SUGGESTED TNI MODIFICATIONS

Item #	TNI PROVISION			ELTAC RECOMMENDATION	ELTAC AGREEMENT	SAPC RECOMMENDATION	SAPC AGREEMENT	ELAP DETERMINATION
	Module	Section	Summary					
A	2	4.1.5 (k)	Relevance of Activities	Delete	No Vote [1]	Do Not Delete	Only one Agency commented [2]	Delete
B	2	5.6.4.1	Reference standards and reference materials	Delete sentence that precedes subsection (a)	7-9 in Favor	Agree to Delete sentence that precedes subsection (a)	Only one Agency commented [2]	Delete
C	5	1.7.3.7 (b) (ii) (a)	Autoclaves	Delete	No Vote [1]	Modification not discussed [3]	--	Delete
D	2	4.1.7.1 (d)	QA Manager training/experience	Delay until ELAP defines expectations	≥ 10 in Favor	Agree with ELTAC's recommendation to delay until ELAP can offer better definition of expectation	5 in Favor 1 Absent	Delay
E	2	4.3	Document Control	Delay for 3 years	≥ 10 in Favor	Agree with ELTAC's recommendation to delay with a phased implementation	5 in Favor 1 Absent	Delay
F	2	4.8	Complaints	Delay until ELAP can provide training and support documents	≥ 10 in Favor	Agree with ELTAC's recommendation to delay until ELAP can provide training and support documents	5 in Favor 1 Absent	Delay
G	2	4.11	Corrective action (documentation requirements)	Delay until ELAP provides training and support documents	≥ 10 in Favor	Agree with ELTACs recommendation to delay until ELAP provides training and support documents	5 in Favor 1 Absent	Delay
H	2	4.12	Preventive action (documentation requirements)	Delay until ELAP provides training and support documents	≥ 10 in Favor	Agree with ELTACs recommendation to delay until ELAP provides training and support documents	5 in Favor 1 Absent	Delay
I	2	4.13	Control of Records (documentation requirements)	Delay until ELAP provides training and support documents	≥ 10 in Favor	Agree with ELTACs recommendation to delay until ELAP provides training and support documents	5 in Favor 1 Absent	Delay
J	2	4.15	Management reviews (documentation requirements)	Delay until ELAP provides training and support documents	≥ 10 in Favor	Agree with ELTACs recommendation to delay until ELAP provides training and support documents	5 in Favor 1 Absent	Delay
K	All	Notes	Notes provide clarification of the text	Revise - boldly state notes are not enforceable	≥ 10 in Favor	Recommendation deferred [4]	--	Add clarifying language
L	1	4.2.4	LOQ Requirements	Remove any reference to LOQ and replace with something more specific to CA regulatory agency needs (for example DLR for DW). ELTAC will work with SAPC	7-9 in Favor	Follow LOQ requirements unless already specified by program or method	4 in Favor 2 Absent	Add clarifying language
M	1	4.3.5	LOQ Requirements	Remove any reference to LOQ and replace with something more specific to CA regulatory agency needs (for example DLR for DW). ELTAC will work with SAPC	7-9 in Favor	Follow LOQ requirements unless already specified by program or method	4 in Favor 2 Absent	Add clarifying language
N	1	4.3.7 (and sub-sections)	LOQ Requirements	Remove any reference to LOQ and replace with something more specific to CA regulatory agency needs (for example DLR for DW). ELTAC will work with SAPC	7-9 in Favor	Follow LOQ requirements unless already specified by program or method	4 in Favor 2 Absent	Add clarifying language
O	1	5.0	PT Frequency	Revise	No Vote [1]	Agree to limit to one PT sample per year.	Only one Agency commented [2]	Add clarifying language
P	1	5.2.1.1	PT Assessments	Revise - make Section 5.2.1.1 consistent with the requirement of one PT per year	≥ 10 in Favor	Recommendation deferred [4]	--	Add clarifying language
Q	2	2.0	Normative References	Defer to SAPC	7-9 in Favor	It would be easier to cite the references rather than to try to include all their text in the regulations.	Only one Agency commented [2]	Add clarifying language

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	Module	Section	Summary					
R	2	3.1	MDL Verification	Remove any reference to MDL as currently specified; work with SAPC to come up with solution that more adequately meets their needs	7-9 in Favor	Follow MDL requirements unless already specified by program or method	5 in Favor 1 Absent	Add clarifying language
S	2	4.1.2	Reference to "International Standard"	Revise	No Vote [1]	Agree that where it means ELAP it should say so	Only one Agency commented [2]	Add clarifying language
T	2	4.1.6	Staff Communication	Delete	No Vote [1]	Recommend ELAP provide training/clarity on how this provision will be audited against.	4 in Favor 2 Absent	Add clarifying language
U	2	4.1.7.1 (c)	QA Officer Impartiality	Modify or clarify	≥ 10 in Favor	Modify to say something like: "without influence from others within or outside the lab."	Only one Agency commented [2]	Add clarifying language
V	2	4.1.7.2 (e)	Requirements when Tech. Mgr. is absent > 15 days	Delete timeframe for notification, require an alternate when on leave; or delete and replace with current ELAP language	≥ 10 in Favor	Lab would develop procedure for when lab director leaves, which would include what the qualifications of the interim lab director needs to operate the lab accordingly.	4 in Favor 2 Absent	Add clarifying language
W	2	4.2.2.3	Reference to "International Standard"	Revise	No Vote [1]	Agree that where it means ELAP it should say so	Only one Agency commented [2]	Add clarifying language
X	2	4.2.4	Staff Communication	Delete	No Vote [1]	Recommend ELAP provide training/clarity on how this provision will be audited against.	4 in Favor 2 Absent	Add clarifying language
Y	2	4.2.6	Reference to "International Standard"	Revise	No Vote [1]	Agree that where it means ELAP it should say so	Only one Agency commented [2]	Add clarifying language
Z	2	4.4	Review of Requests, Tenders and Contracts	Remove	No Vote [1]	Recommendation deferred [4]	--	Add clarifying language
AA	2	4.5	Subcontracting	Modify	≥ 10 in Favor	Replace "this International Standard" with a reference to ELAP.	Only one Agency commented [2]	Add clarifying language
AB	2	4.5.1	Reference to "International Standard"	Revise	No Vote [1]	Agree that where it means ELAP it should say so	Only one Agency commented [2]	Add clarifying language
AC	2	4.5.4	Reference to "International Standard"	Revise	No Vote [1]	Agree that where it means ELAP it should say so	Only one Agency commented [2]	Add clarifying language
AD	2	4.11.5	Reference to "International Standard"	Revise	No Vote [1]	Agree that where it means ELAP it should say so	Only one Agency commented [2]	Add clarifying language
AE	2	4.14.1	Reference to "International Standard"	Revise	No Vote [1]	Agree that where it means ELAP it should say so	Only one Agency commented [2]	Add clarifying language
AF	2	4.14.5 (c)	Internal Audits	Modify - require internal audits during years ELAP is not performing assessment	7-9 in Favor	Keep audit frequency of every year, but modify provision to allow the laboratory to determine what will be audited in any given year.	5 in Favor 1 Absent	Add clarifying language
AG	2	5.2.6 (all)	Technical Manager Qualifications	Modify	7-9 in Favor	Add a sentence saying if the technical manager does not meet qualifications in TNI Standard, the lab should describe how they will ensure this does not adversely affect the quality of the work.	Only one Agency commented [2]	Add clarifying language
AH	2	5.2.6.1 (f)	Technical Manager Qualifications (for labs analyzing radon in air)	Remove	No Vote [1]	Not Applicable	Only one Agency commented [2]	Add clarifying language
AI	2	5.4	Use of Non-Standard Methods	Modify	7-9 in Favor	Add a sentence saying that the State regulatory agency can approve methods.	Only one Agency commented [2]	Add clarifying language

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Item #	TNI PROVISION			ELTAC RECOMMENDATION	ELTAC AGREEMENT	SAPC RECOMMENDATION	SAPC AGREEMENT	ELAP DETERMINATION
	Module	Section	Summary					
AJ	2	5.4	Requirements for calibration labs	Revise	No Vote [1]	Be careful not to delete references to calibration of equipment such as balances and pipets to traceable standards.	Only one Agency commented [2]	Add clarifying language
AK	2	5.4.1	Use of Non-Standard Methods	Modify	No Vote [1]	Add a sentence saying that the State regulatory agency can approve methods.	Only one Agency commented [2]	Add clarifying language
AL	2	5.4.3	Lab Developed Methods	Modify - add to regs labs shall be able to generate data that is reproducible (by interlaboratory comparison) by other labs and process has to go to SAPC for method approval (see 1-page ELTAC recommendation)	≥ 10 in Favor	Add to regulations: Comparability of non-standard methods should be demonstrated by interlaboratory study or analysis of split samples by an independent laboratory. ELTAC propose comparability language for non-chemical methods.	Only one Agency commented [2]	Add clarifying language
AM	2	5.4.4	Lab Developed Methods	Modify - add to regs labs shall be able to generate data that is reproducible (by interlaboratory comparison) by other labs and process has to go to SAPC for method approval (see 1-page ELTAC recommendation)	≥ 10 in Favor	Add to regulations: Comparability of non-standard methods should be demonstrated by interlaboratory study or analysis of split samples by an independent laboratory. ELTAC propose comparability language for non-chemical methods.	Only one Agency commented [2]	Add clarifying language
AN	2	5.4.5	Lab Developed Methods	Modify - add to regs labs shall be able to generate data that is reproducible (by interlaboratory comparison) by other labs and process has to go to SAPC for method approval (see 1-page ELTAC recommendation)	≥ 10 in Favor	Add to regulations: Comparability of non-standard methods should be demonstrated by interlaboratory study or analysis of split samples by an independent laboratory. ELTAC propose comparability language for non-chemical methods.	Only one Agency commented [2]	Add clarifying language
AO	2	5.4.6.1	Requirements for calibration labs	Revise	No Vote [1]	Be careful not to delete references to calibration of equipment such as balances and pipets to traceable standards.	Only one Agency commented [2]	Add clarifying language
AP	2	5.5	Requirements for calibration labs	Revise	No Vote [1]	Be careful not to delete references to calibration of equipment such as balances and pipets to traceable standards.	Only one Agency commented [2]	Add clarifying language
AQ	2	5.5.1	Reference to "International Standard"	Revise	No Vote [1]	Agree that where it means ELAP it should say so	Only one Agency commented [2]	Add clarifying language
AR	2	5.6.2.1.1	Requirements for calibration labs	Revise	No Vote [1]	Be careful not to delete references to calibration of equipment such as balances and pipets to traceable standards.	Only one Agency commented [2]	Add clarifying language
AS	2	5.6.2.2.2	Requirements for calibration labs	Revise	No Vote [1]	Be careful not to delete references to calibration of equipment such as balances and pipets to traceable standards.	Only one Agency commented [2]	Add clarifying language
AT	2	5.8	Handling Samples	Remove and simplify and make more specific.	No Vote [1]	Do not delete; consider adding the DoD clarifications and additions.	Only one Agency commented [2]	Add clarifying language

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	Module	Section	Summary					
AU	2	5.9	Requirements for calibration labs	Revise	No Vote [1]	Be careful not to delete references to calibration of equipment such as balances and pipets to traceable standards.	Only one Agency commented [2]	Add clarifying language
AV	2	5.9.3	LOQ Requirements	Remove any reference to LOQ and replace with something more specific to CA regulatory agency needs (for example DLR for DW). ELTAC will work with SAPC	7-9 in Favor	Follow LOQ requirements unless already specified by program or method	4 in Favor 2 Absent	Add clarifying language
AW	2	5.10	Requirements for calibration labs	Revise	No Vote [1]	Be careful not to delete references to calibration of equipment such as balances and pipets to traceable standards.	Only one Agency commented [2]	Add clarifying language
AX	2	5.10.7	Reference to "International Standard"	Revise	No Vote [1]	Agree that where it means ELAP it should say so	Only one Agency commented [2]	Add clarifying language
AY	4	1.5.2.1	LOQ Requirements	Remove any reference to LOQ and replace with something more specific to CA regulatory agency needs (for example DLR for DW). ELTAC will work with SAPC	7-9 in Favor	Follow LOQ requirements unless already specified by program or method	4 in Favor 2 Absent	Add clarifying language
AZ	4	1.5.2.1.2	MDL Verification	Remove any reference to MDL as currently specified; work with SAPC to come up with solution that more adequately meets their needs	7-9 in Favor	Follow MDL requirements unless already specified by program or method	5 in Favor 1 Absent	Add clarifying language
BA	4	1.5.2.2	LOQ Requirements	Remove any reference to LOQ and replace with something more specific to CA regulatory agency needs (for example DLR for DW). ELTAC will work with SAPC	7-9 in Favor	Follow LOQ requirements unless already specified by program or method	4 in Favor 2 Absent	Add clarifying language
BB	4	1.5.2.2.2	MDL Verification	Remove any reference to MDL as currently specified; work with SAPC to come up with solution that more adequately meets their needs	7-9 in Favor	Follow MDL requirements unless already specified by program or method	5 in Favor 1 Absent	Add clarifying language
BC	4	1.7.1	Calibration Requirements (for Chemistry Methods)	Delete last sentence of first paragraph 1.7.1	7-9 in Favor	Accept ELTAC's recommendation	5 in Favor 1 Absent	Add clarifying language
BD	4	1.7.1.1 (f)	Calibration Standards	Modify - only when the method does not specify then the section applies	≥ 10 in Favor	Recommendation deferred [4]	--	Add clarifying language
BE	4	1.7.1.2	MDL Verification	Remove any reference to MDL as currently specified; work with SAPC to come up with solution that more adequately meets their needs	7-9 in Favor	Follow MDL requirements unless already specified by program or method	5 in Favor 1 Absent	Add clarifying language
BF	4	1.7.2.4	Data Reduction	Modify - strike "such as use of linear regression"	≥ 10 in Favor	Agree to delete	Only one Agency commented [2]	Add clarifying language

Footnotes:

[1] Modification not voted on by ELTAC because ELAP had already made a determination
[2] SAPC was asked to review modification independently and respond with comments
[3] Modification not discussed by SAPC because ELAP had already made a determination
[4] SAPC requested more time to discuss intent of modification

ELTAC - Environmental Laboratory Technical Advisory Committee
SAPC - State Agency Partner Committee

SUGGESTED TNI MODIFICATIONS ELAP INTENDS TO REJECT

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	Module	Section	Summary							
A	2	3.1	Definition of MDL	Remove or Modify - to make more consistent with regulations in CA	MDL has specific regulatory meaning in California for compliance with the Clean Water Act. None of this is present in these sections.	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
B	2	3.1	Definition of Verification	Remove or Modify - to make more consistent with regulations in CA	The definition of verification is overly broad and vague. Further it does not match how it is used in different parts of the document.	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
C	2	4.1.4	Conflicts of Interest	Delete	No definition of what conflict of interest is. Conflict of interest is covered under mandatory ethics training	7-9 in Favor	Do not delete	Identifying conflict of interests is part of a robust QA Program	5 in Favor 1 Abstained	Reject
D	2	4.1.5 (b)	Undue Influence	Delete; or modify by removing "have arrangements to"	This is overly broad and general, it is standardless, and unenforceable and produces no benefits for the Regulatory Partners, ELAP, or the laboratories. What are arrangements?	7-9 in Favor	Do not delete	Ensuring management and personnel are free from undue influence is part of a robust QA program	5 in Favor 1 Abstained	Reject
E	2	4.1.5 (c)	Customer Information	Delete	Outside regulatory authority of ELAP. ELAP is not a consumer protection agency. This provision does not assess a laboratories ability to analyze samples.	7-9 in Favor	Do not delete	The State must have confidence that a lab has a policy and procedures for protecting confidential information. Even public labs may have confidential information. If not, then they can simply say as their policy that no information is confidential. For commercial labs it is important that State agencies have confidence information will not be shared with other customers.	Only One Agency Commented [2]	Reject
F	2	4.1.5 (d)	Impartiality	Delete	This is overly broad and general, it is standardless, and unenforceable and produces no benefits for the Regulatory Partners, ELAP, or the laboratories.	No Vote [3]	Modification not discussed [4]	--	--	Reject
G	2	4.1.5 (g)	Supervision of Staff	Delete	The term “adequate” is undefined, vague, ambiguous, and standardless.	No Vote [3]	Do not delete	Adequate in (g) relates, in part, to what is in (f), and for the technical manager what is in 4.1.7.2. It is also something that can be cited by ELAP inspectors if a staff person or trainee does something that is incorrect.	Only One Agency Commented [2]	Reject
H	2	4.1.5 (i)	Direct Access to Management	Delete	The majority of accredited laboratories are not stand–alone facilities but are part of a larger organization where there is a legally defined chain of command and laboratory staff cannot have direct access to the highest levels of management.	No Vote [3]	Do not delete	The Quality Manager should have direct access to whomever can make decisions for the lab in sections such as 4.15.1 and 5.2.2. Commonly this will be the lab manager.	Only One Agency Commented [2]	Reject
I	2	4.1.5 (j)	Management Deputies	Delete	ELAP will cite labs for not having deputies; not applicable to some labs	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
J	2	4.1.7.1 (b)	QA Officer Functions	Delete	Section 4.1.7.1 b contradicts the introductory sentence (where staffing is limited, the technical manager and the quality manager may be the same person). If the QA manager is independent he or she cannot also be the Technical Manager.	No Vote [3]	Do not delete	Part of robust QA/QC program	Only One Agency Commented [2]	Reject

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	Module	Section	Summary							
K	2	4.1.7.2 (d)	Shared Technical Management	Delete	Expense to muni labs. If laboratories can benefit from shared management, why should they be precluded from doing so?	7-9 in Favor	Do not delete	4.1.7.2 (d) already allows a technical manager to oversee more than one lab. Recommend adding that if a lab wants authorization to have a technical manager oversee more than one lab, then the lab shall describe how the technical manager functions will be addressed at each location.	Only One Agency Commented [2]	Reject
L	2	4.2.2	QA Manual Objectives	Delete or Revise	Simply requiring objectives to be written down in a document a set of general objectives serves no purpose. These objectives need to be tied to measures of data quality that can be quantified and assessed.	No Vote [3]	Do not delete	Once QA/QC requirements and objectives are initially documented, laboratories don't typically alter them (unless extenuating circumstances).	5 in Favor 1 Absent	Reject
M	2	4.2.3	Management Improvement	Delete	What is the metric of compliance? How effective management is has no bearing on data quality or legal defensibility. ELAP's job is not assess management but laboratory performance.	No Vote [3]	Do not delete	The commenter is wrong about ELAP's job and appears to lack an understanding that how a lab is managed can affect its ability to perform consistently.	Only One Agency Commented [2]	Reject
N	2	4.2.8.1	Data Integrity System	Delete	This entire section is full of undefined terms with no metric of compliance. How does this measure a laboratory's capabilities to produce data of sufficient quality that the Regulatory Partners can use it for decision making or admissibility to court?	No Vote [3]	Do not delete	Part of robust QA/QC program	4 in Favor 2 Absent	Reject
O	2	4.6	Purchasing Procedures	Delete	Methods already have policies to ensure quality of supplies. There are no "specified requirements" specified. Does nothing to improve data quality or legal defensibility and is busy–work. Very labor intensive.	7-9 in Favor	Do not delete	ELTAC ignores the phrase in 4.6.1 that limits its applicability to those "that affect the quality of tests." This section should not be deleted unless ELAP can confirm that ALL methods that may be covered by ELAP contain adequate information about everything that could affect the quality of the results. Further, this is not only about the quality of supplies. It is also about a lab having documentation so it can perform a root cause analysis if a QC parameter is out of control	Only One Agency Commented [2]	Reject
P	2	4.7.1	Client Service	Remove	Does nothing to improve data quality or legal defensibility and is busy–work. Provides no benefit to laboratories, Regulatory Partners, or ELAP.	No Vote [3]	Do not delete. Recommend ELAP look at the DoD examples of situations for which immediate clarification or feedback from the customer shall be sought.	It is critical that labs perform the correct work for the immediate customer who submitted the samples, and the ultimate customer the regulatory agency whose requirements the customer needs to meet.	Only One Agency Commented [2]	Reject
Q	2	4.7.2	Client Service	Remove	Does nothing to improve data quality or legal defensibility and is busy–work. Provides no benefit to laboratories, Regulatory Partners, or ELAP.	No Vote [3]	Do not delete. Recommend ELAP look at the DoD examples of situations for which immediate clarification or feedback from the customer shall be sought.	A critical aspect of corrective action and continuous improvement is feedback from customers.	Only One Agency Commented [2]	Reject

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	Module	Section	Summary							
R	2	4.9.1	Nonconforming Work	Delete or Revise	The focus should not be on customer needs but compliance with ELAP Technical Standards and the laboratory's Quality Assurance Manual. Quality control failures are better focus for efforts like this.	No Vote [3]	Do not delete	Part of robust QA/QC program	4 in Favor 2 Absent	Reject
S	2	4.10	Management System Improvement	Delete or Revise	This is overly broad and general, it is standardless, and unenforceable and produces no benefits for the Regulatory Partners, ELAP, or the laboratories. How is "effectiveness" of management measured?	No Vote [3]	Modification not discussed [4]	--	--	Reject
T	2	4.16	Data Integrity Investigations	Delete	This entire section is full of undefined terms with no metric of compliance. How does this measure a laboratory's capabilities to produce data of sufficient quality that the Regulatory Partners can use it for decision making or admissibility to court?	No Vote [3]	Do not delete	Part of robust QA/QC program	4 in Favor 2 Absent	Reject
U	2	5.1.1	Calibration and Test Items	Delete or Revise	Eliminate dichotomy	7-9 in Favor	Modification not discussed [4]	--	--	Reject
V	2	5.2.1	Staff Competence	Remove	The term "appropriate" is used but it is not defined. What is an appropriate level of supervision? What is an appropriate level of education, training, or experience? How does a laboratory demonstrate compliance and how does ELAP staff assess compliance.	No Vote [3]	Modification not discussed [4]	--	--	Reject
W	2	5.2.2	Personnel Training Requirements	Remove	This is vague, ambiguous, standardless and does not assess laboratory capabilities. How is the effectiveness of training assessed? How a laboratory trains its staff is outside of ELAP's purview.	No Vote [3]	Modification not discussed [4]	--	--	Reject
X	2	5.2.3	Employment	Remove	This is vague, ambiguous, standardless and does not assess laboratory capabilities. This provision seems pointless. It is also outside the purview of ELAP's authority. A laboratory's employment practices are part of ELAP's job to assess.	No Vote [3]	Do not delete. The DoD clarification should also be considered as an addition.	This sets a standard for the lab, and is citable by an ELAP inspector if problems are found with the employee's competency.	Only One Agency Commented [2]	Reject
Y	2	5.2.5	Authorized Personnel	Remove	There are no metrics for compliance. How is a laboratory to demonstrate compliance and how is an ELAP assessor to assess a laboratories authorization procedures? A better approach is to require that every individual performing a specific analytical method complete a Demonstration of Capability with specific and detailed requirements.	No Vote [3]	Do not delete	This links with 4.1.	Only One Agency Commented [2]	Reject

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	Module	Section	Summary							
Z	2	5.2.7	Data Integrity Training	Remove or Revise	These requirements need specific details about what sorts of actions cannot be ethically used. It would be best to provide definitions and examples for "Time Travel", "Dry–Labbing", and "Curve Shaving." This is an example of 'standardless requirement.'	No Vote [3]	Do not delete	Part of robust QA/QC program	4 in Favor 2 Absent	Reject
AA	2	5.3	Laboratory Facilities	Remove or Modify	Language lacks any specific standards that are applicable. How does a laboratory demonstrate or document that it is complying with this provision? How does an ELAP assessors assess this.	No Vote [3]	Do not delete. Recommend reviewing DoD's clarifications for addition to this section.	This is an important part of ensuring consistent quality. If a lab finds low voltage in the middle of the day causing samples to fail QA/QC, then what happens when they get VOC samples which they cannot re-run? Do they time after time report results with a flag to indicate results out of control? This is not very encouraging for confidence in the lab's ability to produce consistent results.	Only One Agency Commented [2]	Reject
AB	2	5.4.2	Selection of Methods	Remove	Laboratories have never been allowed to use methods other than those specified by the USEPA or California Regulatory Partners. Section makes no mention of a list of methods approved by ELAP, or any accreditation body.	No Vote [3]	Do not delete	This links with other section where a lab can be cited if they use an incorrect method or don't contact the customer if which method to use is unclear.	Only One Agency Commented [2]	Reject
AC	2	5.5.1	Instrument Calibration	Remove	This is redundant as methods that require calibration already have provisions requiring this.	No Vote [3]	Do not delete	This provides citable requirements for ELAP inspectors. If also puts the lab on notice that they think about these things.	Only One Agency Commented [2]	Reject
AD	2	5.5.1	Calibration and Test Items	Delete or Revise	Eliminate dichotomy	7-9 in Favor	Modification not discussed [4]	--	--	Reject
AE	2	5.5.2	Instrument Calibration	Remove	This is redundant as methods that require calibration already have provisions requiring this.	No Vote [3]	Do not delete	This provides citable requirements for ELAP inspectors. If also puts the lab on notice that they think about these things.	Only One Agency Commented [2]	Reject
AF	2	5.5.3	Instrument Calibration	Remove	Redundant and already described in a different section of the TNI, Module 2 4.2.8.4 (Quality Assurance Manual), 4.2.8.5 (Standard Operating Procedures), and 5.2 Personnel.	No Vote [3]	Do not delete	This provides citable requirements for ELAP inspectors. If also puts the lab on notice that they think about these things.	Only One Agency Commented [2]	Reject
AG	2	5.6.1	Measurement Traceability	Remove	This seems completely redundant with 5.5 and with the requirements in the Technical Standard. It may be that this has something to do with Calibration Items but it is unclear.	No Vote [3]	Modification not discussed [4]	--	--	Reject
AH	2	5.6.3.4	Chemical Transport	Delete	Already in the method	7-9 in Favor	Do not delete	Necessary for laboratories operating mobile laboratories	5 in Favor 1 Absent	Reject
AI	2	5.6.4.2	Documentation and Labeling of Standards, Reagents, and Reference Materials	Delete sentence that precedes subsection (a)	Too broad	7-9 in Favor	Do not delete. Take a look at the DoD clarifications	In the absence of the preamble, each chemist could do things differently - a potential threat to data quality.	Only One Agency Commented [2]	Reject
AJ	2	5.6.4.2 (f)	Expiration of Standards	Delete "if reliability is verified"	Standards should not be used after expiration date	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
AK	2	5.7	Sample Collection	Remove	Outside purview of ELAP	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject

SUGGESTED TNI MODIFICATIONS ELAP INTENDS TO REJECT

Item #	TNI PROVISION			ELTAC RECOMMENDATION	ELTAC RATIONALE	ELTAC AGREEMENT	SAPC RECOMMENDATION	SAPC RATIONALE	SAPC AGREEMENT	ELAP DETERMINATION
	Module	Section	Summary							
AL	2	5.8	Calibration and Test Items	Delete or Revise	Eliminate dichotomy	7-9 in Favor	Modification not discussed [4]	--	--	Reject
AM	2	5.8.9 (c)	Waste Disposal	Delete	Outside regulatory authority of ELAP	7-9 in Favor	Do not delete	Having procedures for waste disposal is part of a robust QA/QC program	5 in Favor 1 Absent	Reject
AN	2	5.9.1	Data Monitoring	Remove	Control charts are not needed to produce accurate or precise results. They provide no benefits to the Regulatory Partners, to ELAP, or the laboratories. Further not all procedures are amendable to control charting, the microbiological test for example. This is a classic case of busy work.	No Vote [3]	Do not delete	Part of robust QA/QC program	4 in Favor 2 Absent	Reject
AO	2	5.9.2	Quality Control Data	Remove	Without some sort of requirement for what the criteria are, this provision provides no benefit to the Regulatory Partners, ELAP, or to laboratories. This requires significant amounts of work to produce results that no one will examine or use.	No Vote [3]	Do not delete	This describes taking planning how to address results outside pre-defined criteria, and the need to take the corrective action.	Only One Agency Commented [2]	Reject
AP	2	5.9.3 (including all sub-sections)	Quality Control Procedures	Remove	What criteria are used to assess which principles apply to which test and which laboratory? There are no acceptance or rejection criteria in this provision nor in the corresponding Modules. This will consume considerable amounts of time and labor without improving data quality or legal defensibility. This is busy work.	No Vote [3]	Do not delete	This provides a requirement that the lab have written protocols to monitor specific quality controls. This is not necessarily in the methods.	Only One Agency Commented [2]	Reject
AQ	2	5.10	Calibration and Test Items	Delete or Revise	Eliminate dichotomy	7-9 in Favor	Modification not discussed [4]	--	--	Reject
AR	2	5.10	Reporting the Results	Remove	Outside purview of ELAP	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
AS	4	1.5.2.1	MDL	Remove or Modify - to make more consistent with regulations in CA	May lead labs to use unapproved practices. Allows for possible reductions in data quality	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
AT	4	1.5.2.1.1	MDL	Remove or Modify - to make more consistent with regulations in CA	May lead labs to use unapproved practices. Allows for possible reductions in data quality	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
AU	4	1.5.2.1.1 (Notes)	MDL Procedures	Modify to say "Follow EPA's MDL procedure specified at 40 CFR Part 136 Appendix B." (submitted by Group 2)	May lead labs to use unapproved practices. Allows for possible reductions in data quality	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
AV	4	1.5.2.1.2	MDL	Remove or Modify - to make more consistent with regulations in CA	May lead labs to use unapproved practices. Allows for possible reductions in data quality	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
AW	4	1.5.2.1.2	Ongoing verification of MDL	Remove or Modify - to make more consistent with regulations in CA	May lead labs to use unapproved practices. Allows for possible reductions in data quality	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
AX	4	1.5.2.1.3	MDL	Remove or Modify - to make more consistent with regulations in CA	May lead labs to use unapproved practices. Allows for possible reductions in data quality	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
AY	4	1.5.2.2.1	Initial verification of LOQ	Modify	SAPC will identify specific requirements	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
AZ	4	1.5.2.2.2	Ongoing verification of LOQ	Modify	SAPC will identify specific requirements	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject

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	Module	Section	Summary							
BA	4	1.5.2.3	Verification of MDL/LOQ	Modify	SAPC will identify specific requirements	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BB	4	1.7.1.1	Initial Calibration	Modify - add specific acceptance criteria	Redundant, methods already have provisions. No additional value; stocking stuffer	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BC	4	1.7.1.1 (n)	Initial calibration verification	Modify - add specific acceptance criteria	Redundant, methods already have provisions. No additional value; stocking stuffer	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BD	4	1.7.1.2	Continuing calibration verification	Modify - add specific acceptance criteria	Redundant, methods already have provisions. No additional value; stocking stuffer	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BE	4	1.7.2	Sample Specific Controls	Modify - add specific acceptance criteria (program by program)	Addressed in methods; TNI text is simply adding add'l verbiage and doesn't provide value	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BF	4	1.7.2.3.1	Matrix Spike/Matrix Spike Duplicates (for Chemistry Methods)	Modify - add specific acceptance criteria (program by program)	Addressed in methods; TNI text is simply adding add'l verbiage and doesn't provide value	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BG	4	1.7.2.3.2	Matrix Duplicates (for Chemistry Methods)	Modify - add specific acceptance criteria (program by program)	Addressed in methods; TNI text is simply adding add'l verbiage and doesn't provide value	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BH	4	1.7.2.3.3	Surrogate Spikes	Modify - add specific acceptance criteria (program by program)	Addressed in methods; TNI text is simply adding add'l verbiage and doesn't provide value	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BI	4	1.7.2.3.3	Surrogates (for Chemistry Methods)	Delete	Method already specifies when surrogates are appropriate	7-9 in Favor	Do not delete	Required for reference laboratories	5 in Favor 1 Absent	Reject
BJ	4	1.7.3	Data Acceptance/Rejection Criteria	Modify - add specific acceptance criteria (program by program)	Addressed in methods; TNI text is simply adding add'l verbiage and doesn't provide value	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BK	4	1.7.3.1	Negative Controls	Modify - add specific acceptance criteria (program by program)	Addressed in methods; TNI text is simply adding add'l verbiage and doesn't provide value	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BL	4	1.7.3.2 (a)	Positive Controls	Modify - add specific acceptance criteria (program by program)	Addressed in methods; TNI text is simply adding add'l verbiage and doesn't provide value	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BM	4	1.7.3.2 (b)	Marginal Exceedance for LCS	Delete	Provision weakens the QC of the methods. Any failure should require investigation/corrective action	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BN	5	1.7.3.7 (a)	Laboratory Facilities (for Microbiology Methods)	Delete	This provision is full of undefined terms, vague, ambiguous, and standardless requirements, with not metrics of compliance.	No Vote [3]	Do not delete	If problems occur, you need to do corrective action. If problems occur and you didn't, then you can be cited for non-compliance.	Only One Agency Commented [2]	Reject
BO	5	1.7.3.7 (b)(i)	Temperature Measuring Devices (for Microbiology Methods)	Delete	This is entirely redundant with requirements found in ELAP's Technical Standard i.e. the individual methods but without any specifications.	No Vote [3]	Do not delete	The SWRCB identified TNI as a starting point for requirements in addition to the technical requirements of each method. So, the Technical Standards in TNI also apply (note that the TNI language in some cases defers to the methods, and in other cases imposes additional requirements on the labs.	Only One Agency Commented [2]	Reject
BP	5	1.7.3.7 (b) (iii)	Volumetric Equipment	Delete	It is a tremendous amount of work to check every volumetric piece of equipment and it provides no benefits to the Regulatory Partners, ELAP, or the laboratory.	No Vote [3]	Do not delete	Would anyone trust a lab that says verifying equipment used for measuring volume is unnecessary and provides no benefit? Does the commenter believe measurement equipment should not be verified?	Only One Agency Commented [2]	Reject

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	Module	Section	Summary							
BQ	5	1.7.5.1	Sample Handling – Thermal Preservation	Delete	Addressed in methods; add'l work without benefits	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject
BR	5	1.7.5.2	Sample Handling - Dechlorination	Delete	Addressed in methods; add'l work without benefits	≤ 6 in Favor	Modification not discussed [1]	--	--	Reject

Footnotes:

[1] Modification not discussed by SAPC because ELTAC was in low agreement

[2] SAPC was asked to review modification independently and respond with comments

[3] Modification not voted on by ELTAC because ELAP had already made a determination

[4] Modification not discussed by SAPC because ELAP had already made a determination

ELTAC - Environmental Laboratory Technical Advisory Committee

SAPC - State Agency Partner Committee