# Summary of the Laboratory Accreditation Body Expert Committee Meeting Tuesday, January 21, 2025 1:00 pm Eastern

#### 1. Welcome and Roll Call

Aaren welcomed everyone to this meeting. Attendance is recorded in Attachment 1. There were no objections to the agenda, but without a quorum, only discussion was possible (proposed agenda is shown in Attachment 2).

The election is postponed until the February meeting.

#### Discussion

<u>6.2.2.1</u> – Two versions of proposed revision to §6.2.2.1 were provided by Jody, and Aaren asked to discuss them at the conference session. The alternatives were:

6.2.2.1 Assessors and technical experts must conform to professional and ethical standards of conduct. Assessors and technical experts must exhibit honesty, fairness, professionalism, independence, impartiality, objectiveness, report conflicts between their ethical/professional responsibilities and the CAB being assessed, not participate in an assessment in which they have any personal or financial conflict of interest or the appearance of such conflict, and make and retain full, clear, and accurate records of all assessments performed

or

6.2.2.1 Assessors and technical experts must conform to professional and ethical standards of conduct as set forth by the accrediting body for which the assessor is performing the assessment.

6.2.2.2 Accrediting bodies must have a written professional and ethical standard of conduct which includes the following: (list out what needs to be in the code of conduct)

#### Status Review of Revising the Evaluation Process

Discussions about this topic ground to a halt in 2023, and no one has yet found the time or the interest to take on the issue. Lynn noted that the topic is likely to surface at conference in February, so the various pieces of a revision that had been earlier discussed were brought forward so that new committee members could understand the history.

Aaren had created a draft proposal to address a number of aspects, see Attachment 3. Initial drafts of three additional aspects were mentioned but not discussed further, and these are included as Attachments 4 (Internal Audits and Key Performance Indicators), Attachment 5 (Possible Compliance [Technical Review] Checklist), and Attachment 6 (Assessor Competency Draft Questions). Committee members previously agreed that, for initial AB applicants and for the first evaluation after implementation of a new standard (Volume 2), the complete document review as included in the current Technical Review Checklist should be used.

NOTE: None of the drafts in Attachments 3 - 6 have been reviewed by the full committee previously, and should not be considered as anything other than suggestions, for now.

Cathy reminded the group that she had volunteered to examine all findings from the previous round of NELAP evaluations, to determine if those would have been identified through internal audits, as well as what the most common findings (and repeat findings) are, but that she has not yet had the "spare" time to actually do that analysis, as it is not a trivial task. She also asked if

such a review would be needed to justify using annual internal audits as a substantial component of evaluations, and if not, then the proposed review may not be necessary at all.

Aaren recommended that we pick up this topic in the months after conference, where additional perspectives will likely be discussed.

3. Discuss Agenda for LAB Conference Session, if needed (Wednesday morning, February 5, 3.5 hours)

Paul explained that the Field Activities Committee is revising Volume 2 of the FSMO Standard, and explained the importance of defining a firm, fixed boundary between NEFAP accreditation and NELAP accreditation. This is particularly important for mobile labs, as they currently face a patchwork of accreditation requirements – they must be accredited every time they move into a new NELAP state (no mutual recognition available). NELAP accreditations for mobile labs are recognized by some non-NELAP state certification bodies (GA, OH, WI, at least), but the number is unknown. If a mobile lab were NEFAP accredited, for now, NELAP states do not recognize NEFAP at all, and this is a long-standing concern for mobile labs.

4. New Business

There was no new business.

Next Meeting

The next planned teleconference meeting is scheduled for <u>Tuesday</u>, <u>February 21</u>, <u>2025</u>, <u>at 1:00</u> pm Eastern.

Aaren asks that committee members unable to attend please notify her and Lynn prior to the meeting date.

## Attachment 1 LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
Aaren Alger, Chair	1/30/2026	Other – Alger Consulting & Training	Yes
Aaren.s.alger@gmail.com	(2nd term)		
Socorro Baldonado	1/30/2026	Lab – Metropolitan Water District, La	No
sbaldonado@mwdh2o.com	(2nd term)	Verne, CA	
Nilda Cox	1/30/2025	Lab – Eurofins Eaton Analytical LLC	Yes
nilda.cox@et.eurofinsus.com	(2nd term)	,	
Bill Hall	1/30/2026	AB – NH DES	No
george.w.hall@des.nh.gov	(1st term)	7.5 1111.526	
Sviatlana Haubner	1/30/2025	LAB – Cincinnati Metropolitan Sewer	No
Sviatlana.Haubner@cincinnati-oh.gov	(1 <sup>st</sup> term)	District	INO
Michella Karapondo	1/30/2025	Other – EPA OGWDW TSC/Cincinnati	Yes
Karapondo.michella@epa.gov	(1st term)	Other – EPA OGWDW TSC/Cincinnati	res
Jody Koehler	1/30/2028	AB – TCEQ	Yes
Jody.koehler@tceq.texas.gov	(1st term)		
Michael Perry	1/30/2026	Lab – Southern Nevada Water Authority	No
michael.perry@lvvwd.com	(2nd term)		
Zaneta Popovska	1/30/2025	AB – ANAB	No
zpopovska@anab.org	(2nd term)		
Millie Rose	1/30/2028	AB – IL EPA	No
Millie.Rose@illinois.gov	(1st term)	AD - IL LI A	110
	1/30/27	AD NIV DOLL	Vac
Amy Steuerwald amy.steuerwald@health.ny.gov		AB – NY DOH	Yes
	(1st term)		
Program Administrator:	N/A		Yes
Lynn Bradley@nelac-institute.org			
Associate Members:			
Paul Bergeron		AB – LDEQ	Yes
Paul.bergeron@la.gov			
Debbie Bond		LAB – Alabama Power	No
dbond@southernco.com		LAD Curefine	No
Kathryn Chang Kathryn.chang@et.eurofins.us		LAB – Eurofins	No
Yumi Creason		Other	No
ycreason@pa.gov		Other	INO
Taryn Hurley		AB – OK DEQ	No
taryn.hurley@deq.ok.gov			
Paul Junio		LAB – Pace Labs, Inc.	No
paul.junio@pacelabs.com		·	
LeeAnn Kline		M J Reider Associates	Yes
<u>lkline@mjreider.com</u>			
Ryan Lerch		AB – OK DEQ	Yes
Ryan.lerch@deq.ok.gov			
Marlene Moore		Other – Advanced Systems, Inc.,	No
mmoore@advancedsys.com		Newark, DE	NI-
Mei Beth Shepherd, Vice Chair		Other – Shepherd Technical Services	No
mbshep@sheptechserv.com			

Nicholas Slawson	AB – A2LA	No
nslawson@a2la.org		
Ilona Taunton	Other – TNI Program Administrator	No
llona.taunton@nelac-institute.org		
Cathy Westerman	AB – VA DCLS	Yes
cathy.westerman@dgs.virginia.gov		

#### Attachment 2 - LAB Expert Committee Meeting Agenda

- Welcome and Roll Call
- Approval of Agenda
- Approval of Minutes (December minutes attached)
- Election
  - o Chair
  - o Vice Chair
  - Re-elect Sviatlana and Michella for second terms
  - Nilda and Zaneta have completed the maximum of two terms, but both will remain as associate members
  - o Balance is maintained with 4 ABs, 3 labs and 2 "others"
- Vote on Persuasiveness of Remaining Comments (see attached response-to-comments spreadsheet and current draft V2M1 module this assumes a quorum is present)
- Consider ISO Text Identified for Removal or Clarification (if no quorum)
- Discuss Agenda for LAB Conference Session, if needed (Wednesday morning, February 5, 3.5 hours)
- New Business, if any
- Adjourn

#### Attachment 3 - Proposals 1 and 2

#### **Proposal 1: Revise AB Renewal Application Process**

The current NELAP AB renewal application process includes an extensive Technical Review Checklist that encompasses the entirety of the Volume 2 TNI Standard requirements. The application also consists of submission of particular information that is not specifically relevant to the evaluation of the ABs, as far as specific compliance requirements. This proposal serves to provide specific examples of an amended application form, TR checklist, and applicable attachments to be provided to the Evaluation team with each renewal application from an AB.

#### **Application Form Changes:**

- 1. Remove the specific items for which the AB must complete regarding items 6 8. Instead, request a detailed organizational chart and specific information regarding each individual named on the chart. To include,
  - a. Name
  - b. Title
  - c. Responsibility (i.e. Program Manager, Assessor, Quality Assurance Officer, etc.)
  - d. For assessors,
    - i. Relevant Experience (i.e.: assessor experience, laboratory experience, quality assurance experience, etc.)
    - ii. Technical Responsibilities (i.e.: at a minimum: Chemistry, Microbiology, etc.; or more detailed information based on AB qualification requirements)
    - iii. Dates of Relevant Training
      - 1. Basic Assessor Course
      - 2. Technical Training
      - 3. Refresher Course(s), as applicable
- Remove Items 9 and 10 and replace with spreadsheets for the AB to provide the following information for all laboratories who have applied for, are currently accredited, or were accredited since the most recent application:
  - a. Laboratory Name
  - b. AB's Laboratory Accreditation Number (as applicable)
  - c. TNI Lab ID
  - d. City, State, Zip
  - e. Accreditation Type (Primary or Secondary)
  - f. Primary AB(s) for Secondary Labs
  - g. Assessment Information
    - i. Date of all assessments or reassessments conducted in last 4 years
    - ii. Date of Report of Assessment (if issued)
    - iii. Date of receipt of Corrective Action Report (as necessary)
    - iv. Date of Reply/Response to CAR
    - v. Dates of any subsequent CARs/Responses to CARs, etc.
    - vi. Type of Assessment (initial, reassessment, extraordinary, etc.)
    - vii. Date of Close or other Action
    - viii. Result of the Assessment (renewal of accreditation, reaccreditation, continued accreditation, suspension, revocation, etc.)
      - ix. Number of days elapsed between each activity.
  - h. Application Information (for initial and renewal)
    - i. Date of Application
    - ii. Application Type

- iii. Date of Final Determination of Application
- iv. Action Taken (renewal, grant accreditation, denial, etc.)
- 3. Move Item #11 up.
- 4. Remove Hours of Operation (item #12)
- 5. Remove requirement to submit Areas of NELAP Recognition and replace with "Requested Changes to NELAP Recognition"
- 6. Replace items listed in #14 with the following:
  - a. Personnel List
  - b. Laboratory List
  - c. Organizational Chart
  - d. Quality Manual and SOPs
  - e. Internal Audits from last 4 years
  - f. Management Reviews from last 4 years
- 7. Remove requirement for a signed certification statement.

#### **Technical Review Checklist Changes:**

- 1. Summarize the specifics of the Volume 2 TNI Standard into manageable chunks that are likely to be covered in the same or similar documentation. See attached example.
- 2. The checklist would summarize the elements of the particular section of the standard, without reiterating the entirety of the standard.
- 3. The checklist could also identify where the standard requires a particular piece of evidence to be developed, maintained, documented, etc. and identify these with a particular color-code. Such as:
  - a. Policy or Procedure
  - b. Record of Evidence

Section	General Requirement	Y/N/NA	Documentation/Location
4	General Requirements		
4.2	Accreditation Agreement		
4.2	Provide references within the AB's documentation, application forms, regulations, etc. explain the requirements for a laboratory to conform to the requirements of V2M1: 4.2 a - k.		
4.3	Use of Accreditation Symbols and Other Claims of Accreditation		
4.3.1 - 4.3.5	Provide references to the AB's procedures, policies, regulations, etc. related to a laboratory's responsibilities for use of logos, claims of accreditation, and any actions that will be taken if these provisions are violated.		
4.3.3	The AB must have a documented policy governing the use of accreditation symbol and claims of accreditation status. The policy shall specify the items listed in 4.3.3 a - f.		
4.4	Impartiality Requirements		

4.4.1 - 4.4.13	Provide references to the AB's procedures, policies, regulations, etc. related to the AB's responsibilities for impartiality, objectivity, conflict of interest, determination and evaluation of risk, accessibility to services, consultancy, related bodies, etc.	
4.4.3	The AB shall document and make public an impartiality policy that includes the importance of impartiality in carrying out its accreditation activities, managing conflict of interest, and ensuring objectivity of its accreditation activities.	
4.4.5	The AB shall document and implement a process to provide opportunity for effective involvement by interested parties for safeguarding impartiality.	
4.4.6, 4.4.7	The AB shall document on an ongoing basis the risks to impartiality. Where risks are identified, the AB shall document and demonstrate how it eliminates or minimizes such risks and document any residual risk.	
4.5	Financing and Liability	
4.5.1	Records or documents describing the AB's financial resources and sources of income	
4.5.2	Evaluation of risks from activities and arrangements to cover liabilities	

#### **Proposal 2: Expand the Evaluation Team Member Pool**

The current NELAP Evaluation team consists of a Lead Evaluator (TNI contractor/employee) and one or more members of another NELAP-recognized AB. Occasionally, the USEPA OW participates in the evaluation. This proposal suggests that there are additional resources available to NELAP to broaden the evaluator pool and possibly reduce the workload. This proposal suggests that the NELAP AC Consider expanding the evaluator pool to include individuals from outside the USEPA CO's and NELAP-recognized ABs, such as:

- 1. Non-NELAP ABs, such as Wisconsin, Nevada, California, etc.
- 2. NGABs
- 3. USEPA program offices other than Office of DW, such as CWA or RCRA
- 4. Third-Party Assessors
- 5. Accredited Laboratories

If the NELAP AC were to consider expanding the evaluator pool, the AC should adopt the following provisions:

- 1. Must be an active member in TNI
- 2. Must have successfully completed NELAP Evaluator Training
- 3. Must be volunteer, cannot accept or expect reimbursement or payment
- 4. For a laboratory employee to participate on an ET for a particular NELAP AB, the employing laboratory cannot hold or seek to obtain Primary accreditation from that particular NELAP AB.

- a. The laboratory rep would be limited to review of AB program materials, such as rules, regulations, policies, manuals, SOPs.
- b. The laboratory rep would not participate in activities related to laboratories, the laboratories' files, or other proprietary and/or confidential material.

#### Other Considerations:

- 1. Would additional training specifically related to the requirements of V1 and V2 be necessary?
- 2. Maybe require successful completion of Basic Assessor Training?
- 3. Maybe require confidentiality agreements?

#### Attachment 4 - Internal Audits and Key Performance Indicators

Internal Audits for ABs and KPIs

- Key Performance Indicators for ABs
  - o Complaints:
    - % of complaints with the start of an investigation outside of AB's established timeframe
  - Initial Application:
    - Average time between receiving an initial application for Secondary NELAP accreditation and granting accreditation
    - Average time between receiving an initial application for primary NELAP accreditation and performing the assessment
  - Renewal Processing
  - o What about repeat deviations?
  - Assessment Reports
    - % of assessment reports issued after 30 calendar days from the closing meeting
    - Corrective Action Reports
  - Change Application:
    - Average time between receiving an add FOA application for Secondary NELAP accreditation and granting accreditation
    - Average time between receiving an add FOA application for primary NELAP accreditation and granting accreditation
  - o Assessor Competence/Enough People:
    - % of overall assessors approved to assess microbiology vs. % of primary laboratories accredited for microbiology
    - % of overall assessors approved to assess inorganic non-metals vs. % of primary laboratories accredited for inorganic non-metals
    - % of overall assessors approved to assess trace metals vs. % of primary laboratories accredited for trace metals
    - % of overall assessors approved to assess organic chemistry vs. % of primary laboratories accredited for organics
    - % of overall assessors approved to assess asbestos vs. % of primary laboratories accredited for asbestos
    - % of overall assessors approved to assess toxicity testing vs. % of primary laboratories accredited for toxicity testing
    - % of overall assessors approved to assess radiochemistry vs. % of primary laboratories accredited for radiochemistry
  - o PT Processing/Actions:
    - 45 days
    - 60 days processing
    - Open/Close Date checks
    - 2 out of 3 passing/failing
    - Timeline to take action

### Attachment 5 - Possible Compliance (Technical Review) Checklist

# Internal Assessment Checklist

## **ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM**

Details of the internal / 105es	SHIELLE
Assessment Details	
Accreditation Body Name	
Address	
Telephone No.	
Name(s) and designation(s) of persons /interviewed	
Assessment Type	
Date(s) of Assessment	
Site Visited	
Technical Assessor(s)	
Specialist(s)	
MNELAP Lead Internal Asses	ssor
Name (please print)	
Signature	Date

# MNELAP Internal Assessment Checklist

2009/2016 TNI Standard	Requirements (Administrative)	Yes	No	N/A	Remarks
V2M1: 4.1	Is the accreditation body legally identifiable?				
V2M1: 4.2	Is there an organizational chart showing the organization and management structure of the assessment body?				
V2M1: 4.6	Are the scope of technical activities and its functions clearly defined and documented?				
V2M1: 4.5	Does the accreditation body have adequate liability insurance?				
	Are the conditions on which the accreditation body does its business documented?				
	Does the accreditation body have independently audited accounts?  Does the accreditation body maintain records of its financials?				

2009/2016 TNI Standard	Requirements (Independence, impartiality and integrity)	Yes	No	N/A	Remarks
V2M1: 4.3	Are the personnel of the accreditation body free from any commercial, financial and other pressures which might affect the judgment of assessment?				
V2M3: 4.3	Are there any procedures implemented to ensure that there is no influence by external persons or organization on the results of assessments carried out?				
V2M3: 4.3	Does the accreditation body ensure that each decision on accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment?				

2009/2016 TNI Standard	Requirements (Confidentiality)	Yes	No	N/A	Remarks
V2M1: 4.4	Is there documented policy ensuring that confidentiality of information obtained and proprietary rights are protected?				
	Does the accreditation body take adequate measures and ensure arrangements are in place to protect the confidentiality of the information obtain in the process of its accreditation activates within the AB or with the individuals acting on its behalf?				

2009/2016 TNI Standard	Requirements (Organization and Management)	Yes	No	N/A	Remarks
V2M1: 4.2	Is the organization capable of performing its technical functions satisfactorily?				
V2M1: 4.2	Did the accreditation body define and document the responsibility and reporting structure of the organization?				
	Are the relationships to other depts. of the parent company/related affiliates clearly depicted?				

2009/2016 TNI Standard	Requirements (Manager)	Yes	No	N/A	Remarks
V2M1: 4.2.5	Is there a manager (however named) designated who has the overall responsibility that assessment activities are carried out in accordance to this standard?				
	Is the manager qualified and experienced?				
	Is the Technical Manager a permanent employee?				
	Is there effective supervision for assessment? Is the supervisor familiar with the assessment methods, procedures and objective of the assessment?				
V2M1: 5.2.3	Are deputies appointed for key managerial personnel?				
	Is there a clear job description of all key personnel? The description shall include requirements for education, training, technical knowledge and expertise.				

2009/2016 TNI Standard	Requirements (Quality System/Management System)	Yes	No	N/A	Remarks
V2M1: 5.2 through 5.9	Does the quality manual have a policy and an objective for and commitment to statements on quality by management?				
	Is this policy understood, implemented and maintained at all levels in the organization?				
	Is the quality system appropriate to the type, range and volume of work performed?				
	Is the quality system fully documented in the quality manual?				

2009/2016 TNI Standard	Requirements (Quality System/Management System)	Yes	No	N/A	Remarks
	Is there a quality/management systems manager (however named) designated who has defined authority and responsibility for quality assurance within the assessment body? Does this person have direct access to the management?				
	Is the quality system maintained relevant and current under the quality manager/management systems officer?				
	Is there a system for control of all documentation?				
	Current issues of appropriate documents are available to staff and at appropriate location?				
	Is there proper authorization for amendments?				
	Are revised documents distributed to appropriate location in a timely manner?				
	Are obsolete documents removed from use?				
	Is the quality system audited at planned intervals to verify its compliance with the criteria of this standard? Are the personnel carrying out the audit qualified and independent from the functions being audited?				
	Are there documented procedures for dealing with complaints, feedback and corrective actions when discrepancies are detected?				
	Is the quality/management system reviewed by the management at appropriate intervals to ensure its continued suitability and effectiveness? Are such reviews recorded?				

2009/2016 TNI Standard	Requirements (Personnel)	Yes	No	N/A	Remarks
V2M1: 6.1	Does the accreditation body have sufficient number of permanent staff to carry out its normal functions?				
V2M1: 6.2	Do the assessors, contract assessors and third party assessors/organizations possess relevant qualifications, training, experience and knowledge of the assessment to be carried out?				

2009/2016 TNI Standard	Requirements (Personnel)	Yes	No	N/A	Remarks
	Are the assessors competent to make professional judgments using the examination results?				
	Do the assessors have relevant knowledge of the technology used for laboratory analysis and the associated quality systems?				

2009/2016 TNI Standard	Requirements (Training)	Yes	No	N/A	Remarks
V2M3:4.2	Does the accreditation body have a documented training system for identifying training needs at various stages and its implementation?				
V2M1: 4.2	Does the training include induction period, a supervised working period with an experienced inspector and continual training provided? Are records of training, academic qualifications, etc. maintained for each inspector?				
	Is guidance provided for conduct of its staff?				

20092016 TNI Standard	Requirements (Facilities and equipment)	Yes	No	N/A	Remarks
V2M1: 4.2	Does the accreditation body have adequate facilities and equipment available for assessment services to be carried out?				
	Are there clear rules for the access and use of facilities and equipment?				
	Are facilities and equipment ensured for its continued suitability against their intended use				

2009/2016 TNI Standard	Requirements (Selection of suppliers)	Yes	No	N/A	Remarks
V2M1: 4.2	Are the reference materials used by the accreditation body (where possible) traceable to national or International Standard reference materials?				
	Are procedures for the selection of qualified suppliers documented?				
	Are procedures documented for the assessment of incoming received material?				

2009/2016 TNI Standard	Requirements (Storage facilities)	Yes	No	N/A	Remarks
V2M1: 4.2	Are procedures documented to ensure that items are stored at appropriate facilities?				
	Are stored items assessed at appropriate intervals to detect deterioration?				

2009/2016 TNI Standard	Requirements (Computers and automated equipment)	Yes	No	N/A	Remarks
V2M1: 4.2	Are computer software tested to confirm its adequate use?				
	Are procedures established and implemented for protecting integrity of data?				
	Is maintenance of computers and automated equipment performed to ensure proper functioning?				
	Are procedures established and implemented for maintenance of security of data?				

2009/2016 TNI Standard	Requirements (Assessment Methods and Procedures)	Yes	No	N/A	Remarks
V2M3: 3.7, 6.3	Does the accreditation body use methods and procedures as defined in the requirements?				
	Does the accreditation body have documented instructions on the assessment planning, standard sampling and assessment techniques?				
	Are non-standard assessment methods used? If yes, are they appropriate and documented?				
	Are relevant documents to assessment work made available to staff and maintained up-to date?				

2009/2016 TNI Standard	Requirements (Contract or Work Order Control System)	Yes	No	N/A	Remarks
V2M3: 3.7, 6.3	Is there a Contract or Work Order Control System that ensures the following:				
	Organization has the adequate resources and expertise for work being undertaken?				
	Requirements of client are adequately defined and instructions are understood by staff?				

2009/2016 TNI Standard	Requirements (Contract or Work Order Control System)	Yes	No	N/A	Remarks
	Is work being undertaken is controlled by regular review and corrective action?				
	Are reviews are conducted on completed work to confirm that requirements are met?				

2009/2016 TNI Standard	Requirements (Assessment observations and data)	Yes	No	N/A	Remarks
	Are assessment observations and/or data obtained in the course of assessment recorded in a timely manner to prevent loss? Are calculations and data transfer subjected to appropriate checks?				

2009/2016 TNI Standard	Requirements (Safety)	Yes	No	N/A	Remarks
	Are there documented instructions for assessments to be carried out safely?				

2009/2016 TNI Standard	Requirements (Records)	Yes	No	N/A	Remarks
V2M1: 5.4, 6.4, 7.10 V2M3:4.3	Does the accreditation body maintain a record system to suit its circumstances and applicable regulations?				
	Do the records include sufficient information for satisfactory evaluation of the assessment?				
	Are records held secured in confidence to the client and kept safely for a specified period?				

2009/2016 TNI Standard	Requirements (Assessment reports and certificates)	Yes	No	N/A	Remarks
V2M1: 8.2 V2M3: 6.10, 6.12	Are assessment works carried out covered by a retrievable assessment report or certificate?				
	Does the assessment report contain all the results of examinations and the determination of conformity made from these results as well as all sufficient information needed to understand and interpret them?				
	When subcontractors perform assessment works, are the results clearly identified?				

2009/2016 TNI Standard	Requirements (Assessment reports and certificates)	Yes	No	N/A	Remarks
	Are the reports/assessment certificates signed by authorized signatories?				
	If there are corrections / additions to report to assessment certificates, are the correction / additions recorded and justified according to relevant requirements?				

2009/2016 TNI Standard	Requirements (Subcontracting)	Yes	No	N/A	Remarks
V2M1:7.4 V2M2: 6.2	Does the accreditation body do all its assessments?				
	If the accreditation body subcontracts assessments, does it ensure and be able to demonstrate that its subcontractors are competent? Does the accreditation body inform the client of the subcontract work?				
	Does the accreditation body have documented proof of the client's acceptance of the subcontractor?				
	Does the accreditation body have records of the investigation of the competence of the subcontractors?				
	Does the accreditation body maintain a register of all subcontracting?				
	Does the accreditation body have access to qualified and experienced personnel to assess the results of subcontracted work?				

2009/2016 TNI Standard	Requirements (Complaints and appeals)	Yes	No	N/A	Remarks
V2M1:5.9, 7.6	Does the accreditation body have documented procedures for dealing with complaints?				
	Does the accreditation body have records of all complaints and appeals?				
	Does the accreditation body have documented procedures for consideration and resolution of appeals against results of its assessment?				

2009/2016 TNI Standard	Requirements (Cooperation)	Yes	No	N/A	Remarks
V2M1: 8.2.3	Does the accreditation body participate in an exchange of experience with other				

2009/2016 TNI Standard	Requirements (Cooperation)	Yes	No	N/A	Remarks
	assessment bodies and in the standardization process as appropriate?				

Additional Notes and Observations

Follow up Notes and Discussions on Previous Internal Assessment Findings

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#### **Attachment 6 – Assessor Competency Draft Questions**

Assessor Competency Draft 3 (BH)



Goal: Through interview, evaluate an assessor's knowledge and how well an assessor performs their job.
 Create a standard question list.

#### **Possible Standard Questions**

- Describe your environmental laboratory experience and knowledge (background).
- 2. I see you are approved for <insert specialty/technology>. Describe the training you were provided by the Accreditation Body for this specialty/technology.
  - a. Describe the approval process for assessing on your own.
  - b. How frequently are you observed by your supervisor?
- 3. How would you describe your method of completing analyst interviews and documentation review within the set on-site assessment timeframe?
- 4. You're assigned to review <insert method> at an on-site assessment. How do you <u>prepare</u> for the assessment?
  - a. Do you use a method checklist?
  - b. How much and what type of documentation do you review?
  - c. What specific questions would you ask the laboratory personnel for <insert method>?
- 5. Do you document anything during an analyst <u>interview</u>? If so, what kind of documentation does that include?
  - a. Do you use a method checklist?
  - b. How much and what type of documentation do you review?
  - c. What specific questions would you ask the laboratory personnel for <insert method>
- 6. During an assessment, how much time do you spend reviewing documentation ahead of time, reviewing documentation during the assessment (in the conference room) and interviewing analysts?
- 7. How would you handle an interview with an analyst who is nervous and struggling to understand the questions you are asking?
- 8. You review an initial demonstration of capability for ammonia by SM 4500-NH3 G and find the IDOC concentration level is not 1-4 times the LOQ. What questions do you ask the laboratory?
  - a. Do you ask the analyst if they know about this requirement? Do you check if the analyst has signed off on having read any non-method specific SOPs where this is required?
  - b. Do you ask the supervisor/quality assurance officer if they know about this requirement? Do you ask the supervisor/quality assurance officer how they review IDOCs and evaluate acceptability?
  - c. Do you look into other IDOCs to see if this finding is systemic?
- 9. What do you define as a finding during an on-site assessment?
- 10. Do you offer recommendations to improve processes during an assessment?
- 11. What do you do if a method requirement and the TNI Standard do not agree?
  - a. What if the method is less stringent?

- 12. What do you do if you and the laboratory disagree about a finding?
  - a. What do you do if you and another assessor disagree about a finding?
- 13. If you suspect that an analyst is performing their work in an unethical manner, how do you proceed?
- 14. How and when do you discuss findings with the laboratory during an on-site assessment?
- 15. What do you look for in a corrective action to determine if a finding has been corrected?
- 16. Do you review PT results?