Quality Manual

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1.0 Scope

North American Testing (NAT) is an independent, third party certification body which is committed to a policy of providing exemplary service and impartiality with respect to wastewater treatment product certification. This includes certifying new products and components, continuing product compliance, and engineering evaluations of system modification as well as alternative materials for products/components previously certified by NAT. In general, these services will provide design evaluation and test reports that NAT will use in making their final decision regarding certification of the product. It is the responsibility of NAT to produce unbiased and accurate design evaluations, test reports and certifications according to the applicable Standards, procedures and instructions defined in this manual.

This Quality Manual is considered the master document governing the NAT Quality Management System. The Quality Manual outlines the general principles and policies of NAT in regards to the requirements set forth in ISO/IEC 17065 and the certification scheme. The specific details of certification activities and responsibilities are included in the Quality System Procedures. All quality system procedures (QSP) are referenced in this document and all quality forms (QF) 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 Quality Manual.

NAT regularly leases test sites to manufacturers for product testing under non-certification testing conditions. These non-certification functions are separate from certification functions through various safeguards including computer passwords, locked filing cabinets, limited access to testing areas and observation by NAT employees of non-NAT personnel while on the NAT grounds performing work. Testing conducted for non-certification purposes is not required to conform to the NAT certification schemes, although whenever possible, the provisions of the Quality Management System shall be followed to guarantee accurate testing. All laboratory testing shall conform to the requirements of the Lab Quality Manual and related quality procedures.

2.0 References

1.	ISO/IEC 17065	Conformity assessment - Requirements for bodies certifying products, processes and services
2.	ISO/IEC 17000	Conformity assessment - Vocabulary and general principles
3.	ISO/IEC 17020	Conformity assessment - Requirements for the operation of various types of bodies performing inspection
4.	ISO/IEC 17021	Conformity assessment - Requirements for bodies providing audit and certification of management systems
5.	ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
6.	NSF/ANSI 40	Residential Wastewater Treatment Systems
7.	NSF/ANSI 46	Evaluation of Components and Devices Used in Wastewater Treatment Systems
8.	NSF/ANSI 245	Wastewater Treatment Systems - Nitrogen Reduction
9.	NSF/ANSI 350	Onsite Residential and Commercial Water Reuse Treatment Systems

10. Standard Methods for the Examination of Water and Wastewater.

11. NAT Lab Quality Manual

3.0 Terms and Definitions

The following definitions apply for the purpose of this manual.

3.1 Applicant

The applicant is the entity requesting certification of conformity to a specific Standard(s) and the certification scheme.

3.2 Certification Body

The Certification Body (NAT) is the party that is responsible for ensuring that products meet and continue to meet, the requirements on which certification is based according to ISO/IEC 17065 and the certification scheme.

3.4 Certification Scheme

The certification scheme is the qualification criteria stipulated in NAT's policies and procedures, the certification contract, and the specific Standard under which the product is being evaluated.

3.5 Client

The product manufacturer which is responsible to the Certification Body for ensuring that certification requirements are fulfilled.

3.6 Conformity

Fulfillment by a product of specified requirements of the certification scheme.

3.7 Consultancy

Participation in the designing, manufacturing, installing, maintaining, or distributing of a certified product or a product to be certified.

3.8 Evaluation

Systematic examination of the extent to which the design fulfills specified requirements.

3.9 Exception

Approved limited non-compliance with applied Standards and/or procedures.

3.10 Impartiality

The presence of objectivity and the absence of conflicts of interest which may influence the certification activities.

3.11 Laboratory

Body that performs tests and analyses.

3.12 Non-Conformity

The absence of one or more specified requirements.

3.13 Manufacturer

The entity providing the product who is responsible for assuring conformity with all requirements, particular Standards or specifications and who desires to participate in the certification program and have its product(s) certified.

3.14 Qualified Personnel

Personnel that have demonstrated the capability of fulfilling specified requirements and are authorized to perform specified functions.

3.15 Quality Manual

A document stating the quality policy, quality system, and quality practices of an organization.

3.16 Quality Assurance Officer

The Quality Assurance Officer assesses compliance with policies and procedures.

3.17 Quality Management System

The quality system is the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

3.18 Scope of Certification

Identification of the product for which certification is granted and the Standard to which it is judged that the product complies with.

3.19 Test

A test is a technical operation that consists of the determination of one or more characteristic or performance of a given product, material, equipment, or physical phenomenon according to a specified procedure.

3.20 Verification

Verification is confirmation by examination and provision of evidence that specified requirements have been met.

4.0 General Requirements

4.1 Legal and Contractual Matters

4.1.1 Legal Responsibility

North American Testing, LLC is its own legal entity registered as a Limited Liability Company to do business in the State of Ohio which can be held legally responsible for it's certification activities.

4.1.2 Certification Agreement (Certification Contract QF4.1.2)

NAT and its clients enter into a contract for the provision of the certification activities. The contract is legally binding and outlines the certification responsibilities of both the client and NAT and requires that both parties comply with all respective evaluation and certification responsibilities. The right to perform design evaluations and/or tests is granted by the client. NAT will also accept the right granted by other certification bodies to perform design evaluations and/or tests at the permission of the client. NAT requires that its' clients:

a. Comply with all certification program provisions, as stated by the Standard, the contract, and the certification scheme.

b. Make necessary arrangements for the conducting of the product evaluation, which includes providing and installing the product, continuing compliance audits, and the resolution of customer complaints.

c. Agree that certified products will be manufactured to conform with the scope of certification and the relevant Standards.

d. Make claims regarding the certification only for the applicable scope and never use its product certification in misleading or unauthorized ways.

e. Ensure that product references in media comply with the requirements of NAT.

g. Discontinue use of certification upon suspension or withdrawal of certification.

4.1.3 License, Certificates, and Marks of Conformity

NAT owns and controls a certification mark (symbol) that is registered as a certification mark with the U.S. Patent Office (Registration No. 3,541,258) under the Trade Mark Act of 1946. NAT maintains control of the use of its Certification Mark through the contractual agreement, policies, and surveillance of Mark use. Prompt and well-defined action based on options defined in the contract and the associated policies is carried out for any misuse or unauthorized use of the Mark. Appropriate legal action will be taken for any misuse of the Mark not bound by the contract in place. In addition, NAT will obtain advice from legal counsel and notify appropriate governmental, regulatory, and public bodies with regard to the misuse of the Mark. NAT is fully capable of financing the legal defense of its Certification Mark.

(Licensing Agreement QF7.7.1.1)

4.2 Management of Impartiality

(Procedure for Management of Impartiality QSP4.2)

4.2.1 NAT is dedicated to undertaking certification 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 product certifications and cannot be allowed to influence certification activities.

4.2.2 While NAT program goals include objectives for the broad commercialization of residential wastewater treatment systems, employee salaries and promotion are not dependent upon the commercial or technical success of any specific commercial activity.

4.2.3 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 product certification 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.

4.2.4 When risks to impartiality are identified, NAT takes steps to eliminate or minimize those risks. Possible actions are included in QSP4.2. Evidence of those actions are provided to the Mechanism for Safeguarding Impartiality (See section 5.2).

4.2.5 NAT ensures its senior executives and staff are free from any commercial, financial and other pressures which might influence the results of the certification process. The Board of Directors and the Certification Committee are 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)

4.2.6 The NAT Certification Body does not:

a. Design, manufacture, install, distribute, or maintain products of the type it evaluates.

b. Provide any other products or services which are similar to the type which it certifies which could compromise the confidentiality, objectivity, or impartiality of its evaluation processes and decisions.

c. Advise or provide consultancy services to the applicant as to methods of dealing with barriers to the desired certification.

d. Advise or provide management system consultancy or internal auditing to its clients.

4.2.7 NAT is an independent entity and does not form a part of any other legal entities.

4.2.8 See section 4.2.7.

4.2.9 NAT cannot recommend any organization to a client for consultancy purposes. The activities of NAT will not be marketed or linked with any organization whose activities are those defined in section 4.2.6.

4.2.10 Personnel who have provided consultancy or have any other identified risks to impartiality shall be subject to restrictions on work assignments. Personnel that were involved in the product design will not be involved in the testing, evaluation, or inspection of that product. See QSP4.2 for personnel restrictions.

4.2.11 In order to safeguard the integrity and reputation of the Certification Body, NAT takes actions to respond to any identified risk to impartiality.

4.2.12 Participants in NAT inspection, testing, and evaluation activities must sign an agreement to commit to being free from any commercial, financial and other internal and external pressures that may adversely affect the quality, accuracy, or impartiality of their work.

4.3 Liability and Financing

4.3.1 NAT is a privately owned company that carries liability insurance.

4.3.2 NAT has been in existence since the year 2006 and intends to support the certification activities with funds received from its clients. These funds will be adequate for covering all required activities to meet the procedures defined in the NAT Quality Manual. The cost of operating NAT is equally distributed between all leased sites and tests. Prices for product evaluation and site leases are prorated according to the immediate occupancy of the individual test sites. Prices for lab analyses are fixed.

4.4 Non-discriminatory Conditions

4.4.1 All applicants that meet the criteria outlined in this Quality Manual are eligible for certification. NAT does not discriminate against applicants in any way other than what is outlined in ISO/IEC 17065 to ensure high quality results in certification. The success of NAT depends on the fair and equitable treatment of all applicants.

4.4.2 NAT's services are available to all applicants whose activities fall within the residential wastewater treatment system industry.

4.4.3 Access to certification and testing services is not conditional upon the size of the client or membership in any association or group, nor is certification conditional upon the number of certificates already issued. There are no undue financial conditions; specifically, fees are invoiced on a monthly basis as services are performed. Evaluation prices and site lease fees are fairly distributed between each site and evaluation.

4.4.4 NAT confines its requirements, evaluations, surveillance, review, and decisions concerning certification to the scope defined in ISO/IEC 17065 and the appropriate NSF/ANSI Standards. These specific Standards outline the criteria used in certifying products, components and devices. See section 7.1.

4.5 Confidentiality

4.5.1 NAT 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 performance evaluations, surveillance activities, and any other means 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. All NAT personnel involved in inspection, testing, or evaluation activities sign a Confidentiality and Disclosure Agreement (QF4.5) that resides in their personnel files. 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.

4.5.2 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.

4.5.3 Any information about the client which was obtained from any outside source shall be treated as confidential.

4.6 Publicly Available Information

NAT maintains information about certification which is on its web site northamericantesting.org or is made available upon request including:

a. References to NAT's accredited scopes of certification, evaluation procedures, and certification requirements which are found in the NAT Quality Manual.

b. Conditions for granting, maintaining, suspending, withdrawing, and refusing certification and also extending or reducing the scope of certification. (Certification Contract QF4.1.2)

c. The rights, duties, requirements, and restrictions of clients for maintaining certification. (Certification Contract QF4.1.2)

d. General information concerning the fees charged to clients. (NAT Rate Schedule QF4.6.3)

e. The procedures for handling complaints and appeals which are found in the NAT Quality Manual.

f. A directory of all products certified by NAT which are authorized to bear the NAT mark. (Directory of Certified Products QF7.8)

5.0 Structure of the Certification Body

5.1 Organizational Structure and Top Management

5.1.1 Overall structural impartiality is insured through the NAT Quality System and the Certification Committee that issues the final approval of evaluation reports. No single person within NAT has the authority to grant certification. Multiple signatures are required for authorization and issue of test and design evaluation reports. The NAT Quality System assures that a person different from the one who performed an evaluation, inspection, or test reviews each decision on evaluations, inspections, and tests.

a. Evaluations and tests are conducted by the Laboratory or Field Technician. These evaluations and/or tests are reviewed by the Lab General Manager.

b. Surveillance is conducted by the Certification Compliance and Field Auditor and reviewed by the Program Manager.

c. The Program Manager coordinates and oversees the evaluation process and transfers all evaluation data and results to the Certification Committee.

d. The Certification Committee has the final decision on all certification issues including granting, extending, suspending, or withdrawing certification.

5.1.2 The organizational structure is defined in the company organizational chart. (NAT Org Chart QF5.1)

5.1.3 NAT maintains job descriptions for all personnel which define the responsibilities and authority of each position within the Certification Body. In general, the following activities have a person or committee responsible for them: (Job Descriptions QF6.1.1.2)

a. The Board of Directors delegates the authority to the Program Manager to formulate new policies and policy revisions relating to the operation of the Certification Body. Policies are reviewed and approved by the Board of Directors during management reviews.

b. The Program Manager supervises the finances and implementation of the policies and procedures in the NAT Quality Management System.

c. The Program Manager shall use ISO/IEC 17065 and the certification scheme Standards (section 7.1) as the technical basis for the planning and development of certification activities.

d. The Certification Committee reviews the evaluation results and has the final decision on certification issues including granting, suspending, withdrawing, and refusing certification and also extending or reducing the scope of certification. The Program Manager is then authorized to sign certification documents upon approval of certification by the Certification Committee.

e. The Board of Directors delegates authority to committees or individuals as required to undertake activities on behalf of NAT.

f. The Program Manager is authorized to enter into contracts with applicants for the purpose of product certification services on behalf of NAT. It is the responsibility of the Program Manager to supervise the administration of complaints and appeals (section 7.13).

g. The Lab General Manager is responsible for technical performance of all testing as defined in ISO/IEC Standard 17025 and for the provision of adequate resources to carry out certification activities. The Lab General Manager also supervises the training and assures the competency of NAT personnel.

h. The QA Officer is responsible for quality assurance of testing, inspection, and evaluations.

5.1.4 Members of the Certification Committee are appointed upon the majority consensus from the Board of Directors. There are no limits set for length of service on the committee and the members may continue to serve provided that no conflict of interests exist. The Certification Committee 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. Committee membership and compensation is not dependent upon the voting record of the committee member.

5.2 Safeguarding Impartiality (Conduct of the Mechanism to Safeguard Impartiality QSP5.2)

5.2.1 NAT utilizes a “mechanism” which is designed to safeguard impartiality in the certification process. Individuals invited to participate in the mechanism provide input concerning the NAT policies, tendencies to be biased, and matters which may affect confidence in certification.

5.2.2 The mechanism is composed of a balanced representation of individuals from NAT, the certification client, any peer certification bodies which may be involved in the certification, and any other significantly interested parties. Participants in the impartiality review are provided access to the documents necessary to fulfil the function of the mechanism.

5.2.3 Individuals involved in the impartiality review have the right to take independent action if concerns regarding impartiality are not satisfied. Any input which is in conflict with the necessary operating procedures of NAT or any other mandatory requirements shall not be followed. If independent action is taken, the confidentiality requirements of section 4.5 shall be respected.

5.2.4 Significantly interested parties are identified in section 5.2.2. Any additional significantly interested parties which are identified by any individuals involved in the in the impartiality review may also be invited to participate in the mechanism.

6.0 Certification Body Resources

6.1 Personnel

6.1.1 General

6.1.1.1 The Program Manager ensures that NAT has enough qualified personnel available to evaluate products and meet the requirements defined in this manual.

6.1.1.2 Personnel employed by NAT shall have qualifications for their positions. Such qualifications shall be consistent with the duties of the positions as described in the Job Descriptions which are available to all personnel respective of their position. Product certification personnel are formally authorized to perform work on projects after successful completion of training requirements according to the Program Manager and/or the Lab General Manager judgment of their qualifications, demonstration of capability, and experience in the residential wastewater treatment system industry. NAT clearly documents job descriptions, duties and the minimum qualifications for each position. (Job Descriptions QF6.1.1.2)

6.1.1.3 See section 4.5.1 regarding confidentiality requirements of NAT personnel.

6.1.2 Management of Competence (Employee Training Procedure QSP6.1.2)

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

6.1.2.2 Personnel records are maintained for each employee which contain their resume, training record, authorizations, performance reviews, and all other required documents.
(Employee Training Log QF6.1.2.1)

6.1.3 Obligations of Personnel

NAT requires that all personnel commit themselves to compliance with the rules and procedures defined in the NAT Quality Management System. (Obligations of Employees QF6.1.3)

NAT requires that all personnel declare any situations which may cause a conflict of interest to exist. This information is provided to the mechanism for safeguarding impartiality. See section 5.2.
(Conflict of Interest Statement QF4.2.3.1)

6.2 Resources for Evaluation

6.2.1 Internal Resources

NAT follows the requirements of ISO/IEC 17065 for all of its certification activities.

The NAT lab follows the technical requirements of ISO/IEC Standard 17025 to ensure suitability, accuracy, and competence for all testing activities. The Lab Quality Manual outlines the policies of the NAT lab. Analysis methods follow Standard Methods for the Examination of Water and Wastewater (21st edition) and/or equipment manufacturer's instructions for all laboratory tests.

Surveillance of certified product manufacturers and products are done in conformance with ISO/IEC Standard 17020.

NAT follows the requirements of ISO/IEC 17021 for all of its quality system auditing.

NAT follows the product evalution requirements defined in the Standards within the scope of certification. See section 7.1.

6.2.2 External Resources (Subcontractor Competence Procedure QSP6.2.2.)

6.2.2.1 Whenever possible, NAT uses internal resources and personnel to perform all product testing and certification functions. When certification activities are beyond the capability of NAT, subcontractors shall be chosen which meet the requirements of the following Standards:

a. Testing - ISO/IEC 17025

b. Inspection and surveillance - ISO/IEC 17020

c. Auditing of quality systems - ISO/IEC 17021

6.2.2.2 Subcontractors shall be independent entities with no relationship with the client. Outsourced activities are managed by the Program Manager. 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.

6.2.2.3 All subcontractors are required 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)

6.2.2.4 NAT takes full responsibility for the activities of its subcontractors as they relate to certification. NAT follows a procedure to ensure that sub-contractors are qualified to perform their work assignments and that their activities are monitored. NAT also:

a. Maintains a list of qualified subcontractors. (Qualified Subcontractors QF6.2.2.4.1)

b. Follows the required procedures in section 8.7 for any non-conformances with the requirements of the certification activities stipulated by the Standards referenced in section 6.2.2.1.

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

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

7.0 Certification Process

7.1 General

NAT has documented procedures for evaluating products and implementing the process of certification. NAT confines its requirements, evaluations, surveillance, review, and decisions concerning product certification to the scope defined in ISO/IEC 17065 and the appropriate NSF/ANSI Standards, specifically:

a. NSF/ANSI Standard 40 - Residential Wastewater Treatment Systems

b. NSF/ANSI Standard 46 - Evaluation of Components and Devices Used in Wastewater Treatment Systems

c. NSF/ANSI Standard 245 - Wastewater Treatment Systems - Nitrogen Reduction

d. NSF/ANSI Standard 350 - Onsite Residential and Commercial Water Reuse Treatment Systems

These specific Standards, which are developed and published by NSF International and designated as ANSI Standards, outline the criteria used in certifying products, components, and devices. All NAT certification schemes are based on the current version of the published Standards. The scope of the certification is described in the applicable Standard which are publicly available to the applicant.

7.2 Application for Certification Services (Application for Product Certification QF7.2)

NAT provides potential clients with a copy of the NAT Quality Manual, a Contract for Certification Services (QF4.1.2), and a Rate Schedule (QF4.3.2) for their review. An official Application (QF7.2) is required to begin the certification process, signed by an authorized representative of the client which includes:

a. Identification of the product to be certified.

b. The scope of the product certification requested.

c. Corporate entity, name, legal status, address of its physical location(s) including laboratories and inspection facilities, and any relationships within a larger corporation.

d. Any other information relevant to the scope of certification for which is necessary for initial evaluation and surveillance.

7.3 Application Review (Application Review Procedure QSP7.3)

7.3.1 Before formally accepting to conduct a product evaluation, NAT ensures that it has gathered all required information necessary to determine that it has the capabilities to undertake the product evaluation. The Program Manager will review the application prior to entering into contract to insure that:

a. Sufficient information has been gathered to begin the evaluation process.

b. Any differences in understanding are resolved.

c. The desired scope of certification is clearly defined.

d. NAT has the competence and capability to perform all of the evaluation and certification activities.

7.3.2 NAT is accredited to certify wastewater treatment products to the Standards listed in section 7.1.

7.3.3 See section 7.3.2.

7.3.4 The scope of NAT's services with respect to wastewater treatment product certification includes certification of new products, verification of continuing compliance of certified units, and engineering evaluations of scale-ups, alternate materials, and modifications of certified products. NAT shall decline to undertake the product evaluation and certification if there is a lack of competence or capability for any of the required certification activities.

7.3.5 Additional models of the certified product may be authorized for certification without testing if the client provides scientific evidence to the satisfaction of NAT that the testing and evaluation of the certified model verifies that the additional models will comply with all of the requirements of the certification scheme. See section 7.10.3.

7.4 Evaluation (Evaluation Procedure QSP7.4)

7.4.1 The Program Manager prepares an evaluation plan for the evaluation activities. The Program Manager will further develop a time schedule to implement the evaluation plan considering the availability of personnel and facilities. The time schedule includes a calendar which is a schedule of all testing events for the entire product evaluation. NAT shall inform the customer of any deviations from planned activities. The evaluation plan will be documented and forwarded to the client. (Calendar of Testing QF7.4.1)

7.4.2 The Program Manager assigns the evaluation activities to appropriately qualified personnel based on their qualifications, authorizations, and experience. The confidentiality (section 4.5) and impartiality (section 4.2) requirements shall be followed.

7.4.3 To ensure that a comprehensive and complete evaluation is carried out, the Program Manager provides the appropriate quality system documents and client information to NAT personnel involved in the evaluation and testing. Each certification scheme has a document distribution checklist. See section 8.3. (Evaluation Document Checklist QF7.4.3)

7.4.4 The Program Manager ensures that evaluation activities performed by NAT personnel and subcontractors follow the evaluation plan.

7.4.5 NAT makes decisions on certification based on the information gathered during the evaluation process. If NAT decides to rely on any evidence of conformance which was completed prior to the current evaluation or by other certification bodies, NAT must be able to take responsibility for those activities and results. The requirements for subcontractors (section 6.2.2) shall be satisfied before any previous evaluation

results are considered in the certification decision. The NAT Certification Committee has the final decision on certification.

7.4.6 All non-conformities discovered by NAT during evaluation activities shall be reported to the client as soon as apparent.

7.4.7 Upon notification of non-conformities, the client shall also be informed of which additional evaluation tasks need to be satisfactorily completed to pass the evaluation. NAT may require that the client to repeat only the necessary parts of the evaluation procedure.

7.4.8 If the client chooses to proceed with completion of the additional evaluation tasks, the Program Manager shall revise the evaluation plan, re-assign personnel, distribute additional documents and information, and repeat any other applicable requirements of the evaluation procedures set forth in section 7.4.

7.4.9 The results of all required evaluation activities shall be documented before a formal review of the results, data and information can begin. A document checklist is used as a guide to ensure all required documents and records are complete and collected. (Document Report Checklist QF7.4.9)

7.5 Evaluation Review (Evaluation Review Procedure QSP7.5)

7.5.1 The Program Manager assembles all required information which serves as evidence of the products' conformance to the certification scheme and performs a preliminary review of the evaluation results. The purpose of the preliminary review is to ensure all information is available and complete. The Program Manager then assembles an Interim Evaluation Report which is submitted to the client and to the Certification Committee for official review.

7.5.2 The Certification Committee conducts an official review of the evaluation results immediately prior and in conjunction with their decision.

7.6 Certification Decision (Certification Procedure QSP7.6)

7.6.1 NAT is solely responsible for its decisions to grant, maintain, extend, suspend, or withdraw certifications. NAT shall not delegate authority for granting, maintaining, extending, suspending, or withdrawing certification.

7.6.2 The NAT Certification Committee officially reviews the results of the product evaluation and testing included in the interim evaluation report against the requirements of the certification scheme and Standard. The committee has the final decision concerning certification issues including:

a. Granting initial product certification
b. Extending or reducing the scope of certification
c. Suspension or withdrawal of certification
d. Reinstatement of certification

7.6.3 See section 5.1.4 and 7.6.2.

7.6.4 The NAT Board of Directors exercises organizational control over the activities and decisions of NAT.

7.6.5 All members of the Board of Directors are required to abide by the confidentiality, impartiality, and quality management system requirements set forth in this quality manual.

7.6.6 If the Certification Committee or its member(s) deny approval for certification, they shall identify the reason for disapproval. The Program Manger shall immediately notify the client and follow the steps outlined in sections 7.4.7 and 7.4.8.

7.7 Certification Documents

7.7.1 Upon approval of certification, the product is certified and NAT provides formal certification documents to the client achieving certification which includes:

a. Formal listing of the product on NAT Directory of Certified Products (QF7.8)

b. Licensing Agreement and Authority to Use the Certification Mark (QF7.7.1.1)

c. Product Testing and Evaluation Certification Report (QF7.7.1.2)

d. Certificate of Conformity (QF7.7.1.3)

7.7.2 The Board of Directors authorizes the Program Manager and/or Laboratory General Manager to sign the certification documents upon approval of certification by the Certification Committee.

7.7.3 Formal certification documents are issued only after approval of certification by the Certification Committee. The client must agree to the terms and sign the licensing agreement prior to receiving the formal certification documents and approval to place the certification mark on the certified products.
(NAT Licensing Agreement QF7.7.1.1)

7.8 Directory of Certified Products (QF7.8)

NAT maintains a current directory of every product certified by NAT and authorized to bear the NAT mark. The directory identifies the client name and address, the product, the date of certification, and the Standard under which the product is certified. These documents are part of the publicly available information (section 4.6) and are available upon request.

7.9 Surveillance (Surveillance Procedure QSP7.9)

7.9.1 NAT is required by the certification scheme to conduct annual surveillance audits of its certified clients. Surveillance audits ensure that the certified products and the manufacturer remain in compliance with the NAT certification program and the published Standard(s) under which the product is certified. Certified products are required to be manufactured to the same specifications under which they are certified and retention of a product's certification is maintained by passing the annual compliance audit which verifiies that there have been no changes.

The client is required to conduct its own surveillance on a percentage of its authorized representatives. These records shall be available to the NAT inspector during surveillance audits.

7.9.2 Surveillance is a function of continued product evaluation. Annual surveillance activities shall follow the requirements for evaluation (7.4), specifically:

a. The Program Manager schedules surveillance dates and coordinates visits to the clients' manufacturing facility. The Certification and Compliance Field Auditor completes a surveillance plan which is used as a guide for the surveillance visit.

b. The Program Manager assigns the surveillance activity to the Field Auditor and ensures that the person is qualified, authorized, and has completed the confidentiality and impartiality requirements to conduct surveillance of the client.

c. The document report file for the client and for its certified products are made available to the Field Auditor. The client is required to provide access to all records, product literature, on-site products, personnel, and all other areas of the facility, except those where safety does not permit.

d. The Field Auditor evaluates the product of the client against the requirements of the current Standard as defined in its document report and ensures that the client is abiding by all requirements of the certification scheme and licensing agreement.

e. Any non-conformances are clearly identified in the surveillance report and a copy of the report is provided to the Program Manager and the client. Procedures to address client non-conformances are outlined in section 7.11.

Certification reviews and decisions are not employed during the surveillance activities.

7.9.3 Surveillance activities also include the evaluation of marked products including any related packaging or information which bears the mark to confirm that the product and the manufacturer continue to conform to the certification scheme and the NAT licensing agreement.

7.9.4 NAT only certifies physical products.

7.10 Changes Affecting Certification (Certification Changes Procedure QSP7.10)

7.10.1 The certification requirements are established through the appropriate published Standards and the certification scheme. When the requirements of the Standards or interpretations of the requirements thereof change, NAT's clients will be informed through the NAT web site and in writing.

7.10.2 All changes affecting certified products shall be addressed and evaluated to ensure continued compliance with the certification scheme. Types of changes include:

a. Revision to the certification scheme or Standards. The NAT Program Manager will evaluate the changes to the appropriate published Standards to determine the time period for the manufacturer to meet the additional requirement if applicable.

b. Requests for approval of changes to certified products. The manufacturer shall make a written request and provide documentation and/or proposed drawings showing these changes.

c. Requests for approval of scale-up systems within the approved series. The manufacturer shall provide documentation and scale-up drawings which prove that the proposed product is directly proportional for the intended use.

d. Unapproved changes to certified products. Unapproved changes discovered during surveillance are treated as non-conformances and shall follow the procedures outlined in section 7.11.

e. Scope extensions. Requests for a scope extension under additional certification schemes shall follow the procedures for initial application for product certification (section 7.2).

7.10.3 The Program Manager will review change requests in accordance with the appropriate procedures and Standards. A Professional Engineer with the appropriate technical expertise will evaluate all applicable documents detailing the changes and make a recommendation to the Program Manager for additional testing (if required) and approval. Documented rationale shall be provided for approval of changes and entered into the product document report. For scope extensions, official certification review and decision is required by the Certification Committee.

The client shall not release the modified product displaying the mark until a letter from NAT approving the change is received. This letter will document the rationale for allowing the change and a copy will be kept in the clients file.

Upon approval of scale-up systems and scope extensions, revised certification documents are issued when applicable and the products listed in the directory of certified products. See section 7.7.1.

7.11 Reduction, Suspension, or Withdrawal of Certification

7.11.1 During surveillance, if NAT discovers a non-conformance of a certified product or non-compliance by the client with the certification requirements, the Program Manager shall determine, based on the severity of the non-compliance, the appropriate actions to be taken by NAT. Actions may include:

a. Require the client to provide a reason for the non-conformance and a plan for corrective action taken within 30 days.

b. Require the client to immediately ensure that any continuing production and finished inventory is in compliance.

c. Increased surveillance intervals.

d. Issue a recall or public notice regarding the affected products.

e. Administrative hearing.

f. Reduce the scope of certification.

g. Suspend certification.

h. As a last resort, withdrawal certification.

If the action includes reduction in the scope, suspension, or withdrawal of certification, the Certification Committee shall provide their approval before the action is carried out.

7.11.2 If the non-conformance is a change in which the client would like to be approved in the certification, NAT shall follow the procedure for change requests outlined in section 7.10.

7.11.3 Upon suspension, withdrawal, or a reduction in the scope of a certification, NAT immediately notifies the client of the decision in writing and modifies all formal certification documents to indicate as such. See section 7.7.1. Any revised certification documents are provided to the client. The client shall be required to make the necessary changes to their production process regarding marked product as stipulated in the licensing agreement. See section 7.7.3.

7.11.4 It is the responsibility of the Program Manager to assemble a plan for reinstatement which will allow the client to reconcile their certification status and communicate this plan to the client. The client is to be involved in the planning process. Documented rationale shall be provided in the plan and shall be in accordance with the certification scheme and Standard.

7.11.5 If the plan for reinstatement involves complete re-testing of the product, all applicable processes in section 7.0 for product certification shall be followed.

7.11.6 Upon reinstatement of the certification status or a change in the scope of certification, the procedure for notifications and document modification and reissue in section 7.11.3 shall be followed. The client shall be allowed to resume marking the certified products.

7.12 Records (Record Control Procedure QSP8.4)

7.12.1 NAT retains all records generated during the individual product certification process which provide evidence that all of the requirements of certification are fulfilled. NAT creates a project file on the server as well as a hard copy for each client. All data, correspondence, notes, and records related to the client are maintained in these files. The Program Manager is responsible for the proper archiving and tracking of the documents pertaining to the relevant testing and design evaluation.

7.12.2 The confidentiality requirements of section 4.5 apply to all records retained by NAT. Records are stored, transported, transmitted, and transferred using confidential methods.

7.12.3 All records directly related to individual product certification activities are retained for the previous and the current evaluation cycle. After this period, the materials are returned to the client or destroyed with written notice in advance thereof.

7.13 Complaints and Appeals (Procedure to Address Complaints and Appeals QSP7.13)

7.13.1 NAT has a documented procedure for complaints and appeals directed at NAT which provides requirements for the recording and tracking of complaints and the actions to resolve them. The Program Manager is responsible for addressing complaints.

Complaints raise doubt concerning NAT's compliance with its policies, procedures, the requirements of the NAT Quality System, or the quality of laboratory's tests and design evaluations. NAT is dedicated to the satisfactory resolution of complaints.

7.13.2 Upon receipt of a complaint or appeal, the Program Manager shall confirm whether NAT is responsible for its administration. NAT is responsible for complaints and appeals from applicants and clients regarding NAT certification activities. Complaints from end users of the certified products shall be directed to the manufacturer of the certified product. NAT reviews clients' complaint records during surveillance activities

7.13.3 NAT acknowledges receipt of formal complaints and appeals. Informal or verbal complaints shall be referred to the process for formal complaints. Formal complaints and appeals shall be documented. (Complaint Documentation Form QF7.13)

7.13.4 NAT is responsible for the investigation of complaints including administration, collection, and verification of information to the point of resolution.

7.13.5 Decisions regarding complaints, appeals, and disputes are made or approved by the Board of Directors. Administrative reviews are conducted by the Board of Directors.

7.13.6 The impartiality requirements of section 4.2 shall be followed for personnel assigned to investigate and review complaints.

7.13.7 NAT provides complainants with a formal notice detailing the resolution of the complaint. The confidentiality requirements of section 4.5 shall be followed regarding notification of the resolution of complaints.

7.13.8 NAT provides appellants with a formal notice detailing the outcome of appeals.

7.13.9 NAT takes action in accordance with the decision of the complaint or appeal. The Program Manager is responsible for the supervision and implementation of those actions. Actions to resolve substantiated complaints which reveal a flaw in the NAT Quality Management System shall follow the non-conformance and corrective actions procedure. See section 8.7.

8.0 Quality Management System

8.1 General

This document, plus other documents described herein, defines the quality system supporting the activities required for product certification under NAT's accredited product certification program. This quality system manages all product evaluations, certifications, surveillance, and testing work performed at NAT's facility as well as all field activities. It also governs activities that result in certification and certification-related reports and assures objectivity of the information contained in the reports.

8.2 Management System Documentation

8.2.1 NAT has defined and documented policies and objectives for quality in accordance with ISO/IEC 17065 and the accredited certification scheme 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 Quality Manual and are required to acknowledge their strict adherence to following the procedures and instructions contained in the Quality Manual. All employees are encouraged to report any improprieties by management to either the Certification Committee, the Board of Directors, or ANSI. (Obligations of Employees QF6.1.3)

8.2.2 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.

8.2.3 The Program Manager reports to the Board of Directors and is appointed to oversee the proper implementation of the quality system. The Program Manager is the task leader for certification activities, and therefore has authority to direct the activities of personnel on a day-to-day basis and has significant influence in employment, assignment, disciplinary actions, and termination.

8.2.4 This Quality Manual is considered the master document governing the NAT Quality Management System. The Quality Manual outlines the general principles and policies of NAT in regards to the requirements set forth in ISO/IEC 17065 and the certification scheme. The specific details of certification activities and responsibilities are included in the Quality System Procedures. All quality system procedures (QSP) are referenced in this document and all quality forms (QF) 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 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. 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 Quality Management System folder on the NAT computer system. 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 record control. All records are stored in a secure file cabinet, in case of paper copy, and/or on the NAT server, 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 product certification activities. These type of records shall be identified by the NAT project code or the product name and are retained for the previous and the current evaluation cycle.

b. Records which are generated internally by NAT for administrative reasons and fulfillment of the requirements of ISO/IEC 17065. These type of records are identified by the document control number and are retained for 7 years.

8.4.2 NAT shall follow 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. See section 7.12.

8.5 Management Review (Management Review Procedure QSP8.5)

8.5.1 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 product certification under ISO/IEC 17065 and the certification schemes. The review also ensures the effectiveness of the quality system for satisfying the requirements of NAT's stated quality policies and objectives.

8.5.2 The Program Manager provides the Board of Directors with a current copy of the 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.

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

8.6 Internal Audits (Internal Audit Procedure QSP8.6)

8.6.1 NAT has a procedure for the conduct of internal audits. The Program Manager is responsible for arranging or conducting internal audits annually.

8.6.2 Internal audits of the Certification Body follow the Checklist for the Accreditation Requirements (PRO-FR-105-ISO/IEC 17065) in accordance with ISO/IEC 17065. Internal audits of the laboratory follow the Checklist for the Competence of Testing Laboratories in accordance with ISO 17025.

8.6.3 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.

8.6.4 The person(s) conducting the audit shall be knowledgeable and experienced concerning the certification scheme, Standards, and documents related to the NAT Quality Management System and cannot audit their own work.

Non-conformances and opportunities for improvement are identified and addressed through the non conformance and corrective actions procedure. See section 8.7. All NAT personnel are informed of the results of internal audits.

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 implement corrective actions.

8.7.2 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.

8.7.3 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 certification program. Management evaluates the significance of the non-conformity and may immediately stop the affected work.

8.7.4 A non-conformity is any action which does not comply with the requirements of NAT's Quality Management System or the certification scheme. Client and/or product non-conformances are not NAT quality system issues and are handled separately in section 7.11.

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 Preventive Actions

(Preventive Actions Procedure QSP8.8)

8.8.1 NAT has a procedure to identify and reduce or eliminate sources of potential non-conformances.

8.8.2 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.

8.8.3 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-conformances has been identified, preventive actions are taken which follow the same process used for non-conformances including identification, documentation, and re-evaluation for effectiveness.