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Considerations Regarding the Establishment of Accreditation Systems for Laboratories Testing for SARS-CoV-2 in Wastewater

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WHO IS TNI?

- A 501(c)3 non-profit organization.
- A voluntary consensus standards development organization accredited by the American National Standards Institute (ANSI).
- An organization that administers the National Environmental Laboratory Accreditation Program (NELAP).

National Environmental Laboratory Accreditation Program (NELAP)

- Purpose is to establish and implement a program for the accreditation of environmental laboratories conducting testing in the US.
- Program components:
  - The recognition of Accreditation Bodies (AB),
  - The adoption of acceptance limits for proficiency testing (PT), and
  - The adoption of consensus standards for use in the program.

https://nelac-institute.org/docs/comm/advocacy/White%20Papers/TNI's%20National%20Environmental%20Laboratory%20Accreditation%20Program.pdf

Laboratory Accreditation Standards

- Volume 1: Laboratory Requirements
  - Module 1: Proficiency Testing
  - **Module 2: Quality Systems General Requiremen**
  - Module 3: Asbestos Testing
  - Module 4: Chemical Testing
  - Module 5: Microbiological Testing
  - Module 6: Radiochemical Testing
  - Module 7: Toxicological Testing
- Volume 2: Accreditation Body Requirements
- Volume 3: Proficiency Testing Provider Requirements
- Volume 4: Proficiency Testing Oversight

LABORATORY REQUIREMENTS

- Module 2 contains the General Requirements that apply to all laboratories
  - Management Requirements
  - Technical Requirements
- Modules 3 though 7 are Technical Requirements for different types of labs
  - Method Selection, Validation and DOC
  - Instrument Calibration
  - Quality Control
  - Sample Handling

TNI's Quality Management System

- Developed over a 25-year period by a consensus body, the TNI Quality Systems committee.
- Committee has a balanced representation from all affected stakeholders: Accreditation Bodies, laboratories, data users, and other interests.
- Based on ISO/IEC 17025 with additional specificity to address specific issues associated with environmental testing.
- Focus is on generation of authentic data (*i.e., data of known and documented quality generated according to accepted professional practices of the industry).*

DOCUMENT COMPARISON

ISO/IEC 17025

- Generic Requirements
  - Testing Laboratories
  - Calibration Laboratories

TNI Standard

- 17025 Requirements

PLUS

- Specific Requirements for Environmental Laboratories

AND

- Data Integrity

EXAMPLE: INSTRUMENT CALIBRATION

ISO/IEC 17025

- Before being placed into service, equipment shall be calibrated to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use.

TNI Standard

- 6 pages of specific details related to initial calibration and calibration verification for Chemistry.
  - Removing calibration points
  - Evaluation of goodness
- Calibration for non-chemistry tests in those modules.
- Extensive requirements for support equipment

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SUMMARY

- TNI Standard contains all of ISO/IEC 17025 (2005)
- Laboratories in compliance with the TNI Standard will be in compliance with 17025
- Additional details clarify language to assist labs and avoid arguments between labs and lab assessors

IMPACT OF TNI STANDARD

- Used by 14 NELAP ABs to accredit over 1400 laboratories
- Used as basis for DoD and DOE programs
- Accepted by 14 other states
- Accepted by EPA Office of Water for drinking water certification
- Accepted by DMRQA as a substitute for their program

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Does Laboratory Impementing a Quality Management System Make a Difference?

2020 NEMC, August 2020

FINDINGS FROM 2020 EFFORT

- We need to rethink the definition of "data quality."
- Quality is much more than getting the right answer and being able to reconstruct the result.
- Quality includes confidence in the data as well as better laboratory operations.
- Laboratories accredited to the TNI standard have documented significant improvements.
  - Efficiency, additional capability, quicker reports, …
- Laboratories accredited to the TNI standard have more confidence in their data.
  - Traceability, training, sample tracking, documentation, better decisions…

2020 WHITE PAPER

There is no doubt that implementing a QMS based on the TNI standard makes a difference in the quality of the data and in laboratory performance.

- Accreditation is not just about a quantitative improvement in data quality but about generating data that can be relied on for use in decision making.

https://nelac-institute.org/docs/comm/advocacy/White%20Papers/WP-Value_101420.pdf

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OUR NEW GUIDING PRINCIPLE

Data you can trust.

- Implementing a QMS provides confidence in the data
  - The reported result is good estimate of the true concentration.
  - The reported result is of known and documented quality.
  - The laboratory complied with mandated method requirements.
  - The laboratory implemented a strong quality management system to ensure confidence in the result.
  - The laboratory met customer requirements.
- Implementing a QMS improves laboratory performance
  - Better trained analysts
  - Better systems

DATA YOU CAN TRUST

- Result can be reconstructed
  - Sufficient documentation for sample, calibration, QC results, and SOP in use to fully reconstruct the processes leading to the result.
- Traceable
  - Reference materials, reference standards, and reagents are all traceable.
- Competent analysts
  - Training records, PT results, DOC results all demonstrate competency of analyst.
- Sample handled correctly
  - Ability to trace sample from receipt to reported result
- Quality control results document data quality
- Reliable and transparent data through known laboratory activities

Should Laboratories be Accredited for SARS-COV-2?

- Only 20% run negative controls
- Only 38 % run positive controls
- Only 25% evaluate calibration curves
- LOD and LOQ concepts mostly not appropriately applied
- QC Results mostly not reported

Environmental Microbiology Minimum Information Guidelines: qPCR and dPCR Quality and Reporting for Environmental Microbiology
July 21, 2021
https://pubs.acs.org/doi/pdf/10.1021/acs.est.1c01767

BUT COVID IS NOT AN ENVIRONMENTAL CONTAMINANT

- No, but TNI already accredits over 850 wastewater laboratories in 48 states.
- No, but The Quality Systems module provides a framework for testing environmental media for non-traditional contaminants.
  - TNI Accreditation Bodies already accredit 30 laboratories for parasites and bacteria such as *Cryptosporidium*, *Giardia*, and *Legionella*.
- The scope of these laboratories could be easily expanded to include the quantitative Polymerase Chain Reaction (PCR) assay and SARS-CoV-2 as the analyte.

HOW MIGHT A SYSTEM BE ESTABLISHED?

- Add SARS-CoV-2 and the PCR assay to TNI's Laboratory Accreditation Management System
  - ✓ Done
- Create a method checklist for laboratory assessors to use.
  - ✓ Almost Done; ACIL led effort
- Develop implementation guidance for Accreditation Bodies and technical training for assessors on the PCR assay.
- Explore feasibility of proficiency testing, interlaboratory comparison studies, or other comparable actions to objectively verify the competency of the laboratories.
- Publicize the benefits of this program to the CDC, State agencies, and other trade associations such as ACIL, APHL, and WEF.
- Consider modifying the Microbiology module to incorporate technical requirements for PCR.

WW/COVID Checklist covers several steps in the testing process

1. Sample Checks
2. Standard Curve (RT-PCR)
3. Pretreatment
4. Concentration
5. Extraction of RNA
6. PCR, either RT-PCR or ddPCR
7. Results interpretation, data reporting

Collaborative Development of an Analytical Method Audit checklist, Patsy Root in DHS/NIST Workshop: Standards to Support an Enduring Capability in Wastewater Surveillance for Public Health – June 18, 2021

Checklist includes six parameters to consider for each step in the method

Quality Control Measure	Description	Frequency	Purpose	Control Limit	Corrective and Preventative Actions?
SAMPLE CHECKS					
Chain of Custody	Details to identify specific sample under analysis	Every sample	Sample traceability through entire testing procedure	**Documentation** describing at a minimum: Sample ID; Client ID; Time and Date; Custodian, Analysis requested	Do not initiate analysis without information required OR contact client
Temperature of sample and subsamples	Temperature is measured upon receipt of sample; on initiation of analysis of sample/sub-sample (if >4h post-receipt)	See column B	Determine if there are significant temperature changes post-storage or subsampling	Temperature between samples should be within 5 C of each other	If >5C, discard sample/subsample and re-sample OR confirm sample use as agreed with client OR note deviation on report
pH of sample and subsamples	pH is measured upon receipt of sample and during the subsampling process if subsampling applied	At subsampling	Determine if there are significant pH changes during subsampling	pH of subsamples within ±1 of original sample pH	If >pH1, note on report

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PCR TRAINING

a) Basic theoretical and operating principles and associated instrumentation and software.
b) Critical steps and processes of the technology that must be executed to ensure quality data, including critical quality control (QC) measures and QC criteria.
c) Major sources of error, and how to control them.
d) Inappropriate procedures.
e) Key information required to document completely the reported results.
f) Essential elements for assessing data generated.
g) Ways to detect improper practices.
h) Traceability of raw data to reported results.

EXPLORE CHANGINGTNI MODULE 4: MICROBIOLOGY

- The module is focused on traditional technologies like enzyme/substrate methods where concepts such as calibration curves, laboratory control samples, matrix spikes, and detection limits are not applicable.
- PCR is a quantitative technique where these concepts do apply.
- Module 4 is focused on technical issues like quality and sterility of materials used, constant and consistent test conditions, and positive and negative controls.
- The method checklist developed by ACIL could be used as an interim measure while the committee addresses any needed changes.

OPTIONS FOR ACCREDITATION

17025 (2017)

- Strong QMS foundation
- Implemented by NGABs
- Best suited for non-environmental laboratories and those not already accredited under NELAP.
- Incorporates Risk-Based approach

TNI Standard

- Strong QMS foundation
- Implemented by state agencies who may not have authority to add to their FOA
- Can also be used by NGABs
- Best suited for labs already accredited by a NELAP AB

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CONCLUSIONS

- Accreditation provides confidence that decisions are based on reliable, authentic data and assurance that the laboratory has been evaluated and has met accepted standards established by experts in the laboratory profession.
- Accreditation advances the field of laboratory science by promoting uniform accepted standards of practice and advocating rigorous adherence to these standards.
- The checklist developed by ACIL can be used by laboratory assessors to "promote high quality laboratory processes and procedures to assure data are fit for purpose."
- The TNI laboratory accreditation standard is one option for laboratories to consider. Accreditation to ISO/IEC 17025 is another acceptable option.
- More work needs to be done to fully implement this initiative.

NEXT STEPS

- Seek approval from the TNI Board of Directors to pursue this initiative.
- Task TNI's Advocacy Committee to begin work on guidance documents and develop outreach materials.
- Task TNI's Training Committee to find someone to develop a course.
- Task TNI's Proficiency Testing Executive Committee to look into the feasibility of PT samples.
- Task TNI's Microbiology Committee to look at potential changes o Module 4.

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THANK YOU!

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