descriptions. NAT maintains records of the qualifications of all personnel (See QF4.2.5).

5.3 Accommodation and Environmental Conditions

- 5.3.1** Various tests performed in the lab may be affected by environmental conditions. The procedure for each test directs the technician to monitor these conditions if applicable. Tests shall be stopped if the environmental conditions jeopardize the test results (See LQSP5.4.1.3 through 5.4.1.15).
- 5.3.2** Same as 5.3.1.
- 5.3.3** The individual test procedures specify measures necessary to prevent cross-contamination where and if applicable.
- 5.3.4** All NAT personnel are qualified and have authorized access to the lab.
- 5.3.5** All employees are responsible for housekeeping. Special procedures shall be prepared when necessary.

5.4 Test and Calibration Methods and Method Validation

5.4.1 General

The lab uses appropriate methods and procedures for all tests and calibrations within its scope. Methods published in "Standard Methods For The Examination of Water And Wastewater (21st Edition)" are used. NAT has rewritten the methods as Lab Quality System Procedures to facilitate ease of use by NAT personnel.

- 5.4.2** The laboratory uses test methods which meet the needs of the client and which are appropriate for the tests it undertakes. The laboratory uses the latest valid edition of any applicable standard. Individual testing results from NAT Lab Quality System Procedures serve to confirm that it can properly perform the standard methods.
- 5.4.3** The NAT lab does not develop methods.
- 5.4.4** The NAT lab does not use non-standard methods.

5.4.5 Validation of Methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that studies the particular requirements for a specific intended use are fulfilled. Method Detection Level determinations shall be conducted for all applicable test methods and all lab analysts prior to initial data reporting. Subsequent MDL determinations are required once yearly for each applicable analysis that the lab performs.

5.4.5.2 The NAT lab does not use non-standard methods, develop methods or use standard methods outside their intended scope.

5.4.6 Estimation of Uncertainty of Measurement

5.4.6.1 NAT uses procedures to estimate the uncertainty of measurement for the equipment calibrations and testing measurements it performs (See LQSP5.4.6.1 and LQF5.4.6.1).

5.4.6.2 NAT satisfies this clause by using well-recognized test methods and following the methods reporting instructions.

5.4.6.3 All uncertainty components are taken into account using appropriate methods of analysis.

5.4.7 Control of Data

5.4.7.1 Individual Work Instructions and Lab Quality System Procedures contain checks of calculations and data transfers.

5.4.7.2 Any NAT lab automated equipment used for the acquisition of data shall utilize the equipment manufacturer's software designed for the particular application. NAT uses computer software suitable for the processing, recording, reporting, storage and retrieval of test data. NAT has a procedure for data protection (See QSP4.9.1.1). Computers are maintained to ensure proper functioning in a climate-controlled environment.

5.5 Equipment

5.5.1 The lab is furnished with sampling, measurement and test equipment required for the correct performance of tests necessary to certify wastewater treatment components to particular standards (See LQF5.5.1.1).

5.5.2 Equipment is calibrated per the manufacturer's instructions and to ensure it complies with the relevant standard specifications (See LQSP5.5.5.1).

5.5.3 All lab personnel are trained and authorized to use lab equipment (See LQSP5.4.1.1). Up-to-date instructions on the use and maintenance of equipment is readily available for use by the designated personnel.

5.5.4 Equipment is identified with a unique serial number (See LQF5.5.1.1).

5.5.5 The Field Technical Manager is responsible for the calibration and maintenance of equipment. Calibration and maintenance records are kept on file in the lab office (See LQF5.5.1.1).

5.5.6 Personnel authorized to operate equipment are responsible for its accurate operation (See LQSP5.4.1.1).

5.5.7 If equipment is suspected to be defective or providing inaccurate results, the operator will immediately isolate the equipment and tag it "out of service". The equipment will remain out of service until the Field Technical Manager arranges for repair and/or recalibration of the equipment (See LQSP5.4.1.1).

- 5.5.8** Equipment requiring outside calibration will have a label visibly displayed showing the date, when last calibrated and the date when calibration is due.
- 5.5.9** If equipment goes outside the direct control of the laboratory for any reason, the equipment shall be calibrated per LQSP5.5.5.1 to ensure proper function.
- 5.5.10** If certain equipment requires intermediate checks to maintain confidence in the calibration status of the equipment, LQSP5.5.5.1 shall be followed (See QF5.5.5.1).
- 5.5.11** This clause does not apply to the lab.
- 5.5.12** Test equipment is safeguarded from adjustments which would invalidate the test results as defined in LQSP5.4.1.1.

5.6 Measurement Traceability

- 5.6.1** All lab equipment used for testing or sampling shall be calibrated before being put into service. The lab has an Equipment Calibration Procedure (See LQSP5.5.5.1).

5.6.2 Specific Requirements

5.6.2.1 Calibration

The procedure for calibration of equipment is designed and followed to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI). When calibrations cannot be made in SI units, the lab uses certified reference materials provided by a competent supplier to give a reliable characterization of a material (See LQSP5.5.5.1).

5.6.2.2 Testing

The lab shall use only certified reference materials provided by an approved supplier. Lab SOP's contain direction on preparation of standards. Lot numbers of reagents and chemicals are recorded on LQF4.6.2.1

5.6.3 Reference Standards and Reference Materials

The lab has a procedure for calibration of its reference standards. (See LQSP5.6.3.1). For testing purposes, once per quarter the lab shall utilize a second source calibration standard for internal proficiency purposes. The analyst must achieve a recovery within the specified range or take corrective action if results are outside of the acceptance range.

5.7 Sampling

- 5.7.1** The NAT lab has sampling procedures for all on-site sampling activities. Composite sampling programs are tailored specifically for individual flow patterns..
- 5.7.2** Any deviations from the sampling procedures or programs are documented on QF10.1a and noted in the Test Report. Deviations from the sampling procedures requested by the customer are reviewed, recorded in the customer's file and communicated to the appropriate personnel.
- 5.7.3** Relevant sampling data is recorded on QF10.1a and QF10.2.1.

5.8 Handling of Test Items

- 5.8.1** NAT has a procedure for the transportation, receipt, handling, protection, storage, retention and/or disposal of test items (See LQSP5.8.1.1).

- 5.8.2 NAT has a system for identifying test items as described in LQSP5.8.1.1.
- 5.8.3 Upon receipt of test items, abnormalities are recorded as explained in LQSP5.8.1.1. When there is doubt as to the suitability of the item for testing, the Lab General Manager shall consult the client for further instructions.
- 5.8.4 The laboratory has the proper accommodations for storage, handling and preparation of test items as required in "The Standard Methods for the Examination of Water and Wastewater". LQSP5.8.1.1 defines these procedures.

5.9 Assuring the Quality of Test and Calibration Results

NAT has quality control procedures to ensure the validity of the tests performed by lab personnel. These quality control functions are contained in the various individual Lab Procedures where applicable. Once per year, the lab shall analyze proficiency tests for all applicable test methods.

5.10 Reporting the Results

- 5.10.1 Individual test results are recorded on the appropriate form according to the appropriate LQSP. The individual test results are then compiled in a Test Report when applicable.
- 5.10.2 Test Reports shall include all relevant required information as specified in clauses 5.10.2 and 5.10.3 of ISO/IEC Standard 17025.
- 5.10.3 See 5.10.2.

5.10.4 Calibration Certificates

The NAT Lab does not generate Calibration Certificates.

5.10.5 Opinions and Interpretations

When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a Test Report.

- 5.10.6 Testing results from subcontractors are clearly identified as such on the Test Report.
- 5.10.7 In the case of electronic transmission of test results, the requirements of ISO/IEC Standard 17025:2005 shall be met.
- 5.10.8 The format of Test Reports will be such as to accommodate ease of interpretation.
- 5.10.9 Material amendments to a Test Report after issue shall be made only in the form of a further document, or data transfer, which included the statement:
"Amendment to Test Report # XXXXX".
Such amendments shall meet the requirements of ISO/IEC Standard 17025:2005. When it is necessary to issue a complete new Test Report, this shall be uniquely identified and shall contain a reference to the original that it replaces.