

Quality Management System Expert Committee (QMS) Meeting Summary

July 31, 2023

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Central in Minneapolis, MN on July 31, 2023. Voting members present: Debbie Bond, Michael Demarias, Tony Francis, Nick Slawson, Amy Schreader, Nicole Cairns, Earl Hansen, Zaneta Popovska and Kathi Gumpfer.

Debbie prepared a presentation she will be referring to throughout the meeting. It is included in Attachment A.

2. Definitions Workgroup

See slides in Attachment A.

3. Year in Review

Sees slides in Attachment A.

Technical Specialist

- Facility is not geared towards people qualified to be a Technical Specialist. If he leaves, there is no one that can fill this role. Nuclear power plant.
- Seems like there are a lot of different things required in different modules. Debbie - each technical area decided what was important.
- What if you start a new Radiochemistry lab? Can you add more than one technology per year?
- Training could come from the vendors.
- Has DW looked at this? Jerry - Dan and Jennifer have been in meetings where these concepts have been discussed.
- Paul Junio - CSDP EC - if not caught - use “annually” instead. Not to exceed 13 months.

The remaining slides were reviewed.

4. Technologies

Technologies were discussed in San Antonio. The group has not met yet. It is being lead by CSDP.

5. Definitions Workgroup Update

See Attachment A. Paul Junio presented the definitions on the slides. The following comments were received.

- Duplicates. Depends on purpose of the duplicate. To meet method criteria vs. pulling duplicate samples? May be a lab specific thing.
- Lab duplicate - could be two different people.
- Duplicate is a measurement of precision. A lab thinks adding the term laboratory duplicate confuses thing. Other labs agreed.
- Why are the same personnel important? A duplicate of a sample.
- Used to say specifically that a procedure had to be written or not. If you use this definition, you need to check the whole standard. Paul - The group did go through the whole standard.
- AB - List of things you don't need written procedures for.
- Annual and yearly mean different things.
- Bob Wyeth - be careful about moving some of these definitions.
- Trainer - Field duplicate - should be treated as just another sample.
- Field duplicate as written could cause a problem.
- Under identical conditions should be added.
- ISO 17025 does not require all written procedure. ISO uses procedure differently than what it looks like .
- Need to make sure we are using terms correctly.

Debbie will work on a list where "procedure is.

- They started using video for procedures. How does this translate.

- Written procedures need to be in a controlled document.
- She has SOPs and work instructions. Everything has to be written down.
- Duplicate - thinking about Micro - analyzed in the same batch - have to run at same time and with same person.
- There are field replicates. The definition for replicates is a problem.
- Look at USGS language for replicate samples.
- Why are we defining these? Could be confusing.
- No definition for duplicate that she and Paul could define.
- Jerry - same or similar objects. Measure repeatability. ISO Guide 99 VIM.

Paul thinks they should be cleared - remove sample duplicate or replicate.

6. Language Workgroup

See Attachment A. Nick Slawson presented the slides. The following comments were received.

Internal Audit Language

Nick emphasized it is proposed language.

Module 1 and 3-7. Typo. Include Module 1

- Should it be annually instead of 12 months.
- No other comments.

Technical Records

- Bob Wyeth - If a lab is required to reconstruct data - would that mean the 5 years starts over?
- She is more in favor of last entry. There could be exception. This makes it easier to assess. Example - DOCs keep longer. Validations kept longer. Hates to see labs spend time on developing a way to do "last use". It was mentioned that really old DOCs may be out of date technically - should they really be kept that long? Traceability on supplies.
- Training records would be tough. Some records may not exist for older employees.

- This is a burden. What question are you trying to solve? Require that chemical logs be maintained instead of what you are proposing.
- Hybrid between the two and what last use intent really is.
- Jerry questioned whether this is even needed. Some labs just shut down and you can't find the lab. Lab goes out of business or burns down.
- It's not the labs data ... it is the clients'.
- Clients don't care about old data.
- Data to a customer is the report they have in hand. Not sure this is helpful.
- There is a big difference between transfer and closing of a laboratory. Needs to be looked at differently.
- It doesn't say you have to have the records, you have to have a plan.
- Get rid of "for the labs"
- All states are a little different. Some require that you tell them about data that is being destroyed.
- Keep it simple.


7. Supplies and Services

The Consumables Task Force is working on guidance for purchasing supplies and services.

Debbie presented the slides in Attachment A and then gathered comments:

- Legally defensible is an oxymoron.
- Traceability has to do with the supplies.
- Help labs understand the services that are critical to performing the service. Not looking at criteria for purity of the supply.
- Trying to simplify things. Labs are asked for lots of traceability documents. Need to identify which supplies are critical to the result . To know what documentation you really have. Focus on critical supplies. Need to figure out what is critical.
- Asked that it not go into the Standard. It would be difficult to implement. Start with guidance and then build it up in stages.

- It becomes critical if I can't pass QC.
- 4-5 years ago - 2 vendors - BoD and Micro. The problems wouldn't have been caught in QC. Develop guidance or a Standard for suppliers. We could accredit suppliers to this Standard.
- Change limits to values on Certificate.
- Jerry - This does not belong in Module 2.
- Requiring this could be a problem if you only have one supplier and they won't do this.
- Maybe this is a training opportunity. Look at it from that stand point




Quality Management Systems Expert Committee

Volume 1 Module 2

July 31, 2023
Minneapolis, MN

Debbie Bond – Alabama Power General Test Laboratory
QMS Chair

Kathi Gumpfer – ChemVal Consulting
QMS Vice-Chair




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QMS COMMITTEE

Member	Organization	Representation
Stephanie Atkins	Pace Analytical	Lab
Nicole Cairns	NYSDOH	Lab
Michael Desmarais	SVL Analytical	Lab
Tony Francis	SAW Environmental	Other
Earl Hansen	Retired	Other
Ashley Larssen	KC Water	Lab
Jenna Majchrzak	NJ DEP	AB
Carla McCord	Virginia	AB
Zaneta Popovska	ANAB	AB
Amy Schreuder	UC Laboratory	Lab
Nicholas Slawson	AZLA	AB



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AGENDA

- Recap since winter meeting
- Update from Language & Definitions Workgroups - feedback
- Proposed for Critical Supplies & Services (5.6.4) - feedback

Break

- SIR Review – continued
- Draft V1M2 review, if time permits



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YEAR IN REVIEW

- **Technical Specialist - informational overview**
- **SIR 453**
- **Workgroups and looking ahead**
- **Technologies**



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TECHNICAL SPECIALIST

- **Formerly known as Technical Manager (and Technical Director)**
- **Background**
 - The Competency Task Force provided acceptable language
 - Proposed language was reviewed and updated by Technical Module Expert Committees
 - QMS Expert Committee reviewed language and made additional edits
- **The proposed language can be tweaked but the overall intent must remain**




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TECHNICAL SPECIALIST

- **Clarified that the Technical Specialist does not require supervisory responsibilities**
- **If TS for more than one location, provide a plan detailing availability at each location. AB evaluates and approves**
- **Instead of starting a clock when TS is absent, the clock starts when the TS is not available**
- **Laboratory is responsible for showing how education/training is equivalent, for equivalent coursework, college education, or scientific discipline**
- **Rearranged TS qualifications to match up with Modules**



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TECHNICAL SPECIALIST

- **Asbestos (Module 3)**
 - Specified "scientific discipline" for earned degree or coursework
 - Changed "under supervision" to "with experienced analyst available"
 - For phase contrast microscope, specified NIOSH 582 course
- **Chemical Testing (Module 4)**
 - Specified "chemical engineering" instead of "engineering" for earned degree
 - Removed credit hour options
 - For inorganic, non-metals, 1 year of experience instead of 2; and masters/doctorate can substitute for 6 months experience




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TECHNICAL SPECIALIST

- **Microbiological Testing (Module 5)**
 - Specified "biochemical engineering" and "molecular biology engineering" instead of "engineering" for earned degree
 - Removed credit hour options
 - Exception for fecal coliform, total coliform, and E. coli is now for presence/absence tests; membrane filtration; multi-tube fermentation; multi-well culturing devices; or heterotrophic plate count techniques
 - Presence/absence... changed 4 credit hour microbiology course to 1 course
 - Presence/absence... changed 2 years experience to 1; masters/doctorate can substitute 6 months



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TECHNICAL SPECIALIST

- **Radiochemical Testing (Module 6)**
 - Limited education to any combo of chemistry, physics, equivalent
 - Changed credit hours to number of courses
 - Added technology specific training for each tech, up to 4 trainings
 - Experience (in new tech) >2-year can substitute some education (6 courses min)
 - 1 year substitutes one course
 - Removed specific requirements for radon in air (associates degree/2-years of college and 1 year of radon/radon progeny experience)



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TECHNICAL SPECIALIST

- **Toxicity Testing (Module 7) NEW**
 - Degree in biological sciences, chemistry, physical sciences, environmental sciences or environmental engineering
 - 4 college-level biological or environmental courses required
 - 2 years experience
 - Masters/doctorate can substitute 1 year of experience
 - Each additional year experience can substitute 1 course, up to 2 courses can substitute



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TECHNICAL SPECIALIST

- **Toxicity Testing (Module 7) NEW**
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 - Each additional year can substitute 1 course, up to 2 courses



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TECHNICAL SPECIALIST EXCEPTIONS

- **An individual approved as TD/TM/TS with previous exceptions remains approved; approval can continue in other lab, pending AB approval**
- **Lab can apply for an education waiver if:**
 - Associate's instead of bachelor's degree with 4 years experience
 - Four courses (instead of ___) with 5 years experience
 - Plant operator certificate; limited to scope of regulated permit
- **Lab must keep record of waiver (more than 5 years?)**
- **Instead of education, TNI credential – no applying to ABs for waiver**
- **New technology – demonstrated performance instead of experience**
 - Radiochemistry limits one new technology per year per TS



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SIR


- **SIR 453 (volume verification for repeater pipettor)**

Disclaimer

The following SIR is not complete. Any response described must be approved by LASEC and the AC before it may be posted. The response may change.




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SIR 453

- **SIR 453 on V1M2, 5.5.13.1 e) iii.**
 - The question relates to quarterly calibration verification of manual repeating pipettes where the settings on the mechanical device are (for example) 1-5 step-wise by 0.5, but these settings don't directly correlate to a volume dispensed. (Here is an example device for reference - <https://brandtech.com/product/handystep-repeating-pipettes/>)
 - Question: Is it sufficient to verify the calibration of the device using the range of SETTINGS on the device and one tip size, or does the range of VOLUMES measured with the device and its multiple tip sizes need to be used instead (which would necessitate using multiple tip sizes and possible difficulty hitting the midpoint range of BOTH settings and volumes)?




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CURRENT WORKGROUPS

- **Definitions Workgroup - GOAL: present to QMS by September 11**
 - Review of all terms in V1M2, composing definitions for possibly 14 terms
 - Reviewing full V1M2 to limit use of "procedure" where a written procedure is required
- **Language Workgroup – GOAL: present to QMS on September 11**
 - Completed revision to SOP headings (4.2.8.5), ID of samples (5.8.5), internal audit
 - 4.13.3 revision to records retention continues
- **Data Integrity Workgroup – GOAL: present to QMS on September 11**
 - Update to 4.2.8.1 (clarify 'periodic', procedure, records) and 5.2.7 (training)
 - Launched June 20, 2023



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UPCOMING WORKGROUPS

- **Subcontracted Work – GOAL: present to QMS on November 13**
 - Valid/non-valid SIR review highlighted needed edits for, 4.5.5
 - Proposed requirements for certificates for services – will request feedback
 - Launched June 30, 2023, but waiting on your feedback
- **Measurement Traceability – GOAL: present to QMS on November 13**
 - Clarify records/labeling for purchased vs. prepared standards and reagents, 5.6.4
 - Proposed requirements for certificates for purchased – will request feedback
 - Will launch after receiving your feedback today



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LOOKING AHEAD

- **Based on SIRs submitted, the following will likely have WGs:**
 - Calibration Requirements (V1M2, 5.5)
 - Test Items (V1M2, 5.8)
- **Valid/non-valid SIR review may discover needed edits**
- **A deep review for improvements may help minimize confusion**

Volunteers needed for Language WG and other WGs!

- **Committee review of Draft V1M2 starting January 2024?**



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TECHNOLOGIES IN LAMS

- **Suggestion during Winter TNI Conference to review technologies in LAMS**
 - There are about 120 technologies listed in TNI LAMS
 - Can they be categorized into clear groups of representative technologies?
- **Technology Workgroup is launched**
 - Chair is Paul Junio and workgroup is part of CSDP EC
 - Membership is made of a committee members from various expert committees
 - Will review technologies and attempt classifying into representative technologies
 - Ideal outcome would be to define how to classify technologies
 - Helps with internal auditing and technical specialist requirements, and more

See LAMS_technologies.xlsx




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Definitions Workgroup Update

July 31, 2023
Minneapolis, MN

Paul Junio – Pace Analytical
CSDP EC Chair



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WORKGROUP MEMBERS

Debbie Bond – Alabama Power
Lizbeth Garcia – ORELAP
Paul Junio – Pace Analytical
Jenna Majchrzak – NJ DEP
Amy Schreder – UC Laboratory



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REVISED DEFINITIONS

Annual – A period of 12 months, not to exceed 13 months


Contract – A written or oral agreement to provide a customer with testing services, such as is found on a chain of custody

Corrective Action – An action taken by the laboratory to eliminate or correct the causes of an existing nonconformance to prevent the recurrence of the nonconformance

Customer – A person or organization that requests analysis from the laboratory. NOTE – a customer may be internal or external to the laboratory.



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REVISED DEFINITIONS


Duplicate – Two aliquots of the same sample prepared and analyzed with identical procedures. Duplicate and replicate are not equivalent terms.

- **Field Duplicate** – a sample that is a representative companion collected in the same event and at the same place as the original sample.
- **Laboratory Duplicate** – a separate aliquot of sample prepared in the same batch and analyzed in the same batch as the original sample.

Replicate – A repeated measurement, such as a measure of absorbance, that is performed within a short timeframe so that the analytical or measurement process is identical. Replicate and duplicate are not equivalent terms.



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REVISED DEFINITIONS


Procedure – written instructions detailing the performance of a task, process, or other laboratory activity

Quarterly – A period of 3 months not to exceed 4 months, and occurring 4 times annually

Test Item – The original field sample and any leachates, digestates, extracts, or similar sub samples that are subjected to testing



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NOT DEFINED


Method Validation – ISO 17025:2017 essentially defines the term by describing the combination of items that could make up a method validation (7.2.2.1)

Policy – Websters covers this

Verification – ISO term (Terms and Definitions, Module 2)



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NOT DEFINED


Support Equipment – the goal with this definition was to avoid a list of the typical equipment that is ‘support’. (1) We’d miss something, and (2) it implies that equipment is either support or analytical

We chose to modify the language in Module 2 hoping for clarity. The key addition:

Depending on the intended use of the data, a device may be considered support equipment in some instances, and analytical equipment in others




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GLOSSARY

A draft SOP (1-129 TNI Maintenance of the Glossary) has been started. It describes how the Policy Committee will maintain the Glossary. The Glossary will consist of terms that have been defined in the Standards, as well as those defined in TNI Policies or SOPs, and will include the source of the term (i.e., ISO, Specific TNI Module, Specific TNI SOP or Policy).

Terms defined in the Standards have a greater precedence than those defined in Policies or SOPs. Where conflicts are identified, terms will be modified so that we only have a single definition for a given term. These conflicts will be a point of review as the current Standards are being revised.



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Contact Information

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Language Workgroup Update

July 31, 2023
Minneapolis, MN

Nick Slawson
Program Manager – A2LA



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WORKGROUP MEMBERS

Nick Slawson – A2LA
John Gumpfer – ChemVal Consulting
Lisa Parks – Jackson Family Wines
Meera Neb – Technical Testing International




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Internal Audit Language

Internal Audit Suggested Language preferred during the QMS Session in San Antonio, January 2023:

- The laboratory shall audit all elements of applicable Technical Modules 1, and 3-7 annually using a representative selection of analytical technology(?) that covers at least one-third of the laboratory's scope of accreditation.
- We will still need to require an audit schedule/plan, I think, to show the lab's intent to cover at least 1/3 of the scope each year. But if there's a better idea, we can consider it.




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Internal Audit Language

- Current DRAFT Internal Audit Language
 - 1. In addition to the requirements listed in 8.8.1 and 8.8.2, the internal audit program shall include:
 - A pre-defined schedule covering a 2-year period
 - The interval for each audit shall be determined by the laboratory and shall not exceed:
 - 24 months for methods/technologies on the scope of accreditation
 - Note: Technologies are defined in the TNI Laboratory Accreditation Management System
 - 12 months for the elements in Module 2 of this standard
 - Note: Laboratories must ensure they follow the most stringent requirements, where applicable




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Proposed IA Language Additions

- 8.8.3 In addition to the requirements listed in 8.8.1 and 8.8.2, the internal audit program shall:
 - a. include a pre-defined schedule covering a 3-year period
 - b. include review of all requirements of TNI Module 2 at least every 12 months
 - c. include review of all elements of the technical TNI modules 3-7 over the course of the audit schedule.
 - Cover all method under which the laboratory performs its accredited testing over a 3-year period with at least one-third of the methods being reviewed annually.
 - Include a representative selection of analytes, matrices, and technologies.




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4.13.3 – Technical Records

- 4.13.3 Additional Requirements
 - A) The laboratory shall retain all records for a minimum of five (5) years from the last use of the records. Records are considered “in use” when they are required to support current laboratory activities.
 - Note: Examples of records that are required to support current laboratory activities include, but are not limited to, method validation records, training records of personnel, equipment installation and calibration records, and records of standard preparation.




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4.13.3 – Technical Records

- Use of “last use” vs. “last entry”
 - Last use was chosen initially because records are used even after their last point of entry.
- Clarification on “last entry”
 - Validations for lab developed methods
 - Traceability records for supplies
 - Incubator distribution and equilibration studies




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4.13.3 – Technical Records

- f) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients’ instructions in the event that a laboratory transfers ownership or goes out of business. In addition, appropriate regulatory and state legal requirements concerning laboratory records shall be followed.
- We want to take a look and see if this needs to be clearer. We don’t want data to disappear, so we are looking into this.




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Contact Information

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SUPPLIES AND SERVICES

- Consumables Task Force is working on guidance for purchasing supplies and services
- **Definition requested:**
Critical Supplies and Services - 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.
- **Additional requirements around records for purchased critical supplies and services could also help.**
 - Proposed requirements for chemicals and for services based on ISO Guide 31, but limited to minimum to support lab traceability and defensibility

See Critical lab supplies and services.doc



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CHEMICAL CERTIFICATE

- **Propose requiring the following from critical supply certificates**
 - Manufacturer name & contact information, if different from supplier
 - Name of material
 - Unique identification for material
 - Instructions (for use, storage, etc.)
 - Certified values or specifications
 - Uncertainty limits, for CRMs
 - Traceability, for CRMs
 - Date of Certification
- **For V1M2, 5.6.4 (or ISO 17025:2017, 6.6)**



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SERVICE CERTIFICATE

- **Propose requiring the following from critical services certificates**
 - Service provider name and contact information
 - Credentials of service provider
 - Title (certificate, information sheet, etc.)
 - Description of service provided
 - Unique ID of equipment serviced
 - Certified values
 - Uncertainty limits, for calibration services
 - Traceability, for calibration services
 - Date of service and certification
 - Signature of certifier/technician
- **For V1M2, 4.5.5 (or ISO 17025:2017, 6.6)**




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Valid and Non-Valid SIR Review - continued Volume 1 Module 2

See SIR-Summary-20230728.xls




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