ELAP ELTAC Group 2 'TNI-lite" Feedback to ELAP

Item #	Section	Sub - Section	Name	Page # of the Module (T=48)	Yes	No	Maybe	NA	Modification Requested				Modification languange	Group 2 vote during conference call (10/20/16)	Notes:
									Delete	Modify	Delay	Needs Discussion at ELTAC			
	1.0		Introduction, Scope and Applicability	1	-										
		1.1	Introduction	1	x										
		1.2	Scope	1	x										
	2.0		Normative Reference	2	x										
	3.0		Terms and Definitions	2	x										
		3.1	Additional Terms and Definitions	2 to 7											
		3.2	Sources	7	x										
		3.3	Exclusion and Exceptions	7				x							
	4.0		Management Requirements	8	-										
		4.1	Organization	8	-										
		4.1.1		8	x										
		4.1.2		8	x										
		4.1.3		8	x										
		4.1.4		8	x				X					5 out of 6 agree	
		Note 1		8	x										
		Note 2		8	x										
		4.1.5	The Laboratory Shall	8	x										
		a)		8	x										
		b)		8	x										

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		c)		8				x		x			Revise to: "Commercial laboratories shall: have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;"	5 out of 6 agree	
		d)		8	x										
		e)		8	x										
		f)		9	x										
		g)		9	x					x			Strike "provide adequate spervision of" and replace with "assure that"	5 out of 6 agree	
		h)		9	x									5 out of 6 agree	
		i)		9			x			X			Add: "Each lab will need to determine when their size is sufficient to require a seperate Quality Manager."	5 out of 6 agree	
		j)		9	x									5 out of 6 agree	
		Note												5 out of 6 agree	
		k)		9	x									5 out of 6 agree	
		4.1.6	To Management shall….	9	x									5 out of 6 agree	
		4.1.7	Additional Requirements for Lab….	9										5 out of 6 agree	

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		4.1.7.1		9						X			Add: "Each lab will need to determine when their size is sufficient to require a seperate Quality Manager."	5 out of 6 agree	
		a)		9	x									5 out of 6 agree	
		b)		9	x									5 out of 6 agree	
		c)		9	x									5 out of 6 agree	
		d)		9	x									5 out of 6 agree	
		e)		9	x									5 out of 6 agree	
		f)		9	x					x			Add "one person laboratories can perform internal audits every other year, alternating with their ELAP audit"	5 out of 6 agree	
		g)		9	x					x			add "it is assumed that a one person laboratory wil notify themselves."	5 out of 6 agree	
		h)		9	x										
		4.1.7.2	Technical Manager	9											
		a)		9	x										
		b)		10	x										
		i)		10	x										
		ii)		10	x										

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		d)		10		x				X			Modify to apply to commercial labs	5 out of 6 agree	
		i)		10		x				X					
		ii)		10		x				X			See 4.1.7.2 d) above	5 out of 6 agree	
		iii)		10		x				X					
		e)		10						X			Remove arbitray temporal timelines and require the assignement of alternates when the Technical Managers on leave.	5 out of 6 agree	
		f)		10									See comment for Section 5.2.6.1 below		
		4.2	Management	10											
		4.2.1		10	x										
		4.2.2		10	x										
		a)		10	x										
		b)		10	x										
		c)		10	x										
		d)		10	x										
		e)		10			x								
		e		11	x										
		4.2.3		11											
		4.2.4		11											
		4.2.5		11	x										
		4.2.6		11	x										
		4.2.7		11											
		4.2.8	Additional MS Requirements	11											

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									Delete	Modify	Delay	Needs Discussion at ELTAC			
		4.2.8.1		11	x										
		a)		11	x										
		b)		11	x										
		4.2.8.2		11	x										
		4.2.8.3	The QAM shall obtain	11 to 12											
		a-i		12											
		4.2.8.4	Shall contain or reference	12											
		a-r		12 to 13	x										
		4.2.8.5	SOPs	13	x										
		4.3	Document Control	14 to 15							X		Request assistance from ELAP and a 3 year implementation	5 out of 6 agree	
		4.4	Review of Requests, Tenders, and Contracts	15		x				X			Revise to indicatae applies to commercial laboratories	5 out of 6 agree	

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									Delete	Modify	Delay	Needs Discussion at ELTAC			
		4.5	Subcontracting of Environmental tests	16		x				X			Revise to: 1) remove requirement to comply with the International Standard and replace with complying with CA standard or higher, and 2) delete Section 4.5.2	5 out of 6 agree	
		4.6	Purchasing Services and Supplies	16		x			X					5 out of 6 agree	Busy Work that is already addressed in the methods.
		4.7	Service to the Client	16									Feedback element should only required for labs that perform work outside their own agency.		
		4.7.1		16 to 17	x					X				5 out of 6 agree	
		4.7.2		17	x										
		4.8	Complaints	17	x						X		Request assistance from ELAP to provide supporting documentation/SOPs for municipal labs	5 out of 6 agree	
		4.9	Control of non conforming Environmental Testing Work	17	x									5 out of 6 agree	
		4.10	Improvement	18										5 out of 6 agree	

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									Delete	Modify	Delay	Needs Discussion at ELTAC			
		4.11	Corrective Action	18							X		Request assistance from ELAP to provide supporting documentation/SOPs for municipal labs	5 out of 6 agree	
		4.12	Preventive Action	19							X		Request assistance from ELAP to provide supporting documentation/SOPs for municipal labs	5 out of 6 agree	
		4.13	Control of Records	19-21							X		Have a phase in implementation and ELAP to provide assistance.	5 out of 6 agree	
		4.14	Internal Audits	21-22			x			X		X	see above (relaxed frequency for small labs)	5 out of 6 agree	
		4.15	Management Audits	22-23			x					X		5 out of 6 agree	ELAP should proivide training and a checklist
		4.16	Data Integrity	23	x										
	5.0		Technical Requirements	23											
		5.1	General	23											
		5.1.1		23	x										
		5.1.2		23	x										
		5.2	Personnel	23											
		5.2.1		23	x										

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									Delete	Modify	Delay	Needs Discussion at ELTAC			
		Note 1		23											
		Note 2		23-24											
		5.2.2		24	x										
		5.2.3		24						X			Replace with what ELAP currently has in their regulations (applies to all of Section 5.21-5.2.6)	5 out of 6 agree	
		5.2.4		24				x							
		5.2.5		24				x							
		5.2.6	Technical Manager	24,25,26											
		5.2.6.1-5.2.6.2		24-26			x								
		5.2.6.2		26			x								
		5.2.6.2.a		26			x								
		5.2.7	Data Integrity	26,27	x									5 out of 6 agree	
		5.30	Environmental conditions	27	x									5 out of 6 agree	
		5.40	environmental methods, validation	27										5 out of 6 agree	
		5.4.1		27	x									5 out of 6 agree	

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		5.4.2		28	x					x			Revise to add: "1) only US EPA or State agencies can approve methods. ELAP must review the State agency permit and/or EPA ATP before issuing certification for any unregulated method/ unapproved analysis. 2) Certified modified methods must be publically accessible and available for review. 3) Clients must approve the use of any modified method prior to use."	5 out of 6 agree	
		5.4.3		28				x							
		5.4.4		28				x							
		5.4.5		29				x							
		5.4.5.2	Validation of Methods	29			x								
		5.4.5.3		30	x										
		5.4.5.4		30	x										
		5.4.5.4		30			x								
		5.2.6.1	Technical Manager Qualifications	24-26						x			Need to add Title 22 exception for treatment plant operators.	5 out of 6 agree	
		5.4.6.2		31	x										

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		5.4.6.3		31	x										
		5.4.7		31	x										
		5.5	5.5.1 to 5.5.13	31,32	x										
		5.6.2.1		34,35				x	x					5 out of 6 agree	Needs to be removed; Does not apply to testing laboratories-only applies to calibration labs
		5.6.2.2		35				x							
		5.6.3		36	x				x					5 out of 6 agree	Procedures for transport and storage of reference materials is in the method, if necessary. If not, no need.
		5.6.4		36	x				x					5 out of 6 agree	The additional paperwork is an undue administrative cost.

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		5.7		37	x					x			"The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration	5 out of 6 agree	Sampling plans should be based on appropriate statistical method. Who determines this? The auditor?
		5.8		38				x							
		5.8.1													

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		5.8.5		38,39			x			x			"Except for process laboratories and field samples, the laboratory shall have a documented system for uniquely identifying the sample containers that hold samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent	5 out of 6 agree	Many process labs use sample bottles repeatedly with the sample name on the container. Conversely, they may collect the sample in a beaker and do analysis immediately. This requirement is not meant for process labs.
		5.8.6		39			x								
		5.8.7		39,40				x							
		5.8.8		40	x										
		5.8.9(c)		40	x				x					5 out of 6 agree	Outside of ELAP's legal purview (CalOSHA & local government are the regulators).
		5.9		41,42	x										
		5.9.3													
	5.10	5.10.1		42				x							
		5.10.2		42				x							
		5.10.3		43	x										

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		5.10.3.1.c	Reporting	43			x								
		5.10.3.2		44	x										
		5.10.4		44				x							
		5.10.5		44,45				x							
		5.10.6		45	x										
		5.10.7		45	x										
		5.10.8		45	x										
		5.10.9		45	x										
		5.10.10		45	x										
		5.10.11		46			x								
Volume 1 Module 3			NOT reviewing Asbestos Testing - does not apply to my lab												
Volume 1 Module 4															
		1.5.2.1.1								x			"Follow EPA's MDL procedure specified at 40 CFR Part 136 Appendix B."	5 out of 6 agree	May lead labs to use unapproved practices. Allows for possible reductions in data quality
		1.7.1.1.f							x				Increased costs to labs. Lab procedures may need to be changed. Training would need to be done for the method changes. Likely does not improve quality, if the method requirements are different.	5 out of 6 agree	Remove. The method specifies the minimum number of calibration points.
		1.7.2.3.3 (b)							x				Remove. The method will specify if surrogates are or are not appropriate.	5 out of 6 agree	Remove. The method will specify if surrogates are or are not appropriate.

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		1.7.2.4							x				The benefit of documentation is unclear. Compliance may be open to interpretation. Adds undue administrative burden.	5 out of 6 agree	Unclear what this means. Oftentimes, the procedure for data reduction is done by software. Unclear what kind of documentation is required.
		1.7.2.5.c.								x			"The laboratory shall verify the concentration of prepared titrants in accordance with written laboratory procedures."	5 out of 6 agree	For commercially purchased titrants, labs should not be required to standardize.
		1.7.3.2	Positive Control b)	17						x			"If any analyte exceeds the LCS control limit, the source of the error shall be located and corrective action taken."	5 out of 6 agree	All analytes should be within LCS acceptance limits to report data - not a percentage of them. This section is less stringent than promulgated methods and according to the standard, the most stringent requirement must be followed. This section must be deleted, except for the (revised) last sentence.

Training Documents Comments: