

Consumables Task Force

2020 Charter

June 9, 2020

Mission

Support the current TNI Environmental Laboratory Sector Standard (ELSS) requirement for purchased services, supplies, reagents, and consumables, that directly impact the quality of tests or calibrations, to meet criteria suitable to ensure data of known and documented quality. The group, which includes appropriate representation of the vendor community, will identify what critical supplies and services are. Next, the group will develop essential criteria enabling users to ensure that products and support services meet a minimum quality expectation, are in accordance with appropriate applicable standards, and can provide documentation that represents an adequate level of traceability. The task force will work with laboratories, providers, regulators, data users and others to effectively develop a process that is complementary of and in compliance with the TNI standards.

Composition of the Committee

Committee will consist of a range of volunteers knowledgeable of the laboratory accreditation process, the manufacture, verification, and distribution of commercial products, and in the purchasing of supplies and equipment by stakeholders.

Objectives:

1. Explore the feasibility of developing implementation guidance, and ultimately, a standard for laboratory consumables.

Goal: Discuss the requirements of the TNI 2016 ELV1M2 Standard Section 4.6 and determine the elements that are highest priority. Understand and identify the use of the term “critical consumables, services and supplies”. Using the terms consumables, services, and supplies, create content for each category. Example: Services - weight verification, balance calibration, thermometer verification, etc.

Goal: Relative to critical consumable categories, provide expanded and detailed information related to documentation necessary for meeting the requirements of 4.6.3.

“Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release. NOTE: The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.”

Goal: Define the evaluation criteria necessary to meet the requirements 4.6.4 “The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.”

The criteria will be different for distributors, manufacturers, service providers, etc.

2. **Consider forming an Expert Committee to turn guidance into a standard once the initial effort is complete.** (Engage laboratory assessors, regulators, other TNI community committees and any other relevant group to provide suggestions and input throughout the process.)

Goal: Utilize the TNI community for valuable insight and information related to audit findings, criteria, performance standards, and other factors that drive expectations of conformance for certain products or services.

Example: Thermometer verification must be traceable to a NIST certified thermometer. What is the proof, documentation, tolerances, timeframe, other related?

Goal: Evaluate the information to determine the need for a standard, guidance document, mandatory process/procedure, certification/accreditation, or other appropriate action or expectation.

Task 1: Determine a master list of details that can be used to meet specific criteria and can be met by all suppliers and service providers.

Task 2: Require that all suppliers and service providers meet the criteria as established and recommended by this taskforce.

Decision Making

Any necessary decisions to be made by the Task Force will be made based upon the following decision making rules. A quorum is defined as >50% of the members and a quorum is required for any decision making by the Task Force. For passage of administrative matters such as agenda, minutes, adjournment, etc, a simple majority of members present is required and a 2/3 vote of all members is required for passage/approval of matters related to guidance or standards development and other matters that are defined as the objectives of the Task Force. Voting options are: Yeah, Nay or Abstain.

Available Resources:

- Volunteer committee members
- TNI web site for on-line storage, maintenance and archiving of SOPs, Policies, SIRs and related documents
- Existing national and international consensus-based standards
- Teleconference and A/V services
- Program Administrator support
- Other TNI Committees (Expert and Administrative) for feedback on committee documents
- Participating organizations and other entities as the committee sees fit, that pertain to our mission

Anticipated Meeting Schedule:

- Teleconferences: Currently scheduled on the 2nd Tuesday of each month at 2:00-3:30 PM ET. Schedule is subject to change. Participants will be notified of any changes. The Task Force schedule will be posted on the TNI Website.
- Face-to-face meetings as needed.