Quality Management System Expert Committee (QMS)
Meeting Summary

August 18, 2025

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on August 18, 2025. Attendance is recorded in Attachment A – there were 9 voting members present as noted. Associate members present: Paul Junio, Debra Zeller, Anagha Chitre, Matt Sowards, Katie Strothman, Kim Fielder, Linda O'Donnell, Jasmina Kuljanac, Rebecca Pierrot, Alexander Chieh, Lisa Parks, Lee Ann Kline, Nicholas Evans, Bill Reeves, Ty Atkins, T Kreutzer, Nicole Van Aken, Fida Kased, Lien Nguyen, Sumy Cherukara, Homer Youngblood, Kristin Brown, Alma McCammond, Carol Barrick, Sushmitha Reddy, Brian Eichelbeger, and Stephanie Drier.

There were no changes made to the agenda. The agenda was approved by unanimous consent.

In July, there was a Committee meeting and two Workgroup meetings. Summaries from the two Workgroup meetings are included in the July meeting minutes. Caitie made a motion to approve the July 14, 2025, meeting minutes as presented. The motion was seconded by Tony and unanimously approved.

2. St Louis Meeting

Debbie provided a summary of the meeting that included the following highlights:

- The Definitions being proposed for removal were shared.
- SIR 504 was shared.
- Shared a certificate of analysis that comes with some digestion vessels. The manufacturer is doing a very thorough verification (more than most labs do) of the volume on the vessels. Is there an issue with using that certificate of analysis?
- Ilona, Debbie, Kristin Brown and Aaren Alger worked on an alternate proposal for Technical Specialist that was presented in St. Louis. Ilona was concerned about the Analytical Disciplines discussion at the last QMS meeting and drafted some ideas. Debbie and Ilona also met with the NELAP AC and made a few more modifications that were then presented at the QMS meeting on Thursday morning. Review of this document is on the meeting agenda today.
- The work on the Crosswalk between the 2016 and DRAFT Standard was presented.
- QMS will have two sessions in Boston.

A summary of the meeting can also be found in Attachment B that includes copies of the slides presented by Debbie at the conference.

3. Technical Specialist

Debbie presented the DRAFT language reviewed during the St. Louis meeting on August 6, 2025. See Attachment C for language and updates made during the meeting.

Discussion:

- Concern about the term "absent". What does this mean now that people are able to work remotely? Change to "unable to fulfill their responsibilities". Additional changes made can be found in Attachment C.
- Suggestions were made to streamline and clarify language as found in Attachment C.
- There was extensive discussion on how soon a deputy need to be appointed and then how long a deputy could fulfill a role until a more permanent solution is needed.
- Extensive discussion on Deputy qualifications/requirements. They may not need to be the same as the Technical Specialist, but aren't there some? Procedure now needs to define any associated qualifications for designated alternates.
- Designated alternate vs. deputy. Going with "designated alternate".
- With the laboratory's scope, a laboratory may have one or more technical specialists that may also hold additional primary job responsibilities. Annex C provides examples of how a laboratory may define this structure.
- There was discussion surrounding a concern about what happens if the AB denies the laboratory's plan to replace a Technical Specialist? The NELAP AC wanted it to be clear that an AB can decide not to approve a plan and it could affect accreditation status.
- Ilona sent a note to Aaren Alger about adding the approval step and timing to Volume 2 of the Standard. Ilona is now the PA for the LAB Expert Committee. The AB has 30 days to review and decide on approval of the plan.
- There was discussion on the comments in St. Louis to add STEM to the Masters and Phd option also.
- The NELAP AC is still concerned about the credentialing option. They want to see what it looks like. Ilona spoke to Jerry Parr about this and he is planning to put something together to share with the NELAP AC. The Credentialing Committee has been working on Non-metals Inorganics and have enough information ready that they can share this with the NELAP AC.
- The NELAP AC is also concerned if other Credentials outside of TNI need to be accepted. The ABs don't want to have to do this additional review.
- 3 or more CEUs are being required because that means it is a 30+ hour course.
- Debbie will send out an email requesting information on Operator certificates verses licenses. What is the proper term to use.

4. New Business

    - We have been losing voting members during the meeting at 2pm Eastern. Debbie will look into whether starting the meeting 30 minutes earlier would help people stay on the call so the Committee can meet quorum through the whole meeting.

    (Addition: The Committee received applications for Voting Members. A motion was made by Joann by email on August 18, 2025, to add Rebecca Pierrot as a voting member to the Quality Management Systems Expert Committee. The motion was seconded by Caitie by email on August 18, 2025, and unanimously approved by email vote: 8-22-25: FOR - Stephanie, Caitie, Amy, Joann, Michael, Carol, Tony, Nicole 8-25-25: FOR – Carla, Zaneta, Ashley. The motion passed and Rebecca is added as a voting member to the Committee.)

5. Action Items

    A summary of Action Items can be found in Attachment D.

6. Next Meeting and Close

    The next Committee meeting will be on September 8, 2025 at 1pm Eastern.

    Debbie adjourned the meeting at 2:30 pm Eastern.

Attachment A
Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) **Present**	Alabama Power	2026	Lab	dbond@southernco.com
Carla McCord **Absent**	Virginia	2028	AB	carla.mccord@dgs.virginia.gov
Nicole Cairns **Present (left at 2:01pm Eastern)**	NYSDOH	2027	Lab	nicole.cairns@health.ny.gov
Michael Demarais **Present**	SVL Analytical	2026	Lab	michael@svl.net
Tony Francis **Present**	SAW Environmental	2026	Other	tfrancis@sawenviro.com
Carol Gebhart **Absent**	ALS Global	2027*	Lab	Carol.gebhart@alsglobal.com
Stephanie Atkins **Absent**	Pace Analytical	2027	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson **Absent**	A2LA	2026	Accrediting Body	nslawson@a2la.org
Joann Slavin **Absent**	Wadsworth Center/Environmental Laboratory Approval Program	2027*	Accrediting Body	joann.slavin@health.ny.gov
Caitie Van Sciver **Present**	NJDEP	2027*	Accrediting Body	Caitie.vansciver@dep.nj.gov
Zaneta Popovska **Present (left at 1:57pm Eastern)**	ANAB	2028	AB	zpopovska@anab.org
Sean Hayes **Present**	ORELAP	2026*	AB	sean.hayes@oha.oregon.gov
Amy Schreader **Present (left at 1:55pm Eastern)**	UC Laboratory	2027	Lab	amy@uclaboratory.net
Ashley Larssen **Present at 1:15pm**	Pace Analytical	2027	Lab	ashley.larssen@pacelabs.com
Ilona Taunton (Program Admin) **Present**	The NELAC Institute	n/a	n/a	Ilona.taunton@nelac-institute.org

Attachment B – Summary of QMS meeting in St. Louis – August 6, 2025

Voting Member Attendance: Michael Demarais, Amy Schreader, Nicholas Slawson, Joann Slavin, and Carol Gebhart.

Presentation Slides: See Attachment 1.

Debbie introduced the voting members of the Quality Management System (QMS) Expert Committee as presented in the slides.

Overview Since January 2025

Debbie reviewed Slides 4-18.

Comments:

- The support equipment table is now numbered to allow use of a checklist.
- Changes split Reference Materials and Reagents you purchase verses those you prepare in your laboratory.

Technical Specialist

New language was drafted by Ilona, Debbie, Kristin Brown and Aaren Alger yesterday and presented to members of the NELAP AC present at the conference. A few additional changes were made. This language and the changes made based on comments during the QMS session can be found in Attachment 2.

Comments:

- 5.5.1 - Need plan or a procedure. Deleted plan.
- A lab might have one Technical Specialist or the role may have to be split up with multiple technical specialists to ensure requirements are met. See examples in Attachment 2 of how some labs might do this.
- Masters and doctorial degree should also state STEM.
- Masters and doctorial degree should be 2 years of experience - not 1 year.
- Is 60 days the right time frame for notifying the AB if a qualified technical specialist cannot resume responsibilities? Some medical leaves of absences can be longer. Lab will work with the AB on a plan if this happens.
- Annex C will include recommended relevant courses the Asbestos, Microbiology and Radiochemistry course requirements.
- Qualifications for Deputy are missing. Should be added. Not just anyone can do this.
- CEUs of 3 (30 hours) or higher is noted because it makes it clear it is not just a 2 hour course.
- NELAP AC may need to review their mutual recognition policy and how this might relate to Technical Specialist.
- What if plan for replacing a Technical Specialist is denied - do you need to stop work?

- What happens with multiple primary ABs - what if one accepts it and another does not? This relates to comment about need for review of the mutual recognition policy.
- The language listed in possible Annex C about a Technical Specialist not needing a DOC for every method in their jurisdiction should be included in the Standard and not just in Annex C. Experience does not just need to be at the bench level. An AB commented that they would like to see it left in Annex C because there is no requirement or implication in the current Standard that this was ever required. No need to audit a lab to this language – so leave in Annex C. If a Technical Specialist is also an analyst … then they would need a DOC.
- Should the language in Annex C be in a Guidance Document instead? Agreement was reached that Annex C is the appropriate location because it is informative.
- California had to write their own language regarding Technical Specialist because of a pre-existing regulation. This new language might be something CA can adopt.
- Concerned that another AB will provide an exemption that another AB won't like. Do we need more language about what the exemptions are because it could affect reciprocity? It may need to be only an exemption with the primary AB, so lab would need to apply with each AB.
- Anyone who is currently a Technical Specialist can continue as a Technical Specialist.
- The change to the Technical Specialist language being presented today means that the Expert Committees no longer need to add a Section 4 to their Standards. It will all be covered in Module 2.
- Ilona is sending the LAB Expert Committee (Aaren Alger – Chair) a recommendation that Volume 2 include language tha the AB must respond within 30 days to a plan submitted by a lab to replace a Technical Specialist.
- More work is needed on Section 6.2.2.3 – Exemptions.

Proposed Changes to Definitions

Debbie reviewed Slides 20-29.

The Committee reviewed definitions and recommended removal of definitions where the term is well defined within the Standard language or the term does not appear in Module 2 is not used in multiple Expert Modules. For example, the new data integrity language makes it clear what this is, so it is being recommended for removal from the definitions list. Debbie reviewed the list and noted reasons for some removals (Attachment 3).

Comments:

- The crossed out definitions are ones being removed.
- Reconsider the removal of Chain-of-Custody. It needs to be clear what legal chain of custody is.
- Module 5 (Microbiology) may need to define Verification. They will talk to Module 4 (Chemistry).
- After review of Blank, there was support for its removal.

- There was support to keep Lot. ISO/IEC Guide 30 will be published by the end of the year and this definition should be reviewed.

Crosswalk

A Workgroup is working on the Crosswalk from V1M2 2015 to the new DRAFT. See slides 30-31.

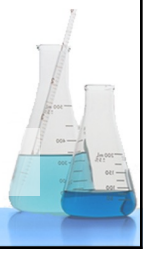
Comments:

- Maybe AI can help with this.

Quality Management Systems Expert Committee
Volume 1 Module 2

Summer Conference
8/6/2025

Debbie Bond – Chair
dbond@southernco.com
Carla McCord – Vice-chair



1

Quality Management Systems Expert Committee

Member	Organization	Representation
Stephanie Atkins	Pace Analytical	Lab
Debbie Bond - Chair	Alabama Power	Lab
Nicole Cairns	NYSDOH	Lab
Michael Desmarais	SVL Analytical	Lab
Tony Francis	SAW Environmental	Other
Carol Gebhart	ALS	Lab
Sean Hayes	ORELAP	AB
Ashley Larssen	KC Water	Lab
Carla McCord – Vice Chair	Virginia	AB
Zaneta Popovska	ANAB	AB
Amy Schreader	UC Laboratory	Lab
Joann Slavin	NYSDOH ELAP	AB
Nicholas Slawson	A2LA	AB
Caitie Van Sciver	NJDEP	AB

2

Quality Management Systems Expert Committee

AGENDA

- Overview since January 2025
- Technical Specialist
- Proposed Changes to Definitions
- V1M2 2016 → V1M2 202X Crosswalk

3

Quality Management Systems

COMMITTEE OVERVIEW SINCE JANUARY 2025

- Responded to 1 SIR – SIR 504
- Reviewed Module 2 draft with feedback the Winter session
  - Support Equipment Table (6.4.6.1)
  - Reference Materials & Reagents (6.6.4)
- Technical Specialist - Simplified TS Qualifications Concept
  - Strong support and additional changes from Jacksonville
  - Discussed with AC for additional changes
  - After edits…Now everyone is happy!
- Identified definitions that can be removed from V1M2
- Launched our V1M2 Crosswalk Workgroup

4

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The SIR we're about to discuss is not complete. Until it is posted on the TNI site, there is a possibility it may change.

5

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SIR 504 for V1M2 2016, 5.5.13.1 e) ii.

V1M2 2016, 5.5.13.1 e)
If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, the laboratory shall verify volumetric measuring devices as follows:

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

Describe the problem:
Is it acceptable to perform this verification at one location of a network laboratory, and share that verification documentation among its laboratories, providing the required documentation of verification to any network laboratory that uses the lot in question?

6

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On a related note

(that does not affect SIR 504)….

7

environmental express

Digestion Vessels - Certificate of Volume Accuracy and Metals Background

Representative samples of this lot of digestion cups have been tested for volume accuracy at all graduation lines by the procedures set forth in ASTM E542-01 *Standard Practice for Calibration of Laboratory Apparatus*. Volume accuracy was found to be within the Class A tolerance set forth in ASTM 1272-02 *Standard Specification for Laboratory Glass Graduated Cylinders*. Balances used in test procedures are certified yearly and traceable to NIST. Complete test results and test conditions are available at www.envexp.com.

Metals Background Analysis Report

Samples of disposable digestion cups are collected randomly from each manufacturing lot for analysis. Blank samples are digested and analyzed using current ICP-MS or CVAFS methodology. Results are reported in the chart below. Field results may vary with environmental conditions, analytical techniques, and handling procedures. Care should be taken in storage and handling to prevent background contamination.

Element	Results (ug/L)	Element	Results (ug/L)	Element	Results (ug/L)	Element	Results (ug/L)	Element	Results (ug/L)	Element	Results (ug/L)
Ag	< 0.1	Cr	< 1.5	Ho	< 0.1	Nd	< 0.25	Sb	< 0.5	Tm	< 0.1
Al	< 30	Cs	< 0.1	In	< 0.1	Ni	< 0.25	Sc	< 0.2	U	< 0.08
As	< 0.2	Cu	< 0.5	Ir	< 0.1	Os	< 0.1	Se	< 0.25	V	< 0.5
Au	< .25	Dy	< 0.1	K	< 50	P	< 10	Si	< 50	W	< 0.1
B	< 10	Er	< 0.25	La	< 0.1	Pb	< 0.25	Sm	< 0.25	Y	< 0.1
Ba	< 1	Eu	< 0.1	Li	< 0.5	Pd	< 0.1	Sn	< 1	Yb	< 0.1
Be	< 0.1	Fe	< 25	Lu	< 0.1	Pr	< 0.1	Sr	< 2.5	Zn	< 2
Bi	< 0.1	Ga	< 0.5	Mg	< 15	Pt	< 0.5	Ta	< 0.1	Zr	< 1
Ca	< 150	Gd	< 0.1	Mn	< 0.1	Rb	< 0.1	Tb	< 0.1		
Cd	< 0.2	Ge	< 0.1	Mo	< 0.1	Re	< 0.1	Te	< 0.5		
Ce	< 0.2	Hf	< 0.1	Na	< 50	Rh	< 0.1	Ti	< 0.5		
Co	< 0.1	Hg	< 0.0005	Nb	< 0.1	Ru	< 0.1	Tl	< 0.08		

Lot Number: LV24070610-4304

Contact us for more information!

+1.800.343.5319 or +1.843.881.6560 | info@envexp.com

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8

Representative Samples of 50mL Digestion Cups for Volume Accuracy

Part #s	UC475	UC474	UC482	UCC000-50	Lot# LV24070610

Test Date:	09/27/2024	
Air Temp:	24.03	°C
Water Temp:	24.03	°C
Water Density:	0.99740	g/cm³

Cavity	13	16	21	24	60	65	70	74	Mean	RSD
5mL Wt	4.99	4.98	4.97	5.00	4.99	5.00	4.99	5.00	4.99	0.20%
Tolerance	0.02	0.03	0.04	0.01	0.02	0.01	0.02	0.01	0.02	
10mL Wt	10.00	10.00	9.99	9.98	9.99	9.99	10.00	10.00	9.99	0.07%
Tolerance	0.03	0.03	0.04	0.05	0.04	0.04	0.03	0.03	0.03	
15mL Wt	15.00	14.98	14.99	15.00	14.99	14.98	14.99	14.98	14.99	0.05%
Tolerance	0.04	0.06	0.05	0.04	0.05	0.06	0.05	0.06	0.05	
20mL Wt	19.98	20.00	20.01	20.00	19.99	19.98	19.99	19.99	19.99	0.05%
Tolerance	0.07	0.05	0.04	0.05	0.06	0.07	0.06	0.06	0.06	
25mL Wt	25.00	24.99	25.00	24.99	24.98	25.00	24.99	24.99	24.99	0.03%
Tolerance	0.07	0.08	0.07	0.08	0.09	0.07	0.08	0.08	0.07	
30mL Wt	29.98	29.99	29.99	30.00	29.98	29.99	29.97	30.00	29.99	0.03%
Tolerance	0.10	0.09	0.09	0.08	0.10	0.09	0.11	0.08	0.09	
35mL Wt	35.00	34.99	35.00	34.98	35.00	35.00	34.99	34.98	34.99	0.02%
Tolerance	0.09	0.10	0.09	0.11	0.09	0.09	0.10	0.11	0.10	
40mL Wt	39.97	39.95	40.00	40.00	39.98	39.99	40.00	39.99	39.99	0.04%
Tolerance	0.13	0.15	0.10	0.10	0.12	0.11	0.10	0.11	0.12	
45mL Wt	45.00	44.98	44.99	44.97	44.99	44.98	45.00	44.98	44.99	0.02%
Tolerance	0.12	0.14	0.13	0.15	0.13	0.14	0.12	0.14	0.13	
50mL Wt	50.00	49.99	50.00	49.99	50.00	49.98	50.00	50.00	50.00	0.01%
Tolerance	0.13	0.14	0.13	0.14	0.13	0.15	0.13	0.13	0.14	

Class A Tolerance +/- 0.25mL

All weights reported in grams (g).
All weights reported in grams (g).
All weights are adjusted based on Water Density at time of testing.
Class A Tolerance based on "To Contain" requirements of Class A graduated cylinder.

Wt = Total raw weight of water (g) prior to density adjustment

9

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Changes for Support Equipment Table

V1M2 202x, 6.4.6.1

10

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Requested Changes – committee will review soon

- Consider allowing labs to extend period of validity on risk evaluation
- Remove mid-point verification for single-use, non-Class A volumetric equipment
- Remove mid-point verification on mechanical measuring devices
- Remove information on how to verify weights

See preview on next slide

11

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6.4.6.1 a) Table: Support Equipment – Ongoing Verification & Calibration Frequencies

	Equipment	Activity	Frequency
i.	Balances	Verify the range of use	Daily Before Use
ii.	Gastight syringes and Class A glassware	Exempt from verification requirements beyond what is stated in Sections 6.6.1 and 6.6.2;	Not applicable
iii.	Mechanical Volumetric Dispensing Equipment	If used at one volume, verify the volume of use If used at more than one volume, verify at volumes bracketing the range of use and at the mid-point	Prior to first use and Quarterly
iv.	Disposable, non-Class A volumetric equipment	If used at one volume, verify the volume of use If used at more than one volume, verify at volumes bracketing the range of use and at the mid-point	Once per lot prior to or in conjunction with its first use

12

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6.4.6.1 a) Table: Support Equipment – Ongoing Verification & Calibration Frequencies

	Equipment	Activity	Frequency
v.	All other volumetric support equipment	If used at one volume, verify the volume of use If used at more than one volume, verify at volumes bracketing the range of use and at the mid-point	Prior to or in conjunction with its first use
vi.	Temperature Measuring Equipment – Working	Verification or Calibration If used ≤10°C range, single-point within range of use If used >10°C range, bracket range of use	Annually
vii.	Weights - Working	Verification or Calibration Option 1: comparison to calibrated reference weights not in daily use. Option 2: check on balance immediately (same day) after required balance calibration from accredited calibration provider.	Annually

13

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6.4.6.1 a) Table: Support Equipment – Ongoing Verification & Calibration Frequencies

	Equipment	Activity	Frequency
viii.	Monitoring of other equipment requiring temperature checks	Evaluate against reference method or laboratory requirements, whichever is more stringent	Each day before use, or as required by reference method, whichever is more frequent
ix.	All other support equipment	Verification or Calibration If used at one measurement, use a single-point If used at more than one measurement, bracket the range of use	Annually

14

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Changes for Reference Materials & Reagents

V1M2 202x, 6.6.4

15

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Requested Changes – committee will review soon

- For purchased chemicals, if no lot # is provided, lab assigns unambiguous identifier
- **Keep** allowance to verify standards past expiration date:
  - multiple layers of QC to ID problems
  - better to use hazardous materials than discard
  - removing doesn't improve V1M2
  - no examples of abusing this allowance
- **Remove** allowance to verify standards
  - Causes issues in Micro: clarify may not apply to all Modules
  - TNI should provide guidance if allowed
- Remove records requirements as ISO addresses in 7.5.1 Technical Records

16

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6.6.4 Additional Requirements for Reference Materials and Reagents (including Media)

6.6.4.1 The laboratory shall have a procedure for the purchase, receipt and storage of reference materials and reagents (including media) used for laboratory activities.

6.6.4.2 The laboratory shall retain records for all reference materials and reagents (including media) that include, where available, the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity, the expiration date, the date of receipt, and the manufacturer's recommended storage conditions.

6.6.4.2.1 If an expiration date is provided by the manufacturer or vendor, it shall be recorded on the original container. If an expiration date is not provided by the manufacturer or vendor, then one is not required.

17

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6.6.4.3 The laboratory shall have procedures for the subsequent preparation of reference materials and reagents (including media) that meet method requirements.

6.6.4.3.1 The laboratory shall retain records for these preparations that include an unequivocal link to the equipment used, products used, mass, volumes, and/or quantities used, date of preparation, expiration date, and preparer's initials.

6.6.4.3.2 All containers of these preparations shall bear an expiration date and identifier with an unequivocal link to the preparation records.

6.6.4.4 Purchased or prepared reference materials and reagents (including media) shall not be used beyond their expiration dates unless verified for acceptable use by the laboratory. The laboratory shall have a procedure for and retain records of the verification.

18

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TECHNICAL SPECIALIST DISCUSSION

Note: Provided language on screen instead of original language prepared for this discussion. Deleted original slides 20-33.

19

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DEFINITIONS

20

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DEFINITIONS WE CONSIDERED REMOVING FROM M2

Blank / Method Blank
Calibration Curve
Calibration Standards
Certified Reference Material
Chain of Custody Form
Confirmation
Contract
Correction
Corrective Action
Critical Supplies and Services
Data Integrity
Data Reduction
Document
Internal Standard
In-depth Data Monitoring
Laboratory Control Sample
Legal Chain of Custody
Limit of Quantitation/Detection
Matrix Spike / MS Duplicate
Measurement System
Method
Mobile Laboratory
NIST
Proficiency Testing Program
Proficiency Testing Sample
Quality System Matrix
Standard Operating Procedure
Preservation
Quality Manual
Record
Reference Material

21

Quality Management Systems

DEFINITIONS WE CONSIDERED REMOVING

Blank / ~~Method Blank~~
~~Calibration Curve~~
~~Calibration Standards~~
Certified Reference Material
~~Chain of Custody Form~~
~~Confirmation~~
~~Contract~~
Correction
Corrective Action
~~Critical Supplies and Services~~
~~Data Integrity~~
~~Data Reduction~~
Document
~~Internal Standard~~
~~In-depth Data Monitoring~~
~~Laboratory Control Sample~~
~~Legal Chain of Custody~~
~~Limit of Quantitation/Detection~~
~~Matrix Spike / MS Duplicate~~
~~Measurement System~~
Method ?M3 & M7?
~~Mobile Laboratory~~→ Mobile Facility
~~NIST~~
~~Proficiency Testing Program~~
~~Proficiency Testing Sample~~
~~Quality System Matrix~~→Matrix
~~Standard Operating Procedure~~
Preservation
~~Quality Manual~~
Record
Reference Material

22

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DEFINITIONS TO DROP FROM V1M2

TERM	REASON FOR REMOVAL
Standard	self-explanatory in V1
Data Integrity	defined in draft M2 section 4
In-depth Data Monitoring	defined in draft M2 section 4
Legal Chain of Custody	defined in draft M2 section 7.4.1.2
Quality Manual	defined in draft M2 section 8.2.4.1
Critical Supplies and Services	no longer used in V1
Contract	not used in any Module
Mobile Laboratory	now Mobile Facility w/FAC definition
Quality Management System Matrix	Combined with "Matrix" as Matrix
Standard Operating Procedure	"Procedure" to include link to SOP
Method Blank	Methods and Tech Modules define

23

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DEFINITIONS TO DROP FROM V1M2 (cont'd)

TERM	REASON FOR REMOVAL
Field of Accreditation	used & defined in Module 1
Proficiency Test Sample (PT)	used & defined in Module 1
Proficiency Testing Program	used & defined in Module 1
Chain of Custody Form	only used in Module 3
National Institute of Standards and Technology (NIST)	Used in Module 2 but listed in document references; also used in Module 3

24

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DEFINITIONS TO DROP FROM V1M2 (cont'd)

TERM	REASON FOR REMOVAL
Calibration Standard	needed in Module 4
Internal Standard	needed in Module 4
Limit(s) of Quantitation (LOQ)	needed in Module 4
Verification	needed in Module 4
Matrix Spike	used in Module 4 (& 7 for support tests)
Matrix Spike Duplicate	used in Module 4
Limit of Detection (LOD)	used in Module 4 (M3 may use too)
Measurement System	needed in Module 4; used in M7 but differently

25

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DEFINITIONS TO DROP FROM V1M2 (cont'd)

TERM	REASON FOR REMOVAL
Calibration Curve	used in Module 6
Data Reduction	used in Module 6
Confirmation	used in Module 7
Physical Parameter	used in Module 7

26

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ADDITIONAL DEFINITIONS TO CONSIDER REMOVING

Blank: A sample that has not been exposed to the analyzed sample stream to monitor contamination during sampling, transport, storage or analysis.
* Methods and technical modules do a better job describing how to make and use.

Lot: A definite amount of material produced during a single manufacturing cycle and intended to have uniform character and quality.
* V1M4 received several SIR for the secondary source standard. Defining "lot" may help but, does it?

27

Quality Management Systems

SIRs for CHEMISTRY MODULE that Reference LOT

Question: What input variables (analyte lot, solvent lot, balance, operator, etc.) must change in order for a second lot of standard to be considered to be prepared independently?
TNI Response: 5.5.5.2.2.1 d states that a standard obtained from a second lot may be used if the lot can be demonstrated from the manufacturer as prepared independently from other lots. In our mind, this is analogous to a preparation batch being prepared with the same process, personnel and reagents during a set timeframe. Assuming the manufacturer prepares a specific quantity of standard and declares that quantity a "lot", another lot prepared at another time would be independent of the first. The laboratory would be expected to contact the manufacturer to verify that one lot is not the same as another. The 2003 and 2009 standards have identical language. This section was slightly reworded in 2016 and a definition of "lot" was added to V1M2: Lot: A definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality. The SIR still has some relevance in further explaining this issue.

28

Quality Management Systems

SIRs for CHEMISTRY MODULE that Reference LOT

Question: What is the interpretation…with regard to the following options:
1. Same supplier - two independently prepared lots from the same raw material.
2. Same supplier - two independently prepared lots from different manufacturer raw materials when available.
3. Two different suppliers for each of the primary and secondary lot standards.
TNI Response: The purpose is to verify that the standards used for calibration have been properly prepared. The verification standard must be prepared independently from the calibration standard(s). The best option is standards from two different vendors; alternatively, standards from the same vendor but different lot numbers. While the original source (manufacturer) of the neat standard is important, the standard stresses independent preparation. The 2003 and 2009 standards have identical language. This section was slightly reworded in 2016 and a definition of "lot" was added to V1M2: Lot: A definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality. The SIR still has some relevance in further explaining this issue.

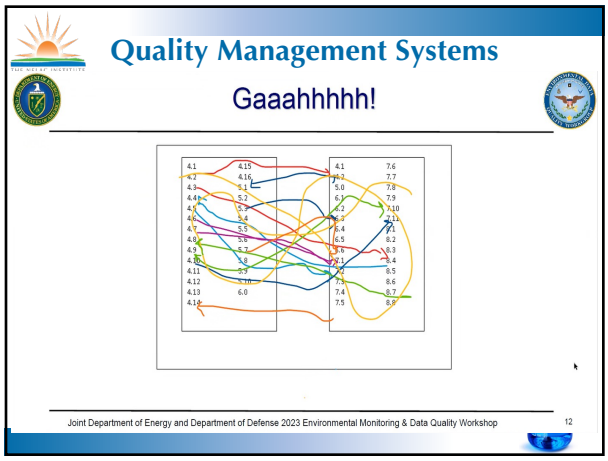
29

Quality Management Systems

Introducing:

V1M2 2016 → V1M2 202X CROSSWALK

30


Quality Management Systems
Gaaahhhhh!
Joint Department of Energy and Department of Defense 2023 Environmental Monitoring & Data Quality Workshop
12

31

Attachment 2 – Language Reviewed During QMS Meeting on 8-6-25 in St. Louis

Note: The changes noted as Paul Junio were made during the Session in St. Louis on the podium computer.

5 Structural requirements

5.1 *The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.*

NOTE For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

5.2 *The laboratory shall identify management that has overall responsibility for the laboratory.*

5.3 *The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.*

5.4 *Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.*

5.5 *The laboratory shall:*

a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;

b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;

c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5.5.1 The laboratory must have a procedure for how the roles and responsibilities are filled when the personnel responsible for the laboratory, the review and release of analytical data, or the quality management systems, including review of quality control data, are absent. Refer to Section 5.6.5 for specific absence requirements for a Technical Specialist. The procedure must define what processes may continue or be halted when those personnel are absent and what tasks can be accomplished by designated alternates (also called "deputies") and associated timeframes.

5.6 *The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:*

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing laboratory activities;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to laboratory management on the performance of the management system and any need for improvement;

e) ensuring the effectiveness of laboratory activities.

5.6.3 The laboratory must have a Technical Specialist(s) to provide technical guidance to laboratory personnel for all work associated with the laboratory's scope of accreditation. The laboratory must clearly define its technical structure and how Technical Specialist responsibilities align with the laboratory's

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-Asbestos
-Inorganic Chemistry - Nonmetals
-Inorganic Chemistry - Metals
-Organic Chemistry
-Microbiology
-Radiochemistry
-Whole Effluent Toxicity

I think the disciplines would be better presented as a list rather than within the paragraph.

scope. A laboratory may have one or more Technical Specialists that may also hold additional primary job responsibilities. Annex C-xx provides examples of how a laboratory may define this structure.

Technical Specialist(s) must:

a) provide guidance and oversight to laboratory personnel as needed to ensure activities related to the generation of analytical data and test results, including but not limited to method development and validation, procedure development, sample preparation, instrument calibration, sample analysis, quality control, and data reduction, comply with the laboratory's quality management system and with relevant regulatory requirements for which the data will be used and

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5.6.4 A Technical Specialist may be appointed across multiple laboratories, subject to approval by the primary accrediting body. Requests for approval must include a plan outlining how the Technical Specialist will meet the requirements in section 5.6.3 across multiple locations. Records of the accrediting body's approval, including the approved plan, must be retained.

5.6.5 If a Technical Specialist is unable to fulfill the duties in sections 5.6.3 a) and b) for fifteen (15) consecutive calendar days,

a) a deputy must be appointed and assume the responsibilities of the technical specialist or

b) work in that area of responsibility must be halted or subcontracted to another qualified laboratory.

The deputy is not required to meet the qualification requirements of a Technical Specialist.

5.6.6 When a deputy assumes the responsibilities of a Technical Specialist, the laboratory must notify the primary accreditation body within sixty (60) days if a qualified Technical Specialist does not resume the responsibilities. The notification must be in writing for accreditation body approval and must include a plan with a timeline for appointing a qualified Technical Specialist. (If approval is not granted your accreditation may be suspended.)

6 Resource requirements

6.1 General

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

6.2 Personnel

6.2.1 *All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.*

6.2.2 *The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.*

6.2.2.1 Technical Specialist Qualifications

The laboratory shall retain a record showing that each Technical Specialist meets the requirements of 6.2.2.2 or exceptions of 6.2.2.3. Where coursework is required, the laboratory must retain records that show courses were successfully completed (e.g., certificate, letter, transcript).

6.2.2.2 A Technical Specialist must meet one combination of education and experience qualifications listed below, where experience is in the area of responsibility. In addition, areas of responsibility in TNI Asbestos, Microbiology, and Radiochemistry Technical Modules, require a relevant technical course. Information on relevant technical courses and examples of experience can be found in Annex C-xx.

a) a master's or doctoral degree and one (1) year of experience,

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5.6.3→The laboratory must have (a) Technical Specialist(s) to provide technical guidance to laboratory personnel for each TNI-defined analytical discipline associated with the laboratory's scope of accreditationeach field of accreditation on the laboratory's scope. If a laboratory has multiple Technical Specialists, it must clearly specify which Technical Specialist is responsible for each field of accrediation.A single individual may be appointed as the Technical Specialist for one or more TNI-defined analytical disciplines and may also hold additional primary job responsibilities. The TNI-defined analytical disciplines are: Technical Specialist(s) may hold additional primary job responsibilities.¶
Asbestos¶
Inorganic Chemistry – Nonmetals¶
Inorganic Chemistry – Metals¶ ... [1]

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Commented [DB15]: We typically use "maintain records" is there a difference between maintaining and retai ... [5]

Commented [NC16R15]: I just ran across this in the chemistry module. I did a review of the ISO 17025 ... [6]

Commented [PJ17]: This doesn't address an Associates Degree, but that's what the Technical Modules reference

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b) a bachelor's degree in a STEM (science, technology, engineering, or math) field and two (2) years of experience,
c) an associate's degree in a STEM field and three (3) years of experience, or
d) four (4) college level STEM courses and four (4) years of experience. A credential applicable to the areas of the Technical Specialist responsibilities can be substituted for the college level STEM courses. Vendor courses with certificates and a minimum of 3 CEUs may be considered equivalent to a college level STEM course.

6.2.2.3 Technical Specialist Qualification Options for Exempting Education and Experience Requirements

a) Any person who was formerly recognized as a Technical Specialist (however named) based on requirements or exceptions in previous revisions of this Standard will continue to be eligible as Technical Specialist for the same areas if responsibility at any accredited laboratory. Appropriate records must be available to show previous recognition as a Technical Specialist.

b) Any person who is an employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility and has two (2) years of laboratory experience is eligible as Technical Specialist at facilities where the treatment plant operator's certificate is recognized and for the scope covered by that certificate.

c) If an accrediting body provides an exemption other than those listed in a) and b), the laboratory must retain the record of the exemption for the same time period as required for the data generated during the employment of that technical specialist.

"ANNEX C" THOUGHTS

Technical Specialist – Laboratory Structure

Examples:

1. One TS responsible for entire Scope

2. A lab may have the following structure:
   - Wet Chemistry Manual TS
   - Wet Chemistry Instrument TS
   - Metals TS
   - Organics TS
   - Radiochemistry Prep TS
   - Radiochemistry Counts TS
   - Microbiology TS

3. Another laboratory example:
   - Inorganic Non-Metals TS
   - Inorganic Metals TS
   - Microbiology TS
   - SVOA TS
   - VOA TS
   - Organic Prep TS
   - WETT TS

4. One more laboratory example:
   - Asbestos TS
   - Chemistry TS
   - Microbiology TS
   - Radiochemistry TS
   - WETT TS

Commented [PJ23]: Seems like Associates Degree ought to be the next step in this set of options. Why is a Bachelors Degree the same as a valid treatment plant operator's license (each need it plus 2 years of experience)?

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Commented [IT24]: Needs more input. See comment from Kristin on 7/15/25. Should the Credential replace all STEM course work? Or a particular number of courses?

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Commented [DB28]: From Jacksonville '25 (Elizabeth Lesold): Potential conflict because some TP Operator certification (b) and credentialing (c) may overlap enough to cause confusion. For b) must have experience; what about for c)?

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Commented [DB29]: From Jacksonville '25: Add that appropriate records must be maintained to show previous recognition as TS."

Deleted: analytical disciplines

Commented [DB30]: From Jacksonville '25: Is this lab experience or experience as an operator? Or does it matter?

Commented [DB31]: Should we add analytical discipline to this experience?

Commented [DB32]: Review again after LAB meets in St. Louis.

Commented [PJ33R32]: This would have to be applied for from each AB

Experience:

What it can be:
Hands on analysis
Data validation and review
QA oversite
Training classes
Credentials
Similar work in another industry

What it may not be:
It is not requiring a DOC for every method that is within the Technical Specialists scope of work. It is not having run every method that is within the Technical Specialists scope of work. The Technical Specialist's capabilities are a combination of education and experience. Experience does not have to be exclusively bench level.

Commented [PJ34]: Add to the body of V1M2

Page 2: [1] Deleted **Ilona Verrips Taunton** **8/6/25 11:45:00 AM**

Page 2: [2] Commented [KD12] **Kirstin Daigle** **9/13/24 10:06:00 AM**

I replaced responsibility with guidance and oversight. "responsibility to manage" by common definition implies the technical specialist has supervisory or management responsibility, which is not required. I think oversight is a better description of intent.

I also removed "key personnel" which I know is controversial. In some labs the TS may be key personnel. In a lab like PAS, a role is not key personnel until it is at the Director or Officer level, which the exception of the Quality Manager. We have 1 Chief Technical Officer for our 80+ labs and I think 4 Technical Directors. Tech Spec for TNI are usually bench analysts. Bench analysts are not involved in decisions that affect our business - they are not key personnel, the CTO is. Also the whole concept of key personnel is that here is a deputy to maintain - Section 5.6.5 essentially fulfills the intent of key personnel so I don't think the removal of the statement that TS are key personnel is significant.

Page 2: [3] Commented [DB13] **Bond, Debbie** **4/8/24 1:18:00 PM**

Ensure we are not requiring environmental experience where non-environmental will be just as valuable.

Page 2: [4] Commented [DB14] **Bond, Debbie** **7/14/25 1:23:00 PM**

Consider adding to Annex C a link to the site that includes equivalency of different country's degrees to USA degrees.

Page 2: [5] Commented [DB15] **Bond, Debbie** **7/25/25 9:41:00 AM**

We typically use "maintain records" is there a difference between maintaining and retaining? If so, which is correct and should this be a change throughout M2?

Page 2: [6] Commented [NC16R15] **Cairns, Nicole L (HEALTH)** **7/25/25 2:41:00 PM**

I just ran across this in the chemistry module. I did a review of the ISO 17025 standard language, and when it comes to records, they always use the term retain, not maintain. It was something I was going to mention to you. We may want to switch to retain for consistency with ISO.

Page 2: [7] Deleted **Bond, Debbie** **8/5/25 10:43:00 PM**

Page 2: [8] Commented [BD18] **Bond, Debbie** **7/24/24 4:52:00 PM**

To qualify as a technical specialist, a candidate must have experience in the analytical disciplines for the area of responsibility and the education or training listed in one of the options listed below:

Page 2: [9] Deleted **Bond, Debbie** **8/5/25 10:58:00 PM**

Page 2: [10] Commented [DB19] **Bond, Debbie** **7/25/25 9:43:00 AM**

Do we need to include more specific information about these relevant technical courses somewhere?

Page 2: [11] Commented [NC20R19] **Cairns, Nicole L (HEALTH)** **7/25/25 2:51:00 PM**

Either here or in the corresponding module. Don’t know what “relevant technical course” means. How is this assessable?

Attachment 3

Definitions to Remove from Volume 1 Module 2

Term	Comments	Definition
Standard	all technical modules listed as "Ok to Drop"	The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of standard setting and meets the approval requirements of standard adoption organizations procedures and policies.
Data Integrity	defined in draft M2 section 4	The condition that exists when data are sound, correct, complete and accurately reflect activities and requirements.
In-depth Data Monitoring	defined in draft M2 section 4	A review and evaluation of records related to the data generation process that includes items such as preparation, equipment, software, calculations and quality controls for the purpose of confirming data integrity activities. Such monitoring must determine if the laboratory uses appropriate data handling, data use and data reduction activities to support the laboratory's data integrity policies and procedures.
Legal Chain of Custody	defined in draft M2 section 7.4.1.2	In addition to the requirements of a Chain of Custody Form, the tracking of the possession of a sample from receipt, through all steps in the analytical process within the laboratory through the retention time specified by the client or program. Legal chain of custody is typically used for evidentiary purposes, such as when the results of sample analysis are expected to be taken to court.
Quality Manual	defined in draft M2 sectopm 8.2.4.1	A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.
Critical Supplies and Services	no longer used in V1	A supply, product, or service that affects the result, therefore requiring traceability and verification to ensure data that is method compliant, legally defensible, and of known documented quality.
Contract	not used in any Module	A written or oral agreement to provide a customer with testing services, such as is found on a chain of custody.
Mobile Laboratory	now Mobile Facility and definition is revised (see Definition column)	A portable enclosed structure within which testing is performed by analysts. Examples include but are not limited to trailers, vans, and skid-mounted structures configured to house testing equipment and personnel. A Mobile facility is also known as a mobile laboratory.
Quality Management System Matrix	now using "Matrix" which includes the matrix types that are under Quality System Matrix now; Module 6 may consider if how they use the term: should be defined in Module 6 or start using "Matrix"?	These Matrix definitions are to be used for the purposes of batch and quality control requirements:
Standard Operating Procedure	now we define "Procedure" (see question for M4)	A written document that details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps.
Method Blank	this is the only type of blank that was defined in M2, so we're going to let labs rely on technical modules and/or methods/regulations for MB.	A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.
Field of Accreditation	defined in **Module 1**	Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.
Proficiency Test Sample (PT)	defined in **Module 1**	A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.
Proficiency Testing Program	defined in **Module 1**	The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

Chain of Custody Form	used in **Module 3**	Record that demonstrates the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses. See also Legal Chain of Custody.
National Institute of Standards and Technology (NIST)	used in **Module 3**	A federal agency of the US Department of Commerce's Technology Administration that is designed as the United States national metrology institute (NMI).
Calibration Standard	used in **Module 4**	A substance or reference material used for calibration.
Internal Standard	used in **Module 4**	A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.
Limit(s) of Quantitation (LOQ)	used in **Module 4**	The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.
Verification	used in **Module 4**	Confirmation by examination and objective evidence that specified requirements have been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.
Matrix Spike	used in **Module 4** (also in **Module 7**, but only as relates to how supporting Chemistry tests are performed, so the definition in M4 would work for M7)	A sample prepared, taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a referenced method, by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.
Matrix Spike Duplicate	used in **Module 4**	A replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.
Limit of Detection (LOD)	used in **Module 4**; depending on how Module 4 decides to define, it may also work for Module 3 instead of "Sensitivity"	The minimum result which can be reliably discriminated from a blank with a predetermined confidence level.
Measurement System	used in **Module 4**; may keep, depending on M7	A method, as implemented at a particular laboratory, and which includes the equipment used to perform the test and the operator(s).
Calibration Curve	used in **Module 6**	The mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.
Data Reduction	used in **Module 6**	The process of transforming the number of data items by arithmetic or statistical calculation, standard curves, and concentration factors, and collating them into a more useful form.
Confirmation	used in **Module 7**	Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to: Second column confirmation, Alternate wavelength, Derivatization, Mass spectral interpretation, Alternative detectors, or Additional cleanup procedures.
Physical Parameter	used in **Module 7**	A physical characteristic or property of a sample.

Note:
Comments noted as "Paul Junio" are changes made at the podium to the DRAFT Ilona prepared for the QMS meeting in St. Louis on 8-6-25. Comments noted as Debbie Bond are the changes made in response to discussion at the QMS meeting on 8-18-25.

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- the work that must be halted when those personnel are unable to fulfil responsibilities,
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- any associated qualifications for designated alternates.

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Deleted: provide guidance and oversight to laboratory personnel as needed to

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Commented [DB8]: Ensure we are not requiring environmental experience where non-environmental will be just as valuable.

Commented [DB9]: Consider adding to Annex C a link to the site that includes equivalency of different country's degrees to USA degrees.

Commented [DB10]: We typically use "maintain records" is there a difference between maintaining and retaining? If so, which is correct and should this be a change throughout M2?

Commented [NC11R10]: I just ran across this in the chemistry module. I did a review of the ISO 17025 standard language, and when it comes to records, they always use the term retain, not maintain. It was something I was going to mention to you. We may want to switch to retain for consistency with ISO.

Commented [PJ12]: This doesn't address an Associates Degree, but that's what the Technical Modules reference

6.2.2.2 A Technical Specialist must meet one combination of education and experience qualifications listed below, where experience is in the area of responsibility. In addition, areas of responsibility in TNI Asbestos, Microbiology, and Radiochemistry Technical Modules require a relevant technical course. Information on relevant technical courses and examples of experience can be found in Annex C-xx.

a) a master's or doctoral degree in a STEM (science, technology, engineering, or math) field and one (1) year of experience,
b) a bachelor's degree in a STEM field and two (2) years of experience,
c) an associate's degree in a STEM field and three (3) years of experience, or
d) four (4) college level STEM courses and four (4) years of experience. A credential applicable to the areas of the Technical Specialist responsibilities can be substituted for the college level STEM courses. Vendor courses with certificates and a minimum of 3 CEUs may be considered equivalent to a college level STEM course.

6.2.2.3 Technical Specialist Qualification Options for Exempting Education and Experience Requirements

a) Any person who was formerly recognized as a Technical Specialist (however named) based on requirements or exceptions in previous revisions of this Standard will continue to be eligible as Technical Specialist for the same areas of responsibility at any accredited laboratory. Appropriate records must be available to show previous recognition as a Technical Specialist.

b) Any person who is an employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate or license appropriate to the nature and size of such facility and has two (2) years of laboratory experience is eligible as Technical Specialist at facilities where the treatment plant operator's certificate or license is recognized and for the scope covered by that certificate license.

c) If an accrediting body provides an exemption other than those listed in a) and b), the laboratory must retain the record of the exemption for the same time period as required for the data generated during the employment of that technical specialist.

"ANNEX C" THOUGHTS – Ilona will help draft this.

Technical Specialist – Laboratory Structure

Examples:

1. One TS responsible for entire Scope

2. A lab may have the following structure:
   - Wet Chemistry Manual TS
   - Wet Chemistry Instrument TS
   - Metals TS
   - Organics TS
   - Radiochemistry Prep TS
   - Radiochemistry Counts TS
   - Microbiology TS

3. Another laboratory example:
   - Inorganic Non-Metals TS
   - Inorganic Metals TS
   - Microbiology TS
   - SVOA TS
   - VOA TS
   - Organic Prep TS
   - WETT TS

Commented [BD13]: To qualify as a technical specialist, a candidate must have experience in the analytical disciplines for the area of responsibility and the education or training listed in one of the options listed below:

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Deleted: for each analytical disciplinethe work/scope of accreditation for which they are responsible., ~~where the required experience is in the corresponding analytical discipline(s).~~

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Deleted: to qualify as Technical Specialist over fields of accreditat

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Deleted: analytical disciplines forwork/scope of accreditation that is relevant to TNI's Asbestos, Microbiology and Radiochemistry Technical Modules require a relevant technical course.

Commented [PJ14]: Consider making this a way to exempt 1 year of experience

Deleted: (see Annex C-xx for examples of commensurate/relevant experience)

Deleted: (science, technology, engineering, or math)

Commented [PJ15]: Seems like Associates Degree ought to be the next step in this set of options. Why is a Bachelors Degree the same as a valid treatment plant operator's license (each need it plus 2 years of experience)?

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Commented [IT16]: Needs more input. See comment from Kristin on 7/15/25. Should the Credential repla... [1]

Commented [DB17R16]: Are we able to specify "TN... [2]

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Commented [DB21]: From Jacksonville '25 (Elizabe... [4]

Deleted: <#>~~Technical Specialist credential for ...~~ [3]

Commented [DB22]: From Jacksonville '25: Add th... [5]

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Commented [DB23]: From Jacksonville '25: Is this ... [6]

Commented [DB24]: Should we add analytical disc... [7]

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Commented [DB25]: Review again after LAB meets ... [8]

Commented [PJ26R25]: Comment St. Louis Mtg: Th... [9]

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4. One more laboratory example:
   - Asbestos TS
   - Chemistry TS
   - Microbiology TS
   - Radiochemistry TS
   - WETT TS

Experience:

What it can be:
Hands on analysis
Data validation and review
QA oversite
Training classes
Credentials
Similar work in another industry

What it may not be:
It is not requiring a DOC for every method that is within the Technical Specialists scope of work.
It is not having run every method that is within the Technical Specialists scope of work. The Technical Specialist's capabilities are a combination of education and experience.
Experience does not have to be exclusively bench level.

Commented [PJ27]: Add to the body of V1M2

Ilona: Jerry thinks something like this is important to be included in the Standard and not just in Annex C.

Page 3: [1] Commented [IT16] **Ilona Verrips Taunton** **8/5/25 6:19:00 PM**

Needs more input. See comment from Kristin on 7/15/25. Should the Credential replace all STEM course work? Or a particular number of courses?

7/5/25: See 6.2.2. 2.d). Credential now included as possible replacement for college courses, but 4 years of experience required. This is different than the e) option previously discussed. This new modified option has more support.

Page 3: [2] Commented [DB17R16] **Bond, Debbie** **8/18/25 1:21:00 PM**

Are we able to specify "TNI Credential"? Otherwise, we may be opening up to any credentialing program that may not be as rigorous as TNI's. It also becomes very difficult to look at all credentialing programs to decide if they are equivalent to TNI's.

Page 3: [3] Deleted **Ilona Verrips Taunton** **8/5/25 6:24:00 PM**

Page 3: [4] Commented [DB21] **Bond, Debbie** **3/12/25 1:57:00 PM**

From Jacksonville '25 (Elizabeth Lesold): Potential conflict because some TP Operator certification (b) and credentialing (c) may overlap enough to cause confusion. For b) must have experience; what about for c)?

Page 3: [5] Commented [DB22] **Bond, Debbie** **3/12/25 2:03:00 PM**

From Jacksonville '25: Add that appropriate records must be maintained to show previous recognition as TS."

Page 3: [6] Commented [DB23] **Bond, Debbie** **3/12/25 2:06:00 PM**

From Jacksonville '25: Is this lab experience or experience as an operator? Or does it matter?

Page 3: [7] Commented [DB24] **Bond, Debbie** **4/14/25 1:30:00 PM**

Should we add analytical discipline to this experience?

Page 3: [8] Commented [DB25] **Bond, Debbie** **7/21/25 12:48:00 PM**

Review again after LAB meets in St. Louis.

Page 3: [9] Commented [PJ26R25] **Paul Junio** **8/6/25 2:32:00 PM**

Comment St. Louis Mtg: This would have to be applied for from each AB

Attachment D: QSM Action Item Summary – 2024/2025

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
1	Update V1M2	V1M2		Ongoing	Ongoing	Ongoing		See #6 – Review SIRs See #2 – Workgroups See #3 – Technical Specialist 12/10/23: Reviewing the DRAFT Standard and working on finalizing language that was inserted from work done by the various language workgroups and making sure language is properly placed in the new format. Additional language editing is being done through this review. The Summary of Changes/Justification document will be updated through this review process. The Committee is looking at changing the Quality Manager title to Quality Specialist. 1/8/24: Edited Data Integrity Section. 5/13/24: Started review of language again. Continued review of language June, July, August, September, October, November. 12/9/24: Finished up review of language and started review of Definitions. Considering how to handle extensive list – are all definitions needed? Work with Ilona and Paul before next meeting. 7/14/25: Review of the definitions has been completed. Some definitions are being removed, but some of those will now be in Expert Modules where only one expert module still needed it. Work

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
								has resumed on Technical Specialist language to prepare for St. Louis.
2	Develop Workgroups to work on language in specific section of the Standard.	V1M2		Ongoing	Ongoing	Ongoing	CLOSED	Language Workgroup tasks: – Internal Audits – Document/Record Retention – Quality Manual – Define "Appropriate QC" in Section 7.7 (ISO/IEC 17025:2017) – Consistent use of Procedure and Policy - Clarification of unique ID 2/6**/23**: Working on defining Technology. Will work with PTPEC, Chemistry and LAMS to further this work. 3/6/23: Working on records retention language. 4/11/23: Committee sending ideas for records retention language to Workgroup for consideration. 7/10/23: Language formulated is now being added to the DRAFT Standard. 8/11/23: The Definitions Workgroup presented information on definitions and there was a lot of discussion surrounding duplicate, replicate, records, policies and procedures (written). 9/11/23: A number of new workgroups have been formed to continue work on the standard. Workgroups now include: - Definitions (presenting 9/11/23) - Language (present Oct) – on Oct agenda - Data Integrity (present Oct) – delayed to Nov - Subcontracted Work (present Dec)

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
								- Measurement Traceability (present Dec) - Calibration Requirements (not started) - Handling Test Items (not started) 9/13/23: The Definitions WG has completed their task to evaluate ~12 terms and compose definitions, if needed, and review full V1M2 Draft for correct use of the term 'Procedure.' The update included the final items that no definitions for duplicate or replicate will make it into V1M2, and defining Procedure as "written" is not in conflict with any ISO 17025:2017 usage of procedure. 11/15/23: The WG for Subcontracting Work (V1M2 4.5.5) completed its task and the draft language is incorporated into Draft V1M2. Data Integrity WG (V1M2 4.2.8.1 & 5.2.7) is almost done but will need to review the most recently proposed additions to match up with QSM 6.0 V1M2. Workgroups Measurement Traceability (5.6), Calibration Requirements (5.5), and Handling Test Items (5.8) just launched this month and will begin tackling suggested edits to these sections. 12/11: Continued updates can be found above in the work for the Standard update since the Committee is now focused on reviewing language in the DRAFT Standard. WORKGROUPS HAVE COMPLETED THEIR WORK.

3	INITIAL Technical Specialist Language	V1M2		Ongoing	Ongoing	Ongoing	Complete	1/11/23: Worked on Exceptions. 2/13/23: Made updates based on conference comments. Working on language to make it clear current technical managers may continue as technical specialists for same areas of responsibility. 8/7/23: Technical Specialist status was reviewed at the Conference and comments ranged from concern that it still won't work for smaller labs to concern that the differing requirements between the Expert Committees makes it confusing. 12/10/23: Received a batch of recommended changes from NELAP AC. Debbie plans to talk to the NELAP AC about the changes. 2/12/24: The Committee started going through the table of recommended changes from the NELAP AC and included Committee Decisions that will be voted on after the table review is complete. 5/13/24: The table was completed in April and the results were presented in the minutes. The minutes and the decisions included were approved 5/13/24. Debbie will send out the comments relevant to the Expert Committees so they can start thinking about whether they need to update their Standard to include more Technical Specialist language. 9/9/24: Workgroup in August reviewed and Committee discussed during regular meeting. Experience requirement going to 1 year. QMS will set a minimum requirement and the Expert Committees

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
								can add more to their Standard if more is needed. 12/9/24: There will be a session in Jacksonville that will discuss concept of Analytical Disciplines and Technical Specialists.
4	Defining Technology (Analytical Disciplines)	Various TNI Standards	Paul Junio Tony Francis Debbie Bond	January 2023	12/11/23			1/11/23: Will work with Paul Junio's group to define Technology. PT, AB, QSM, etc. 12/11/23: Paul has started email communication on this topic, but the Workgroup has not met yet. 5/13/24: Need an update. Group has not met formally. September Update: CSDP EC is developing an Analytical Disciplines Workgroup. October: Workgroup began meeting. There will be a session in Jacksonville devoted to this topic. Will impact Training, Credentialing, and Technical Specialist. 8/6/25 & 8/18/25: Analytical Disciplines removed from Technical Specialist language.
5	Respond to SIRs	SIR 453 SIR 465		Ongoing	Ongoing	Ongoing	Lynn Bradley – LASEC PA	**3/13/23**: Responded to SIR 453 regarding quarterly calibration verification of manual repeating pipettes. 8/14/23: Responded to SIR 465 regarding Class A glassware.

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
8	Address NEFAP request for recommended language in Section 7.3.	V1M2 – Section 7.3	Tracy Szerszen-NEFAP Chair	7/10/23	7/10/23	1/24/24		7/10/23: Alternate language recommended to NEFAP. 12/10/23: Debbie will meet with NEFAP at the conference to look at the language. 1/24/24: Language was reviewed during the conference and placed into the DRAFT Standard.
10	Internal Audit		Ilona Debbie	12/10/23	12/10/23	2/13/24		12/10/23: Checklists were added to Internal Audit Database to internal audit can be performed. Scheduled for 1/4/23. 1/4/24: Audit performed by Debbie and Ilona. 2/12/24: Internal Audit shared with the Committee and Corrective Action was completed. Ilona will send to CSDP EC for final review . *(Addition: 2/13/24: Sent to Paul Junio and Bob Wyeth on 2/13/24.)*
11	Implementation Tool: Prepare a crosswalk for old vs new Standard.				TBD			6/20/24: Ilona noted that there is a crosswalk for the ISO language, but TNI language would need to be added. 7/14/25: Work in progress.
12	Respond to SIR 489	SIR 489		7/8/24	7/8/24	7/8/24		7/8: Committee approved response.
13	Respond to SIR 504	SIR 504		12/9/24	12/9/24	2/11/25		12/9/24: Complete SIR by email because no quorum on call.
14	Technical Specialist Language			7/14/25				7/14/25: Update from the CSDP EC and NELAP AC are being taken into consideration and language is being updated. 8/6,18/25: New Language presented to Committee. Analytical Disciplines removed.