California Laboratory Assessment Checklist

2016 TNI Addendum Checklist

Laboratory Name: _____

Location: _____

ELAP Certificate ID: _____

Assessment Date(s): _____

Inspection Type: Renewal ☐ Amendment ☐ Initial ☐ Other ☐

Assessor(s): _____

_____

Assessment Agency: _____

Acronyms Used

ACRONYM	***FULL NAME***
2016 TNI	The NELAC Institute's 2016 Standard
CA-NV/AWWA	California-Nevada Section - American Water Works Association
CCR	California Code of Regulations
CWEA	California Water Environment Association
DDW	Division of Drinking Water
ELAP	Environmental Laboratory Accreditation Program
FOA	Field of Accreditation
MCL/MRDL	Maximum Contaminant Level/Maximum Residual Disinfectant Level
OSA	On-Site Assessment
PT	Proficiency Testing
QM	Quality Manual
SOP	Standard Operating Procedure
V_M_	Volume _, Module _ of the 2016 TNI standard, revision 2.1

DISCLAIMER

This is a guidance checklist and not a regulation. It does not change or substitute for any legal requirement. While ELAP has made every effort to ensure the accuracy of the items in the checklist, the obligations of the regulated community are determined by the relevant statutes and regulations.

Laboratory Changes and Corrections

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
		Previous OSA Review				
§ 64802.20 (i)		Has the laboratory implemented corrective actions to all findings made during the previous OSAs?				
§ 64814.05		Has the ownership, technical manager, or quality manager changed since the last assessment?				
		If yes, has ELAP been notified of the change?				
		Does the laboratory utilize sophisticated technologies, defined in § 64801.00(v)?				
§ 64812.05 (e)		If Yes, has the laboratory made a change to its Sophisticated Technology?				
		If yes, has the laboratory: [(1) – (4)]				
§ 64812.05 (e)(1)		Updated the Quality Manual necessitated by the change of sophisticated technology?				
§ 64812.05 (e)(2)		Updated or created SOP(s) necessitated by the change of sophisticated technology?				
§ 64812.05 (e)(3)		Submitted an amendment application package, if the sophisticated technology is a new technology to the laboratory?				
§ 64812.05 (e)(4)		Retained all records necessary to determine compliance?				

General Inspection, Equipment, and Personnel

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
		General				
§ 64814.10 (a)		Has the laboratory identified information as a trade secret?				
§ 64810.00 (a)		Is the main laboratory a fixed, permanent facility or a fixed-in-place vehicle?				
		Does the laboratory operate a satellite or mobile laboratory?				
Multiple references		If yes, do laboratory reports identify which laboratory performed the analysis?				
Multiple references		Were the satellite or mobile laboratory(s) inspected during this inspection?				
§ 64802.20 (a)(2)		Does the inspection cover all analytical methods used for each FOA for which the laboratory seeks to obtain or maintain accreditation?				
§ 64802.20 (j)		Did the inspection occur within 6 months from the initially scheduled assessment date?				
§ 64802.20 (a)(4)		Has the laboratory violated any ELAP statute or regulation not listed in this checklist?				
§ 64812.05		**Laboratory Facilities and Equipment**				
§ 64802.20 (a)(3)		Does the laboratory's instrumentation and equipment meet the requirements of § 64812.05?				
§ 64812.05 (a)(1)		Does the Laboratory Facility comply with 2016 TNI V1M2 §§ 5.3, 5.5, and 5.6				
§ 64812.05 (c)	General review only	Does the laboratory store and handle hazardous materials in accordance with CCR, title 8, division 1, chapter 4, subchapter 7, General Industry Safety Orders?				
§ 64812.05 (d)	General review only	Does the laboratory dispose of chemical wastes and maintain records of disposal in accordance with Health and Safety Code § 25200.3.1, and CCR, title 22, division 4.5, chapter 12, Standards Applicable to Generators of Hazardous Waste?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64812.00		**Laboratory Personnel**				
§ 64812.00 (g)		Does the laboratory designate a Quality Manager?				
§ 64812.00 (g)		Does the Quality Manager meet the requirements and responsibilities of 2016 TNI V1M2 §§ 4.1.5(i), 4.1.7.1, 4.2.6, 4.2.8.2 and 4.14.1?				
§ 64812.00 (a)		Does the laboratory designate a Technical Manager?				
§ 64812.00 (a)(1)		Does the Technical Manager possess at least baccalaureate degree in chemistry, biochemistry, biology, microbiology, natural or physical science, or environmental engineering, sanitary engineering or chemical engineering?				
§ 64812.00 (b)	EXCEPTION to (a)(1)	Does the Technical Manager hold a valid CWEA Laboratory Analyst certification or CA-NV/AWWA Water Quality Analyst certification in accordance with § 64812.00 (b) Table 3?				
§ 64812.00 (a)(2)		Does the Technical Manager have at least three (3) years' experience in the analysis of chemical, biological, or microbiological samples in an environmental laboratory, prior to being designated Technical Manager, subject to allowances in (a)(2)(A) or (B)?				
§ 64812.00 (c)(1)	EXCEPTION to (a)(1) and (a)(2)	Has the Technical Manager continuously held the position at an environmental testing laboratory since the laboratory was first accredited on or before December 31, 1994?				
§ 64812.00 (c)(2)	EXCEPTION to (a)(1) and (a)(2)	Is the Technical Manager a director of a public health laboratory, pursuant to Health and Safety Code §§ 101150 and 101160?				
§ 64812.00 (d)(1)		Does the Technical Manager comply with 2016 TNI V1M2 § 4.1.7.2 (except [f])?				
		Sophisticated Technologies				
		Does the laboratory utilize sophisticated technologies, defined in § 64801.00(v)?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64812.00 (j)		Is sophisticated technology in the laboratory operated by the Technical Manager or other personnel designated by the Technical Manager?				

Quality Systems, Records, and Reports

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64802.20		**Quality Systems**				
§ 64802.20 (b)(1)		Does the laboratory's quality assurance and quality control procedures meet the requirements of § 64802.05?				
§ 64802.05 (a)(1)		Does the Quality System employed by the laboratory comply with 2016 TNI V1M2 except § 4.1.7.2(f) and 5.2.6?				
§ 64802.05 (a)(2)		Does the Quality System employed by the laboratory comply with 2016 TNI V1M3?				
§ 64802.05 (a)(2)		Does the Quality System employed by the laboratory comply with 2016 TNI V1M4?				
§ 64802.05 (a)(2)		Does the Quality System employed by the laboratory comply with 2016 TNI V1M5?				
§ 64802.05 (a)(2)		Does the Quality System employed by the laboratory comply with 2016 TNI V1M6?				
§ 64802.05 (a)(2)		Does the Quality System employed by the laboratory comply with 2016 TNI V1M7?				
§ 64812.00 (f)		Does the Quality Manual, or referenced document, reference that if a Technical Manager is absent longer than: (1) Fifteen (15) consecutive days, a person meeting the qualifications of the Technical Manager shall be designated to serve as a temporary Technical Manager; or (2) Thirty-five (35) consecutive days, ELAP must be notified in writing.				
§ 64814.00 (f)(1)		Does the Quality Manual, or referenced document, contain requirements for subcontractors, compliant with 2016 TNI V1M2 § 4.5?				
§ 64802.15		**Proficiency Testing Requirements**				
§ 64802.15 (b)(1)		Does the laboratory comply with 2016 TNI V1M1 except § 5.0 and 8.0?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64802.15 (n)		Does the Quality Manual, or referenced document, identify a prohibition on maintaining a financial interest, familial relationship, or contractual agreement for consultation with the provider of a PT study?				
§ 64802.15 (h)		Does the Quality Manual, or referenced document, identify after receipt of a “not acceptable” score, within 45 days the laboratory must: (1) Notify ELAP of the “Not Acceptable” score; (2) Document the root cause of the failure; (3) Take corrective action; (4) Achieve an acceptable score in a subsequent PT; (5) Notify ELAP of the “Acceptable” score; and **NOTE:** (6) not listed				
§ 64802.15 (j)		Does the Quality Manual, or referenced document, identify the procedure upon receipt of a second, subsequent “not acceptable” score, including: (1) Notifying ELAP of the “Not Acceptable” result within three (3) days; (3) Cease reporting of results for regulatory purposes for that corresponding FOA; (4) Notify affected clients of second “Not Acceptable” PT result by registered mail, email with return receipt, or electronic signature document; (5) Within thirty (30) days: investigate and document the root cause of the failure and take corrective action; **NOTE:** (2) and (6) not listed				
§ 64814.00		**Notification and Reporting**				
§ 64814.00 (a)		Does the laboratory document any additional State Regulatory Agencies or federal agencies reporting requirements?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64814.00 (b)		Does the Quality Manual, or referenced document, identify that if an analytical result warrants a client notification, then the notification shall occur after the Technical Manager, or designee, has approved of the result?				
§ 64814.00 (h)(1)		Does the laboratory report to its clients in accordance with 2016 TNI V1M2 § 5.10?				
§ 64814.00 (n)(1)		Does the laboratory's record system comply with 2016 TNI V1M2 § 4.13?				

Specific Requirements for Types of Testing

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
		Drinking Water Specific Requirements				
§ 64814.00 (j)		For laboratories testing for bacteria in drinking water, does the laboratory report the results consistent with DDW requirements? [ref. 22 CCR § 64423.1(c)(2) & (c)(3)]				
§ 64814.00 (k)		For laboratories performing chemical, radiological and microbiological analyses on drinking water samples, does the laboratory report the results consistent with the DDW requirements? [ref. 22 CCR § 64814.00(k)(1) & (2)]				
§ 64814.00 (*l*)		Are drinking water results provided to the DDW before the 10th of the month after completion of analysis?				
§ 64814.00 (c)		Does the Quality Manual, or referenced document, detail procedures when client notification is required?				
§ 64814.00 (c)(1)(A)		Are clients notified in 24 hours when the presence of total or fecal coliforms, or E. coli is confirmed?				
§ 64814.00 (c)(1)(B)		Are clients notified in 24 hours when a bacterial sample cannot be reported and must be invalidated due to **interference**? [ref. 22 CCR § 64425(b)]				
§ 64814.00 (c)(1)(C)		Are clients notified in 24 hours when a nitrate sample exceeds the MCL?				
§ 64814.00 (c)(1)(D)		Are clients notified in 24 hours when a chlorite sample result collected at the entry point of a water distribution system exceeds the MCL?				
§ 64814.00 (c)(2)(A)		Are clients notified in 48 hours when a perchlorate sample result exceeds the MCL?				
§ 64814.00 (c)(2)(B)		Are clients notified in 48 hours when a chlorine dioxide sample result exceeds the MRDL?				
§ 64814.00 (c)(2)(C)		Are clients notified in 48 hours when a chlorite sample result exceeds the MCL?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64814.00 (d)		Does the Quality Manual, or referenced document, detail procedures to contact the DDW when clients cannot be contacted directly within the required timeframes?				
§ 64814.00 (f)(2)(E)		When drinking water samples are subcontracted, does the laboratory provide the required notification for drinking water testing, unless there is an arrangement in writing that the subcontractor will provide the required notification?				
§ 64814.00 (e)		Does the Quality Manual, or referenced document, detail procedures when a water supplier requests invalidation of samples, after reporting the results to the DDW, due to **laboratory accident or error**, including: [(1) – (6)]				
§ 64814.00 (e)(1)		A letter from the Technical Manager to the water supplier confirming the laboratory accident or error and agreeing to the invalidation request				
§ 64814.00 (e)(2)		Complete sample identification, laboratory sample log number (if used), date and time of collection, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question				
§ 64814.00 (e)(3)		Complete description of the error alleged to have invalidated the result(s)				
§ 64814.00 (e)(4)		Copies of all analytical, operating, and quality assurance records pertaining to the incident in question				
§ 64814.00 (e)(5)		Any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question				
§ 64814.00 (e)(6)		A corrective action plan that contains a root cause analysis of the laboratory accident or error, the corrective actions that will take place, and the date the finding(s) will be corrected.				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
		Bioassay Specific Requirements				
§ 64802.15 (*l*)(1)		Does the laboratory achieve acceptable scores in a PT study, where available, for each FOA for which the laboratory is requesting accreditation?				
§ 64802.15 (*l*)(2)		Does the laboratory Perform reference toxicant tests, at a minimum, annually for each method, organism, and endpoint?				
§ 64802.15 (*l*)(3)		Does the laboratory plot and maintain control charts of reference toxicant test results for each method, organism, and endpoint?				