

SUBGROUP 1

Proposed Modifications of the TNI Standard

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Workgroup Assertions:

TNI Standard Implementation

1. Resources and training in TNI implementation are available to address most concerns.
2. ELTAC recommendation for 3 years implementation provides the delays necessary to comply with TNI.

TNI Section	Modification/Delay	Rationale
Volume 1, Module 2		
Section 4.0 Management Requirements		
4.1.7.1 (d)	Exemption/Delay	Addtl Requirements for Laboratories (Mgmt): Poorly defined definition of 'documented training and/or experience in QA/QC procedures and the laboratory's quality system.' ELAP may wish to exempt small 1-2 person labs from this requirement or delay implementation until ELAP can offer better definition of expectation in a small lab.
4.1.7.2 (d)	ELAP authorization	Addtl Requirements for Laboratories (Mgmt): Where a technical director may have responsibility for oversight of multiple small, 1-2 person labs, ELAP can authorize exception to the clause based on the criteria listed in TNI.
4.1.7.2 e)	N/A	Addtl Requirements for Laboratories (Mgmt): notification of absence of technical manager requirement is less stringent than current ELAP requirements

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4.14	N/A	Internal Audits: Concern has been expressed regarding the resources needed to conduct internal audits or processes and analytical procedures annually. ISO language is not specific about frequency, only that 'The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities...' This issue can be addressed by spreading out and conducting audits over time rather than all at once (unless this is convenient to the agency because it outsources this activity).
4.14.5 c)	Exemption/Delay	Internal Audits: ELAP may wish to exempt CA from requiring an annual internal audit of every method or process, but rather request the lab define the audit schedule they propose to follow. Software updates and other factors besides changes in personnel make periodic internal audits pertinent.

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4.4	N/A	Review of Requests, Tenders and Contracts: compliance can be simple for public agencies. Example: A statement that the section covering Tenders and Contracts does not apply and the NPDES permit can be considered as the Request. Requires a simple statement regarding the process used to review the permit when it changes, or when the laboratory is requested to do a new test. The manual for small labs and the QA Manual template includes boiler plate language where the laboratory can simply fill in the blanks with the responsible party(ies).
4.5	N/A	Subcontracting of Environmental Tests: For a small wastewater lab this can be a simple statement that the section does not apply, or if a plant engineer or other supervisor not working in the lab arranges the subcontracting of analyses, then that person becomes the responsible party.
4.5 a)	N/A	Subcontracting of Environmental Tests: TNI does not require a separate person conduct data review, so in a one or two person lab this can be discussed as an activity rather than as requiring a separate person.
4.6	N/A	Purchasing Services and Supplies: When the laboratory is part of a larger organization and does not have complete control over this process it was recommended that the purchasing policy of the parent organization be incorporated by reference into the QA Manual.

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4.8	N/A	Complaints: The section deals with external rather than internal, possibly HR related, complaints. Laboratory must document the process used for dealing with complaints about the data produced by the laboratory coming from those outside the laboratory, ie. district engineers, regulators, other data users, etc. One process suggestion of a phone log and/or email log and follow-up action taken to resolve problem.
5.2.6.1	N/A	Technical Manager Qualifications: Existing State ELAP requirements are as rigorous, or more rigorous for individuals operating instrumentation, than TNI. TNI also has the exceptions in 5.2.6.2 (b) for small wastewater treatment plant labs and the qualifications of existing staff that address the concerns of those facilities.