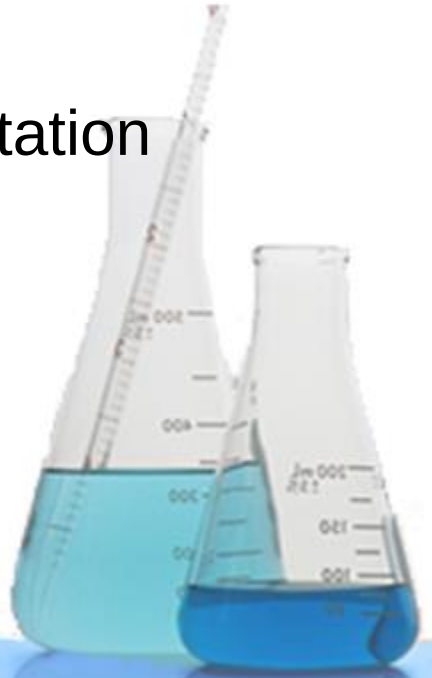
THE NELAC INSTITUTE

TNI QUALITY SYSTEMS

Tulsa – Forum on Environmental Accreditation

01/26/16



Ground Rules

- Silence cell phones
- Please identify yourself and your organization when speaking at the microphone
- No sidebar discussions
- If you need to leave, please quietly close the door behind you to keep the outside noise out

Quality Systems

Labs (6) – Paul Junio (Chair), Jessica Jensen (Vice Chair), Patty Carvajal, Shari Pfalmer, Dale Piechocki, Matt Sowards

ABs (2) – Kristin Brown, Shannon Swantek

Others (5) – Katie Adams, Chris Gunning, Silky Labie, Michelle Wade, Janice Willey

Quality Systems

- **Accomplishments**
  - Clarify requirements for verification of support equipment
  - Finalize changes made to Module 2
- **Plans**
  - Complete re-write of the Small Lab Handbook to remove inconsistencies, address above changes, and provide a single ‘voice’ to the document.

Quality Systems

- **Accomplishments**
  - **Lot:** A definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality

Balance

- The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. There shall be a minimum of three interest categories for any Expert Committee.
- The criteria for balance are that no single interest category constitutes a majority of committee members on any Expert Committee. The suggested interest categories are:
  - accreditation bodies and other governmental agencies that operate accreditation programs (federal or state);
  - laboratories and other organizations directly involved in providing sampling and measurements
  - all others (consultants, proficiency test providers, state and federal agencies that do not run accreditation programs, etc.).

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Member	Organization	Expiration	Group
Mr. Paul Junio	Northern Lake Service	2018	Lab
Ms Kristin Brown	Utah DOH	2018*	AB
Ms Patty Carvajal	San Antonio River Authority	2017*	Lab
Mr. Chris Gunning	A2LA	2018*	Other
Ms Jessica Jensen	A & E Analytical Laboratory	2018*	Lab
Ms Silky S. Labie	Env. Lab Consult & Tech	2018	Other
Ms Shari Pfalmer	ESC Lab Sciences	2018*	Lab
Mr. Dale Piechocki	Eurofins Eaton Analytical	2017*	Lab
Mr. Matt Sowards	ACZ Laboratories, Inc.	2017*	Lab
Ms Lizbeth Garcia	Oregon DEQ	2017*	AB
Ms Janice Willey	NAVSEA Programs Field Office	2018	Other

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Voting Draft Standard

- Voting closed on November 30
- 3 votes were received that were ‘Negative with Comment’
- 2 votes were received that were ‘Positive with Comment’

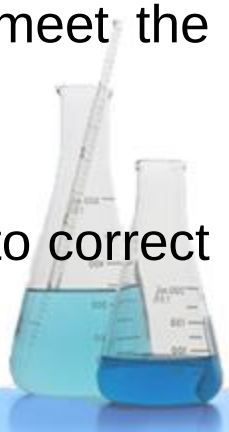
Voting Draft Standard

5.5.13.1 Support Equipment - This Standard applies to all devices that may not be the actual test instrument, but are necessary to support Lab operations. These include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and mechanical volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices).

a) The results of any calibration or verification shall be within the specifications required of the application for which this equipment is used. The Lab shall define the specifications for acceptability if none exist in method or regulation. If any equipment fails to meet the specifications for acceptability:

i) the equipment shall be removed from service until repaired; or

ii) the Lab shall maintain records of established correction factors to correct all measurements.



Voting Draft Standard

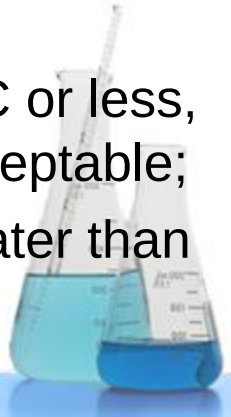
b) The Lab shall maintain all support equipment in proper working order. The records of all repair and maintenance activities, including service calls, shall be kept.

c) On each day the equipment is used, balances, ovens, refrigerators, freezers, incubators and water baths shall be checked and documented. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.

d) Temperature measuring devices shall be calibrated or verified at least annually. Calibration or verification shall be performed using a recognized National Metrology Institute traceable reference, such as NIST, when available.

i) If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable;

ii) If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket the range of use.



Voting Draft Standard

e) If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, the Lab shall verify volumetric measuring devices as follows:

i) Glass microliter syringes and Class A glassware are exempt from any verification requirements beyond what is stated in Section 4.6.2;

ii) Disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with its first use;

iii) Mechanical pipets used at more than one volume shall be checked at 10%, 50%, and 100% of the maximum volume of the pipette. These checks shall be performed prior to first use and on a quarterly basis;

iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use.

Voting Draft Standard

f) All other support equipment shall be calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use.

g) Raw data records shall be retained to document equipment performance.

Negative Comments

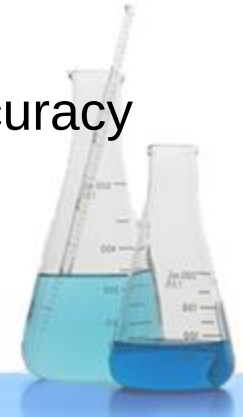
e) If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, the Lab shall verify volumetric measuring devices as follows:

i) Glass microliter syringes and Class A glassware are exempt from any verification requirements beyond what is stated in Section 4.6.2;

ii) Disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with its first use;

iii) **Mechanical pipets used at more than one volume shall be checked at 10%, 50%, and 100% of the maximum volume of the pipette. These checks shall be performed prior to first use and on a quarterly basis;**

iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use.



Interim Draft Standard

From:

iii) Mechanical pipets used at more than one volume shall be checked at 10%, 50%, and 100% of the maximum volume of the pipette. These checks shall be performed prior to first use and on a quarterly basis;

To:

iii) Mechanical devices shall be verified prior to first use and on a quarterly basis. Mechanical devices used at more than one volume shall be verified at volumes bracketing the range of use, and at the mid-point of the volumes used by the device;

Interim Draft Standard

e) If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, the Lab shall verify volumetric measuring devices as follows:

i) Glass microliter syringes and Class A glassware are exempt from any verification requirements beyond what is stated in Section 4.6.2;

ii) Disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with its first use;

iii) Mechanical devices shall be verified prior to first use and on a quarterly basis. Mechanical devices used at more than one volume shall be verified at volumes bracketing the range of use, and at the mid-point of the volumes used by the device;

iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use.

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Small Lab Handbook

It's been on our plate for a long time, and we really haven't addressed it

Our time has been spent on other issues

We will get to this, I promise

Quality Systems

SIR – 2009 V1M2 5.5.13.1

The standard states "Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis." Would class A plasticware be considered the same as Class A glassware ie - you do not need to check it on a quarterly basis? Or would Class A pastic ware be considered the same as non-class A labware?

The same question for V1M5 section 1.7.3.7 iii.2 “equipment such as filter funnels, bottles, non-Class A glassware, and other containers with volumetric markings (including sample analysis vessels) shall be verified once per lot prior to first use. This verification may be volumetric or gravimetric.“ Would you need to check Class A plasticware once per lot?

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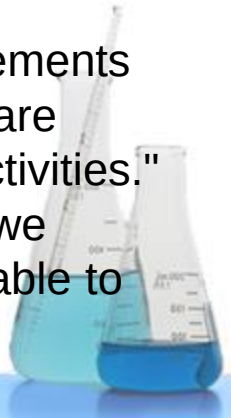
Response - By definition, Class A plasticware does not exist. So, something that is called Class A plasticware would be required to meet the same requirements as non-Class A labware.

Quality Systems

SIR – 2003 5.4.13.1

5.4.13.1 The laboratory shall periodically, in accordance with a predetermined schedule and procedure, and at least annually, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this Standard. The internal audit program shall address all elements of the quality system, including the environmental testing activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out.

The standard states that "The internal audit program shall address all elements of the quality system, including the environmental testing activities." We are unclear as to what is expected in reference to "Environmental Testing Activities." For example, if we have 10 methods used for environmental testing are we required to audit each of those specific test methods yearly, or is acceptable to audit the laboratory as a whole is operating under the quality system.



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Response - Are elements equivalent to just methods? Are elements PT samples, analytical SOPs, non-method SOPs, training records, management statements…. Can this be reflected in technologies (i.e., ICP/MS, GC/MS), so that you catch all analytes over two years?

All methods may not have the same in-depth annual internal audit (this may be an analyst interview, observation of the method, or some other assessment), but all methods are fully assessed over a set timeframe. The laboratory is obligated to expand its assessment schedule if issues are identified during its internal audit.

Quality Systems

SIR – 2009 V1M2 5.8.5 a

Do labs have to uniquely identify sample containers when received at the lab?

The 2009 standard states: "The laboratory shall have a documented system for uniquely identifying samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates."

The 2003 standard stated the same but also added: "The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample."

Since the 2009 standard dropped the wording above in the third paragraph, some are interpreting this to mean the labs do not need to uniquely identify sample containers anymore. However, since the 2009 standard does still include sample containers in the last sentence of the second paragraph, above, some are interpreting that sample containers must be uniquely identified.

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Response - The laboratory shall assign a unique identifier to each sample container received.

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Open Discussion

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- What do we need to clarify in the TNI Standards?
- What do you like, dislike
- What's on your wish list?

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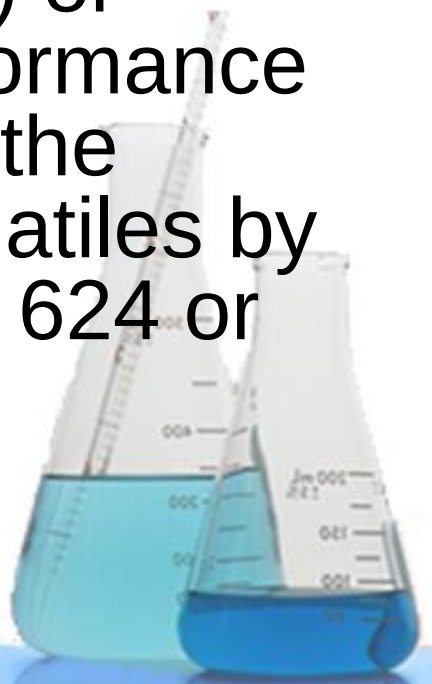
- What do we need to clarify in the TNI Standards?
  - *Ongoing DOC – Acceptable performance of a blind sample (single blind to the analyst).*
  - *What's that? Is it a "passing" PT, or is it getting an "Acceptable" on every analyte?*

On-going DOC

1.6.3.2 This on-going demonstration may be one of the following:

a) acceptable performance of a blind sample (single blind to the analyst) or successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260);



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- What do we need to clarify in the TNI Standards?
  - *What sort of thermometers or weights need to be used in the laboratory on a daily basis?*

Quality Systems

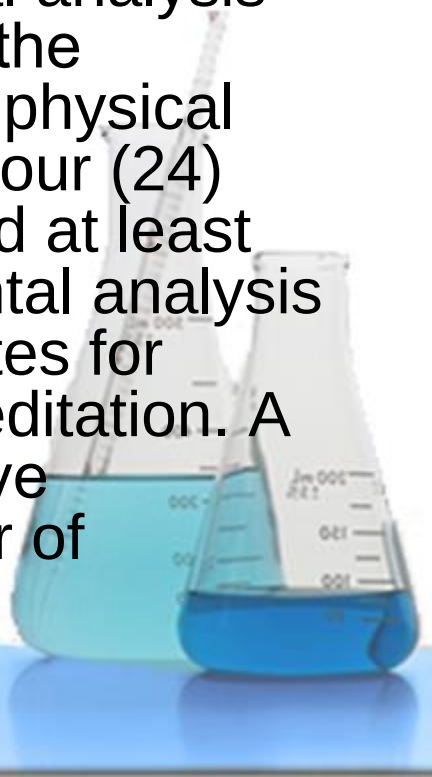
- Technical Manager Requirements
- Quality Manager Requirements

Technical Manager

5.2.6.1 Technical Manager Qualifications

The applicable requirements for technical managers are given below.

a) Any technical manager of an accredited environmental laboratory engaged in chemical analysis shall be a person with a bachelor's degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least twenty-four (24) college semester credit hours in chemistry and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

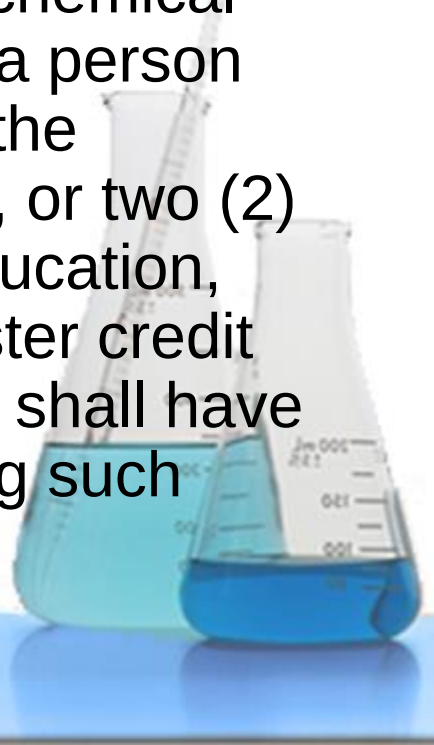


Technical Manager

5.2.6.1 Technical Manager Qualifications

The applicable requirements for technical managers are given below.

b) Any technical manager of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in the chemical, physical or environmental sciences, or two (2) years of equivalent and successful college education, with a minimum of sixteen (16) college semester credit hours in chemistry. In addition, such a person shall have at least two (2) years of experience performing such analysis.



Technical Manager

5.2.6.1 Technical Manager Qualifications

The applicable requirements for technical managers are given below.

c) Any technical manager of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of sixteen (16) college semester credit hours in general microbiology and biology and at least two (2) years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

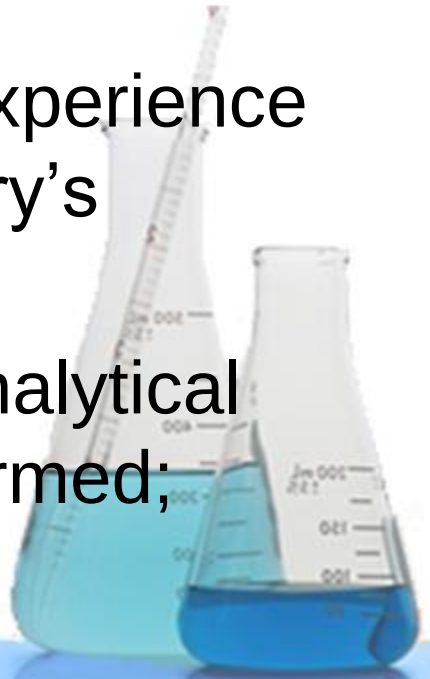
A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four (4) college semester credit hours in general microbiology may be the technical manager(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, E. coli, and standard plate count. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one (1) year of experience in microbiological analyses.

Quality Manager

4.1.7.1 Where staffing is limited, the quality manager and the technical manager may be the same person. The laboratory's quality manager and/or his/her designee(s) shall:

d) have documented training and/or experience in QA/QC procedures and the laboratory's quality system;

e) have a general knowledge of the analytical methods for which data review is performed;



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What else can or should we change?

This doesn't mean it will be quick, but let's start the process

Questions?

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