California Laboratory Assessment Checklist

CA Specific Regulations

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, revision 2.1
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?				
§ 64802.05 (b)(2)		Does the Technical Manager or designee review, and amend if necessary, the quality assurance program and Quality Manual at least annually?				
§ 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)	TNI option	Does the Laboratory Facility comply with 2016 TNI V1M2 §§ 5.3, 5.5, and 5.6				
§ 64812.05 (a)(2)(A)		Are the utilities maintained to the degree necessary to allow the laboratory equipment to function and produce analyses in each FOA(s) for which the laboratory is accredited?				
§ 64812.05 (a)(2)(B)		Are ventilation and environmental control maintained in the laboratory so that analytical results are not adversely affected beyond established quality control limits as specified in the approved test methods or in the laboratory's Quality Manual?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64812.05 (a)(2)(C)		Does the design, arrangement, housekeeping, and operation of the laboratory minimize the potential for sample contamination?				
§ 64812.05 (a)(2)(D)		Does each piece of laboratory equipment meet all operational, quality assurance, quality control, and design criteria established in the approved method(s) employed by the laboratory?				
§ 64812.05 (a)(2)(E)		Is each piece of laboratory equipment operated and maintained by the laboratory as specified in the Quality Manual and SOP(s)?				
§ 64812.05 (a)(2)(F)		Are records kept of all operational and maintenance activities associated with the operation of laboratory equipment?				
§ 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?				
§ 64812.00		**Laboratory Personnel**				
	TNI option	Does the laboratory designate a Quality Manager?				
§ 64812.00 (g)		If yes, 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?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 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)	TNI option	Does the Technical Manager comply with 2016 TNI V1M2 § 4.1.7.2 (except [f])?				
§ 64812.00 (d)(2)(A)		Do the Technical Manager and/or their designee duties include responsibility of all analytical and operational activities of the laboratory, including activities of satellite or mobile laboratories under the same certificate of accreditation?				
§ 64812.00 (d)(2)(B)		Do the Technical Manager / designee's duties include supervision of all personnel employed by the laboratory, including personnel assigned to work in satellite or mobile laboratories under the same certificate of accreditation?				
§ 64812.00 (d)(2)(C)		Do the Technical Manager / designee's duties include responsibility of the accuracy and quality of all data reported by the laboratory, including data from satellite or mobile laboratories under the same certificate of accreditation?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
		Sophisticated Technologies				
		Does the laboratory utilize sophisticated technologies, defined in § 64801.00(v)?				
§ 64812.00 (j)		Is sophisticated technology in the laboratory operated by the Technical Manager, Principal Analyst, or other personnel designated by the Technical Manager?				
§ 64812.00 (h)		Does the laboratory designate users or supervisors of users of sophisticated technology as Principal Analysts?				
		If Yes, do the Principal Analyst(s): [(1) OR (2) & (3)]				
§ 64812.00 (h)(1)		Possess at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, natural or physical sciences, environmental engineering, sanitary engineering, or chemical engineering?				
§ 64812.00 (h)(2)		Possess a certification of participation in, and completion of, a course taught by the manufacturer of the sophisticated laboratory instrument which is being used or supervised by the Principal Analyst?				
§ 64812.00 (h)(3)		Have at least six months experience in the operation of a sophisticated laboratory instrument prior to obtaining the position of Principal Analyst?				

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 (a)(1)		Does the laboratory's quality assurance and quality control procedures meet the requirements of § 64802.05?				
§ 64802.05 (a)(1)	TNI option	Does the Quality System employed by the laboratory comply with 2016 TNI V1M2 except § 4.1.7.2(f) and 5.2.6?			X	
§ 64802.05 (a)(2)	TNI option	Does the Quality System employed by the laboratory comply with 2016 TNI V1M3?			X	
§ 64802.05 (a)(2)	TNI option	Does the Quality System employed by the laboratory comply with 2016 TNI V1M4?			X	
§ 64802.05 (a)(2)	TNI option	Does the Quality System employed by the laboratory comply with 2016 TNI V1M5?			X	
§ 64802.05 (a)(2)	TNI option	Does the Quality System employed by the laboratory comply with 2016 TNI V1M6?			X	
§ 64802.05 (a)(2)	TNI option	Does the Quality System employed by the laboratory comply with 2016 TNI V1M7?			X	
§ 64802.05 (b)(1)(A)		Does the Quality Manual address the quality assurance and quality control practices to be employed by the laboratory?				
§ 64802.05 (b)(2)		Does the Technical Manager review, and amend if necessary, the quality assurance program and Quality Manual at least annually?				
§ 64802.00 (b)(2)		Does the Technical Manager review and amend the quality assurance program and Quality Manual when: (A) Changes to laboratory equipment or instrumentation; (B) Changes to laboratory structure or physical arrangements; or (C) Changes in the laboratory organization;				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64802.05 (b)(3)		Does the laboratory perform annual quality assurance audits documenting compliance, including corrective actions for any noted findings?				
§ 64802.05 (b)(3)		Were the findings made during the quality assurance audit corrected?				
§ 64802.05 (b)(4)		Does the laboratory maintain records of the implementation of its quality assurance program?				
§ 64814.00 (n)(1)	TNI option	Is the laboratory's system of records control in accordance with 2016 TNI V1M2 § 4.13?				
§ 64814.00 (n)(2)		Are the records maintained for a minimum of 5 years?				
§ 64814.00 (n)(2)		Does the laboratory's record system allow the history of the sample and associated data to be readily understood through the documentation?				
§ 64814.00 (n)(2)		Does the laboratory's record system produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and or extracts?				
§ 64812.05 (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)	TNI option	Does the Quality Manual, or referenced document, contain requirements for subcontractors, compliant with 2016 TNI V1M2 § 4.5?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64814.00 (f)(2)		Does the Quality Manual, or referenced document, contain requirements for selecting subcontracting laboratories?				
§ 64814.00 (f)(2)(A)		Does the laboratory inform the customer(s) when tests are subcontracted?				
§ 64814.00 (f)(2)(B)		Does the laboratory maintain a register of all subcontractors that are used for analytical testing?				
§ 64814.00 (f)(2)(C)		Does the laboratory require subcontractors to hold ELAP accreditation in the FOA(s) for analyses being performed for regulatory purposes?				
§ 64814.00 (f)(2)(D)		Does the laboratory include the original of any report(s) prepared by the subcontractor?				
§ 64802.05 (b)(1)(B)		**Does the Quality Manual include or reference the following items?**				
§ 64802.05 (b)(1)(B)(i)		Laboratory organization and job descriptions;				
§ 64802.05 (b)(1)(B)(ii)		Ethics and integrity clause;				
§ 64802.05 (b)(1)(B)(iii)		Quality assurance objectives for measurement data;				
§ 64802.05 (b)(1)(B)(iv)		Sampling procedures (when the laboratory performs the sampling);				
§ 64802.05 (b)(1)(B)(v)		Procedures for sample acceptance/rejection, custody, handling, and disposal of samples;				
§ 64802.05 (b)(1)(B)(vi)		Calibration procedures and frequency;				
§ 64802.05 (b)(1)(B)(vii)		Analytical procedures;				
§ 64802.05 (b)(1)(B)(viii)		Acquisition, reduction, validation and reporting of data;				
§ 64802.05 (b)(1)(B)(ix)		Internal quality control checks;				
§ 64802.05 (b)(1)(B)(x)		Performance and system audits;				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64802.05 (b)(1)(B)(xi)		Preventive maintenance;				
§ 64802.05 (b)(1)(B)(xii)		Assessment of precision and accuracy;				
§ 64802.05 (b)(1)(B)(xii)		Corrective action				
§ 64802.05 (b)(1)(B)(xiv)		Quality assurance reports;				
§ 64802.15		**Proficiency Testing Requirements**				
§ 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; **NOTE:** (6) not listed				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 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				
§ 64802.15 (b)(1)	TNI option	Does the laboratory comply with 2016 TNI V1M1 except §§ 5.0 and 8.0?				
§ 64802.15 (b)(2)(A)		Does the laboratory analyze PT samples in accordance with the laboratory’s routine SOP using the same quality control, acceptance criteria and staff as used for the analysis of routine environmental samples?				
§ 64802.15 (b)(2)(B)		Does the laboratory analyze PT samples of the same matrix as the FOA(s) for which the laboratory holds or seeks accreditation?				
§ 64802.15 (b)(2)(C)		Does the laboratory direct the PT provider to report the PT study results directly to ELAP on or before the closing date of the study?				
§ 64802.15 (b)(2)(D)		Does the laboratory report in such a way that results of the PT study corresponds to the FOA offered by ELAP?				
§ 64802.15 (b)(2)(E)		Does the laboratory retain all records necessary to facilitate reconstruction of the preparation, processing, and reporting of analytical results for PT samples for a minimum of five (5) years?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64802.15 (b)(3)(A)		Does the laboratory identify a prohibition of sending PT study samples, in which the laboratory is participating, to another laboratory for the analysis of a FOA for which it seeks accreditation or is accredited				
§ 64802.15 (b)(3)(B)		Does the laboratory identify a prohibition of knowingly receiving or analyzing any PT samples from another laboratory for which the results are to be used for accreditation				
§ 64802.15 (b)(3)(C)		Does the laboratory identify a prohibition of communicating with any individual at another laboratory concerning the analysis of PT samples of an ongoing study				
§ 64802.15 (b)(3)(D)		Does the laboratory identify a prohibition of attempting to obtain the assigned value of any portion of a PT study from the PT provider				
§ 64802.15 (b)(3)(E)		Does the laboratory identify a prohibition of requesting the PT provider to alter any portion of the laboratory's PT report after it was issued as final				
§ 64814.00		**Notification and Reporting**				
§ 64814.00 (a)		Does the laboratory document any additional State Regulatory Agencies or federal agencies reporting requirements?				
§ 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)	TNI option	Does the laboratory report to its clients in accordance with 2016 TNI V1M2 § 5.10?				

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64814.00 (h)(2)		Does the laboratory report to its clients, in accordance with the request for analysis, the full and complete results of all requested contaminants and pollutants from the analyses of the sample or components thereof?				
§ 64814.00 (n)(1)	TNI option	Does the laboratory's record system comply with 2016 TNI V1M2 § 4.13				
§ 64814.00 (n)(2)		Does the laboratory's record system allow the history of the sample and associated data to be readily understood through the documentation?				
§ 64814.00 (n)(2)		Does the laboratory's record system produce unequivocal, accurate records that document all laboratory activities and related laboratory activities? Examples of records include:				
		laboratory facilities,				
		laboratory equipment,				
		analytical methods,				
		sample receipt,				
		sample preparation,				
		data verification,				
		inter-laboratory transfers of samples and/or extracts				
§ 64814.00 (n)(2)		Are the records maintained for a minimum of 5 years?				

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?				