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Quality Management Plan for The NELAC Institute

1.0 Introduction

This Quality Management Plan (QMP) describes the Quality Management System (QMS) within which The NELAC Institute (TNI) operates. This Plan also provides additional details about the governance and management of TNI. TNI is committed to conducting its operations within a QMS that uses a consensus process for developing goals using strategic planning, measuring accomplishments against stated goals, and meeting customer needs. TNI's customers are the users of the services it provides, and include organizations that generate environmental sampling and measurement data (e.g., laboratories and field sampling and measurement organizations,) organizations that accredit the process of generating data (Accreditation Bodies or ABs) and all other participants that have an interest in the process (e.g., other governmental agencies, consultants, vendors, data users, other environmental and/or data related organizations.) This plan is a dynamic document, subject to TNI review and revision, as deemed necessary and appropriate.

1.1 Mission of TNI

The mission of TNI is to foster the generation of environmental data of known and documented quality through an open, inclusive and transparent process that is responsive to the needs of the community.

TNI accomplishes this mission through the use of volunteers working on committees tasked with specific functions in defined program areas, under the leadership of a Board of Directors, and with staff, all of whom are part-time contract employees. TNI is organized and operated as a non-profit association, under section 501(c)(3) of the Internal Revenue Code of the United States. TNI strives to maintain the highest standards in its corporate governance practices and abides by the code of ethics for non-profit organizations established by the Independent Sector (www.independentsector.org) and has established Corporate Governance Guidelines based on this code. The TNI Code of Ethics and the Corporate Governance Guidelines are posted on the documents page of the TNI website.

1.2 Stakeholder Groups of TNI

TNI operates on the premise that all affected stakeholders have the opportunity to fully participate in the activities of TNI. To that end, TNI has established the term "balanced representation" for the purpose of forming "consensus" in many of TNI's committees, including the Board of Directors, all standards development committees and most of its other committees. To that end, the following stakeholder groups are defined:

- ABs and other entities that operate environmental accreditation programs,
- Laboratories, Field Sampling and Measurement Organizations (FSMOs) and other organizations directly involved in providing sampling and environmental measurements (groups eligible to use the services of the ABs) and
- All others (includes governmental agencies that do not operate accreditation programs, industry and commercial entities, data users and any other non-AB or non-lab entities.)

1.3 The Consensus Process

TNI strongly supports the use of consensus in accordance with rigorous democratic procedures for all its committees and the Board, and relies upon the federal Office of Management and Budget (OMB) Circular A-119 as its underlying philosophy.

OMB Circular A-119 defines a voluntary consensus body as one having the following attributes: (i) openness; (ii) balance of interest; (iii) due process; (iv) an appeals process; and (v) consensus, which is

“general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reason(s) why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.”

For its activities that concern development of consensus standards, TNI is an Accredited Standards Developer by the American National Standards Institute (ANSI.)

1.4 Funding

TNI depends upon the following funding sources to support its programs: membership dues, semi-annual and annual conference registration fees, training course fees, purchase of the TNI Standards, accreditation fees, and cooperative agreements and grants from various agencies such as the U.S. Environmental Protection Agency. Policy 1-111 describes in more detail how TNI uses its funds prudently and ethically in accordance with Circular A-122 from the Office of Management and Budget.

2.0 The Structure of TNI

TNI is exemplary in that most volunteers are familiar with quality management systems. TNI membership includes scientists from throughout the environmental monitoring community, including both government and private sector participants, working in a variety of environmental disciplines that include:

- Sampling organizations (laboratories, consulting and engineering firms, local, state and federal contractors);
- Environmental laboratories (large and small commercial laboratories and local, state and federal government laboratories);
- Municipalities and local government entities, state agencies, and federal agencies;
- Regulated entities that use environmental data; and
- ABs, consulting firms, Proficiency Test (PT) providers, and other vendors to the environmental services industries.

Individuals eligible for membership include any individual who has an interest in environmental sampling or measurement or other environmental accreditation issues in the private, public or academic sectors, so long as they agree to the TNI's Code of Ethics. Organizations eligible for membership include any company, academic institution or governmental agency. Each individual and organizational member is categorized as one of the three stakeholder groups, according to affiliation and field of professional effort. TNI promotes inclusiveness and its staff, Directors and volunteers reflect variety of interests and viewpoints in order to enrich its programmatic effectiveness. The organization takes meaningful steps to promote inclusiveness of all potential stakeholders in its hiring, retention, promotion, board recruitment, committee member appointments and constituencies served.

2.1 Management of TNI

TNI's activities are managed and governed by its Board of Directors (BOD or Board.) This Board is ultimately responsible for the QMS of TNI as it develops and implements the Strategic Plan of the organization through the program and committee structure described herein.

The BOD has supervision, control and direction of the affairs of TNI to determine its policies or changes within the limits of the law or the Bylaws and Articles of Incorporation. The Board actively pursues TNI's mission and has discretion in the disbursement of its funds. Also, the Board does not have authority to supersede the authority of core programs without due cause. Due cause is limited to activities that would

be inconsistent with the TNI Bylaws or put the organization at unacceptable financial or legal risk, as determined by the Board of Directors.

The Executive Committee of the Board of Directors consists of its Officers – the Chair, Past-Chair, Vice-Chair, Secretary and Treasurer. The Executive Committee advises and aids the Executive Director in all matters concerning TNI's interests and the management of TNI's business.

The Executive Director (ED) has day-to-day operational responsibility for TNI, including carrying out TNI's goals and TNI policies. The ED attends all Board meetings, reports on the progress of The NELAC Institute, answers questions of Board members, and carries out other duties as designated by the Board. The ED is a non-voting member of all TNI committees, as is the Chair of the Board.

2.2 Core Programs

There are four “core” programs described in the TNI Bylaws. Each core program is managed by an Executive Committee with a balance of stakeholders such that all interests are represented. The Executive Committee role is to provide strategic direction, growth and fiscal management of the program.

TNI Core Programs
1. Consensus Standards Development
2. National Environmental Field Activities
3. National Environmental Laboratory Accreditation
4. Proficiency Testing

The core programs work in cooperation toward a common vision, as defined by the organization's Strategic Plan (see below.) Each core program has the authority to establish policies and procedures for the program, make decisions and operate independently with the exception of the following restrictions:

- All policies are reviewed by the Policy Committee to ensure policies from different core programs are not in conflict with each other. TNI SOP 1-116, Development and Approval of TNI Policies and SOPs, addresses creation of policies and procedures for the organization.
- Each core program provides monthly reports to the BOD describing progress towards the goal of the program. The BOD will provide feedback to the program for future efforts.

Each core program establishes strategic goals and objectives that are reviewed by the BOD to ensure that the goals and objectives are aligned with TNI's mission and the overall Strategic Plan.

Program Administrators (PAs) are individuals assigned by the Executive Director to provide staff support to TNI's core programs. As such, PAs:

- Ensure that policies and decisions of TNI as they relate to each program are implemented.
- Assist the program committees and subcommittees in achieving their goals.
- Ensure publication of information relating to the program.
- Provide monthly reports to the TNI Board on progress of the program towards goals.
- Assist in the preparation of an annual budget for the program.
- Perform other such duties as may be assigned by the Executive Director.

2.3 Administration and Support

Administration and Support consists of a number of committees that work across all TNI programs and TNI staff that also support TNI's efforts. These groups and individuals ensure an infrastructure exists to support the core programs.

Note: See Appendix 1 for a listing of these committees with their responsibilities and membership.

2.4 Other Activities

TNI is engaged in several other activities that do not fit well with the committee structure described above. These activities include:

- An Educational Delivery System,
- The National Environmental Monitoring Conference,
- The Non-Governmental Accreditation Body Recognition, and
- The Stationary Source Audit Sample program.

The management of these activities is described in SOPs or Work Plans. Each of these activities arose from TNI's strategic planning efforts and was approved by the Board. The Board may, upon advice or suggestion from the Board members, Committees or other organizations or individuals, create new groups to address future needs that meet the TNI Mission and Strategic Plan.

3.0 Roles and Responsibilities for Quality Management System

3.1 Board of Directors

The Board has ultimate responsibility for the structure and oversight of TNI's QMS. The Chair has operational responsibility for the QMS and is the senior manager for quality. This individual holds ultimate responsibility for determining whether any particular issue or aspect of the QMS should be brought to the attention of the entire Board for resolution.

The TNI Board has a diverse composition including representation from all stakeholder groups and many different viewpoints within those groups. Typically included are elected individuals from state and non-governmental ABs, laboratories, field sampling entities, proficiency test providers, private organizations, assessors and appointed representatives of invited federal agencies.

Each new Director is provided an "orientation for new Directors" that includes an introduction to TNI's QMS and a thorough briefing on the current QMP. By influence as well as activities, Directors exemplify successful operation of the QMS.

3.2 Executive Director

The ED has day-to-day responsibility for The NELAC Institute and has authority to enter into contracts for TNI.

The ED is responsible to ensure that all administrative, organizational and program specific activities under his authority comply with the requirements of this QMP. The ED also performs outreach presentations and meetings with interested parties, government and private industry entities which explain the TNI goals and objectives, status of the TNI standards, and new program initiatives. The ED may enlist other staff or volunteers to support him in this effort, as s/he sees fit.

The ED is responsible for the creation, maintenance and delivery of a training course for TNI's Quality Management System and this QMP that is suitable for the Board as well as for committee chairs and TNI staff, and other interested parties, as deemed appropriate.

3.3 Staff, including Program Administrators

All staff and program administrators must be familiar with this Quality Management Plan, and whenever revisions are made, will be required to review it anew by the ED.

Determination of whether staff have particular roles for the QMS will be at the discretion of the Executive Director based on preferences and needs of the individual programs for which staff have programmatic responsibilities, in consultation with the Chair of the Board.

Note: TNI staff work as contract employees, *i.e.*, an individual with whom TNI has formalized a personal services contract, paid hourly but with some latitude regarding the activities to be conducted. This is in contrast to a vendor where there will be a clearly defined activity and product to be delivered as discussed in Section 5.2.

3.4 Committee Members

Committee members are volunteers with knowledge about the area to which they volunteer. They work to ensure that the practices of this QMP are implemented within the committee in which they participate. Once it is available, all committee chairs and vice chairs must have taken TNI's QMS training course within 6 months of appointment.

3.5 General Membership

All members of TNI are made aware of TNI's QMS and the requirement to adhere to the TNI Ethics Policy upon joining TNI, or upon renewing their membership (for existing members, to occur annually.)

4.0 Planning, Implementation, Monitoring and Evaluation of TNI Activities

4.1 Strategic Planning

From its inception, TNI has employed strategic planning to determine the process and timeline for accomplishing its goals. This ensures that TNI's activities are appropriate and aligned with its stated mission and helps ensure the quality of its activities and work products.

Planning begins with a five-year strategic plan developed by the TNI Board and senior staff. TNI's current Strategic Plan contains core strategies that have 3-5 specific goals each. Each goal then has several objectives with a particular committee or individual assigned responsibility and a specific target date for completion.

4.2 Implementation

Each committee has a Charter describing the general composition, mission and measurable expected outcomes, which is based on the TNI strategic plan and approved by either the program Executive Committee or TNI Board, as appropriate.

At the TNI annual meeting, each committee will provide an annual report on their plan of work for the coming year as part of an overall report to the membership. These annual reports are reviewed and approved by the Board using its normal processes for approval of documents as described in the TNI Bylaws. These reports and plans for the committees are the Implementation Plan for the Strategic Plan.

Note: See SOPs 1-101, Operation of TNI Committees, and 2-101, Operation of Expert Committees.

4.3 Monitoring and Evaluation

Progress is assessed through monthly Program Reports to the TNI Board, provided by the Program Administrators and distributed to Board members by the ED, and, as noted in section 4.2, the committees provide annual reports to the TNI Board and membership at the TNI annual meeting. TNI evaluates the monthly and annual committee reports and responds or takes action(s) as appropriate.

5.0 Assuring Competencies of Individuals Carrying out TNI Activities

Especially in an organization where most activity is conducted and managed by volunteers, determining and ensuring the competency of the individual for participation in each level of activity (Board, program, committee, staff and general membership) becomes a crucial factor in the success of the organization.

5.1 Staff and Volunteers

Competencies for staff are the simplest to ensure and document, since TNI has management control over each individual's actions. All staff shall have appropriate experience working in the areas they are expected to support, and a bachelor's degree as minimum education for personnel working in scientific areas. Staff are considered an integral part of the organization, regardless of the area in which they serve. Staff may also participate in other TNI activities as volunteer members. The performance of all TNI staff is assessed continually through on-going discussions with the ED and committee chairs as well as staff meetings held at conferences that include many aspects of performance, such as workload distribution. Acute problems are typically addressed as they arise, so that while it may not be a formal review, performance reviews are occurring continually.

Assuring that volunteers are appropriately knowledgeable as well as willing to work falls to an effective peer selection process. Often, but not always, volunteers join committees related to their fields of employment, and thus the committee member application form provides a basis for assessing knowledge level of the member. Individual committees review applications and make selections based on the qualifications provided from the volunteer in the application. If committee members do not participate regularly and contribute effectively to the Committee's efforts, a process exists whereby the individual can be removed from the committee roster and replaced.

5.2 Vendors

For certain activities needed to fulfill TNI's mission, certain individuals or companies will need to be identified to carry out specialized functions. This type of contract activity is different than the ongoing personal services contracts with individuals considered "TNI staff." Typically, contracts with vendors would be of limited scope with clearly defined activities and deliverables. Examples of this would be database creation, development and presentation of training for a particular purpose or even expertise in a particular software package for some activity.

For actions initiated by TNI, all vendors are selected through the use of a Request for Proposal (RFP) process made public by distribution throughout the environmental data community, publication on the TNI website, and/or by targeted solicitations. TNI also accepts unsolicited proposals.

In addition to stating clearly the tasks or specialized functions to be carried out, such RFPs clearly spell out the expertise needed (including experience and educational requirements of the submitter,) the level of knowledge of the subject matter required of the proposing entity and the fact that all TNI activities are conducted within its QMS. Ideally, multiple proposals would be received.

In most cases, the Finance Committee reviews proposals, as an entity that can impartially evaluate the proposals to select the individual or organization deemed most capable of successfully completing the tasks, while also taking into account the cost estimates included in that proposal and the QMS utilized by the contractor. Occasionally, a special evaluation team consisting of members from the TNI Board of Directors or the executive committee of the relevant program may be formed for purposes of performing a technical review of proposals. Proposals for training courses through TNI's Educational Delivery System are evaluated by the TNI Training Coordinator.

Any award issued, after the process described here, shall be overseen and monitored by the Executive Director or a designated TNI staff person to ensure that TNI funds are disbursed conservatively and that the quality of the work product(s) meets the needs and expectations of the project. A vendor is expected to agree to non-disclosure agreements and to provide sufficient information to assure that no conflict of interest exists. The TNI staff person may include volunteers to assist in assessing whether the work products are acceptable.

Note: See Policy 1-113, Accounting Policies and Procedures for Administration of Assistance Agreements: Procurement Policy, for more information.

6.0 Information Management and Information Technology Activities

The Information Technology (IT)_Committee's mission is to support the IT needs of the TNI programs, committees and membership by providing a user-friendly and attractive communications center and database.

6.1 Web Site Maintenance

The IT Committee has overall responsibility for design and content of the TNI website. It works with the IT Administrator, who maintains and updates the website.

The IT Administrator has a significant role in sustaining the quality of TNI's website. S/He receives day-to-day supervision from the Executive Director, with guidance from the IT Committee about website design and database content and operation. Duties include the development and maintenance of the database; the posting of news, board and committee minutes, conference schedules and committee meetings; and the operation of member services, such as conference registration, membership applications and electronic voting processes. The IT Administrator also exercises professional judgment about items submitted for posting and consults with the IT Committee if there are any concerns to be resolved before a specific document is posted to the website.

6.2 Laboratory Accreditation Management System (LAMS)

The IT Committee is also responsible for the use and maintenance of the LAMS, a database which will list the TNI ABs and all their accredited laboratories. This database now resides on the TNI server. The Database Administrator works with ABs to upload and maintain their laboratory information to the database, so that accurate accreditation status of each laboratory is available to anyone within TNI. The ABs may update their information at any time.

Database quality control practices are documented in the ITQA Plan.

6.3 Other Databases and Lists

There are multiple lists of analyte codes, method codes and Fields of Proficiency Testing tables (FoPTs) used by TNI programs that are essential and integral parts of the accreditation operations for both laboratories and FSMOs. Contents of the lists are maintained by the committee responsible for the list or the IT Committee.

6.4 Document Control

SOP 1-104, Control of TNI Documents, provides the requirements for document control within TNI. As provided in this SOP, TNI maintains a current a list of all TNI controlled documents. The list includes a clear identifier and the issue or effective date. Superseded or obsolete controlled documents are retained to provide a historical reconstruction of a document's revisions and amendments.

6.5 Records Maintenance

In accordance with Policy 1-104, Management of Records, all TNI records – whether in hard copy, electronic, oral, or visual media – are maintained in a manner that ensures their permanence and accessibility, and that facilitates compliance with local, state and federal laws. The Secretary of TNI acts as the custodian for all TNI records, in charge of their storage and disposal and may delegate such custody to Program Administrators or other staff, as warranted.

7.0 Customer Satisfaction

TNI encourages staff and volunteers across the organization to establish communications with clients and stakeholders, to identify process improvement opportunities, and identify and offer solutions to problems. Additionally, TNI's Advocacy Committee has a leadership role in reaching out to other organizations and individuals to seek feedback on TNI's activities. The Small Laboratory Advocate is a designated individual within TNI who is charged with specifically seeking feedback from small laboratories.

8.0 Ethics

TNI is committed to maintaining the highest standards of ethics in all of its operations. To become a member of TNI, one must agree to abide by TNI's Code of Ethics. The specific ethical policies that members are expected to follow are set forth in the Policies 1-102, Ethical Conduct of Members, and 1-107, Membership Code of Ethics.

9.0 Quality Management System Elements

9.1 Continuous Improvement

The organization is committed to improving program and organizational effectiveness and develops mechanisms to promote learning from its activities and the field. These mechanisms include but are not necessarily limited to review of key documents by the Policy Committee, creating special task forces to address specific issues, routine strategic planning and special sessions at TNI meetings. TNI strives to be responsive to the needs of its stakeholders. TNI regularly reviews program effectiveness and has mechanisms to incorporate lessons learned into future programs.

9.2 Audits

9.2.1 Self-Audits and Internal Audits

All TNI committees assess the conformance of their operations to TNI rules and their charters by conducting annual self-audits. These self-audits are performed in conjunction with the annual workplan development of the individual committees. The level of assessment for each auditable element takes into consideration the legal, financial, recognition (by external organizations), and reputation risks incurred by TNI from committee activities.

The TNI Policy Committee approves and maintains checklists that address auditable elements generally applicable to committees.

Audit checklists may also address elements that are applicable to a committee's specific mission. Annual self-audits are conducted by a committee's PA, a committee's Chair, or both. Self-audits for the NELAP Accreditation Council are performed either by its PA or the Chair of the Laboratory Accreditation System Executive Committee (LASEC). The Finance Committee operations are overseen and monitored by the TNI Board of Directors.

At least every five years, an internal audit of a committee is conducted by a TNI PA, chair, or both, external to the committee and that has no conflict of interest with the mission of the committee to be reviewed.

Results of self-audits and internal audits are shared with committees. Corrective actions arising from these audits are coordinated by the PA and the Chair, and are affirmed at the next level of hierarchy within TNI's structure, *i.e.*, an Executive Committee, or the Board.

9.2.2 External Audits

Entities outside of TNI perform audits of the work products of the Finance Committee and Consensus Standards Development Executive Committee (CSDEC.) Those independent organizations, such as ANSI and certified public accountant firms, follow their own auditing procedures and corrective action processes during their evaluations.

The TNI Board reviews all reports and corrective actions resulting from external audits.

9.3 Corrective Actions

Corrective action is the action taken to eliminate the causes of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence. Deficiencies cited in internal audits, customer complaints or managerial reviews are documented and require corrective action. Corrective actions taken are appropriate for the magnitude of the problem and the degree of risk to the organization.

When failures due to systematic errors have been identified, the first step of the corrective action process starts with the initial investigation and determination of root cause(s) of the problem. Records are maintained of nonconformances requiring corrective action to show that the root cause(s) was investigated, and includes the results of the investigation.

Where uncertainty arises regarding the best approach for analysis of the cause of exceedances that require corrective action, appropriate personnel will recommend corrective actions that are appropriate to the magnitude and risk of the problem and that will most likely eliminate the problem and prevent recurrence. The TNI ED ensures that corrective actions are discharged within the agreed upon time frame and monitors implementation and documentation of the corrective action to assure that the corrective actions were effective.

9.4 Complaints

Anyone who has a concern about TNI's activities, actions or procedures may file a complaint using the process described in SOP 1-106, General Complaint Resolution Process. Complaints are tracked and reviewed to identify needed corrective actions.

10.0 References

TNI Bylaws

Office of Management and Budget Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, February 10, 1998

American National Standards Institute, *Essential Requirements: Due Process Requirements for American National Standards*, most recent version

TNI Policies and SOPs, available at <http://nelac-institute.org/content/policy.php>

Uncontrolled copies of the Self-audit and Internal Audit Checklists will be available on the TNI website, when finalized

11.0 Document Approved Changes

Previous Version	New Version	Date of change	Description of Change
None	0.0	June 3, 2016	

Appendix 1: Administrative and Support Committees

Advocacy Committee

The purpose of the Advocacy Committee is to promote and support TNI's core programs. The Advocacy Committee consists of 10 to 16 members with balanced representation. A TNI Director chairs this committee.

The Advocacy Committee:

- Establishes relationships with other organizations (e.g., ACIL, AWWA, WEF) that have an interest in accreditation issues,
- Establishes relationships with EPA program offices,
- Develops presentations and papers to promote national accreditation,
- Develops presentations and papers to promote TNI,
- Provides outreach at national, regional and local meetings,
- Assists with publication of the member newsletter, and
- Helps plan and organize two meetings per year to allow TNI members and the public the opportunity to discuss topics related to laboratory accreditation.

Finance Committee

The Finance Committee consists of at least three (3) Individual Members appointed by the Board Chair whose duty shall be to perform an annual review of the TNI financial records and report the results to the Board. The Chair of this committee is the Treasurer. This Committee also:

- Develops an annual budget for review by the TNI Board,
- Provides periodic reports to the Board on the status of TNI's finances,
- Provides contract and proposal review as needed,
- Makes financial decisions that affect TNI, and
- Publishes an annual Financial Report.

Information Technology Committee

The IT Committee is an unrestricted committee that has members who have the interest and skill set in working on this committee. The IT Committee:

- Provides recommendations as to the design and content of the TNI website,
- Manages the TNI Laboratory Accreditation Management System database,
- Manages the Stationary Source Audit Sample database, and
- Maintains additional TNI databases such as technology codes, method codes and analyte codes.

Nominating Committee

The Nominating Committee consists of immediate Past Chair and two other Individual Members appointed by the Past Chair whose duty is to develop a slate of candidates for election to the TNI Board. From time to time, this group may be asked to recommend candidates for other committees or working groups as requested by the Board. Except for the Past Chair, none of the Members shall be a member of the existing Board.

Policy Committee

Under the direction of the Board, the committee serves as a resource for the development and review of policies, Standard Operating Procedures and related documents. The Policy Committee shall consist of at least one member from each core program, one TNI Director and one at-large member. Other at-large members may be added. The Policy Committee:

- Reviews policies, SOPs and related documents from all programs for conformity with respect to style and for consistency with one another and with the overall mission of TNI. The Policy Committee may return the policy to the originating program for additional work OR forward a program policy to the TNI Board for review for organizational impact (e.g., legal, fiscal or credibility issues);
- Develops general policies, SOPs and related documents for TNI (e.g., travel reimbursement, purchasing, conflict of interest, etc.);
- Reviews and evaluates requests for policies, SOPs and related documents received from the membership and others and provides a recommendation to the Board; and
- Receives and manage complaints against TNI.