

# **Quality System Expert Committee (QS) Meeting Summary**

**January 26, 2016**

## **1. Roll Call and Minutes:**

Paul Junio, Chair, called the meeting to order at 8:05 am Eastern in Tulsa, OK. Attendance is recorded in Attachment A – there were 9 members present.

## **2. Overview**

See Attachment D for the PowerPoint used at the meeting in Tulsa.

### Committee Balance

Expert committees are required to be balanced. Paul reviewed the definition. At this point the committee is out of balance with too many laboratories. Two members of the committee are rotating off and the committee needs two more Other or AB members. Shannon will also be stepping off the committee, but there is another person from Oregon that will be applying to be added to the committee. There are candidates Paul is talking to and hopefully the issue will be resolved by the next meeting.

### Standard

Paul reviewed the history of the changes made most recently to the Standard. He reviewed the language of the Voting Draft Standard (VDS) and pointed out that all comments were on section e) iii). The language was reviewed and changes were submitted as an Interim Standard. This Interim Standard is currently posted for vote and comment through February 22, 2016. If there are no negative comments ... the Standard will become the Final comment.

Paul reviewed the comments as posted on the TNI Website.

There were no comments on the new language posted as the Interim Standard.

## **3. Small Laboratory Handbook**

This is one of the main action items for the committee this next year. The committee plans to begin working on the handbook again at its February meeting.

#### 4. Standard Interpretation Requests (SIRs)

Paul reviewed the SIR process and asked for meeting attendee input to try to close the remaining open SIRs.

SIR # 274:

<b>Standard</b>	2009 TNI Standard
<b>Volume and Module (eg. V1M2)</b>	V1M2
<b>Section (eg. C.4.1.7.4)</b>	5.5.13.1
<b>Describe the problem:</b>	<p>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?</p>
<b>Response:</b>	<p>The same question for V1M5 section 1.7.3.7 iii.2 "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?</p> <p>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.</p>

This SIR was sent back by the LASEC. Paul asked for comments from the membership:

- Comment: There is no difference between Class A plasticware and glassware. Class A is Class A.

Paul noted that he does not believe there is such a thing as Class A plasticware. The commenter will send a picture to Paul showing "Class A" on plasticware. Paul noted that the ANSI definition has "glass" in the definition.

Silky asked for a copy of the certificate for the plasticware.

- Tyler purchased Class A plasticware and he believes the certificate had ISO quoted – not ASTM. (Purchased from VIT LAB)

Paul asked if plasticware can be Class A, should it be treated different than glassware. It should not be treated differently.

Paul reminded everyone about a conversation in Chicago where it has become known that not all Class A glassware is the same. There is some out there that is no better than the regular glassware.

Jessica found plasticware noted as Group A, especially internationally. It was heated to higher temperatures.

Bob Wyeth noted that we should be able to rely on the vendor community. He also asked how long a Class A designation is valid. Michelle noted that we have not put our vendors through much scrutiny at this point and it is not a Standard requirement.

Silky reviewed Class A requirements used by VIT Lab. It does not refer to ASTM and she is not sure the certification statements are from a national body. It looks more like someone checked the labware against some calibration standard, but the labware is not certified.

Bob Wyeth noted that teflon has been used in metals labs and is a different situation – where there is Class A.

Kim Watson noted that glassware is not always used in the field. They purchase plasticware, Teflon and glassware and check it. They try to buy from ISO accredited vendors.

Tyler asked if it would be prudent to say it meets the Class A volume tolerances instead of the language currently used.

Ilona reminded everyone that this is an SIR and it is an interpretation of the Standard – not an opportunity to change the Standard. Paul agreed and noted that any changes needed to the Standard should be listed for the next Standard update.

The new language of the Standard addresses the issue of the SIR, but a response is needed based on the Standard currently in effect.

Bob Wyeth recommended that the committee be careful in their statement that there is no Class A glassware. He also noted that Teflon would be better than glassware.

Robin Cook commented that it is not about whether the ABs like an SIR response ... it is a question of whether they can implement it.

Kim Watson noted that many labs doing pesticides use Class A plasticware and it is accepted in the industry. Paul asked that she send him information on this.

Todd Cowan – The current standard states Class A glassware. It does not state Teflon or plasticware. It falls under volumetric equipment requirements. It is clear.

Though it might be helpful to add Teflon to the term glassware and it might be helpful to look at the validity of plastic Class A labware, the committee cannot update the Standard at this time. This information needs to be added to the list of future updates.

A response should just state something along the lines that the Standard makes an allowance for Class A glassware and plasticware is not glassware.

Paul prepared the final response for vote:

**Plasticware is not glassware. Any volumetric dispensing devices that are not Class A glassware or glass microliter syringes must be checked for accuracy on a quarterly basis.**

Tyler asked if the committee can make an interpretation based on intent. Silky clarified that the intent in the past was to use the term Class A based on glassware.

Michelle noted that the only time intent is considered is when the language is very ambiguous. In this case ... it is not ambiguous.

Michelle motioned to approve the language for the response to SIR #274 noted above. The motion was seconded by Silky and unanimously approved. Paul will forward the response to LASEC.

#### SIR #230, 2003 Standard

Standard	2003 NELAC Standard
Volume and Module (eg. V1M2)	2003 NELAC
Section (eg. C.4.1.7.4)	Sec. 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.

**Describe the problem:**

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.

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?

**Response**

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.

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Every drinking water method is expected to be reviewed in an internal audit annually.

Robin asked why a lab wouldn't want to review every method if assessors are looking at all methods. She also noted that a lab should say what they do and then see if an assessor has an issue with it.

Ilona noted that many labs work on a two year schedule, though some ABs think this should be annually.

Jessica commented that a lab needs to define what the elements are and then follow it.

LASEC has been working on a policy on internal audits, but it has not gotten very far.

Kristin: The majority of the ABs do not require an audit of all methods each year. They look at the outcome of the audits. If they are effective, they don't have an issue with a planned schedule. There were some that did want to see it done annually.

Dave Speis would prefer that the committee not put any hard dates or requirements. Needs to be reasonable and adequate to catch system issues. The lab should define their internal audit procedures. Jessica provided an example of what her lab does. It is continuous and not one internal audit done at one time. It is split up over the year.

The committee will send the SIR back to LASEC since the NELAP AC/LASEC are working on a policy. No final response will be prepared. Paul will provide a summary of the to date discussions with this email.

Looking at the new Standard – the language is similar. It can be argued that the audit schedule should be completed annually and that could mean you need to audit what is on your schedule. A Note is not enforceable, so the italicized note regarding internal audits is not a requirement. It also uses the word “should”.

SIR #246:

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.8.5.a
Describe the problem:	Question: 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.
Comments:	I have heard this may be addressed in the upcoming standard, but I don't know that absolutely.

**Response:**

The laboratory sample ID must appear on each sample container. The sample container ID must be unequivocally linked back to the Sample ID as provided by the client. Where multiple sample containers are provided for a sample, then each sample container must have a unique ID.

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There was general agreement that the standard is clear.

Robin asked what the rationale is for uniquely identifying the sub-samples? How can you say it was preserved properly if there is not a chain?

There was some confusion as to whether the response above was sent to the LASEC. Older versions of the SIR had a different response that the committee agreed should be updated. It was originally returned 9/26/14.

Meeting attendees described different procedures they have used in their labs.

Matt noted that the Standard states there needs to be a system ... not necessarily that a unique ID had to be used.

Todd Cowan commented that he does not think a unique ID on split samples after it comes into the lab is required by the 2009.

Last Response: The laboratory sample ID must appear on each sample container. The sample container ID must be unequivocally linked back to the Sample ID as provided by the client. Where multiple sample containers are provided for a sample, then each sample container must have a unique ID.

**Final Response: The laboratory shall assign a unique identifier to each sample container received.**

A motion was made by Jessica to use the final Response above to SIR #246. The motion was seconded by Michelle and unanimously approved.

Paul will forward the response to Lynn.

## 5. Open Discussion

Paul asked for comments from the meeting attendees:

- Robin – should the standard specify how often NIST Standard thermometers should be recertified? Michelle agreed that there are a number of labs with the same question, but this is not defined anywhere. Silky suggested this could be included in the Best Practices document that Advocacy is working on.
- Sara Hoffman – KS: Reference weights vs. working weights. The ABs are handling this differently and this is another topic worth being discussed. Silky noted there is a section on reference weights and this may be the spot to define this.
- Jessica: More clarification needed on maintenance logs. What should really be included? Todd noted you should be careful about defining minor and major maintenance. Major maintenance needs recalibration.
- Todd: There are State mandated reports that don't include all the TNI reporting elements. He asked if there is any language in the Standard that allows for this. Section 5.10.1 and 5.10.10 apply to this. Regulations trump the Standard – after method requirements.
- Robin: Suggestions made to the Standard update that were too specific are going to be included in the Small Laboratory Handbook update.
- Dale: Commented on Technical Director requirements - “In addition, such a person shall have at least two (2) years of experience performing such analysis.” Some think it is ok to have supervised the lab for 2 years and others think the person had to do the actual analysis. It is not clear.

## 6. Action Items

A summary of action items can be found in Attachment B.

## 7. New Business

- None.

## 8. Next Meeting and Close

The next meeting will be February 8, 2016 at 1pm Eastern. Ilona will send out a conference call and Webex invitation. *(Addition: The meeting date was changed to 2-15-16.)*

A summary of action items and backburner/reminder items can be found in Attachment B and C.



Paul adjourned the meeting. The meeting ended at 11:58 Central. (Motion: Silky Second: Shari Unanimously approved.)

**Attachment A**  
**Participants**  
**Quality Systems Expert Committee (QS)**

<b>Members (Exp)</b>	<b>Affiliation</b>	<b>Balance</b>	<b>Contact Information</b>	
Paul Junio (2018) (Chair) <b>Present</b>	Northern Lake Service	Lab	262-547-3406	<a href="mailto:paulj@nlslab.com">paulj@nlslab.com</a>
Michelle Wade (2016) (Vice-chair) <b>Present</b>	Wade Consulting and Solutions	Other	913-449-5223	michellefromks@gmail.com
Katie Adams (2016)  <b>Absent</b>	USEPA Region 10	Other	360-871-8748	<a href="mailto:Adams.Katie@epa.gov">Adams.Katie@epa.gov</a>
Kristin Brown (2016)  <b>Present</b>	Utah DOH	AB	801-965-2530	kristinbrown@utah.gov
Patty Carvajal (2017*)  <b>Present</b>	San Antonio River Authority	Lab	210-227-1373	pmcarvajal@sara-tx.org
Chris Gunning (2018*)  <b>Absent</b>	A2LA	Other	301-644-3230	cgunning@a2la.org
Jessica Jensen (2018*)  <b>Present</b>	A&E Analytical Laboratory	Lab	316-618-8787	jessica@aelabonline.com
Silky S. Labie (2018)  <b>Present</b>	Env. Lab Consulting & Technology, LLC	Other	850-656-6298	elcatllc@centurylink.net
Shari Pfalmer (2018*)  <b>Present</b>	ESC Lab Sciences	Lab	615-773-9755	spfalmer@esclabsciences.com
Dale Piechocki (2017*)  <b>Present</b>	Eurofins Eaton Analytical	Lab	574-472-5523	DalePiechocki@eurofinsUS.com
Matt Sowards (2017*)  <b>Present</b>	ACZ Laboratories, Inc.	Lab	970-879-6590	matts@acz.com
Shannon Swantek (2017*)  <b>Absent</b>	Oregon Public Health Division	AB	(503) 693-4130	<a href="mailto:shannon.swantek@state.or.us">shannon.swantek@state.or.us</a>
Janice Willey (2018)  <b>Absent</b>	NAVSEA Programs Field Office	Other	843-794-7346	<a href="mailto:Janice.willey@navy.mil">Janice.willey@navy.mil</a>
Ilona Taunton (Program Administrator) <b>Present</b>	The NELAC Institute	n/a	(828)712-9242	<a href="mailto:Ilona.taunton@nelac-institute.org">Ilona.taunton@nelac-institute.org</a>

**Attachment B**

**Action Items – QS Executive Committee**

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
8	Send new wording for Section 5.5.13.1 to Cathy Westerman and get input.	Paul	7/13/15	10/11/15
9	Look at the Handbook Table of Contents and volunteer for sections.	All	8/10/15	
12	Send update to Lynn regarding SIR #290.	Paul	9/21/15	
19	Send updated SIR responses to Lynn.	Paul	2/8/16	
20	Follow on potential committee members.	Paul	2/8/16	
21	All committee members vote on Standard before 2/22/16.	All	2/22/16	

## Attachment C


## Backburner / Reminders – QS Executive Committee

[illegible]




## 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 Pfallmer, 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.).





## Quality Systems



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

## Quality Systems

### 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



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

## Quality Systems

### 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 plastic 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?

## Quality Systems

**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.

## Quality Systems

**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?

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## 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."

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## Quality Systems

**Response** - The laboratory sample ID must appear on each sample container. The sample container ID must be unequivocally linked back to the Sample ID as provided by the client. Where multiple sample containers are provided for a sample, then each sample container must have a unique ID.





## Open Discussion





## Quality Systems

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









## Quality Systems

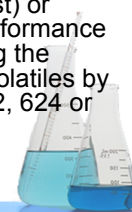

- What do we need to clarify in the TNI Standards?
  - Ongoing DOC – Acceptable performance of a blind sample (single blind to the analyst).
  - What's that? Is it a "passing" PT, or is it getting an "Acceptable" on every analyte?

## 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);


## Quality Systems

- 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

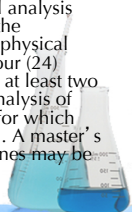

- Technical Manager Requirements
- Quality Manager Requirements

## Technical Manager

5.2.6.1 Technical Manager Qualifications  
The applicable requirements for technical managers are given below.

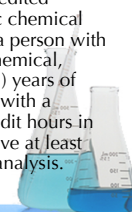
- a) Any technical manager of an accredited environmental laboratory engaged in chemical analysis shall be a person with a bachelor's degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least twenty-four (24) college semester credit hours in chemistry 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.





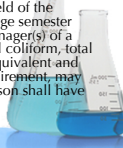

## Technical Manager

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;

## Quality Systems

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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