North American TESTING

Lab Quality Manual

201 A Plank Road
Norwalk, OH 44857

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Laboratory Manager : Nianfa Tang, Ph.D., P.E. ph. 1-440-376-0788
Approved: _____ Date: _____
Quality Assurance Officer : Douglas Steele ph. 1-419-706-6688
Approved: _____ Date: _____

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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 performing accurate testing and analysis of environmental water and wastewater samples. The NAT lab provides laboratory testing for the NAT Certification Body and any customer requesting lab analysis under the scope of testing. The lab conforms to ISO/IEC Standard 17025 and TNI 2016 Laboratory Standard.

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 (23rd 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 — Residential Wastewater Treatment Systems - Nitrogen Reduction.
7. NSF/ANSI Standard 350 — Onsite Residential and Commercial Water Reuse Treatment Systems
8. NSF/ANSI Standard 385 — Disinfection Mechanics
9. TNI 2016 Laboratory Standard — Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis.
10. New York State Regulations — Title 10, Subpart 55-2 - Approval of Laboratories Performing Environmental Analysis

3.0 Terms and Definitions

For the purposes of this document, the relevant terms and definitions given in ISO/IEC Guide 99, ISO/IEC 17000, and ISO/IEC 17025 apply.

4.0 General Requirements

4.1 Impartiality (Procedure for Management of Impartiality QSP4.2)

4.1.1 The NAT lab is dedicated to undertaking testing activities impartially and also eliminating risks to impartiality which arise from its activities and the activities of its personnel. NAT has policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity. Conflicts of interest cast doubt on the accuracy and validity of results and cannot be allowed to influence testing activities.

4.1.2 NAT ensures its senior executives and staff are free from any commercial, financial and other pressures which might influence the results of the testing process. The Board of Directors is composed of respectable area business people free from any commercial, financial or other pressures that might influence decisions and sign Conflict of Interest agreements stating as such.
(Confidentiality and Disclosure Agreement QF4.5)

4.1.3 The NAT lab is responsible for the impartiality of its activities. NAT 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. Employee salaries and promotions are not dependent upon the outcome of testing or any related commercial activity.

4.1.4 NAT routinely identifies risks to impartiality that arise from its activities and relationships, and the activities and relationships of its personnel. Risks are identified and evaluated through the following means:

a. Personnel conflict of interest questionnaires at the time of hiring, before undertaking any testing, and before any job reassignment. (Conflict of Interest Questionnaire QF4.2.3.1)

b. Written assessments of the impartiality of personnel which is reviewed by the Board of Directors.

c. Annual impartiality reviews.

d. Annual management reviews.

4.1.5 When risks to impartiality are identified, NAT takes steps to eliminate or minimize those risks.

4.2 Confidentiality

4.2.1 The NAT lab and its personnel are legally obligated to keep confidential all information supplied to it by the client as well as all data, records, and information obtained during testing activities except for information required or considered to be publicly available unless authorized by the client. NAT shall inform the client in advance of any information it intends to make publicly available, unless prohibited by law. Confidentiality is maintained by the use of computer passwords, locks on doors and filing cabinets, padlocked covers on equipment under test as well as observation by NAT personnel.

4.2.2 Where the law or contractual agreements require information to be made public or disclosed to any other party, the client shall be informed in advance of what information was provided unless the law prohibits such notification.

4.2.3 Any information about the client which was obtained from any outside source shall be treated as confidential. The source of such information shall also be considered confidential.

4.2.4 All NAT personnel and subcontractors involved in testing activities sign a Confidentiality and Disclosure Agreement (QF4.5).

5.0 NAT Structure (NAT Organizational Chart QF5.1)

5.1 The NAT lab is a division of North American Testing which is a legal entity registered as a Limited Liability Company to do business in the state of Ohio.

5.2 The Lab General Manager has overall responsibility for the technical operations, quality assurance, and the provisions of the resources needed for laboratory operations.

5.3 The NAT lab scope of testing includes all required testing defined in NSF/ANSI Standards 40, 46, 245, 350, 385, and the following analytes:

CBOD5/BOD5 (Carbonaceous / Biochemical Oxygen Demand)
TSS (Total Suspended Solids)
pH

Alkalinity
Temperature
Dissolved Oxygen
Turbidity
Chlorine
Fecal Coliforms
E. Coli
Total Coliforms
TKN-N (Total Kjeldahl Nitrogen)
NH3-N (Ammonia Nitrogen)
NO2-N (Nitrite Nitrogen)
NO2+NO3-N (Nitrite+Nitrate Nitrogen)
PO4-P (ortho-Phosphate)
Total Phosphorus

5.4 NAT shall carry out its testing and calibration activities according to the requirements of ISO/IEC Standard 17025, the TNI 2016 Laboratory Standard, and to satisfy the needs of the customer. This management system covers work carried out by NAT employees at the NAT permanent facilities, the NAT test site, and field activities.

5.5 NAT defines the organization and management structure of the laboratory. The NAT management system specifies the responsibility, authority and interrelationships of all personnel and has deputies for key positions as feasible. (Job Descriptions QF6.1.1.2)

5.6 The NAT lab has the personnel with the authority and resources to carry out their duties including implementation, improvement, and identification of departures from the quality system or from the procedures for performing tests, and to initiate actions to prevent or minimize such departures. These duties are identified in the personnel job descriptions.

5.7 The Program Manager is responsible for ensuring that all NAT personnel are aware of the importance of meeting customer requirements. All staff is required to read and understand the NAT Lab Quality Manual as documented in QF6.1.3. 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

6.0 Resource Requirements

6.1 General

The NAT lab is equipped and staffed with adequate resources necessary to perform its laboratory activities.

6.2 Personnel (Employee Training Procedure QSP6.1.2)

6.2.1 The NAT lab shall only use employees who are employed by, or under contract to NAT, and have completed the impartiality and confidentiality requirements of NAT.

6.2.2 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 descriptions (See QF6.1.1.2).

6.2.3 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 QSP6.1.2).

6.2.4 NAT maintains Job Descriptions for all positions (See QF6.1.1.2).

6.2.5 NAT has a procedure which defines the requirements for the competencies, training goals, formal authorization, demonstration of capability, and monitoring of personnel.

6.2.6 NAT formally authorizes only certain personnel to perform certain tasks. These tasks include quality system maintenance, method verification, data validation, and lab analyses. NAT maintains records of the qualifications and training of all personnel (See QF6.1.2.1).

6.3 Facilities and Environmental Conditions

6.3.1 Various tests performed in the lab may be affected by environmental conditions. Tests shall be stopped if the environmental conditions jeopardize the test results (NAT Lab Standard Operating Procedures LQSP5.4.1.3 through LQSP5.4.1.18).

6.3.2 The environmental conditions which interfere with accurate analysis are documented in the applicable lab Standard Operating Procedure (SOP).

6.3.3 The Standard Operating Procedure (SOP) for each test directs the technician to monitor and perform testing in the correct environmental conditions for the applicable analyses.

6.3.4 The procedures also specify measures necessary to prevent cross-contamination where and if applicable. All employees are responsible for housekeeping. Special procedures shall be prepared when necessary.

6.3.5 The requirements for accommodation of environmental conditions and cross contamination are met regardless of the location. This includes testing conducted at the NAT laboratory, the NAT test site, and any field activities.

6.4 Equipment (Equipment Operation Procedure LQSP5.4.1.1)

6.4.1 The NAT lab is furnished with supplies, reference materials, and equipment required for the correct performance of tests. (Lab Equipment List LQF5.5.1.1)

6.4.2 If equipment goes outside the direct control of the laboratory for any reason, the equipment shall be re-calibrated to ensure proper function.

6.4.3 NAT has procedures for the correct handling, storage, calibration, and preventive maintenance of test equipment. Personnel qualified and authorized to operate equipment are responsible for its accurate operation.

6.4.4 All measuring equipment shall be verified to conform to the manufacturers specifications prior to being placed into service at the lab. Equipment is calibrated per the manufacturer's instructions and to ensure it complies with the relevant standard specifications.

6.4.5 Equipment purchased for measurement is selected to be capable of achieving measurement accuracy specified by the method.

6.4.6 All measuring equipment shall be calibrated against a traceable reference material according to the specified calibration schedule. All equipment calibrations shall be kept current. If there is doubt concerning the accuracy of piece of equipment, the equipment shall be taken out of service and re-calibrated.

6.4.7 Calibration intervals are specified on the Lab Equipment List (LQF5.5.1.1). Calibration intervals are reviewed and adjusted by the QA Officer. The Field Technical Manager is responsible for the calibration and maintenance of equipment.

6.4.8 Equipment and reference materials are identified with a unique serial number or lot number. Equipment requiring calibration and/or verification will have a label visibly displayed showing the date, when last calibrated and the date when calibration is due. (LQF5.5.1.1)

6.4.9 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. (LQSP5.4.1.1)

6.4.10 If certain equipment requires intermediate checks to maintain confidence in the calibration status of the equipment, LQSP5.5.5.1 shall be followed (Equipment Calibration Records LQF5.5.5).

6.4.11 When equipment calibration or intermediate checks reveal a correction factor in the readings, these values are implemented and taken into account for data reporting. The allowance for calibration correction factors does not include lab-fortified blank failures.

6.4.12 Test equipment is safeguarded from adjustments which would invalidate the test results as defined in LQSP5.4.1.1.

6.4.13 Records are maintained for each piece of equipment which include identification of the equipment, operator manuals, calibrations, maintenance, and repairs. Up-to-date instructions on the use and maintenance of equipment is readily available for use by the designated personnel. Calibration and maintenance records are kept on file in the lab office.

6.5 Measurement Traceability

(Equipment Calibration Procedure LQSP5.5.5.1)

6.5.1 All measurements are traceable through an unbroken chain of calibrations or reference materials. Calibration records and certificates of analysis are maintained according to the equipment calibration and record control procedures.

6.5.2 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. The lab only uses calibration labs meeting the requirements of ISO/IEC 17025. The lab shall use only certified reference materials provided by an approved supplier. Lot numbers of reagents and chemicals are recorded in the Chemical/Reagent Log (LQF4.6.2.1).

6.5.3 When traceability to the (SI) system is not possible, traceability is made to certified reference materials provided by an approved and certified provider.

6.6 External Resources

6.6.1 When lab activities are beyond the capability of NAT, subcontractors shall be chosen which meet the requirements of the following Standards:

a. Testing and calibration - ISO/IEC 17025
b. Auditing of quality systems - ISO/IEC 17021
c. Certified reference materials - ISO/IEC Guide 34
d. Proficiency testing - ISO/IEC 17043

6.6.2 NAT has procedures for approval of subcontractors and the selection and purchasing of services and supplies it uses that affect the quality of the tests and calibration of equipment. Purchased materials are not used until they are verified as complying with specifications defined in the methods for the applicable tests. (Purchasing Procedure LQSP4.6.1)

The Lab General Manager collects records which provide evidence for confidence in the subcontractors’ work. Records may include proficiency testing reports, inter-laboratory comparisons, certificates, and quality system audit reports. (Subcontractor Competence Procedure QSP6.2.2.)

6.6.3 NAT takes full responsibility for the activities of its subcontractors except in the case where the client or regulatory agency specifies which subcontractor is to be used. NAT follows a procedure to ensure that sub-contractors and suppliers are qualified to perform their work assignments and that their activities are monitored. NAT also:

a. Maintains a list of qualified subcontractors and a record of their compliance with appropriate International Standards. (Qualified Subcontractors QF6.2.2.4.1)

b. Maintains records of approved suppliers. (Approved Suppliers LQF4.6.4.1)

c. Follows the procedures for non-conformances related to subcontractors and suppliers.

d. Asks its clients to provide their consent before any work is allowed to be subcontracted. (Subcontractor Authorization Request QF6.2.2.4.2)

e. May require sub-contractors to read any quality system documents applicable to their work activities.

f. Requires all subcontractors to sign legally binding confidentiality agreements and declare any situations within their organization which may cause conflicts of interest. (Confidentiality Agreement QF6.2.2.3)

7.0 Process Requirements

7.1 Review of Requests, Tenders and Contracts

7.1.1 NAT has a procedure for the Review of Requests, Tenders and Contracts (See LQSP4.4.1).

7.1.2 The NAT labs uses nationally recognized and current testing methods.

7.1.3 Test results requiring a statement of conformity to a standard or regulation shall identify the reference, the criteria, and the calculation method if applicable. NAT does not issue calibration certificates.

7.1.4 The NAT lab requires legally binding contracts for certification related testing activities. All other testing may be completed in the form of request. NAT shall decline to undertake the testing if there is a lack of competence or capability for any of the required activities.

7.1.5 Deviations from the agreement and non-conformities affecting the accuracy of reported testing results shall be reported to the client as soon as apparent. Any deviations requested by the customer shall be documented. Requested deviations which are unethical shall not be considered or accepted.

7.1.6 Amendments to the contract or request may require additional review including revision to the evaluation plan, re-assignment of personnel or resources, and distribution of additional documents and information.

7.1.7 NAT affords clients cooperation to clarify the client's request and to monitor the lab'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.

7.1.8 Records of pertinent discussions, reviews, requests, tenders and contracts shall be retained per the record control procedure. Verbal requests shall be confirmed in writing.

7.2 Selection, Verification and Validation of Methods

7.2.1 Selection, and Verification of Methods (Demonstration of Capability Procedure LQSP5.2.1)

7.2.1.1 The NAT 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 (23rd Edition)" are used. NAT has rewritten the methods as Lab Standard Operating Procedures (SOP) to facilitate ease of use by NAT personnel.

7.2.1.2 All reference materials required by authorized personnel are available to them. Personnel are assigned their own copy of procedures for their use. All documents are kept current and tracked through document control procedures.

7.2.1.3 Revised methods are updated annually. Revised methods are not adopted into the NAT Lab Quality System until review and approval.

7.2.1.4 All methods are appropriate for the applicable measurement parameter and concentration. 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 and approved edition of any applicable standard.

7.2.1.5 Methods selected by the NAT lab are verified before adoption into use at NAT. Standard Operating Procedures (SOP) specifically for use by NAT personnel shall be written for each method. Revised methods are re-verified. Lab personnel shall complete an Initial Demonstrations of Capability (DOC) following successful training for each applicable lab analysis prior to initial data reporting. Ongoing Demonstrations of Capability (DOC) shall be performed annually. The lab shall also participate in semi-annual proficiency testing from an outside authorized proficiency test provider for all analytes and methods that it is authorized to perform.

7.2.1.6 The NAT lab does not develop methods. The NAT lab does not use non-standard methods.

7.2.1.7 Any deviations from verified methods shall be documented and reported by the technician, justified and authorized by the Lab Manager, and be acceptable by the customer.

7.2.2 Validation of Methods

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

7.3 Sampling

7.3.1 The NAT lab has sampling procedures for all on-site sampling activities. Composite sampling programs are tailored specifically for individual flow patterns. All sampling locations are labeled.

7.3.2 Detailed instructions for collecting samples on-site at NAT are contained in the sampling procedures. A sampling plan shall be developed for sampling conducted by NAT personnel at locations off-site.

7.3.3 Relevant sampling data is recorded on the Chain of Custody (LQF5.8.1) or the Field Report (QF7.4.5). Any deviations from the sampling procedures or programs are documented on the Chain of Custody (LQF5.8.1) 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.

7.4 Handling of Test Items (Test Item Handling Procedure LQSP5.8.1.1)

7.4.1 NAT has a procedure for the transportation, receipt, handling, protection, storage, retention, disposal and/or return of test items.

7.4.2 NAT has a sequential numbering system for identifying test items.

7.4.3 Upon receipt of test items, abnormalities are recorded on the Chain of Custody. When there is doubt as to the suitability of the item for testing, the Lab General Manager shall consult the client for further instructions. Deviations from acceptable conditions are included in the report.

7.4.4 The laboratory has the proper accommodations for preservation, storage, handling, and preparation of test items as required by the methods. Storage conditions are monitored and recorded.

7.5 Technical Records

7.5.1 NAT has a procedure for the execution and retention of technical records and bench sheets 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. Dates and personnel conducting the test activity is recorded for all testing. Original measurements, data, and calculations shall be recorded at the time they are made.

7.5.2 Correction and alterations of data are required to be initialed and dated. Original records are kept with the revised records.

7.6 Measurement Uncertainty (Procedure to Estimate Uncertainty LQSP5.4.6.1)

7.6.1 NAT uses procedures to estimate the uncertainty of measurement for the equipment calibrations and testing measurements it performs. 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.

7.6.2 Calibrations of equipment are evaluated for measurement uncertainty and documented in the calibration record.

7.6.3 All uncertainty components are taken into account using appropriate methods of analysis. If uncertainty cannot be calculated, an estimation is provided.

7.7 Assuring the Validity of Results (Reference Standard Calibration Procedure LQSP5.6.3.1)

7.7.1 NAT has quality control procedures to ensure the validity of the tests performed by lab personnel. Results of quality control testing are tracked. These quality control functions are contained in the various individual Lab Procedures where applicable.

7.7.2 Semi-annually, the primary lab analysts shall analyze proficiency tests for all authorized test methods. The lab utilizes a second source calibration standard for internal proficiency purposes. The analysts must achieve a recovery within the specified range defined by the provider or take corrective action if results are outside of the acceptance range.

7.7.3 Data from quality control testing is used to improve analysis techniques and identify non-conformances. The criteria for quality control testing is set by the proficiency testing provider or included in the applicable lab SOP.

7.8 Data Reporting

7.8.1 General

7.8.1.1 All test data is reviewed and test reports are authorized and signed by the Lab General Manager and/or the Program Manager.

7.8.1.2 Test reports include all of the results requested by the customer. Copies of every test report are kept on file. Test reports can be issued electronically or hard copy.

7.8.1.3 Test results and data may be reported in the form of a lab report, a final evaluation report, or a data spreadsheet. The form of the report shall be suitable for the type of testing and fulfill the customers needs. The format of Test Reports is such as to accommodate ease of interpretation.

7.8.2 Minimum Requirements for Test Reports

7.8.2.1 NAT lab test reports are clear, complete, and include certain basic information. This includes:

a. The name and address of the lab and location of testing

b. The name and contact information of the customer.

c. Identification of the persons performing the tests and authorizing the report

d. A title, page numbers, and a unique test report number on every page.

e. Dates for collection, receipt, analysis, and the report.

f. The results, units of measurement, and any deviations.

7.8.2.2 The NAT lab is responsible for sampling conducted by the lab and data produced by the lab and its authorized subcontractors. Testing results from subcontractors are clearly identified as such on the Test Report. Data and sampling provided by the customer is clearly marked as such. The NAT lab is not responsible for data and sampling conducted by the customer. Test results relate only to the items identified as tested in the report.

7.8.3 Specific Requirements for Test Reports

7.8.3.1 When applicable, certain other information is included in the test reports. This may include environmental conditions, measurement uncertainty parameters, and opinions or interpretations.

7.8.3.2 Details of sampling activities are included in the test reports. See section 7.8.5.

7.8.4 Calibration Certificates

The NAT Lab does not generate Calibration Certificates.

7.8.5 Sampling Reports

When NAT collects the samples, detailed information is also included in the test reports. This includes the location of sampling, a reference to the sampling plan, the sampling method, and environmental conditions.

7.8.6 Statements of Conformity

The NAT Lab reports only the data and does not issue statements of conformity.

7.8.7 Opinions and Interpretations

7.8.7.1 The Lab General Manager is the only person authorized to express or report opinions or interpretation regarding lab activities, analysis methods, or the data. The laboratory shall document the basis upon which the opinions and interpretations have been made.

7.8.7.2 Opinions and interpretations shall be clearly marked as such in the report.

7.8.7.3 Opinions and interpretations provided verbally are documented.

7.8.8 Amendments to Reports

7.8.8.1 Amended test reports include identification of which information was changed and the reason for the change. Amended reports shall meet all of the requirements of section 7.8 for test reports.

7.8.8.2 Material amendments to a Test Report after issue shall be made only in the form of a further document, or data transfer, which includes the statement: “Amendment to Test Report # XXX-XXXXXX”.

7.8.8.3 When it is necessary to issue a completely new test report, it is uniquely identified and contains a reference to the original that it replaces.

7.9 Complaints (Complaint Procedure QSP7.13)

7.9.1 NAT has a procedure for the resolution of complaints received from clients or other parties.

7.9.2 The NAT complaint procedure is available upon request to anyone. If the complaint is misdirected, NAT will direct the complainant to the appropriate contact.

7.9.3 Records are maintained of all complaints, investigations and corrective actions taken by the laboratory. Complaints are logged and tracked.

7.9.4 NAT is responsible for the investigation and resolution of all submitted complaints.

7.9.5 NAT acknowledges receipt of all complaints and provides regular updates on the status of the investigation.

7.9.6 The investigation, communication, and decision resolving the complaint shall be made by persons not involved in activities related to the complaint.

7.9.7 The outcome of complaint investigations are communicated to the complainant.

7.10 Non-Conformances Non-Conformance and Corrective Actions Procedure (QSP8.7)

7.10.1 NAT has a procedure for the handling of non-conformances.

7.10.2 Records are maintained of all on-conformances, investigations, root causes, and corrective actions taken by the laboratory. Non-conformances are logged and tracked.

7.10.3 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 Non-Conformance and Corrective Actions Procedure should be promptly followed.

7.11 Control of Data

7.11.1 NAT collects, stores, or has access to all information required to perform it's functions.

7.11.2 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 QSP8.4). Computers are maintained to ensure proper functioning in a climate-controlled environment.

7.11.3 Data and information stored at NAT is password protected or locked and stored in appropriate environmental conditions. Paper copies are backed up electronically. Electronic copies are backed up and stored off-site.

7.11.4 NAT manages, stores and maintains its own data.

7.11.5 All reference materials required by authorized personnel to perform their duties are available to them. Personnel are assigned their own copy of procedures for their use.

7.11.6 All data transfers and calculations are checked and verified by a secondary person.

8.0 Quality Management System

8.1 General

This document, plus other documents described herein, defines the quality system supporting the testing activities at the NAT lab. This quality system manages all testing work performed at the NAT lab as well as all field activities. It also governs reports and assures objectivity of the information contained in the

reports.

8.2 Management System Documentation

8.2.1 The NAT lab has defined and documented policies and objectives for quality in accordance with ISO/IEC 17025 and TNI 2016 Laboratory Standard by establishing this Quality Manual and every other document in the Quality Management System. The Program Manager ensures that these policies are acknowledged, implemented, and maintained at all levels of the operations. The Program Manager also ensures that all employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives. All employees shall read the Lab Quality Manual and are required to acknowledge their strict adherence to following the procedures and instructions contained in the Lab Quality Manual. All employees are encouraged to report any improprieties by management to either the Certification Committee, the Board of Directors, ANSI, NYSDOH, or any other regulatory authority.
(Obligations of Employees QF6.1.3)

8.2.2 The Quality Management System includes policies and procedures which ensure competent and accurate testing. The NAT lab also has procedures to ensure the impartiality of its personnel and activities.

8.2.3 The Lab General Manager reports to the Board of Directors and is appointed to oversee the proper implementation of the quality system in the lab. The Lab General Manager is the leader for testing activities, and therefore has authority to direct the activities of lab personnel on a day-to-day basis and has significant influence in employment, assignment, disciplinary actions, and termination. NAT is committed to the improvement and proper implementation of the entire Quality Management System. The Quality Management System is regularly reviewed for proper implementation and for areas of improvement during:

a. Management reviews (8.5)

b. Annual internal audits (8.6)

c. Corrective actions (8.7)

d. Monthly preventive actions meetings (8.8)

Records of these actions provide evidence that the quality system is being followed and improved upon.

8.2.4 This Lab Quality Manual is considered the master document governing the NAT lab. The Lab Quality Manual outlines the general principles and policies of the NAT lab in regards to the requirements set forth in ISO/IEC 17025 and TNI 2016 Laboratory Standard. The specific details of testing activities and responsibilities are included in the Lab Quality System Procedures. All quality system procedures (LQSP) are referenced in this document and all quality forms (LQF) are referenced in those quality system procedures. The entire quality system is linked as a network and all quality system documents can be found through this Lab Quality Manual.

8.2.5 All personnel are provided access to the Quality Management System through this Quality Manual and are required to read the Quality Manual soon after hiring. The Program Manager identifies the documents which are distributed to the appropriate personnel for them to properly fulfill their duties and notifies all employees when any changes to the Quality Manual have been made.

8.3 Document Control

(Document Control Procedure QSP8.3)

8.3.1 NAT has a procedure for the control of documents which are generated internally and form a part of the NAT quality system. NAT maintains current versions of external documents. Original paper copies of approved versions of quality system documents are contained in the Quality Management System master binder. Electronic versions of quality system documents are contained in the online Quality Management System folder in Google Drive. The Program Manager has responsibility for document control. No other employees are authorized to alter documents or the directory in which they are kept.

8.3.2 NAT document control ensures that:

a. Only current versions of approved documents are circulated for use.

b. All documents are reviewed at least annually and updated as needed.

c. All NAT quality system documents have a document control number and a revision number.

d. Personnel are assigned their own copy of documents for their use and document distribution is tracked. (Documents Issued Log (QF7.4.3)

e. Documents which have become degraded or illegible are replaced.

f. The distribution of external documents is also controlled.

g. Obsolete documents are retrieved, archived or destroyed, and replaced with approved versions.

8.4 Record Control (Record Control Procedure QSP8.4)

8.4.1 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, corrective actions and preventive actions. All records shall be legible and stored in a safe manner. NAT follows all legal requirements (state and federal) regarding the control of documents. Records generated and stored at NAT are maintained so as to protect confidential information. In the event that NAT is purchased, all records are the property of the new owners. In the event that NAT goes out of business or becomes bankrupt, the Program Manager is obligated to become the custodian of records and will maintain the records according to all document/record control procedures.

8.4.2 All records are stored in a secure file cabinet, in case of paper copy, and/or on the NAT computer system, in case of electronic documents. Both the file cabinet and the area on the server have restricted access. A cyclic backup of electronic files is carried out weekly and the backup copies are maintained in a different building for increased data safety, e.g. to prevent damage by fire. Long-term archiving and retrieval is the responsibility of the Program Manager.

Types of records include:

a. Records which are generated directly from individual testing activities. These type of records shall be identified by the NAT project code or the product name. These records are retained for the previous and the current evaluation cycle for a minimum of 7 years.

b. Records which are generated internally by NAT for administrative reasons and fulfillment of the requirements of ISO/IEC 17025. These type of records are identified by the document control number and are retained for 7 years.

8.5 Risks and Opportunities

8.5.1 NAT is dedicated to undertaking activities impartially and also eliminating risks to impartiality which arise from its activities and the activities of its personnel. Conflicts of interest cast doubt on the accuracy and validity of results and cannot be allowed to influence testing activities. NAT maintains the integrity of data and ensures the ethical conduct of its personnel. NAT conducts annual data integrity and ethics training for all employees and ensures its personnel are aware of the relevance of their activities and how they contribute to the achievement of the objectives of the NAT management system. See Management Requirements Procedure (LQSP4.1.5.2).

8.5.2 NAT routinely identifies risks to impartiality that arise from its activities and relationships, and the activities and relationships of its personnel. Risks are identified and evaluated through the following means:

a. Personnel conflict of interest questionnaires at the time of hiring, before undertaking any testing, and before any job reassignment. (Conflict of Interest Questionnaire QF4.2.3.1)

b. Written assessments of the impartiality of personnel which is reviewed by the Board of Directors.

c. Annual impartiality reviews.

d. Annual management reviews.

8.5.3 When risks to impartiality are identified, NAT takes steps to eliminate or minimize those risks. Actions are equal in magnitude to the risk. Possible actions are included in QSP4.2.

8.6 Improvement (Preventive Actions Procedure QSP8.8)

8.6.1 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. Suggestions for improvements to the quality system and sources of potential non-conformances are received and discussed during the monthly staff meeting. Once a potential source of non-conformance has been identified, preventive actions are taken which follow the same process used for non-conformances including identification, documentation, and re-evaluation for effectiveness. NAT has a procedure to identify and reduce or eliminate sources of potential non-conformances.

8.6.2 Preventive actions are implemented to address the reason for the potential non-conformance and shall be equal in magnitude to the effect the potential non-conformance may cause. NAT solicits feedback from its customers. This questionnaire is distributed to the customer upon project completion.
(Customer Survey LQF4.7.1)

8.7 Corrective Actions (Non-Conformance and Corrective Actions Procedure QSP8.7)

8.7.1 NAT has a procedure to identify, document, and analyze quality system non-conformances and implementing corrective action when non-conforming work or departures from the procedures and policies in the management system or technical operations have been identified.. Corrective actions are taken to eliminate or reduce the cause of the non-conformance which may include revising procedures and forms, additional personnel training, or any other effective action.

8.7.2 Corrective actions are implemented to address the reason for the non-conformity and shall be equal in magnitude to the effect the non-conformance has caused in the test, results, or report. Management evaluates the significance of the non-conformity and may immediately stop the affected work.

8.7.3 All quality system non-conformances and corrective actions are tracked and documented. The causes of all quality system non-conformities are identified through a documented root cause analysis and the corrective action shall be designed to reform the reason for which the non-conformance occurred. Corrective actions shall be implemented in a timely manner and the projected dates of completion defined. All corrective actions are re-evaluated at a later date for effectiveness. Where appropriate, NAT will perform additional monitoring to ensure compliance with the quality system.

8.8 Internal Audits (Internal Audit Procedure QSP8.6)

8.8.1 NAT has a procedure for the conduct of internal audits. The Program Manager is responsible for arranging or conducting internal audits annually. Internal audits are performed annually within a 12 month time frame. The projected date for the next internal audit is scheduled during the current internal audit. If the Board of Directors determines that habitual and/or unsatisfactory compliance with the quality management system is occurring, the Board may increase the frequency of internal audits as a function of the management review.

8.8.2 Internal audits of the laboratory follow the Checklist for the Competence of Testing Laboratories in accordance with ISO 17025. The person(s) conducting the audit shall be knowledgeable and experienced concerning the Standards and documents related to the NAT Quality Management System. Auditors cannot audit their own work. Non-conformances and opportunities for improvement are identified and addressed through the non conformance and corrective actions procedure. All NAT personnel are informed of the results of internal audits.

8.9 Management Review (Management Review Procedure QSP8.5)

8.9.1 The NAT Board of Directors conducts a complete review of the NAT Quality Management System and activities on an annual basis. This review ensures that the quality system is adequate for the fulfillment of testing activities under ISO/IEC 17025 and TNI 2016 Laboratory Standard. The review also ensures the effectiveness of the quality system for satisfying the requirements of the NAT lab quality policies and

objectives.

8.9.2 The Program Manager provides the Board of Directors with a current copy of the Lab Quality Manual and all necessary information related to the activities of NAT from the previous year, including:

a. The results of all audits.
b. Feedback from clients, including complaints and appeals.
c. Feedback from impartiality reviews.
d. Personnel issues and employee training.
e. The status of all preventive and corrective actions.
f. The status of objectives and actions from previous management meetings.
g. Any changes that could affect the quality management system.

8.9.3 The Board of Directors reviews the information and decides what changes should be made to improve both the Lab and the implementation of the Quality Management System.