DRAFT – Initial Response to Comments for
Proposed Environmental Laboratory Accreditation Program (ELAP) Regulations

ELAP reviewed 43 comment letters from 37 commenters that were received during the 70-day (October 11, 2019 - December 20, 2019) public comment period. Additionally, ELAP reviewed oral comments from 24 commenters at the Board Workshop on December 18, 2019. Below is a summary of the general categories of comments that were received and draft responses from ELAP. A formal response to each comment received during the public comment period will be included in the Finial Statement of Reason and submitted to the Office of Administrative Law as part of the final rulemaking package.

A: **General Comments Supporting Regulations**: 9 Comments Letters

A1: **General Comments Not Related to the Text of the Proposed Regulations**: 11 Comments

A2: **General Comments Opposing the Regulations**: 14 Comment Letters

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B. DEFINITIONS – 64801.00	
There were several comments that pertained to the lack of definitions or the lack of clarity in the definitions used in the proposed regulations. The commenters identified definitions that they believe are essential to interpretation of the requirements throughout the regulation text. The major definitions that were in question were “fields of accreditation,” “corrective action plan,” “corrective action report,” and “sophisticated technologies.”	For terms that were used in only one section of the proposed regulations, ELAP defines or provides criteria that defines the term within the specific section it is used in. For those terms that were used in many sections, the terms were defined in the definition section. Therefore, even though it may have appeared as if some terms were not defined in the proposed regulations because they were not defined in the definitions section, they were defined in the section they were used in. The one exception to this would be the definition of “corrective action plan”, which was added to the definitions section. ELAP addressed concerns raised about the clarity of the definitions for “fields of accreditation” and “sophisticated technologies” by amending the language to address the confusion. “Corrective action report” was also removed from the proposed regulation text entirely, and ELAP is only using the term “corrective action plan” in the regulation text, which provides clarity to the processes of accreditation described in the text.

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C. APPLICATION PACKAGE - 64802.00	
There were twenty comments on this section, but most of the comments focused on the requirement to "include findings and approved corrective action plan" in the application package. The commenters wanted clarification on who was approving the corrective action plan, specifically when the laboratory is using third-party assessment firms to conduct the onsite assessment.	Even though the Environmental Laboratory Act (ELAA) (Health and Safety Code 100825-100920) and the proposed regulations allow third party assessment agencies to conduct an onsite assessment, ELAP will retain the approval of a corrective action plan in response to the onsite assessment findings and make final determinations as to accreditation.
D. QUALITY SYSTEMS – 64802.05	
There were eight comments made about this section and six of them were about a requirement to review and update the Quality Manual whenever the laboratory updates a Standard Operating Procedure (SOP). The commenters believed that because laboratories frequently update Standard Operating Procedures, updating the Quality Manual in response to these updates would be overly burdensome, especially when SOPs are not listed in the Quality manual but referenced in the Quality Manual.	ELAP agreed with the comments and revised the proposed regulations text to eliminate this requirement.
E. FIELD(S) OF ACCREDITATION – 64802.10	
Several commenters recommended that the field(s) of accreditation that will be offered for accreditation in the program be listed in the proposed regulations.	In section 64811 and 64823 of the current regulations, the test methods and fields of testing, respectively, that ELAP can accredit for are listed. By including the test methods and the fields of testing in the regulation text, the accreditation offerings of the program are stagnant and could only be changed by going through the Administrative Procedures Act

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	(APA) process to update the regulations. The lag time to update regulations has resulted in state agencies, such as the State Water Board, failing to notify or coordinate with ELAP when the state agencies wanted to require new monitoring in permits or orders because ELAP was unable to effectively respond. Since moving to the State Water Board in 2014, ELAP has actively tried to address this situation and ensure that the state agencies have laboratories accredited for the methods required for their regulatory purposes, especially for those of new testing requirements such as testing for perfluorinated alkyl substances (PFAS). There is no requirement in the ELAA that requires that the fields of accreditation be set out in the regulations (Health and Safety Code section 100860.1 was amended in 2016 to remove requirements for fields of testing), so to provide for more flexibility, ELAP is proposing to remove field(s) of accreditation from regulation text and offer accreditation for those field(s) of accreditation that the state agencies require for regulatory purposes. Doing so is consistent with the recommendations of the Expert Panel and helps ELAP to address its core mission, which is to provide accreditation for laboratories that perform analyses for regulatory purposes. (Health and Safety Code 100825(b).) It is the state agencies' needs that drive the program and what methods ELAP should offer for accreditation.
One commenter suggests that laboratories need "to be accredited for new methods that may not yet be required or identified in permits, order, or other regulatory requirements."	If a state agency has not requested accreditation be offered for a particular method, a laboratory does not have a right to be accredited by ELAP for that method or field of accreditation because no regulatory purpose exists. This confusion seems to be at the heart of most of the comments received on this issue.
Many of the commenters expressed that they wanted a process in place that would allow the laboratories to comment on the	State agencies set the requirements for monitoring in their statutes, regulations, permits, orders, and policies. Therefore, the proper venue for laboratories to comment on what methods or testing parameters should

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changes to the Fields of Accreditation and/or allow the laboratories to better control what Fields of Accreditation were being offered, such as having the changes to fields of accreditation be approved by ELTAC.	be required, and therefore, what is included in the field(s) of accreditation offerings by ELAP, would be during the public process whereby those requirements are set by the state agencies. Having ELAP provide a separate process where the laboratories and/or ELTAC weigh in on whether ELAP should change the field(s) of accreditation offerings in response to a request from a state agency could result in problems. For example, if ELTAC disagreed with the state agency on the changes to the field(s) of accreditation, that could prevent or delay a field(s) of accreditation from being offered for methods that are required by permits. Ultimately, it is the state regulatory agencies that decide the monitoring or testing requirements, and therefore drive which field(s) of accreditation are offered, because the analyses are required for compliance with their regulatory program and data needs.
Concerns were also expressed that a laboratory could “find their accreditation removed without warning or recourse.”	Laboratories are accredited for methods that their clients need in order to report compliance with state regulatory agencies statutes, regulation, permits, orders and policies. Many of the field(s) of accreditation that are offered by ELAP are based off the methods listed in federal regulations and approved for use in the federal monitoring programs that state regulatory agencies manage. For example, methods approved for use in the NPDES program and other Clean Water Act compliance monitoring programs are listed in 40 CFR 136, which are the basis for the field(s) of accreditation specific to non-potable water testing that are offered by ELAP. When these regulations are updated, ELAP’s will update the field(s) of accreditation offerings to reflect the change in approved methods. There may be a case where methods that laboratories are accredited for would be removed from the accreditation offering. However, the approved method listing is mostly updated with newer revisions of the method. Only in rare cases are approved methods removed from the federal regulations altogether and not replaced with a newer revision or similar method. This is reserved for antiquated methodologies that do not meet the needs of the monitoring programs.

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	An example of an update of the accreditation offerings was recently completed by ELAP in May 2019. This update was in response to EPA's "Method Update Rule" to update 40 CFR 136. The laboratory community was notified in advance of this update, when the updates were released, and provided information on ELAP's website regarding the changes that were made. Additionally, laboratories were granted a grace period where the laboratory did not have to update their certificate of accreditation to the new field(s) of accreditation offerings until the time of accreditation renewal. Therefore, there was no removal of a field of accreditation "without warning or recourse " Similarly, state agencies must also have the ability to request that fields of accreditation be removed if the methods are inconsistent with their monitoring requirements. For example, when the Division of Drinking Water (DDW) first required testing of waters system for PFAS compounds, the method that was to be offered for accreditation and used by laboratories was EPA Method 537 Rev 1.1. However, it was later requested by DDW that ELAP discontinue to offer accreditation of PFAS testing by EPA 537 Rev 1.1. and start offering accreditation for PFAS testing by EPA 537.1 because it better meets their monitoring needs. In this situation, DDW had a policy to continue to accept data from laboratories that were currently accredited for EPA 537 Rev.1.1. Therefore, laboratories were not required to update their certificate of accreditation to EPA 537.1 until the time of renewal accreditation. ELAP will encourage all agencies that request changes to the accreditation offerings to adopt this policy. ELAP has also been working closely with state agencies to encourage them to come to ELTAC ahead of planned changes to their regulatory activities, explaining the valuable insights ELTAC can provide about which methods of analysis would be most appropriate and to understand existing laboratory capacity to do the analysis that will be required. This

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	is another way that the laboratory community will be informed of pending updates to the field(s) of accreditation offerings. ELAP anticipates that the state agencies will be more interested in seeking out the input of ELAP, and particularly ELTAC, as part of its regulatory development process. In fact, ELAP has been working to appoint an ELTAC committee that will be responsive to all the new and emerging areas of regulatory oversight anticipated by the state agencies, including more advance monitoring efforts of PFAS, microplastics and compounds of emerging concern, as well as, advanced testing techniques and technologies that have been historically reserved for testing in research facilities and academia.
Another concern raised by one of the parties is that without the fields of accreditation listed in the regulations they are "not enforceable."	Fields of accreditation are not meant to be "enforceable" and no new obligations are put on the laboratories when a new field of accreditation is offered. When a state agency requests that ELAP make available a new method or field of accreditation, no laboratory is required to become accredited for that field of accreditation. Whether or not a laboratory seeks accreditation is a business decision for the laboratory. If, however, a laboratory decides to pursue accreditation, the process that they must go through and the fee that they must pay is set out in the regulation and would not change based on the field of accreditation the laboratory was seeking accreditation for. Therefore, although a regulated entity, such as a wastewater treatment plant, may have to test for PFAS compounds, there is no enforceable requirement that a laboratory have accreditation in the field(s) of accreditation specific to PFAS compounds. Each laboratory would only need to be accredited for those specific field(s) of accreditation that it wanted to provide service to their regulated clients. Accreditation requirements would, therefore, not change when new fields of accreditation are added. Furthermore, there may be specific methods that must be used when testing samples for specific regulatory programs. However, ELAP does not "enforce" the use of those methods by the laboratory that provide testing for those programs. It is the state

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	regulatory agency's responsibility and authority to enforce against the regulated entities for not following monitoring requirements if methods that were not approved for the program were used.
F. PROFICIENCY TESTING – 64802.15	
There were 35 comments submitted about this section, but there was no common concern across the comments except clarity of the section or questioning a specific requirement that was included in the section. However, a few commenters joined in questioning the proficiency testing requirements that are required in the three-year period prior to the effective date of the proficiency testing requirements in the 2016 TNI Standard. The commenters note that these requirements are very similar to the TNI Standard and concluded that they were duplicative and should be removed.	In the proposed regulations, the 2016 TNI Standard requirements do not become effective until three years after the effective date of the regulations. The delayed implementation of the TNI requirements was included to provide laboratories more time to implement the quality system requirements of the Standard. The proficiency testing requirements that are required within the three-year implementation period are very similar to the requirements in the TNI Standard but are not exactly the same. These requirements are on activities that a laboratory must comply with when testing proficiency testing samples or must not engage in when testing proficiency testing samples. The reasoning for including these requirements was to preserve the integrity and usefulness of proficiency testing study results. These are not duplicative requirements because there is a sunset clause where the requirements within the three-year implementation are no longer valid and then replaced with the requirements of the 2016 TNI Standard.
G. ON-SITE ASSESSMENT – 64802.20	
There were 17 written comments related to the section about on-site assessments, specifically the requirement that laboratories using sophisticated technologies would be required to rely on third-party assessors to do the on-site assessments. A number of these comments raised concerns about which firms would be able to be third party assessors for the State Water Board, and what minimum standards would they be	Health and Safety code section 100837 allows the state board to contract firms that have been approved to be assessors by TNI or federal agencies, such as the Department of Defense (DOD). TNI and federal agencies, such as DOD, have strict criteria for approving assessor bodies, and the statute allows ELAP to contract with entities that have been found by TNI and federal agencies to meet that criteria. The board resolution for adoption of the regulations includes language that requires ELAP to seek input from stakeholders in creating the terms and conditions that the third-party assessors will need to agree to in order to provide services to laboratories in California. Although ELTAC members

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required to meet. Several commenters suggested ELTAC be involved in that identifying eligible firms and minimum requirements.	could potentially weigh in on the requirements for the third-party assessors, the proposal is for those requirements to go out to all stakeholders for comment, and for the requirements that the assessor agencies would need to meet to come before the board for approval. Those requirements will address areas such as deadlines, minimum qualifications of assessors and conflict resolution.
Similarly, concerns were raised about how the process would work, especially during the interim phase while some labs have not yet transitioned to TNI, including who would be responsible for reviewing the onsite assessment reports, and how disagreements between laboratories and the third party assessors over particular findings would be addressed.	ELAP will make a list of third-party assessor agencies that have signed agreements with ELAP available on its website. Laboratories that use sophisticated technology will call and schedule their assessments with the third-party assessor agencies. Although the assessor agencies will conduct the onsite assessments and issue findings, ELAP will be the one to review the corrective action plans and make the final determinations as to accreditation. If a laboratory disagrees with a finding made in the onsite assessment report, the laboratory can explain in its corrective action plan why it disagrees with a finding. ELAP would be the ultimate arbiter of disagreements between the laboratories and the third-party assessment firms related to findings and accreditation. During the interim period, the third-party assessor agencies will be assessing to whichever standard the laboratory is meeting. If the laboratory has not yet transitioned to TNI, it would be assessed to the current regulations. However, the vagueness of current regulations may present a challenge for third-party assessors because of the multiple ways they can be interpreted. California ELAP assessors will be available to assist during the transition period.
Some raised concerns that third-party assessors would be too expensive.	ELAP's cost estimate was that the cost for an assessment from a third-party assessor agency for a small laboratory would be approximately $5100, the cost for a medium would be approximately $10,100, and the cost for a large laboratory would be approximately $18,800. These estimates were provided by A2LA, an existing third-party assessment firm, and include travel costs of $500 for a small laboratory, $1000 for a

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	medium laboratory, and $1500 for a large laboratory. Laboratories would have to get assessments every two years. Although the fee structure has not yet been set, and will be set separately by emergency regulations, there have been a number of discussions with the laboratory community regarding the fee structure. The fee structure that has been discussed would distinguish an onsite assessment fee for assessments conducted by ELAP assessors that is separate from the other accreditation fees. This structure would mean that those laboratories that pay for onsite assessments by a third-party assessor agency would not pay the onsite assessment fee to ELAP.
At least one commenter stated that ELAP should have to do all of the onsite assessments.	With over 680 labs that are participating in the accreditation program, ELAP cannot continue to do all of the assessments. ELAP does not have the trained staff to conduct all assessments, nor has ELAP been able to hire and retain staff with the necessary knowledge and skillsets to be assessors. Using third-party assessors to conduct onsite assessments for the program is an opportunity to tap into an existing resource of knowledgeable and skilled professionals that are already doing similar assessments for other California regulatory programs, and state and federal laboratory accreditation programs.
Several commenters raised concerns about whether the third-party assessment firms would have a conflict of interest if they were being hired by the laboratories to do the assessments.	Health and Safety code section 100837 allows the state board to contract with firms that have been approved to be assessors by TNI or federal agencies, such as the Department of Defense (DOD). TNI and federal agencies, such as DOD, have strict criteria for approving assessor bodies, including conflict of interest provisions. Hiring a third-party assessor agency to do an assessment is how assessments are done in many other state laboratory programs, including in Florida, New York and New Jersey. Third-party assessors are even used to assess laboratories to the ISO/IEC 17025 Standard in California's Bureau of Cannabis Control's laboratory licensing program. Because of this, ELAP does not

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	anticipate that conflicts of interest will be an issue, but could also address those requirements in the agreements with the assessor agencies.
Commenters also questioned whether there will be enough available firms and auditors to do the onsite assessments.	If the proposed regulations are adopted, over three hundred laboratories will be required to get assessments by contracting with a third-party assessor agency. ELAP has had discussions with the assessment agencies that meet the criteria described in the proposed regulations about meeting the demand of the California market if the proposed regulations are passed. Assessment agencies are looking forward to serving California and have sufficient number of qualified assessors to meet the needs of the program. California represents a large, underserved market, so ELAP does not anticipate problems in getting sufficient numbers of assessor agencies interested in serving California. However, if a laboratory does experience problems with scheduling an assessment because of a lack of available assessors, ELAP will work with the laboratory community to ensure that accreditation does not lapse due to an inability to obtain assessments from a third-party assessor.
Commenters were concerned about assessment firms price gauging because the laboratories are forced to use them.	Third-party assessor bodies that are recognized by TNI or federal agencies have to be accredited by ISO/IEC 17011: Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies. These standards have strict provisions to ensure impartiality and prohibit price fixing by the assessment bodies. In the proposed regulations, only the assessor bodies that are recognized by TNI and federal agencies can be utilized as a third-party assessor in the program.
Comments were made that the regulations should impose a penalty on ELAP, or provide discount for the laboratories fees, when ELAP does not comply with timelines for getting out the onsite assessment	ELAP understands that laboratories are concerned about delays or hold ups in the accreditation process. To hold ELAP accountable, the program implements a quality management system to improve internal processes and procedures to meet its responsibilities and improve response times. ELAP is also moving towards implementing program policies and

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reports, and concerns were raised about what happens to accreditations when the holdup is because of ELAP or because there are no third party assessors available to do the assessment.	procedures that conform to ISO/IEC 17011: Conformity Assessment - Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies. New technologies that the program is considering will also help manage and continue to improve workflows. Changes made to the structure and organization of ELAP, as well as, utilizing resources like the third-party assessors described in the proposed regulations is another way ELAP is targeting delays in meeting its requirements. ELAP is committed to ensuring that no laboratory's accreditation lapses due to ELAP or a third-party assessor agency failing to meet their obligations to provide the onsite assessment report on time
H. ACCREDITATION FEES - 64802.25	
There were numerous comments submitted during the public comment period about the proposed fee structure and the potential impacts the proposed fee structure would have on laboratories.	The public comment period for the proposed regulations is part of a Regular APA Rulemaking Process. However, the fees and associated fee structure is not included in this proposal nor managed by ELAP but presented to the Board by the Division of Administrative Services (DAS) as part of an Emergency Rulemaking process. ELAP included a place holder for the fees section (§64802.25 Accreditation Fees) in the proposed regulations, but any comments submitted about this section are outside the scope of this proposal and should be submitted during the Emergency Rulemaking Process. ELAP has, as a courtesy, forwarded all comments pertaining to fees or the proposed fee structure to DAS. Additionally, ELAP has notified the stakeholder community through ELAP's email list subscription of pending stakeholder workshops that will be hosted by DAS for discussion on the proposed fee structure.
I. INITIAL ACCREDITATION – 64808.00	
There were three comments about this section, two of which were about clarifying language. The one comment that was not about clarifying language argued that the requirement for an initial application to be	ELAP agreed with this comment and changed the "withdrawn from consideration "to "denied". Denial of an application is an action that ELAP is authorized to take under Health and Safety Code, Section 100850(a)(5) and requires a formal notification and provides a laboratory the right to petition for reconsideration under Health and Safety Code

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completed within 30 days from notification of an incomplete application or be "withdrawn from consideration" is not allowable under Health and Safety Code, Section 100850(a)(5) and ELAP has to take an official action on the application.	section 116701. ELAP notes, however, that in the situation where an application is denied because it is incomplete, the laboratory will most likely want to resubmit the missing information and move forward with a new application, and is not required to petition the denial.
J. RENEWAL ACCREDITATION – 64808.05	
There were 8 written comments submitted about this section and most of them were similar to the concerns raised regarding the regulatory language for the section regarding "initial accreditation," including whether an incomplete application can be "withdrawn from consideration". One comment that was not raised in the initial accreditation section pertained to the use of the term "lapse of accreditation." The commenter raised concerns that "lapse of accreditation" is similar to actions that ELAP can take against a laboratory (denial, suspension, revocation) but eliminates the due process provision described in the Health and Safety Code. The commenter believes the term "lapse of accreditation" is a term that should not be used in the proposed regulations.	When a certificate of accreditation is issued to a laboratory, it is for a defined term, with a set expiration date. The accreditation status of a laboratory does not continue in perpetuity and must be renewed before it expires, or there is a loss of accreditation. To renew the accreditation, a laboratory must submit a complete renewal application by a required due date. If a laboratory does not submit a renewal application, or if it does not correct an incomplete application, then the certificate of accreditation will expire or lapse. Similarly, if a renewal application is submitted past the due date, processing of the application may result in a lapse in accreditation because a new certificate of accreditation could not be issued before the expiration date of the old certificate of accreditation. Therefore, a lapse in accreditation is not an action taken by ELAP on an application or a laboratory, but a change in the status of a certificate of accreditation as a result of failure to timely renew the accreditation. Provisions for due process do not apply to this situation, because an action was not taken by ELAP.
K. RECIPROCITY ACCREDITATION – 64808.10	
There were seven comments submitted about this section and the comments were mostly directed at whether laboratories that were accredited by states that had not yet	Reciprocity accreditation is reserved for out-of-state laboratories only and ELAP would only recognize another state's accreditation standard if it had accreditation requirements that were at least as stringent as the proposed 2016 TNI Standard. Therefore, ELAP would have to evaluate

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adopted the 2016 revisions to TNI would be eligible for reciprocity accreditation, because the proposed regulations require that only those laboratories whose accreditation is for a standard at least as stringent as the 2016 TNI standard can receive reciprocity. Commenters noted that most state accreditation programs that use the TNI Standard as their accreditation standard are currently offering accreditation to an earlier revision of the Standard, and not the 2016 TNI Standard. There is worry that out-of-state laboratories would be able to receive accreditation even if their accreditation is in an earlier Standard.	the earlier revisions of the TNI Standard and determine whether or not these accreditation standards have requirements that are equivalent to those in the 2016 revision of the TNI Standard. However, this evaluation may not be necessary if, as it has been asserted will occur, all state laboratory accreditation programs that are currently TNI accreditation bodies will be using the 2016 TNI Standard for their program before the end of 2020.
L. AMENDMENT ACCREDITATION – 64808.15	
There were 23 comments submitted about this section and the majority of the comments pertained to the amendment accreditation process when a laboratory is applying for a change in location. Commenters noted that the proposed requirements of this process limit the laboratory and would not allow the laboratory to continue doing business through the transition to the new location.	ELAP agrees with the comment letters and has revised the section by removing the limiting requirements, as suggested by the commenters. The intent of the proposed requirements for this process is for ELAP to be notified of a pending change of location, ensure that the quality systems of the laboratory are maintained throughout the move, and to for the laboratory to receive an onsite assessment at the new location when the move is complete.

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M. MAIN LABORATORY – 64810.00	
Only one person commented about this section. The comment pertained to the formatting of the section and the lack of examples that do not meet the criteria of a main laboratory.	This section is in the proposed regulations to provide the criteria for a main laboratory. The types of laboratories that do not fit the criteria for a main laboratory are described in the other sections of Article 4: Types of Laboratories.
N. SATELLITE LABORATORY – 64810.05	
There were three comments submitted about this section. Two of the comments were based off of previous drafts of the proposal and the issues had already been addressed in the proposed regulation text. The remaining comment was critical of the criteria that defines the satellite laboratory because the commenter believes the criteria does not limit the number of laboratories that could apply to be a satellite laboratory.	The commenter recommends that a limit on the laboratory size or a defined distance away from the main laboratory be included as criteria for a satellite laboratory to limit the number of laboratories that would be able to apply for multiple satellite locations. In the proposed regulations, the number of laboratories that can apply to be a satellite location is limited by requirement that the satellite be operated with oversight from the main laboratory, and that the main and satellite location have the same Technical Manager. These two criteria would also limit the potential size of the satellite laboratory, as well as, the distance of the satellite laboratory from the main laboratory, which eliminates the need to include additional criteria for a satellite location.
O. MOBILE LABORATORY – 64810.10	
Only one person commented about this section. The comment pertained to the formatting of the section and the lack of examples of what would not meet the criteria of a mobile laboratory.	This section is in the proposed regulations to provide the criteria for a mobile laboratory. The types of laboratories that do not fit the criteria for a mobile laboratory are described in the other sections of Article 4: Types of Laboratories.
P. LABORATORY PERSONNEL – 64812.00	
There were 28 comments submitted about this section and most of the comments were about the use of requirements that are in the current regulations and continue for three years until the effective date of the proposed TNI requirements.	The personnel requirements that are in effect for the first three years of the proposed regulations are a continuation of the requirements that are in the current regulations. Three years from the effective date of the proposed regulations, personnel requirements align with the personnel requirements in the 2016 TNI Standard, except for the qualification requirements of the Technical Manager, and the personnel requirements

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	of the current regulations will sunset. Allowing current regulations to remain in effect for three years is proposed to provide laboratories more time to implement the quality system requirements of the 2016 TNI Standard, which includes defining the roles and responsibilities of laboratory personnel.
There was one commenter that suggested that the requirements for what grade of CWEA laboratory analyst certification or CA-NV/AWWA Water Quality Analyst certification was necessary to qualify to be the laboratory Technical Manager align with the scope of the testing at the laboratory, instead of the scope of testing in the facility's permit	ELAP agrees with the commenter on allowing the grade of CWEA laboratory analyst certification or CA-NV/AWWA Water Quality Analyst certification that is necessary to qualify to be Technical Manager to align with the scope of the testing at the laboratory, instead of the scope of testing in the facilities permit. ELAP continued the exemption to the Technical Manager qualification requirements provided for drinking water and wastewater treatment facilities in proposed regulations, but included language to make sure that the certificate grade was appropriate for the knowledge and experience with analytical methods and instrumentation needed for the position. ELAP did not account for some testing required in the permit being sent to a commercial laboratory and therefore not done within the laboratory of the facility. In these cases, the Technical Manger would not be required to be knowledgeable and experienced in these methods or technologies that are being performed by an outside laboratory. The requirements were revised as recommended by the commenter.
Q. LABORATORY FACILITIES AND EQUIPMENT – 64812.05	
There were six comments submitted about this section. Most of the comments focused on the requirements for a laboratory to properly handle and store hazardous waste material in accordance with California Code of Regulation, Title 8. The commenters believe that this is outside the capabilities and training of ELAP assessors or third-	The requirements for proper handling and storage of hazardous waste that are included in the proposed regulations are a carryover from the current regulations. ELAP assessors or third-party assessors do not actively assess compliance to this requirement during the onsite assessment. All Cal-EPA Boards, Departments and Office inspectors, which includes ELAP, must have cross-media awareness to conduct quality inspections. It is retained in the proposed regulations so ELAP has the authority to immediately suspend accreditation of a laboratory

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party accessors, as well as, a duplication of oversight as the Certified Unified Program Agency (CUPA) would be overseeing compliance to these regulations.	that demonstrates gross negligence or complete disregard for proper handling or storage of hazardous waste materials that could impact the safety of laboratory personnel or ELAP assessors. In addition, the appropriate CUPA will be notified of the findings.
One commenter suggested that the additional hazardous waste handling and storage requirements in the Health and Safety Code should be added for completeness if these hazardous waste requirements are not removed.	ELAP agrees with the suggestion to add the hazardous waste requirements in the Health and Safety Code as an additional requirement for laboratories.
R. NOTIFICATION, REPORTING, AND CONTROL OF RECORDS – 64814.00	
There were 15 comments submitted about this section. The most common comment in this section is regarding the following statement “State Regulatory Agencies and federal agencies to whom data is reported may have notification, reporting, and record retention requirements that are in addition to requirements here, and it is the responsibility of the laboratories to know those additional regulatory requirements.” The commenters want the other state or federal agency requirements to be listed in this section. The belief is that ELAP will enforce on other regulations or requirements.	This subsection is only to clarify that the notification, reporting and records retention requirements that are included in this section are only the minimum requirements that are required by ELAP. However, there may be alternative requirements that other programs may have regarding these areas and any laboratory participating in these programs should be knowledgeable of the requirements. For instance, the Lead and Copper Rule in the National Primary Drinking Water regulations requires records to be retained for at least twelve years. However, ELAP only requires records to be kept for 5 years. ELAP would only be assessing laboratories to the requirements in this section and not to other regulations or program policies. Therefore, all the requirements of other programs are not required to be listed in this section but the responsibility of the participating laboratory to know.
S. NOTIFICATION OF CHANGE OF TECHNICAL MANAGER OR CHANGE OF OWNERSHIP – 64814.05	
There were three comments on this section. One comment was a request to include	ELAP did not accept the recommended alternatives because it would put more strenuous requirements on the laboratories to comply. A diploma

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alternatives in the requirements to allow copies of transcripts to be accepted in leu of a copy of the diploma	would already be in the applicant's possession and a copy of the diploma would be an easy task. However, contacting a university or college to send transcripts would be more burdensome and can take time to be completed.
One comment was requesting clarity on the status of the certificate of accreditation when a laboratory changes ownership	The notification requirements that are included in the proposed regulations will inform ELAP of any potential impacts to quality of data as a result of change of ownership. The section was not edited for clarity because the language in statute and the proposed regulations clearly states that transfer of a certificate of accreditation is not guaranteed with a change in ownership but must be requested by the new owner. Also, the information that must be included in the request is clearly identified in the proposed regulations.
T. TRADE SECRETS – 64814.10	
One comment was received about this section and it recommended that a denial process be included for laboratories who use trade secrets to maintain a competitive edge.	Denial of accreditation because of use of trade secrets is outside the authority granted to ELAP in the ELAA. Additionally, the regulatory framework on which the accreditation process operates limits the use of trade secrets as a competitive advantage because the methods for use in regulatory programs are generally approved for use in federal regulations and are not proprietary, and laboratory equipment and supplies are commercially available and prescribed in the analytical methods.
U.V.W. REASONS FOR DENIAL, CITATION, SUSPENSION OR REVOCATION – ARTICLE 7: 664816.00, 64816.05 AND 64816.10	
Many of the comments requested that the language from the Health and Safety Code regarding the petition process and the due process procedures for the suspension and revocation process be incorporated into the regulations.	When the language already exists in the statute, there is generally no need to add it into the regulations. However, because of concerns that laboratories may not be aware of the rights to petition denial of accreditation and enforcement actions, language was added to 64816.00 and 64816.05 that identifies the statutory rights of laboratories to file petitions for reconsideration. Health and Safety Code section 100816.10 also identifies the statutory rights of laboratories that have been issued a

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	notice of suspension or revocation to request a hearing within twenty days
Another issue that many of the commenters expressed concerns about was that they felt the reasons for which ELAP could deny accreditation, issue a citation, or suspend or revoke accreditation were too vague, and should include more details.	Currently under the existing statutes, ELAP has very broad discretion to take enforcement actions. Both Health and Safety Code section 100880 and 100905 allow ELAP to take enforcement if it determines a laboratory is in violation of the ELAA or any regulations adopted thereunder. Therefore, the list of laboratory actions or activities that may result in an enforcement action is only to provide illustrations of the types of violations that may result in enforcement action and not an exhaustive list. ELAP changed the enforcement sections to identify the list of activities as examples of actions for which ELAP "may" take enforcement, rather than "shall" take enforcement. This change helps to signal that these sections are not creating new violations, but rather identifying examples of activities for which ELAP already has the ability to take action under existing statutes.
Similarly, concern was expressed that the list of potential reasons for which ELAP may take enforcement did not differentiate between what would be subject to a citation versus a suspension versus revocation.	ELAP did not make any changes in response to these comments, as it is too difficult to set out in the regulations those fact-specific situations that would cause ELAP to pursue a citation versus a suspension. Each situation will be unique, and there may be a number of fact-specific factors that influence that decision. As noted previously, however, the proposed regulations do not modify what ELAP can already do. As noted above, both Health and Safety Sections 100880 and 100905 allow ELAP to take a wide variety of enforcement actions for violations of the statutes and regulations. These sections merely identify actions that ELAP has seen and are examples of when it would consider taking enforcement.
A few commenters expressed concerns that by including these provisions in the regulations ELAP would be discouraging the laboratories from self-reporting.	ELAP agrees that it does not want to discourage self-reporting and would use its prosecutorial discretion when considering whether to take enforcement against a laboratory whose violation came to ELAP's notice because the laboratory self-reported the problem. ELAP believes that it

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	is necessary to have these enforcement options available, however, because it knows that not all laboratories will self-audit or self-report.
Several commenters questioned ELAP's ability to issue regulations related to citations, suspensions or revocations.	ELAP is provided broad authority to adopt regulations establishing requirements for accreditation in 100830(a). Although subsection (a) includes a list of things that must be included in the regulations, that section identifies that the regulations are not limited to just those matters identified, and therefore could also include those types of activities that could lead to enforcement. Similarly, although 100830(b) only mentions setting regulations regarding the issuance, denial, renewal or suspension of accreditation, it is clear that ELAP has the ability to identify in regulations those types of actions that could lead to revocation of accreditation or issuance of a citation since both 100880 and 100905 allow ELAP to revoke or issue a citation for any violation of the regulations.

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At least one person has questioned whether the regulations result in an expansion of ELAP statutory authority since there are already specific reasons for suspension and revocation set out in the statutes.	Although Health and Safety Code section 100851 identifies seven reasons for suspension, this statute is only applicable to "TNI recognized accrediting body" suspending the accreditation of a "TNI accredited laboratory." To be a TNI recognized accrediting body would require additional steps that California is not ready to take and becoming a TNI accredited laboratory would require the lab to implement all of TNI, and to get accredited from a TNI accrediting body. ELAP is not a TNI accrediting body, and the labs that it will be accrediting will not be TNI accredited labs, even though they will be required to eventually implement most of the 2016 TNI Standards. As noted previously, section 100905(a) gives ELAP broad authority to suspend or revoke accreditation for violations of the ELAA or any regulations adopted thereunder. All of the actions set out in the regulations that could lead to enforcement are all obvious violations of the ELAA, and no one has questioned whether any of the examples set out are not actual violations. ELAP is not attempting to expand its enforcement abilities and create new actions that would be considered violations of the ELAA or the regulations. The regulations simply set out more clearly for the laboratories those types of activities for which ELAP could take enforcement, and most are examples of laboratory activities for which ELAP has already been taking enforcement.
X. INITIAL STATEMENT OF REASON (ISOR)	
A number of commenters assert that ELAP has not presented any data that there are any problems that require new regulations, and therefore ELAP has not met the requirement that the proposed regulations are necessary.	ELAP's regulations have not been updated since 1994. A lot of changes have occurred in the laboratory industry since 1994, and the current regulations desperately need updating. As was detailed in the ISOR, the program was broken when it was moved over to the State Water Board. One of the key findings from the Expert Panel that was assembled to independently assess the program, was that the current regulations were inadequate and needed to be updated with a standard that included quality management system requirements.

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	Addressing specific concerns with data quality was not primary issue driving the need for new regulations or even the incorporation of TNI quality management system requirements into the regulations. However, ELAP became aware of concerns about laboratory data quality from reviewing the findings from on-site assessments of drinking water laboratories conducted by NV5/Dade Moeller, a national laboratory assessment firm that was contracted to help train ELAP assessors and help perform on-site assessments of ELAP-accredited laboratories analyzing drinking water contaminants for regulatory purposes. The findings of deficiencies were alarming. Many of the laboratories had large numbers of significant deficiencies related to quality assurance requirements. The trend over the last quarter century since ELAP's regulations were adopted is for accreditation standards to include quality management systems requirements that set up procedures and processes for a laboratory to follow to self-ensure that the data it is providing to its clients is of known and documented quality. A quality management system is a structured and documented system for how the laboratory daily ensures the quality of its processes and products. The details for such a system were absent from the current regulations and resulted in a lack of standardized practices and variation across laboratories, which is not the hallmark of an effective accreditation program. An effective accreditation standard requires consistent and uniform implementation of requirements, which can only be assured with more detailed requirements than what were included in the current regulations, which were much more like guidance than requirements. Although the documentation requirements that are part of the quality management system do not guarantee improvements in data quality, they do ensure that the data coming out of the laboratory is of documented quality. Even though the laboratory may be following the

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	requirements of the specific quality assurance and control procedures of the standard method, without documentation it is impossible to ensure the data is of known and documented quality. For example, even though the laboratory may be following the standard method, if it does not have a procedure for ensuring its reagents are purchased from a qualified and reputable vendor to ensure the reagents are appropriate for the testing and free of contamination, its results would be uncertain.
The State Water Board needed to provide the alternatives considered and must provide evidentiary support for rejection of the alternatives.	There is no requirement that the agency make the detailed analysis of alternatives available to the public. Section 11346.2(b)(4)(A) of the Government Code requires that the agency provide "a description" of the reasonable alternatives that were considered and the agency's reasons for rejecting them. Alternatives are reasonable if they "are less burdensome and equally effective in achieving the purposes of the regulations in a manner that ensures full compliance either the authorizing statute or other law being implemented or made specific by the proposed regulation." In addition, subsection (b)(4)B) requires the agency to provide "a description of reasonable alternatives to the regulations that would lessen any adverse impacts on small businesses and the agency's reasons for rejecting them." The ISOR provided descriptions of alternatives considered, including the California Quality Management System (QMS) that was developed and offered for consideration by municipal laboratories. A copy of the iteration of the CA-QMS that was used in the evaluation of alternatives was included in the references relied upon. Additionally, multiple iterations of the CA-QMS are in the rulemaking file, as they were submitted by Amber Baylor during the public comment period. The ISOR lays out in substantial detail the rationale for rejecting the alternatives. Section IV of the ISOR lays out how alternatives were developed, considered, and ultimately rejected. The pros and cons of the alternatives were identified and were multi-faceted. Rejection of the

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	California QMS, which was essentially the 2016 TNI Standard headings with details of the requirements removed, was rejected for a number of reasons, including that it excluded necessary detail and specificity for an effective accreditation standard. In addition, as each iteration of the California QMS proposal added in more of the TNI Standard in order to garner more support, ELAP realized that there would be few advantages to ending up with a standard that mirrored TNI, but without the benefits that come with relying on TNI. The benefits of relying on TNI as opposed to modifying the TNI standard include being able to take advantage of the tools, templates and trainings that TNI provides to its members, including a handbook for small laboratories that provides templates for those documents small laboratories need for their quality manual. The standard itself is constantly analyzed and discussed by membership committees, which California laboratories can be part of. As a result of those discussions, updates to the standards are voted upon and approved by the membership, which California could then adopt into its regulations. If California were to create its own standard, it would have to find resources to create its own templates and trainings, and would need to continue to update its regulations on its own so that its regulations kept pace with changes in the laboratory industry and did not fall behind again. Conforming to a national standard also made the opportunities for relying upon third-party assessor bodies a greater possibility. ELAP has struggled to find and retain assessors, and as a result has had a hard time completing all of the necessary on-site assessments necessary to keep the program going. Being able to rely on third-party assessor agencies, especially for assessment of laboratories using more sophisticated technologies, is key to ELAP's success. Although assessor agencies might be willing to learn and assess to a California-only standard that is similar to, but distinct from, TNI, it is uncertain whether or not this would be successful. Therefore, any alternative to TNI would not

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	be as effective, would be more burdensome in terms of the additional work ELAP would have to do itself, and would not be more cost-effective as it would require ELAP to expend resources, as opposed to being able to rely on the work that TNI is already doing to update the standard and create tools, templates and trainings for its membership.
Y. ECONOMIC IMPACT ANALYSIS (STD FORM 399)	
Per the requirements of the APA Rulemaking process, ELAP is required to estimate the economic impacts of the proposed regulations in the Economic Impact Statement (STD Form 399). In the STD Form 399, environmental laboratories accredited by ELAP are identified as the businesses that would be impacted by the proposed regulations. Total costs to these businesses from implementation of the proposed regulations were estimated based on the costs to hire new laboratory personnel, costs to hire a consulting firm to help with the implementation of the proposed accreditation standards, and, for a subset of accredited laboratories, the costs to hire a third-party assessment agency to conduct an onsite assessment. The comment letters received on the estimated economic impacts disagreed with the estimated costs to hire a new laboratory personnel and believe these estimated costs are underestimated and not representative of costs in California. Furthermore, the total economic impacts of	Strategies to implement the TNI Standard are highly variable and dependent on the business and management decisions of the laboratory. Each laboratory will implement the TNI Standard in the way that makes the most sense for their business, and the implementation strategies could be different for laboratories of similar size, analytical capabilities, and resource availability. Therefore, an evaluation of costs to implement the TNI Standard for each individual environmental testing laboratory in California is unrealistic. ELAP is, however, required to come up with a reasonable estimation of the total costs to implement the 2016 TNI Standard. For the purpose of this economic and fiscal impact analysis, laboratories were grouped by a size class and cost estimates were assigned to each size class. The implementation strategies of the various size classes were determined based on responses from ELAP-accredited laboratories on the proposed regulations, interviews with environmental testing laboratories that have implemented the TNI Standard, and other state accreditation programs that adopted the TNI Standard for their program. For the purpose of the economic analysis, it is assumed that all small laboratories will hire a consulting firm to determine areas of the laboratory that need modifying to be compliant with the proposed regulations and help with the initial implementation process and seventy percent of small laboratories will hire one full-time laboratory personnel to transition the laboratory to the 2016 TNI Standard. It is assumed that medium sized laboratories will also hire a consulting firm to determine the

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the proposed regulations were estimated to be below the $50 million threshold that would require a Standardized Regulatory Impact Assessment (SRIA). Some commenters believe the underestimated costs to the laboratory are the reason the total economic costs of the proposed regulations did not surpass the $50 million threshold.	areas of the laboratory that need modifying to be compliant with the proposed regulations and help with the implementation of the 2016 TNI Standard, and that fifty percent of the medium-sized laboratories will hire one part-time laboratory personnel to help with the transition to the 2016 TNI Standard. Larger laboratories have the infrastructure and resources to dedicate to the transition to the 2016 TNI Standard without hiring new laboratory personnel or investing in a new or upgraded LIMS. However, it is assumed that larger laboratories will hire a consulting firm to assess the laboratory's current operations and determine the areas of the laboratory that need modifying to be compliant with the proposed regulations. It should be noted that the 2016 TNI Standard does not require a laboratory to hire new personnel or a consulting firm and, in fact, there are many examples of laboratories implementing the TNI Standard without hiring new personnel or a consulting firm. Therefore, the estimated costs based on the assigned implementation strategies represents a conservative estimate of costs. The implementation strategies assigned to each size class was not the area of the economic analysis that comments were directed at, but rather the costs assigned to the different strategies, especially the cost to hire new employees. The State Water Board estimated the cost of a full-time employee to be $66,192. The estimate is based off of 2017 salary data published by the Bureau of Labor Statistics for a chemical technician. The salary listed for a chemical technician was then multiplied by 1.4 to account for costs of benefits and employment taxes. The basis for the comments is the belief that the TNI Standard would require laboratories to hire a manager level personnel (Quality Assurance Manager) to implement the standard, which would carry an estimated cost of $100,000 per year to a laboratory. Note, that this estimated salary is from the comment letters and not from a published resource. Furthermore, commenters argue that the assigned salary for a chemical technician based on the Bureau of Labor Statistics is not reflective of the actual cost

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	to hire a chemical technician in California. Upon further review of the Bureau of Labor Statistics salary ranges, ELAP determined that the salary used for the economic analysis was not California-specific and should be updated. The salary range for a chemical technician in California is $66,892. This salary will be used to update the total economic impacts of the proposed regulations in the STD 399; however, the increase will not raise the total economic impact of the proposed regulations above the $50 million threshold. The 2016 TNI Standard does describe the roles and responsibilities of a Quality Assurance Manager in the laboratory. However, this does not mean that a Quality Assurance Manager is required to be hired. The TNI Standard allows multiple roles to be filled by a single individual when resources are not available, which means that the Quality Assurance Manager role can be filled by current employees, including those required in current regulations (i.e. Laboratory Director). Furthermore, ELAP disagrees with the statement that a Quality Assurance Manager is necessary to be able implement the TNI Standard because that is contradictory to what laboratories that have implemented the TNI standard and state accreditation programs that adopted the TNI Standard for their program have said about the implementation process. Most have said that laboratories, even small municipal laboratories, were able to implement the standard with existing personnel or by hiring non-manager level personnel, as long as they were provided the templates, tools and training to succeed. Additionally, hiring a Quality Assurance Manager represents the same resource to laboratory as hiring an additional employee and a consulting firm, and is almost the same estimated costs for those two that were included in STD 399. ELAP assumed that a laboratory would hire a consulting firm to help develop and implement the policies and procedures required in the TNI Standard. Hiring a consulting firm alleviates pressure on the staff and provides a service that can guide implementation on a step-by-step basis. Although we have evidence of

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	small, municipal laboratories being able to implement the standard without hiring additional personnel, it is assumed that fifty percent of medium laboratories and seventy percent of small laboratories will hire a one full-time laboratory personnel to transition the laboratory to the 2016 TNI Standard. This assumption is based on potential implementation strategy voiced during public comment periods by some laboratories who are concerned that existing staff will not have sufficient time to put in and maintain TNI requirements in addition to their current workloads. Hiring a Quality Assurance Manager would serve the same roles and be an equivalent resource for a laboratory as hiring a consultant for the implementation period and a full-time employee to continue on with the laboratory to help maintain the additional work in the laboratory. In addition, the estimated costs to the laboratory for an employee ($66,192 salary) and a consulting firm ($31,000) is on par with the estimated salary of the Quality Assurance Manager ($100,000 salary). Therefore, ELAP does not believe that the cost estimate of the 399 is underestimated
Z. 2016 TNI STANDARD	
There were numerous comments that objected to the incorporation of the 2016 TNI Standard in the proposed regulations as the accreditation standard for the program. The overall sentiment from these comments was that TNI Standard is overburdensome to small laboratories and does not provide benefits to the laboratory or improve the quality of data.	Although there is no requirement in the TNI Standard that cannot be implemented by a small laboratory, other state programs observed that smaller laboratories required more time to implement the TNI Standard, which is why ELAP is proposing a three-year implementation grace period. Potential impacts to small laboratories are of great concern for the State Water Board, which is why ELAP supported the TNI Mentorship Initiative, which was initiated in California by the American Council of Independent Laboratories (ACIL). This initiative united mentor laboratories that have implemented TNI and are currently TNI-accredited with small laboratories of the state. The objective of the program is for mentor laboratories to help the small laboratories with the implementation process and identify needs of the laboratory to become compliant with the proposed

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	regulations and the 2016 TNI Standard (with two California-specific exceptions). This program has been very successful, with five small laboratories implementing the 2016 TNI Standard within six to eight months without additional costs or new personnel. The success of this program has even got attention from TNI, which is looking to provide similar resources to laboratories at a national level. ELAP was told that the biggest help to the small laboratories during the TNI Mentor Initiative was having the mentor resources available to help them as they went through the implementation process. This information has helped shape the opportunities ELAP proposes to offer the laboratory community during the three-year implementation period. ELAP will be contracting with an outside vendor to host statewide workshops that will be aimed at helping small laboratories work through the documentation requirements in TNI. ELAP is also proposing implementation workshops and webinars hosted by ELAP staff to be offered throughout the three-year implementation period. Small laboratories will have plenty of opportunities to take advantage of resources being made available to the laboratory community to aide in the implementation process and reduce costs to the laboratory.
Commenters that were against the incorporation of the TNI Standard were in favor of the CA-QMS alternative standard, which is TNI Standard-based but removes many of the details of the quality management system requirements.	The CA-QMS lacks specificity and detailed requirements and allows for varying interpretation by laboratories, which is the same problem that exists with the current regulations. For example, the CA-QMS requires that a laboratory have procedures for achieving traceability of measurements in the laboratory's quality manual (also a 2016 TNI Standard requirement). However, excluded from the CA-QMS are the minimum criteria to achieve the traceability. Therefore, each laboratory could have different procedures that result in varying degrees of effectiveness at achieving traceability of measurements, which means that the requirement does not standardize the laboratories activities and is not auditable This is continued throughout the alternative, where

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	laboratories are only required to include or reference content in the quality manual but are not provided the minimum criteria required to be compliant to the standard. The varying interpretations of the alternative standard by laboratories eliminates the alternative as an effective accreditation standard because it does not standardize laboratory activities and practices. Ultimately, the lack of sufficiently detailed and auditable quality system requirements leads to the same fundamental problem that ELAP faces with the current accreditation standard and regulations.
Commenters also recommended that the rulemaking process be delayed so the CA-QMS alternative accreditation standard can be further developed and refined.	It is ELAP's conclusion that all alternative options considered would ultimately lead to the development and selection of an accreditation standard that closely mirrors the 2016 TNI Standard but lacks the core quality system requirements to retain the benefits of the 2016 TNI Standard. In fact, in an effort to reach consensus support from ELTAC and ELAP, each iteration of the CA-QMS contained increasingly more of the quality system requirements of the 2016 TNI Standard. Each iteration was considered but not supported by ELAP or a consensus of ELTAC because it excluded the necessary detail and specificity for an effective accreditation standard.
Additional concerns were raised about incorporating by reference the 2016 TNI Standard because it is copyrighted and would be against the APA provisions because it is not freely available and must be purchased.	The price for the 2016 TNI, Volume 1 is $215 for members and $290 for non-members. Membership is $75 per year. Because revisions to the standard are only about every 3-5 years, it would cost a laboratory about $120-150 per year for the standard and membership or about $60-100 for the standard without the membership. This is similar to what many of the other standards that laboratories currently have to purchase, such as Standard Methods and ASTM Standards, which are incorporated by reference in federal and state Clean Water and Safe Drinking Water regulations. (e.g. 40 CFR 136; 40 CFR 141.25). For example, in the findings prepared for the 2019 Methods Update Rule, where the US EPA is considering incorporating by reference changes to Standard Methods

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	and ASTM analytical methods, the US EPA found that because the proposed methods are available to everyone at a cost "generally from $40 to $80" that the cost of obtaining these methods is not a significant financial burden for a discharger or environmental laboratory, "making the methods reasonably available." Having to purchase a standard that is incorporated into law is not unusual. The Federal and state governments rely on many voluntary consensus standards, such model plumbing and building codes, standard methods for the examination of water and wastewater, and laboratory accreditation standards, such as the ISO 17025 standard used by cannabis laboratories, and the TNI standard. By relying on such standards and incorporating them into regulations, agencies are able to eliminate costs of developing their own standards and benefit from the years of education and experience of the volunteer committee members that develop the standard in consensus with their peers. In fact, federal law encourages this practice, recognizing the many benefits and costs savings of doing so. (National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, § 12.) In order to support their work, which includes not only developing standards, but also holding conferences and providing trainings, these voluntary consensus standard bodies copyright their product and provide their standards for a fee. Unlike the TNI 2016 standard, which is being incorporated by reference into ELAP's regulations, and the "ISO 17000, Conformity assessment – Vocabulary and general principles," which is identified as "indispensable" for the application of the TNI Standard, and is available for free on ANSI's website at: https://www.iso.org/obp/ui/#iso:std:iso-iec:17000:ed-1:v1:en, the ISO 17011 standard has not been incorporated by reference into the regulations and is not indispensable to the application of TNI.

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Several commenters questioned whether it is legal to incorporate the TNI Standard by reference into the regulations.	There are several reasons to conclude that incorporating TNI Standard by reference into the regulations is legal: 1. Meets requirements of CCR for Incorporation by Reference Section 20 of title 1 of the California Code of Regulations (CCR) allows for a regulation printed in the CCR to make provisions of another document part of the regulation by reference to the other document. That section sets out requirements that must be met, including: • Demonstrating in the final statement of reasons that it would be cumbersome, unduly expensive or otherwise impractical to publish the document in the CCR. • Demonstrating in the final statement of reasons that the document was made available upon request directly from the agency, or was reasonably available to the affected public from a commonly known or specified source, and where it was not available from a commonly known source and could not be obtained from the agency, the regulations shall specify how a copy of the document may be obtained. • The informative digest in the notice of the proposed action clearly identifies the document to be incorporated by title and date of publication or issuance. • The regulation text states that the document is incorporated by reference and identifies the document by title and date of publication or issuance. • The regulation text specifies which portions of the document are being incorporated by reference. Here, all the requirements will be met. Because the TNI Standard is a copyright protected standard that has to be purchased, it is impractical to publish it in the CCR. It has, however, been made available to anyone seeking to review the standard for purposes of this rule-making process. Since the inception of the regulations' development process more than

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	three years ago, ELAP worked with TNI to make the 2016 version of the standard available to the environmental laboratory community. For example, copies were distributed to the Environmental Laboratory Technical Advisory Committee to assist them in commenting on the requirements during the preliminary phase of the draft regulations. Similarly, the standard has been made available to be reviewed at all of the State Water Board's regional board and Division of Drinking Water district offices. In addition, TNI made a "read-only" version of the standard available on its website during the initial comment period on the regulations, and also during the formal public comment period. TNI has also made a special deal with California, making the standards available for $195 with a free six-month membership, and approximately 350 California labs (or entities representing laboratories) purchased the 2016 TNI Standard since that offer was made available. After adoption, the 2016 TNI Standard, Vol. 1, Rev.2.1 will continue to be made available through purchase from TNI, for $215 for members and $290 for non-members. Membership is $75 per year. Because revisions to the standard are only about every 3-5 years, it would cost a laboratory about $120-150 per year for the standard and membership or about $60-100 for the standard without the membership. This is similar to what many of the other standards that laboratories currently have to purchase, such as Standard Methods for the Examination of Water and Wastewater and ASTM Standards, which are incorporated by reference in federal and state Clean Water and Safe Drinking Water regulations. (e.g. 40 CFR 136.3; 40 CFR 141.25). In addition to the standard being reasonably available during and after the rulemaking process, the informative digest in the notice of the proposed rulemaking action clearly identified that Volume 1, Revision 2.1 of the 2016 Standard was being incorporated into the regulations, and it was again made clear in the regulation text. 2. 11th Circuit Case before US Supreme Court is Distinguishable

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	Several commenters questioned whether an Eleventh Circuit case that is currently before the U.S. Supreme Court, *Code Revision Commission for General Assembly of Georgia v. Public.Resource.Org*, 906 F.3d 1229 (2018), should give ELAP pause in incorporating the TNI Standard into the regulations, suggesting that an adverse ruling could make ELAP unable to incorporate the TNI Standard by reference. The case at issue, however, is distinguishable from the present case. In that case, the court found that the annotations contained in the Official Code of Georgia Annotated (OCGA), which were authored by the Georgia General Assembly and made an inextricable part of the official codification of Georgia's laws, were not copyrightable. Unlike the TNI Standard, which was created by a third-party consensus body, the work at issue in this case was created by the State, and as the work of a sovereign body, it was not copyrightable. "The general rule that legislative codifications are uncopyrightable derives from an understanding of the nature of law and the basic idea that the People, as the reservoir of all sovereignty, are the source of our law. For purposes of the Copyright Act, this means that the People are the constructive authors of those official legal promulgations of government that represent an exercise of sovereign authority. And because they are the authors, the People are the owners of these works, meaning that the works are intrinsically public domain material and, therefore, uncopyrightable." (Public.Resource.Org, 906 F.3d 1229, 1232-1233.) In deciding the case, the court looked to 1) who authored the work; 2) the authoritativeness of the work; and 3) and the process by which the work was created. "Where all three point in the direction that a work was made in the exercise of sovereign power -- which is to say where the official who created the work is entrusted with delegated sovereign authority, where the work carries authoritative weight, and where the work was created through the procedural channels in which sovereign power ordinarily flows -- it follows that the work would be attributable to

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	the constructive authorship of the People, and therefore uncopyrightable." Obviously, the TNI Standard does not fit this same mold. It is not authored by the State, although states may choose to incorporate the standards into its laws. Although the standards are intended to be authoritative, the process by which they are created is done outside of the channels of government. One commenter, in their assessment of the case, asserts that the annotations were prepared by a third party, and therefore the court's ruling "is particularly relevant here, given that, like the TNI Standard, the annotations were written by a third party." However, although the court noted that the annotations were initially prepared by Mathew Bender & Co., Inc., an operating division of the LexisNexis Group, (Lexis), they were written pursuant to an agreement with the State of Georgia, and under the terms of the agreement, Georgia held the copyright in the annotations in its own name. Because of this, and the fact that the State's Code Revision Commission supervised the work of Lexis and had final editorial control over the contents of the OCGA, the court found the State was the author, not Lexis. This is distinct from the situation here, where the TNI Standard is developed by a third-party voluntary consensus body, on its own initiative, and not under control or direction of any state. Although states may choose to incorporate the standards into its laws, the standards are created outside of the channels of government. 3. It Was Not Necessary for Public to be able to Weigh in on Development of 2016 TNI Standard Several other commenters also questioned whether it is possible to incorporate by reference the 2016 Standard because the public were not afforded an opportunity to weigh in on the development of the standard. This, however, is not what is required. The public was provided the opportunity to weigh in on the incorporation of the 2016 TNI Standards,

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	with two exceptions. The standard was made available to the public during the public comment period. When additional changes are made to the TNI Standard, those changes would not be automatically incorporated into California's requirements, and instead would have to go through the APA rulemaking process before they could be added. This is distinguishable from the situation in *California Association of Sanitation Agencies v. State Water Resources Control Board*, 208 Cal.App.4th 1438, 1468 (2012), where the court allowed the prospective incorporation of standards for drinking water into the beneficial use designations in the Central Valley Regional Water Quality Control Board's water quality control plan.. In that case, water quality objectives were set for water designated for use as domestic or municipal supply (MUN) by referring to the maximum contaminant levels set out in title 22 of the California Code of Regulations. The basin plan noted that "this incorporation-by-reference is prospective, including future changes to the incorporated provisions as the changes take effect." There, the court held that because the drinking water standards adopted by the Department of Health Services (DHS) must be adopted pursuant to the APA, which provides for public participation, that prospective changes in the drinking water standards promulgated by the DHS were properly incorporated by reference.